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HTA Core Model® Online

Disclaimer
This information collection is a core HTA, i.e. an extensive analysis of one or more health technologies using all nine domains of the HTA Core Model. The core HTA is intended to be used as an information base for local (e.g. national or regional) HTAs.

Collection name
Structured telephone support (STS) for adult patients with chronic heart failure
Scope

Structured telephone support (STS) for adult patients with chronic heart failure compared to Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) in the prevention of Chronic cardiac failure in adults and elderly with chronic heart failure (CHF) AND hospitalization due to heart failure at least once AND without implanted devices

(See detailed scope below)

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Structured telephone support (STS) for adult patients with chronic heart failure

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Collection summary

Health problem and current use of technology (CUR)

According to the European Society of Cardiology, heart failure is a clinical syndrome in which patients have typical symptoms and signs resulting from an abnormality of cardiac structure or function. Although often life threatening, typical symptoms and signs resulting from an abnormality of cardiac structure or function, i.e. heart failure, leading to failure of the heart to deliver oxygen at a rate corresponding to the needs of the body are usually less dramatic than those associated with a myocardial infarction {77}.

HF is a large and global public health problem that will become more important with the aging of the world population. Up to one person in five is expected to develop HF at some point in their life in economically developed countries {70}.

Telemedicine is an approach using remote monitoring e.g. by structured telephone support of prognostic factors in order to promote an early identification of clinical deterioration in HF patients, prevent hospital readmission for acute decompensated HF, and avoid further complications {3}. Signs and symptoms reported by patients are collected by a healthcare professional who subsequently enters and stores the data into a monitoring system. The data are then reviewed by healthcare professionals, usually physicians or nurses. Appropriate action can be initiated, and deterioration can be rapidly detected, which leads to decrease in unnecessary hospital visits, a decrease in hospital (re-)admissions, an improved quality of life. {75}. The highest risk period for hospital readmission is the first few weeks after discharge {90}. Overall, telemonitoring has the potential to improve patient safety and quality of care {21}.

Substantial heterogeneity among studies was noted {119}, the content of the telemedicine interventions vary between patient groups and with regard to duration and content.

Most studies report care provided by a multidisciplinary team, but a great deal of heterogeneity regarding the professionals involved was described. Collaboration between primary care and secondary care was scarcely reported. In almost all the studies, nurses played a coordinating or leading role, but description of the specialization of clinical background were lacking. A different variation of systems for telemonitoring was found, ranging from assessment of symptoms and/or vital signs to data transmission and automatic alarms. {51}

Generally, telemedicine and telemonitoring can be seen as relatively new, currently as an adjunct to current care with the chance of more patient-self-care-involvement and improved quality of therapeutic monitoring, but without a clear unique idea where it should lead to and how it should be implemented.

Structured telephone support may not be not suitable for every patient diagnosed with HF.

Patients with cognitive impairment, a mental illness, a life expectancy less than one year, hearing impairment, language barrier or another chronic disease are often not eligible for a telemonitoring intervention such as structured telephone support {93}.

Description and technical characteristics of technology (TEC)

The non-invasive telemedicine/telemonitoring mainly contains the following aspects (seperately or combined):

- patient education
- self-care supportive strategies
- monitoring and (daily) transmission of vital parameters and weight
- telephone-follow up
- medication management (adherence),
- fluid management (adherence)
- problem solving
- exercise recommendation
- diet adeherence
- goal setting

Usual care mainly consists of

- standard post-discharge care without intensified attendance at cardiology clinics
- clinic-based CHF disease management programme
- home visiting

There is no consensus definition of the fundamental terms utilized.

Telemedicine/ telemonitoring interventions can be used in all different settings (outpatient, outpatient clinic, hospital based, home, mixed setting), they are mainly provided in outpatient organisations, the most important part ist the additional setting at the patients‘ home.

The reference values for heart failure diagnostic (- monitoring) are mainly a) mortality and b) hospitalisation (rate).

The needs for a sustainable telemonitoring include

- Qualified professionals (human resources) doing the monitoring/ statistics/emergency prioritisation
- Economic resources to provide the infrastructure for data transmission (GSM network, analogue phoneline, internet, software) and telephone support, documentation, home visits, etc.
- Transparent selection of patients who benefit best

Information to patients outside the target group and the general public should focus on the reasons and the explanation for inclusion or exclusion of people/ patients for access to structured telephone support. People should be informed that structured telephone support is not suitable for all individuals nor is it appropriate under all medical circumstances

There is also an „upcoming“ topic called mHealth meaning mobile health through mobile phones and similar devices using software applications (apps). There is increasing interest on mhealth, especially with the hope of easy and equal acces for information, tele-diagnostic or –care aspects and data collection and use for health purpose. Some major aspects are to be worked out (like network issues, data security, information quality, legal and regulatory aspects etc.) and are aim within the EU horizon 2020.

Safety (SAF)

To determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure/ improves clinical outcomes and quality of life, has impact on patients’ satisfaction and function, change in management or utilization of health service and patients’ and technical safety (technical reliability), in comparison with current practice, a systematic literature search according to the predefined search strategy (not limited by publication date but limited to English language), was performed according to the Cochrane methodology, in standard medical and HTA databases. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme, and the predefined inclusion/exclusion criteria. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR. Of the included RCTs, only three were judged to be of low risk of bias.

In the most recent SR no evidence on potential harms was found on STS interventions. None of 19 included RCTs specifically mentioned adverse events (AEs) as primary or secondary outcomes. In only one RCT which specifically mentioned AEs no adverse events were reported and only one RCT provided explanation on the reason why it did not monitor AEs. Since little evidence was identified on the potential harms of STS, it was not possible to assess overall benefits and harms of STS in adults with chronic heart failure.

The sources were not sufficient to answer the questions on STS safety in patients with chronic heart failure. No evidence was found to answer technical safety.

Clinical effectiveness (EFF)

To determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure/ improves clinical outcomes and quality of life, has impact on patients' satisfaction and function, change in management or utilization of health service and patients' and technical safety (technical reliability), in comparison with current practice, a systematic literature search according to the predefined search strategy (not limited by publication date but limited to English language), was performed according to the Cochrane methodology, in standard medical and HTA databases. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme, and the predefined inclusion/exclusion criteria. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR. Of the included RCTs, only three were judged to be of low risk of bias.

STS produced a mortality benefit and reduced HF-specific readmission rates. For the outcomes QoL and utilization the evidence was insufficient. Yet, the majority of studies presented statistically significant QoL improvements. A majority of the RCTs found no significant difference in the number of emergency room visits in either group. No evidence found to answer some assessment element questions, related on outcomes such as work ability, return to previous living conditions, activities of daily living, worthwhile of STS and willing to use STS again.

STS reduces HF-specific readmission and mortality. A majority of the studies presented statistically significant improvements in QoL. Some research gaps and transferability issues were recognized. Further research is needed on effects of STS on QoL and utilization outcomes as well as patient satisfaction during long term follow-up.

Costs and economic evaluation (ECO)

It became apparent from the results of our systematic literature search and our review of the results from other domains that the meaning of the term Structured telephone support (STS) varies quite widely across the studies. Hence, there is no explicit definition STS and, instead, the term is refers to a diverse set of approaches to care management for adults with chronic heart failure using telephonic networks.

Depending on the approach taken to STS, a range of different pieces of information can be collected by telephone from patients, and any such information can be handled and utilised by the management team or system in a large number of ways.

Therefore, one main result of the ECO domain is that variation in the nature of the intervention poses major challenges to undertaking meaningful examination of intervention costs and to undertaking economic evaluations.

If each type of STS intervention, has both different components and consequences, this has a significant effect on ability to make meaningful estimates of costs and to undertake robust economic evaluations. For this reason, we do not summarise the results of the studies *per se* but, instead, briefly describe those studies found.

Ethical analysis (ETH)

The current domain outlines some ethical issues arising from the use of the particular technology, i.e. structured telephone support for adult patients suffering from CHF. Together with all the clinical efforts in the management of this devastating condition, part of the recent research has been concentrated on finding low-cost therapeutic alternatives as telemedicine and further understanding of the psychological, ethical, legal and social aspects of handling the particular technology and its impact on the patients themselves, their families and friends, the healthcare personnel and the healthcare providers as well as the society as a whole.

In compliance with the preliminarily outlined domain framework, the following issues have been considered in the text – all of them abiding by the generally accepted ethical principles: beneficence/nonmaleficence; autonomy; respect for persons and justice and equity:

- Improving patients' quality of life;
- Challenges associated with the digital gap;
- Challenges posed by the remote interaction between a physician and a patient;
- Fair and balanced distribution of resources;
- Equal access to treatment;
- Stigmatization.

As already mentioned, on the agenda stand many ethical challenges, with the border between the benefits and harms associated with telemedicine remaining vague and fluid rather than sharply defined. This is due to the virtual environment, where electronically mediated communication replaces personal interaction and physical contact.

Since the issues discussed are highly controversial, the current text does not pretend to be a detailed or comprehensive analysis but provides some thoughts and reflections. Instead of giving certain prescriptions, the authors aim at providing a balance between norms and values through the consideration of social, political, cultural, legal, religious and economic aspects arising from the opposition to the generally accepted environmental values, healthcare system goals and the application of new technologies.

A particular problem that could affect the quality and nature of the conclusions in the text stems from the fact that, like many other innovations in the healthcare field, almost all of the studies from the available literature, assessing the positive and negative impact of telemedicine, focus primarily on the purely economic, technical and clinical parameters, particularly emphasizing on cost reduction and technological efficiency but ignoring the ethical considerations at the same time.

Generally, scientific literature demonstrates that the effect of telemedicine on patient-centered care varies more or less. Some studies see the negatives, but most find neutral or positive effects. In view of all these and acknowledging some of the literature gaps already mentioned, the authors may conclude that the basis of empirical studies is still too poor to allow any solid conclusions at this stage.

Organisational aspects (ORG)

When planning the introduction of a TM intervention in general, there are several questions that need to be addressed concerning: the choice of patients targeted by these programmes; the parameters that will be monitored; the more efficient way to monitor them; the training of patients and healthcare personnel; how to organize the response of the health care professionals to data obtained from monitoring to optimize patient care. Possibly management will need to deal with (de)employment of new resources, new information systems, new equipment for STS provisions, new administrative leadership and new group culture that promotes quality improvement.

STS can be carried out in very different settings, from primary care to tertiary care. There is little information in the studies on the changes of the workflow – usually for the STS an additional nurse was used who had access to patient data, carried out the STS, monitored the patient, recorded the symptoms and data and reinforced and adapted the plan of care for the patient.

In STS the most important thing is training and education of nurses and patients and communication. The STS support starts being planned while the patient is in hospital through education and meeting with the HF nurse. Education and practising with the technology follows and the materials are given to the patients as well as explained to the relatives. At the point of discharge the timing of the first call is agreed. The frequency of calls varies greatly among the studies but in common the calls are weekly at least first two weeks after discharge and then get biweekly until two months after discharge. After that they become monthly. The number of telephone contacts per week should not be too high, not even in the first week as this may affect adherence. Adherence is reported from 55,1% to 84% across the studies, adaptation to the technology to 90% or higher, more than 90% of patietns are statisfied with the use of technology.

It is not clear how long the intervention should last: there are different periods, going from 3 months up to 2 years after the discharge. It is not clear when the effect is biggest, possibly within first 3 months. A published communication strategy is important, including patient support strategy, communication between patient: nurse, patient: medical doctor, patient: pharmacist, the brochures, diaries to record daily control measurements, web pages with disease information and with instructions, instructions for family members to share a best practise. In general, STS provides greater access to care in geographical terms and no specific problems were mentioned regarding financial accessibility.

In spite of various methods of costs calculation, which makes them highly incomparable, it is posisble to establish that the average costs of intervention across the studies amounted from $23,6 to $443, the reported savings amounted from $30,9 to $536 per patient per month. None of the studies analyzed a shift of cost, from specialits to HF nurse to GP.

Eligibility to new technology depends on an assessment of the general practitioner of a patient’s condition and the patient's willingness and ability to participate. Access to new technologies depends on support of healthcare providers as they are rarely reimbursed.

Social aspects (SOC)

The aspects related to patients’ quality of life and satisfaction with STS, patients’ views, perceptions and probable improvements in self care allowed by the use of this intervention, are an important part of the success of this technology.

In the studies where quality of life (QoL) is measured with standardised instruments, there is a significant improvement of QoL in the intervention group or no difference between the usual care and the intervention. Pandor’s systematic review shows that 4 studies which had quality of life as a secondary outcome and where about STS, reported improvements in QoL, with significant improvements in physical [Angermann, 2011] and overall [Barth, 2001, Wakefiled, 2008] measures, but one study found no significant differences between the groups [Riegel, 2006]. Oher (primary) studies we selected gave scattered results. Dunagan et al. 2005 found that nurse-administered, telephone-based disease management intervention had some impact on functional status and quality of life. Piotrowicz et al. 2015 found that the in the intervention group there was a similar improvement in total QoL index as in the control group. Patients who underwent home-based tele rehabilitation observed an improvement mainly in the mental categories. On the other hand Ramachandran et al, 2007 found and increase in quality of life, as a whole and in many dimensions the intervention group that persisted over time. For Jerant 2003 telenursing at least did not have any large negative impact on patient satisfaction or health status. In the study by Boyne et al. 2014 authors conclusions says that tailored telemonitoring was found to educate patients with HF and to improve their self-care abilities and sense of self-efficacy. Domingues and collegues state that in thier study (2011) the educational nursing intervention performed during the hospitalization period brought improved knowledge of HF and self-care in all patients regardless of telephone contac.

The organisational differences among the variuos STS interventions in the selected studies (programs offering exercise, education and behavioral interventions on patients’ psychological outcomes, or monitoring systems of vital signs led by nurses or physician etc.) can help to explain those differences in findings and results and make trasferability and comparability of them difficoult.

To have a deeper understanding about how patients experience the care when it is moved outside of the hospital to their homes with the support of STS, we also selected qualitative studies which allow to highlight perceptions of patients about complex interventions. From this perspective selected qualitative studies show that there can be positive and negative aspects in using telemedicine and its application such as STS. Lynga et al. 2013 interviews to patients who used the intervention showed, that the technology was easy to perform, made patients active in their own care, and increased their self-care activities. However, there were concerns of potential deterioration: transmission of body weight reminded patients of illness, deterioration in their health, increase of diuretic dose (inconvenience in the patient’s daily life) and some experienced also a perception of fear that affected their psychological well being.

As regard tro the barriers to the use of the technology, digital divide related to the age or socio-economical status which could avoid patients to use the facilities related to the intervention, we could not retrive definitive and conclusive studies. The qualitative literature that gave an answer to this reaserch question would show digital divide due to age as not being a relevant problem. Seto et al. shows that relatives of those not technology-accustomed would be able to provide support to patient [Seto 2012]. Bond, 2014 finds that most people found the telehealth system easy to use and in the study of Prescher, 2013 most of the patients reported an easy and robust handling of the devices. Nontheless more quantitative studies about the influence of age, gender etc. on the use of STS should be developed to better understand implications of thoses macrosocial variables on the use of STS.

Legal aspects (LEG)

For the implementation of telemonitoring one has to look at least for existing property rights on the used system, the implemented software, existing patents, and to secure/regulate the permission for use.

For structured telephone support as a telemonitoring approach for patients with chronic heart failure there is a need of patient-cooperation which implies the will of the patient to take this kind of healthcare.

Data networks and data communication between providers of tele-healthcare and patients have to secure and protect data sources according to legal data protection regulations.

In any case the data protection should be on awareness, especially with low-level support via usual telephone or cell phone line. The informed consent with the patient and the (written) agreement are necessary.

Limited access to structured telephone support as a telemonitoring service for special persons have to be based on the balance between evidence of best outcome rates, economic calculations for the costs and reduction of possible disadvantages due to i.e. lack of compliance. The decision for inclusion/ exclusion into a structured telephone support service has to be transparent.

Usually there is no health care tourism expected for structured telephone support for chronic heart failure patients. In case of (emergency) treatment abroad and re-transfer into the home-country the appropriate information and continuity of care has to be guaranteed. The routine provision of structured telephone support across borders (in our outside Europe) is expected to be limited by language.

There seem to be no major differences in product safety aspects comparing structured telephone support with usual care. The product safety and responsibility duties have to be followed in both settings. If telemonitoring/ stuctured telephone support is newly implemented there should be appropriate awareness for the safety structure to be equal/similar (or better) as in ”usual care”

Within structured telephone support provided by a physical person (like a nurse) and/or a group of professionals evaluating deterioration from the collected data by STS, the guarantee for quality can be given via the professional licencing regulations as it is handled within hospitals.

The Directive on public contracting assures price control of servies in case of contracting the whole STS service or in case of material purchasing for HF patients at home. Pricining within reimbursement system for STS (like DRG) is subject to national legislation. The pricing within DRG system must therefore take into account all national legislation and regulation, like national policy on wages or depreciation. However, when the material costs are built into DRG, again the procedures for the public contracting is important, in case of STS it oculd apply to the telephone lines and various equipment that is given to HF patients to monitor their health status at home (scales, meters for circumference of ankles etc).

Within medical services and/or medical devices advertising is regulated by local governments to prevent misinterpretation about the device or service.

There is still legal uncertainty within the provision of structured telephone support for patients with chronic heart failure in terms of

- Cross border healthcare services
- Funding aspects
- Reimbursement
- Procurement
- Sustainable business models
- Data protection via telephone line
- Provider responsibilities

For the provision of telemedical services/ STS several different legal regulations have to be followed, like:

- Occupational laws
- Hospital legislations
- Good clinical practice
- Health telematic law
- Data protection law
- E-government law
- Consumer protection law
- Signature law
- E-commerce-law
- Telecommunication law
- Copyright/ patent protection
- Media law

(list not exhaustive)

Collection methodology

Objective

To produce a Core Health Technology Assessment (HTA) assessing the effects of Structured telephone support (STS) for adult patients with chronic heart failure based on the EUnetHTA Core Model and working within the a mixed Collaborative Model organisational framework.

Methods

The work was based on the HTA Core Model application for Medical and Surgical Interventions (2.0) , which was developed during the EUnetHTA Joint Actions 1 and 2.

The first phase was the selection of the technology to be assessed using the Core Model; this phase was carried out through a three-step process that is described in our MSP.

Then a check of Partners' availability to assume responsibility for taking the lead in one of the nine evaluation domains was carried out. At the same time, the nine domain teams were built-up in accordance with partners' preferences and some general guidelines (see the MSP).

Finally the specific work plan was shared, according with the general WP4 3-year work plan and objectives. This specific work plan included the phases scheduled in the "HTA Core Model Handbook" (Production of Core HTAs and structured HTA information).

An editorial team was set up for discussion and major decisions on basic principles and solutions related to the content of core HTA. The editorial team was chaired by Tom Jefferson (Agenas) and composed of all the primary investigators of the domains.

To allow collaboration between partners a draft protocol for Core Model use was agreed by the researchers involved. The research questions for each of the nine domains of the Core Model were formulated and the corresponding relevant assessment elements (AEs) were selected. The legal domain was included in the assessment.

The research strategy was carried out by Agenas with input from the other partners.

Evidence from published and manufacturer sources was identified, retrieved, assessed, and included according to pre-specified criteria, and summarised to answer each AE. Domain assessments were done by a single agency and by different investigators from different agencies, in a mixed organisational model. The final text has not been proof read.

Introduction to collection

This brief document provides background information on the preparation and development of the Core HTA on Structured telephone support (STS) for adult patients with chronic heart failure. The core HTA document was produced during the course of the second EUnetHTA Joint Action (JA2) 2012-2015.

The idea behind EUnetHTA's Core Model is to provide a framework for structuring relevant HTA information while at the same time facilitating local use and adaptation of the information or guiding its production.

The Model is based on nine dimensions or "domains" of evaluation:

1. Health Problem and Current Use of the Technology (CUR)
2. Description and technical characteristics of technology (TEC)
3. Safety (SAF)
4. Effectiveness (EFF)
5. Costs and economic evaluation (ECO)
6. Ethical analysis (ETH)
7. Organisational aspects (ORG)
8. Social aspects (SOC)
9. Legal aspects

The Core Model application for Medical and Surgical Interventions (2.0) was tested by assessing the effects of Structured telephone support (STS) for adult patients with chronic heart failure. We produced a Core HTA structured as in the nine documents that follow, one for each domain.

This Core HTA was prepared using an experimental Collaborative Model (COLMOD) in which groups of researchers from different HTA Institutions produced the domain texts. For the Core HTA on Structured telephone support (STS) for adult patients with chronic heart failure the experimental organisational model added an element of challenge but probably helped to forge strong links across participants.

In the next few months an intensive validation programme including interviews and consultations will elicit comments and feedback both from those who contributed to the Core HTA and from those who read a Core HTA for the first time. As scheduled in the 3-year work plan, the Core HTA will be sent to the Stakeholder Advisory Group (SAG) for feedback before the final Public Consultation, during which the Core HTA will be made publicly available.

The results from the Validation and SAG consultation should provide useful information to improve the product.

Scope

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Health Problem and Current Use of the Technology

Authors: Ingrid Wilbacher, Nadine Berndt, Francesca Gillespie

Summary

CUR1: For which health conditions and for what purposes is structured telephone support (STS) for adult patients with chronic heart failure used?

Structured telephone support, as subject of the current Core HTA, is one specific type of remote heart failure monitoring. It is monitoring and/or self-care management using simple telephone technology, usually initiated by a healthcare professional (e.g. nurse, physician, social worker or pharmacist), and in which data is stored by a computer.

Telemedicine is an approach using remote monitoring e.g. by structured telephone support of prognostic factors in order to promote an early identification of clinical deterioration in HF patients, prevent hospital readmission for acute decompensated HF, and avoid further complications {3}. Signs and symptoms reported by patients are collected by a healthcare professional who subsequently enters and stores the data into a monitoring system. The data are then reviewed by healthcare professionals, usually physicians or nurses. Appropriate action can be initiated, and deterioration can be rapidly detected, which leads to decrease in unnecessary hospital visits, a decrease in hospital (re-)admissions, an improved quality of life. {75}. The highest risk period for hospital readmission is the first few weeks after discharge {90}. Overall, telemonitoring has the potential to improve patient safety and quality of care {21}.

CUR2: What kind of variations in use are there across countries/regions/settings?

There were 62 studies from Europe cited in the reviews. Out of the 62 European studies 16 mentioned educational strategies within the telemedicinal programme. The involved persons were cardiologists (3 studies), multidisciplinary teams at least for the care plan (25 studies), physician-/primary care led (1 study each), nurse-led (4 studies), not mentioned in the reviews (32 studies).

The transfer mode was in 17 studies via telephone/ cell phone transmission, in 4 studies through implantable devices, 1 study describes interactive videoconferencing, transtelephonic monitoring, 1 study described hospital-at-home service, 2 studies just described non-invasive telemonitoring, in 36 the transfer mode was not clear.

Most studies report care provided by a multidisciplinary team, but a great deal of heterogeneity regarding the professionals involved was described. Collaboration between primary care and secondary care was scarcely reported. In almost all the studies, nurses played a coordinating or leading role, but description of the specialization of clinical background were lacking. Almost all programmes also had physicians involved, which could be cardiologists, and/or primary care physicians or other specialists such as geriatricians or internists. Additionally, other professionals (i.e. psychologist, dietician, physical therapist, social worker, pharmacist) were involved in the programmes, mostly as a member of the multidisciplinary team or occasionally as the main provider of an intervention (e.g. a pharmacist). A different variation of systems for telemonitoring was found, ranging from assessment of symptoms and/or vital signs to data transmission and automatic alarms. {51}

Substantial heterogeneity among studies was noted {119}, the content of the telemedicine interventions vary between patient groups and with regard to duration and content.

CUR3 / ORG1: Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?

Three of the reviews reported eligibility and exclusion criteria for patients included in the studies, but there was no answer on who decides or who should decide to use telemedicine for what patient.

CUR4: Is structured telephone support (STS) for adult patients with chronic heart failure a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?

Eight of the included reviews try to look at the indicators for novelty and how they lead to a novel attitude – like including the patient - and new settings – like different patient- and physician roles - of health care. They still describe telemedicine as „changing modality“, „promising“, „complementary“, „potentially“, „modality“, and a common insecurity about what exactly is defined as telemedicine and what kind of programmes were modified into telemedicine (like disease management programmes which are technically supported) seems to occur.

Generally, telemedicine and telemonitoring can be seen as relatively new, currently as an adjunct to current care with the chance of more patient-self-care-involvement and improved quality of therapeutic monitoring, but without a clear unique idea where it should lead to and how it should be implemented.

CUR5: What is the target population in this current assessment of structured telephone support for adult patients with chronic heart failure?

In this current assessment of structured telephone support for adult patients with chronic heart failure, the target population is patients who have signs or symptoms of HF, or an underlying non-diagnosed abnormality of the cardiac structure that is likely to lead to HF.

According to the large number of studies that have been conducted on the clinical effectiveness of telemonitoring in HF patients, the appropriate target population of telemonitoring generally concerns elderly, with a definitive clinical diagnosis of HF, with a mean age generally around the 70s (patients may also be significantly younger or older), or with chronic HF, often who have had a cardiovascular hospitalization or a hospitalization for HF within the previous 12 months, who have been discharged to home, often with moderate or severe symptoms of HF (New York Heart Association, NYHA class II-IV), a LVEF ≤ 30 %, and who are administered diuretics, ACE inhibitors and beta blockers.

Structured telephone support may not be not suitable for every patient diagnosed with HF. According to Koehler et al. 2011 {64}, telemonitoring is particularly suitable for patients who are recently hospitalized due to HF, medically unstable, or classified being in the NYHA Class II and III. Koehler also recommends performing telemonitoring during the 12 event-free months after hospitalization for HF {64}.

Guidelines of the ESC recommend remote monitoring of patients reporting symptoms (including drug adverse effects) and signs of HF (Class I recommendation, Level of Evidence: C) {19}.

Patients with cognitive impairment, a mental illness, a life expectancy less than one year, hearing impairment, language barrier or another chronic disease are often not eligible for a telemonitoring intervention such as structured telephone support {93}. This has been confirmed by Paré et al. 2010 {92} who outlined on the basis of their systematic review on the clinical effects of home telemonitoring in the context of diabetes, asthma, HF and hypertension that telemonitoring likely to not be suitable for everyone, because most studies excluded patients with a moderate to severe cognitive, physical, visual or hearing disability. Patients who did not own a phone or who a very short life expectancy (less than 1 year) were often excluded as well. The beneficial effects on state of health are observed mostly among those patients whose health state is rather serious {92}.

CUR6: How many people belong to the target population?

HF is a large and global public health problem that will become more important with the aging of the world population. The number of patients with HF is predicted to increase considerably in countries with fast ageing populations, like Japan. Up to one person in five is expected to develop HF at some point in their life in economically developed countries {70}. In 2007, it was already estimated that approximately 1–2 % of the adult population in developed countries had HF and that the incidence approached on average 5–10 per 1000 persons per year with a significantly higher incidence in higher age groups {82}.

In 2011, it was estimated that 26 million adults worldwide were living with HF {6}, leading some to describe it as a global pandemic {2}. Of these patients at least 15 million are European {19}, whereas almost 7 million Americans ≥ 20 years of age have HF {120}. According to the AHA, at least 850.000 patients are yearly newly diagnosed with HF in the US with the incidence approaching 1 per 100 people 65 years of age and older. %Data on the incidence and prevalence of HF in the

developing world are largely absent, but it is estimated that there is also an increasing number of patients with HF in the developing countries due to the emerging pandemic of cardiovascular diseases {78}. % % %

HF is a condition that becomes more common with increasing age. In North America and Europe, persons 50 years of age or under are hardly ever found to have HF {32},{7},{107}, and more than 80 % are 65 years of age or older {6}. Hence, particularly in those older than 50 years of age the prevalence and incidence increase progressively with age. Generally speaking, in 2007 the prevalence was estimated to be 10-20 % in persons with the age between 70 and 80 while it was rising significantly to ≥10 % among persons 70 years of age or older {82}. In the Dutch Rotterdam study, the prevalence of HF was 1 % in the age group of 55-64 years, 3 % in the age group of 65-74 years and 13 % in the age group of 75-85 years {81}. Moreover, according US estimates, the remaining lifetime risk for development of new HF remains at 20 % at 80 years of age, even in the face of a much shorter life expectancy {83}.

Overall, the prevalence of systolic HF and diastolic HF is estimated to be equal between men and women. According to the ESC (2012), at least half of patients with HF have a low or reduced ejection fraction. HF with a preserved ejection fraction or diastolic HF is present in approximately 50 % the patients with HF {77},{29}. In younger age groups, systolic HF occurs more frequently in men than in women because myocardial infarction occurs at an earlier age in men. Diastolic HF is more common in the elderly, in women, in individuals with longstanding hypertension, diabetes, renal failure, anemia, and atrial fibrillation {19}. Studies show that the accuracy of the diagnosis of HF by clinical means alone is often inadequate. This applies particularly to female, elderly, and obese patients, leading to a potential underrepresentation of the patients who have HF {106},{60},{77}.

The globally increasing prevalence of HF is not merely due to the ageing of the population. It is also due to improvements in the treatment of acute coronary syndromes, effective prevention in those at high risk or those who have already survived a first coronary event, a longer survival of cardiac patients and HF patients, and the increasing epidemiology of cardiovascular diseases in the developing countries {84},{100},{116}. An increase in risk factors for HF such as diabetes, sedentary behavior and obesity also contribute to the increasing pool of HF patients. Factors that on the other hand decrease the incidence of HF are a decline in the number of new cases with myocardial infarction, a decline in the severity of acute myocardial infarction and the improvement of care {40},{85}. The improvement of care for hypertension and coronary artery disease, particularly in Western Countries, also account for a decreasing incidence {86}.

Although various studies have been conducted in the past to capture the epidemiology of HF, there is still a scarcity of epidemiological data. The absence of gold-standard criteria for the diagnosis of HF, together with a lack of agreement on a definition of HF itself, explains why studies fail to use a uniform assessment of HF.

CUR7: What is the disease or health condition in the scope of this assessment?

According to the European Society of Cardiology, heart failure is a clinical syndrome in which patients have typical symptoms and signs resulting from an abnormality of cardiac structure or function. Although often life threatening, typical symptoms and signs resulting from an abnormality of cardiac structure or function, i.e. heart failure, leading to failure of the heart to deliver oxygen at a rate corresponding to the needs of the body are usually less dramatic than those associated with a myocardial infarction {77}.

The current 10th edition of the International Classification (ICD) system classifies heart failure as an intermediate, not underlying cause of death. It is described as congestive heart failure including congestive heart disease and right ventricular failure. It is also defined as left ventricular failure including cardiac asthma, left heart failure, and oedema of lung and pulmonary oedema with mention of heart disease (unspecified) or heart failure. Heart failure (unspecified) can be due to cardiac, heart or myocardial failure not otherwise specified. Heart failure is further defined as the incidence of heart failure due to rheumatic heart disease, hypertensive heart disease, ischemic heart disease and inflammatory heart disease. Complicating abortion or ectopic or molar pregnancy, obstetric surgery and procedures are excluded. Moreover, heart failure due to hypertension (with renal disease), heart failure following cardiac surgery or due to presence of cardiac prosthesis, and neonatal cardiac failure are excluded from the classical definition of heart failure by the ICD-10 {113}.

CUR8: What are the known risk factors for the disease or health condition?

Risk factors for HF (AHA):

-increasing age (AHA);

-male gender (AHA);

-African American race (AHA);

-hypertension (AHA);

-obesity (AHA);

-low socio-economic status (AHA);

-cigarette smoking (AHA);

-history of atrial fibrillation (AHA);

-diagnosis of CHD (AHA);

-atherosclerosis {115},{77};

-low level of adiponectin and a high level of pro-B-type natriuretic peptide (BNP) in the bloodstream {83};

-increased urinary albumin excretion, an elevated serum γ-glutamyl transferase, higher levels of hematocrit, increased circulating concentrations of resistin, cystatin C, inflammatory markers (interleukin-6 and tumor necrosis factor-α) and low serum albumin levels {83};

-previous recognized or unrecognized viral infection {77};

-increased alcohol intake {77};

-chemotherapy {77};

-‘idiopathic’ dilated cardiomyopathy.

Risk factors for hospitalization in heart failure {30}:

-higher age;

-nonwhite race;

-low socio-economic status;

-lack of employment ;

-living alone, smoking;

-ischemic etiology;

-low systolic blood pressure;

-higher NYHA class (III or IV);

-prior HF hospitalization;

-presence of hypertension;

-diabetes mellitus;

-anemia;

-hyponatremia;

-history of renal insuffiency;

-worsening renal function;

-chronic obstructive pulmonary disease;

-obstructive sleep apnea;

-depression;

-low quality of life;

-absence of emotional support or social network;

-low adherence to therapies (Giamouzis et al., 2011).

Risk factors for hospital readmission among older persons with a new onset of HF {8}:

- diabetes mellitus;
- NYHA class III or IV;
- chronic kidney disease;
- reduced ejection fraction (< 45 %);
- muscle weakness;
- slow gait;
- having a depression.

Greater survival for patients with established CHF (“reverse epidemiology”) {54}:

- obesity;
- < >< >

  Substantial heterogeneity in the results {33};
- Telehealth programmes demonstrated clinical effectiveness in patients with CHF compared with usual care {114};
- It was not clear as to the extent to which these effects were due to tele-monitoring per se or to the improvement in access to care{44};
- Despite the beneficial effects reported by meta-analyses of small non-controlled studies, major randomized controlled trials have failed to demonstrate a positive impact of this strategy {102};
- Prior to being accepted as a standard of care, more evidence from large, randomized clinical trials is required {34};
- Structured telephone support and telemonitoring are effective in reducing the risk of all-cause mortality and CHF-related hospitalisations; in patients with CHF; they improve quality of life, reduce costs, and evidence-based prescribing {48};
- The present review demonstrated that home telemonitoring is generally clinically effective, and no patient adverse events were reported in the included studies {93};
- Telemonitoring appears to be an acceptable method for monitoring of HF patients {75}.

CUR12: What are the differences in the management for different stages of the disease or health condition?

There is interest in new approaches of telemonitoring {1}, but at the moment there is no guideline recommendation available (possible) {45,24,1,110,3,33,44} for telemonitoring in general but for multidisciplinary CHF management programmes {87}.

CUR13: How is the disease or health condition currently diagnosed according to published guidelines and in practice?

Most guidelines agree on three essential stages of care for patients with heart failure:

-Diagnosis (should be timely and accurate);

-Treatment (should be appropriate to each patient and available urgently if necessary);

-Longterm management (should include follow-up, monitoring and support).

Disagree is observed on which diagnostic tools should be used for all patients with suspected heart failure and in which order.

Especially for invasive diagnostics there are some differences and challenges according to the interpretation of the diagnostic and prognostic value.

CUR14: How is the disease or health condition currently managed according to published guidelines and in practice?

Global assessment

-Despite clear recommendations regarding evidence-based medications, many patients with heart failure do not receive a prescription for potentially beneficial medication because they do not always comply with guidelines {45}

Europe

-In Europe prescription doses are often below those recommended {26},{28},{65};

-In Europe guidelines incorporate follow-up, monitoring and support, however, about a quarter (7/26) of the countries reported having heart failure management programmes in more than 30 % ot their hospitals {49} and even when in place, they are not always used.

USA

-In the US most hospital had fewer than half of 10 key recommended practices in place and fewer than 3 % had 10 in place {4};

-In the US more than a quarter of patients with heart failure did not receive an appropriate prescription {26},{28},{65}.

Australia

- A recent Australian consensus statement {88}report that the management of chronic heart failure remains a pressing problem, with many apparent indicators of poor case detection, including discordant management with evidence-based treatment, recurrent hospital admission, and disconnected care issues these that are amplified among marginalised populations.

CUR15: What is the marketing authorisation status of Telemonitoring in home care for patients with chronic cardiovascular diseases?

For equipment used as „telemedicine“ or „telemonitoring“ in a (community-)setting and/or within a disease management programme the devices seem to be individually created for the local need and based on a software for data-collection via mobile App, internet or as a database where data are written in while telephone interviews.

There is a database for medical devices within the EU (http://ec.europa.eu/health/medical-devices/market-surveillance-vigilance/eudamed/index_en.htm) which is access-restricted.

CUR16: What is the reimbursement status of structured telephone support (STS) for adult patients with chronic heart failure across countries?

This question is left un-answered. Due to the situation of high complexity among the use and settings within the terminus of „telemonitoring/ telemedicine“ and the new or developmental status of the intervention(s) no explicit answer can be provided in the frame of an HTA.

Introduction

The present domain describes the current state of the health condition, i.e. chronic heart failure and the current state of the health technology, i.e. structured telephone support under consideration for this Core HTA. HF is generally characterized by an underlying cardiac dysfunction that impairs the ability of the left ventricle to either fill with blood or contract to eject blood. It is not a disease but a collection of signs, symptoms, and pathophysiology. Typical symptoms are dyspnea or fatigue. Different stages of chronic HF are distinguished, particularly earlier and later stages, and acute and chronic stages {47}{86}. Patients diagnosed with HF have a high risk of readmission especially in the first weeks after hospital discharge. HF is associated with significant reduced quality of life, morbidity, and mortality {90}.

In 2011, it was estimated that 26 million adults worldwide were living with HF {6}, leading some to describe it as a global pandemic {2}. Due to the aging population, an improved survival after a cardiac event and better treatment of HF, the prevalence rates of HF are expected to rise {75}. Particularly in those older than 50 years of age the prevalence and incidence of HF increase progressively. Up to one person in five is expected to develop HF at some point in their life in economically developed countries {70}.

HF puts a considerable burden on the healthcare systems around the globe, largely due to high hospital (re)admission rates, and long hospital stays. The rising healthcare costs, rapid advances in communication and diagnostic technology, and the availability of low-cost telemedicine equipment are important factors that have significantly contributed to the increasing use of telemedicine for the provision of care {71}. A range of different technological modalities for monitoring and/or self-care management exists in telemedicine, including structured telephone support {13}.

Structured telephone support is one specific type of remote heart failure monitoring. It is monitoring and/or self-care management using simple telephone technology, usually initiated by a healthcare professional (e.g. nurse, physician, social worker or pharmacist) who collects relevant patient data and stores them in a computer. Data can hence be reviewed by the healthcare professional and if necessary, action can immediately be untaken {47},{ 99}(Chaudry et al., 2007).

For the PICO question as defined in October 2014, we focused on adult persons (aged 16 or more) suffering from congestive heart failure getting home-telemonitoring (defined as domiciliary detection, recognition, identification, location and transmission of vital functions and other biological information) compared to no home telemonitoring. After the PICO was adjusted in the beginning of 2015, we focused on adult patients with chronic heart failure receiving structured telephone support (STS) compared to no structured telephone support.

This domain provides basic information about heart failure and telemonitoring aspects.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
A0001	Utilisation	For which health conditions and for what purposes is the technology used?	yes	For which health conditions and for what purposes is structured telephone support (STS) for adult patients with chronic heart failure used?
A0012	Utilisation	What kind of variations in use are there across countries/regions/settings?	yes	What kind of variations in use are there across countries/regions/settings?
G0009	Utilisation	Who decides which people are eligible for the technology and on what basis?	yes	Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?
F0001	Utilisation	Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?	yes	Is Structured telephone support (STS) for adult patients with chronic heart failure a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?
A0011	Utilisation	How much is the technology utilised currently and in the future?	no	Overlapping with Question B0003
B0003	Utilisation	What is the phase of development and implementation of the technology and the comparator(s)?	no	This overlaps with the "management" in the CUR domain and will be answered there
A0007	Target Population	What is the target population in this current assessment of the technology?	yes	What is the target population in this current assessment of Structured telephone support (STS) for adult patients with chronic heart failure?
A0023	Target Population	How many people belong to the target population?	yes	How many people belong to the target population?
A0002	Target Condition	What is the disease or health condition in the scope of this assessment?	yes	What is the disease or health condition in the scope of this assessment?
A0003	Target Condition	What are the known risk factors for the disease or health condition?	yes	What are the known risk factors for the disease or health condition?
A0004	Target Condition	What is the natural course of the disease or health condition?	yes	What is the natural course of the disease or health condition?
A0005	Target Condition	What are the symptoms and burden of disease for the patient at different stages of the disease?	yes	What are the symptoms and burden of disease for the patient at different stages of the disease?
A0009	Target Condition	What aspects of the consequences / burden of disease are targeted by the technology?	yes	What aspects of the consequences / burden of disease are targeted by Structured telephone support (STS) for adult patients with chronic heart failure?
A0006	Target Condition	What are the consequences of the disease or the health condition for the society (i.e. the burden of the disease)?	no	We will answer the epidemiological aspects in A0023
A0017	Current Management of the Condition	What are the differences in the management for different stages of the disease or health condition?	yes	What are the differences in the management for different stages of the disease or health condition?
A0024	Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	yes	How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?	yes	How is the disease or health condition currently managed according to published guidelines and in practice?
A0018	Current Management of the Condition	What are the other typical or common alternatives to the current technology?	no	The comparator is defined in the PICO. The different telemedical tools are not seen as "alternatives".
A0020	Regulatory Status	What is the marketing authorisation status of the technology?	yes	What is the marketing authorisation status of Structured telephone support (STS) for adult patients with chronic heart failure?
A0021	Regulatory Status	What is the reimbursement status of the technology across countries?	yes	What is the reimbursement status of Structured telephone support (STS) for adult patients with chronic heart failure across countries?

Methodology description

Information sources

The basic common project search was used for this domain, added by guidelines and references found within the search results (handsearch). Methodological differences are mentioned in each assessment element.

Quality assessment tools or criteria

For the basic description of the health problem and the current management options within this domain a descriptive review without data use was provided, therefore no quality assessment about the studies' methodology was done.

Analysis and synthesis

The common literature search that was done by the project leaders' librarian for this Core HTA was scanned, in case articles were selected as being relevant based upon their title and abstract they were read in fulltext from all three authors, and relevant answers for the assessment element questions were extracted. The three authors divided the questions into three parts. Each part had a main researcher and was checked by the other two. The draft document was sent to the domain reviewers, and their feedback was considered and implemented.

Result cards

Utilisation

Result card for CUR1: "For which health conditions and for what purposes is structured telephone support (STS) for adult patients with chronic heart failure used?"

View full card

CUR1: For which health conditions and for what purposes is structured telephone support (STS) for adult patients with chronic heart failure used?

Method

For this question the results of the CUR domain search were used. In fact, the CUR domain literature was a selection of studies from the basic search done for the whole project done by the project coordinator, and a range of studies (n=14) were selected that provided answers to the question. The results of these studies are described below.

Short Result

Structured telephone support is one specific type of remote heart failure monitoring. It is monitoring and/or self-care management using simple telephone technology, usually initiated by a healthcare professional (e.g. nurse, physician, social worker or pharmacist) who collects relevant patient data and stores them in a computer. Data can hence be reviewed by the healthcare professional and if necessary, action can immediately be untaken.

Healthcare costs, rapid advances in communication and diagnostic technology, and the availability of low-cost telemedicine equipment are important factors that have significantly contributed to the increasing use of telemedicine for the provision of care {71}. There is a range of different technological modalities for monitoring and/or self-care management. Data may be transferred automatically or manually, through the telephone line, mobile networks or a secure web server to those with expertise in interpreting the data. A distinction is often made between invasive or non-invasive telemedicine interventions for heart failure. Invasive interventions are implanted devices measuring clinical variables which are most often automatically transmitted, whereas non-invasive remote monitoring for heart failure include telemonitoring or structured telephone support {48}. Telemonitoring is specific branch of telemedicine. It is defined as the use of electronic information processing technologies to monitor and transmit clinical data related to patient health status between geographically separated individuals, the choice of data collected is determined by the health problem {99}, it concerns digital, broadband, satellite, wireless or blue-tooth transmission of clinical data {47}. Telemedicine is an approach using remote monitoring by structured telephone support of prognostic factors in order to promote an early identification of clinical deterioration in HF patients, prevent hospital readmission for acute decompensated HF, and avoid further complications {3}. Signs and symptoms reported by patients are collected and subsequently entered and stored in a computer system by the healthcare professional, usually physicians or nurses. The data are then remotely reviewed by healthcare professionals. Appropriate action can be initiated, and deterioration can be rapidly detected, which leads to decrease in unnecessary hospital visits, a decrease in hospital (re-)admissions, an improved quality of life {75}. The highest risk period for hospital readmission is the first few weeks after discharge {90}. Telemonitoring provides the opportunity for the patient to get involved in his own disease management and has the potential to improve patient safety and quality of care {21}.

Result

With particular reference to heart failure (HF), the clinical indications, the clinical benefit, and underlying purposes of telemedicine, of which structured telephone support is one specific intervention, have been clearly outlined in the literature:

The rising healthcare costs, rapid advances in communication and diagnostic technology, and the availability of low-cost telemedicine equipment are important factors that have significantly contributed to the increasing use of telemedicine for the provision of care {71}. A range of different technological modalities for monitoring and/or self-care management exists in telemedicine.

Technologies vary from devices such as:

-implantable pacing, defillibrator technologies or cardiac resynchronization devices (remote monitoring by integration of signals from several monitored variables);

-structured telephone support (normal telephone, usually conducted by nurses who call patients to provide monitoring of the patients' signs and symptoms, supported by a computer that collects and stores the data);

-videophone or video-consulting, interactive voice response systems (a computer voice guides the patient to press phone keys in response to questions);

-telemonitoring in which clinical data are electronically transmitted to a health-care team including telephone touch-pad-based telemonitoring modalities and website-based telemonitoring modalities {75},{14}.

In telemonitoring data may be transferred automatically or manually, through the telephone line, the GSM or a secure web server to those with expertise in interpreting the data, whereas in structured telephone support a healthcare professional conducts the call with the patient to gather data that is entered in a computer system. A distinction is often made between invasive or non-invasive telemedicine interventions for heart failure. Invasive interventions are implanted devices measuring clinical variables which are most often automatically transmitted, whereas non-invasive remote monitoring for heart failure include telemonitoring or structured telephone support {48}.

Telemonitoring is a specific branch of telemedicine. It is defined as the use of electronic information processing technologies to monitor and transmit clinical data related to patient health status between geographically separated individuals. Telemonitoring may be continuous or intermittent, usually event-triggered, and the choice of data collected is determined by the health problem of the individual patient {99}. As such, in specialized telemonitoring devices and telephone touch-pads for data entry, patients need to enter their signs, symptoms, and other necessary clinical data such as blood pressure and heart rate {75}. It concerns digital, broadband, satellite, wireless or blue-tooth transmission of clinical data for remote follow-up of a patient over a longer period of time. Home telemonitoring is the remote care delivery or monitoring between a healthcare provider and a patient at a distant location {47}. Structured telephone support, as subject of the current Core HTA, is one specific type of remote heart failure monitoring. It is monitoring and/or self-care management using simple telephone technology, usually initiated by a healthcare professional (e.g. nurse, physician, social worker or pharmacist), in which data is stored on a computer {47}.

Structured telephone support as one particular telemonitoring intervention comes along with several practical general advantages. One important advantage of structured telephone support is an improvement of the observation of patients implying long-term monitoring to detect changes in the patients' condition and thereby having the potential to improve outcomes {99}. Structured telephone support may be particularly suited to make care more accessible to a larger number of patients including those constrained by geography, transport or infirmity {75},{14}. It thereby can also meet the needs of healthcare systems regarding the shortage of healthcare professionals and increasing costs which are problems many countries are facing {92}. It is a patient management care, also labelled as integrated care approach, that ensures appropriate monitoring and treatment of an increasing number of chronically ill patients at a relatively low cost {91}. Structured telephone support shifts health care out of a clinical setting into the patient's home environment or another non-hospital setting facilitating supported self-care, giving the patient enhanced autonomy and control of their disease. Structured telephone support can assist patients in self-monitoring their signs and symptoms and be individually tailored and flexible {11}, {47}, and often includes education or self-care training {25}. It is accepted by patients and likely to be patient-friendly and to enable daily contact with patients without the need for face-to-face contact {47}, {48}, {95}. The underlying purpose is to provide health professionals with accurate and timely information required to remotely detect any deviant health parameter and complications associated with the disease, before an emergency or a scheduled face-to-face follow-up visit is required. It is not an emergency system but helps to generate a fast response. Participation of patients in a telemonitoring programme on a daily basis holds the potential favorable effect to improve health behaviors including adherence to medical recommendations {8},{99} {24}.

Structured telephone support as one particular telemonitoring intervention comes along with several advantages that apply especially to cardiac patients, but that may also apply to patient groups with other chronic diseases including diabetes, chronic obstructive pulmonary disease, asthma and hypertension {91},{118},{62}. The systematic review of Paré et al. {91} revealed evidence concerning the reliability and accuracy of home telemonitoring as an approach to patient management among patients with these chronic diseases, in particular in the cases of pulmonary conditions and HF. The positive effects of telemonitoring in the above named chronic diseases (including HF) primarily result from the fact that telemonitoring allows for frequent patient follow-up, and as a result warning signs of the health state can be detected and appropriate action can be initiated on time. On the other side, telemonitoring has revealed to promote an improvement of patients' self-management and treatment adherence {92}. According to Woottoon 2012 {118}, the main aims of telemonitoring are to support integrated care in chronic disease management by providing information and education in order to improve patients' self-management, facilitating contact with the healthcare professional and improving electronic records {118}.

In HF, telemedicine is an approach using remote monitoring of prognostic factors by structured telephone support in order to promote an early identification of clinical deterioration in HF patients, prevent hospital readmission for acute decompensated HF, and avoid further complications {3}. Prognostic factors that are monitored include weight, blood pressure, pulse oximetry, respiratory rate, body temperature, oxygen saturation, electrocardiograph (ECG) changes, fluid status, ankle swelling over time, infection, intrathoracic impedance, arrhythmias, heart rates during rest and exertion {3}, but also other factors including self-care, education, lifestyle modification, and medicine administration {47}. As already mentioned, one favorable consequence of structured telephone support is that may promote HF patients' treatment adherence and self-management {8},{99}.

With frequent structured telephone support, signs and symptoms reported by patients are collected and subsequently entered by the healthcare professional who is talking over the phone with the patient in a computer system. The data can then be remotely reviewed by healthcare professionals, usually physicians or nurses. If the clinical data do not correspond with agreed parameters or in case complications are observed by an increase in the severity of HF signs and symptoms, healthcare professionals are alerted. Appropriate action can be initiated, and deterioration can be rapidly detected and addressed, for example by adjusting medication or arranging a clinical visit. A timely medical care response or improvement in treatment adherence is prompted and this, in turn, may potentially lead to a decrease in unnecessary hospital visits, a decrease in hospital (re-) admissions, an improved quality of life, fewer events and deteriorations for HF, and reduced healthcare costs {75}. Because the highest risk period for hospital readmission is the first few weeks after discharge, it is suggested that daily telephone support is of particular high benefit during that period {90}. Last but not least, structured telephone support as one particular telemonitoring intervention has the potential to improve patient safety and quality of care {21}.

Importance: Important

Transferability: Completely

Result card for CUR2: "What kind of variations in use are there across countries/regions/settings?"

View full card

CUR2: What kind of variations in use are there across countries/regions/settings?

Method

For this AE the results of the basic search were used,

Additionally the following article was used from handsearch:

MAST REgioNs of Europe WorkINg toGether for HEALTH (Grant Agreement No 250487). D1.12 v1.5 Renewing Health Final Project Report - Public

All provided text-parts about variations in different settings were used, mainly provided descriptively in the studies.

Short Result

Most studies report care provided by a multidisciplinary team, but a great deal of heterogeneity regarding the professionals involved was described. Collaboration between primary care and secondary care was scarcely reported. In almost all the studies, nurses played a coordinating or leading role, but description of the specialization of clinical background were lacking. Almost all programmes also had physicians involved, which could be cardiologists, and/or primary care physicians or other specialists such as geriatricians or internists. Additionally, other professionals (psychologist, dietician, physical therapist, social worker, pharmacist) were involved in the programmes, mostly as a member of the multidisciplinary team or occasionally as the main provider of an intervention (e.g. a pharmacist). A different variation of systems for telemonitoring was found, ranging from assessment of symptoms and/or vital signs to data transmission and automatic alarms. {51}

Substantial heterogeneity among studies was noted {119 }, the content of the telemedicine interventions vary between patient groups and with regard to duration and content.

Result

Among the included 15 reviews 188 references were cited about telemedicine for patients with heart failure. 69 (37 %) of these references are from Europe, 30 (16 %) are from South America, Asia and New Zealand, and 89 (47 %) are from the US.

There were 62 studies from Europe cited in the reviews. Out of the 62 European studies, 16 mentioned educational strategies within the telemedicinal programme. The involved persons in the educational programmes were cardiologists (3 studies), multidisciplinary teams at least for the care plan (25 studies), physician-/primary care led (1 study each), and nurse-led (4 studies) programmes. The other reviews did not mention their specific programme used (32 studies).

In 17 studies, the transfer mode was via telephone/ cell phone transmission, in 4 studies through implantable devices, 1 study described interactive videoconferencing, transtelephonic monitoring, 1 study described hospital-at-home service, 2 studies just described non-invasive telemonitoring, and in 36 studies the transfer mode was not clear.

There are differences in the level of complexity among the technologies and decision systems within telemedicine.{14} Many studies (i.e. n=69, 99 % of the included studies in {51}) report care provided by a multidisciplinary team, but the involved professionals are heterogeneous. Scarcely reported is the collaboration between primary care and in-hospital care provider. In almost all the studies, nurses played a coordinating or leading role, described as homecare nurses, hospital nurses, HF nurses, cardiac rehabilitation nurses, research nurses, practice nurses, and/or district nurses. The description of the specialization of clinical background was lacking. Physicians were involved in almost all programmes, described as cardiologists, primary care physicians, or other specialists such as geriatricians or internists. Additionally, other professionals (psychologist, dietician, physical therapist, social worker, pharmacist) can be involved in the programmes, as a member of the multidisciplinary team or occasionally as the main provider of an intervention (e.g. a pharmacist). The different variations of systems for telemonitoring range from assessment of symptoms and/or vital signs to data transmission and automatic alarms. {51}Substantial heterogeneity among studies was also noted in regard to intervention components, methodologic quality, target population, clinical setting, telemedicine technology, outcomes assessed, personnel involved, and other key factors {52}, There was also a variation within the monitored parameters, the HF selection criteria and lacked detail in the components of the RM (remote monitoring) care packages and usual care.{90}The content of the telemedicine interventions also vary between patient groups and in duration and content. Some include videoconferencing between patients and healthcare professionals, others include monitoring of disease-specific health data by use of medical devices, and some include elements of health coaching. {119}

The used strategies described as telemonitoring for the European studies in the used reviews are listed in the table at appendix 1.

Importance: Important

Transferability: Completely

Result card for CUR3 / ORG10: "Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?"

View full card

CUR3 / ORG10: Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?

Method

Three studies out of the basic literature search provided some information relating the selection of patients for telemonitoring.

Short Result

Three of the reviews reported eligibility and exclusion criteria for patients included in the studies, but there was no answer on who decides or who should decide to use telemedicine for what patient.

One could take the eligibility criteria used in the studies as a surrogate for the decision basis: clinical severity aspects, aspects of positive attitudes towards self-management, and criteria for acceptance and compliance. The used criteria within the studies are listed below.

Several exclusion criteria were used in the studies. Most commonly patients were excluded from the studies in case they:

-had a moderate or serious cognitive, visual, or physical disability {92};

-did not own a phone or who had a life expectancy measured in months rather than years {92};

-were discharged to a long term care facility {42};

-had some form of cognitive impairment or psychiatric disorder {42};

-had a terminal disease or severe co-morbidity {42}.

When determining eligibility criteria, it cannot be denied that some patients appear to benefit more than others. Several studies have suggested that the beneficial effects on state of health are observed mostly among patients:

-whose state of health is considered serious (e.g., the studies by Kwon et al {66} and Trappenberg et al {108}); in {92};

-who want to play an active role in the management of their illness (eg, the studies by Madsen et al {72}, Rickerby and Woodward {97}, DelliFraine and Dansky {18}, and Hopp et al {43}) in {92};

-who are interested in using this type of technological device (eg, the studies by Vähätalo et al {109}, and Madsen et al {72}) in {92};

-with a mean age varied between 56–86 years {42} or 59-82 years {25};

-with a proportion of men from 27–99 % among the studies {42} {25};

-with recorded baseline ejection fractions, with trial means varying from 22–43 % {42};

-with New York Heart Association functional class > II {50} {42} {25};

-with a proportion of patients with coronary artery disease or prior myocardial infarction (MI) ranged from 27 percent to 61 percent in most trials {25}.

In terms of the technology, important acceptance criteria are

-the user-friendliness of the device installed in the home and its nonintrusiveness in the lives of patients, particularly for the youngest patients {92};

-level of technological skill {92};

-level of education {92};

-professional constraints {92} ;

-lifestyle {92};

-having a visual or motor deficit {92}.

Eligibility to new technology depends on an assessment of the general practitioner of a patient’s condition and the patient's willingness and ability to participate. Access to new technologies depends on support of healthcare providers. In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patient is willing to incorporate these technologies into their care or patients at high-risk {40}. Having an access to a touchtone telephone is an essential inclusion criterion {1} . By Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

Result

Three of the reviews reported eligibility and exclusion criteria for patients included in the studies, but there was no answer on who decides or who should decide to use telemedicine for what patient.

One could take the eligibility criteria used in the studies as a surrogate for the decision basis: clinical severity aspects, aspects of positive attitudes towards self-management, and criteria for acceptance and compliance. The used criteria within the studies are listed below.

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-with a proportion of men from 27–99 % among the studies {42} {25};

-with recorded baseline ejection fractions, with trial means varying from 22–43 % {42};

-with New York Heart Association functional class > II {50} {42} {25};

-with a proportion of patients with coronary artery disease or prior myocardial infarction (MI) ranged from 27 percent to 61 percent in most trials {25}.

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-level of technological skill {92};

-level of education {92};

-professional constraints {92} ;

-lifestyle {92};

-having a visual or motor deficit {92}.

Patient self management of chronic conditions, both the disease and the symptoms, is an aged practice that is accelerating and disseminating throughout the world, fueled in part by home-based and portable technologies. Ethically problematic assumptions have the potential to harm some patients and unnecessarily exclude others from self management. A new and higher standard than the current provider-based practice; that readiness to learn, literacy and intact cognitive function are frequently not essential to competent patient self management; that patients, however, are still excluded from it based on apparent defects in these characteristics; and that quality control standards for self management are essential but are not sufficiently rigorous. Barriers to improved outcomes from self management include the virtual absence of objective measures of patient competence to self manage, and of explicit, publicly available and well-argued descriptions of risk and benefit {1450}.

In clinical trials included the selection of patients was made by the researchers on the basis of specific inclusion criteria. For example, in all STS RCTs reviewed by Inglis et al {490}, having access to a touchtone telephone was an essential inclusion criterion. In a RCT of telephone or videophone communication vs. UC {1}, a Mini Mental Status Examination Score above a certain threshold and a phone line at home were among the inclusion criteria. In the clinical trial reported by Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patients are willing to incorporate these technologies into their care or, patients at high-risk could be a main target group for these programmes {40}.

Importance: Important

Transferability: Partially

Result card for CUR4: "Is Structured telephone support (STS) for adult patients with chronic heart failure a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?"

View full card

CUR4: Is Structured telephone support (STS) for adult patients with chronic heart failure a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?

Method

Eleven studies out of the basic literature search and one study from an additional handsearch provided information to answer this question.

Short Result

Generally, telemedicine and telemonitoring can be seen as relatively new, currently as an adjunct to current care with the chance of more patient-self-care-involvement and improved quality of therapeutic monitoring, but without a clear unique idea where it should lead to and how it should be implemented.

Result

One of the included studies provides a historical overview of the published studies, starting with 1987, growing in the late 1990s, but most published after 2000, mainly from the US. The study mentions that: „The data show that home telemonitoring programmes have appeared quite recently. Even though the first study on this subject was published in 1987, most early projects to be described in the literature began to appear in the early 1990s. Studies published between 1991 and 1995 represent 6 % of the total sample. The number of published studies then grew in the second half of the decade (1996 to 1999),

representing 15 % of the sample. The number then increased significantly: more than three quarters of the studies in the sample were published after 2000. The data also show that 45 % of the studies were carried out in the United States, approximately a third were conducted in Europe, while 6 % were conducted in Asia and in Canada. Finally, almost three quarters of the studies in our sample were RCTs, both small and large.“ {92}, 2010

Giamouzis et al. (2012) describes telemedicine as a novel diagnostic modality in 2012{31}; Sousa et al. as a novel tool {102}, 2014.

Eight of the included reviews try to look at the indicators for novelty and how they lead to a novel attitude – like including the patient - and new settings – like different patient- and physician roles - of health care. They still describe telemedicine as „changing modality“ {15}, „promising“ {91}, 2007, „complementary“ {99}, 2010, „potentially“ {35}, 2011, „a modality to improve care“ {34}, 2012, and a common insecurity about what exactly is defined as telemedicine and what kind of programmes were modified into telemedicine (like disease management programmes which are technically supported) seems to occur. The importance and necessity of individual self-care in the overall HF management is recognized {96}, 2012, but currently only a relatively small proportion of HF patients have access to such programmes {102}, 2014. Telemonitoring moves patient care out of a clinical setting shifting the burden of care to the patient’s home, but also giving the patient enhanced autonomy and control {47} in {95}, 2014.

Remote monitoring is still described as an adjunct to current out-of-hospital management of advanced heart failure {63} and is still not widely adopted due to a number of social, technological and reimbursement issues. Remote monitoring will not replace face-to-face clinical review, but it will be part of the solution to the increasing numbers of patients with heart failure and/or an implantable device.{14}

Importance: Important

Transferability: Partially

Target Population

Result card for CUR5: "What is the target population in this current assessment of Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

CUR5: What is the target population in this current assessment of Structured telephone support (STS) for adult patients with chronic heart failure?

Method

For this AE the results of the CUR domain search were used. Most of the studies and literature reviews selected for the CUR domain provided some kind relevant information on the target population of the intervention. The two latest published guidelines of the European Society of Cardiology (ESC) on the diagnosis and treatment of HF and the website of the ESC were additionally consulted to find relevant answers to this AE.

Short Result

Structured telephone support may not be suitable for every patient diagnosed with HF. According to Koehler et al. 2011 {64}, telemonitoring is particularly suitable for patients who are recently hospitalized due to HF, medically unstable, or classified being in the NYHA Class II and III. Koehler also recommends performing telemonitoring during the 12 event-free months after hospitalization for HF {64}. Since structured telephone support is one specific intervention of telemedicine, these eligibility criteria equally apply.

Guidelines of the ESC recommend remote monitoring of patients reporting symptoms (including drug adverse effects) and signs of HF (Class I recommendation, Level of Evidence: C) {19}.

Patients with cognitive impairment, a mental illness, a life expectancy less than one year, language barrier, hearing impairment, or another chronic disease are often not eligible for structured telephone support (Polisena et al., 2010) {93}. This has been confirmed by Paré et al. 2010 {92} who outlined on the basis of their systematic review on the clinical effects of home telemonitoring in the context of diabetes, asthma, HF and hypertension that telemonitoring likely to not be suitable for everyone, because most studies excluded patients with a moderate to severe cognitive, physical, visual or hearing disability. Patients who did not own a phone or who a very short life expectancy (less than 1 year) were often excluded as well. The beneficial effects on state of health are observed mostly among patients whose health state is rather serious {92}. However, the fact that certain groups have been excluded from studies does not mean that telemonitoring may not be suitable for them. According to the current literature this remains unknown and further research may identify if telemonitoring is also suitable for these patients.

Result

In this current assessment of structured telephone support for adult patients with chronic heart failure, the target population concerns patients who have signs or symptoms of HF, or an underlying non-diagnosed abnormality of the cardiac structure that is likely to lead to HF.

Further considerations for the target population: According to the large number of studies that have been conducted on the clinical effectiveness of telemonitoring in HF patients, including structured telephone support, the appropriate target population generally concerns:

-the elderly, with a definitive clinical diagnosis of HF;

-with a mean age generally around 70 years old (patients may also be significantly younger or older);

-or with chronic HF;

-often who have had a cardiovascular hospitalization or a hospitalization for HF within the previous 12 months;

-who have been discharged to home;

-often with moderate or severe symptoms of HF (New York Heart Association, NYHA class II-IV), a LVEF ≤ 30 %;

-who are administered diuretics, ACE inhibitors and beta blockers.

In this group, the highest benefit of structured telemonitoring may be reached.

Importance: Critical

Transferability: Completely

Result card for CUR6: "How many people belong to the target population?"

View full card

CUR6: How many people belong to the target population?

Method

Although the basic search for the CUR domain was used to answer this question, no article of the basic search was selected to be relevant for this assessment element. Therefore, a manual search was done to find relevant information about the incidence and prevalence of the health condition as published in evidence-based guidelines and (international) reports on the HF epidemiology. European and American guidelines for the diagnosis and treatment of acute and chronic HF were consulted by doing a manual search on the website of the ESC and the American Heart Association (AHA), and the references of the ESC guidelines published in 2008 and 2012 and the AHA practice guideline published in 2013 were reviewed. These guidelines led occasionally to an additional article that was relevant for this question. Moreover, the 2015 Update of Heart Disease and Stroke Statistics of the AHA was reviewed. The website of the ESC was additionally searched for relevant studies that have been published so far on the epidemiology of HF worldwide and in developed and developing countries (search terms epidemiology OR incidence OR prevalence AND heart failure). The additional search resulted in 22 additional relevant studies. The searches for the additional studies and guidelines were additionally conducted the 06th of January 2015 by one of the investigators. Two additional studies were included during the consultation phase.

Short Result

Although various studies have been conducted in the past to capture the epidemiology of HF, there is still a scarcity of epidemiological data. The absence of gold-standard criteria for the diagnosis of HF, together with a lack of agreement on a definition of HF itself, explains why studies fail to use a uniform assessment of HF. This has led to considerable variations in the estimates of the incidence and prevalence of HF. Moreover, the highly selected patients and retrospective analysis as present in the majority of the clinical trials is likely to bias the real prevalence and incidence numbers. The epidemiological data presented is further limited to hospitalized patients who do not provide information on non-diagnosed patients with mild and asymptomatic HF {116}. In addition, other non-cardiac related conditions such as diabetes, obesity, chronic obstructive pulmonary disease or a restrained physical fitness may mask HF since these chronic diseases may be viewed as the primary diagnosis. To assess the actual epidemiology of HF, random samples in the general population may be useful using validated surveys, physical examinations and objective methods to identify HF and the underlying cardiac dysfunction {82}. In consequence, available epidemiological data in HF are not comprehensive since they only describe a fraction of patients with this syndrome.

Result

Cardiovascular disease (CVD) is the most common cause of death worldwide, being responsible for almost 30% of all deaths. In Europe CVD is responsible for 45% of all deaths equating to >4 million deaths per year, causing almost twice more deaths as cancer. Although mortality from CVD has decreased substantially in the past decade, there are wide inequalities in terms of death but also in terms of rates of treatment between (European) countries (Nicols et al., 2014; Townsend et al., 2015). {123,124} The most common forms of CVD are coronary heart disease, stroke and HF. HF is a large and global public health problem that will become more important with the aging of the world population. The number of patients with HF is predicted to increase considerably in countries with fast ageing populations. Up to one person in five is expected to develop HF at some point in their life in economically developed countries {70}. In 2007, it was already estimated that approximately 1–2 % of the adult population in developed countries had HF and that the incidence approached on average 5–10 per 1000 persons per year with a significantly higher incidence in higher age groups {82}.

In 2011, it was estimated that 26 million adults worldwide were living with HF {6}, leading some to describe it as a global pandemic {2}. Of these patients at least 15 million are European {19}, whereas almost 7 million Americans ≥ 20 years of age have HF {120}. According to the AHA, at least 850.000 patients are yearly newly diagnosed with HF in the US with the incidence approaching 1 per 100 people 65 years of age and older. According to projections of the AHA, the prevalence of HF will increase 46 % from 2012 to 2030 {83} revealing that at least an additional 3 million adults will have HF {120}. Currently, at least 5 million Americans have a clinically manifest HF {115}. Data on the incidence and prevalence of HF in the developing world are largely absent, but it is estimated that there is also an increasing number of patients with HF in the developing countries due to the emerging pandemic of cardiovascular diseases {78}. However, it is known that unlike in the US and Europe, individuals in sub-Saharan Africa countries are diagnosed with HF at a significant younger age. HF is common in South Africa, and approximately half of patients with newly diagnosed cardiovascular disease have HF, whereas only 10 % have coronary artery disease {101},{16}. Across Asia, the prevalence of HF ranges between 1.3 % and 6.7 %. According to a recent study on the global burden of ischemic heart disease {80}, HF in men was most prevalent in North America, Oceania, and Eastern Europe (> 5 per 1000). In women, the prevalence of HF was highest in Oceania, North America and North Africa and the Middle East (4.5 per 1000). HF was lowest in west sub-Saharan Africa for both men and women (< 1 per 1000). Many populations are facing a “double HF burden” caused by communicable and non-communicable diseases {80}.

HF is a condition that becomes more common with increasing age. In North America and Europe, persons 50 years of age or under are hardly ever found to have HF {32},{7},{107}, and more than 80 % are 65 years of age or older {6}. Hence, particularly in those older than 50 years of age the prevalence and incidence increase progressively with age. In 2007 the prevalence was estimated to be 10-20 % in persons with the age between 70 and 80 while it was rising significantly to ≥10 % among persons 70 years of age or older {82}. In the Dutch Rotterdam study, the prevalence of HF was 1 % in the age group of 55-64 years, 3 % in the age group of 65-74 years and 13 % in the age group of 75-85 years {81}. Moreover, according US estimates, the remaining lifetime risk for development of new HF remains at 20 % at 80 years of age, even in the face of a much shorter life expectancy {83}.

Overall, the prevalence of systolic HF and diastolic HF is estimated to be equal between men and women. According to the ESC (2012), at least half of patients with HF have a low or reduced ejection fraction. HF with a preserved ejection fraction or diastolic HF is present in approximately 50 % the patients with HF {77},{29}. In younger age groups, systolic HF occurs more frequently in men than in women because myocardial infarction occurs at an earlier age in men. Diastolic HF is more common in the elderly, in women, in individuals with longstanding hypertension, diabetes, renal failure, anemia, and atrial fibrillation {19}. Studies show that the accuracy of the diagnosis of HF by clinical means alone is often inadequate. This applies particularly to female, elderly, and obese patients, leading to a potential underrepresentation of the patients who have HF {106},{60},{77}.

The globally increasing prevalence of HF is not merely due to the ageing of the population. It is also due to improvements in the treatment of acute coronary syndromes, effective prevention in those at high risk or those who have already survived a first coronary event, a longer survival of cardiac patients and HF patients, and the increasing epidemiology of cardiovascular diseases in the developing countries {84},{100},{116}. An increase in risk factors for HF such as diabetes, sedentary behavior and obesity also contribute to the increasing pool of HF patients. Factors that on the other hand decrease the incidence of HF are a decline in the number of new cases with myocardial infarction, a decline in the severity of acute myocardial infarction and the improvement of care {40},{85}. The improvement of care for hypertension and coronary artery disease, particularly in Western Countries, also account for a decreasing incidence {86}.

Importance: Critical

Transferability: Completely

Target Condition

Result card for CUR7: "What is the disease or health condition in the scope of this assessment?"

View full card

CUR7: What is the disease or health condition in the scope of this assessment?

Method

The basic search for the CUR domain was used to answer this question with 1 article. Moreover, a manual search was done to find relevant information about the HF syndrome as published in evidence-based guidelines and in 8 additional scientific studies on HF. European and American guidelines for the diagnosis and treatment of acute and chronic HF were consulted by doing a manual search on the website of the ESC and the AHA, and the references of the ESC guidelines published in 2008 and 2012 and the AHA practice guideline published in 2013 were reviewed and these led occasionally to an additional article that was relevant for this assessment element. Moreover, the ICD-10 of the World Health Organization was consulted. The searches for the ICD-10 and guidelines were additionally conducted the 06th of January 2015 by one of the investigators.

Result

HF is not a disease but a collection of signs, symptoms, and pathophysiology {86}. HF is generally characterized by an underlying structural abnormality or cardiac dysfunction that impairs the ability of the left ventricle to either fill with blood or contract to eject blood, especially during physical activity. Its prevalence, incidence, and clinical outcome are related to a range of cardiovascular and non-cardiovascular conditions that cause cardiac impairment {86}. HF is associated with significant reduced quality of life, morbidity, and mortality. Moreover, it puts a considerable burden on the healthcare systems around the globe, largely due to high hospital admission and readmission rates, and long hospital stays. In fact, HF patients have a high risk of readmission especially in the first weeks after hospital discharge, with 20-30 % of the patients being readmitted with a month. This rises up to 60 % after six months of hospital discharge {90}.

According to the ESC, HF is a complex clinical syndrome in which patients have typical symptoms and signs resulting from an abnormality of cardiac structure or function. Although often life-threatening, typical symptoms and signs resulting from the abnormality of cardiac structure or function (as present in HF), lead to failure of delivering oxygen {77}. The most typical symptoms of HF are shortness of breath at rest or during exertion, fluid retention reflected in pulmonary congestion or peripheral edema (ankle swelling), fatigue, and dizziness {19},{75}. The most typical clinical signs HF patients may have are tachycardia, tachhypnoa, pleural effusion, hepatomegaly, elevated jugular peripheral edema, pulmonary edema, venous pressure, pulmonary crackles, fluid overload, and displaced apex beat. According to the ESC guideline published in 2008, most definitions emphasize the need for both the presence of HF symptoms and physical signs of fluid retention {19}.

There is no single diagnostic test for HF but it is rather a clinical diagnosis based on a careful history and physical examination {115}. The diagnosis of HF can be difficult when relying solely on symptoms and signs. Objective evidence of an abnormality of the cardiac structure is required. Many of the symptoms of HF are of limited diagnostic value to discriminate between HF and other health abnormalities because they are non-specific. One typical symptom of HF is peripheral edema, but because it has other causes as well, it is particularly non-specific. More specific symptoms (i.e. orthopnoea and paroxysmal nocturnal dyspnoea) are less common, especially in patients with milder symptoms, and are, therefore, insensitive. More specific signs, such as elevated jugular venous pressure and displacement of the apical impulse, are hard to detect and, thus, less reproducible (i.e. agreement between different physicians examining the same patient may be poor) {74},{89},{27},{55}. Symptoms and signs may be difficult to identify and interpret in specific patients, such as obese individuals, elderly, patients with pulmonary disease, and patients with a poor physical condition or ischemia {38}. Many of the HF signs result from sodium and water retention (e.g. peripheral edema). These symptoms may, however, be absent or lead to quick symptomatic improvements in patients receiving diuretic therapy. Therefore, these symptoms are also not specific. In case of uncertainty, a favorable response to treatment directed towards HF is warranted. Nonetheless, a clinical response to treatment for HF is not sufficient for the diagnosis, but it can aid when the diagnosis remains unclear after appropriate diagnostic tests. To the diagnosis of HF, an underlying cardiac cause has to be demonstrated.

Conditions that cause pressure overload (eg. hypertension, aortic stenosis), idiopathic dilated cardiomyopathy, and abnormalities of ventricular diastolic function, heart valves, pericardium, endocardium, heart rhythm, and conduction can cause HF. However, HF usually results from myocardial infarction causing an impaired systolic left ventricular function {77}.

Table 1 Symptoms and signs typical for heart failure

Typical symptoms	**More specific signs**
Breathlessness	Elevated jugular venous pressure
Orthopnoea	Hepatojugular reflux
Paroxysmal nocturnal dyspnoea	Third heart sound (gallop rhythm)
Reduced exercise tolerance	Laterally displaced apical impulse
Fatigue, tiredness, increased time	Cardiac murmur
to recover after exercise	
Ankle swelling	
Less typical symptoms	**Less specific signs**
Nocturnal cough	Peripheral edema (ankle, sacral, scrotal)
Wheezing	Pulmonary crepitations
Weight gain (>2 kg/week)	Reduced air entry and dullness to percussion at lung bases (pleural effusion)
Weight loss (in advanced HF)	Tachycardia
Bloated feeling	Irregular pulse
Loss of appetite	Tachypnoea (>16 breaths/min)
Confusion (especially in the elderly)	Hepatomegaly
Depression	Ascites
Palpitations	Tissue wasting (cachexia)
Syncope	

Systolic versus Diastolic Heart Failure

HF is mainly described using a measurement of the left ventricle ejection fraction (usually measured by echocardiography or, in a minority of cases, with use of radionuclide technique or MRI). The ejection fraction has a prognostic value since a reduced ejection fraction indicates a poorer survival. Most clinical trials select patients based upon the ejection fraction. A normal ejection fraction in healthy subjects is generally considered to be > 50 % {77}.

A distinction is frequently made between systolic and diastolic HF. Most patients have both abnormalities of systolic and diastolic dysfunction {115}. The weakened ability of the left ventricle to contract and empty is known as ‘systolic dysfunction’. In patients having left ventricular systolic dysfunction, the heart is unable to pump sufficient blood into the body circulation during systole due to an inability to pump efficiently {19},{77}. Left ventricular systolic dysfunction is a complication of myocardial infarction that greatly increases the risk of HF. Besides myocardial infarction leading to left ventricular systolic dysfunction and subsequent HF, myocardial infarction may lead to papillary muscle dysfunction and mitral regurgitation or provoke arrhythmias, like atrial fibrillation, which in turn leads to HF. In other patients, preexisting myocardial ischemia may impair myocardial relaxation impeding the left ventricle to dilate {12}. Echography is most often utilized to assess left ventricular systolic dysfunction or systolic HF, which according to the ESC signifies a reduced ejection fraction of ≤ 35 %. In fact, the heart ejects a smaller fraction of a larger volume while stroke volume is maintained by an increase in the end-diastolic volume because the left ventricle dilates. The major clinical trials have also included patients with systolic HF with a reduced left ventricular ejection fraction (HFREF) ≤ 35 %. Nevertheless, uncertainties concerning the appropriate threshold remain {19},{77}.

Generally speaking, diastolic HF is HF with an inability of the heart to relax normally at diastole. As a result, it does not fill properly. The syndrome is an impaired filling of the left ventricle in response to a volume load, despite normal ventricular contraction. It is characterized with a preserved left ventricular ejection fraction (HFPEF) which signifies an ejection fraction of > 40-45 % {19},{77}. HFPEF has, however, also been classified as EF 50 % and ≥ 55 %, leading to variable prevalence rates of HFPEF which generally is around 50 % {115}. In HFPEF, patients have a normal left ventricular function, i.e. the heart contracts normally, but higher filling pressures are needed to obtain a normal end-diastolic volume of the left ventricle. These patients do not have an entirely normal ejection fraction but also no major reduction in systolic function. Therefore, these patients are considered to have HF with a ‘preserved’ ejection fraction. More recent trials have included diastolic HF patients with an ejection fraction > 40-45 % and no other causal cardiac abnormality. Patients with an ejection fraction varying between 35 % and 50 % probably have a mild ‘systolic dysfunction’ and represent a grey area. The diagnosis of HF with a ‘preserved’ ejection fraction is difficult because potential non-cardiac causes may account for the patient’s symptoms (e.g. anemia or chronic pulmonary disease). Nevertheless, most have evidence of diastolic dysfunction, which is generally accepted as the likely cause of HF in these patients. Therefore, the term diastolic HF is common to describe this specific syndrome of HF {19},{77}.

In sum, patients with diastolic HF have symptoms and/or signs of HF and a preserved left ventricular ejection fraction (LVEF) > 40–50 % and patients with systolic HF have symptoms and/or signs of HF and a reduced left ventricular ejection fraction (HF-REF) ≤35 %. There is no agreement concerning the cut-off for preserved versus reduced EF {19},{77}.

The current 10th edition of the International Classification (ICD) system classifies HF as an intermediate, not underlying cause of death. It describes HF as congestive HF including congestive heart disease and right ventricular failure. HF is also defined as left ventricular failure including cardiac asthma, left HF, and heart disease (unspecified) or HF with edema of lung and pulmonary edema. HF is further defined as the incidence of HF due to rheumatic heart disease, hypertensive heart disease, ischemic heart disease and inflammatory heart disease. Complicating abortion or ectopic or molar pregnancy, obstetric surgery and procedures are excluded from the

classical definition of HF by the ICD-10. Moreover, HF due to hypertension (with renal disease), HF following cardiac surgery or due to presence of cardiac prosthesis, and neonatal cardiac failure are excluded {113}.

Importance: Critical

Transferability: Completely

Result card for CUR8: "What are the known risk factors for the disease or health condition?"

View full card

CUR8: What are the known risk factors for the disease or health condition?

Method

- The basic search for the CUR domain was used to answer this question article selected to be relevant for this assessment element.

- Moreover, a manual search was done to find relevant information about risk factors and determinants of the HF syndrome as published in evidence-based guidelines and in additional scientific studies on HF. European and American guidelines for the diagnosis and treatment of acute and chronic HF were consulted by doing a manual search on the website of the ESC and the AHA, and the references of the ESC guidelines published in 2008 and 2012 and the AHA practice guideline published in 2013 were reviewed and these led occasionally to an additional article that was relevant for this assessment element. Moreover, the 2015 Update of Heart Disease and Stroke Statistics of the AHA and the report “Heart failure: preventing disease and death worldwide” published by the World Heart Failure Alliance was also consulted for this AE were reviewed. Finally, an additional search on the website of the ESC was done with the key words “risk factors” AND “heart failure” resulting in the studies listed below, which occasionally led to an additional reference in order to refer to the original study. The additional searches were conducted the 06th of January 2015 by one of the investigators.

Short Result

Risk factors for HF vary from lifestyle factors (e.g. smoking, alcohol intake, sedentary lifestyle and a unhealthy diet) to consequences of a unhealthy lifestyle (diabetes, obesity, arteriosclerosis) to socio-demographic factors (e.g. higher age, socio-economic status) and hereditary factors (e.g. race, hypercholesteria, atherosclerosis) and disease history (e.g. history of atrial fibrillation, presence of hypertension, diagnosis of CHD, chemotherapy, viral infection) and more specific biological factors (e.g. higher levels of hematocrit, increased circulating concentrations of resistin, cystatin C).

Many developing countries are now facing the similar risk factors due to a shift towards a Western-type lifestyle. Risk factors for hospital (re-) admission are highly comparable to the risk factors for developing a HF.

A greater survival has been noted for patients with established CHF (“reverse epidemiology”,) who have obesity, hypercholesterolaemia and hypertension.

Result

Coronary artery disease notably increases the likelihood of developing HF. According to Hellermann et al. (2003) {40}, at least one third of patients will experience HF in less than 10 years after having experienced a myocardial infarction, especially those who have left ventricular systolic dysfunction during admission {40}. Although people who have hypertension have a smaller likelihood of developing HF than those who have had a myocardial infarction, hypertension contributes considerably to the population burden of HF as it is much more prevalent than myocardial infarction {69}. Hypertension leads to a myocardial overload and thus to left ventricular systolic and diastolic dysfunction that in turn can lead to congestive HF. Especially an elevated level of systolic blood pressure is a major risk factor for HF. Data suggest that patients with hypertension have a particularly high incidence of left ventricular diastolic dysfunction {115}. Obesity, caused by a sedentary behavior and an unhealthy diet and increasingly present in Western societies, doubles the likelihood of developing HF after adjustment for associated risk factors {56}. Another risk factor associated with obesity is the metabolic syndrome signifying abdominal adiposity, hypertriglyceridemia, a high level of low high-density lipoprotein in the blood, and fasting hyperglycemia {115}. Diabetes also increases the risk for developing HF. Valvular abnormalities, factors indicative of heart disease (left ventricular hypertrophy, left ventricular dilatation, cardiomyopathy), atrial fibrillation, myocarditis, ischemic heart disease, angina pectoris, a parental history of HF, congenital heart disease, as well extracardiac conditions (renal insufficiency, obstructive pulmonary disease, rheumatic fever, sleep apnea) all increase the risk of HF {57},{82}, {58}. There is no doubt on the relation of obesity, increased cholesterol values and hypertension to cardiovascular morbidity and mortality {82}. According to the AHA, seventy-five percent of HF cases have antecedent hypertension {83}.

As regards socio-demographic and clinical factors, the Heart Disease and Stroke Statistics of the AHA reveal various risk factors for HF that have been identified by a range of studies. As such, an increasing age, a male gender, an African American race, hypertension, obesity, a low socio-economic status, a history of atrial fibrillation, and a diagnosis of CHD are socio-demographic risk factors that increase the likelihood for developing HF. Lifestyle risk factors that increase the risk of HF are smoking, an unhealthy diet, high alcohol consumption, a sedentary behavior, and high salt intake {83}. Atherosclerosis is another very important clinical risk factor for the development of HF {115}. Other clinical risk factors associated with incident HF relate, amongst others, to a low level of adiponectin and a high level of pro-B-type natriuretic peptide (BNP) in the bloodstream, a high sodium level in the blood, an increased urinary albumin excretion, an elevated serum γ-glutamyl transferase, higher levels of hematocrit, increased circulating concentrations of resistin, cystatin C, inflammatory markers (interleukin-6 and tumor necrosis factor-α) and low serum albumin levels. Moreover, cardiomyopathy, ventricular premature complexes, left ventricular mass index, cardiac (high-sensitivity) troponin, and changes in high-sensitivity troponin levels have been significantly associated with incident HF {117},{83}. Several of these risk factors do slightly differ between HFPEF and HFREF underscoring differential pathophysiological mechanisms for both subtypes of HF. As such, a higher age, a female gender, cystatin C, increased urinary albumin excretion, and a history of atrial fibrillation have been strongly associated with the new onset of HFPEF. Conversely, a male gender, current smoking, an increased highly sensitive troponin T or an increased pro-B-type natriuretic peptide, and previous myocardial infarction have revealed to significantly increase the likelihood for HFREF {5}.

According to the ESC 2012 {77}, HF with reduced ejection fraction or systolic HF is the best understood type of HF in terms of pathophysiology and treatment. Coronary artery disease is the cause of approximately two-thirds of cases of systolic HF, although hypertension and diabetes are probable contributing factors in many cases. There are many other causes of systolic HF, which include previous recognized or unrecognized viral infection, an increased alcohol intake, chemotherapy, and 'idiopathic' dilated cardiomyopathy {77}.

HF with a preserved ejection fraction or diastolic HF seems to have a different epidemiological and etiological profile from HF with a reduced ejection fraction. Patients with diastolic HF are more often older, female have a history of hypertension and are obese compared with those with systolic HF. They are less likely to have coronary heart disease but more likely to have hypertension and atrial fibrillation {77}. Coronary artery disease, diabetes mellitus, and hyperlipidemia are also highly prevalent in HFPEF patients {115}. Patients with diastolic HF have a better prognosis than those with systolic HF {77}.

Many developing countries are facing similar risk factors as developed countries due to a shift towards a Western-type lifestyle. Other risk factors related to infections caused by bacteria and tropical parasites contribute to the development of HF in these countries as well. Infections remain an important cause HF in many developing countries such as rheumatic fever due to preventable bacterial infections. HIV is also an important risk factor for heart-related disease since it leads to increased risk for infections due to a weakened immune system. Although rheumatic HF is the most common cause for HF in certain countries of South Asia, trends towards an ischemic cause for HF have also been observed in Asia, China and Japan {98}. In areas of South America, Chagas, a parasitic infection, is the cause for HF in almost 50 % of all HF cases {73}. In tropical areas, Davies has been a major risk factor for HF {111}. According to the systematic review and pooled analysis by Khatibzadeh et al. 2013 {58}, risk factors of HF vary considerably among six world regions. In their review, crude proportion of HF patients with an ischemic heart disease was highest in Europe and North America, followed by East Asia, Latin American and the Caribbean, and lowest in Sub-Saharan Africa. Hypertension was an important risk factor in all regions, whereas cardiomyopathy was the most common risk factor in Latin America, the Caribbean, Sub-Saharan Africa, and Asia Pacific High Income. Cardio-pulmonary disease was most prevalent in HF patients in East Asia, likely due to the high smoking prevalence. Rheumatic heart disease appeared to be most prevalent in East Asia and Sub-Saharan Africa {58}. These findings are similar to two reviews that revealed a high proportion of HF attributed to ischemic heart disease in developed countries, and a higher proportion of HF attributed to rheumatic heart disease and non-ischemic cardiomyopathies in developing countries {61},{78}.

As regards risk factors for hospitalization in HF, these concern a higher age, a nonwhite race, a low socio-economic status, lack of employment, living alone, smoking, ischemic heart disease, a low systolic blood pressure, a higher NYHA class (III or IV), prior HF hospitalization, the presence of hypertension, diabetes mellitus, anemia, hyponatremia, a history of renal insufficiency, worsening renal function, chronic obstructive pulmonary disease, obstructive sleep apnea, depression, a low quality of life and absence of emotional support or social network, and a low adherence to therapies, to name a few {30}. Risk factors for hospital readmission among older persons with a new onset of HF have also been identified. These concern diabetes mellitus, NYHA class III or IV, chronic kidney disease, a reduced ejection fraction (< 45 %), muscle weakness, slow gait, and having a depression {8}.

Healthy lifestyle factors such as a normal weight, nonsmoking, regular exercise, moderate alcohol intake, a healthy diet (consumption of fruit and vegetables and consumption breakfast cereals) are related to a lower risk of HF. Moreover, high circulating individual and total omega-3 fatty acid concentrations decrease the likelihood for developing HF {83}.

Evidence exists that obesity, an elevated blood cholesterol level and hypertension are associated with a greater survival in HF patients. This phenomenon has been termed "reverse epidemiology" {54}. Although the phenomenon is not yet clearly understood, proposed explanations are the syndrome of cardiac cachexia, reverse causation and time discrepancies among competitive risk factors. The reverse epidemiology does not hold for all conventional risk factors, as smoking cessation improves prognosis in HF patients {105}.

Importance: Critical

Transferability: Completely

Result card for CUR9: "What is the natural course of the disease or health condition?"

View full card

CUR9: What is the natural course of the disease or health condition?

Method

- The basic search for the CUR domain was used to answer this question. No article of the basic search was relevant for this assessment element. Therefore, a manual search was done to find relevant information about the natural course of the health condition as published in evidence-based guidelines on the HF epidemiology. European and American guidelines for the diagnosis and treatment of acute and chronic HF were consulted by doing a manual search on the website of the European Society of Cardiology (ESC) and the American Heart Association (AHA), and the references of the ESC guidelines published in 2008 and 2012 and the AHA practice guideline published in 2013 were reviewed and this led to one additional article that was relevant for this assessment element (Mosterd & Hoes, 2007) {82}. The references from the selected studies for the CUR domain were also reviewed, leading to seven additional relevant references.
- The searches for the guidelines were additionally conducted the 06th of January 2015 by one of the investigators (NB).

Result

In patients with left ventricular systolic dysfunction, the maladaptive changes occurring in the cardiac muscle after myocardial infarction lead to pathological adaptation of the ventricle with dilatation and impaired contractility. This in turn is one measure of a reduced ejection fraction {76}. In the absence of treatment of the systolic dysfunction, these maladaptive changes worse progressively over time, leading to further enlargement of the left ventricle and further decline in the ejection fraction. The patient may yet initially not reveal any particular HF symptoms. Two mechanisms are thought to account for this progression. The first is occurrence of recurrent myocardial infarction leading to additional myocyte death. The other is the systemic responses induced by the decline in systolic function, particularly neurohumoral activation. Two important neurohumoral systems activated in HF are the renin-angiotensin-aldosterone system and sympathetic nervous system. In addition to causing further myocardial injury, these systemic responses have destructive effects on the blood vessels, kidneys, muscles, bone marrow, lungs, and liver. They account for many clinical features of the HF syndrome. Clinically, the maladaptive changes after myocardial infarction account for the development of HF

symptoms (pump failure or ventricular arrhythmia) and these worsen over time. The ultimate consequences are a reduced quality of life, a reduced functional capacity, decompensation leading to hospital (re-)admission, and death. The impaired cardiac function also depends on atrial contraction, synchronized contraction of the left ventricle, and a normal interaction between the right and left ventricles. Events affecting any of these or imposing an additional load on the heart (e.g. anemia) can lead to acute decompensation {77}.

The initial cause of HF influences its further prognosis. As such, HF caused by viral myocarditis may lead to complete recovery, while acute myocardial infarction complicated by HF significantly increases the risk of mortality. Comorbidities known to lead to premature death in HF patients include renal dysfunction, depression and anemia. Patients with both HF and chronic renal failure have an extremely poor prognosis {82}.

Not even three decades ago the majority of HF patients died a few years after the diagnosis, and admission to hospital with worsening symptoms was frequent and recurrent. This led to high hospitalization rates for HF in many countries. Effective treatment has reduced hospitalization rates for HF to 30–50 % and has led to small but significant decreases in mortality {104},{53}. Nowadays, the mortality rate reaches approximately 50 % within 5 years of admission among HF patients {19}. Patients with a new onset of HF have a mortality risk varying generally between 20 % and 40 % within the first year after hospital admission for HF {121}, {68},{53}, {36}. Between 20 and 30 % patients are readmitted within the first month after hospital discharge and almost 50 % at 6 months. Due to the aging population these percentages are expected to rise {37},{30}. Hence, life expectancy is considerably reduced in HF patients and acute or slow worsening of HF occurs in most of the patients leading to a (highly) reduced quality of life {82}.

The pattern of readmissions in HF patients has been referred to as the “three-phase terrain” of HF readmissions because epidemiological data revealed that 30 % of readmissions occur during the first two months after hospital discharge, 50 % of readmissions occur within the last two months before death, and the remaining 20 % of readmissions occur in-between {122}.

Importance: Critical

Transferability: Completely

Result card for CUR10: "What are the symptoms and burden of disease for the patient at different stages of the disease?"

View full card

CUR10: What are the symptoms and burden of disease for the patient at different stages of the disease?

Method

- The basic search for the CUR domain did not provide any relevant information to answer this assessment element. Hence, a manual search was done to find relevant information about symptoms and burden of disease for the patient at different stages of the HF syndrome as published in evidence-based guidelines on the HF epidemiology. European and American guidelines for the diagnosis and treatment of acute and chronic HF were consulted by doing a manual search on the website of the ESC and the AHA resulting in the following guidelines and references:
- Since the Killip classification describes the severity of a patient’s HF condition in the context of myocardial infarction in different stages and this was mentioned in the ESC guidelines from 2012, two additional studies were consulted on this classification system:
- Furthermore, the website of the ESC was consulted which led to one additional position paper on advanced chronic HF relevant for this assessment element:
- The searches for the additional guidelines were conducted the 06th of January 2015 by one of the investigators (NB).

Result

Burden of disease for different stages of heart failure

According to the ESC guidelines published in 2012 {77}, “a patient who has never exhibited the typical signs or symptoms of HF is described as having asymptomatic left ventricular systolic dysfunction (or whatever the underlying cardiac abnormality is)”. HF generally is a chronic condition and patients who have had HF for some time are often said to have ‘chronic HF’. A treated patient with symptoms and signs that have unchanged for at least a month is said to be ‘stable’.

‘Acute HF’ is the term used to describe the rapid onset of, or change in, HF symptoms and signs. Acute HF is an event with severe symptoms and signs of considerable prognostic importance. Causes of acute HF include arrhythmias, myocardial ischemia, and acute preload or afterload changes. In most cases, acute HF arises as a result of deterioration in patients with chronic stable HF who had a previous diagnosis of HF. Hence, the patient may be described as ‘decompensated’. AHF usually requires admission to hospital and immediate intervention. Acute HF may also be the first presentation of HF (‘de novo’ acute HF). In that case, acute HF may be caused by an abnormality of a cardiac function such as acute myocardial infarction, for example in a patient who has had asymptomatic cardiac dysfunction, often for an indeterminate period, and may persist or resolve. In that case, patients may become ‘compensated’. Patients with pre-existing HF often have a clear trigger, such as an arrhythmia or discontinuation of diuretic therapy in a HF patient with a reduced ejection fraction, and volume overload or severe hypertension in HF patients with a preserved ejection fraction. The acuteness may vary. Patients may experience a period of days or even weeks of deterioration (e.g. increasing breathlessness or edema) whereas others develop HF within a few hours to minutes (e.g. in association with an acute myocardial infarction).

HF symptoms can range from life-threatening pulmonary edema or cardiogenic shock to worsening peripheral edema. Although symptoms and signs may resolve in patients with a new HF, the underlying cardiac dysfunction may not. These patients have an increased risk of recurrent ‘decompensation’. Sometimes, however, a patient may have HF due to a problem that resolves completely (e.g. acute viral myopericarditis). Particularly those patients with ‘idiopathic’ dilated cardiomyopathy may show considerable or complete recovery of left ventricular systolic function with modern treatment including an angiotensinconverting enzyme inhibitor, beta-blocker, and mineralocorticoid receptor antagonist.

‘Congestive HF’ is a term may describe acute or chronic HF with evidence of congestion (i.e. sodium and water retention). Congestion, though not other symptoms of HF (e.g. fatigue), may resolve with diuretic treatment {77}. Many patients may further progress to ‘advanced chronic HF’. The ESC developed a definition of advanced HF with objective criteria that is helpful. According to the ESC, these patients often have severe symptoms (NYHA class III or IV), episodes with clinical signs of fluid retention and/or peripheral hypofusion, objective evidence of severe cardiac dysfunction, severe impairment of physical exercise, history of at least 1 HF hospitalization the previous 6 months, and presence of all the named features besides optimal therapy. These patients generally have a poor prognosis and high risk of events {79}.

‘End-stage HF’ indicates a highly advanced and irreversible stage of HF where conventional HF treatment cannot lead to an improvement. In these patients, palliative care or heart transplantation are indicated. Many or all of these terms may be accurately applied to the same patient at different times, depending upon their stage of illness {77}.

A useful classification of HF based on the nature of clinical representation has been revealed by the ESC guidelines on the diagnosis and treatment of HF:

Table 2. Classification of heart failure

Classification of heart failure	
New onset	First presentation (‘de novo’) Acute or slow onset
Transient	Recurrent or episodic
Chronic	Persistent Stable, worsening, or decompensated

Source: ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (Dickstein et al., 2008) {19}

New-onset HF refers to the first presentation of HF. Transient HF refers to symptomatic HF over a particular time period, although long-term treatment may be indicated. Examples are patients with mild myocarditis from who almost recover completely, patients with a myocardial infarction who need diuretics in the coronary care unit but who don’t need long-term HF treatment, or transient HF caused by ischemia and resolved by revascularization. Worsening HF in chronic HF (decompensation) is a very common form of HF leading to hospital admission. Treatment should be based on the clinical presentation for which specific therapy is indicated (e.g. pulmonary edema, hypertension emergency, acute MI) {19}.

Classification of heart failure by its symptoms and functional capacity

The severity of the symptoms and limitations of physical activity of HF are usually assessed according to the New York Heart Association (NYHA) functional classification. This classification system has been proven to be clinically useful. Patients in NYHA class I are essentially asymptomatic and have no symptoms attributable to heart disease or are well treated and their symptoms may have relieved. Patients in NYHA class II have mild symptoms of HF and a slight limitation in physical activity; those in class III have moderate symptoms and symptoms while walking on the flat; and those in class IV are said to have severe symptoms while being breathless at rest and essentially housebound {77},{115}.

It is important to note that symptom severity correlates poorly with underlying cardiac dysfunction. Although there is a clear relationship between severity of symptoms and survival, patients with mild symptoms may still have a relatively high absolute risk of hospital admission and death (McMurray, 2010; Chen et al., 2011; Dunlay et al., 2009) {76},{9},{22}. HF symptoms can also change promptly. As such, a stable patient with mild symptoms can become abruptly breathless at rest with the onset of an arrhythmia, and an acutely unwell patient with pulmonary edema and NYHA class IV symptoms may recover quickly with diuretic treatment. Deterioration in symptoms increase the likelihood of hospital admission and death {77}.

Table 3. New York Heart Association functional classification based on functional capacity

Classification	Severity of symptoms and physical activity
Class I (Asymptomatic)	No limitation of physical activity. Ordinary physical activity does not cause symptoms (undue breathlessness, fatigue, or palpitations).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class IV (Severe)	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.

Source: Hunt et al., Circulation 2005;112:e154–e235. {46}

Another classification by the American Heart Association (AHA) and the American College of Cardiology (ACC) describes HF in stages based on structural changes and symptoms as follows:

Table 4. ACC/AHA stages of heart failure

Stage	Stage of heart failure based on structure and damage to heart muscle

Stage I	At high risk for developing heart failure. No identified structural or functional abnormality; no signs or symptoms.
Stage II	Developed structural heart disease that is strongly associated with the development of heart failure, but without signs or symptoms.
Stage III	Symptomatic heart failure associated with underlying structural heart disease.
Stage IV	Advanced structural heart disease and marked symptoms of heart failure at rest despite maximal medical therapy. Stage IV HF is sometimes called refractory HF to indicate a lack of response specifically to diuretic treatment.

Source: Yancy et al., JACC 2013;16:e148-e231. {115}

The ACCF/AHA stages recognize that risk factors and abnormalities of the heart are associated with HF. The stages are progressive and violate, meaning that once a patient moves to a higher stage, regression to a former HF stage is not possible. The NYHA functional classification rates the severity of symptoms in those with structural heart disease and the stage in which a patient resides can change short time periods. Whereas the ACCF/AHA classification system of HF emphasizes the development and progression of disease and can be used to describe patient, the NYHA classification focuses on exercise capacity and the symptomatic status of the disease {115}.

The Killip classification may be used to describe the severity of a patient's HF condition in the context of myocardial infarction. In fact, patients are categorized according to the presence or absence of simple physical examination findings that suggest ventricular dysfunction in order to provide a clinical estimate of the severity of acute myocardial infarction {59}. According to this classification system, patients are classified into four levels during physical examination. Patients in Class I demonstrate no evidence of congestive HF due to the absence of clinical signs of cardiac decompensation. Patients in Class II have findings and clinical signs consistent with mild to moderate HF (i.e. lung rales, pulmonary venous hypertension, pulmonary congestion). Patients in Class III demonstrate severe HF by overt pulmonary edema with rales throughout the lung fields. Patients in Class IV are in cardiogenic shock with clinical signs of hypotension and evidence of peripheral vasoconstriction {23}.

Table 5. The Killip classification for the severity of a patient's HF condition in the context of myocardial infarction

Class I	**no evidence of congestive HF**	**absence of clinical signs of cardiac decompensation**
Class II	**mild to moderate HF**	**i.e. lung rales, pulmonary venous hypertension, pulmonary congestion**
Class III	**severe heart failure**	**overt pulmonary edema with rales throughout the lung fields**
Class IV	**cardiogenic shock**	**clinical signs of hypotension and evidence of peripheral vasoconstriction**

Sources: De Gaere et al., 2001 {17 }; El-Menyar et al., 2010 {23}

Importance: Critical

Transferability: Completely

Result card for CUR11: "What aspects of the consequences / burden of disease are targeted by Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

CUR11: What aspects of the consequences / burden of disease are targeted by Structured telephone support (STS) for adult patients with chronic heart failure?

Method

Basic search was used for this question and only articles reporting data related to the telemonitoring impact on the burden of disease were selected. No further research was needed. Systematic reviews and most recent article were taken in to account first. No quality assessment tool of articles was used. We just provide the information relative to structured telephone support. 6 reviews were selected.

Short Result

Telemonitoring impact on burden of heart failure is measured here as decrease in heart failure related hospitalization, heart failure related length of stay, and all cause mortality.

In short the listed reviews gave the foloowing information:

- There is substantial heterogeneity in the results {33}.
- Telehealth programmes demonstrated clinical effectiveness in patients with CHF compared with usual care {114}.
- It was not clear as to the extent to which these effects were due to tele-monitoring per se or to the improvement in access to care {44}.
- Structured telephone support and telemonitoring are effective in reducing the risk of all-causemortality andCHF-related hospitalisations; in patients with CHF; they improve quality of life, reduce costs, and evidence-based prescribing {48}.
- Home telemonitoring is generally clinically effective, and no patient adverse events were reported in the included studies {93}.

- Telemonitoring appears to be an acceptable method for monitoring of HF patients {75}.

The provided effectiveness data were

For mortality

- Fixed effect model risk ratio 0.76, 95 % CI 0.66 to 0.88 {114} – mortality
- hazard ratio [HR]: 0.97; p=0.87 {102}– mortality
- RR 0.66; 95 % CI 0.54 - 0.81; P < 0.001 {48} for invasive telemonitoring – mortality
- RR 0.88; 95 % CI 0.76 –{48} for structured telephone support– mortality
- risk ratio ¼ 0.64; 95 % CI: 0.48–0.85 {93}– mortality

for CHF related hospitalisation

- Random effect model risk ratio 0.72, 95 % CI 0.61 to 0.85 {114}– hospitalisation
- hazard ratio (HR: 0.89; p=0.44 {102} – hospitalisation
- RR 0.79; 95 % CI 0.67 - 0.94; P = 0.008 {48} for invasive telemonitoring – hospitalisation
- RR 0.77; 95 % CI 0.68- 0.87; P < 0.0001). 1.01; P = 0.08 {48} for structured telephone support– hospitalisation

Result

Gorthy 2014 {33} included in a systematic review 14 RCTs (from January 1975 to August 2014) evaluating the efficacy of non-invasive telemonitoring. 2 out of 12 studies reporting *cardiac* or *all-cause mortality* demonstrated a significantly positive effect, 3 out of 13 reported a significant reduction of *all-cause hospitalization* and 3 out of 10 reported reduction in *HF hospitalization*. 1 study demonstrated significant improvement of *b-type naturetic peptide levels* and *quality of life* using a mobile-phone-based telemonitoring system. 2 studies compared structured telephone support against non-invasive telemonitoring:

- The first (TEN-HMS) randomized 426 patients to usual care (n = 85), structured telephone support (n = 173), or to non-invasive telemonitoring (n = 168)] demonstrated significant reduction in all-cause mortality of both intervention arms compared to usual care with no significant difference in HF/all-cause mortality and hospitalization between the two inteventions.
- The second randomized 160 patients to usual care and 301 patients to one of three intervention groups. Strategy 1 employed structured telephone support alone (n = 104), strategy 2 employed structured telephone support plus weekly transmission of vital signs including changes in weight, blood pressure and symptoms (n = 96), and strategy 3 employed the same intervention used in strategy 2 plus a monthly 24-h cardiorespiratory recording (n = 101). *All-cause hospitalization*, *HF hospitalization,* and *mortality* were not significantly reduced in the more intensive strategy 2 and 3 intervention groups compared to strategy 1 patients. There was no significant effect of Home telemonitoring in reducing *bed-days occupancy for HF* or *cardiac death* plus *HF hospitalization*.

Gorthy et al. report substantial heterogeneity in the results. They mention that telephone or non-invasive telemonitoring have the advantage to reach large numbers of patients in regionally distant areas or are limited in travel. They assume that structured telephone support should be a relatively inexpensive treatment option. Non-invasive requires a certain degree of health-literacy of patients who must interact with the system to provide the information to the healthcare provider. The authors conclude that one approach applied to a broad spectrum of different patient types may not be effective.

Xiang 2013 {114} included in their systematic review 26 studies (of 33) concerning tele-monitoring from 2001-2012 with 7530 patients (*15 of the 33 articles were in Gorthy 2004 review)* and report within their meta-analysis that telehealth programmes had significant overall effectiveness in reducing all-cause mortality (Fixed effect model risk ratio 0.76, 95 % CI 0.66 to 0.88), CHF-related hospitalization (Random effect model risk ratio 0.72, 95 % CI 0.61 to 0.85) and CHF-related length of stay (Random effect model mean difference 21.41 days, 95 % CI 22.43 to 20.39). In addition, telehealth programmes showed significantly greater effectiveness in reducing mortality and hospitalizations among patients with higher New York Heart Association (NYHA) categories. The authors conclude that telehealth programmes demonstrated clinical effectiveness in patients with CHF compared with usual care.

A NICE 2010 Guidance {44} included 8 RCTs on telemonitoring from 2003-2010 (5 of these double with in above listed articles). They report that the trials reviewed showed an improvement in all-cause mortality and all cause-hospitalisation rates when tele-monitoring, with intensive reviews and contact with the specialist team, was compared to standard care. The authors discuss that it was not clear as to the extent to which these effects were due to tele-monitoring per se or to the improvement in access to care by the patients assigned to tele-monitoring and no recommendation was made.

Inglis 2010 {48}, a Cochrane Review, included 27 controlled studies (from January 1966 to 6 May 2006) of which 11 used non-invasive telemonitoring (2,710 patients) and 16 used structured telephone support (5,613 patients) into a meta-analysis. The authors report an *all-cause mortality* significantly reduced by non-invasive telemonitoring (RR 0.66; 95 % CI 0.54 - 0.81; P < 0.001) but not by structured telephone support (RR 0.88; 95 % CI 0.76 – 1.01, P = 0.08). *HF hospitalizations* were significantly reduced by both telemonitoring (RR 0.79; 95 % CI 0.67 - 0.94; P = 0.008) and structured telephone support (RR 0.77; 95 % CI 0.68- 0.87; P < 0.0001). 1.01; P = 0.08). The authors conclude that structured telephone support and telemonitoring are effective in reducing the risk of all-causemortality and CHF-related hospitalisationsin patients with CHF; the interventions improve quality of life, reduce costs, and evidence-based prescribing.

Polisena 2010 {93} included 21 studies from 1998-2008 with 3082 patients in a systematic review and report that home telemonitoring reduced mortality (risk ratio ¼ 0.64; 95 % CI: 0.48–0.85) compared with usual care. Several studies suggested that home telemonitoring also helped to lower the number of hospitalizations and the use of other health services. Patient quality of life and satisfaction with home telemonitoring were similar or better than with usual care. The authors conclude that their review demonstrated that home telemonitoring is generally clinically effective, and no patient adverse events were reported in the included studies. More studies of higher methodological quality are required to give more precise information about the potential clinical effectiveness of home telehealth interventions.

Maric 2009 {75} included 56 articles on telemonitoring from before 2007 into a systematic review. The authors report that most studies demonstrated improvements in outcome measures, including improved quality of life and decreased hospitalizations. However, not all studies reported the same improvements and in several cases the sample sizes were relatively small. The authors conclude that telemonitoring appears to be an acceptable method for monitoring of HF patients. Controlled, randomized studies directly comparing different modalities and evaluating their success and feasibility when used as part of routine clinical care, are now required.

Importance: Critical

Transferability: Partially

Current Management of the Condition

Result card for CUR12: "What are the differences in the management for different stages of the disease or health condition?"

View full card

CUR12: What are the differences in the management for different stages of the disease or health condition?

Method

Basis search was not sufficient and a search (mainly on Medline) of all available guidelines in English was done. No quality assessment of guidelines was done. Focus was made on telemonitoring indications within the reviewed guidelines. Three additional studies were included during the consultation phase.

Result

There is interest in new approaches of telemonitoring {1}, but at the moment there is no guideline recommendation available (possible) {45,24,1,110,3,33,44} for telemonitoring in general but for multidisciplinary CHF management programmes {87}.

Following is a brief description of how telemonitoring is included in available guidelines:

The Global heart failure Awareness Programme (Heart failure: preventing disease and death worldwide. http://www.escardio.org/communities/HFA/Documents/WHFA-whitepaper-15-May-14.pdf?hot=highlighton) {45} includes telemonitoring devices among the new approaches to long-term management outside hospital and encourage more research on these approaches before recommending for they are promising but yet failing to provide clear improval of survival.

The ESC guideline {77} states that for telemonitoring with implantable devices, a guideline recommendation is not yet possible and reports two studies, one about thoracic impedence monitoring which has not yet shown to improve {110} and another one that measures pulmonary artery preassure which did reduce hospital admission for HF in one RCT {1}. Nevertheless, more recent studies have revealed that automatic implant-based multiparameter telemonitoring devices are likely to improve clinical outcomes in patients with chronic heart failure (Hindriks et al., 2014; Parthiban et al., 2015). {125} {126} Relatively to remote monitoring without implantable devices to date they have given inconsistent results and not yet support a guideline recommendation {3}.

Other diagnostic factors, such as asymptomatic atrial fibrillation, patient activity, mean resting heart rate, right ventricular pacing percentage, and cardiac resynchronization therapy pacing percentage, might help. Combined heart failure device diagnostics have been demonstrated to improve the identification of patients at a higher risk of subsequent heart failure hospitalizations. Recently, the Implant-based Multiparameter Telemonitoring of Patients with Heart Failure randomized clinical trial demonstrated that daily automatic remote monitoring enabled early action to be taken in response to the warning signs of acute decompensated heart failure (not including thoracic impedance), resulting in lower all-cause mortality and hospital admission rates for heart failure (Slotwiner et al., 2015).

A recent consensus paper recommends all patients with a cardiac implantable electric device should be offered remote monitoring as part of the standard follow-up management strategy. This implies that all patients with a cardiac implantable electric device will have the recommendation to be followed with remote monitoring, with the possibility of easy implementation of remote monitoring or telemonitoring with telephone support also for heart failure. (Slotwiner et al., 2015).{127}

Pulmonary artery pressure monitoring using a wireless, passive, radiofrequency sensor implanted into a distal branch of the descending pulmonary artery was approved by FDA for implant in NYHA class III HF patients who have been hospitalized for HF in the previous year {33}.

NICE chronic heart failure guidilens {44} given the difficulties of interpretation of the evidence, the GDG did not make specific recommendations for home telemonitoring but agreed that a research recommendation should be made.

The Australian guidelines (National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand) {87} state that all patients hospitalised for heart failure should have post-discharge access to best-practice multidisciplinary chronic HF care that is linked with health services, delivered in acute and subacute healthcare settings and that priority should be given to face-to-face management while the application of remote management assisted by structured telephone support and telemonitoring should be considered for those patients who do not have ready access to a chronic HF management programme (Grade A recommendation).

Importance: Important

Transferability: Partially

Result card for CUR13: "How is the disease or health condition currently diagnosed according to published guidelines and in practice?"

View full card

CUR13: How is the disease or health condition currently diagnosed according to published guidelines and in practice?

Method

Basis search was not sufficient and a search (mainly on Medline) of all available guidelines in English was done. No quality assessment of guidelines was done. Focus was made on diagnosis indications within the reviewed guidelines.

Result

Most guidelines agree on three essential stages of care for patients with heart failure:

-Diagnosis (should be timely and accurate);

-Treatment (should be appropriate to each patient and available urgently if necessary);

-Longterm management (should include follow-up, monitoring and support).

Disagreement is observed on which diagnostic tools should be used for all patients with suspected heart failure and in which order.

Especially for invasive diagnostics there are some differences and challenges according to the interpretation of the diagnostic and prognostic value {45}

The Global heart failure Awareness Programme {45} reported that many guidelines have been published [North America (Canada: CCS and USA: ACCF/AHA, HFSA), Europe (England and Wales: NICE, France: HAS, Germany: DEGAM, Scotland: SIGN) and Aia (Japan: JSC, Singapore: MoH) for heart failure patients and although they may differ in what evidence is included and how it is assessed and in what is considered appropriate, the all agree on three essential stages of care for patients with heart failure: diagnosis (should be timely and accurate)-treatment (should be appropriate to each patient and available urgently if necessary)-longterm management (should include follow-up, monitoring and support. They state that an international consensus recommendation leading to greater clarity about best practice with endorsement from credible local bodies would be of help. Although published guidelines agree on which diagnostic tools are useful, they disagree on which should be used for all patients with suspected heart failure and in which order. Making an accurate diagnosis requires a range of diagnostic tools, in conjunction with clinical judgement and expert knowledge.

The ESC guidelines {77} highlight particular challenges related to diagnosis of HF-PEF (heart failure with ‘preserved’ ejection fraction) remains a particular challenge, and the optimum approach incorporating symptoms, signs, imaging, biomarkers, and other investigations is uncertain. The following questions are posed: Strain/speckle imaging—value in diagnostic and prognostic assessment of both HF-REF (heart failure with reduced ejection fraction) and HF-PEF? Diastolic stress test —value in diagnosis of HF-PEF?

A recent Australian consensus statement {88} recognizes that many individuals are not diagnosed in a timely manner, and once a diagnosis is made, treatment is frequently sub-optimal.

Importance: Important

Transferability: Partially

Result card for CUR14: "How is the disease or health condition currently managed according to published guidelines and in practice?"

View full card

CUR14: How is the disease or health condition currently managed according to published guidelines and in practice?

Method

Basis search was not sufficient and a search (mainly on Medline) of all available guidelines in English was done. No quality assessment of guidelines was done. Focus was made on management indications within the reviewed guidelines.

Result

The Global heart failure Awareness Programme {45} reports that despite clear recommendations regarding evidence-based medications, many patients with heart failure do not receive a prescription for potentially beneficial medication because they do not always comply with guidelines.

In the US more than a quarter of patients with heart failure did not receive an appropriate prescription and in Europe doses are often below those recommended {26}, {28},{65}.

In Europe guidelines incorporate follow-up, monitoring and support however about a quarter (7/26) of the countries reported having heart failure management programmes in more than 30 % ot their hospitals {49} and even when in place, they are not always used. In the US most hospital had fewer than half of 10 key recommended practices in place and fewer than 3 % had 10 in place {4}.

A recent Australian consensus statement {88} report that the management of chronic heart failure remains a pressing problem, with many apparent indicators of poor case detection, including discordant management with evidencebased treatment, recurrent hospital admission, and disconnected care issues these that are amplified among marginalised populations.

Tele-monitoring can be considered on add-on for the existing management options.

Global assessment

-Despite clear recommendations regarding evidence-based medications, many patients with heart failure do not receive a prescription for potentially beneficial medication because they do not always comply with guidelines {45}.

Europe

-In Europe prescription doses are often below those recommended {26},{28},{65};

-In Europe guidelines incorporate follow-up, monitoring and support, however, about a quarter (7/26) of the countries reported having heart failure management programmes in more than 30 % ot their hospitals {49} and even when in place, they are not always used.

USA

-In the US most hospital had fewer than half of 10 key recommended practices in place and fewer than 3 % had 10 in place {4};

-In the US more than a quarter of patients with heart failure did not receive an appropriate prescription {26},{28},{65}.

Australia

- A recent Australian consensus statement {88} report that the management of chronic heart failure remains a pressing problem, with many apparent indicators of poor case detection, including discordant management with evidencebased treatment, recurrent hospital admission, and disconnected care issues these that are amplified among marginalised populations.

Importance: Important

Transferability: Partially

Regulatory Status

Result card for CUR15: "What is the marketing authorisation status of Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

CUR15: What is the marketing authorisation status of Structured telephone support (STS) for adult patients with chronic heart failure?

Method

The listed devices in the included studies were searched for their CE status using google and the device-specific websites.

European Commission at http://ec.europa.eu/growth/index_en.htm

The database for medical devices within the EU (http://ec.europa.eu/health/medical-devices/market-surveillance-vigilance/eudamed/index_en.htm) is access-restricted. And could not be consulted

Italy has a comprehensive national database for medical devices which is in Italian and is accessed only by authorized operators. An open access classification of medical devices in Italian language only (http://www.salute.gov.it/imgs/C_17_pubblicazioni_1687_allegato.pdf) is needed for the research in the database itself, so no results can be provided.

There is also a medical devices registration database for medical devices in Austria, but the access is closed. (http://www.medizinprodukteregister.at/de/start).

An Austrian expert was asked for information.

Result

For equipment used within structured telephone support in a (community-)setting and/or within a disease management programme the devices seem to be individually created for the local need and based on a software for data-collection via App, internet or as a database where data are written in while telephone interviews.

Different related devices like mobile phone applications, bluetooth adaptations (sending data from the scale or bloodpressure device, etc., via telephone to the healthcare center), are used within structured telephone support.

Usually a telephone does not need to be registered as a healthcare device, but any related medical device as regulated within the European Commission at http://ec.europa.eu/growth/index_en.htm

The information from the expert consultation in Austria lead to two homepage information-links which give information about the status of authorisation, another two systems were not found. It is not known whether these systems are used elsewhere than in Austria:

-The AIT Telemonitoringsystem of the Medical University of Graz provides a DMP monitoring device named *TMScardio* which is used in hospitals and a healtnetwork in Tyrol. There is some official information at http://www.meduni-graz.at/cms.php?pageName=301&year=2013&newsId=25852 (last check on 2.7.2015) and on http://www.ait.ac.at/research-services/research-services-digital-safety-security/health-information-systems/telemonitoring-and-therapy-management/heart-failure/?L=1 (last check 6.7.2015), but not about CE registration (needed ?).

-ELICARD Heart Telemonitoring System, DMP monitoring system, which uses the TMScardio. Information is avaliable at http://bmg.gv.at/cms/home/attachments/4/5/9/CH1417/CMS1423479059781/9_ait_factsheet_telemonitoring_herzinsuffizienz.pdf (last check 6.7.2015), includes the same technical product AIT as mentioned above, we did not find any information about CE mark.

-Two further systems were mentioned, a telerehabilitation discharge-home training-monitoring and a bloodpressure SMS, but with no further information and no hint to a CE mark.

Importance: Important

Transferability: Partially

Result card for CUR16: "What is the reimbursement status of Structured telephone support (STS) for adult patients with chronic heart failure across countries?"

View full card

CUR16: What is the reimbursement status of Structured telephone support (STS) for adult patients with chronic heart failure across countries?

Method

No valid method found. Theoretically every single health system (parts of Europe also with different federal situations) could be studied in details or a survey could be conducted. To get this information one has to clearly know where to look for, and whom to ask (there are maybe more than one organisations to consult for different settings).

We did not provide a survey due to time restriction of this HTA report. A valid selection of experts who know about the reimbursement details in each country or health system, the creation of a questionnaire including all relevant details about settings of STS and potential correlated services, and reduced to patients with chronic heart failure (where the definition within the studies varies) would be a separate project and exceed the ressources of this HTA.

The research on European statistical databases did not result in any information about reimbursemnet (Eurostat, OECD).

The resarch among different Eurpoean websites from healthsystems or related organisations is limited by language and if not, it often does not provide clear information about reimbursement.

No information in the included studies found.

Short Result

This question is left un-answered. Due to the situation of high complexity among the use and settings within the terminus of „telemonitoring/ telemedicine“and the new or developmental status of the intervention(s) no explicit answer can be provided within this HTA.

Result

Due to the situation of high complexity among the use and settings within the terminus of „telemonitoring/ telemedicine“ and the new or developmental status oft he intervention(s) no explicit answer can be provided.

In Europe disease management programmes are used and reimbursed in national or regional level or within project level. Whether and how they include telemonitoring and what is reimbursed or and by whom exceeds the time-frame of this review.

It is not clear how to define „reimbursement“:

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) of the carers time/ effort;

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) of the infrastructure (computer, telephone, database, software, etc.);

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) of the usual care and additional telehealthcare;

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) of only the additional telehealthcare;

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) of devices;

-As the payment (or reimbursement within benefit baskets/ lump sum payment, etc.) for the data-collection and evaluation.

Importance: Optional

Transferability: Not

Discussion

We found clear descriptions and stages for heart failure, despite the fact that HF is more or less a range of (increasingly frequent) symptoms than a disease with a certain cause and treatment. There is a long list of underlying risk factors for developing and worsening the condition which also can be used as monitoring indicators for deterioration. In 2007, it was already estimated that approximately 1–2 % of the adult population in developed countries had HF and that the incidence approached on average 5–10 per 1000 persons per year with a significantly higher incidence in higher age groups {82}.

However, available epidemiological data in HF are not comprehensive since they only describe a fraction of patients with this syndrome. Due to the absence of gold-standard criteria for the diagnosis of HF and the lack of agreement on a definition of HF, there are considerable variations in the estimates of HF. Moreover, the highly selected hospitalized patients, retrospective analysis, and other non-cardiac related may bias the real estimates {116},{82}.

The condition starts symptom-free and is worsening by impairment in daily living (physical activity) due to increasingly frequent symptoms. The stages/ classes are described in detail (ESC, NYHA, ACC/AHA, Killip).

For telemonitoring there is a long list on expectations for potential advantages within the care of chronically ill patients (with HF). The idea is to shift a part of care (the observation of deterioration) towards the patient self- or homecare. Studies from Europe mainly highlight educational strategies within the telemedicinal programme. The involved health professionals are cardiologists, multidisciplinary teams and physician-/nurse- primary care. At the moment there is no guideline recommendation

available for telemonitoring in general but for multidisciplinary CHF management programmes. The transfer mode described for telemonitoring is mainly via telephone/ cell phone transmission, or through implantable devices, interactive videoconferencing, transtelephonic monitoring are other options. Substantial heterogeneity among studies was noted. Telemonitoring is mainly described as new and additive technology, especially for Europe, although the history of telemedicine started in 1987 in the US.

Telemonitoring may not be suitable for every patient. It is particularly suitable for patients who are recently hospitalized due to HF, medically unstable, or classified being in the NYHA Class II and III. Guidelines of the ESC recommend remote monitoring of patients reporting symptoms (including drug adverse effects) and signs of HF (Class I recommendation, Level of Evidence: C). Patients with cognitive impairment, a mental illness, a life expectancy less than one year, language barrier or another chronic disease are often not eligible for a telemonitoring intervention {93},{92}. Patients who do not own a phone were often excluded from the studies as well. The beneficial effects on state of health are observed mostly among those patients whose health state is rather serious {92}.

Most guidelines agree on three essential stages of care for patients with heart failure, which are a timely accurate diagnosis, appropriate treatment and long-term management, but there is disagree observed on which diagnostic tools should be used for all patients with suspected heart failure and in which order. Especially for invasive diagnostics there are some differences and challenges according to the interpretation of the diagnostic and prognostic value.

For the invasive device-monitoring there are companies mentioned in the included studies which provide their registration status online. For other equipment used as „telemedicine“ or „telemonitoring“ in a (community-)setting and/or within a disease management programme the devices seem to be individually created for the local need and based on a software for data-collection via a telephone app, internet or as a database where data are written in while telephone interviews. Due to restricted access for the European registries and some no-name descriptions of the content of telemonitoring, the registration could not be followed for all systems found in the studies. Also the reimbursement status was not evaluated due to the huge heterogeneity of different products and different product-combinations.

We did not restrict the included studies in this domain by study-methodology, because we wanted to provide a basic overview. For some of the assessment elements we had to exceed the common basic literature search.

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Appendices

The used strategies described as telemonitoring for the European studies in the used reviews

Study	country	found where?	who?	what?	transfer mode	education?
Aguado 2010	Spain	Jaarsma 2013	multidisciplinary team	multidisciplinary team care plan educational strategies optimized treatments increased access to care		yes
Aimonino 2007	Italy	Jaarsma 2013	physician-led	multidisciplinary team educational strategies optimized treatments increased access to care	hospital-at-home-service	yes
Aldamiz-Echevarria 2007	Spain	Feltner 2014		home-visiting programmes		
Angermann 2011	Germany	Pandor 2013		symptoms and medication monitoring	telephone	yes
Antonicelli 2008	Italy	Conway 2014; Gorthi 2014; Jaarsma 2013; Pandor 2013; Xiang 2013	multidisciplinary team	BP, HR, weight, 24h urine output, and ECG; care plan educational strategies optimized treatments increased access to care; telemonitoring; Disease Management Programmes	non-invasive Telemonitoring	
Antonicelli 2010	Italy	Giamouzis 2012		weight, blood pressure, heart rate, 24h urine, weekly ECG	telephone	
Balk 2008	NL	Conway 2014; Gorthi 2014; Jaarsma 2013; Xiang 2013	multidisciplinary team	care plan educational strategies increased access to care; scale, medication, dispenser; Disease Management Programmes; Teleguidance	non-invasive Telemonitoring	
Barlow 2007	UK	Schmidt 2010		home-telemonitoring		
Blue 2001	Scotland	Whellan 2005, Jerant 2005, Gorthi 2014, Jaarsma 2013, Xiang 2013	multidisciplinary team, nurse-led	care plan educational strategies optimized treatments, case management, DMP		yes
Bondmass 2001	Europe	Jerant 2005	multidisciplinary team		telephone	

Boyne 2011	NL	Xiang 2013		scale, pulse monitoring		
Brotons 2009	Spain	Jaarsma 2013	multidisciplinary team	multidisciplinary team care plan educational strategies optimized treatments increased access to care		yes
Cabezas 2006	Spain	Feltner 2014		structured support	telephone	
Capomolla 2002	Italy	Jerant 2005, Gorthi 2014, Whellan 2005	cardiologist	Disease Management Programmes Using Outpatient Visits	telephone	
Capomolla 2004	Italy	Conway 2014, Clark 2007, Pandor 2013, Gorthi 2014, Xiang 2013		weight, systolic BP, HR, vital signs (including weight, systolic blood pressure, heart rate), DMP	interactive voice response	
Cleland 2005	Europe, Germany, NL, UK	Conway 2014, Jaarsma 2013, Chaudry 2007, Xiang 2013, Giamouzis 2012, Gorthi 2014, Pandor 2013, Clark 2007	nurse, multidisciplinary team	education and monitoring; weight, BP, and ECG; increased access to care;weight	telephone	yes
Cline 1998	Sweden	Gorthi 2014, Whellan 2005	cardiologist	Disease Management Programmes Using Outpatient Visits		
Dar 2009	UK	Feltner 2014, Giamouzis 2012, Gorthi 2014, Jaarsma 2013, Pandor 2013, Xiang 2013	multidisciplinar team	weight, blood pressure, heart rate, pulse oximetry; care plan optimized treatments educational strategies increased access to care; DMP	telephone	
de la Porte 2007	NL	Gorthi 2014		Disease Management Programmes Using Outpatient Visits		
de Lusignan 2001	UK	Jerant 2005, Conway 2014, Clark 2007, Xiang 2013		multidisciplinary clinic; pulse, BP, weight; vital signs (pulse, blood pressure, weight) and clinical status;	interactive videoconferencing, transtelephonic monitoring	
Del Sindaco 2007	Italy	Jaarsma 2013	multidisciplinary team	care plan optimized treatments educational strategies increased access to care, hybrid DM programme		yes
Dendale 2011	Belgium	Pandor 2013		weight, blood pressure, heart rate; scale, pulse	cell phone transmission	
Ekman 1998	Sweden	Jerant 2005, Feltner 2014, Gorthi 2014, Whellan 2005	Primary care physician	outpatient clinic-based interventions	telephone	
Giordano 2009	Italy	Conway 2014; Giamouzis 2012; Gorthi 2014, Jaarsma 2013, Xiang 2013	multidisciplinary team	one-led ECG, weight, blood pressure, ECG, drug dosage, education and monitoring; adherence to diet and treatment, monitoring of symptoms, control of fluid retention, and daily physical activity; multidisciplinary team care plan optimized treatments educational strategies increased access to care;	telephone	yes
Holland 2007	UK	Feltner 2014, Gorthi 2014, Jaarsma 2013	multidisciplinary team	educational strategies increased access to care, home-visiting programmes, Disease Management Programmes		yes
Jaarsma 1999	NL	Feltner 2014, Gorthi 2014, Jaarsma 2013, Whellan 2005, Jerant 2005	multidisciplinary team, nurse-led	Disease Management Programmes Using Home Visits		yes
Jolly 2009	UK	Xiang 2013		scale monitoring		
Kielblock 2007	Germany	Conway 2014, Pandor 2013, Xiang 2013		weight, scale telemonitoring		
Klersy 2009	Italy	Schmidt 2010, Sousa 2014		technology assisted strategies	telephone, technology (?)	
Koehler 2011	Germany	Giamouzis 2012, Gorthi 2014		weight, blood pressure, ECG, drug dosage; Disease Management Programmes	cell phone transmission	
Koronowski 1995	Israel	Jaarsma 2013	multidisciplinary team	intensive home-care surveillance		
Landolina 2012	Italy	Gorthi 2014		Disease Management Programmes Using Invasive Hemodynamic Monitoring		
Ledwidge 2002	Ireland	Gorthi 2014		Disease Management Programmes Using Outpatient Visits		
Linne 2006	Sweden	Feltner 2014				yes
Lynga 2012	Sweden	Xiang 2013		scale monitoring		
MacDonald 2002	Ireland	Whellan 2005	cardiologist	clinic follow up, cardiologist supervision		

Martinez-Fernandez 2006	Spain	Schmidt 2010		home monitoring		
Massie 2001	Italy	Jerant 2005	multidisciplinary team	standard telephone calls, transtelephonic monitoring	telephone	
McDonald 2001	Ireland	Feltner 2014		outpatient clinic-based interventions		
McDonald 2002	Ireland	Feltner 2014,Jerant 2005	multidisciplinary team	outpatient clinic-based interventions	telephone	
Mendoza 2009	Spain	Jaarsma 2013	multidisciplinary team	increased access to care, hospital at home model		
Mortara 2004	Europe	Jaarsma 2013	multidisciplinary team	optimized treatments educational strategies increased access to care		yes
Mortara 2009	Europe, Italy, UK, Poland	Conway 2014, Gorthi 2014, Giamouzis 2012, Xiang 2013		education and monitoring; weight, systolic BP, HR, and symptoms, respiration rate, and physical activity; weight, BP, and symptoms; asthenia score, oedema score, changes in therapy, blood results;	telephone call, interactive voice response	
Nucifora 2006	Italy	Feltner 2014				yes
Peters-Klimm 2010	Germany	Jaarsma 2013	multidisciplinary team	care plan educational strategies increased access to care, HF case management		yes
Piotrowicz 2010	Poland	Jaarsma 2013	multidisciplinary team	care plan educational strategies increased access to care; new home TeleCardia Rehab programme		yes
Robinson 2004	Germany	Jaarsma 2013	multidisciplinary team	care plan increased access to care, telehomecare		
Rondinini 2008	Italy	Jaarsma 2013	multidisciplinary team, domiciliary-based nurse-led strategy	care plan educational strategies increased access to care		yes
Scherr 2009	Austria	Giamouzis 2012, Pandor 2013, Xiang 2013		weight, blood pressure, heart rate, dosage of medication; scale, medication dispenser, pulse monitoring	cell phone transmission	
Schmidt 2007	Germany	Schmidt 2010		telemedicine		
Stromberg 2003	Sweden	Feltner 2014, Gorthi 2014, Jerant 2005	multidisciplinary clinic	Disease Management programmes Using Outpatient Visits	telephone	
Thompson 2005	UK	Feltner 2014, Jaarsma 2013	multidisciplinary team	optimized treatments educational strategies increased access to care, home-visiting programmes ,		
TIM-HF 2011, Koehler 2010	Germany	Sousa 2014		TM (daily ECG, blood pressure, weight) sent to telemedical centers		
Van Veldhuisen 2011	NL	Gorthi 2014		Disease Management programmes Using Invasive Hemodynamic Monitoring		
Vavouranakis 2003	Greece	Jaarsma 2013	multidisciplinary team	optimized treatments educational strategies increased access to care		
Villani 2007	Italy	Xiang 2013		scale, symptoms, pulse, urine output		
Wierzchowiecki 2006	Poland	Jaarsma 2013	multidisciplinary team	care plan optimized treatments educational strategies increased access to care		
Zugck 2008	Germany	Xiang 2013		scale, ECG, SPO2 monitoring		

Description and technical characteristics of technology

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Summary

TEC1: Who manufactures Telemonitoring in home care for patients with chronic cardiovascular diseases?

We did not answer this question in the TEC domain. Please find the overlapping results in CUR_ 15

TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases?

The answer was created out of statements in nine of the included studies from the general literature search and an additional unstructured search in google for more information.

The studies providing information about the staff qualification mainly content of

-management according to a multidisciplinary/ physicians care plan

-provision of monitoring and reaction in case of abnormities by nurses

The results of the survey with 15 experts in Germany {1} provide a conclusive overview of expected skills:

-methodological competence (analytical thinking, ability of reflexion, autonomy, linguistic, anamnestic competence, ability of abstraction, ability of reaction)

-social competence (empathy, communication skills, politeness, social sensitivity, authority, motivation skills, kindness)

-professionality (basic medical knowledge, secure technical skills, practical medicinal experience, knwoledge of basic health legislation, knwoledge about the health system, psychological motivational skills, knowledge in quality management)

-personal competence (self-knowledge, psychical capacity, steadiness, distress-resistancy, learning motivation, professional distance, IT-skills)

Structural quality:

-How telemonitoring or telemedicine is implemented and to whom varies (see also CUR and LEG domain).

Process quality:

-The quality assurance seems to be lacking.

TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

In the ten included studies for this question the following training/ patient education aspects were adressed:

1. General heart failure education

-detection of deterioration

-use of medication

-diet

-physcial activity/ exercise training

-Smoking cessation

2.telemonitoring specific training

-training to use devices (technically)

-training to manage the information (empowerment and self-care), interpret the vital signals and efficiently utilize them

3.Other training/ education

-coping with difficult emotions

-relaxation and cognitive symptom management techniques

-lifestyle aspects: alcohol intake, sexual activity

-necessity of vaccinations

-capabilities of patients to travel or work

-coping with individual problems, often related to comorbid conditions

-training of relatives/ caregivers

How is the training suggested to be provided:

-could be carried out in groups of 10-15 people, where patients can assist and help each other

-through leaflets and online manuals, depending on the service

TEC4: What information of Telemonitoring in home care for patients with chronic cardiovascular diseases should be provided for patients outside the target group and the general public?

Information to patients outside the target group and the general public should therefore focus on the reasons and the explanaition for inclusion or exclusion of people/ patients for access to structured telephone support. People should be informed that structured telephone support is not suitable for all individuals nor is it appropriate under all medical circumstances

TEC5: What is Telemonitoring in home care for patients with chronic cardiovascular diseases and the comparator(s)?

The non-invasive telemedicine/telemonitoring contains the following aspects (seperately or combined):

-remote access control (transfer of physiological data)

-nurse-led management program after hospital discharge

-disease management program (including cardiologists, nurses, GPs)

-patient education

-regular outpatient contact

-self-care supportive strategies

-case management interventions

-monitoring and (daily) transmission of vital parameters and weight

-telephone-follow up

-home-visits

-remote consultation with a nurse by video-camera

-weigh daily and respond to questions concerning heart failure symptoms

-daily data-transfer to a secure Internet site

-response to questions from a computerized interactive voice response system

-medication management (adherence),

-fluid management (adherence)

-problem solving

-exercise recommendation

-diet adeherence

-goal setting

-structured telephone support

-human-to-human contact (HH) or human-to-machine interface (HM)

Usual care

-standard post-discharge care without intensified attendance at cardiology clinics

-clinic-based CHF disease management programme

-home visiting

There is no consensus definition of the fundamental terms utilized.

There is also an „upcoming“ topic called mHealth meaning mobile health through mobile phones and similar devices using software applications (apps). There is increasing interest on mhealth, especially with the hope of easy and equal acces for information, tele-diagnostic or –care aspects and data collection and use for health purpose. Some major aspects are to be worked out (like network issues, data security, information quality, legal and regulatory aspects etc.) and are aim within the EU horizon 2020.

TEC6: In what context and level of care are Telemonitoring in home care for patients with chronic cardiovascular diseases and the comparator used?

Conclusion: telemedicine/ telemonitoring interventions can be used in all different settings (outpatient, outpatient clinic, hospital based, home, mixed setting), they are mainly provided in outpatient organisations, the most important part ist the additional setting at the patients‘ home.

TEC7: Are the reference values or cut-off points clearly established?

The reference values for heart failure diagnostic (- monitoring) are mainly a) mortality and b) hospitalisation (rate).

There are more clearly established results for the diagnostic accuracy within monitoring the implantable device-based indicators, alone or combined with weight and symptoms.

The reference values used for telemedical approaches with structured interviews are more or less standardized (like in www. klinik.uni-wuerzburg.de/medizin1/inh-heartnetcarehf { Rec #: 200}, but there is also a subjective category which cannot be clear established, like „listening into a patients‘ kind of reporting“, „detecting differences within a knwon patient“, that require a human sense approach.

The reference value of „mortality“ and „hospitalisation“ requires a competent listening/ monitoring person who decides when the emergency chain has to be initiated.

TEC8: What material investments are needed to use Telemonitoring in home care for patients with chronic cardiovascular diseases?

Despite the implantable devices, further materials are needed for telemonitoring/ telemedicine:

Patients home

-patient near unit (funk transmission)

-telephone/ cell phone with telephone line

-scale

-camera

-PC with internet

Data transfer

-Secure data sending line (internet)

-Telephone line

-Secured technical interoperability/ adaptiveness

Receiver of data/ care center/ nurse

-PC, software

-Telephone

-Usual office infrastructure

-Ev. car for home visits

There is a need for further research in knowledge representation, and the used data analysis methods. Current barriers for adaptation include uncertainty about the response protocols, payment systems, and prescribing protocols. {29}

TEC9: What kind of special premises are needed to use Telemonitoring in home care for patients with chronic cardiovascular diseases and the comparator(s)?

No special premises were found in the literature.

TEC10: What equipment and supplies are needed to use Telemonitoring in home care for patients with chronic cardiovascular diseases and the comparator?

We provide the answer within TEC 8

TEC11: What kind of data and records are needed to monitor the use of Telemonitoring in home care for patients with chronic cardiovascular diseases and the comparator?

The needs for a sustainable telemonitoring include

-Qualified professionals (human resources) doing the monitoring/ statistics/emergency prioritisation

-Economic resources to provide the infrastructure for data transmission (GSM network, analogue phoneline, internet, software) and telephone support, documentation, home visits, etc.

-Transparent selection of patients who benefit best

TEC12: What kind of registers are needed to monitor the use Telemonitoring in home care for patients with chronic cardiovascular diseases and comparator?

There are no specific registries to monitor or register the use of structured telephone support for heart failure specifically. If a national registry is already existing and/or the EU registry is used/ planned to be used there needs to be no further register installed for telemonitoring in heart failure patients.

The telemonitoring aspects – at least „on telemonitoring yes/no“, what kind of telemonitoring is used, entry-exit date – can be easily added into an existing registry.

Introduction

In this domain we aim to explain what is meant by „structured telephone support (STS) within telemonitoring“, to detect whether „telemedicine“ means the same as „telemonitoring“or something different, what wordings and explanations are currently in use and what do they mean. We aim to describe the forms of existing telemonitoring technologies, their use and functioning as well as major issues that stem from the use of these technologies. Also exsposed are the preconditions for the use of telemonitoring, educational needs on the side of patients and families as well as professional teams. Regarding the use of telemonitoring all forms of telemonitoring devices are categorized according to their settings etc. The reference values that trigger the interventions are looked into and material investments as well as necessary equipment and supplies for the use of telemonitoring by STS are researched. The registers are listed to monitor the use of the technology and comparator.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
A0022	Other	Who manufactures the technology?	yes	Who manufactures structured telephone support (STS) for adult patients with chronic heart failure?
B0012	Training and information needed to use the technology	What kind of qualification and quality assurance processes are needed for the use or maintenance of the technology?	yes	What kind of qualification and quality assurance processes are needed for the use or maintenance of Structured telephone support (STS) for adult patients with chronic heart failure?
B0014	Training and information needed to use the technology	What kind of training and information should be provided for the patient who uses the technology, or for his family?	yes	What kind of training and information should be provided for the patient who uses Structured telephone support (STS) for adult patients with chronic heart failure, or for his family?
B0015	Training and information needed to use the technology	What information of the technology should be provided for patients outside the target group and the general public?	yes	What information of Structured telephone support (STS) for adult patients with chronic heart failure should be provided for patients outside the target group and the general public?
B0013	Training and information needed to use the technology	What kind of training and information is needed for the personnel/carer using this technology?	yes	
B0001	Features of the technology	What is this technology and the comparator(s)?	yes	What is Structured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?
B0005	Features of the technology	In what context and level of care are the technology and the comparator used?	yes	In what context and level of care are Structured telephone support (STS) for adult patients with chronic heart failure and the comparator used?
B0018	Features of the technology	Are the reference values or cut-off points clearly established?	yes	Are the reference values or cut-off points clearly established?
B0002	Features of the technology	What is the approved indication and claimed benefit of the technology and the comparator(s)?	no	This is overlapping with the CUR domain and will be answered there. The indication is selected within the PICO definition
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	no	This overlaps with the "management" in the CUR domain and will be answered there
B0004	Features of the technology	Who performs or administers the technology and the comparator(s)?	no	This overlaps with the "management" in the CUR domain and will be answered there
B0007	Investments and tools required to use the technology	What material investments are needed to use the technology?	yes	What material investments are needed to use Structured telephone support (STS) for adult patients with chronic heart failure?
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	yes	What kind of special premises are needed to useStructured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator?	yes	What equipment and supplies are needed to use Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?
B0010	Investments and tools required to use the technology	What kind of data and records are needed to monitor the use of the technology and the comparator?	yes	What kind of data and records are needed to monitor the use of Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?
B0011	Investments and tools required to use the technology	What kind of registers are needed to monitor the use the technology and comparator?	yes	What kind of registers are needed to monitor the use Structured telephone support (STS) for adult patients with chronic heart failure and comparator?

Methodology description

Domain frame

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. For some answers additional handsearch was used, and for some AEs we did a google search in other resources than scientific literature (i.e. for TEC_11).

The extracted studies and the reason for not using them is provided in the annex 1 at the end of the domain report. The issue (research question) specific methods will be reported later in the methods field of the result card.

Information sources

Common basic project literature search

Handsearch (additional reference found/ provided)

Google (for registries)

Quality assessment tools or criteria

We did not rate the quality of the included studies, but mentioned whether the information was extracted from systematic reviews or single studies (i.e. RCTs) or other resources.

Analysis and synthesis

Two investigators divided the amount of studies by alphabeth, each scanned the half of the studies and double-checked the other.

Result cards

Other

Result card for TEC1: "Who manufactures structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

TEC1: Who manufactures structured telephone support (STS) for adult patients with chronic heart failure?

Result

Please find the overlapping results in CUR_ 15 What is the marketing authorisation status of Telemonitoring in home care for patients with chronic cardiovascular diseases?

Importance: Unspecified

Transferability: Unspecified

Training and information needed to use the technology

Result card for TEC2: "What kind of qualification and quality assurance processes are needed for the use or maintenance of Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Structured telephone support (STS) for adult patients with chronic heart failure?

Method

Additionally to the basic literature search a qualitative handsearch (google; keywords: telemonitoring, telemedicine, qualification) was done adding two studies, the results are provided in descriptive way.

Literature included for this AE: Whellan 2005 {66}, Jaarsma 2013 {37}, Radhakrishnan 2012 {52}, MAST report {47}, Wakefield 2013 {65}, Clark 2011 {72}, Grustam 2014 {28}, Chaudhry 2007 {6}, Cleland 2010 {12}, BUDYCH {70}.

Short Result

The answer was created out of statements in eight of the included studies from the general literature search and an additional handsearch in google for more information.

The studies providing information about the staff qualification mainly contains information on:

-management according to a multidisciplinary/ physicians care plan

-provision of monitoring and reaction in case of abnormities by nurses

The results of the survey with 15 experts in Germany {70} provide a conclusive overview of Expected skills:

-methodological competence (analytical thinking, ability of reflexion, autonomy, linguistic, anamnestic competence, ability of abstraction, ability of reaction)

-social competence (empathy, communication skills, politeness, social sensitivity, authority, motivation skills, kindness)

-professionality (basic medical knowledge, secure technical skills, practical medical experience, knwoledge of basic health legislation, knowledge about the health system, psychological motivational skills, knowledge in quality management)

personal competence (self-knowledge, psychical capacity, steadiness, distress-resistancy, learning motivation, professional distance, IT-skills. The quality assurance seems to be lacking.

Structural quality:

-How telemonitoring or telemedicine is implemented and to whom varies (see also CUR and LEG domain).

-Process quality:Marketing authorisation and licensing is partly provided (and discussed in CUR and LEG domains) and differs among health systems and continents. A regulative norm should be able to distinguish between technical and staff-related quality aspects. {15}

Result

Technological usability, responsible innovation, health literacy, behaviour change, caregiver perspectives and motivational issues of professionals influence the efficient use of telemedicine. {47}

The professional knowledge about how and when to react on monitored data is a crucial aspect within telemonitoring (and monitoring at all).

The healthcare professional should not over-react to the risk identification, as this could lead to increased clinical activity and hospitalization without improving outcome. High quality professional education should lead to a sufficient rather than just a more frequent decision-making. {15}

Some expect that over the next decades the number of patients with heart failure increases, and the number of cardiologists decreases.{57},{24}Study results are discussed with a focus on a possible bias if only cardiologists or primary health care physiscians supervised the call-center and disease management interventions. In the review of Whellan {66} it is stated, that the outcomes of the postdischarge interventions depend on the type of provider, providing supervision: number of hospitalisationsin case of cardiologist supervision decrease, which is not true for those supervised by primary health care physicians. The author himself is a cardiologist. The Heart Failure Association of European Society of Cardiology also addressed the need for appropriate education and training of healthcare professionals recently. {72}{66}Telemonitoring produces a lot of data, if a large number of patients transmit quantities of data daily. Resources to deal with the high amount of data adequately and process them automatically have to be provided.The final goal of remote monitoring is likely to be further empowerment of the patient. Primary care physicians are described as being responsible, cardiologist as to supervise the drug prescription and titration, in some cases nurses adjust diuretics, angiotensin-converting enzyme inhibitors, or beta blockers under the supervision of a cardiologist. Patient education to patients (and families) is provided by nurses or in some cases pharmacists. {72}.

In the WHARF trial, cardiac nurses reviewed data whereas the patients' physicians took the responsibility for acting on the regularly updated information. {6}

Specific training for nurses is mostly described{37} in general terms such as for example:

- "a specific HF programme based on AHCPR guidelines","trained nurses",
- "advanced practice nurse",
- "one day training course".
- "Nurses underwent brief training programme regarding problems and treatment options associated with this particular group of patients".

The way how to train practitioners (nurses) is described varying {37} between

- „interactive“,
- “ role playing and audio taping“,
- “ increase the skills in communicating“ and
- „motivating the patients to treatment instructions adherence“,
- „2-months orientation and training programme“,
- „developing competences related to detection of deterioration in HF in elderly patients“,
- < >

  „optimal therapeutic management“,
- „educational and behavioural strategies in the home“,
- „address patients and caregivers unique learning skills“.

For other healthcare providers, specific training is even less well described {37} such as:

- " a highly scripted training process"
- " combined experience and completed a one-year clinical residency in home care". {37}

Provided services (by nurses) include:

- reviewing transmitted clinical data {52}
- assessing individuals, coaching, and installing telehealth. { 52}
- supervising automatic patient data transmission by means of telemonitoring devices {8}
- providing telephone support and education. {28}
- playing a coordinating or leading role {37}

- telephone based monitoring and education {6}
- using a software program to determine call frequency {6}
- using a standardized algorithm to adjust diuretic doses or recommend urgent medical visits {6}
- making the phone calls could adjust the medication over the phone or organized clinic appointments {15}
- visiting and monitored patients' clinical status and educating them about heart failure and pharmacologic management {6}
- initiating and regulating medications for heart failure {6}

The telemedicine providers were described {37} as:

- homecare nurses, {37}
- hospital nurses, {37}
- HF nurses, {37}
- cardiac rehabilitation nurses, {37}
- research nurses, {37}
- practice nurses{37}
- district nurses {37}
- registered nurses {65}
- advanced practice nurses who were considered specialists for HF patients {65}
- cardiologist {37}
- primary care physicians {37}
- other specialists such as geriatricians or internists {37}
- teams with different profiles like „collaboration between the primary care physician and cardiologist, trained doctor's assistant and a primary care physician or physician, physiotherapist, ECG technician and a psychologist“ {37}
- additional involvement of other professionals (psychologist, dietician, physical therapist, social worker, pharmacist) {37}
- nurses trained in management of heart failure {6}

The description of the specialization or clinical background are lacking within the studies. {37}, {15}

Physicians were rarely directly involved in intervention delivery. Furthermore, information about patient progress during the study was sent to physicians in fewer than half of the studies.“ {65} {15}„In TIM-HF trial monitoring was done by call centres that were otherwise not directly involved with the patients' care.“ {12}

Qualification requirements found in the handsearch:

Qualification	Requirements from	source
„Qualified providers are home health agencies enrolled with Vermont Medicaid. Qualified providers must follow data parameters established by a licensed physician's plan of care. Qualified providers must use the following licensed health care professionals to review data: registered nurse (RN), nurse practitioner (NP), clinical nurse specialist (CNS), licensed practical nurse (LPN) under the supervision of a RN, or physician assistant (PA). In the event of a measurement outside of the established individual's parameteres, the provider shall use the health care professionals noted above to be responsible for reporting the data to a physician. The data transmission must comply with standards set by the Health Insurance Protability and Accountability Act (HIPAA).“	Vermont Medicaid, USA. Contract status.	Part 7702.2 Qualified providers (10/29/2014, 14-05P) available at: http://dvha.vermont.gov/budget-legislative/dvha-bulletin-14-05p-adopted-rule-for-website-13oct14.pdf (2014-01-08)
„Nursing staff monitor data readings twice daily and abnormalities are escalated based on the severity of the concern to patients and caregivers via SMS and email. All parties are able to view the data and nurses are able to advise appropriate actions to keep the patient on track and in good health.“	HCF, Telstra launch health telemonitoring program, Australia; Website information	http://www.itnews.com.au/News/390532,hcf-and-telstra-launch-large-scale-health-telemonitoring-program.aspx
„Required competences: • methodological competence (analytical thinking, ability of reflexion, autonomy, linguistic, anamnestic competence, ability of abstraction, ability of reaction) • social competence (empathy, communication skills, politeness, social sensitivity, authority, motivation skills, kindness) • professionality (basic medical knowledge, secure technical skills, practical medicinal experience, knwoledge of basic health legislation, knwoledge about the health system, psychological motivational skills, knowledge in quality management) • personal competence (self-knowledge, psychical capacity, steadiness, distress-resistancy, learning motivation, professional distance, IT-skills)“	Results of a study based on a questionnaire to 15 experts in the telemedicine branche 2009-2010 in Germany.	http://www.telemed-berlin.de/telemed/2010/beitrag/beitrag_budych317_391.pdf

Importance: Critical

Transferability: Partially

Result card for TEC3: "What kind of training and information should be provided for the patient who uses Structured telephone support (STS) for adult patients with chronic heart failure, or for his family?"

View full card

TEC3: What kind of training and information should be provided for the patient who uses Structured telephone support (STS) for adult patients with chronic heart failure, or for his family?

Method

The basic literature search and one additional reference were used. Forteen studies ({3}, {37}, {15}, {16},{22}, {32}, {31},{11},{17},{27}, {58}, {59}, {43},{47}) provided answer to this question, whereas 12 of them are systematic reviews, one an RCT {43}, and one an HTA {47}.

Short Result

In the forteen included studies for this question the following training/ patient education aspects were adressed:

General heart failure education

-detection of deterioration

-use of medication

-diet

-physcial activity/ exercise training

-Smoking cessation

Telemonitoring specific training

-training to use devices (technically)

-training to manage the information (empowerment and self-care), interpret the vital signals and efficiently utilize them

Other training/ education

-coping with difficult emotions

-relaxation and cognitive symptom management techniques

-lifestyle aspects: alcohol intake, sexual activity

-necessity of vaccinations

-capabilities of patients to travel or work

-coping with individual problems, often related to comorbid conditions

-training of relatives/ caregivers

How is the training provided:

-in groups of 10-15 people, where patients can assist and help each other

-through leaflets and online manuals, depending on the service

- home visits
- videophone
- telephone calls or letters to the patient at home
- 1-hours, in-person patient education program with usual discharge care
- by technology through predischarge viewing of an educational CD-RIM
- video to be viewed at home
- predischarge nurse-led intensive education about HF symptoms and treatment followed by 1 telephone to reinformce education

Result

Patient education

Fiveof the included reviews adressed

- education on HF in general {37} {16} {31} {11}

-detection of deterioration {37}

- advice and instruction on use of medication {37} {16} {31}
- diet {37} {16} {31}
- physcial activity/ exercise training {37} {31}

- symptom monitoring and self-management advice {16} {31} {11}
- training in the use of equipment {11} {15}

One systematic review also adressed

-Smoking cessation coping with difficult emotions {37}

- communication with family and healthcare providers, using relaxation and cognitive symptom management techniques {37}

-alcohol intake {37}

-sexual activity {37}

-necessity of vaccinations {37}

-capabilities of patients to travel {37}

-individual problems related to comorbid conditions{37}

Implementation of education:

- home visits {16}
- videophone {16}
- home physiological monitoring {16}
- telephone calls or letters to the patient at home{16}
- 1-hours, in-person patient education program with usual discharge care {3}
- HF education delivered by technology through predischarge viewing of an educational CD-ROM {58}
- a 60-minute video that was intended to be viewed at home {59}
- predischarge nurse-led intensive education about HF symptoms and treatment followed by 1 telephone call 3 to 5 days after discharge to reinforce education {43}
- in groups of 10-15 people, where patients can assist and help each other{47}
- through leaflets and online manuals {47}

Statements about patient education among the included studies:

- Education and training is seen as the basic for effective monitoring and decision making. {47}
- the greatest benefit in terms of education and medication patterns is accrued within a few weeks and that long-term monitoring is redundant {32} {31}
- Eliminating the travel time for nurses by using tele-education could help reduce workload {11}
- knowledge allows the patients to take greater responsibility for their own care and management {11}
- increased patient empowerment can help reduce reliance on the nurse {11}
- The caregiver and relatives can also be important, as they can assist the patient with monitoring and help if needed {47}

Evaluation of patient education:

„Moreover, although the provision of education during remote follow-up would theoretically lead to improved self-care in patients with heart failure, a recent review that focused specifically on this issue noted that results from trials are equivocal.“ {17}

„As early as 2002, Krumholz et al identified education as a key point in global management of HF; leading a 37% reduction (P=0,004) if readmission to the hospital for HF or for cardiovascular disease.“ {27}

Importance: Critical

Transferability: Completely

Result card for TEC4: "What information of Structured telephone support (STS) for adult patients with chronic heart failure should be provided for patients outside the target group and the general public?"

View full card

TEC4: What information of Structured telephone support (STS) for adult patients with chronic heart failure should be provided for patients outside the target group and the general public?

Method

Nine studies out of the general literature search and one additional reference provided answer for this question ({54}, {47},{20}, {26},{27},{29},{31},{9},{32},{7})

Short Result

The informed consent of a patient using telemonitoring can be shown in the level of participation and compliance. The effectiveness of telemonitoring is directly related to attitudinal and behavioural aspects like

-Compliance with symptom entry

-Compliance with data transmission

-Awareness for an earlier detection of decompensation

-Positive attitude to empowerment

-Satisfaction with self-competence

To reach a higher level of compliance the MAST study reports

-A regularly feedback about the monitoring results

-Daily videoconferencing for follow-up was accepted and clinically useful

-tele-consultations, as they resulted in 76% of the patients feeling safer or more secure

-both verbal and nonverbal communication

-There is a need to rethink how communication and feedback is given to the patients

Information to patients outside the target group and the general public should therefore focus on the reasons and the explanaition for inclusion or exclusion of people/ patients for access to structured telephone support. People should be informed that structured telephone support is not suitable for all individuals nor is it appropriate under all medical circumstances{15}

Result

The reported effects and impacts of telemonitoring can be divided into five categories: {54}

- data quality
- patient clinical condition
- patient attitude and behavior
- clinical effectiveness
- economic viability

The most commonly assessed telemonitoring effects are at the attitudinal and/or behavioral level (like medication compliance, compliance with symptoms entry and data transmission, awareness, empowerment, satisfaction). {54}

Attitudinal and behavioral changes can be achieved with

- feedback to patients with telemedicine services {47}
- a regular follow-up about every 3-4 month {47},videoconferencing for follow-up {47}
- tele-consultations (resulting in 76% of the patients feeling safer or more secure after discharge) that offer both verbal and nonverbal communication {47}
- the way of information and feedback communication taking into account the needed levels in different generations of care levels {47}

Patient empowerment due to self-mangement can

- decrease in heart failure hospitalization risk and a reduction in mortality {33}, {15}{32}
- lead to a better drug therapy and compliance {15}
- lead to an earlier detection of decompensation, so that interventions can be made that reduce the need for subsequent hospitalization {15}
- Reported benefits for the patients‘ psychological well-being, and safety {20}
- patients require fewer overall visits to the follow-up clinic {20}
- RM detects clinical abnormalities that would be either completely missed by less frequent in-office visits, or detected significantly without continuous remote monitoring data assessment. {20}

Recommendations and statements among the included studies

- The Heart Failure Society of America and The European Society of Cardiology heart Failure Association recommend enrollments in disease management programs (DMP) for patients with HF who have been recently hospitalized or for high-risk HF patients. {26}Dedicated telemonitoring for heart failure may be a practical adjunct in selective centres and patients on top of usual care, but it should never replace it as a standard of care because sicentific evidence remains conflicting, insufficient and heterogeneous. {27}{27}
- Telemonitoring is not suitable for all individuals nor is it appropriate under all medical circumstances. Knowing the aim of the intervention for a specific patient is a key success factor. {29}

  The knowledge about HF can be increased by TM, but the evidence is conflicting (2 hospitals measured increased knowledge for patients, one showed no difference to the control group in the proportion of correct answers to questions about medication in three groups (i.e. telephone, videophone, control) at 90- and 180 days) {7}

Importance: Critical

Transferability: Completely

Features of the technology

Result card for TEC5: "What is Structured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?"

View full card

TEC5: What is Structured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?

Method

We used the description out of studies (47},{27},{22}, {15}), 21 from the general literature search, 3 from handsearch and one additional reference. The studies used are provided in the table below.

Result

Definitions

Telemonitoring using structured telephone support is intended to remove time and distance barriers for the delivery of healthcare services. (The American Nurses Association)

Technology

Using structured telephone support means that the patient stays at home and is instructed to measure and observe the symptoms related to the heart disease. Several measuring devices can be in use, like a scale, a blood pressure device, a 2 channel ECG, a pedometer, etc.) {47}.

The transfer of the measured data is done by telephone, meaning a contact between health care providers and patient, where the observation of symptoms is asked by the healthcare providers and reported by the patient. Within this telephone call the healthcare provider documents the physiological data reported and can ask additional questions, give advice, treatment instructions, medication support and provide education or information accordingly. {27}

The structured telephone support is scheduled regularly and follows a pre-defined system of what is asked and what kind of advice is given. Beside the structure of the monitoring for patients with chronic heart failure the telephone support allows additional individual questions from patients and health care providers. {27} {22} {15}

The data are documented by the health care providers using a kind of database, an interactive option to view the data by both, patients and personnel can be added, requiring an internet connection and a computer on both sides. {47} The internet connection has to be secured within the frame of health care data protection.

Structured telephone support is a modality to replace direct physical patient-physician contact by contact via telephone for monitoring, education, or self-management or various combination using simple telephone technology after discharge in a structured format {22}.

Comparator

Usual care as the comparator requires a careful awareness for temporal changes of standard of care that might have affected the results. The management of care for HF patients changed within the last 15 years and usual care now includes multidiciplinary care, education of the patient and guideline conform medication. {27}

Most trials do not describe specific details of UC but provide explanations like »standard discharge instructions« or »follow up with outpatient provider as usual«. The follow-up setting (primary care or follow-up in a specialty clinic) or the timing of outpatient follow-up in the usual care group are rarely defined. {22}.

Depending on the area, organization and setting „Usual care“ differs between the studies. Usual care also can include regular specialist CHF department visits and extensive information on the disease and training to the patient. {11}.

The contents of standard and usual care vary among studies, and could include regular visits to outpatient clinics, training, education or information on disease-specific self-care behaviour, hospital follow-up by nurse and cardiologist and care within primary care providers, with or without home visits to assess vital signs and medication adherence. {7}

Limitations

The limitations of telephone support models are that the telephone calls are primarily initiated by the professional at the preset times (usually protocol driven) and they are thus unable to detect more rapid changes in the condition. {15}.

Descriptions and definitions

The following table lists the descriptions and explanations found in the studies included.

TEC-5 Table 1">

Comment

Excursus on mHealth

Structured telephone support includes

- Human to human service - landline phone line/ telephone call by nurse (other healthcare provider) - mobile phone/ telephone call by nurse (other healthcare provider)
- Human to machine service - smart phone/ table/ App for bluetooth transfer (i.e. from scale)

„m-health“

- focuses on the human to machine part

For this excursus we did an additional google search (unscientific information collection) with keyword „mhealth“ and a short Pubmed search (broad search for scientific overview) with keyword „mhealth, mobile health AND chronic heart disease“ (– no results found despite some related to „telemedicine“ which is already covered by the general literature search).

Definition of mobile health

Mobile health (short “mhealth”) means the use of mobile devices like mobile phones, smartphones, tablet computers or PDAs (personal digital assitant) {73} {74} for health services or information {3}, whereas “health” could be meant as lifestyle, prevention, diagnostic assessment, monitoring, support, collecting data for health research, delivery of healthcare information, direct provision of care, reminder of medication time, behaviour, etc. {75} {76} Mobile health also includes the application software (Apps) and the transmitters (like sensors in bracelets or watches). {76}

Mobile technologies enable physicians and other healthcare providers to reach their patients more timely or even in regional distance. The way of communication includes SMS, e-mail, visualizing static text, visual image information and tagging voices. With the use of GPS a geographical mapping component can be added which is now already used for emergency services. The support function can include a decision algorithm out of the collected data. Data collection requires a device for collecting the data (mobile phone, etc.) and a software to house the information. {73}

Current status

There is a rapidly rising market for apps, mainly available for smartphones, and the market of apps is dominated by individuals (30%) or very small companies with 2-9 employees (34%).{77}

Recent estimations count about 97.000 available mhealth apps on the global market, 70% of them target the wellness and fitness segments, 30% target health professionals, access to patient data, patient consultation and monitoring, diagnostic imaging and pharmaceutical information. {84} {78}

Increasing data collection and -use needs a storage capacity to handle the huge amount of data, secure cloud solutions are already worked on within the European Commission cloud computing strategy. {79} {80}

Within Europe a third of people do have internet access through mobile phones, with significant differences between member states (Sweden 63%, Bulgaria 13%, Portugal 16%). {81}

mHealth depends on high capacity and flexible networks. The Commission recently adopted a legislative package (Connected Continent: Building a Telecoms Single Market) {82}, which recognises the need of high-speed and high-quality networks for eHealth at a greater degree of harmonisation. Under Horizon 2020 EU funding will be provided for mHealth with intended support, digital health literacy, and equal access to healthcare. {83}

Conclusion

The non-invasive telemedicine/telemonitoring contains the following aspects (seperately or combined):

-remote access control (transfer of physiological data)

-nurse-led management program after hospital discharge

-disease management program (including cardiologists, nurses, GPs)

-patient education

-regular outpatient contact

-self-care supportive strategies

-case management interventions

-monitoring and (daily) transmission of vital parameters and weight

-telephone-follow up

-home-visits

-remote consultation with a nurse by video-camera

-weigh daily and respond to questions concerning heart failure symptoms

-daily data-transfer to a secure Internet site

-response to questions from a computerized interactive voice response system

-medication management (adherence),

-fluid management (adherence)

-problem solving

-exercise recommendation

-diet adeherence

-goal setting

-structured telephone support

-human-to-human contact (HH) or human-to-machine interface (HM)

Usual care

-standard post-discharge care without intensified attendance at cardiology clinics

-clinic-based CHF disease management programme

-home visiting

There is no consensus definition of the fundamental terms utilized.

There is also an „upcoming“ topic called mHealth meaning mobile health through mobile phones and similar devices using software applications (apps). There is increasing interest on mhealth, especially with the hope of easy and equal acces for information, tele-diagnostic or –care aspects and data collection and use for health purpose. Some major aspects are to be worked out (like network issues, data security, information quality, legal and regulatory aspects etc.) and are aim within the EU horizon 2020.

Importance: Critical

Transferability: Completely

Result card for TEC6: "In what context and level of care are Structured telephone support (STS) for adult patients with chronic heart failure and the comparator used?"

View full card

TEC6: In what context and level of care are Structured telephone support (STS) for adult patients with chronic heart failure and the comparator used?

Method

The basic literature search was used. Additionally the resulst of Assessment Element TEC5 (B0001) were used to categorize into the settings.

The following studies provided information about the context: {54},{27},{47},{66},{53},{37},{18},{21},{72},{9},{7},{15}

Short Result

Conclusion: telemedicine/ telemonitoring interventions can be used in all different settings, they are mainly provided in outpatient organisations, the most important part is the additional setting at the patients‘ home.

Result

A change into multidisciplinary management of HF patients was observed over the last 15 years. {27} Education is seen as one of the key points leading a 37% reduction (P=0.004) of readmission to the hospital for HF or for cardiovascular disease. {42} Telemonitoring aims to shift the focus on control of the disease towards the patient who is supported by the care team. A good relationship between care providers and patients is important. {27} Tele-healthcare can also be seen as an intensification of more conventional methods of delivering care towards optimal comprehensive care as recommeded by guidelines. {27}

The primary function of telemedicine is to provide specialist consultation to distant communities, rather than to provide support for self-management of chronic disease. However, home telecare is a rapidly evolving domain and increasingly focused on supporting the patient rather than the health professionals. Home telemonitoring is used for different modalities and encompasses the use of audio, video, and other telecommunication technologies to monitor patient status at a distance. {49}, {,35},{44}, {18} It can be seen as an automated process for the transmission of data on a patient’s health status from home to the respective health care setting. {54} {72}. Hence, telemonitoring does not involve the electronic transmission of data by a health care professional at the patient’s location. {54} {15}.

The tele monitoring interventions are heterogeneous in terms of monitored parameters and HF (heart failure) selection criteria and lack detail in the components of the care packages and usual care {53}

Also the telemedicine equipment varies in the different projects, as do the roles, numbers and education of healthcare professionals, which also makes it difficult to generalise the results from one project to another. The legal framework diverge from country/region to country/region {47} and has to be carefully studied and compared to those of the countries/regions where the studies took place.

There seems to be potential for self care at home to reduce mortality and morbidity and to improve symptoms in patients suffering from HF, whereas lack of knowledge about disease-specific self-care behaviours is associated with non-adherence to recommended self-care practices. {37}In Europe HF clinics are common and often situated at the hospital or at primary health care centre. Very few of the HF management programmes offer home care and there is a lack of collaboration across the primary-secondary care interface and a lack of continuity of care. {37}

„Monitoring is not a treatment but rather a different way of systematically organizing effective care.“ {9}.

This continuity of care is seen to be achieved by nurses acting as case manager for the patients at home and in liason among members of the health care team. {21}.

Settings {21}{72}{9}{7}{15}

telemedical intervention	Primary care/ oupatient	Secondary care/ hospital outpatient	Tertiary care/ inpatient	Patient home	
fluid status monitoring		yes		yes	
register heart rate, body temperature, patient activity,	yes	yes		yes	
nurse-led management program after hospital discharge	yes	yes		yes	
disease management program (including cardiologists, nurses, GPs)	yes			yes	
patient education	yes	yes	yes	yes	
self-care supportive strategies				yes	
case management interventions	yes			yes	
monitoring and (daily) transmission of vital parameters and weight		yes		yes	
telephone-follow up	yes			yes	
home-visits	yes			yes	
remote consultation with a nurse by video-camera	yes			yes	
weigh daily and respond to questions concerning heart failure symptoms	yes			yes	
daily data-transfer to a secure Internet site		yes		yes	
response to questions from a computerized interactive voice response system				yes	
medication management (adherence)	yes			yes	
fluid management (adherence)	yes			yes	
problem solving	yes			yes	
structured telephone support	yes			yes	
human-to-human contact (HH) or human-to-machine interface (HM)	yes	yes	yes	yes	
standard post-discharge care without intensified attendance at cardiology clinics			yes	yes	
clinic-based CHF disease management programme		yes		yes	
home visiting				yes	

Importance: Important

Transferability: Completely

Result card for TEC7: "Are the reference values or cut-off points clearly established?"

View full card

TEC7: Are the reference values or cut-off points clearly established?

Method

Five studies provided an overview of reference measurements in a more detailed way than „guideline conformity“: {27},{20},{26},{15},{29}

Short Result

The reference values for heart failure diagnostic (- monitoring) are mainly a) mortality and b) hospitalisation (rate).

The reference values used for telemedical approaches with structured interviews are more or less standardized (like in www. klinik.uni-wuerzburg.de/medizin1/inh-heartnetcarehf { Rec #: 200}, but there is also a subjective category which cannot be clear established, like „listening into a patients‘ kind of reporting“, „detecting differences within a known patient“, that require a human sense approach.

The reference value of „mortality“ and „hospitalisation“ requires a competent listening/ monitoring person who decides when the emergency chain has to be initiated.

Result

The accuracy for detection of alerts depends on the predefined algorithm within the telemonitoring tool or process. {20}. Several indicators to identify patients at risk of worsening heart failure are available and combined differently, like weight, blood pressure, quality of life, patient activity, increase in pacing tresholds, increase in the percentage of right ventricular pacing, decrease in the left ventricular pacing, artrial and ventricluar tachyarrythmia, thoracic impedance, heart rate variability, respiratory rate. Commercially available methods include assessment of weight as well as intrathoracic impedance. {1}. Speed of weight gain is more sensitive and specific for heart failure decompensation than absolute weight change, with an increase of more than 2 kg over a period of 72 hours being considered clinically significant. Despite the widespread use of weight monitoring, its accuracy is limited. A weight gain of greater than 2 kg over 48-72 h has good specificity but poor sensitivity for predicting clinical deterioration. In case of weight change all the other symptoms and physiological measurements have to be taken into account to reflect the overall heart failure status. Arrhythmia is common in patients with heart failure, but adding a single-lead ECG monitoring to external monitoring equipment increases the complexity of monitoring without evidence of additional benefit.“ {15}.

Currently available diagnostics provide valuable data in patient evaluation and enable physicians to identify those patients at greater risk of heart failure decompensation, but they have not yet been shown to impact patient outcomes and are often not sufficiently accurate for therapy adjustment. Effective adjustment of medical therapy relies on an accurate assessment of several parameters and involves in person care, telehomecare, and the emerging intervention of telemedicine or remote monitoring. Telemonitoring of basic physiological parameters did not reach the expectations now. {27}

There is a need for individual baselines and for using trend and multiple signals. Most current TM systems use simple thresholds as the basis for triggering an alert that are barely adequate as the basis for reliable triggering. {29}.

Importance: Important

Transferability: Completely

Investments and tools required to use the technology

Result card for TEC8: "What material investments are needed to use Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

TEC8: What material investments are needed to use Structured telephone support (STS) for adult patients with chronic heart failure?

Method

- We used information provided by the studies {25},{29},{17},{5},{26},{20} of the basic literature search.
- We used the table of different telemonitoring appraoches and linked suggested needs for material investments in a qualitative way due to our best knoewledge.

Short Result

Despite the implantable devices, further materials are needed for telemonitoring/ telemedicine:

Patients home

-patient near unit (funk transmission)

-telephone/ cell phone with telephone line

-scale

-camera

-PC with internet

Data transfer

-Secure data sending line (internet)

-Telephone line

-Secured technical interoperability/ adaptiveness

Receiver of data/ care center/ nurse

-PC, software

-Telephone

-Usual office infrastructure

-Ev. car for home visits

There is a need for further research in knowledge representation, and the used data analysis methods. Current barriers for adaptation include uncertainty about the response protocols, payment systems, and prescribing protocols. {29}

Result

Telemonitoring involves transmission of physiological data…from a measuring device (self measuring or data input manually) to a central server. The transmission works via telephone, satellite, or broadband capabilities, and the interpretation is done by the health care team. More complex information technology infrastructure is required to facilitate telemonitoring as opposed to a simple telephone call, which might limit the extent to which telemonitoring can be made available for heart failure patients to access. Several studies show that even a required IT infrastructure is not limiting the use and implementation of telemonitoring. {17}.

In most of the studies a domestic telephone line or cell phones were used for data transmission {44}, {41}{25}

A trial from Argentina indicate both the relevance and the capacity to implement telemonitoring interventions in middle-income countries. India and China both expect to find technological solutions to healthcare delivery problems, and telemonitoring is an attractive option. {5}{26}{20}

material needed			
telemedical intervention	**patient home**	**data transfer**	**receiver/ care provider**
fluid status monitoring	patient near unit, scale	secure data sending line (internet, telephone)	data receiver, PC, software
register heart rate, body temperature, patient activity,	patient near unit	secure data sending line (internet, telephone)	data receiver, PC, software
patient education	leaflets		training courses
self-care supportive strategies	leaflets		training courses
monitoring and (daily) transmission of vital parameters and weight	patient near unit, scale	secure data sending line (internet, telephone)	data receiver, PC, software
telephone-follow up	telephone	telephone line	telephone, PC
home-visits			transport system (car), documentation device (PC)
remote consultation with a nurse by video-camera	camera	secure data sending line (internet)	camera, checkpoint infrastructure
weigh daily and respond to questions concerning heart failure symptoms	scale, telephone or PC for internet contact	secure data sending line (internet, telephone)	data receiver, PC, software
daily data-transfer to a secure Internet site	patient near device	secure data sending line (internet, telephone)	data receiver, PC, software
response to questions from a computerized interactive voice response system	telephone, PC	secure data sending line (internet, telephone)	data receiver, PC, software
medication management (adherence)	telephone, patient near device	secure data sending line (internet, telephone)	checkpoint/ organisation infrastructure
fluid management (adherence)	scale, telephone or PC for internet contact	secure data sending line (internet, telephone)	checkpoint/ organisation infrastructure
problem solving	telephone	telephone line	nurse-checkpoint infrastructure
structured telephone support	telephone	telephone line	nurse-checkpoint infrastructure
human-to-human contact (HH) or human-to-machine interface (HM)	telephone, PC	ev secure data sending line (internet, telephone)	transport system (car) or data receiver, PC, software or nurse-checkpoint infrastructure
home visiting			transport system (car)

Importance: Important

Transferability: Completely

Result card for TEC9: "What kind of special premises are needed to useStructured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?"

View full card

TEC9: What kind of special premises are needed to useStructured telephone support (STS) for adult patients with chronic heart failure and the comparator(s)?

Result

There was no answer in the literature about special premises needed. The thoughts of {29} and from the assessment element TEC8 are taken.

As the remote TM is used in homes and is coordinated in usual facilities by nurse or other coordinator, TM fits in with the usual working environment and no information on special premises were found in the literature.

Importance: Unspecified

Transferability: Unspecified

Result card for TEC10: "What equipment and supplies are needed to use Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?"

View full card

TEC10: What equipment and supplies are needed to use Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?

Result

Double with TEC8, please see there.

Importance: Unspecified

Transferability: Unspecified

Result card for TEC11: "What kind of data and records are needed to monitor the use of Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?"

View full card

TEC11: What kind of data and records are needed to monitor the use of Structured telephone support (STS) for adult patients with chronic heart failure and the comparator?

Method

With the knowledge we got out of the literature we created a list of aspects, which could help to specify the best implementation strategy for each setting if they were included in the study data. The studies screened for this review provide wide knowledge about structured telephone support and telemonitoring aspects, but there is a lack of comparable structure to filter out what kind of supprot is needed for whom, how long and what can be expected.

Short Result

The needs for a sustainable telemonitoring include

-Qualified professionals (human resources) doing the monitoring/ statistics/emergency prioritisation

-Economic resources to provide the infrastructure for data transmission (GSM network, analogue phoneline, internet, software) and telephone support, documentation, home visits, etc.

Transparent selection of patients who benefit best

Result

The implementation and sustainability of telemonitoring approaches is influenced on how much and what is used on devices and human resources. {25}

For the monitoring of the intervention data should be provided about

Used technical equipment

-What kind of equipment is used

-How frequently is it used

-Are there different provider for the equipment (i.e. the patient provides the telephone connection at home and pays the fee; the cardiological unit provides the database and the data storage; the health system provides the server; etc.)

Involved staff

-What kind of professionals are involved

-How many hours are they involved (by profession and patient)

-What kind of (additional) qualification do they have

-Is the involved staff from different organisations/ settings (and if yes, which ones)

Patients characteristics

-Clinical selection parameters (depending on the heart failure diagnosis)

-Statistical selection parameters (age, gender, region, etc.)

-Social selection criteria (ability to communicate, compliance, ability to use the devices/ telephone, financial aspects, availability of relatives)

Other

-Number of emergency situations

-Number of emergency- failures

-Causes of

Importance: Important

Transferability: Partially

Result card for TEC12: "What kind of registers are needed to monitor the use Structured telephone support (STS) for adult patients with chronic heart failure and comparator?"

View full card

TEC12: What kind of registers are needed to monitor the use Structured telephone support (STS) for adult patients with chronic heart failure and comparator?

Method

A google-handsearch was done to detect already existing national and EU registers. Keywords used were „heart failure registry“, „heart registry“, heart failure audit“ and the several EU/ EUnetHTA country-names.

Short Result

There are no specific registries to monitor or register the use of structured telephone support for heart failure specifically. If a national registry is already existing and/or the EU registry is used/ planned to be used there needs to be no further register installed for telemonitoring in heart failure patients.

The telemonitoring aspects – at least „on telemonitoring yes/no“, what kind of telemonitoring is used, entry-exit date – can be easily added into an existing registry.

Result

Several existing heart registries were found among Europe.

Examples of national registries for heart failure/ acute heart events	links
Austrian Heart failure registry	http://www.atcardio.at/fileadmin/content_atcardio/img/HI-Register.pdf
Different registries (some just regional) i.e. Deutsches Register für angeborene Herzfehler	http://www.herzregister.de/register/hintergrund/
Swedish heart failure registry	http://www.ucr.uu.se/rikssvikt-en/index.php/regarding-s-hfr/7-about-the-swedish-heart-failure-registry
Norwegian heart failure registry	http://heartfailure.no/research/
UK National heart failure audit	http://www.ucl.ac.uk/nicor/transparency/2013/heartfailure
Netherlands cardiovascular registry	http://www.cvon.eu/cvoncms/wp-content/uploads/2012/07/Eur-Heart-J-2013-CardioPulse-321-6.pdf

Irish national registry for Cardiac arrest	http://www.nuigalway.ie/ohcar/downloads/ohcar_5th_annual_report_2013.pdf
Czech republic acute heart failure registry	http://ahead.registry.cz/
Polish Silesian Center for Heart Diseases	http://www.sccs.pl/en/modules/page/upload/files/SilesianCenterforHeartDiseases-cardiovascularresearch-portfolio-1.pdf
The Danish Heart register	http://sjp.sagepub.com/content/39/7_suppl/46.refs
Lithuania Herat failure longterm registry	http://www.secardiologia.es/images/stories/file/insuficiencia-cardiaca/hf-lt_slides_amsterdam_1sep2013.pdf
Latvian registry of acute coronary syndromes	http://www.internationaljournalofcardiology.com/article/S0167-5273(07)00724-3/abstract
Belgian TVI registry	http://sbhci.org.br/wp-content/uploads/2010/11/SLIDES-DE-APRESENTA%C3%87%C3%83O52.pdf
French Registry on Acute ST-elevation and non ST-elevation Myocardial Infarction 2010	http://heart.bmj.com/content/98/9/699
BADAPIC Registry	http://www.ncbi.nlm.nih.gov/pubmed/15617639
National Registry on Cardiac Electrophysiology Portugal	http://www.elsevier.pt/en/revistas/revista-portuguesa-cardiologia-334/artigo/national-registry-on-cardiac-electrophysiology-2010-and-2011--90193330
Portuguese Registry on Acute Coronary Syndromes (ProACS)	https://clinicaltrials.gov/ct2/show/NCT01642329
Portuguese Registry on Interventional Cardiology (PRIC)	https://clinicaltrials.gov/ct2/show/NCT01867801
AMIS Plus - National Registry of Acute Myocardial Infarction and Unstable Angina in Switzerland	http://www.research-projects.uzh.ch/p4865.htm

There are already existing European registries which can be participated in.

European heart failure registry	http://www.escardio.org/guidelines-surveys/eorp/surveys/heart-failure/Pages/long-term-registry.aspx
European registry of cardiac arrest	https://www.eureca-one.eu/

Importance: Important

Transferability: Partially

Discussion

We found a wide range of interpretation of what is meant by telemonitoring/ telemedicine in the included literature. There are variations of telemonitoring like disease management programs, hospital based external monitoring structure, data-transfer and reaction by staff and/or device, structured or unstructured telephone support and involvement of professionals (i.e. cardiologist, nurse, GP).

The non-invasive monitoring, which includes structured telephone support gives the impression to be often implemented from „bottom up“ with therefore different solutions, contents and settings – as appropriate to the innovative bottom-up idea.

There is a need of a structured care outside the hospital for patients who do not need continous in-hospital care but should be monitored for a sudden deterioration or emergency-situation.. The solution of a high-frequent GP contact is not feasible as the number of control visits would increase enormously due to increase in chronic diseases.

The idea of a monitoring at distance saves time and efforts, but the solution seems to lack in structural and surrounding details like „whom to involve“, „how to train whom“ and „what should be done with the data“ (data security, data secure transfer, transmisson line system, etc.), influencing the studies outcomes.

We did not restrict the included studies in this TEC domain by study-methodology, because we wanted to have a valid description of projects and implemented system approaches for telemonitoring.

For structured telephone support it has to be taken into account

- Who calls whom when for what
- Who collects what data for what purpose
- What happens with the data
- Who reacts on the collected information and when and how
- Is there a need of technical support or function maintainance
- Is the target group of heart failure patients ready for the planned intervention (i.e. what kind of telephone are they able to use)

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of mHealth apps" (Vol. 3). In [6]

Appendices

Annex 1

Excluded literature from the basic literature search

Source	EndNote Number	P People aged 16 or more with CHF (defined as I50	I Home telemonitoring (defined as domiciliary detection, recognition, identification, location and transmission of vital functions and other biological information of a person)	C No home telemonitoring	O Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL, harms, device use	D Evidence synthesis studies (SRs, HTA reports) [updating RCTs i.e. RCT fitting the PICO which have been published after the last search date of the latest SR/HTA document]	CUR_TEC domain?	other reason for exclusion
Mair F.S. Does remote monitoring improve outcome in patients with chronic heart failure? Commentary. Nat. Clin. Pract. Cardiovasc. Med. 2007; 4(11):588-9.	Rec #: 1260					no		
Redman B.K. Ethically problematic assumptions regarding patient self management and barriers to improved outcomes. Expert Rev. Pharmacoecon. Outcomes Res. 2006; 6(5):489-94.	Rec #: 1450						no	
Costa A.P., Hirdes J.P. Clinical characteristics and service needs of alternate-level-of-care patients waiting for long-term care in Ontario hospitals. Healtc. Policy 2010; 6(1):32-46. Rec #: 1400	Rec #: 1400		no					
Agarwal R, Bills JE, Hecht TJ, Light RP. Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control: a systematic review and meta-analysis. Hypertension 2011; 57(1):29-38.	Rec #: 460	no						
Mengden T, Ewald S, Kaufmann S, vor dem Esche J, Uen S, Vetter H. Telemonitoring of blood pressure self measurement in the OLMETEL study. Blood Press Monit 2004; 9(6):321-5.	Rec #: 650	no						
Omboni S, Gazzola T, Carabelli G, Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. J Hypertens 2013; 31(3):455-67; discussion 467-8.	Rec #: 380	no						
Omboni S, Guarda A. Impact of home blood pressure telemonitoring and blood pressure control: a meta-analysis of randomized controlled studies. Am J Hypertens 2011; 24(9):989-98.	Rec #: 450	no						
Parati G, de Leeuw P, Illyes M et al. Blood pressure measurement in research. Blood Press Monit 2002; 7(1):83-7.	Rec #: 670	no						
Shepperd S. Hospital at home: The evidence is not compelling. Ann. Intern. Med. 2005; 143(11):840-1.	Rec #: 1470					no		
Zartner P, Handke R, Photiadis J, Brecher AM, Schneider MB. Performance of an autonomous telemonitoring system in children and young adults with congenital heart diseases. Pacing Clin Electrophysiol 2008; 31(10):1291-9.	Rec #: 600	no						
Jaana M, Pare G. Home telemonitoring of patients with diabetes: a systematic assessment of observed effects. J Eval Clin Pract 2007; 13(2):242-53.	Rec #: 620	no						
Baztan J.J., Suarez-Garcia F.M., Lopez-Arrieta J., Rodriguez-Manas L., Rodriguez-Artalejo F. Effectiveness of acute geriatric units on functional decline, living at home, and case fatality among older patients admitted to hospital for acute medical disorders: Meta-analysis. BMJ (Online) 2009; 338(7690):334-6.	Rec #: 1440		no					
Crawford-Faucher A. Home- and center-based cardiac rehabilitation equally effective. Am. Fam. Phys. 2010; 82(8):994-5.	Rec #: 1390		no					
Hwang R, Redfern J, Alison J. A narrative review on home-based exercise training for patients with chronic heart failure (Provisional abstract). Physical Therapy Reviews .	Rec #: 890		no					
Hwang R., Marwick T. Efficacy of home-based exercise programmes for people with chronic heart failure: A meta-analysis. Eur. J. Cardiovasc. Prev. Rehabil. 2009; 16(5):527-35.	Rec #: 1420		no					
Daskalopoulou SS, Khan NA, Quinn RR et al. The 2012 Canadian hypertension education program recommendations for the management of hypertension: blood pressure measurement, diagnosis, assessment of risk, and therapy. Can J Cardiol 2012; 28(3):270-87.	Rec #: 740	no						
McKinstry B, Hanley J, Wild S et al. Telemonitoring based service redesign for the management of uncontrolled hypertension: multicentre randomised controlled trial. BMJ 2013; 346:f3030.	Rec #: 360	no						
Inglis Sally C, Clark Robyn A, McAlister Finlay A *et al*. Structured	Rec #:							double

telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane Database of Systematic Reviews . CD007228	780							
Feltner C, Jones CD, Cene CW et al. Transitional care interventions to prevent readmissions for persons with heart failure: a systematic review and meta-analysis. Ann Intern Med 2014; 160(11):774-84.	Rec #: 10							double
Chien C L, Lee C M, Wu Y W, Chen T A, Wu Y T. Home-based exercise increases exercise capacity but not quality of life in people with chronic heart failure: a systematic review (Structured abstract). Australian Journal of Physiotherapy .	Rec #: 900		no					
Taylor Rod S, Dalal Hayes, Jolly Kate, Moxham Tiffany, Zawada Anna. Home-based versus centre-based cardiac rehabilitation. Cochrane Database of Systematic Reviews .	Rec #: 930		no					
Chaudhry S.I., Phillips C.O., Stewart S.S. et al. Telemonitoring for Patients With Chronic Heart Failure: A Systematic Review. J. Card. Fail. 2007; 13(1):56-62.	Rec #: 1300							double
Samartzis L., Dimopoulos S., Tziongourou M., Nanas S. Effect of psychosocial interventions on quality of life in patients with chronic heart failure: A meta-analysis of randomized controlled trials. J. Card. Fail. 2013; 19(2):125-34.	Rec #: 1040						no	
Clark R.A., Inglis S.C., Mcalister F.A. et al. Remote (non-invasive) monitoring in heart failure: Effect on length of stay, quality of life, knowledge, adherance and satisfaction in 8,323 heart failure patients: A systematic review. Eur. Heart J. 2010; 31:944-5.	Rec #: 1190						no	
Clark R.A., Inglis S.C., Mcalister F.A. et al. Results from a systematic review and meta-analysis of remote (non-invasive) monitoring in 8,323 heart failure patients on length of stay, quality of life, knowledge, compliance and satisfaction. Eur. J. Heart Fail. Suppl. 2010; 9:S51-S52.	Rec #: 1210						no	
Clark A.M., Spaling M., Harkness K. et al. Determinants of effective heart failure self-care: A systematic review of patients' and caregivers' perceptions. Heart 2014; 100(9):716-21.	Rec #: 1330						no	
Kraai I.H., Luttik M.L.A., De Jong R.M. et al. Measuring patient satisfaction of heart failure patients with telemonitoring: A systematic review. Eur. J. Cardiovasc. Nurs. 2011; 10:S31.	Rec #: 1160						no	
Aballea S., Verpillat P., Neine M.-E., Goryakin Y., Toumi M. Development of a model predicting the medico-economic impact of telemonitoring for patients with heart failure in france. Pharmacoepidemiol. Drug Saf. 2012; 21:16.	Rec #: 1100						no	
Brennan A., Thokala P., Baalbaki H., Stevens J.W., Wang J., Pandor A. Telemonitoring after discharge with heart failure-costeffectiveness modelling of alternative service designs. Value Health 2012; 15(7):A360.	Rec #: 1090						no	
Burri H, Sticherling C, Wright D, Makino K, Smala A, Tilden D. Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK. Europace 2013; 15(11):1601-8.	Rec #: 60						no	
Klersy C, De Silvestri A, Gabutti G et al. Economic impact of remote patient monitoring: an integrated economic model derived from a meta-analysis of randomized controlled trials in heart failure. Eur J Heart Fail 2011; 13(4):450-9.	Rec #: 150						no	
Thokala P., Baalbaki H., Brennan A. Telemonitoring after discharge from hospital with heart failure - Cost-effectiveness modelling of alternative service designs. Value Health 2013; 16(7):A530.	Rec #: 1000						no	
Thokala P., Brennan A., Baalbaki H. Cost-effectiveness modelling of telemonitoring after discharge from hospital with heart failure. Value Health 2013; 16(3):A290.	Rec #: 1030						no	
Conway A, Inglis SC, Chang AM, Horton-Breshears M, Cleland JG, Clark RA. Not all systematic reviews are systematic: a meta-review of the quality of systematic reviews for non-invasive remote monitoring in heart failure. J Telemed Telecare 2013; 19(6):326-37.	Rec #: 20	other source						double with Rec#1020
Feltner C, Jones CD, Cene CW et al. 2014. Transitional care interventions to prevent readmissions for persons with heart failure: a systematic review and meta-analysis. Ann Intern Med. 2014 Jun 3;160(11):774-84. doi: 10.7326/M14-0083.	Rec #: 260							double with REC#950
Inglis SC, Clark RA, McAlister FA et al. Structured telephone support or telemonitoring programmes for patients with chronic	Rec #: 490							double with Rec#1240

heart failure. Cochrane Database Syst Rev 2010; (8):CD007228.								
Pandor A. Home telemonitoring or structured telephone support programmes for patients with heart failure. Health Technol. Assess. 2013; 17(32).	Rec #: 1010							double with Rec#1010
Rychlik R., Rulhoff H. Socioeconomic relevance of selected treatment strategies in patients with chronic heart failure. Expert Rev. Pharmacoecon. Outcomes Res. 2005; 5(3):277-86.	Rec #: 1510						no	
Kitsiou S, Pare G, Jaana M. Systematic reviews and meta-analyses of home telemonitoring interventions for patients with chronic diseases: a critical assessment of their methodological quality. J Med Internet Res 2013; 15(7):e150.	Rec #: 340	no	no	no	no	no	no	critical appraisal of systematic reviewing
Abu-Awwad R., Alkhatib Y., Bukannan A. et al. Telemonitoring in patients with heart failure: A single-center experience. J. Gen. Intern. Med. 2012; 27:S313.	Rec #: 1110							only abstract available
Clark A.L. Heart failure. Arch. Cardiol. Mex. 2011; 81(4):383-90.	Rec #: 1130		no			no		
Cleland J.G.F., Coletta A.P., Buga L. et al. Clinical trials update from the American Heart Association Meeting 2010: EMPHASIS-HF, RAFT, TIM-HF, Tele-HF, ASCEND-HF, ROCKET-AF, and PROTECT. Eur. J. Heart Fail. 2011; 13(4):460-5.	Rec #: 1150							only abstract, refers to '130
Cleland JG, Coletta AP, Clark AL. Clinical trials update from the joint European Society and World Congress of Cardiology meeting: PEP-CHF, ACCLAIM and the HHH study. Eur J Heart Fail 2006; 8(6):658-61.	Rec #: 640					no		only abstract
Grustam AS, Severens JL, van Nijnatten J, Koymans R, Vrijhoef HJ. Cost-effectiveness of telehealth interventions for chronic heart failure patients: a literature review. Int J Technol Assess Health Care 2014; 30(1):59-68.	Rec #: 310							cost domain
Jaarsma T., Van Veldhuisen D.J., Gustafsson F., Arnold J.M.O. Heart failure management: How much COACH-ing is needed? (multple letters). Eur. Heart J. 2005; 26(3):314-5.	Rec #: 1520	no	no	no	no	no	no	letter to the editor
Oxberry SG, Johnson MJ. Review of the evidence for the management of dyspnoea in people with chronic heart failure. Curr Opin Support Palliat Care 2008; 2(2):84-8.	Rec #: 610						no	no informatio for cur, tec or leg
Seto E. Cost comparison between telemonitoring and usual care of heart failure: a systematic review. Telemed J E Health 2008; 14(7):679-86.	Rec #: 210						no	no informatio for cur, tec or leg
Stamp KD, Machado MA, Allen NA. Transitional care programs improve outcomes for heart failure patients (Provisional abstract). J Cardiovasc Nurs .	Rec #: 880						no	no informatio for cur, tec or leg
Stewart S. Comprehensive care in heart failure: Where to from here? Evid.-Based Healthc. Public Health 2005; 9(6):396-7.	Rec #: 1490						no	no informatio for cur, tec or leg
Van Spall H.G.C., Mytton O., Coppiens M., Shiga T., Haynes B., Connolly S. Comparative effectiveness of transitional care services in patients discharged from the hospital with heart failure (HF): A meta-analysis. Cardiology 2014; 128:470.	Rec #: 940							only abstract available
Whellan DJ, Adams S, Bowerman L. Review of advanced heart failure device diagnostics examined in clinical trials and the potential benefit from monitoring capabilities. Prog Cardiovasc Dis 2011; 54(2):107-14.	Rec #: 760		no					
Winkler S., Koehler F. A Meta-Analysis of Remote Monitoring of Heart Failure Patients. J. Am. Coll. Cardiol. 2010; 55(14):1505-6.	Rec #: 1220					editorial	no	no informatio for cur, tec or leg
Zhang Y., Mabote T., Atkin P. *et al*. Outcome of patients discharged after an episode of worsening heart failure into a heart failure specialist service supported by home telemonitoring. Eur. J. Heart Fail. Suppl. 2012; 11:S35-S36.	Rec #: 1120							only abstract available
Duffy JR, Hoskins LM, Chen MC. Nonpharmacological strategies for improving heart failure outcomes in the community: a systematic review. J Nurs Care Qual 2004; 19(4):349-60.	Rec #: 240	other source	no					

Casas J.P., Kwong J., Ebrahim S. Telemonitoring for chronic heart failure: not ready for prime time. Cochrane Database Syst Rev 2011; 2011:ED000008.	Rec #: 1370							Editorial
Metra M., Nodari S., Bardonali T., Milani P., Dei Cas L. Clinical trials update from the World Congress of Cardiology 2006. Expert Opin. Pharmacother. 2007; 8(6):881-9.	Rec #: 1290		no					
Brignole M, Auricchio A, Baron-Esquivias G et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J 2013; 34(29):2281-329.	Rec #: 50		no					implantable devices overview

Safety

Authors: Mirjana Huic, Pernilla Östlund, Romana Tandara Hacek, Jelena Barbaric, Marius Ciutan, Silvia Florescu, Silvia Gabriela Scintee

Summary

Aim: To determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure has impact on patients' and technical safety (technical reliability).

Methods: A systematic literature search, according to the predefined search strategy (not limited by publication date but limited to English language), was performed according to the Cochrane methodology, in standard medical and HTA databases. Relevant references (after duplicates were removed) were screened and assessed for eligibility independently by two reviewers. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme (as described in Project Scope), and the predefined inclusion/exclusion criteria. The quality of the included systematic reviews (SRs) was assessed using AMSTAR tool {Shea 2007}. The results from the included SRs were included according to the methodology suggested by Whitlock 2008 { } and Robinson 2014 { } on how to integrate existing SRs into new SRs. Risk of bias of included RCTs was evaluated independently by two reviewers using the Cochrane risk of bias checklist and EUnetHTA methods guidelines on internal validity of RCTs. Data extraction was performed by one reviewer on pre-defined extraction tables and double-checked regarding completeness and accuracy by a second reviewer. Any differences in extraction results were discussed to achieve consensus; any disagreements were resolved by a third reviewer. Quantitative synthesis from existing SRs were used and presented in Result section when available for specific assessment element questions. No new meta-analysis was performed. Primary outcomes were adverse events (AE): frequency of any AE, serious-SAE, most frequent AE; and discontinuation due AE. A secondary outcome was technical safety (technical reliability).

Results: 591 records were identified through database searching and 28 additional records were identified through other sources; 428 remained after duplicates were removed. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR. Of the included RCTs, only three were judged to be of low risk of bias. In the most recent SR no evidence on potential harms was found on STS interventions. None of 19 included RCTs specifically mentioned adverse events (AEs) as primary or secondary outcomes. In only one RCT which specifically mentioned AEs no adverse events were reported and only one RCT provided explanation on the reason why it did not monitor AEs.

Conclusion: *T*he sources were not sufficient to answer the questions on STS safety in patients with chronic heart failure. No evidence was found to answer technical safety.

Introduction

The Safety Domains describes the direct and indirect harms of a technology for patients, staff and environment, and how to reduce the risk of harms {HTA Core Model Handbook Online, Version 1.5}.

Aim of this assessment was to determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure, has impact on patients' and technical safety (technical reliability).

More specifically our primary outcomes were adverse events (AE): any AE, serious-SAE, most frequent AE; and discontinuation due AE. A secondary outcome was technical safety (technical reliability).

For this relative effectiveness assessment we planned to find and update recent, high quality systematic review (SR), with PICO (Patient-Intervention-Comparison-Outcome) scheme relevant for this assessment. Whitlock et al. 2008 { } and Robinson et al. 2014 { } in their published articles, regarding how to integrate existing systematic reviews into new systematic reviews, found that consensus among systematic review organizations and the Evidence-based Practice Centers (EPCs) about some aspects of incorporating existing systematic reviews already exist, but areas of uncertainty remain: how to synthesize, grade the strength of, and present bodies of evidence composed of primary studies and existing systematic reviews. According their published data, use of existing systematic reviews may include: (1) using the existing systematic review(s)' listing of included studies as a quality check for the literature search and screening strategy conducted for the new review (Scan References); (2) using the existing systematic review(s) to completely or partially provide the body of included studies for one or more Key Questions in the new review (Use Existing Search); (3) using the data abstraction, risk of bias assessments, and/or analyses from existing systematic reviews for one or more Key Questions in the new review (Use Data Abstraction/Syntheses), or (4) using the existing systematic review(s), including conclusions, to fully or partially answer one or more Key Questions in the new review (Use Complete Review).

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
C0001	Patient safety	What kind of harms can use of the technology cause to the patient; what are the incidence, severity and duration of harms?	yes	What is the frequency of all AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? What is the frequency of discontinuation of Structured telephone support (STS) due to adverse events in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? What is the frequency of and what are the serious-SAEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? What is the frequency of SAE leading to deaths with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? What are the most frequent AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
C0005	Patient safety	Are there susceptible patient groups that are more likely to be harmed through use of the technology?	yes	Are there susceptible patient groups that are more likely to be harmed through use of the home telemonitoring Structured telephone support (STS)
C0007	Patient safety	Are there special issues in the use of the technology that may increase the risk of harmful events?	yes	Are there special issues in the use of the Structured telephone support (STS) that may increase the risk of harmful events?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	no	Not important for STS.
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	no	Not important for STS.
C0006	Patient safety	What are the consequences of false positive, false negative and incidental findings generated by using the technology from the viewpoint of patient safety?	no	Not important for Structured telephone support (STS).
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	no	Duplication of C0001, please see C0001.
C0060	Safety risk management	How does the safety profile of the technology vary between different generations, approved versions or products?	yes	How does the safety profile of the Structured telephone support (STS) vary between two different approach (human to human or human to machine interface)?
C0062	Safety risk management	How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?	yes	How can one reduce safety risks for adults with chronic heart failure (including technology-, user-, and patient-dependent aspects)?
C0061	Safety risk management	Can different organizational settings increase or decrease harms?	no	Not relevant for STS.
C0063	Safety risk management	How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?	no	Not important for STS.
C0064	Safety risk management	How can one reduce safety risks for environment (including technology-, user-, and patient-dependent aspects)	no	Not important for STS.
C0020	Occupational safety	What kind of occupational harms can occur when using the technology?	no	Not important for STS.
C0040	Environmental safety	What kind of risks for public and environment may occur when using the technology?	no	Not important for STS.

Methodology description

A systematic literature search, according the predefined search strategy (**Appendix 1**) (not limited by publication date but limited to English language), was performed according to the Cochrane methodology {Higgins 2011}, in standard medical and HTA databases.

Information sources

Specifically, the following databases were searched: MEDLINE accessed through OVID or Pubmed; CINAHL with Full Text (EBSCOhost), SCI-EXPANDED (Web of Science™ Core Collection) and Cochrane Library searching the following databases: The Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Database of Systematic Reviews (Cochrane Reviews), The Database of Abstracts of Reviews of Effects (DARE) and The Health Technology Assessment Database (HTA).

This was complemented by hand search of the following websites: http://www.cadth.ca/en/products/health-technology-assessment; http://www.york.ac.uk/inst/crd/publications.htm; http://guidance.nice.org.uk/Date; http://hta.lbg.ac.at; http://kce.fgov.be; http://www.hiqa.ie/; http://www.agenas.it. The reference lists of relevant systematic reviews and health technology assessment reports were checked for relevant studies.

In addition, the following clinical trials registries were assessed, for registered ongoing clinical trials or results posted: ClinicalTrials.gov, ISRCTN, EU Clinical Trials Register, and International Clinical Trials Registry Platform (ICTRP).

Relevant references (after duplicates were removed) were screened and assessed for eligibility independently by two reviewers. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme (as described in Project Scope), and the inclusion/exclusion criteria listed below:

Q What are the effects of Structured telephone support (STS) on adults with chronic heart failure?

P Individuals aged 16 or more with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure

I Structured telephone support (STS)

C Usual care (UC) without Structured telephone support (STS)

O Domain Specific Outcomes: Adverse events (AE) (frequency of any AE, serious-SAE, most frequent AE; discontinuation due AE); technical safety (technical reliability)

Study Design

D Evidence synthesis studies (SRs, HTA reports) [updating RCTs i.e. RCT fitting the PICO which have been published after the last search date of the latest SR/HTA document]

Inclusion criteria:

1. SRs and HTAs and RCTs comparing chronic heart failure patients management /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure/ delivered via structured telephone support with usual care;
2. Patients should be randomized to structured telephone support or usual care without structured telephone support (STS);
3. One or more of the SAF outcomes were reported;
4. Sufficient methodological details are reported to allow critical appraisal of study quality;
5. Publication in English;
6. Report on humans only.

Exclusion criteria:

Primary or secondary studies which:

1) Do not involve adult patients with CHF /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), CRTs or pacemakers, who have been admitted to hospital at least once for chronic heart failure/;

2) Do not compare CHF management delivered via structured telephone support with usual care in patients with CHF living within the community;

3) Home visits were performed as part of the intervention or by the clinical staff involved in the intervention

4) Do not provide data for our outcomes of interest in an extractable format;

5) Papers with RCTs without sufficient methodological details to allow critical appraisal of study quality;

6) The papers (publications) published in a language other than English;

7) Duplicate of original publication.

Differences in selection results were discussed in order to achieve consensus; a third reviewer were involved in case of disagreement. The study selection process was presented according to the PRISMA flowchart {Liberati 2009} (**Appendix 2**).

Finding and updating a recent, high quality SR (with PICO scheme relevant for this relative effectiveness assessment) was planned. The publications by Whitlock et al. 2008 { } and Robinson et al. 2014 { }, regarding how to integrate existing SRs into new SRs, were used. To answer our research questions all four approaches in using existing systematic reviews, described in Robinson et al. 2014 { }, were used: (1) using the existing SR(s)' listing of included studies as a quality check for the literature search and screening strategy conducted for the new review (Scan References); (2) using the existing SR(s) to completely or partially provide the body of included studies for one or more Key Questions in the new review (Use Existing Search); (3) using the data abstraction, risk of bias assessments, and/or analyses from existing SRs for one or more Key Questions in the new review (Use Data Abstraction/Syntheses), and (4) using the existing SR(s), including conclusions, to fully or partially answer one or more Key Questions in this SR (Use Complete Review).

Quality assessment tools or criteria

The quality of the included systematic review was assessed using AMSTAR {Shea 2007}.

Risk of bias was evaluated independently by two reviewers using the Cochrane risk of bias checklist and EUnetHTA methods guidelines on internal validity of RCTs {Higgins 2011; EUnetHTA 2013}

Direct evidence related to primary outcomes of our assessment was planned to assess by using the GRADE-methodology {Guyatt 2008}. This approach specifies four levels of quality:

High: further research is very unlikely to change our confidence in the estimate of effect;

Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimates;

Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate;

Very low: we are very uncertain about the estimate.

Analysis and synthesis

Data extraction was performed by one reviewer on pre-defined extraction tables and double-checked regarding completeness and accuracy by a second reviewer. Any differences in extraction results were discussed to achieve consensus; a third reviewer was involved in case of disagreement.

The following information was extracted from included **secondary studies** (SRs or HTAs):*Study general information:* Author; Year of publication; Reference number; Study objectives; *Study characteristics:* Study types included in the review; Number of studies included in the review; Review timeframe; Comparison(s); Patients groups (number of patients and health technology used) in the included studies; *Outcomes and follow-up:* Main outcomes reported; Main study findings; *Conclusions:* Authors' conclusions. Please look in EFF Domain (**Appendix 3)**

The following information was extracted from included **primary studies**:

Data on *Study characteristics* (study design, registration number, country and centre, study period, ethics committee approval, sponsor, study methodology); *Patient characteristics* (age, gender, NYHA I-IV); *Outcomes*; *Intervention*; *Comparato*r; *Flow of patients*; *Statistical analysis*; *Results* on primary and secondary outcomes; and *Conflict of interest* data were extracted. Please look in EFF Domain (**Appendix 4)**

Quantitative synthesis from existing SRs were used and presented in Resut section wherever appropiate. No new meta-analysis was performed.

Result cards

Patient safety

Result card for SAF1a: "What is the frequency of all AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?", SAF1b: "What is the frequency of discontinuation of Structured telephone support (STS) due to adverse events in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?", SAF1c: "What is the frequency of and what are the serious-SAEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?", SAF1d: "What is the frequency of SAE leading to deaths with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?" and SAF1e: "What are the most frequent AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

SAF1a: What is the frequency of all AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Introduction to Results section

591 records were identified through database searching and 28 additional records were identified through other sources; 428 remained after duplicates were removed. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR (**Appendix 3 and 4**). Of the included RCTs, only three were judged to be of low risk of bias. The PRISMA flowchart outlining the study selection process is presented in **Appendix 2**.

Updating only one SR of already available SRs was not possible due to different, and a wide range of our research questions, as well as different inclusion criteria and duration of follow-up of RCTs included. If data from existing SRs or HTAs was not available we used data from the included 19 RCTs.

Five high quality SRs were found to answer some of the assessment element questions {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007}, details can be found in **Appendix 3**. Only three RCTs on STS in chronic heart failure patients {Laramee 2003, Riegel 2002, Riegel 2006} were included in all five SRs (see **Appendix 5**). Becausue not all assessment element questions could be answered by the results from the five included SRs, 19 published RCTs (**Appendix 4 and 6)** were included in order to answer the remaining assessment element questions. Out of them, 17 RCTs were already included in one or several of the five SRs (**Appendix 5)**.

The two most recent RCTs, published by Angermann et al 2012 { } and Krum et al 2013 { } were not included in the SR published by Kotb et al 2015 { }, and RCT published by Krum et al 2013 { } was not included in the SR published by Feltner et al 2014 { }. Out of the 19 RCTs (see **Appendix 4 and 6**), only three were judged to be of low risk of bias {DeBusk 2004, GESICA 2005, Chaudhry 2010}, five as unclear risk of bias {Tsuyuki 2004, Cleland 2005, Riegel 2006, Sisk 2006, Krum 2013} and the remaining 11 were rated as high risk of bias {Gattis 1999, Rainville 1999, Barth 2001, Riegel 2002, Laramee 2003, Galbreath 2004, DeWalt 2006, Ramachandran 2007, Wakefield 2008, Mortara 2009, Angermann 2012}. The majority of RCTs (17 RCTs) had a follow-up period of 6 or 12 months or more; more specifically two RCTs had 3 months period {Barth 2001, Laramee 2003}; eight had 6 months follow-up period {Gattis 1999, Riegel 2002, Tsuyuki 2004, Riegel 2006, Ramachandran 2007, Wakefield 2008, Chaudhry 2010, Angermann 2012}; for six RCTs follow-up period was 12 months {Rainville 1999, DeBusk 2004, DeWalt 2006, Sisk 2006, Wakefield 2008, Krum 2013}. One RCT had follow-up period of 8 months {Cleland 2005}, one of 16 months {GESICA 2005} and one RCT had 18 months {Galbreath 2004} follow-up period. Only one ongoing RCT was found in publicly available register noted that participants were not yet being recruitinig (**Appendix 7**).

Answers on specific assessment element questions

One SRs, published by Feltner et al, 2014 { } and 19 RCTs were included to answer domain assessment element questions { }. Little evidence identified on the potential harms of STS.

Feltner et al, 2014 { } included 13 RCTs described in 15 publications comparing STS with usual care. Most trials averaged 1 or 2 calls during the intervention period, with the first contact occurring within 7 days of discharge. Interventions differed in whether predischarge education was delivered with STS or not. Most trials included a patient-initiated hotline for questions or additional support. One three-arm trial compared two modes of delivering STS (standard telephone versus videophone) with usual care. Trial sample sizes ranged from 32 to 715; only one trial reported a readmission rate at 30 days.

All but three trials included in this SR were rated as at medium risk of bias; three trials at high risk of bias primarily for high risk of selection bias and measurement bias. Most trials were conducted in the United States: three in multicenter settings and all others at a single center. Three trials were conducted in multicenter settings in Europe and Canada and one trial was conducted at a single center in Brazil (**Appendix 3**). In this most recent SR and HTA {Feltner et al, 2014}, **no evidence on potential harms was found on STS interventions.**

None of 19 included RCTs specifically predefined adverse events (AEs) as primary or secondary outcomes. The same is true for one identified trial in publicly available clinical trial register (Appendix 4 and 7).

Only one RCT specifically mentioned AEs and only one RCT provided explanation for the reason why they did not monitor AEs. Chaudhry et al, 2010 { }, in 6 months treatment period, multicenter, randomized, single-blind, low risk of bias controlled trial, with aim to assess whether telemonitoring would reduce the combined end point of readmission or death from any cause among patients recently hospitalized for heart failure, **no adverse events were reported**. Authors discussed that the primary anticipated adverse event associated with telemonitoring was a **delay in seeking care for urgent or emergency situations** because of a belief that the telemonitoring data would immediately alert clinicians. **Sisk et al, 2006**, explained that s**ince both, nurse management and usual care, involved only services delivered in routine practice, the study did not monitor adverse effects.**

Details could be found in **Appendices 3, 4 and 7:**

Appendix 3 Characteristics of included secondary studies: Systematic reviews/HTA, main study findings and authors conclusions. Assessing the quality of included SRs – AMSTAR Criteria

Appendix 4 RCTs included in SR of effectiveness and safety: Evidence tables and Risk of bias tables

Appendix 7 List of Ongoing RCTs in clinical trials registries

Importance: Critical

Transferability: Partially

SAF1b: What is the frequency of discontinuation of Structured telephone support (STS) due to adverse events in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

To answer on ”What is the frequency of discontinuation of Structured telephone support (STS) due to adverse events in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” please see assessment element C0001.

Importance: Critical

Transferability: Partially

SAF1c: What is the frequency of and what are the serious-SAEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

To answer on ”What is the frequency of and what are the serious-SAEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” please see assessment element C0001.

Importance: Critical

Transferability: Partially

SAF1d: What is the frequency of SAE leading to deaths with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

To answer on ” What is the frequency of SAE leading to deaths with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” please see assessment element C0001.

Importance: Critical

Transferability: Partially

SAF1e: What are the most frequent AEs with Structured telephone support (STS) in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Please see assessment element C0001.

Importance: Critical

Transferability: Partially

Result card for SAF2: "Are there susceptible patient groups that are more likely to be harmed through use of the home telemonitoring Structured telephone support (STS)"

View full card

SAF2: Are there susceptible patient groups that are more likely to be harmed through use of the home telemonitoring Structured telephone support (STS)

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs were found to answer question ”Are there susceptible patient groups that are more likely to be harmed through use of the home telemonitoring Structured telephone support (STS)”.

Importance: Important

Transferability: Partially

Result card for SAF3: "Are there special issues in the use of the Structured telephone support (STS) that may increase the risk of harmful events?"

View full card

SAF3: Are there special issues in the use of the Structured telephone support (STS) that may increase the risk of harmful events?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs were found to answer question ”Are there special issues in the use of the Structured telephone support (STS) that may increase the risk of harmful events?”.

Importance: Important

Transferability: Partially

Safety risk management

Result card for SAF4: "How does the safety profile of the Structured telephone support (STS) vary between two different approach (human to human or human to machine interface)?"

View full card

SAF4: How does the safety profile of the Structured telephone support (STS) vary between two different approach (human to human or human to machine interface)?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs were found to answer question ”How does the safety profile of the Structured telephone support (STS) vary between two different approach (human to human or human to machine interface)?”.

Importance: Important

Transferability: Partially

Result card for SAF5: "How can one reduce safety risks for adults with chronic heart failure (including technology-, user-, and patient-dependent aspects)?"

View full card

SAF5: How can one reduce safety risks for adults with chronic heart failure (including technology-, user-, and patient-dependent aspects)?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs were found to answer question ”How can one reduce safety risks for adults with chronic heart failure (including technology-, user-, and patient-dependent aspects)?”.

Importance: Important

Transferability: Partially

Discussion

Aim of this relative effectiveness assessment was to determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure has impact on patients’ and technical safety (technical reliability).

More specifically, our primary outcomes were adverse events (AE): any AE, serious-SAE, most frequent AE and discontinuation due AE. A secondary outcome was technical safety (technical reliability).

Five existing SRs have been integrated {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007} according to the methodology described in Whitlock et al. 2008 { } and Robinson et al. 2014 { }, into this SR. Additionally, 19 RCTs have been included to answer domain assessment element questions that were not answered by the five SRs. We were faced with already recognized areas of uncertainty: how to appropriately synthesize, grade the strength of, and present bodies of evidence composed of primary studies and existing systematic reviews.

In the most recent SR and HTA {Feltner et al, 2014} no evidence on potential harms was found on STS interventions.

Also none of 19 included RCTs specifically predefined adverse events (AEs) as primary or secondary outcomes. The same is true for one identified trial in publicly available clinical trial register. Only one RCT specifically mentioned AEs Chaudhry et al, 2010 { } and only one RCT provide explanation the reason why they did not monitor AEs Sisk et al, 2006 { }. Chaudhry et al, 2010 { } in 6 months treatment period, multicenter, randomized, single-blind, low risk of bias controlled trial with aim to assess whether telemonitoring would reduce the combined end point of readmission or death from any cause among patients recently hospitalized for heart failure no adverse events were reported. Authors discussed that the primary anticipated adverse event associated with telemonitoring was a delay in seeking care for urgent or emergency situations because of a belief that the telemonitoring data would immediately alert clinicians. Sisk et al, 2006 { }, explained that since both nurse management and usual care involved only services delivered in routine practice, the study did not monitor adverse effects.

Kidholm et al, 2012 { } provide a Model for Assessment of Telemedicine Applications, MAST, a structure for future assessment of telemedicine applications. MAST was tested during 2010–13 in twenty studies of telemedicine applications in nine European countries in the EC project Renewing Health on different chronic diseases: Diabetes Mellitus type 2, COPD and Congestive Heart Failure {Kidholm et al, 2014}.

In RCT assessed remote monitoring of CHF (only 29 patients were analysed in the control group and 30 in the telemonitoring group) safety data was not mentioned {Dafouluas et al, 2014}.

The whole data of Renewing Health project, on telemonitoring application in patients with all three chronic diseases, has demonstrated that the telemedicine services tested are safe as usual care {Kidholm et al, 2014}.

The findings of our literature search are consistent with other studies who address outcomes reporting bias on safety outcomes.

McLean et al, 2013 { } in their systematic review of systematic review with aim to generate a high level synthesis of the evidence on telehealth care applications showed that there was very little in the systematic reviews specifically concerning patient safety. It was not clear whether adverse events did not occur or whether there was a lack of reporting.

Several studies non-specifically connected with telemedicine interventions have documented underreporting of low-grade AEs, recurrent AEs and inconsistent and incomplete characterization and reporting of high-grade AEs {Scharf et al, 2006; Ethgen et al, 2009; Pitrouet al, 2009}.

In study published by Saini et al, 2014 { } with aim to determine the extent and nature of selective non-reporting of harm outcomes in clinical studies that were eligible for inclusion in a cohort of systematic reviews outcome reporting bias for harms was evident in nearly two thirds of all primary studies included in systematic reviews.

In contrast, in the sample of the RCTs analysed in study published by Huic et al, 2011 { } in which technologies other than pharmaceuticals were presented in 30% of total sample, serious and non-serious AEs were mentioned in more than 80% of the published articles.

In our assessment the sources were not sufficient to answer the questions due the fact that little evidence was identified on the potential harms of STS. No RCTs were found at all to answer some assessment element questions, like technical safety. Possible limitation of our assessment is that we looked only for SRs and RCTs, and not for prospective observational comparative studies or registries data.

The poor reporting of harms data (safety data is inadequately reported or not reported at all) has major implications for proper judging the benefit-risk ratio.

Limitations of data from published studies are obvious, so further research is needed on safety of STS interventions in chronic heart failure patients. Due another limitation - narrow scope of our assessment, our results are not applicable to patients with chronic heart failure with implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy defibrillators (CRT-Ds) or pacemakers. Hindricks et al. 2014 and Parthiban et al. 2015 recently published data on remote monitoring in this selected group of patients { }.

Several methodological issues should be solved when conducting the RCTs like masking outcome assessment as well as clear description of usual care. Pragmatic RCTs as well as observational real world data should also address this issue. Data reporting should be according evidence-based reporting guidelines, specifically CONSORT Statement extension on better reporting of harms in RCTs and trials assessing nonpharmacologic treatments {Ioannidis et al, 2004; Boutron et al, 2008}.

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Appendices

Please see the appendices in EFF Domain

Appendix 1. Search strategy, June 2015

Appendix 2. Flow chart of study selection

Appendix 3. Characteristics of included secondary studies: Systematic reviews/HTA, main study findings and authors conclusions. Assessing the quality of included SRs – AMSTAR Criteria

Appendix 4. RCTs included in SR of effectiveness and safety: Evidence tables and Risk of bias tables

Appendix 5. List of included studies (RCTs) in the secondary studies (SRs or HTAs)

Appendix 6. List of included studies (RCTs) in this Systematic review of Clinical Effectiveness/Safety with Follow-up duration and Risk of bias

Appendix 7. List of Ongoing RCTs in clinical trials registries

Clinical Effectiveness

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Summary

Aim: To determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure improves clinical outcomes and quality of life, has impact on patients' satisfaction and function, and change in management or utilization of health service compared with current practice.

Methods: A systematic literature search, according to the predefined search strategy (not limited by publication date but limited to English language), was performed according to the Cochrane methodology, in standard medical and HTA databases. Relevant references (after duplicates were removed) were screened and assessed for eligibility independently by two reviewers. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme (as described in Project Scope), and the predefined inclusion/exclusion criteria. The quality of the included systematic reviews (SRs) was assessed using AMSTAR tool {Shea 2007}. The results from the included SRs were included according to the methodology suggested by Whitlock 2008 { } and Robinson 2014 { } on how to integrate existing SRs into new SRs. Risk of bias of included RCTs was evaluated independently by two reviewers using the Cochrane risk of bias checklist and EUnetHTA methods guidelines on internal validity of RCTs. Data extraction was performed by one reviewer on pre-defined extraction tables and double-checked regarding completeness and accuracy by a second reviewer. Any differences in extraction results were discussed to achieve consensus; any disagreements were resolved by a third reviewer. Quantitative synthesis from existing SRs were used and presented in Result section when available for specific assessment element questions. No new meta-analysis was performed. Primary outcomes were mortality (overall and disease-specific), morbidity (disease-specific symptoms, disease progression) and Health-related quality of life (HRQoL). Secondary outcomes were impact on re-hospitalization rate (disease-specific, all-cause); emergency room visit rate; cardiology visit rate; primary care visit rate; body functions; work ability; return to previous living conditions; activities of daily living and patient satisfaction (worthwhile use, willing to use again).

Results: 591 records were identified through database searching and 28 additional records were identified through other sources; 428 remained after duplicates were removed. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR. Of the included RCTs, only three were judged to be of low risk of bias. STS produced a mortality benefit and reduced HF-specific readmission rates. For the outcomes QoL and utilization the evidence was insufficient. Yet, the majority of studies presented statistically significant QoL improvements. A majority of the RCTs found no significant difference in the number of emergency room visits in either group. Since little evidence was identified on the potential harms of STS (described in the Safety Domain), it was not possible to assess overall benefits and harms of STS in adults with chronic heart failure. No evidence found to answer some assessment element questions, related on outcomes such as work ability, return to previous living conditions, activities of daily living, worthwhile of STS and willing to use STS again.

Conclusion: STS reduces HF-specific readmission and mortality. A majority of the studies presented statistically significant improvements in QoL. Some research gaps and transferability issues were recognized. Further research is needed on effects of STS on QoL and utilization outcomes as well as patient satisfaction during long term follow-up.

Introduction

The Clinical Effectiveness Domains describes the range and size of beneficial health effects expected through the use of the technology {HTA Core Model Handbook Online, Version 1.5}. The two key elements are that effective interventions should be directly compared and studied in patients who are typical of day-to-day health care settings {HTA Core Model Application for Pharmaceuticals, 2.0}.

The aim of this relative effectiveness assessment was to determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure, improves clinical outcomes and quality of life, has impact on patients' satisfaction and function, and change in management or utilization of health service compared with current practice.

Primary outcomes were mortality (overall and disease-specific), morbidity (disease-specific symptoms, progression) and Health-related quality of life (HRQL).

Secondary outcomes were impact on re-hospitalization rate (disease-specific, all-cause); emergency room visit rate; cardiology visit rate; primary care visit rate; body function; work ability; return to previous living conditions; activities of daily living and patient satisfaction (worthwhile use, willing to use again).

For this relative effectiveness assessment we planned to find and update recent, high quality systematic review (SR), with PICO (Patient-Intervention-Comparison-Outcome) scheme relevant for this assessment. Whitlock et al. 2008 { } and Robinson et al. 2014 { } in their published articles, regarding how to integrate existing systematic reviews into new systematic reviews, found that consensus among systematic review organizations and the Evidence-based Practice Centers (EPCs) about some aspects of incorporating existing systematic reviews already exist, but areas of uncertainty remain: how to synthesize, grade the strength of, and present bodies of evidence composed of primary studies and existing systematic reviews. According their published data, use of existing systematic reviews may include: (1) using the existing systematic review(s)' listing of included studies as a quality check for the literature search and screening strategy conducted for the new review (Scan References); (2) using the existing systematic review(s) to completely or partially provide the body of included studies for one or more Key Questions in the new review (Use Existing Search); (3) using the data abstraction, risk of bias assessments, and/or analyses from existing systematic reviews for one or more Key Questions in the new review (Use Data Abstraction/Syntheses), or (4) using the existing systematic review(s), including conclusions, to fully or partially answer one or more Key Questions in the new review (Use Complete Review).

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
D0001	Mortality	What is the expected beneficial effect of the intervention on overall mortality?	yes	What is the effects of Structured telephone support (STS) on overall mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0002	Mortality	What is the expected beneficial effect on the disease-specific mortality?	yes	What is the effects of Structured telephone support (STS) on disease-specific mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS) ?
D0003	Mortality	What is the effect of the technology on the mortality due to causes other than the target disease?	no	Relevant only for the target disease.
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the target condition?	yes	How does Structured telephone support (STS) affect disease-specific symptoms and findings (severity, frequency) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0006	Morbidity	How does the technology affect the progression (or recurrence) of the target condition?	yes	How does Structured telephone support (STS) affect the progression of chronic heart failure of adults patients, compared to standard care without Structured telephone support (STS)?
D0010	Change-in management	How does the technology modify the need for hospitalization?	yes	Does Structured telephone support (STS) impact on the re-hospitalization rate (disease-specific and all-cause) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0023	Change-in management	How does the technology modify the need for other technologies and use of resources?	yes	Does Structured telephone support (STS) impact on the emergency room visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? Does Structured telephone support (STS) impact on the cardiology visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)? Does Structured telephone support (STS) impact on the primary care visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0012	Health-related Quality of life	What is the effect of the technology on generic health-related quality of life?	yes	What is the effect of Structured telephone support (STS) on generic health-related quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0013	Health-related Quality of life	What is the effect of the technology on disease specific quality of life?	yes	What is the effect of Structured telephone support (STS) on disease specific quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0011	Function	What is the effect of the technology on patients' body functions	yes	What is the effect of Structured telephone support (STS) on body functions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0014	Function	What is the effect of the technology on work ability?	yes	What is the effect of Structured telephone support (STS) on work ability of adults with chronic heart

				failure, compared to standard care without Structured telephone support (STS)?
D0015	Function	What is the effect of the technology on return to previous living conditions?	yes	What is the effect of Structured telephone support (STS) on return to previous living conditions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0016	Function	How does use of the technology affect activities of daily living?	yes	How does Structured telephone support (STS) affects activities of daily living of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?
D0017	Patient satisfaction	Was the use of the technology worthwhile?	yes	Was the use of Structured telephone support (STS) worthwhile?
D0018	Patient satisfaction	Is the patient willing to use the technology again?	yes	Are adults with chronic heart failure willing to use the Structured telephone support (STS) again?
D0029	Benefit-harm balance	What are the overall benefits and harms of the technology in health outcomes?	yes	What are the overall benefits and harms of the Structured telephone support (STS) in adults with chronic heart failure?
C0006	Patient safety	What are the consequences of false positive, false negative and incidental findings generated by using the technology from the viewpoint of patient safety?	no	Not important for Structured telephone support (STS).

Methodology description

A systematic literature search, according the predefined search strategy (**Appendix 1**) (not limited by publication date but limited to English language), was performed according to the Cochrane methodology {Higgins 2011}, in standard medical and HTA databases.

Information sources

Specifically, the following databases were searched: MEDLINE accessed through OVID or Pubmed; CINAHL with Full Text (EBSCOhost), SCI-EXPANDED (Web of Science^{TM} Core Collection) and Cochrane Library searching the following databases: The Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Database of Systematic Reviews (Cochrane Reviews), The Database of Abstracts of Reviews of Effects (DARE) and The Health Technology Assessment Database (HTA).

This was complemented by hand search of the following websites: http://www.cadth.ca/en/products/health-technology-assessment; http://www.york.ac.uk/inst/crd/publications.htm; http://guidance.nice.org.uk/Date; http://hta.lbg.ac.at; http://kce.fgov.be; http://www.hiqa.ie/; http://www.agenas.it. The reference lists of relevant systematic reviews and health technology assessment reports were checked for relevant studies.

In addition, the following clinical trials registries were assessed, for registered ongoing clinical trials or results posted: ClinicalTrials.gov, ISRCTN, EU Clinical Trials Register, and International Clinical Trials Registry Platform (ICTRP).

Relevant references (after duplicates were removed) were screened and assessed for eligibility independently by two reviewers. References have been included or excluded according to the overall research question, Population-Intervention-Control-Outcome (PICO)-scheme (as described in Project Scope), and the inclusion/exclusion criteria listed below:

Q What are the effects of Structured telephone support (STS) on adults with chronic heart failure?

P Individuals aged 16 or more with chronic heart failure (New York Heart Association (NYHA) I-IV), without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure

I Structured telephone support (STS)

C Usual care (UC) without Structured telephone support (STS)

O Domain Specific Outcomes: mortality (overall and disease-specific); morbidity (disease-specific symptoms, progression); re-hospitalization rate (disease-specific, all-cause); emergency room visit rate; cardiology visit rate; primary care visit rate; Health-related quality of life (HRQL): both generic and disease-specific; body function; work ability; return to previous living conditions; activities of daily living; patient satisfaction (worthwhile use, willing to use again)

Study Design

D Evidence synthesis studies (SRs, HTA reports) [updating RCTs i.e. RCT fitting the PICO which have been published after the last search date of the latest SR/HTA document]

Inclusion criteria:

1) SRs and HTAs and RCTs comparing chronic heart failure patients management /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), cardiac resynchronization therapy (CRTs) or pacemakers, who have been admitted to hospital at least once for chronic heart failure/ delivered via structured telephone support with usual care;

2) Patients are randomized to structured telephone support or usual care without structured telephone support (STS);

3) One or more of the EFF outcomes were reported;

4) Sufficient methodological details are reported to allow critical appraisal of study quality;

5) Publication in English;

6) Report on humans only.

Exclusion criteria:

Primary or secondary studies which:

1) Do not involve adult patients with CHF /New York Heart Association (NYHA) I-IV, without implantable cardiac defibrillators (ICDs), CRTs or pacemakers, who have been admitted to hospital at least once for chronic heart failure/;

2) Do not compare CHF management delivered via structured telephone support with usual care in patients with CHF living within the community;

3) Home visits were performed as part of the intervention or by the clinical staff involved in the intervention

4) Do not provide data for our outcomes of interest in an extractable format;

5) Papers with RCTs without sufficient methodological details to allow critical appraisal of study quality;

6) The papers (publications) published in a language other than English;

7) Duplicate of original publication.

Differences in selection results were discussed in order to achieve consensus; a third reviewer were involved in case of disagreement. The study selection process was presented according to the PRISMA flowchart {Liberati 2009} (**Appendix 2**).

Finding and updating a recent, high quality SR (with PICO scheme relevant for this relative effectiveness assessment) was planned. The publications by Whitlock et al. 2008 { } and Robinson et al. 2014 { }, regarding how to integrate existing SRs into new SRs, were used. To answer our research questions all four approaches in using existing systematic reviews, described in Robinson et al. 2014 { }, were used: (1) using the existing SR(s)' listing of included studies as a quality check for the literature search and screening strategy conducted for the new review (Scan References); (2) using the existing SR(s) to completely or partially provide the body of included studies for one or more Key Questions in the new review (Use Existing Search); (3) using the data abstraction, risk of bias assessments, and/or analyses from existing SRs for one or more Key Questions in the new review (Use Data Abstraction/Syntheses), and (4) using the existing SR(s), including conclusions, to fully or partially answer one or more Key Questions in this SR (Use Complete Review).

Quality assessment tools or criteria

(Write your text here)

The quality of the included SR was assessed using AMSTAR {Shea 2007}.

Risk of bias of included RCTs was evaluated independently by two reviewers using the Cochrane risk of bias checklist and EUnetHTA methods guidelines on internal validity of RCTs {Higgins 2011; EUnetHTA 2013}.

Direct evidence on primary outcomes was planned to be assessed by using the GRADE-methodology {Guyatt 2008}. This approach specifies four levels of quality:

High: further research is very unlikely to change our confidence in the estimate of effect;

Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimates;

Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate;

Very low: we are very uncertain about the estimate.

Analysis and synthesis

(Write your text here)

Data extraction was performed by one reviewer on pre-defined extraction tables and double-checked regarding completeness and accuracy by a second reviewer. Any differences in extraction results were discussed to achieve consensus; a third reviewer was involved in case of disagreement.

The following information was extracted from included **secondary studies** (SRs or HTAs):*Study general information:* Author; Year of publication; Reference number; Study objectives; *Study characteristics:* Study types included in the review; Number of studies included in the review; Review timeframe; Comparison(s); Patients groups (number of patients and health technology used) in the included studies; *Outcomes and follow-up:* Main outcomes reported; Main study findings; *Conclusions:* Authors' conclusions. (**Appendix 3)**

The following information was extracted from included **primary studies**:

Data on *Study characteristics* (study design, registration number, country and centre, study period, ethics committee approval, sponsor, study methodology); *Patient characteristics* (age, gender, NYHA I-IV); *Outcomes*; *Intervention*; *Comparato*r; *Flow of patients*; *Statistical analysis*; *Results* on primary and secondary outcomes; and *Conflict of interest* data were extracted. **(Appendix 4)**

Quantitative synthesis from existing SRs were used and presented in Result section wherever appropiate. No new meta-analysis was performed.

Result cards

Mortality

Result card for EFF1: "What is the effects of Structured telephone support (STS) on overall mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF1: What is the effects of Structured telephone support (STS) on overall mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Introduction to Results section

591 records were identified through database searching and 28 additional records were identified through other sources; 428 remained after duplicates were removed. One hundred full-text articles were assessed for eligibility and after the exclusion of 76 full-text articles, five high quality SRs and 19 full text published RCTs were included in our SR (**Appendix 3 and 4**). Of the included RCTs, only three were judged to be of low risk of bias. The PRISMA flowchart outlining the study selection process is presented in **Appendix 2**.

Updating only one SR of already available SRs was not possible due to different, and a wide range of our research questions, as well as different inclusion criteria and followed-up duration of RCTs included. If data from existing SRs or HTAs was not available we used data from the included 19 RCTs.

Five high quality SRs were found to answer some of the assessment element questions {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007}, details can be found in **Appendix 3**. Only three RCTs on STS in chronic heart failure patients {Laramee 2003, Riegel 2002, Riegel 2006} were included in all five SRs (see **Appendix 5**). Becausue not all assessment element questions could be answered by the results from the five included SRs, 19 published RCTs (**Appendix 4 and 6)**, were included in order to answer the remaining assessment element questions. Out of them, 17 RCTs were already included in one or several of the five SRs (**Appendix 5)**.

The two most recent RCTs, published by Angermann et al 2012 { } and Krum et al 2013 { } were not included in the SR published by Kotb et al 2015 { }, and RCT published by Krum et al 2013 { } was not included in the SR published by Feltner et al 2014 { }. Out of the 19 RCTs (see **Appendix 4 and 6**), only three were judged to be of low risk of bias {DeBusk 2004, GESICA 2005, Chaudhry 2010}, five as unclear risk of bias {Tsuyuki 2004, Cleland 2005, Riegel 2006, Sisk 2006, Krum 2013} and the remaining 11 were rated as high risk of bias {Gattis 1999, Rainville 1999, Barth 2001, Riegel 2002, Laramee 2003, Galbreath 2004, DeWalt 2006, Ramachandran 2007, Wakefield 2008, Mortara 2009, Angermann 2012}. The majority of RCTs (17 RCTs) had a follow-up period of 6 or 12 months or more; more specifically two RCTs had 3 months period {Barth 2001, Laramee 2003}; eight had 6 months follow-up period {Gattis 1999, Riegel 2002, Tsuyuki 2004, Riegel 2006, Ramachandran 2007, Wakefield 2008, Chaudhry 2010, Angermann 2012}; for six RCTs follow-up period was 12 months {Rainville 1999, DeBusk 2004, DeWalt 2006, Sisk 2006, Wakefield 2008, Krum 2013}. One RCT had follow-up period of 8 months {Cleland 2005}, one of 16 months {GESICA 2005} and one RCT had 18 months {Galbreath 2004} follow-up period. Only one ongoing RCT was found in publicly available register noted that participants were not yet being recruitinig (**Appendix 7**).

Answers on specific assessment element questions

All five high quality systematic reviews were used **to answer the question** "What is the effects of Structured telephone support (STS) on **overall mortality** in adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?" {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007}, as well as two more recent RCTs {Angremann 2012, Krum 2013}, details can be found in **Appendices 3 and 4**.

Data found on overal mortality in STS group compared with usual care **were conflicting.** One SR **Feltner et al, 2014** { }, including RCT published by **Angermann 2012** { } and one SR with network meta analysis published by **Kotb et al, 2015** { } were found which ***reported significantly lower overal mortality in STS group comparing with usual care***. RCT published by **Cleland 2005** { } found ***significantly lower overal mortality in STS group (***UC=20 (24%) vs NTS=27 (16%), **P=0.0397)** as well.

The three other SRs and two out of 19 RCTs, reported ***non-significant difference*** in overall mortality in STS group compared to usual care {Pandor 2013, Inglis 2011, Clark 2007, Angermann 2012, Cleland 2005}.

Seven studies ({Krum et al 2013, Gatiss 1999, Rainville 1999, DeWalt et al 2006 { }, Chaudhry et al 2010 { }, Angermann et al 2013, DeBusk et al 2004) assessed the composite outcome (*composite end point of all-cause death or hospitalisation or* combined outcome of *rehospitalisation, emergency department visit, or death).* Only three of them {Krum et al 2013, Gatiss 1999, Rainville 1999}, found a ***significant reduction*** on this outcome.

Feltner et al, 2014 { } included 13 RCTs with follow-up period of 3-6 months, described in 15 publications, in which STS was compared with usual care. Most trials used ab average of 1 or 2 calls during the intervention period, with the first contact occurring within 7 days of discharge. Interventions varied in whether predischarge education was delivered with STS. Most trials included a patient-initiated hotline for questions or additional support. One three-arm trial compared two modes of delivering STS (standard telephone versus videophone) with usual care. Trial sample size ranged from 32 to 715; only one trial reported a readmission rate at 30 days.

All but three trials in this SR were rated at a medium risk of bias; three trials were rated at high risk of bias primarily for high risk of selection bias and measurement bias. Most trials were conducted in the United States: three in multicenter settings and all others at a single center. Three trials were conducted in multicenter settings in Europe and Canada one trial was conducted at a single center in Brazil. In this most recent SR and HTA { }, STS interventions produced a mortality benefit, with **RR (95% CI)** of **0.74 (0.56–0.97)**, at 3-6 months, with **NNT** of **27** (Table 1). Specific RR with 95% CI was listed for already included RCTs in previous SRs and in our new SR {Laramee 2003, Riegel 2006, Wakefield 2008, Angermann 2012}. According the Angermann et al, 2012 { } results, mortality was ***significantly lower in STS group*** comparing with usual care (HR, 0.62; 0.40–0.96; ***P*=0.03**)

Table 1. Mortality data from six RCTs on STS compared with usual care, Feltner et al, 2014 { }

Outcome	Outcome timing	Trials (Participants) number	RR (95% CI)	NNT	SOE*
Mortality	3–6 months	6 (2011)	**0.74 (0.56–0.97)** ***Laramee et al, 2003***: 0.90 (0.44–1.82) ***Dunagan et al, 2005***:	**27**	Moderate for benefit

			1.18 (0.38–3.71) ***López Cabezas et al, 2006***: 0.46 (0.18–1.15) ***Riegel et al, 2006***: 0.58 (0.20–1.68) ***Wakefield et al, 2008***: 0.78 (0.29–2.08) ***Angermann et al, 2012***: **0.63 (0.42–0.96)**		

Abbreviations: NNT = number needed to treat; RR = risk ratio; SOE = strength of evidence according the Feltner et al 2014 { }

Kotb et al, 2015 { } with direct comparisons of data from 15 trials showed mortality Odds Ratio (OR) of 0.85 (0.73 to 1.0), compared to usual care. In Network meta-analysis (NMA), compared to usual care, structured telephone support ***significantly reduced the odds of mortality*** (**Odds Ratio 0.80; 95% Credible Intervals CrI [0.66 to 0.96**]).

Pandor et al, 2013 { } included 11 studies evaluating STS [10 used standard telephone equipment using human to human (HH) support and one provided support via an automated telephone interactive response system (HM) with an alert system]; 1 study assessed both STS and telemonitoring compared with usual care. The duration of follow-up ranged from 6 months to 18 months.

Compared with usual care, STS HH ***did not show statistically significant*** benefit in reducing all-cause mortality [hazard ratio (HR) 0.77, 95% CrI 0.55 to 1.08]. No favourable effect on mortality was observed with STS HM.

In SR published by **Inglis et al, 2011** { }, out of the 25 full text peer-reviewed studies included in the meta-analysis, 16 evaluated structured telephone support (5613 participants), 11 evaluated telemonitoring (2710 participants), and two tested both interventions. Structured telephone support demonstrating a ***non-significant positive effect*** on all-cause mortality (RR 0.88, 95% CI 0.76 to 1.01, P = 0.08) (Box 1). In sensitivity analysis done on 9 RCT with a follow-up period longer than 6 months, also included in our new SR, difference between two groups was ***not statistically significant*** {Rainville 1999, DeBusk 2004, Galbreath 2004, Cleland 2005, GESICA 2005, DeWalt 2006, Sisk 2006, Wakefield 2008, Mortara 2009}.

Box 1. All-cause mortality, structured telephone support in comparison with usual care, in SR published by Inglis et al, 2011 { }

All-cause mortality

STS vs UC RR 0.88 (95% CI 0.76 to 1.01, P = 0.08) (15 published trials, n= 5563)

Sensitivity analysis: Follow-up period (>6 months), 9 published trials, n=4292, RR 0.87 [0.74, 1.02]:

Cleland et al, 2005 (Struct Tele): 0.66 [0.40, 1.11]

DeBusket al, 2004: 0.74 [0.44, 1.26]

DeWalt et al, 2006: 0.79 [0.18, 3.37]

Galbreath et al, 2004: 0.70 [0.47, 1.04]

GESICA 2005 (DIAL): 0.88 [0.77, 1.00]

Mortara et al, 2009 (Struct Tele): 1.51 [0.62, 3.68]

Rainville et al, 1999: 0.25 [0.03, 2.04]

Sisk et al, 2006: 1.00 [0.57, 1.75]

Wakefield et al, 2008: 1.12 [0.60, 2.09]

Adding two studies on structured telephone support (Angermann 2007; Krum 2009 (CHAT) which were not full peer-reviewed publications to the meta-analysis increased the effect of structured telephone support (RR 0.85, 95% CI 0.75 to 0.97, P = 0.02, I^2 0%).

Abbreviations: RR = risk ratio; STS: structured telephone support; UC: usual care

In SR published by **Clark et al, 2007** { } 14 randomised controlled trials (4264 patients) on remote monitoring met the inclusion criteria: four evaluated telemonitoring, nine evaluated structured telephone support, and one evaluated both.

Structured

telephone support, based on 10 RCTs results (also included in our SR) {Cleland 2005, Rainville 1999, Gattis 1999, Barth 2001, Riegel 2002, Laramee 2003, DeBusk 2004, Tsuyuki 2004, GESICA 2005, Riegel 2006} ***not statistically significant*** reduced all-cause mortality by 20% (8% to 31%); RR 0.85 (0.72 to 1.01, P=0.06, based on 482 deaths in 3542 patients)(Box 2).

Box 2. All-cause mortality, structured telephone support in comparison with usual care, in SR published by Clark et al, 2007 { }

All-cause mortality

Structured telephone support **RR 0.85 (0.72 to 1.01, P=0.06**), based on 482 deaths in 3542 patients;

Cleland et al, 2005: **RR 0.61 (0.40 to 0.94)**

Gattis et al, 1999: RR 0.61 (0.15 to 2.46)

Rainville et al, 1999: RR 0.25 (0.03 to 2.01)

Barth et al, 2001: RR not estimated

Riegel et al, 2002: RR 0.88 (0.50 to 1.54)

Laramee et al, 2003: RR 0.90 (0.44 to 1.82)

DeBusk et al, 2004: RR 0.74 (0.44 to 1.26)

Tsuyuki et al, 2004: RR 1.30 (0.64 to 2.64)

GESICA Investigators 2005: RR 0.95 (0.75 to 1.20)

Riegel et al, 2006: RR 0.71 (0.26 to 1.93)

Angermann et al, 2012 { } in open, randomized, 2-armed, parallel-group, multicenter 6 months trial, aimed to clarify the mode of action of the program and individual patient requirements, thus providing a rational basis for more targeted health care strategies in heart failure, showed overall mortality ***significantly lower*** in intervention group in comparison to usual care group. Overall, 32 (9%) patients in the intervention group and 52 (14%) patients in the usual care group died (**HR, 0.62; 0.40–0.96; *P*=0.03**). Five of these deaths occurred after dropout (HNC: n=4, UC: n=1).

Krum et al, 2013 { } aimed at determining whether an *automated telephone support system* would improve quality of life and reduce death and hospital admissions for rural and remote heart failure patients in Australia, at 12 months follow up. This RCT reported that 16 out of 209 patients in the usual care (UC) group and 17 out of 170 patients in UC + Intervention (I) group died during the study. This resulted in an ***non statisticaly significant*** unadjusted hazard ratio (HR) for all-cause death of **1.3 (range 0.65–2.77, P = 0.43**) and an adjusted hazard ratio of **1.36 (0.63–2.93, P = 0.439**).

Despite the fact that study **Krum et al, 2013** { } found no change in the primary endpoint (Packer clinical composite score, a clinical composite consisting of mortality, overnight hospitalization for worsened HF and NYHA class global self-assessment), the intervention did lead to a ***significant reduction*** in the risk of the ***composite of all-cause death or hospitalization***, as well as ***all-cause hospitalization alone***. 124 of 209 UC and 86 of 170 UC + I patients reached the endpoint of all-cause death or all-cause hospitalization. This resulted in an unadjusted hazard ratio of 0.75 (range 0.57–0.99, **P = 0.045**) and an adjusted hazard ratio of 0.70 (range 0.53–0.92, **P = 0.011**). The same is true for other RCTs that looked at **composite end point of all cause mortality and rehospitalization** for heart failure or all cause hospitalization {Gatiss 1999, Rainville 1999}. DeWalt et al 2006 { }, Chaudhry et al 2010 { }, and Angermann et al 2013 did ***not find*** *any* ***significant reduction*** in the risk of the ***composite of all-cause death or hospitalization*** or in the **combined outcome of rehospitalization, emergency department visit, or death,** DeBusk et al 2004 { } .

Details can be found in **Appendix 3 and 4.**

Importance: Critical

Transferability: Partially

Result card for EFF2: "What is the effects of Structured telephone support (STS) on disease-specific mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS) ?"

View full card

EFF2: What is the effects of Structured telephone support (STS) on disease-specific mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS) ?

Method

The same methodology was used as described in section for the whole domain.

Result

Only three RCTs {Angremann 2012, Cleland 2005, DeBusk 2004} with different follow-up period (6, 8 and 12 months) were found to answer question "What is the effects of Structured telephone support (STS) on disease-specific mortality in adults with chronic heart failure, compared to standard care without Structured telephone support (STS) ?". They did not find any statistically significant different rates between two groups.

Angremann et al, 2012 { }, at 6 months, reported a lower disease specific mortality in the Intervention group (22 [6%] versus 35 cases [10%]) in usual care group (UC), but this difference was ***not statistically significant; HR 0.66 (0.38 –1.12; P=0.12***).

Cleland et al, 2005 { } reported circulatory failure in UC=14 (16.5%) patients versus NTS=21 (12.3%) patients, as well as sudden death in UC=4 (4.7%) patients, in comparisons to NTS=5 (3%) patients, with a follow-up period of 8 months.

DeBusk et al, 2004 { } in randomized, controlled trial of usual care with nurse management versus usual care alone with aim to determine whether a telephone-mediated nurse care management program for heart failure reduced the rate of rehospitalization for heart failure and for all causes over a 12 months follow-up period, reported a disease specific mortality in UC: 29 (79%) versus STS: 21 (62%) patients. Of these deaths, 13 in the treatment group and 23 of 29 (79%) in the usual care group were due to cardiac causes.

Details could be found in **Appendix 4.**

Importance: Important

Transferability: Partially

Morbidity

Result card for EFF3: "How does Structured telephone support (STS) affect disease-specific symptoms and findings (severity, frequency) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF3: How does Structured telephone support (STS) affect disease-specific symptoms and findings (severity, frequency) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

One SR {Inglis et al, 2011} with four RCTs reporting on this specific question (three overlapping with our SR {Ramachandran et al, 2007, Galbreath et al, 2004, Cleland et al, 2005} and one recently published full text RCT Angermann et al, 2012 { } were found to answer question ”How does Structured telephone support (STS) affect **disease-specific symptoms and findings (severity, frequency)** of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?”.)?”. **Data on this outcome were conflicting**.

In SR published by **Inglis et al, 2011** { }, three RCTs (Angermann 2007 published only as Abstract; Ramachandran 2007, Galbreath 2004) out of four assessing it (Cleland et al 2004 in addition) showed a ***significant improvement in*** **NYHA Functional Class. Ramachandran et al, 2007** { }, in RCT aimed to assess 6 months role of telephonic disease management programme in improving the quality-of-life (QOL) of patients with heart failure showed that for every 20 patients in the intervention group, 14 patients improved by 1 functional class while in the control group this was observed in only 3 patients for every 20 treated. ***Significant improvement in functional capacity*** of patients was found in the intervention group compared with controls over a 6-month period, measured by the 6-minute walk test in the intervention group (from 202.2 [81.5] to 238.1 [100.9] metres, p<0.05) but not in the control group (193.8 [81.5] to 179.7 [112.0] metres). **Galbreath et al, 2004** { } in RCT with aim to evaluate the effectiveness of telephonic disease management (DM) as a clinical and cost-containment strategy in both systolic and diastolic CHF over a longer time period (18 months) and with a larger and more heterogeneous sample than those of previous studies, reported a ***statistically significant improvements*** **in NYHA class in intervention group (P=0.001**), but 6-minute walk data from 217 patients in whom data were available at each visit showed no significant benefit from telephonic DM (P=0.08). **Cleland et al, 2005** { } showed similar, ***not statisticaly different*** NYHA functional class after 8 months in the two groups. **Angermann et al, 2012** { }, in published full text article, reported HR of 0.73 (0.53-1.00), ***statistically significant*** more favourable results regarding NYHA class (**P=0.05**), in Intervention group patients, after clinical evaluation at 6 months. No differences between groups were found regarding pump function, heart rate, and blood pressure.

Details could be found in **Appendix 3 and 4.**

Importance: Important

Transferability: Partially

Result card for EFF4: "How does Structured telephone support (STS) affect the progression of chronic heart failure of adults patients, compared to standard care without Structured telephone support (STS)?"

View full card

EFF4: How does Structured telephone support (STS) affect the progression of chronic heart failure of adults patients, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

No RCTs were found to answer question “How does Structured telephone support (STS) affect the progression of chronic heart failure of adults patients, compared to standard care without Structured telephone support (STS)?”. Some indirect answers could be found in assessment element D0005.

Importance: Important

Transferability: Partially

Change-in management

Result card for EFF5: "Does Structured telephone support (STS) impact on the re-hospitalization rate (disease-specific and all-cause) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF5: Does Structured telephone support (STS) impact on the re-hospitalization rate (disease-specific and all-cause) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

All five high quality systematic reviews were used **to answer the question** "Does Structured telephone support (STS) impact on the **re-hospitalization rate (disease-specific and all-cause)** of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?" {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007}, as well as two recently published RCTs {Angermann 2012, Krum 2013}; studies' details can be found in **Appendices 3 and 4**.

Data found on **all-cause** and **HF-specific re-hospitalization** rate in STS group comparing with usual care **were conflicting. The majority (included 5 published SRs)** ***reported significantly lower*** **HF-specific re-hospitalization** rate in STS group {Feltner 2014, Kotb 2015, Pandor 2013, Inglis 2011, Clark 2007}. When sensitivity analysis was done including only RCT with follow-up period longer than 6 months this difference was not statistically significant anymore {Inglis 2011}.

On the contrary, two recently published RCTs {Angermann 2012, Krum 2013} with 6 and 12 months follow-up period, respectively, reported a ***non-significant difference in*** **HF-specific re-hospitalization between STS and Usual care groups.**

In the most recent SR and HTA published by **Feltner et al, 2014** { } whilst structured telephone support (STS) interventions ***statistically significant reduced HF-specific readmission*** (high strength of evidence, SOE) but not all-cause readmissions (moderate SOE), **in follow-up period of 3-6 months**, with NNT of 14 (Table 1).

Table 1. All-cause and heart failure (HF)-specific re-hospitalisation data from 8 RCTs on STS compared with usual care, at 3-6 months follow-up period, Feltner et al, 2014 { }

Outcome	Outcome timing	Trials (Participants) number	RR (95% CI)	NNT	SOE*
All-cause readmission	30 d	1 (134)	0.80 (0.38–1.65) Riegel et al, 2006	NA	Insufficient
All-cause readmission	3–6 mo	8 (2166)	0.92 (0.77–1.10) ***Laramee et al, 2003***: 1.10 (0.79–1.53) ***Riegal et al, 2002***: 0.86 (0.68–1.09) ***Tsuyuki et al, 2004***: 1.12 (0.84–1.50) ***Dunagan et al, 2005***: 0.56 (0.40–0.79) ***López Cabezas et al, 2006***: 0.58 (0.35–0.95) ***Riegel et al, 2006***: 1.02 (0.76–1.36) ***Domingues et al, 2011***: 1.14 (0.72–1.82) ***Angermann et al, 2012***: 1.10 (0.89–1.35)	NA	Moderate for no benefit
HF-specific readmission	30 d	1 (134)	0.63 (0.24–1.87)	NA	Insufficient
HF-specific readmission	**3–6 mo**	7 (1790)	**0.74 (0.61–0.90)**	**14**	High for benefit

Abbreviations: NNT = number needed to treat; RR = risk ratio; SOE = strength of evidence assessed by Feltner et al 2014 { }

Kotb et al, 2015 { } in ***direct comparisons*** showed that ***statistically significant fewer*** patients receiving structured telephone support interventions were hospitalized for **all causes** (**0.86 [0.77, 0.97**)] (data from 12 trials) and due to **heart failure** (**0.76 [0.65, 0.89**)] (data from 11 trials) than patients who received usual care. ***In Network meta-analysis (NMA),*** compared to usual care, structured telephone support, **significantly reduced** the odds of hospitalizations due to **heart failure** (**0.69; [0.56 to 0.85**]). STS no longer found to significantly reduce all-cause hospitalization compared to usual care.

Pandor et al, 2013 { } showed that, compared with usual care, STS interventions had **no major effect on all-cause hospitalisations.** There were no major effects on **HF-related hospitalisation** for STS HM (HR 1.03, 95% CrI 0.66 to 1.54); **STS HH (HR 0.77, 95% CrI 0.62 to 0.96**) was associated with a **statistically significant** 23% reduction.

In SR published by **Inglis et al, 2011** { }, based on data from 13 RCTs, Structured telephone support ***significantly reduced CHF-related hospitalisations*** (**RR 0.77, 95% CI 0.68 to 0.87, P < 0.0001**) (**Box 1**) as well as risk of ***all-cause hospitalization*** (**RR 0.92, 95% CI 0.85 to 0.99, P = 0.02).** In Sensitivity analysis including only RCTs with a follow-up period >6 months (6 published studies), both risks were **not statistically significant between two groups.**

Box 1. All-cause and HF-specific re-hospitalization, structured telephone support in comparison with usual care, in SR published by Inglis et al, 2011 { }

All-cause hospitalisation (11 published studies, n=4295)

Structured telephone support was effective in reducing the risk of all-cause hospitalisation in patients with CHF (**RR 0.92, 95% CI 0.85 to 0.99, P = 0.02, I² 24%**).

Sensitivity analysis: Follow-up period (>6 months), 6 published studies, n=3058, RR 0.91 [0.83, 0.99]:

Cleland 2005 (Struct Tele): 0.91 [0.71, 1.16]

DeBusk 2004: 1.02 [0.85, 1.22]

GESICA 2005 (DIAL): 0.88 [0.77, 1.00]

Mortara 2009 (Struct Tele): 1.16 [0.82, 1.65]

Sisk 2006: 0.84 [0.64, 1.10]

Wakefield 2008: 0.70 [0.50, 0.97]

With the addition of one study of structured telephone support published as an abstract only (Krum 2009 (CHAT)), the effect of this intervention on all-cause hospitalisation in patients with CHF increased minimally (RR 0.90, 95% 0.84 to 0.97, P = 0.003, I² =32%.

CHF-related hospitalisation outcomes (13 studies, n=4269)

Structured telephone support was effective in reducing the proportion of patients with a CHF-related hospitalisation

RR 0.77, 95% CI 0.68 to 0.87, P < 0.0001, I^2 = 7%

Sensitivity analysis: Follow-up period (>6 months), 6 published studies, n=2948: RR 0.76 [0.65, 0.89]

Cleland 2005 (Struct Tele): 0.70 [0.44, 1.10]

DeBusk 2004: 0.91 [0.61, 1.35]

GESICA 2005 (DIAL): 0.76 [0.61, 0.93]

Mortara 2009 (Struct Tele): 0.97 [0.57, 1.66]

Rainville 1999: 0.40 [0.15, 1.05]

Sisk 2006: 0.62 [0.36, 1.08]

In SR published by Clark et al, 2007 { }, based on 9 RCTs data, structured telephone support **significantly reduced the rates** of admission to hospital **for chronic heart failure** by 21% (95% confidence interval 11% to 31%), **RR 0.78 (0.68 to 0.89), P=0.0003,** but not all-cause hospital admission rate (based on 7 RCTs data provided) (Box 2).

Box 2. All-cause and HF-specific re-hospitalization, structured telephone support in comparison with usual care, in SR published by Clark et al, 2007 { }

All-cause hospital admission RR 0.94 (0.87 to 1.02), P=0.15

Cleland et al 2005: RR 0.91 (0.74 to 1.13)

Riegel et al 2002: RR 0.86 (0.68 to 1.09)

Laramee et al 2003: RR 1.10 (0.79 to 1.53)

DeBusk et al 2004: 1.02 (0.85 to 1.22)

Tsuyuki et al 2004: 1.12 (0.84 to 1.5

GESICA Investigators 2005: 0.88 (0.77 to 1.00)

Riegel et al 2006: 0.99 (0.74 to 1.33)

HF-related hospital admission RR 0.78 (0.68 to 0.89), P=0.0003

Cleland et al 2005: RR 0.70 (0.45 to 1.07)

Rainville 1999: RR 0.40 (0.16 to 1.03)

Barth et al 2001: RR Not estimable

Riegel et al 2002: RR 0.64 (0.42 to 0.98)

Laramee et al 2003: RR 0.89 (0.49 to 1.59)

DeBusk et al 2004: RR 0.91 (0.61 to 135)

Tsuyuki et al 2004: RR 0.95 (0.64 to 1.39)

GESICA Investigators 2005: RR 0.76 (0.61 to 0.93)

Riegel et al 2006: RR 0.90 (0.55 to 1.47)

Angermann et al. 2012 { } showed ***non statistically significant difference*** between STS and usual care groups on **all-cause, *P*=0.28** and **HF-specific re-hospitalization, *P*=0.36**.

Krum et al, 2013 { } showed for **all-cause hospitalization** that there were ***significantly fewer*** patients hospitalized **for any cause** (74 vs. 114, adjusted **HR 0.67 [95% CI 0.50–0.89], P = 0.006**) and who died or were hospitalized (89 vs. 124, adjusted **HR 0.70 [95% CI 0.53–0.92], P = 0.011**), in the usual care (UC) + intervention group (I) versus UC group. **Heart Failure (**HF)-hospitalizations were reduced with UC+I (23 vs. 35, adjusted HR 0.81 [95% CI 0.44–1.38]), although this was ***not significant (P = 0.43)***. There were 16 deaths in the UC group and 17 in the UC+I group (P = 0.43). Authors concluded that although no difference was observed in the primary endpoint (Packer composite score), UC+I significantly reduced the number of HF patients hospitalized among a rural and remote cohort. These data suggest that telephone support may be an efficacious approach to improve clinical outcomes in rural and remote HF patients.

Details could be found in **Appendix 3 and 4.**

Importance: Important

Transferability: Partially

Result card for EFF6a: "Does Structured telephone support (STS) impact on the emergency room visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?", EFF6b: "Does Structured telephone support (STS) impact on the cardiology visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?" and EFF6c: "Does Structured telephone support (STS) impact on the primary care visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF6a: Does Structured telephone support (STS) impact on the emergency room visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

One systematic review were used to answer the question ” Does Structured telephone support (STS) impact on the emergency room visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” {Feltner et al, 2014}, as well as 7 RCTs out of 19 included in our new SR {Ramachandran 2007, Sisk 2006, Cleland 2005, Tsuyuki 2004, Galbreath 2004, DeBusk 2004, Barth 2001}; details can be found in Appendices 3 and 4.

Data found on *the **emergency room (ER) visit rate*** in STS group comparing with usual care **were conflicting,** but **majority of the retrieved evidence found no significant difference** in the number of emergency room visits in either group.

The most recent SR and HTA published by **Feltner et al, 2014** { } reported that STS interventions had ***no effect*** on the rate of ER visits over 3 to 6 months (low SOE). Six STS trials provided data on ER visits at different time points and using different methods; two of them were also included in our SR { Barth 2001, Tsuyuki 2004}. Tsuyuki 2004}. Individual data of these two and of additional five RCTs included in our review are presented below.

Ramachandran et al, 2007 { }, in a RCT aimed to assess 6 months role of telephonic disease management programme in improving the quality-of-life (QOL) of patients with heart failure, found **no significant difference in the number of emergency room visits** between the two groups.

Sisk et al, 2006 { } found **no significant difference in the number of emergency room visits** (total ER visit, 157 usual care group vs 147 in STS group, in follow-up period of 12 months.

Cleland et al, 2005 { } showed a **significant difference in the number of emergency room visits in favour of usual care group** (total ER visit, 8 usual care group vs 54 in STS group, in period of 8 months (Total/1000 days at risk (95% CI): UC= 0.5 (0.2 to 0.8) vs NTS= 1.6 (1.2 to 2.0).

Tsuyuki et al, 2004 { } presented a **non-significant difference in all cause of emergency room visits** between groups (UC=69 vs STS=41, p=0.206), but **significant difference** in the number of **cardiovascular emergency room visits** (UC=49 vs STS=20, **p=0.030**).

Galbreath et al, 2004 { } in a RCT with a treatment period of 18 months, showed that total and CHF-related healthcare utilization, including medications, office or emergency department visits, procedures, or hospitalizations, was **not decreased** by DM.

In the RCT published by **DeBusk et al, 2004** { } **no significant difference** in the number of emergency room visits was found: 126 out of 228 patients (55%) in the care management group made 1 or more emergency department visits for any cause compared with 132 out of the 234 patients (56%) in the usual care group. The mean number of emergency department visits in the treatment and usual care groups during the first year of follow-up was 3.2 (median, 2.0) and 3.5 (median, 2.0), respectively.

In the RCT published by **Barth et al, 2001**, { } **no significant difference** was found: none of the patients in the experimental group had any unexpected emergency department visits during the study period of 3 months. One patient from the control group had an unexpected visit to a local emergency department due to CHF.

Details could be found in **Appendix 3 and 4.**

Importance: Important

Transferability: Partially

EFF6b: Does Structured telephone support (STS) impact on the cardiology visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Assessment element questions EFF6b and EFF6c, based on assessment element: *D0023,* were answered together:

To answer question "Does Structured telephone support (STS) impact on the cardiology visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?" 7, out of 19 RCTs were found {Barth 2001, Riegel 2002, Laramee 2003, DeBusk 2004, Tsuyuki 2004, Cleland 2005, Angermann 2012}, and one more RCT was found {Krum 2013} to answer question "Does Structured telephone support (STS) impact on the primary care visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?". Not all RCTs were specific on cardiology visit rate nor on primary care visit rate. Six RCTs (on cardiology visit rate) found no significant difference, and one {Cleland 2005} found difference, in favour of control group. Two found a difference on primary care visit rate; one in favour of control group and one in favour of STS group {Cleland 2005, Krum 2013}. RCTs varied in follow-up duration period (3 month to 12 months period) as well in sample size.

Barth et al, 2001 { }, in 3 months follow-up period showed that CHF patients who received the structured nurse managed post discharge program did not have any unexpected physician office visit due to exacerbation of CHF during the time they were enrolled in the study. One participant in the control group had an unexpected visit to the physician's office for adjustment of medications.

Riegel et al, 2002 { }, during a 6 months period, showed a non-significant difference in physician office visits (5.63±3.6 in intervention group vs 6.17±4.87 in usual care group).

Laramee et al, 2003 { }, during a 3 months period showed that no significant differences were found in outpatient and inpatient resource utilization between the groups.

DeBusk et al, 2004 { }, showed that in the 12 months, patients in both groups had an average of 3 cardiology outpatient visits, 6 internal medicine visits, and 4 non–internal medicine visits.

Tsuyuki et al, 2004, presented that in 6 months no significant difference was found in physician visits all-cause (p=0.795) or cardiovascular cause (p=0.366) between groups.

Cleland et al, 2005 { }, in 8 months period showed a higher rate of both, cardiology visit (UC=34 vs NTS=117) and primary care visit rates (UC=119 vs NTS=602) for patients in the intervention group. Authors discussed that patient contacts were evaluated only once every four months in the usual care group compared with monthly in NTS group, which may led to under-reporting of contacts in the control group.

Angermann et al, 2012 { }, during the 6 months period, showed a non-significant difference: across the entire study population, mean numbers of visits to cardiologists were 0.7±2.3 and 0.7±2.6 per patient in HNC and UC, respectively (*P*=0.86), and of visits to other specialists were 1.3±5.4 and 2.1±9.9, respectively (*P*=0.17). In HNC, this included also specialist care arranged by the INH team. Average numbers of contacts per alive patient/month, out of hospital, and under observation were 2.4±1.8 versus 2.4±2.1 (GP p=0.82), 0.1±0.4 versus 0.1±0.4 (cardiologists, *P*=0.88), and 0.2±0.9 versus 0.4±1.7 (other specialists, *P*=0.12) in HNC and UC, respectively.

Authors {**Angermann et al, 2012**}, showed non-significant difference for GPs visits as well: across the entire study population, mean contact frequencies with GPs (home and office visits) were 13.5±10.6 in HNC and 12.9±11.1 in UC, respectively (*P*=0.46). Average numbers of contacts per patient month alive, out of hospital, and under observation were 2.4±1.8 versus 2.4±2.1 (GP p=0.82), 0.1±0.4 versus 0.1±0.4 in HNC and UC, respectively.

Krum et al, 2013, during 12 months period, showed that patients in the usual care group visited their general practitioner more frequently compared with those in UC + intervention group (12.55 GP visits/patient [UC] vs. 5.85 GP visits/patient [UC + I]). **Reduction in the utilization of general practitioners**, with the control group visiting their general practitioner more than twice as often as the intervention group, may be due to compliance (in 65%) with the automated telephone support system in the intervention group, reducing the need for participants in the intervention group to visit their general practitioner.

Details could be found in **Appendix 4.**

Importance: Important

Transferability: Partially

EFF6c: Does Structured telephone support (STS) impact on the primary care visit rate (disease-specific) of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Assessment element questions EFF6b and EFF6c, based on assessment element: *D0023,* were answered together, please see above.

Importance: Important

Transferability: Partially

Health-related Quality of life

Result card for EFF7: "What is the effect of Structured telephone support (STS) on generic health-related quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF7: What is the effect of Structured telephone support (STS) on generic health-related quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

Assessment element questions D0012 and D0013 (EFF7 and EFF8) were answered together:

Three SRs were used to answer ”What is the effect of Structured telephone support (STS) on generic health-related quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” and ”What is the effect of Structured telephone support (STS) on disease specific quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” {Feltner 2014, Pandor 2013, Inglis 2011}, with 8 RCTs overlappin with those from our sample of 19 RCTs {Riegel 2006, Angermann 2012, Barth 2001, Wakefield 2008, DeWalt 2006; GESICA 2005; Ramachandran 2007; Sisk 2006}. Data found was controversial, but majority presented statisticaly significant QoL improvements.

In the most recent SR and HTA published by **Feltner et al, 2014** { } STS interventions **did not improve HF-specific quality of life** at 3 or 6 months. Meta-analysis {**Feltner et al, 2014**} (two trials, ***Riegel et al, 2006*** and ***Dominiquez et al, 2011***) found no difference in Minnesota Living With Health Failure Questionnaire (MLWHFQ) scores among patients receiving STS and those receiving usual care at either 3 months (WMD, -3.78; 95% CI, -10.39 to 2.83) or 6 months (WMD, -7.14; 95% CI, -21.07 to 6.78).

Three additional trials reported on quality of life at 6 months {***Angermann et al, 2012, Dunagan et al, 2005, Barth et al, 2001***}; in one trial, patients receiving STS had **significantly better** NYHA classification and SF-36 physical functioning subscale and physical health summary measure scores at 3 months than patients receiving usual care {***Angermann et al, 2012***}. Another trial reported on physical and emotional subscales of the MLWHFQ and on physical and mental health summary measures of the SF-12; patients receiving STS had **significantly better** scores on the SF-12 physical scale than controls at 6 months, but all other comparisons were not significant {***Dunagan et al, 2005***}**.**

Barth et al, 2001 { } found no significant difference between the groups in the emotional dimension of the questionnaire prior to discharge (t = .36, p = .718) or the physical dimension of the questionnaire prior to discharge (t =.83, p = .414). The total scores for the two groups on the LHFQ were not significantly different (t = .22, p =.829) before discharge from the acute-care setting. A t test for paired samples was done on the scores of the LHFQ obtained from the participants at the conclusion of their involvement in the study. Within the **control group**, the comparison of means on the emotional dimension of the LHFQ predischarge with the emotional dimension of the LHFQ at the conclusion of the study revealed that there was **not a statistically significant difference** (t = 2.53, p = .022). There also was not a statistically significant difference between the prescores and postscores in the control group on the physical dimension (t = .93, p = .367) or for the total scores (t = 1.81, p = .088).

A paired sample *t* test was used to determine if there was a difference in LHFQ scores prior to discharge and at the study conclusion for the **experimental group**. All three areas were found to be **statistically significant**, with participants showing improvement in their perceived quality of life at the conclusion of their involvement in the study. Participants in the experimental group showed significant improvement in the **physical dimension (*t* = 6.63, *p* ≤.0005)**, the **emotional dimension (*t* = 4.55, *p* ≤ .0005)**, and the **total LHFQ score (*t* = 7.80, *p* ≤ .0005)**.

Pandor et al, 2013 { } showed that STS **improved QoL**. Three of the four STS studies reported improvements in QoL {***Angermann 2012, Barth 2001, Wakefield 2008***}, with significant improvements in physical (***p* = 0.03**) {***Angermann 2012***} and overall (MLHFQ, ***p* < 0.001**) measures {***Barth 2001, Wakefield 2008***}. One study found no significant differences between groups in either the MLHFQ or the EQ-5D measure {***Riegel 2006***}.

In SR published by **Inglis et al, 2011** { }, Quality of Life (QoL) was a secondary outcome for 16 of the 30 included studies.

Several different psychometric tools were used for evaluation (Chronic Heart Failure Symptomatology Questionnaire (CHFSQ); Minnesota Living with Heart Failure Questionnaire (MLWHFQ); Kansas City Cardiomyopathy Questionnaire (KCCQ); Short Form 12 Item (SF-12); Short Form 36 Item (SF-36) and Health Distress Score (HDS)).

Six structured telephone support studies {***Angermann 2007; DeWalt 2006; GESICA 2005 (DIAL); Ramachandran 2007; Sisk 2006; Wakefield 2008***} demonstrated a ***significant improvements in component scores or overall QoL measures.*** Studies which assessed both telemonitoring and structured telephone support {*Cleland 2005, Mortara 2009*} did not report QoL outcomes.

Details could be found in **Appendix 3 and 4.**

Importance: Important

Transferability: Partially

Result card for EFF8: "What is the effect of Structured telephone support (STS) on disease specific quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF8: What is the effect of Structured telephone support (STS) on disease specific quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

To answer on ”What is the effect of Structured telephone support (STS) on disease specific quality of life of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” please see assessment element D0012.

Importance: Important

Transferability: Partially

Function

Result card for EFF9: "What is the effect of Structured telephone support (STS) on body functions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF9: What is the effect of Structured telephone support (STS) on body functions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

To answer on ”What is the effect of Structured telephone support (STS) on body functions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” please look assessment element D0005.

Importance: Optional

Transferability: Partially

Result card for EFF10: "What is the effect of Structured telephone support (STS) on work ability of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF10: What is the effect of Structured telephone support (STS) on work ability of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs that addressed question “What is the effect of Structured telephone support (STS) on work ability of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” were identified.

Importance: Optional

Transferability: Partially

Result card for EFF11: "What is the effect of Structured telephone support (STS) on return to previous living conditions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF11: What is the effect of Structured telephone support (STS) on return to previous living conditions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs that addressed question “What is the effect of Structured telephone support (STS) on return to previous living conditions of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” were identified.

Importance: Optional

Transferability: Partially

Result card for EFF12: "How does Structured telephone support (STS) affects activities of daily living of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?"

View full card

EFF12: How does Structured telephone support (STS) affects activities of daily living of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs that addressed question “How does Structured telephone support (STS) affects activities of daily living of adults with chronic heart failure, compared to standard care without Structured telephone support (STS)?” were identified.

Importance: Optional

Transferability: Partially

Patient satisfaction

Result card for EFF13: "Was the use of Structured telephone support (STS) worthwhile?"

View full card

EFF13: Was the use of Structured telephone support (STS) worthwhile?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs that addressed question “Was the use of Structured telephone support (STS) worthwhile?” were identified.

Importance: Optional

Transferability: Partially

Result card for EFF14: "Are adults with chronic heart failure willing to use the Structured telephone support (STS) again?"

View full card

EFF14: Are adults with chronic heart failure willing to use the Structured telephone support (STS) again?

Method

The same methodology was used as described in section for the whole domain.

Result

No SRs or HTAs or RCTs that addressed question “Are adults with chronic heart failure willing to use the Structured telephone support (STS) again?” were identified.

Importance: Optional

Transferability: Partially

Benefit-harm balance

Result card for EFF15: "What are the overall benefits and harms of the Structured telephone support (STS) in adults with chronic heart failure?"

View full card

EFF15: What are the overall benefits and harms of the Structured telephone support (STS) in adults with chronic heart failure?

Method

The same methodology was used as described in section for the whole domain.

Result

Due the fact that little evidence identified on the potential harms of STS (please see SAF Domain) it is not possible to answer this question: “What are the overall benefits and harms of the Structured telephone support (STS) in adults with chronic heart failure?”.

Importance: Important

Transferability: Partially

Discussion

The aim of this relative effectiveness assessment was to determine whether treatment with Structured telephone support (STS) in adults with chronic heart failure (New York Heart Association (NYHA) I-IV) and without implantable cardiac defibrillators (ICDs), CRTs or pacemakers who have been admitted to hospital at least once for chronic heart failure, improves clinical outcomes and quality of life, has impact on patients' satisfaction and function, and change in management or utilization of health service compared with current practice.

Five existing SRs have been integrated {Feltner et al, 2014; Kotb et al, 2015; Pandor et al, 2013; Inglis et al, 2011; Clark et al, 2007} according to the methodology described in Whitlock et al. 2008 { } and Robinson et al. 2014 { }, into this SR. Additionally, 19 RCTs have been included to answer domain assessment element questions that were not answered by the five SRs. We were faced with already recognized areas of uncertainty: how to appropriately synthesize, grade the strength of, and present bodies of evidence composed of primary studies and existing systematic reviews.

STS produced a mortality benefit and reduced HF-specific readmission rates. In the most recent SR and HTA published by Feltner et al, 2014 { }, STS interventions produced a mortality benefit, with RR (95% CI) 0.74 (0.56–0.97), in time period of 3-6 months, with Number needed to treat (NNT) of 27. Kotb et al, 2015 { } in Network meta-analysis (NMA), reported that structured telephone support significantly reduced the odds of mortality (Odds Ratio 0.80; 95% Credible Intervals [0.66 to 0.96]) compared to usual care. Pandor et al, 2013 { } with data from 11 studies evaluated STS, with duration of follow-up ranged from 6 months to 18 months, found that compared with usual care, STS HH was beneficial (but not statistically significant) in reducing all-cause mortality [hazard ratio (HR) 0.77, 95% credible interval (CrI) 0.55 to 1.08]. No favourable effect on mortality was observed with STS HM.

A majority of the studies (included in five published SRs) *reported significantly lower* HF-specific re-hospitalisation rate in STS group {Feltner 2014, Kotb 2015, Pandor 2013, Inglis 2011, Clark 2007}. Feltner et al, 2014 { } reported that 14 patients needed to be treated with structured telephone support (STS) interventions to reduced *HF-specific readmission (NNT of 14).* When sensitivity analysis was done including only RCT with follow-up period longer than 6 months this difference was not statisticaly significant anymore {Inglis 2011}. Two recently published RCTs {Angermann 2012, Krum 2013} with 6 and 12 months follow-up period, reported *non-significant difference in* HF-specific re-hospitalization between STS and Usual care groups.

Few RCTs measured QoL or function using the same measures at similar time points; the limited data showed conflicting results. Insufficient evidence was found to answer questions related with utilization outcomes as well, so the evidence base was inadequate to make final conclusion for these outcomes. However, a majority of the studies presented statistically significant QoL improvements. Data found on *the emergency room (ER) visit rate* in STS group comparing with usual care was conflicting, but a majority of the results found no significant difference in the number of emergency room visits in either group. The same is true for the the most recent SR and HTA published by Feltner et al, 2014 { }; STS interventions had no effect on the rate of ER visits over 3 to 6 months. According the number of general practitioners visits, Krum et al, 2013 { }, during 12 months period, showed reduction in the utilization of general practitioners, with the control group visiting their general practitioner more than twice as often as the intervention group.

Since little evidence identified on the potential harms of STS {Chaudhry et al, 2010}, as described in Safety Domain, it was not possible to answer on overall benefits and harms of the Structured telephone support (STS) in adults with chronic heart failure.

We could not find answers to some of the assessment element questions, such as work ability, return to previous living conditions, activities of daily living, worthwhile of STS and willing to use STS again. For example no SRs, HTAs or RCTs have addressed the question "Was the use of Structured telephone support (STS) worthwhile?". Indirect answers could be found in further RCTs (included in Inglis et al SR, published 2011 { }); showing that satisfaction (acceptance) of patients receiving health care via technology was rated between 76% to 100% {Clark 2007b; Krum 2009; Cleland 2005}. In the work by Laramee et al, 2003 { } patients in the intervention group were significantly more satisfied with their care in 13 of 16 items than the usual care group (P=.01). In RCT published by Riegel et al, 2002 { } patients in the intervention group were significantly more satisfied at 6 months with their care in STS than the usual care group (22.88±2.85 vs 6.17±4.87).

Out of 19 RCTs included in our new SR only three RCTs were judged as low risk of bias {DeBusk 2004, GESICA 2005, Chaudhry 2010},

Direct evidence on primary outcomes was not assessed by using the GRADE-methodology {Guyatt 2008} as planned, because of heterogeneity of follow up periods and quantitative synthesis from existing SRs was used and presented in the result section for specific outcomes.

Further research is needed on effects of STS on QoL and utilization outcomes as well as long term follow-up of patient satisfaction. Several methodological issues should be solved in future research on STS on QoL and utilization outcomes, like masking outcome assessment as well as clear description of usual care and long term follow up (12 month or longer). For answering questions related to patient satisfaction, other study designs than RCT could be appropriate; this part of assessment could be completely covered by Social aspects (SOC) Domain of the future versions of the full Core HTA Model.

Some methodological limitations that may affect comparability and applicability of the data reported in RCTs and SRs could be listed, such as different approaches of usual care as well of structured telephone support (different telephone follow-up, information or education provided pre-discharge, etc.); different providers of STS interventions (provided by pharmacist, physicians or nurses) and their experience in providing the STS.

The STS interventions presented in this assessment are applicable only to patients who are discharged to their home; it remains unclear whether STS interventions would benefit patients who are discharged to another institution. Also, due another limitation - narrow scope of our assessment, our results are not applicable to patients with chronic heart failure with implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy defibrillators (CRT-Ds) or pacemakers. Hindricks et al. 2014 and Parthiban et al. 2015 recently published data on remote monitoring in this selected group of patients { }. Due the fact that RCTs included in our assessment were published in a time period ranging from 1999 to 2013, "usual care" in trials published earlier probably is not the same as "usual care"used in the most recent RCTs. Moreover, in general, trials did not report details of usual care. It also remains unclear if STS interventions in adults with chronic heart failure (who have been admitted to hospital at least once for chronic heart failure) will lead to different outcomes in rural or urban settings.

Authors of this assessment found some difficulties in full Core HTA Model, previously recognized, which will be solved in future versions of the Core Model (for example possible overlaps or duplication with other Domains assessment elements questions, need for grouping some of assessment element questions to avoid unnecessary slicing, as well as some problems with format of reporting).

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Appendices

Appendix 1. Search strategy, June 2015

Appendix 2. Flow chart of study selection

Figure 1. Flow chart of study selection, according to the PRISMA flowchart {Liberati 2009}

Appendix 3. Characteristics of included secondary studies: Systematic reviews/HTA, main study findings and authors conclusions

Appendix 4. RCTs included in SR of effectiveness and safety: Evidence tables and Risk of bias tables

Appendix 5. List of included studies (RCTs) in the secondary studies (SRs or HTAs)

Appendix 6. List of included studies (RCTs) in this Systematic review of Clinical Effectiveness/Safety with Follow-up duration and Risk of bias

Appendix 7. List of Ongoing RCTs in clinical trials registries

Costs and economic evaluation

Authors: Neill Booth, Taru Haula and Heidi Stuerzlinger (supported by Ingrid Rosian-Schikuta).

Summary

In this summary, as set out in the guidance for undertaking this pilot assessment using the HTA Core Model 2.0, we only summarise the results of the ECO domain. The results themselves can be found from the Results Card –section of the ECO domain. Details on the aim of the ECO domain and its research questions can be found from the ECO Introduction. Details on the methods used can be found from the ECO Methodolgy sections, and discussion can be found from the ECO discussion -section and from the Collection summary.

It became apparent from the results of our systematic literature search (see the Methodology section below) and our review of the results from other domains that the meaning of the term Structured telephone support (STS) varies quite widely across the studies. Hence, there is no explicit definition STS and, instead, the term is refers to a diverse set of approaches to care management for adults with chronic heart failure using telephonic networks. Depending on the approach taken to STS, a range of different pieces of information can be collected by telephone from patients, and any such information can be handled and utilised by the management team or system in a large number of ways. Therefore, one main result of the ECO domain is that variation in the nature of the intervention poses major challenges to undertaking meaningful examination of intervention costs and to undertaking economic evaluations. If each type of STS intervention, has both different components and consequences, this has a significant effect on ability to make meaningful estimates of costs and to undertake robust economic evaluations. For this reason, we do not summarise the results of the studies *per se* but, instead, briefly describe those studies found.

Four published pieces of research from the systematic review were found to be useful in this domain ({1, 3, 4 & 5}, see also **Appendix ECO-2**: PRISMA 2009 Flow Diagram). One of these, a European economic evaluation by Klersy et al. (2011) {1}, was only used to describe costs and three of these were also used to produce the results pertaining to economic evaluation {3, 4 & 5}. The first of the included economic evaluations is a North American modelling study published in 2009 by Miller et al. (2009) {3}, it estimates the cost-effectiveness for a subset of the patients with chronic heart failure, namely for patients with systolic heart failure. The second was a cost-effectiveness study by Klersy et al. (2011) {1} and reported an analysis which combined evidence on both remote monitoring (RM) and on STS. However, as this article included information from cardiovascular implantable electronic devices, it was, as an example of an economic evaluation, classified as being outside the scope of this pilot assessment using the HTA Core Model 2.0. One additional study, Herbert et al. (2008) {2}, was found through the search of the references of the papers retrieved following the systematic search. Although this study reported a trial-based cost-effectiveness analysis, it was excluded due to its focus on a very specific, non-European ethnic population. The third and fourth economic evaluations were pieces of British research by Pandor et al. (2013) {4} and Thokala et al. (2013) {5}. It both of these it was noted that clear descriptions of STS interventions and usual care were not provided in many of the studies they reviewed and that this has potentially major implications for the robustness of analyses of costs, outcomes, and economic efficiency.

Introduction

The ‘Costs and economic evaluation’ -domain (ECO) within the HTA Core Model 2.0 aims to provide information about the relative costs and ‘cost-effectiveness’ of the health-care technologies under assessment {6}. This pilot assessment presents information on costs and economic evaluation about structured telephone support (STS) and ‘usual care’ for adults with chronic heart failure (i.e., patients with New York Heart Association (NYHA) Functional Classification I to IV and without implantable cardiac defibrillators, cardiac resynchronisation therapy devices or pacemakers) who have been admitted to hospital at least once for chronic heart failure). As set out in the TEC -domain, STS refers to a specific set of approaches to remote heart-failure monitoring or self-care management. Often using simple telephone technology, STS contacts can be planned according to a schedule, or initiated by a computerised system or by a healthcare professional (e.g., nurse, physician, social worker or pharmacist). As part of a wide variety of approaches to STS, different types of patient data are collected and stored electronically. In the case of a STS human-to-machine interfaces (HM) this can be done by a computerised system or, in the case of a STS human-to-human interactions (HH), this can be done by a healthcare professional. Data can then be reviewed by healthcare professionals and, if necessary and possible, action can be undertaken. Extensive details concerning usual care are not, in general, well reported in the clinical effectiveness literature (see EFF discussion).

Within the constraints of this HTA Core Model 2.0 pilot assessment we surveyed the potential for the creation of a costing template or a model to assess budget impact (e.g., a cost template for Budget Impact Analysis (BIA)). However, after systematically searching the literature and reviewing the information from the CUR, TEC, SAF, EFF, SOC and ORG domains, it was clear that it would not be viable to attempt to produce a useful BIA costing template or a de novo economic model. This was mainly due to the diverse nature of the interventions covered by the label STS, and due to a lack of robust evidence on both costs and effectiveness. Therefore, in what follows we report a qualitative analysis of the available information, starting with the information on costs, we offer as full an answer as we can to the research questions which deal with costs, i.e., in ECO1, ECO2 and ECO3. In ECO4 we report findings from the literature and from other domains, such as SAF and EFF on the effectiveness of ‘STS’ versus ‘usual care’. In ECO 5 we describe some of the information from the economic evaluation literature relating to ‘STS’ versus ‘usual care’, and in ECO6, ECO7 and ECO8 we extend this qualitative assessment of the available information.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition.

	Target population description Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
E0001	Resource utilization	What types of resources are used when delivering the assessed technology and its comparators (resource-use identification)?	yes	What types of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, usual care' without STS (resource-use identification)?
E0002	Resource utilization	What amounts of resources are used when delivering the assessed technology and its comparators (resource-use measurement)?	yes	What amounts of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use measurement)?
E0009	Resource utilization	What were the measured and/or estimated costs of the assessed technology and its comparator(s) (resource-use valuation)?	yes	What were the measured and/or estimated costs of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use valuation)?
E0005	Measurement and estimation of outcomes	What is(are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s)?	yes	What is (are) the measured and/or estimated health-related outcome(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?
E0006	Examination of costs and outcomes	What are the estimated differences in costs and outcomes between the technology and its comparator(s)?	yes	What are the estimated differences in costs and outcomes between Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?
E0010	Characterising uncertainty	What are the uncertainties surrounding the costs and economic evaluation(s) of the technology and its comparator(s)?	yes	What are the uncertainties surrounding the costs and economic evaluation(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?
E0011	Characterising heterogeneity	To what extent can differences in costs, outcomes, or 'cost effectiveness' be explained by variations between any subgroups using the technology and its comparator(s)?	yes	To what extent can differences in costs, outcomes, or 'cost effectiveness' be explained by variations between any subgroups using Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?
E0012	Validity of the model(s)	To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of the technology and its comparator(s)?	yes	To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Methodology description

A systematic literature search was conducted in May 2015 by information specialist Jaana Isojärvi (THL, Finland) to find published studies on the costs and economic evaluation of structured telephone support for adult patients with chronic heart failure.

Information sources

The following databases were searched:

- Centre for Reviews and Dissemination (HTA, NHS EED, DARE)
- Cochrane Database of Systematic Reviews
- Cochrane Central Register of Controlled Trials
- MEDLINE (via Ovid)
- NLM PubMed
- SCOPUS
- Journals@Ovid Full Text
- CINAHL (via EBSCOhost)
- PsycInfo (via EBSCOhost)
- Web of Science
- CEA Registry

A methodological search filter based on the filter developed in Healthcare Improvement Scotland was used. The systematic search strategy for this domain is presented in **Appendix ECO-1**.

In addition to database searches, we looked at the search results from Clinical Effectiveness, Safety and Social Aspects domains as well as the results from the searches undertaken according to the scope of the whole assessment using the HTA Core Model 2.0.

Articles that fit with the agreed PICO structure and presented estimations of outcomes and costs were searched using a two-stage process. All titles and abstracts were examined for inclusion by at least two reviewers and those chosen for potential inclusion were then examined as full-text articles by the same reviewers. Any disagreements were resolved through deliberation. In the end, four articles relevant for the questions in ECO domain were included from the 55 potentially relevant records identified through searching the databases and other sources. A flow-chart prepared according to the 2009 PRISMA statement is presented in **Appendix ECO-2**. Although the methodological quality of the included studies was not formally assessed, we undertook to describe the available information concerning costs and to describe relevant information from economic evaluations, using the method outlined in the section 'Quality assessment tools or criteria' below.

Quality assessment tools or criteria

We utilised the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement checklist ({7}) in the following way: each item in the checklist was examined by two authors for coherence between the reporting in the economic evaluations reviewed and the CHEERS checklist -items and any disagreements were resolved through discussions (see **Appendix ECO-3**). Although the CHEERS checklist is primarily intended for researchers reporting economic evaluations and the editors and peer reviewers assessing them for publication, when reviewing existing literature it has a potential role in identifying issues which may make the use of information from any economic evaluation less appropriate when undertaking assessment using the HTA Core Model 2.0.

Analysis and synthesis

The ECO -domain authors had the intention to produce a costing template for budget impact analysis (BIA) modelling, but due to a lack of robust evidence on costs (e.g., as noted by the ORG domain) and a lack of robust evidence on effectiveness (e.g., as noted by the SAF and EFF domains), the ECO -domain authors could not justify attempting to produce a de novo health-economic model or a costing template. Therefore, in what follows we report a qualitative analysis of the information which was available, starting with the information on costs. We offer as full an answer as we can to the research questions which deal with costs, i.e., in ECO1, ECO2 and ECO3. In ECO4 we report findings from the literature and from other domains, such as SAF and EFF on the effectiveness of 'STS' versus 'usual care'. In ECO5 we describe some of the information from the economic evaluation literature relating to 'STS' versus 'usual care', and in ECO6, ECO7 and ECO8, go on to try to extend this qualitative assessment of the available information.

Result cards

Resource utilization

Result card for ECO1: "What types of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, usual care' without STS (resource-use identification)?"

View full card

ECO1: What types of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, usual care' without STS (resource-use identification)?

Method

For this section we used results from the domain search (including domain searches from EFF and ORG; search strategy and selection criteria are described in the general methodology description) as well as results from additional hand searching, e.g. within study references. Also results from the TEC domain regarding description of the interventions were used.

Result

Two studies were identified which include a cost effectiveness analysis on structured telephone support (STS) vs. usual care for heart failure (HF) patients and also include intervention costs. From the same research project, both Pandor et al. (2013) and Thokala et al. (2013) ({4} and {5}) used the perspective of the National Health System of the United Kingdom and included estimates of resource use associated directly with the interventions themselves as well as the estimates of resource use associated with hospitalization. Miller et al. (2009) {3} also took a healthcare system perspective and included resource utilisation based on a clinical trial {8}.

As characterized by Pandor et al. (2013) **resource consumption directly associated with the intervention** can be divided into three parts:

1. Resources used at the patient's home
2. Resources used at the support centre
3. Other health care resources used to deal with events or alerts (e.g., office visits or home visits at, or by, family practitioners or specialists, emergency room visits)

It should be noted that interventions in this field are heterogeneous and rarely described in detail (see also *TEC domain*). The same applies to the **comparator (usual care)**. Pandor et al. (2013) used data from a randomised study conducted across 16 hospitals in Germany, the Netherlands and the UK (in the years of 2000 to 2002) comparing home telemonitoring, nurse telephone support, and usual care {9} to estimate the amounts of health care resources used to deal with events/alerts. Miller et al. (2009) include 'additional costs for the administration of the disease management program' without specifying individual cost components.

None of the identified cost effectiveness analysis studies includes potential indirect **resource consumption due to any negative effects or adverse events** associated with STS. This may be partly explained by the absence of significant evidence of adverse events but, alternatively, could just be a simplifying assumption.

The following table lists resource items identified by the authors as potentially relevant, together with the units by which they can be measured, and indicates if they have been included in Pandor et al. {4}. This is done – here and further below - using the study by Pandor et al. (2013) as the other study (Miller et al. (2013)) does not provide sufficient methodological and other details.

Table 1: *Resource consumption for STS and usual care: resource items identified as potentially relevant*

Structured telephone support (human to human)		
Resources	***Unit***	***Included in Pandor et al. 2013***
AT THE PATIENT'S HOME		
Telephone	device	X

Telephone call minutes	minute	
Scale	device	X
Pedometer	device	
PC	device	
Internet connection	month	
Blood pressure measurement device	device	X
2 channel ECG	device	
Measures of patient education	*depends (e.g. hours, telephone call minutes, DVD)*	
IN THE SUPPORT CENTRE		
Employed nurse* (telephone calls, triage, decision making)	hour	X
Specific training for involved nurse (or other providers)	training course	
Specialist / general practitioner (supervision/consultation)	hour	
Telephone	device	
Telephone call minutes	minute	
Data management software	site licence	X
Maintenance	month	
Internet connection	month	
Measures of healthcare data protection	depends (e.g., month)	
* the type of nurse(s) or other person(s) providing STS, e.g., medical practitioner would also normally be relevant.		
Structured telephone support and usual care		
OTHER HEALTH CARE RESOURCES		
Family practitioner	office visits	X
	home visits	X
	consultation service (to the support centre)	
Specialist	office visits	X
	home visits	X
	consultation service (to the support centre)	
Nurse and other	office visits	X
	home visits	X
Pharmaceuticals	e.g., defined daily dose (DDD)	
Emergency room	emergency room visits	X
Other outpatient services	outpatient visits	

In addition to these resource items, a cost-effectiveness analysis usually attempts to take account of other changes in the consumption of health care resources which are relevant to the chosen perspective. In the case of STS, one of the most important effects or outcomes is estimated to be on the number of **hospitalizations**, since

heart failure is an important cause of hospitalizations. However, hospitalizations are only an intermediate outcome indicator and although each hospitalization utilises health care resources, hospitalizations do not necessarily provide a robust measure of either costs or effectiveness. Three of the identified studies included the effect on hospitalizations into their analysis {1, 3, 4}. Klersy et al. 2011 {1} took the perspective of a third-party payer and (only) included healthcare resource consumption caused by HF related hospitalization (this was based on the assumption that expenditures for included patients are dominated by HF hospitalization costs).

Within a model analysis that takes lifetime perspective, other costs may also be relevant. Pandor et al. (2013), for example, modelling a 30-year time horizon, include routine clinical assessments as well as laboratory tests into their analysis with regard to **long-term health care costs**.

The above-mentioned resource items refer to resource consumption from a **payer's perspective**. It can be argued that telemedicine interventions generate cost savings outside the healthcare system (e.g., through reduced patient travel costs) {10}, which would be highlighted, e.g., when including a **patients' perspective**. Another related question is whether or not to include indirect costs in terms of productivity losses through, e.g., taking a **societal perspective**. The average age of the included study populations however usually lies between 60 and 75 years. Although a societal perspective is sometimes recommended, it may be argued that the proportion of people either retired or being off work because of their HF may be very high (thus estimates of, e.g., production losses would likely be rather negligible, even though, ideally, sensitivity analysis would be able to be performed surrounding such 'productivity costs') {10}, {3}.

The following table lists the identified resource items according to the cost and resource categories above.

Table 2: *Resource items according to different cost (and resource) categories*

Resource/cost category	Klersy et al. 2011**	Miller et al. 2009***	Pandor et al. 2013 / Thokala et al. 2013*
2.1 Direct costs			
2.1.1 Public health care costs	***Included resource items***	***Included resource items***	***Included resource items***
Medical devices	Not included	Disease management program costs are included, not specified further	Blood pressure measurement devices
Pharmaceuticals	Not included	Non-cardiovascular and cardiovascular drugs	Not included *Remark: costs assumed to be the same between usual care and intervention*
Laboratory tests	Not included	Included (not specified)	Serum urea, electrolytes, creatinine, estimated glomerular filtration rate *Remark: included for (long term) "usual care" after intervention period has ended*
Primary care staff	Not included	Included (office visits, not specified further)	
Family practitioner			Office visits, home visits
Specialist			Office visits, home visits
Nurse and other			Office visits, home visits, telephone calls and triage
Hospital services			
Outpatient	Not included	Emergency room visits, outpatient procedures	Emergency room visits
Inpatient	HF† hospitalizations per person year	HF related inpatient admissions, other-cause inpatient admissions, inpatient procedures	HF related inpatient admissions, other-cause inpatient admissions
2.1.2 Private health care costs	***Included resource items***		***Included resource items***
Medical devices	Not included	Not included	Not included
Pharmaceuticals	Not included	Not included	Not included
Laboratory tests	Not included	Not included	Not included
Primary care staff	Not included	Not included	Not included
Family practitioner			
Specialist			
Nurse and other			
Hospital services	Not included	Not included	Not included
Outpatient			
Inpatient			
2.1.3 Public non-health-care			

costs			
Devices / hardware	Not included	Disease management program costs are included, not specified further	Telephone, scale
Non-physical assets / software	Not included		Data management software (at the support centre)
2.1.4 Private non-health-care costs	Not included	Not included	Not included
Devices / hardware			
Non-physical assets / software			
Time costs / opportunity costs			
Travel costs			
2.2 Indirect costs			
2.2.1 Productivity lossses	Not included	Not included	Not included

*perspective: UK NHS, time horizon: 30 years, ** perspective: third-party payer, time horizon: 1 year, *** healthcare system perspective, time horizon: lifetime
†HF=heart failure

Comment

Further information concerning the types of costs associated with ‘STS’ and ‘usual care’ can be found in **Appendix ECO-4**, this appendix attempts to summarise the information from the TEC domain, from the viewpoint of the ECO domain.

Importance: Critical

Transferability: Completely

Result card for ECO2: "What amounts of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use measurement)?"

View full card

ECO2: What amounts of resources are used when delivering Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use measurement)?

Method

For this section we used results from the domain search (including domain searches from EFF and ORG; search strategy and selection criteria are described in the general methodology description) as well as results from an additional hand search, e.g. within study references. Also results from the TEC domain regarding description of the interventions were used

Result

Different approaches have been used for the quantification of resource consumption. Miller et al. (2009) generally followed a micro-costing approach as they used data from a clinical trial. They give resource expenditures in U.S. Dollars but do not provide detailed data on resource consumption in units. Klersy et al. (2011) only regard the (average) number of HF hospitalizations per patient per year (calculated using a meta-analytical approach) {1}. Pandor et al. (2013) rely on different sources for their cost effectiveness analysis and include data from a randomized trial for the frequency of medical care visits {4}. For resource consumption related to the interventions themselves a bottom-up approach is used relying on advice from clinical experts as well as literature {11}. Long term costs are determined in reference to NICE clinical guidelines.

The following table lists resource items for intervention and comparator as well as long-term costs included in Pandor et al. (2013) together with quantification per 6 months of treatment as given within the study.

Table 3: *Resource consumption for STS and usual care: quantification of resources*

Resources	***Unit***	***Amounts and ranges in Pandor et al. 2013 {4} (per six months of treatment)***		
Structured telephone support (human to human)				
		low	high	average
AT THE PATIENT'S HOME				
Telephone	device	0.50	0.50	0.50

Blood pressure measurement device	device	0	0.50	0.114*
2 channel ECG	device	0	0.50	0.114*
IN THE SUPPORT CENTRE				
Employed nurse (telephone calls, triage, decision making)	hour	16.00	16.00	16.00
Data management software	site licence	0.00067**	0.00067**	0.00067**
OTHER HEALTH CARE RESOURCES				
Family practitioner	office visits	3.37	3.37	3.37
	home visits	1.04	1.04	1.04
Specialist	office visits	0.66	0.66	0.66
	home visits	0.02	0.02	0.02
Nurse and other	office visits	0.58	0.58	0.58
	home visits	1.15	1.15	1.15
Emergency room	emergency room visits	0.30	0.30	0.30
Usual care				
OTHER HEALTH CARE RESOURCES				
Family practitioner	office visits	1.33	1.33	1.33
	home visits	0.47	0.47	0.47
Specialist	office visits	0.38	0.38	0.38
	home visits	none	none	none
Nurse and other	office visits	0.40	0.40	0.40
	home visits	0.30	0.30	0.30
Emergency room	emergency room visits	0.09	0.09	0.09
post treatment / long term costs				
OTHER HEALTH CARE RESOURCES				
Family practitioner / Specialist	office visits	1	1	1
laboratory tests	Set of tests	1	1	1

* Pandor et al. give yearly costs and include this only in a high cost scenario and obviously partly in the baseline scenario ** 3-year depreciation, centre has a monitoring capacity of 250 patients

Importance: Critical

Transferability: Partially

Result card for ECO3: "What were the measured and/or estimated costs of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use valuation)?"

View full card

ECO3: What were the measured and/or estimated costs of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS (resource-use valuation)?

Method

For this section we used results from the domain search (including domain searches from EFF and ORG; search strategy and selection criteria are described in the general methodology description) as well as results from an additional hand search, e.g. within study references. Also results from the TEC domain regarding description of the interventions were used.

Result

The following table lists the resource items included in the three studies {1, 3, 4} that were selected as exemplifying STS cost items, together with measured and/or estimated costs as given in those studies. Concerning costs, in the modelling study of Miller et al. (2009) it should be noted that only patients with systolic heart failure were included. Miller et al. also use the assumption that both the intervention and the subsequent effects of the intervention last for the modelled patients' lifetimes. In contrast, Pandor et al. (2013) {4} assume 1) the intervention lasts for six months, and 2) there are benefits due to reduced hospitalisations (producing HRQoL benefits) as well as 3) reduced mortality in the first 6 months. A lifetime perspective on health effects and costs is modelled by there being more people alive in the intervention group, after the first six months, than in the 'usual care' group, and this results in relatively more life years, and associated costs, in the STS groups.

Table 4: *Resource consumption for STS, usual care, long term care and hospitalization: measured and/or estimated costs*

Structured telephone support (human to human)				
Resources	***Unit***	***Costs per 6 months of treatment****		
		KLERSY ET AL. 2011 {1} (2009 Euros)	MILLER ET AL. 2009 {3} (2003 U.S. Dollars)	PANDOR ET AL.*** 2013 {4} (2013 Euros)
AT THE PATIENT'S HOME				
Telephone	device	Not included	107.00 = average program cost per patient per month	16.00
Scale	device	Not included		23.00
Blood pressure device	device	Not included		
IN THE SUPPORT CENTRE				
Employed nurse (telephone calls, triage, decision making)	hour	Not included	See above	640.00
Data management software	site licence	Not included		3.00
OTHER HEALTH CARE RESOURCES				
Family practitioner	office visits	Not included	241.66 - 280.66** = resource expenditures for "office visits"	155.00
	home visits	Not included		108.00
Specialist	office visits	Not included		30.00
	home visits	Not included		2.00
Nurse and other	office visits	Not included		15.00
	home visits	Not included		44.00
Pharmaceuticals	unclear	Not included	Noncardiovascular: 1539.89-1978.61**	Not included
			Cardiovascular: 794.24-871.60	
Emergency room	emergency room visits	Not included	HF: 18.49-66.78**	39.00
			Non HF: 47.23-96.69**	
Other outpatient services	outpatient procedures	Not included	555.00-765.33**	Not included
Laboratory tests	unclear	Not included	49.18-65.40**	Not included
Usual care				
Resources	***Unit***	***Costs per 6 months of treatment***		
OTHER HEALTH CARE RESOURCES				

Family practitioner	office visits	Not included	204.40 - 296.64** = resource expenditures for “office visits”	61.00
	home visits	Not included		49.00
Specialist	office visits	Not included		18.00
	home visits	Not included		
Nurse and other	office visits	Not included		10.00
	home visits	Not included		11.00
Pharmaceuticals	e.g. DDD	Not included	Noncardiovascular: 1441.81-1936.88**	Not included
			Cardiovascular: 814.38-876.04	
Emergency room	emergency room visits	Not included	HF: 13.74-48.80**	12.00
			Non HF: 43.65-83.82**	
Other outpatient services	outpatient procedures	Not included	560.08-893.54**	Not included
Laboratory tests	unclear	Not included	45.53-61.82**	Not included
Post treatment / long term costs				
Resources	***Unit***	***Costs per 6 months of treatment***		
OTHER HEALTH CARE RESOURCES				
Family practitioner / Specialist	office visits	Not included	Costs assumed to be the same as for the first 6 months, see above	46.00
Laboratory tests	test	Not included		3.00
Hospitalizations				

Resources	***Unit***	***Costs per inpatient admission***				
		All	STS:		Usual care:	All
HF related hospitalization	inpatient admissions	3473.00	299.66-1062.10**		176.15-1098.09**	2514.00
Other-cause hospitalization	inpatient admissions	Not included	740.16-1876.72**		677.59-1422.11**	1530.00
Inpatient procedures	Inpatient procedure fees		260.72-536.48**		198.45-497.23**	

* If not indicated otherwise.

** Range, depending on New York Heart Association (NYHA) Functional Classification –status. *** Only the average values of Table 3 are reported here.

The above table gives an idea about the rough dimensions of costs. Cost values however cannot directly be compared – not only because of different currencies and cost years, but also because of differing interventions, different modelling assumptions, and different populations between the studies.

All the studies reviewed here use charges or fees for estimating costs of the health care sector. Although these prices may not reflect the true opportunity costs of resource use, they seem to be justified for pragmatic reasons. Perhaps because of the assumptions in their model, Pandor et al. (2013) conclude that intervention costs only constitute a small part of the overall costs, hospitalization costs being the main contributor to those overall costs {4}. However, in all studies the question of the duration of treatment effects (whether of six to 18 months or lifetime -duration) and the implied costs is important.

Comment

The results from ORG8 provide the information that more than 70% of the studies reviewed by Grustam et al. (2014) did not take into account some cost items, or any costs, in at least one of the following categories: healthcare sector; other sectors; costs to patients or family; and productivity losses for the patient or family {15}. None of the studies broadly analysed the shift of cost, for instance, from specialist HF nurses to general practitioners. In 80% of those studies the perspective, the source and the methods of the evaluations were not clear {15}. Authors mostly focused on direct costs and did not include indirect costs (e.g., productivity gains or losses) or ‘intangible costs’ (such as relief from pain, lost leisure time for patients or families). Of course, depending on the chosen analytical perspective, such approaches can be justified, however, some costs were not clearly included across majority of the studies, such as those costs related to the intervention’s overheads, costs associated with the training of personnel, and patient-related costs. It is also possible to value participant time, in terms of labour, using either wages or a value for unpaid work. The valuation of participant time can be considered to be particularly relevant if the intervention has a long duration. Despite such considerations, the

quality of evidence in much of the available scientific literature is poor, therefore, more studies on all aspects of costs related to STS would be needed to reach an unbiased conclusion {15}.

Importance: Critical

Transferability: Not

Measurement and estimation of outcomes

Result card for ECO4: "What is (are) the measured and/or estimated health-related outcome(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?"

View full card

ECO4: What is (are) the measured and/or estimated health-related outcome(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Method

In ECO4 we report findings from the literature and from other domains, such as SAF and EFF on the effectiveness of ‘STS’ versus ‘usual care’ as they relate to health-related outcomes which can be considered important in the ECO domain. Given the weaknesses of the available evidence, we do not report extensive numerical results from the included studies but, instead, briefly describe some of the findings from those studies. This description includes information from the included economic evaluation studies in general, and Pandor et al (2013) {4} and Thokala et al (2013) {5} in particular.

Result

In the most recent cost-effectiveness analysis (Pandor et al (2013) {4}; Thokala et al (2013) {5}) the main outcomes of interest all-cause mortality and hospitalisations. In these studies a Markov model was developed to estimate the prognosis for each HF patient using the monthly probability of death and monthly risks for hospitalisation from HF-related and other causes. Effectiveness parameters during the treatment period were the hazard ratios (HR) for all-cause mortality, all-cause hospitalisations and HF-related hospitalisations. Cost parameters, either estimated or based on clinical opinion, included both the costs of the intervention and costs related to hospitalisation.

The study of Miller et al (2009) estimated the long-term impact of telephonic disease management (TDM) in systolic heart failure patients from the results of an 18-month South Texas trial with a Markov model (Galbreath et al. 2004 {8}). Effectiveness was expressed as discounted QALYs saved with the DM compared to control group without TDM. The utility-adjustment weights were developed by NYHA class from the baseline results of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) collected from all trial participants, and the estimated mean utility-adjustment weights were 0.75 for NYHA I, 0.64 for NYHA II and 0.58 for NYHA III and IV.

Comment

It was noted in the work by Pandor et al (2013) {4} and Thokala et al (2013) {5} presenting results from the same cost-effectiveness modelling study that clear descriptions of the interventions and usual care were not provided in many of the studies and that this had implications for the robustness of analyses of effectiveness. In addition, results from the EFF domain show that at least half the studies included in Feltner et al. 2014 {12} are classified as having a high risk of bias. Although "all-cause death" appears to be reduced in some studies (in a statistically significant manner), a similar reduction is not reported for "disease-specific" or "disease-related" death. This could be due to small sample sizes in the trials, but although Krum et al. (2013) {13} report all-cause hospitalisation to occur more frequently in the control group, their clinical indicator, the Packer clinical composite score, does not show a statistically significant difference between the arms. Moreover, it is not clear to what extent the combination of the endpoints of “all-cause death” and “HF hospitalisation” which are used in a number of studies can be seen as valid, composite, health-related outcomes. Further, the intermediate health-related outcome “HF hospitalisation rate” alone does not tell us to what extent there could be “over-treatment” in a ‘Usual Care’ -group or “under-treatment” in a ‘STS’ –group, nor does it necessarily provide information related to any associated changes in costs.

Importance: Important

Transferability: Partially

Examination of costs and outcomes

Result card for ECO5: "What are the estimated differences in costs and outcomes between Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?"

View full card

ECO5: What are the estimated differences in costs and outcomes between Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Result

Two of the articles identified through the systematic literature review present results from the same cost-effectiveness study (Pandor et al (2013) {4}, which is a National Institute for Health Research (NIHR) Health Technology Assessment -report, and Thokala et al (2013) {5}, which is a journal article). Information from both studies are presented when it is possible that it would be useful. In those two pieces of research STS is divided into two different approaches: STS via human to machine (STS HM) interface and STS via human to human (STS HH) contact. The estimations and analyses in this study also include a third intervention, home telemonitoring (TM), in which transmitted data is reviewed by medical staff or medical support is provided during office hours. The cost-effectiveness of each of these three interventions is estimated in relation to usual care, which is defined as usual care for patients discharged in the past 28 days with a heart failure (HF)-related hospitalisation as per the NICE Clinical Guidelines for the Management of Adults with Chronic Heart Failure. It is mentioned in the articles that the actual impact of each intervention is for the first six months after an initial discharge, since after 6 months it is assumed that all the patients receive usual care according to the aforementioned clinical guidelines. Pandor et al. (2013) {4} and Thokala et al. (2013) {5} thus both present results of a study employing a Markov model for a hypothetical cohort of 250 heart-failure patients, using a 30-year (or patient lifetime) horizon, with an annual discount rate of 3.5% for both costs and outcomes. The perspective is that of the NHS in England and Wales. The base-case cost-effectiveness results of each strategy compared to usual care and to the next most effective alternative are presented from this study. The probabilities presented below, of each strategy being the ‘most cost-effective’ at varying levels of willingness to pay per QALY gained, are from Pandor et al. (2013) {4}, since the results of Thokala et al. (2013) {5} are from the same study and quite similar. In the probabilistic sensitivity analysis (PSA) the percentage of model runs in which an intervention was the ‘most cost-effective’ strategy (at a £20 000 per QALY threshold) was 44% for TM (during office hours), 36% for human-to-human STS (STS HH), 18% for human-to-machine STS (STS HM) and 2% for ‘usual care’. When one study, the Home-HF study {14}, was excluded, the probability for TM increased to 73%. In the base-case analyses (including or excluding the Home-HF study) TM was found to be the ‘most cost-effective’ strategy, then STS HH. Results for the different scenarios were also presented: higher usual care cost scenario, lower TM cost scenario, higher TM cost scenario, higher STS HH cost scenario and lower STS HH cost scenario. The conclusions regarding the relative cost-effectiveness of TM did not substantially change in the analyses using higher usual care cost, lower TM cost and higher STS HH cost. In the scenario with higher TM cost TM was dominated by STS HH, since the difference in expected QALYs between these interventions was small (0.0006), the change in the difference between the costs leads to a sizeable change in the ICER. However, in the same scenario, after exclusion of the Home-HF study, TM was still the most cost-effective strategy. It is stated in both articles that there is substantial uncertainty as to which strategy is the optimal in terms of net benefit, since the CEAC (cost-effectiveness acceptability curve) suggests that the best strategy is cost-effective in less than half of the PSA runs (with base-case costs and Home-HF study included). It was reported that this uncertainty was lower in the analyses that excluded the Home-HF study.

In the study by Miller et al. (2009) {3}, a Markov model was developed to estimate the cost-effectiveness of a telephonic disease management (TDM) program compared to control group without TDM. Both costs and effects were discounted at a rate of 3% per year. Costs are expressed as the difference in total discounted lifetime costs with and without TDM and effectiveness as discounted QALYs saved with TDM. The discounted effect in terms of QALYs was 0.111 and the discounted net TDM cost was $4 850 per patient; costs per QALY saved were estimated to be $43 650.

Comment

In the study by Pandor et al (2013) {4} and Thokala et al (2013) {5} uncertainties remain about the assumptions made in the estimation of both costs and effectiveness.

In the study by Miller et al. (2009) {3} the authors concluded that model results indicated both that TDM could be thought of as ‘cost-effective’ in the long term and that short-term results from a clinical trial alone might not reveal long-term cost-effectiveness.

Importance: Important

Transferability: Partially

Characterising uncertainty

Result card for ECO6: "What are the uncertainties surrounding the costs and economic evaluation(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?"

View full card

ECO6: What are the uncertainties surrounding the costs and economic evaluation(s) of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Result

As shown in ECO1, Table 2, only hospitalisation costs were included and other costs such as costs related to the remote monitoring of patients, outpatient visits and drug costs were not considered in the study by Klersy et al. 2011 {1}. In the study by Miller et al. (2009) {3}, the authors provided only an average cost of the STS programme and did not provide the breakdown of the individual cost components {4}. In summary, as noted in ORG8, it is useful to note that the methods of cost calculation vary widely across the studies related to STS {15}.

From the EFF domain and from Pandor et al. (2013) {4} we see that the varied estimates of effectiveness are also based on a variety of methods of calculation ranging from estimates based on a single trial, to those based on network meta-analysis (NMA). As Pandor et al. (2013) note, it is important to consider different approaches to STS separately as they are likely to have different clinical effectiveness and costs associated with them. Therefore, specific approaches to STS would ideally be fully described before estimating the cost-effectiveness of the interventions {4}. In the study by Pandor et al (2013) {4} and Thokala et al (2013) {5} individual patient-level data was not used and no adjustment was made for potential biases arising from study quality of the studies included in the NMA. The study by Miller et al. (2009) {3} mainly uses information from Galbreath et al. 2004 {8}, which is classed in EFF1 as having a high risk of bias, and the potential extent of the effect of structural uncertainty on results is not described. For these reasons, it is not fully possible to assess the effect of parameter and structural uncertainty on the results presented in the three cost-effectiveness studies reviewed here ({1}, {4} and {5}).

Importance: Critical

Transferability: Partially

Characterising heterogeneity

Result card for ECO7: "To what extent can differences in costs, outcomes, or ‘cost effectiveness’ be explained by variations between any subgroups using Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?"

View full card

ECO7: To what extent can differences in costs, outcomes, or ‘cost effectiveness’ be explained by variations between any subgroups using Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Result

The available primary and secondary studies were not sufficient to provide an answer to this question.

Comment

The lack of information concerning subgroups was noted, for example, by Pandor et al. (2013) {4}. They suggested that future studies should publish data in such a way as to identify which patient subgroups benefited most from the intervention.

Importance: Important

Transferability: Completely

Validity of the model(s)

Result card for ECO8: "To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?"

View full card

ECO8: To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of Structured telephone support (STS) for adult patients with chronic heart failure and its comparator, 'usual care' without STS?

Result

Because of the results presented in ECO1, ECO2, ECO3, ECO4, ECO5 and ECO6, serious doubts are raised about the extent to which the estimates of costs, the estimates relating to health-related outcomes, and economic evaluations *per se* can be considered as providing valid descriptions of Structured telephone support (STS) for adult patients with chronic heart failure compared with its comparator, 'usual care' without STS.

Importance: Important

Transferability: Completely

Discussion

Because of the results presented in ECO1, ECO2, ECO3, ECO4, ECO5 and ECO6 serious doubts are raised about the extent to which the estimates of costs, health-related outcomes, and economic evaluations can be considered as providing valid descriptions of structured telephone support (STS) for adult patients with chronic heart failure compared with its comparator, 'usual care' without STS

The other issue which has an effect on the interpretation of the findings in all the result cards of this domain is the varied definition of ‘STS’ and ‘usual care’ in the literature and its relationship to the way in which ‘STS’ and ‘usual care’ are defined in the scope of this pilot assessment using the HTA Core Model 2.0.

Perhaps the most serious doubts about the cost-effectiveness information are raised by the fact that individual patient-level data was not used and no adjustment was made for potential biases arising from study quality of the studies included in the NMA in the study by Pandor et al (2013) {4} and Thokala et al (2013) {5}. Further, the study by Miller et al. (2009) {3} mainly uses information from Galbreath et al. 2004 {8}, which is classed in EFF1 as having a high risk of bias, and the potential extent of the effect on results of structural uncertainty is not described. The quality of evidence in much of the available scientific literature is poor, therefore, more studies on all aspects of costs related to STS would be needed to reach an unbiased conclusion. Further, the lack of information concerning subgroups was noted, for example, by Pandor et al. (2013) {4}. They suggested that future studies should publish data in such a way as to identify which patient subgroups benefited most from the intervention.

Although analyses of subgroups of interventions can be undertaken, there is little peer-reviewed information available to support such analysis, such as robust estimates of the cost of software acquisition and maintenance when using different STS interventions. More importantly, perhaps, robust estimates of the impact of different types of STS on subsequent healthcare costs, as well as estimates of the impacts on costs outside the healthcare sector, are not available.

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Appendices

Appendix ECO-1: ECO domain literature search strategies

Appendix ECO-2: PRISMA 2009 Flow Diagram

Appendix ECO-3: CHEERS coherence table

Appendix ECO-4: Potential cost drivers for ‘STS’ and ‘usual care’

Ethical analysis

Authors: Plamen Dimitrov, Gottfried Endel, Anelia Koteva

Summary

STS assessment in adult patients suffering from CHF has been developed in compliance with the fundamental ethical principles: beneficence/nonmaleficence, autonomy, respect for persons and justice and equity. Identified and discussed are the challenges that the use of this technology may provoke for both the patients themselves and their families, on the one hand as well as for the medical staff and healthcare system management, on the other hand.

Scientific literature demonstrates that the effect of telemedicine on patient-centered care varies more or less. Some studies see the negatives, but most find neutral or positive effects. The basis of empirical studies, however, is still too poor to allow any solid conclusions.

As will be discussed later in the text, on the agenda stand many ethical challenges, with the border between the benefits and harms associated with telemedicine remaining vague and fluid rather than sharply defined. This is due to the virtual environment, where electronically mediated communication replaces personal interaction and physical contact, thus posing several challenges:

- When shifting the physician-patient relationship from the conventional face-to-face communication to the electronically mediated one, these relations are frequently transformed towards the introduction of new social and interpersonal dynamics. This results in redefining the roles and responsibilities of both patients and health professionals;
- The context of indirect, distant relations between a physician and a patient raises the question of the legal regulation of possible mistakes and abuses of health personnel. There is no clarity as to who bears the legal responsibility and under what circumstances one should be liable to court. Therefore, practicing telemedicine should be accompanied by a proper legal and regulatory framework, stipulating clear standards and rules, compliant with the rights of patients, while at the same time maintaining parity between professional and ethical standards applied to all aspects of physician's practice;
- The digital gap expansion generated by the lack of established telecommunications infrastructure in rural and some urban areas may be another issue. Too often restrictions are associated with not only limited access to network environment but also with a deficit of knowledge, skills, experience, familiarity and a sense of comfort when handling new technologies. Telemedicine is totally dependent on digitization and could not exist isolated from it. Here of crucial importance is to distinguish between the concepts of "availability" and "accessibility" since both terms are not necessarily interchangeable in meaning. Although some resources may be available, they may as well be inaccessible for a number of reasons (as mentioned).

Introduction

The current domain outlines some ethical issues arising from the use of the particular technology, i.e. structured telephone support for adult patients suffering from CHF. Together with all the clinical efforts in the management of this devastating condition, part of the recent research has been concentrated on finding low-cost therapeutic alternatives as telemedicine and further understanding of the psychological, ethical, legal and social aspects of handling the particular technology and its impact on the patients themselves, their families and friends, the healthcare personnel and the healthcare providers as well as the society as a whole.

Since the issues discussed are highly controversial, the ethical analysis does not give certain prescriptions but aims at providing a balance between norms and values through the consideration of social, political, cultural, legal, religious and economic aspects arising from the opposition to the generally accepted environmental values, healthcare system goals and the application of new technologies.

The following areas have been debated:

- Improving patients' quality of life;
- Challenges associated with the digital gap;
- Challenges posed by the remote interaction between a physician and a patient;
- Fair and balanced distribution of resources;
- Equal access to treatment;
- Stigmatization.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)

Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
F0010	Beneficence/nonmaleficence	What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?	yes	What are the known and estimated benefits and harms for patients when implementing or not implementing STS?
F0011	Beneficence/nonmaleficence	What are the benefits and harms of the technology for other stakeholders (relatives, other patients, organisations, commercial entities, society, etc.)?	yes	What are the benefits and harms of STS for other stakeholders (relatives, other patients, organisations, commercial entities, society, etc.)?
F0100	Beneficence/nonmaleficence	What is the severity level of the condition that the technology is directed to?	no	This question is the subject of discussion in the "CUR"-domain and it is extraneous to clarify the ethical considerations of technology and therefore does not belong in this domain.
F0003	Beneficence/nonmaleficence	Are there any other hidden or unintended consequences of the technology and its applications for different stakeholders (patients/users, relatives, other patients, organisations, commercial entities, society etc.)?	no	The answer to this question overlaps with regard to the answers to the previous two questions
F0005	Autonomy	Is the technology used for patients/people that are especially vulnerable?	yes	Is STS used for patients/people that are especially vulnerable?
F0004	Autonomy	Does the implementation or use of the technology affect the patient´s capability and possibility to exercise autonomy?	yes	Does the implementation or use of STS affect the patient´s capability and possibility to exercise autonomy?
F0006	Autonomy	Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?	yes	Is there a need for any specific STSs or supportive actions concerning information in order to respect patient autonomy when STS is used?
F0007	Autonomy	Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?	yes	Does the implementation or withdrawal of STS challenge or change professional values, ethics or traditional roles?
F0009	Respect for persons	Does the implementation or use of the technology affect the user´s moral, religious or cultural integrity?	yes	Does the implementation or use of STS affect the user´s moral, religious or cultural integrity?
F0101	Respect for persons	Does the technology invade the sphere of privacy of the patient/user?	yes	Does STS invade the sphere of privacy of the patient/user?
F0008	Respect for persons	Does the implementation or use of the technology affect human dignity?	no	Human dignity is legal category and not ethical. It is defined as "fundamental and inalienable human right" and therefore subject to the law, not ethics
F0012	Justice and Equity	How does implementation or withdrawal of the technology affect the distribution of health care resources?	yes	How does implementation or withdrawal of STS affect the distribution of health care resources?
F0013	Justice and Equity	How are technologies with similar ethical issues treated in the health care system?	yes	How are technologies with similar ethical issues treated in the health care system?
H0012	Justice and Equity	Are there factors that could prevent a group or persons to participate?	yes	Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?
F0014	Legislation	Does the implementation or use of the technology affect the realisation of basic human rights?	yes	Does the implementation or use of STS affect the realisation of basic human rights?
F0016	Legislation	Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?	no	
F0017	Ethical consequences of the HTA	What are the ethical consequences of the choice of end-points, cut-off values and comparators/controls in the assessment?	yes	What are the ethical consequences of the choice of end-points, cut-off values and comparators/controls in the assessment?
F0102	Ethical consequences of the HTA	Does the economic evaluation of the technology contain any ethical problems?	yes	Does the economic evaluation of STS contain any ethical problems?
F0103	Ethical consequences of the HTA	What are the ethical consequences of the assessment of the technology?	yes	What are the ethical consequences of the assessment of STS?

Methodology description

The Ethical Domain has been developed in compliance with the fundamental ethical principles, basically following the method of principalism. Consistently presented are ethical arguments related to the autonomy and benefits for the patient as well as possible limitations pertaining to the implementation of the technology discussed, without aiming to give a precise answer or “ethical prescription”, as already said.

The domain comprises 19 issues grouped into 5 sections, as listed below:

- Section 1 – Beneficence/Nonmaleficence;
- Section 2 – Autonomy;
- Section 3 – Respect for Persons;
- Section 4 – Justice and Equity;
- Section 5 – Legislation.

We have answered 15 issues. The other 4 issues we consider either irrelevant or have marked them as a “skipped issue”. More specifically unanswered are:

- Issue 3 (marked as irrelevant);
- Issue 4 (marked as irrelevant);
- Issue 11 (marked as irrelevant);
- Issue 16 (marked as skipped).

Literature

The text is based on 24 literary sources, as shown in the references. All of them are in the English language, no Cyrillic information sources have been used.

The literature has been obtained by searching the Internet engine Google, Google scholar and PubMed by key words for each aspect concerned. No other scientific databases have been used.

Nevertheless, we believe that the literature provides a great variety of views that have been reflected in the current analysis. Since the issues are of highly controversial nature, the current text does not pretend to be a detailed or comprehensive analysis but provides some thoughts and reflections. Official sources such as reports of the WHO, statements, guidelines of the American Telemedicine Association, research papers as well as various peer-reviewed articles in specialized medical journals, primarily focusing on cardiology, ethics, medical informatics, telemedicine and telecare, etc., have been thoroughly reviewed and helped in the understanding of the topic. All citations have been marked by pointing the authors of the source, its title, place and date of publication as well as by a link to the information source itself, basically in a pdf-format. All of the sources, on which the analysis is based, are as of recent years.

Result cards

Beneficence/nonmaleficence

Result card for ETH1: "What are the known and estimated benefits and harms for patients when implementing or not implementing STS?"

View full card

ETH1: What are the known and estimated benefits and harms for patients when implementing or not implementing STS?

Result

New Ethical Challenges Posed by the Intersection of Medicine, Telecommunications and Home

Although met with initial enthusiasm for their potential to bring a number of improvements and positive changes in the way healthcare is provided, teletechnology-related opportunities should not be overemphasized, especially in the context of scarce empirical material. As will be discussed later in the text, on the agenda stand many ethical challenges, with the border between the benefits and harms associated with telemedicine remaining vague and fluid rather than sharply defined. This high ambivalence, interrelation and two-way impact hamper them from being placed in a dichotomous category as either benefits or harms, but for the purposes of the present paper such a categorization will be made.

In the literature the benefits associated with the provision of medical/health services at a distance through the use of ICT are widely recognized , where the benefits can be viewed from several points: 1.) for patients; 2.) for health personnel and healthcare providers; 3.) for the families and relatives of patients and 4.) for society as a whole.

As far as the focus is on the positive and negative impact for patients solely, here an attempt will be made to present both sides.

Anticipated Benefits and Positive Effects for Patients-Recipients of Telecare:

In general, the expected effects are oriented in the direction of improving patients' health status and quality of life through:

1. Overcoming/Minimizing temporal and geographical boundaries – teletechnologies allow transfer of synchronized real-time information, thus making it possible to deliver the right care at the right time and in the right place for an individual patient (especially useful in emergency situations);
2. Applicability in remote, hardly accessible and isolated regions; reducing transportation costs to the hospital and avoiding difficult and inconvenient travelling for patients in serious condition or those living in very remote areas. On the other hand, the decrease in travelling costs and time may reciprocally increase their time spent on pleasant daily activities, hobbies, household chores, etc.;
3. Ensuring equal access to medical care for patients living in isolated areas;
4. Reducing the risk of complications; decreasing rehospitalization and repeated invasive procedures or at least achieving prolonged remission periods;
5. Increasing patients' confidence/tranquility in obtaining an adequate advice and/or qualified care; the remote monitoring system may serve as a reminder of getting certain prescribed medications by controlling their intake and the one of regular meals (for lonely patients or those exhibiting cognitive problems);
6. Avoiding the "white coat syndrome";
7. Potential improvement in verbal sharing on the part of anxious or easily disturbed patients, who generally tend to avoid face-to-face communication;
8. Highly promising sector for improved patient access to services and information as well as expanding the scope of services provided;
9. Facilitating the management, storage and transmission of health information;
10. Opportunities for patients to be treated in the comfort of their own home combined with lower costs as a result of the replacement of institutional care with homecare;
11. Opportunities for patients, their families and friends to access unlimited online health information and resources about certain diseases, potential therapies and specific healthcare providers (partially applicable in the case of mobile phones/smartphones). In the majority of cases, patients may get access to the same medical information that healthcare providers normally are entitled to. Although too much medical information that may be hard to understand by a layman could be as dangerous as a total lack of information, it may also be true that most verified and accurately presented information could often produce better informed patients and families, providing more power in their hands as to the selection of specific healthcare professionals and the decision-making process – this is the result of the ongoing changes in recent years, thanks to the mass media and education, demystification of medical practices and adoption of liberal democracy values and market culture, the corollary of which is the growing desire of patients for more control over their own health together with the recognition of their active role. Due to the process of "importing" medical culture from clinical into home environment, with an increasing number of medical procedures being carried out in the homes of patients and their families, thus leading to a close acquaintance and better understanding of medical technology and procedures, it may be quite unlikely to expect that patients would remain just passive recipients of care;
12. The culture of modernity as well as the growing share of noncommunicable diseases (NCDs) have led to transition from paternalism towards greater equality and autonomy of patients, indicative of which are the desire to control one's own health and daily schedule, combined with a growing trend of empowerment and "self-care", assuming more personal health responsibilities for the patient and diminishing the role of the physician by placing doctor's functions as secondary, supporting;
13. Shifting health services from previously primarily clinical to domestic environment may minimize the intrusion of outsiders into the house. Therefore, remote consultations are of key significance to the maintenance of the physical privacy and integrity over the non-public and intimate sphere that home implies, thus reducing undesired penetration of healthcare professionals within its boundaries;
14. Avoiding the depressing clinical atmosphere that normally makes patients feel helpless in managing their condition;
15. Communication with the patient through a variety of means: 1.) telephone: highly effective communication tool allowing flexibility and enabling both sides to keep one another mutually cognizant of therapeutic advances and complications. To a certain extent telephone may replace unnecessary, unwanted and expensive clinical visits. The phone could also be an excellent instrument in maintaining empathy by conveying the emotional nuances in the tone of voice and an adequate tool for articulating time-sensitive information crucial to the health of home patients; 2.) online groups for mutual support and medical websites: their value is in providing the chronically ill and their family caregivers with places for virtual meetings for sharing personal experiences, information and mutual support. By

providing psychosocial support online groups have the potential to reduce social isolation, improve adherence to the therapy as well as reduce costs as a result of the increased welfare of persons (applicable in the case of smartphones);

16. Computerized patient records: its advantages are related to the opportunity for home patients to view, modify, correct their file and have a personal copy of it (applicable to the use of smartphones);

17. Structured telephone support contributes in preventing the trend of leaving elderly parents in nursing homes through the reduction of fear and anxiety of family caregivers and allowing the elderly to remain in the comfort of their own home, thereby reducing the costs associated with institutional care.

Expected Negative Implications, Inconveniencies and Harms to Patients-Recipients of Telecare:

1. Telemedicine poses the risk of dehumanizing medical profession through the modification of the physician-patient relationship and by weakening the preliminarily built mutual trust and empathy, shifting all these at the background while undermining the importance of the patient individual approach at the same time. The fear is that the machines will create a cold and impersonal abyss between the clinician and the patient, with the doctor simply being seen as a mechanic repairing the human body insofar as he/she treats the disease itself but not the person. Here the conflict between medicine as science and medicine as an art is clearly manifested. A view of the human should be adopted that is not fragmented but calls for more holism and comprehensiveness. In the context of electronic environment, personal interaction between both parties in the relationship is minimized, with the interaction being reduced to an abstract and digitized patient data set. Main drawbacks are the undervalued affective aspects of the bilateral relationship where, instead, the role of scientific facts is favorized and doctors are perceived as only technicians responsible for the diagnosis and therapeutic options; although the verbal element in the communication regarding the choice and implementation of a structured telephone support is not completely lost, a serious disadvantage may pertain to healthcare taken not by the clinician-therapist, to whom the patient is accustomed and has built a relationship of trust but by a completely unknown healthcare staff – most frequently an unfamiliar nurse charged with the duty to conduct the telephone interviews;

2. The association between the quality of clinical communication and positive health outcomes should not be underestimated. The more cumbersome and insufficient communication is (which is more or less true for the structured form that healthcare is provided in), the less likely patients are to be improved;

3. The prevalence of information over humans and their relations may prove problematic in ethical terms, particularly in the context of telemedicine, where empathy is less valued compared to timely and accurate health service;

4. Disadvantages of some of the communication tools: 1.) telephone: highly vulnerable as far as unauthorized third parties may intercept unprotected information that is being transmitted through the mobile network as well as anyone having access to the healthcare provider's account could log in, alter and answer the patient on the pretext of being an authoritative figure (applicable to mobile devices/smartphones); 2.) interactive video connection, also accompanied by some restrictions: by changing the temporal and spatial organization of movements, typical of a video picture, some non-verbal gestures, body positions and movements can be underestimated (for example: some facial expressions, subtle glances, etc.), to the extent that the gesture one produces may be transformed, distorted and received in quite a different manner by the other in the interaction. Similarly, when communicating via landlines that do not permit a video image, some nonverbal bodily characteristics, particularly delicate facial expressions bearing relevant information, may remain hidden for both parties in the communication process and therefore undervalued;

5. The concerns related to privacy and confidentiality of identifiable personal information will be discussed in detail in the next section; here they will be mentioned only briefly. Generally, they are concentrated around the risk of leakage of information to third parties in the process of collecting, handling, transmitting and storage of information, all mediated by mobile devices and applications, unauthorized access to personal data, security breaches, abuse of one's official position, being the target of hacker attacks, data manipulation and destruction, technical errors, etc., resulting in diminished public confidence in the new technologies in the field of medicine. A reasonable question arises as to whether the fine membrane separating the public from the private sphere won't be dissolved as well as won't the overuse of medical equipment result in too great and undesirable medicalisation of the intimate space called "home": 1.) the issue of "cookies" allowing to track users' IP addresses when visiting certain websites and online servers installed by web developers and sponsors (applicable in the case of smartphones). This potential lack of anonymity could be especially problematic for patients suffering from socially stigmatized conditions; 2.) electronic information can be more easily accessed (including anonymously), altered, viewed, copied, disclosed or deleted in comparison with traditional paper records; 3.) at risk is the information privacy of patients since personal physiological data may leak electronically and be shared with other clinicians and researchers; 4.) it is by the malefactor's wish that only basic information that has been consistently collected about a specific person through cookies may be sufficient to restore the victim's full medical profile, this time bringing his/her individual characteristics; 5.) next, medical websites and online groups for mutual support also face serious problems concerning the accuracy and quality of medical information (for example: anyone can put a badge on the Internet claiming that he/she is a doctor, i.e. self-proclaim himself/herself as such) (applicable when using smartphones); 6.) even assuming that all medical information generated on medical websites and online groups for mutual support is accurate, patients and their family caregivers can easily be overwhelmed by too much medical information that they have not been trained to read and comprehend, which may be attributed to their lack of knowledge of research methodology and statistical data interpretation making it hard for them to compare the results of several medical studies (applicable to smartphones);

6. The "One size fits all." principle is not valid. One should abstain from giving standardized regulations and prescriptions; the approach to the patient should be individual since what may be good and beneficial for one person may be detrimental to another. Everyone has his/her own preferences and needs that have to be respected and taken into consideration by the medical personnel, with the service provided to be tailored to patients' individual characteristics and needs. E-health may increase marginalization of groups. The "digital divide" brings additional groups to the risk of marginalization;

7. New may not be necessarily best – both practice and time prove this. Instead of blindly believing that new is always better, one must balance the enthusiasm for the potential of telemedicine against the recognition of the need for scientific (evidence-based) verification and evaluation. Therefore, hasty adoption on the basis of only early and insufficient empirical data, whose effectiveness has been demonstrated as limited, may not be the right point;

8. Lack of trained personnel to work with telemedical technologies; people are still to be taught, but learning takes time and enough practice. The issue of applying teletechnologies in medicine is an interdisciplinary, multi-faceted field, which requires the need of broadening the narrow knowledge of the medical staff involved in the teletechnology application. Since of crucial significance are the privacy issues, the staff is required to have expertise on legal and ethical matters, as well;

9. A humane field as medicine claims to be must not tolerate universalization, generalization and unification. Historically, universalization has always led to depersonalization;

10. Excessive technologization in the field of medicine implies another drawback – lowering the clinical skills of the physician insofar as the doctors rely solely on technology, thus "forgetting" how to perform a simple routine physical examination, for example. Instead of the clinician it is the technology that is in charge of conducting a patient's check-up and setting his/her diagnosis;

11. If fallen in the wrong hands, any tool could cause damage, which in turn necessitates the presence of detailed regulations and guidelines for the application of the new technology;

12. In the cases, in which risk is overestimated, telemedicine can restrict the freedom of the patient that may lead to strengthening his/her social isolation. Therefore, the right balance between patient's autonomy and ensuring his/her health protection needs to be found;

13. Despite the tendency of favorizing the automatization of most tasks, the need for patients to trust their doctors will never disappear as far as confidence in the physician is believed to be a key component of therapy. Often downplayed, the good character and virtues of a doctor are deemed crucial in the moral practice of medicine and the lack of the relevant emotional relationships between patients and healthcare providers could be interpreted as an unacceptable moral defect in clinical medicine.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH2: "What are the benefits and harms of STS for other stakeholders (relatives, other patients, organisations, commercial entities, society, etc.)?"

View full card

ETH2: What are the benefits and harms of STS for other stakeholders (relatives, other patients, organisations, commercial entities, society, etc.)?

Result

Positive Implications for Healthcare Personnel/Healthcare Providers:

- The automatization of processes in caring for patients suffering from noncommunicable diseases using ICT may substantially facilitate the exchange of information, automate routine practice and ease documentation flow, thereby improving patient clinical care. Electronic health records are purposefully designed to reduce the time for consultation, facilitating the management of patient information and decreasing the burdens pertaining to documentation procedures;
- To the extent that telemedicine is less dependent on the physical presence of healthcare professionals, overcoming geographical barriers saves time and travel costs to the patient's home by minimizing unwanted and costly home visits, thereby allowing healthcare professionals to use ICT for diagnosis, treatment and monitoring of patients from a distance;
- The exponential growth of teletechnologies allows the development of a fully-integrated healthcare system as well as more flexibility, and enables physicians' connection in a network with clinicians from other specialties so as to discuss complicated clinical cases and provide the best evidence-based care (more globally viewed and applicable to mobile communication);
- Modern technological facilities that healthcare professionals are provided with enable them to remotely analyze the physiological and psychological functions of their patients by exchanging with one another high resolution images, real-time sound and video. Facilitated is the establishment of an objective scientific nosology, allowing physicians to diagnose a disease based on objective evidence and not on subjective patient's reporting. Doctors do not need sharing on behalf of the patient since the medical tool acts as a lens, through which the doctor sees the disease exempted from patient interpretations (applicable to smartphones).

Negative Effects for Healthcare Staff/Healthcare Providers:

- When shifting the physician-patient relationship from the conventional face-to-face communication to the electronically mediated one, these relations are frequently transformed towards the introduction of new social and interpersonal dynamics. This results in redefining the roles and responsibilities of both patients and health professionals, whose direct manifestation is the transition from paternalism to autonomy and equality. For many theorists, medical anthropologists and experts in bioethics the gradual equalization of power positions in the doctor-patient relationship has been and continues to be a consequence of the culture of modernity. As a result of the increasingly informed public and the unprecedented growth in medical knowledge over the past few decades, due to the role of media and education, the image of medicine has begun to demystify itself, becoming more accessible to laymen. This situation, supported by the desire of modern individuals to control their own lives, has modified the relationship in the direction of greater equality between the two parties, with the net effect of modernity being the progressively trimmed authority and prestige of physicians in favor of more equal interactions between a patient and a doctor. Placing restrictions on the professional autonomy of healthcare personnel has forced it to compete in providing a better health product or service. Additionally, in an effort to control healthcare costs, health organizations have further limited the power and prestige of medical staff compelling doctors to comply their therapeutic decisions with cost guidelines and restrictions;
- On the other hand, the "importing" of medical culture in the home of patients as well as the access to vast medical information (including specialized medical articles, virtual books, the possibilities offered by online groups for mutual support and the e-mail, enabling the sharing of therapies workable in a particular case, personal preferences and opinions on certain healthcare providers, etc.) may question the authority and professional expertise of those healthcare providers. Doctors and traditional health personnel will therefore be viewed as one of the numerous sources of medical knowledge, though not the most reliable one (applicable to smartphone use);
- The circumstance that patients may in many cases have access to the same volume of information (if not even more) as doctors have, forcing the latter to acquire more medical knowledge than their predecessors and orienting them to increasingly narrower specializations;
- Need of additional training and certification for doctors and other health staff to work in telemedicine environment, facing them with the challenge of entering new and unknown professional depths and learning in detail medical informatics and legal matters in order to provide adequate care, i.e. this brings on the agenda the need of a broader interdisciplinary view requiring further qualification and gaining new multi-faceted knowledge and skills;
- Lengthening and hindering the documentation process when using traditional paper patient records, not an electronic one. Extending the time spent on the telephone (referring to some cases when using landline telephones for communication);
- Excessive technologization in the field of medicine implies another drawback – lowering the clinical skills of the physician insofar as the doctors rely solely on technology, thus "forgetting" how to perform a simple routine physical examination, for example. Instead of the clinician it is the technology that is in charge of conducting a patient's check-up and setting his/her diagnosis;
- Too wide range of physiological indicators to be monitored, because of which in order to avoid information overload, doctors should select from the set of biometric markers being monitored only those relevant parameters that are of greatest importance to them (applicable to smartphones).

Positive Effects for the Families and Relatives of Patients-Recipients of Telecare:

The benefits are somewhat commensurate with the ones to patients. In particular, the positive effects are as follows:

- Overcoming some of the drawbacks of institutional care by reducing the intrusion of outsiders in the home, thereby preserving its intimate space by preventing or decreasing unwanted home visits on the part of health professionals for monitoring the patient's condition; most physical privacy guaranteed by teleconsultations has the potential to protect the intimate and non-public space of the home, enhancing the autonomy, tranquility and well-being of both patients and their families;
- More flexibility and independence in daily activities together with reduced travelling costs and time of family caregivers – time that can be spent on working, engaging in pleasant activities, household chores, gardening, grandchildren, etc.;
- Contributing in preventing the trend of abandonment of elderly parents in nursing homes by allowing them to remain in the comfort of their own home through the reduction of family caregivers' anxiety and lowering the costs associated with institutional care;
- Access to vast health information and resources combined with opportunities to get familiar with the medical terminology and medical procedures, particularly when shifting them from clinical to home environment – a fact that alone may increase the confidence, self-esteem and independence of families and relatives taking care of patients with NCDs, and turns them into active participants in the therapeutic process as opposed to just passive recipients.

Negative Implications for the Families and Relatives of Patients-Recipients of Telecare:

- Although security breaches are a relatively uncommon phenomenon, their potential for damage is enormous, especially when the security of socially stigmatizing health information has been compromised. Patients and their families may not only lose their privacy but also be subjected to social ostracism, discrimination at work, extortion, etc.;

- Insufficient knowledge, skills and equipment by home caregivers to provide adequate care;
- Neglecting the needs, desires and claims of family members regarding the therapeutic modalities as far as healthcare professionals traditionally presume patient's interests to dominate those of the family. Another problem is that clinicians fail to listen sufficiently to the voice of family caregivers and relatives, who are perceived as solely external and secondary figures to let them have their opinion. However, as the chosen therapy is not encapsulated on the patient only but may indirectly affect the habits, lifestyle, financial status, emotional and psychological well-being of family caregivers, as well, they should not be excluded from the decision-making process;
- The access to the vast sea of medical information and resources can result in overloading family caregivers with too much medical terminology and data, for the interpretation and understanding of which family members lack the necessary biomedical background – they have a deficit of knowledge of research methodology and statistical data interpretation making it hard for them to compare the results of several medical studies;
- Dependence of the care and support provided by the family on the biological progression of the disease, varying primarily from its stage and the availability of caregivers, ready to bear the burden in the event of impossibility by the patient. This may affect the division of labor in the household as well as the social contacts, etc.

Positive Impact on Society:

- Highly promising sector because of its potential to reduce healthcare costs, improve patient access to services, expand the scope of services, enhance the quality of care and facilitate the management of information flow (for example: patient records today are interactive with an option to be accessed by multiple public stakeholders and users of the documentation – not only physicians but also various funding organizations – applicable when using smartphones);
- Opportunities for controlling patients' condition and consulting them "at the right time" as well as reduced duration of inpatient treatment and lowering the number of outpatient visits;
- Prerequisites for the establishment of a consistent and universal telecommunications infrastructure, an integrated healthcare system, greater connectivity and flexibility. Improving communication between health professionals and healthcare coordination, making it possible to attract additional specialists from various fields and reach greater professional expertise in quite rare and complicated cases (more globally viewed);
- Digitization contributes in decreasing information transfer costs as far as the process is less dependent on geographical barriers (when using mobile communication);
- With the increased share of generations living longer but in poorer quality life, healthcare costs are expected to rise in proportion to the growing number of the elderly chronically ill persons. Telemedicine constitutes an alternative to overcoming this flaw by making it possible to minimize institutional costs as patients are taken out of the expensive hospitals;
- Structured telephone support could be a practical solution for non-serviced rural areas given the need to control health costs, the closure of rural clinics and the practical difficulties in recruiting health professionals in rural areas. However, whether it will actually become such a decision, depends on the creation of an adequate telecommunications infrastructure in rural regions, bridging the digital gap (applicable to smartphones);
- Improving the qualification of human resources in healthcare in various areas including deepening physicians' knowledge and skills pertaining to information systems necessary for the implementation of their daily clinical tasks (viewed more globally);
- Remote care is often seen as equivalent to expensive and cumbersome high-tech medical equipment, intimidating in its complexity;
- To summarize, the overall synergistic effect of the implementation of these innovations is the introduction of the progressive liberal democracy principles in a rigid field such as medicine and the transition from paternalism towards a greater equality between patients and healthcare providers.

Negative Implications for Society and Barriers to Telemedicine's Full Potential:

- Digital gap expansion generated by the lack of established telecommunications infrastructure in rural and some urban areas. Too often restrictions are associated with not only limited access to network environment but also with a deficit of knowledge, skills, experience, familiarity and a sense of comfort when handling new technologies. Telemedicine is totally dependent on digitization and could not exist isolated from it;
- Rigidity of the medical community manifested in health professionals' resistance to innovation. Physicians are less willing to accept a technology, promoting greater self-care by the patient since doctors view this as a challenge to their traditional role and position of control and power. Reluctance to make major investments in a sector that may trim their professional autonomy and authority;
- Growing "technological imperative"/"technological fix" that seeks solutions to complex moral issues through technologies, not through patients and healthcare professionals. In modern technological and scientific supremacy, the human element is undermined, which is also evident from the principles of contemporary medical training, encouraging technological spread, thus ignoring physical and psychological contact;
- Reinforcing public distrust with regard to the security and reliability of the transmitted and stored computer-based health information – the debate on ensuring privacy and confidentiality tends to polarize in two directions – on the one hand, the easier traffic of medical information poses personal privacy and confidentiality with serious risks, whereas on the other hand, the overall progress in health reforms is dependent on and unthinkable without the adoption of teletechnologies and e-health;
- Especially problematic would be the disclosure of socially stigmatizing health information, which may result in discrimination at work, social isolation or may be harmful to the reputation of the person concerned. On the other hand, without preliminarily guaranteed privacy and confidentiality by healthcare providers, there is a fear that patients would not seek treatment, revealing otherwise physically and psychologically intimate details about themselves, whereas these details are considered necessary ingredients of trust and openness of communication. The absence of these two conditions will not only result in negative effects for patients but will also be detrimental to the public confidence in the medical and health institutions;
- Telemedical realities call for revision of the concept of confidentiality and its consideration as *prima facie* moral right as far as other social goods, such as medical research and public health, require placing limits on the privacy of health information and allowing exceptions when other moral values or social goods are threatened (for example: as stipulated under law in case of infectious diseases, child abuse, etc.);
- Cases of unauthorized access to medical information tend to have isolated nature, being usually committed by one person; however, many are the examples of privacy and confidentiality violations by authorized persons, who have been legally entitled to access personal medical information (referred to as an "authorized abuse"). Given its daily and continuous, rather than sporadic, character, the second category may presuppose more hazards. Even seemingly legal, it may be of highly questionable moral nature;
- Ethically problematic would be a situation in which empathy is less valued compared to timely and accurate health service (quite typical at the current stage);
- The context of indirect, distant relations between a physician and a patient raises the question of the legal regulation of possible mistakes and abuses of health personnel. There is no clarity as to who bears the legal responsibility and under what circumstances one should be liable to court;
- Need to allocate additional funds and develop training programmes for the human resources engaged in the provision of the new healthcare services (already discussed);
- Balancing between the two manifestations of medicine – medicine as a science and medicine as an art – is quite a difficult task. Increasingly more weight is given to science in the face of standardized clinical guidelines and practice manuals, automated procedures and technology compared to the expertise, intuition and autonomous judgment of an individual health professional. Unlike constantly changing medical science, art of medicine embodies universal, sustainable, immutable categories, such as the experience of the disease, the feeling of vulnerability, dependence, the very sense of caring. Therefore, both the art and science of health are desirable and necessary in providing a technically robust health system and the establishment of adequate ethical relationships;

- A problem may be caused by the narrow interpretation of the term “quality of care” that is often understood as the ability of a new medical technology to improve care and outcome for the patient. Sometimes, however, the adoption of a new medical technology by healthcare professionals could stem from their own faith or belief, rather than actually being the demonstration of improved patient care. Moreover, broadly speaking, quality refers to not only to the delivering of services so as to avoid any errors but also to providing them in a competent, compassionate and respectful way – that is why, the question of whether telemedicine enhances or reduces the quality of health services hasn’t been answered yet;
- Despite the fact that many studies focus on the advantages of teleinnovations, some significant drawbacks are still neglected – for example, the increased access to health services is unlikely to be a good long-term solution since it makes health services more expensive at general level by involving more people in the healthcare system, thereby leading to a growth in the percentage of utilization, i.e. even if healthcare expenditures per capita showed a downward trend, there would still be a threat of a rise in the aggregate (total) health expenditures. If this proves to be true, it is very unlikely that telemedicine will be an economical solution;

(text continues in the "Comment" section)

Comment

(continues from "Result" section)

- Risk of dehumanization, depersonalization and alienation generated by the growing medicalization of the electronically mediated environment and downplaying the role and importance of the physical contact with the patient. Despite the domination of technologies and the automatization of most tasks, patients will always need to trust their doctors as far as having confidence in a particular physician may be crucial in one’s therapy. Therefore, the recommendations are oriented to refraining from using telemedicine as an end in itself and avoiding turning it into a substitute for the traditional care and human contact. It should be justified only as a complementary tool to conventional care and solely for patients, with whom a clinician has already established a bilateral relationship of trust. However in the long run, it might be a substitute.
- Excessive technologization in the field of medicine implies another drawback – lowering the clinical skills of the physician insofar as the doctors rely solely on technology, thus “forgetting” how to perform a simple routine physical examination, for example. Instead of the clinician it is the technology that is in charge of conducting a patient’s check-up and setting his/her diagnosis;
- Due to the rapid pace of innovation all regulations quickly become obsolete and cannot serve adequately at any time, while legislation is more cumbersome and subject to slower amendments;
- Scientific literature demonstrates that the effect of telemedicine on patient-centered care varies more or less. Some studies see the negatives, but most find neutral or positive effects. The basis of empirical studies, however, is still too poor to allow any solid conclusions.

Importance: Unspecified

Transferability: Unspecified

Autonomy

Result card for ETH3: "Is STS used for patients/people that are especially vulnerable?"

View full card

ETH3: Is STS used for patients/people that are especially vulnerable?

Result

Yes, since it generally refers to the case of elderly persons with accompanying diseases (comorbidity) and having initial or more pronounced cognitive impairments. Difficulties in the selected telephone mode of communication may also be expected in patients with hearing or visual problems. Combined with the typical risk of privacy violations of the telemedicine , this vulnerability increases.

In general, to the answer to this question are valid all previous comments debating the negative implications.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH4: "Does the implementation or use of STS affect the patient´s capability and possibility to exercise autonomy?"

View full card

ETH4: Does the implementation or use of STS affect the patient´s capability and possibility to exercise autonomy?

Result

Patient autonomy is a cornerstone principle of medical ethics and widely discussed issue in specialized literature. In general, patient autonomy can be defined as self-determination, an expression of one’s own will, based on the ability of a person to guide and manage his/her own life in accordance with rational principles and rules, thus allowing him/her to consciously accept or refuse medical interventions. The right to self-determination is ensured by the presence of valid consent by adherence to the principle of voluntariness and after the patient has been thoroughly introduced to the objective, nature of the procedures, potential risks, duration, anticipated effect of the intervention, etc.

In the context of telemedicine practice, the major obstacle to the patient's ability to exercise autonomy, as mentioned above, may be the advanced age, frequently accompanied by additional factors, such as comorbidity and the aged-physiologically determined less or more severe mental limitations as well as present or expected to emerge auditory or visual deficits. Moreover, when there is a decline in cognitive functions, reflecting on the comprehension of perceived information, medical specialists are required to explain to patients thoroughly, calmly and patiently all the details on the chosen procedure.

Although patient autonomy is considered to be a key point and prerequisite for any medical intervention and has therefore been well debated in the literature on bioethics, data on ethical aspects regarding the application of specific telemedicine practices are scarce at best or missing, thereby resulting in too general conclusions, not grounded on a solid empirical base.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH5: "Is there a need for any specific STSs or supportive actions concerning information in order to respect patient autonomy when STS is used?"

View full card

ETH5: Is there a need for any specific STSs or supportive actions concerning information in order to respect patient autonomy when STS is used?

Result

In a virtual environment, in which physical contact is often replaced by an intelligent software intermediary among the parties and explicit boundaries are transformed into blurred and fluid ones, would somewhat be unrealistic the notion of total, intact autonomy. The very nature of the new environment poses ethical challenges to the protection of the privacy of personal space.

While security breaches are relatively uncommon, their potential for damage is enormous, especially when the security of socially stigmatizing health information has been compromised that could directly or indirectly affect the socioeconomic status of patients and their families, denigrating their reputation, subjecting them to social ostracism, discrimination at work, extortion, etc. In such situations, where the health information being protected carries social stigma and penalties, it is the ethical importance of privacy protection that stands out the most.

Not only in this concrete case but also in overall telemedicine reality, an adequate approach would not be seeking universality in the new conditions but instead elaborating procedural criteria to determine what must remain private and confidential by permitting individual patients and their family caregivers to decide for themselves what they would like to keep private and confidential. This manifestation of flexible thinking should be reflected in the design and practice of informed consent, with the latter not perceived within the conventional narrow framework of a single act but viewed as an ongoing process with options for revision, if necessary.

Traditional informed consent, conceived as a single event, is the preferred option in cases of single clinical encounters or in periods of initiation, termination or modification of therapy. In this context, the consent shall be deemed a discrete/isolated event as contrasted to an ongoing process.

In the new realities associated with NCDs, however, the traditional model is not applicable and must be replaced with the concept of informed consent of an ongoing process as far as caring for a patient presumes an extended period of time characterized by a multiplicity of procedures, therapies and technologies. An advantage of this second model is the recognition of the fact that patients may not always be able to fully and immediately understand information regarding their diagnoses and treatment modalities. Furthermore, the procedural approach provides patients with the opportunity to reflect on treatment options in light of their own values, allowing them enough time for rethinking and judging on the selected treatment. In addition, a procedural approach is also useful in that it gives both patients and physicians more time and opportunities to reach an agreement, especially in the case of different opinions on the optimal course of action. Particularly in remote medical practice, that flexibility of the informed consent can be illustrated by a revision of the informed consent in accordance with the dynamic nature of the condition. Additionally, with a view to the rapid technological development, further clarifications to the patient and his/her training in the course of therapy may be required.

These are just a few of a number of proposals that the community of ethicists, lawyers, physicians, IT specialists, politicians, etc. need to focus on in order to articulate them into further measures, ensuring users' autonomy and privacy, while broadly speaking – help increase public confidence in the health institutions and telemedicine practice.

The remaining measures are directly related to information protection and generally refer to establishing control over the collection, transmission, storage and use of personally identifiable data in an uncertain electronic environment:

1. Health information may be disclosed for health purposes with only limited exceptions. However, using health information for purposes not related to health, such as hiring or dismissal, shall be prohibited;
2. Disclosure of patient information to outside parties only with the permission of the patient or if enshrined in law. Necessity to regulate the cases, in which information may be disclosed: for treatment, payment or administrative purposes, etc. Guarantees for its protection by the recipients through measures against accidental or intentional disclosure as well as informing patients about the purposes, for which the information is being used or disclosed to third parties;
3. Need for strict allocation of responsibilities for all persons involved (equipment manufacturers, system installers, operators, clinicians), each with a concretely assigned task, for example: who is in charge of permanent care, of consultations, of laboratory tests, etc.;
4. Limiting information access to only a narrow range of authorized persons by defining different access levels in the chain in order to avoid potential threat of blurring/overlapping of responsibilities among the individuals monitoring the patient's condition by precisely defining the roles of each of them (for example: a nurse, a clinician, a patient, etc.). In the case of medical practice, its administrator must allocate usernames and passwords with the requirement to change passwords at regular intervals, containing a minimum number of characters as well as add biometric scanners, allowing palm, finger, retina or facial recognition, etc., if necessary. Likewise, a patient should be entitled to view, possess a copy of and alter information in his/her records but only in a reproducible way – it has to be seen that a change was made and what was the content before;
5. An awareness of responsibility for improper or illegal viewing and changing data. Criminalization of the act and/or, when necessary, subjecting it to civil penalties/penalty payments;
6. Usage of specific technical means to prevent unauthorized or accidental access and disclosure of confidential health information – universal technological approaches in this relation may be electronic passwords, "firewalls", an antivirus software and a software detecting outsider's intrusion (digital signatures and time stamps as well as data encryption permitting encoding and decoding of information). Need to provide an additional protection when sharing clinical information through mobile phones. This is especially necessary with regard to cell phones since they do not normally run encrypted data and can easily be lost, stolen, damaged. Another good approach would be the use of the still unpopular tool, known as "audit trails", borrowed from the financial accounting field. Audit trails

allow precise tracking of all activity by generating a date and time stamps on each entry with a list of what, how long and by whom has been viewed as well as what pieces of information have been printed and the exact location and a computer, from which a request has been sent, flagging any suspicious activity;

7. Identifying weaknesses in the security system as well as assessment of the threats and risks that are to be articulated in the development of measures, concrete policies and privacy and information security procedures.

The ICT introduction in the intimate home sphere may be seen both ways – on the one hand, new technologies contribute to the enhancement of patient autonomy and well-being, while on the other hand, may produce just the opposite effect on this same autonomy. The adoption of telemedicine should therefore not be an end in itself but a product of a clear public vision of providing really good care.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH6: "Does the implementation or withdrawal of STS challenge or change professional values, ethics or traditional roles?"

View full card

ETH6: Does the implementation or withdrawal of STS challenge or change professional values, ethics or traditional roles?

Result

Yes, particularly if referring to the transformed patient-physician relationship. Personal contact is lost, there is a lack of an intimate face-to-face conversation as well as the very feeling of being examined at the time of the visit are all gone. This could weaken the patient's trust in the physician/staff monitoring his/her condition. The current issue has been thoroughly discussed so far in the previous sections and therefore needs no further comment.

Importance: Unspecified

Transferability: Unspecified

Respect for persons

Result card for ETH7: "Does the implementation or use of STS affect the user´s moral, religious or cultural integrity?"

View full card

ETH7: Does the implementation or use of STS affect the user´s moral, religious or cultural integrity?

Result

The accessible literature that has been reviewed suggests no answer to this question, but here probably could be drawn an analogy with the reflections made in the paper on Alzheimer's disease therapy.

Given the widespread use of mobile phones as of today, smartphones, respectively, it is unlikely, however, still possible that with regard to some ethnic groups, cultures and religious movements, the application of the technology might be problematic because of their denial or non-acceptance of new technologies, or since traditional decisions as to one's relatives' health should be made by the family, not by the patient alone. In this aspect, a conflict may be expected regarding the autonomy of the patient, resulting in its reduction. Therefore, individual autonomy depends largely on the people around him/her, their affiliation to a particular social group or community and cultural values, as well.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH8: "Does STS invade the sphere of privacy of the patient/user?"

View full card

ETH8: Does STS invade the sphere of privacy of the patient/user?

Result

The answer to this question might be quite simple and intuitive – yes! The issue has already been widely debated since it is central to teletechnology.

Importance: Unspecified

Transferability: Unspecified

Justice and Equity

Result card for ETH9: "How does implementation or withdrawal of STS affect the distribution of health care resources?"

View full card

ETH9: How does implementation or withdrawal of STS affect the distribution of health care resources?

Result

One of the key principles in bioethics is the principle of justice linked to law and equality. From an ethical point of view, it can be considered in three different ways and subdivided into three distinct categories, respectively: fair allocation of scarce resources (distributive justice); respect for people's rights (rights-based justice) and compliance with morally acceptable laws (legal justice). Although the right to equal treatment, respectively, equal access to treatment has been formally enshrined in many constitutions, actually, many factors, such as age, place of residence, social status, ethnicity, culture, sexual preference, disability, legal capacity, health budgets, treatment price, insurance coverage, etc. may limit access to treatment. Justice in these cases, without neglecting or underestimating the right of equal access for all, requires that the individual's needs be balanced with the needs of the general public.

In general, distributive justice in healthcare, which is being discussed in the present section, involves the application of fair standards that make quality healthcare both available and accessible to people in an effective way. A health system is deemed fair or equal in the cases when: 1.) persons are not deprived of health services based on criteria, such as class, race, gender and geography, and 2.) persons may be entitled to a guaranteed adequate level of care without **exceptional harms/burdens.**

A problem may be caused by the narrow interpretation of the term "quality of care" that is often understood as the ability of a new medical technology to improve care and outcome for the patient. Broadly speaking, quality refers to not only delivering services so as to avoid any errors but also providing them in a competent, compassionate and respectful way – that is why, the question of whether telemedicine enhances or reduces the quality of health services hasn't been answered yet.

Next, of crucial importance is to distinguish between the concepts of "availability" and "accessibility" since both terms are not necessarily interchangeable in meaning. Although some resources may be available, they may as well be inaccessible for a number of reasons (for example: the digital gap generated by the lack of established telecommunications infrastructure in rural and some urban communities, where too often restrictions are associated with not only limited access to network environment but also with a deficit of knowledge, skills, experience, familiarity and a sense of comfort when handling new technologies; availability of health services in a particular community or region, meanwhile making them inaccessible to some people due to inadequate transportation, etc.).

Given the nature of structured telephone support, substantial conflicts regarding the financing of the selected technology are quite unlikely to be expected insofar as the adopted practice of telephone interviews between the healthcare staff and the patient, whether conducted by landline or through the use of mobile phones, does not presume a requirement for supplementary personal financial contributions by patients on additional installation of telemetry devices payable by the patients themselves and is therefore not an extra financial burden to them.

An essential variable in the equation of distributive justice is efficiency/effectiveness – due to limited health resources and their high demand, signs of inefficiency/ineffectiveness, such as duplicate services, overspendings, errors, etc. should be minimized.

With a view to healthcare distributive justice turning into reality, none of the components already discussed should be pursued for their own sake, while being at the expense of others. What is more, both the democratization and stratification potential of distributive justice must be considered, whose overcoming requires constant trade-offs (for example: increased access to medical services and health information but instead – decreased quality of the bilateral relationship, indicative of which is the lack of face-to-face clinical encounters as well as patient access to vast medical information but unreliable and of questionable quality at the same time).

Therefore, in view of the above considerations and in order to ensure fair and reasonable healthcare spending, it is necessary that decisions are made on a case-by-case basis, particularly in situations characterized by limited resources, unequal opportunities and/or other moral discrepancies.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH10: "How are technologies with similar ethical issues treated in the health care system?"

View full card

ETH10: How are technologies with similar ethical issues treated in the health care system?

Result

Telemedicine is successfully applied with regard to patients suffering from diabetes, respiratory diseases, dementia, mental health problems, risk pregnancy, etc. The concrete teletechnology is used either more widely or isolatedly/segregatedly in some states, including European ones (Germany, England, Scotland, Italy, Spain, Denmark, Sweden, etc.). In the above countries, ethical issues are resolved on a case-by-case basis in compliance with their national legislation.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH11 / SOC3: "Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?"

View full card

ETH11 / SOC3: Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?

Method

We used the domain specific search (described above in the Domain Methodology section) including studies relevant to thisoutcomes but with no restriction of the study design and broader criteria (technology, population) as evidence on that question was poor and scarce. The results are given in a descriptive way summarising the text contents of the studies that gave some information specifically on age, ethnicity, income, geographic area, working staus, gender etc. to use Structured telephone support (STS)?

Short Result

Age-related technical illiteracy, more severe health status, ethnic minority with language problems were find to be reported as possible barriers to access for telemonitoring. No primary study on STS was found to have as a primary outcome the realtionship among the use of STS and the above social variables. In some studies the participation to study- and control group showed differences in terms of income, employness, education or income status. For the being elderly barriers and age illiteracy it has been highlighted that common use of the new technologies such as the internet etc. started about 20 years ago and has rapidly spread among the population so that in the future the elderly will more and more be less digitally illiterate, this allowing the age-barrier being less and less relevant. More studies focussed on understanding the actual existence and the effects of those barriers, are needed.

Result

1. Yes, as already mentioned, some ethnic groups (cultural or religious), though unlikely, might refuse such interference;
2. In rare cases there is a risk of damaging the socially disadvantaged segments of the population, leading in turn to a prerequisite for social discrimination by making telemedicine a potential new form of access discrimination;
3. In comorbid older patients, having more or slightly pronounced mental deficiency, handling smartphones would pose some difficulties due to the need of specific technical knowledge and skills. This technology may prove inaccessible to other groups, as well, particularly those with visual or auditory impairments.

From SOC Domain Team:

Primary studies

A lack of effect for the intervention could be the cohort of HF patients which is usually older and has a special experience with their nature of illness. These are not the baby boomers more experienced with technology and with more sophisticated means of monitoring their health as they age. [Schwarz 2008] In opposite to this the study of Lind [2014] asked for the experiences in using the telemonitoring structure for daily reporting of the health status and patients answered that they quickly were able to manage it and felt empowered and increased their own participation. Fourteen patients (11 men, mean/median age 84/83 years at inclusion) diagnosed with HF, NYHA class II-IV, with a median of two previous hospital admissions during the last 12 months were included in the study. Authors analysis of the interviews allowed to focus on the fact that technology in general, including computers and mobile phones, was regarded at the beginning as “not interesting” and “a bit scaring” but digital illiterate patients expressed admitted that they were going to miss a lot of information this way. During the study the patients began using new daily routines for the reporting of assessments and measurements, and they thought that handling the equipment digital pen was an easy task. According to Lind et al. the HF patients in their study had no experiences of using the internet but quickly accepted and managed to handle the digital pen technology for daily reporting of their health status, making them more empowered and increased their own participation. The study shows that, „given that technologies are tailored to specific patient groups, even “the digital illiterate” may use“ them. [Lind 2014].

In thier qualitative study Lynga et al. did a typology of the patients and linked their habitual status to the telehealth results. There were different ways in understanding the telemonitoring in a dominating or non-dominating way. The five women show a higher summary of points (1 or 2 crosses on table 1) in the habitual category than the 15 men (7/5 versus 12/15, respectively) leading to the assumption that they got the daily weight measure easily into daily routine.

The study of Seto [2010] mentioned the young average age of their study participants and the possible bias by positive attitudes towardas telehealth, „however, the participation refusal rate was very low, which suggests that the bias was minimal. Finally, the mobile phone-based remote monitoring system that was proposed to the participants had functionality that was beyond what is available in current best practice“. [Seto 2010]

Seto [2012] also mentioned the lack of continuity for telemonitoring patients going on vacation without bringing the monitoring equipment with them. On average, every phone call was associated with an increase in perceived health, indicating that the overall process was responsible for the improvement of participants’ health states. Considering the fact that there were significantly more contacts for participants with poorer initial perceived health, it was suspected that there is an effect of severity (NYHA stage) on the outcome variables. However, there wasn’t any evidence for a negative impact of NYHA status on participants’ development over the course of counseling. [Boehme 2012]. The study participants in the study of Brandon 2009 all (100%) had annual income levels < 20.000 $ (median income in this county = 30.952 $), were mainly (7/10 in the intervention group, 8/10 in the control group) high school (with or without degree) or lower level, only 30% of the participants had some college or postgraduate study. In the intervention group 70% were female. There was also an option for cardiac rehabilitation education after discharge from hospital only for those patients who had access to transportation. [Brandon 2009]

Importance: Important

Transferability: Partially

Legislation

Result card for ETH12: "Does the implementation or use of STS affect the realisation of basic human rights?"

View full card

ETH12: Does the implementation or use of STS affect the realisation of basic human rights?

Result

The answer to this question could be quite simple and intuitive. However, the issue is more appropriate to be dealt with in the Legal Domain.

Although health professionals are morally obligated under the Hippocratic Oath to protect patient confidentiality, with the latter understood back then as a sacred obligation or an absolute right, modern healthcare fails to see the concept of confidentiality as a sacred category. What is more, a conflict appears between the limits of confidentiality and the common good, where one is often at the expense of the other. In order to balance the two concepts, a trade-off position should be adopted, allowing exceptions or confidentiality infringement in particular situations of competing health interests, such as a threat to other moral values or social benefits (for example: public health, medical research, child abuse, infectious diseases as stipulated under law, etc.), patient's authorization for disclosure of information and more broadly speaking – maximizing overall public health. Next, in order to cure their patients, healthcare workers must sometimes compromise (override) their privacy, entering their intimate sphere and questioning them on their lifestyle and personal habits.

Practicing telemedicine should be accompanied by a proper legal and regulatory framework, stipulating clear standards and rules, compliant with the rights of patients, while at the same time maintaining parity between professional and ethical standards applied to all aspects of physician's practice.

Existing standards related to the classical face-to-face medical care must be adapted to the new healthcare models, with the regulations comprising: a license for practicing this type of service by medical specialists; a mechanism for physician's selection by the patient (identified or random); identification standard of the provider and the patient upon relationship establishment; standard for evaluation and treatment of the patient; measures for securing and protecting patient's data as well as data of the doctors providing the service; continuity of care; a mechanism for access to archived data; quality and surveillance mechanisms.

It is necessary that the following aspects are also defined and specified:

1. Type of medical services provided;
2. Information on the medical staff (qualification, license, professional experience);
3. Confidentiality conditions – to whom may be disclosed health information regarding the patient and for what purposes, especially in the case of using mobile devices;
4. Patients' rights with regard to the service;
5. Procedures for coordination of services in case of technical problems;
6. Access and timely information as well as information on any additional or altered personal health data of patients;
7. Provided feedback regarding the quality of information/service;
8. Providing a mechanism for registering complaints about services delivered, etc.

Importance: Unspecified

Transferability: Unspecified

Ethical consequences of the HTA

Result card for ETH13: "What are the ethical consequences of the choice of end-points, cut-off values and comparators/controls in the assessment?"

View full card

ETH13: What are the ethical consequences of the choice of end-points, cut-off values and comparators/controls in the assessment?

Result

There is no clear formulation of the question. It should be noted that for the same reason this issue has already been initially rejected as irrelevant and not worthy of discussion. The problem has not been dealt with in the available literature.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH14: "Does the economic evaluation of STS contain any ethical problems?"

View full card

ETH14: Does the economic evaluation of STS contain any ethical problems?

Result

Since the issue is not necessarily associated with the pre-installation of specific devices in the home of patients and the costs of the selected technology are generally covered by private (non-budgetary) funds paid for the private purchase of landline or mobile phones, no significant conflict of interest in terms of financing should be expected.

Importance: Unspecified

Transferability: Unspecified

Result card for ETH15: "What are the ethical consequences of the assessment of STS?"

View full card

ETH15: What are the ethical consequences of the assessment of STS?

Result

With a view to the above, no considerable ethical consequences of the technology assessment are to be expected.

Importance: Unspecified

Transferability: Unspecified

Discussion

In recent years, health vocabulary has been enriched with several new concepts resulting from the penetration of information and communication technologies in public life, particularly in the health field, and the subsequent transformation of the organization of healthcare provision. Neologisms, such as “telemedicine”, “telehealth” and “e-health”, have appeared, whose semantic distinction as of today is not clear enough insofar as they are often considered synonyms. The complexity in determining their terminological scope is largely reinforced by the lack of a universal definition for the three concepts.

On the Etymology of Concepts. Operational Definitions

“Tele-“ (derived from Greek, meaning “far away”, “from a distance”). As already mentioned, there is a great variety of definitions in the available literature, but as they are not a particular focus of the present analysis and serve only to make terminological clarity, the paper will only consider two of them. For example, the American Telemedicine Association provides the following definition: “Telemedicine is the remote delivery of healthcare services and clinical information using telecommunications technology. This includes a wide array of clinical services using Internet, wireless, satellite and telephone media”[1], while the World Health Organization expands the scope of telemedicine as follows: “The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities”[2].

From what has been pointed out one can make the impression that the second definition extends the focus from the purely clinical aspects, typical of telemedicine, to the various non-clinical applications, including prevention, public health, research, health education, etc. With the involvement of an ever growing group of health professionals (not restricted to physicians only) and the emergence of increasingly sophisticated ICT, telemedicine acquires new dimensions approaching it to what is meant by the term “telehealth” (referred to as in the WHO definition above).

Despite the lack of a single, universal understanding of telemedicine/telehealth, experts in the field unite themselves around some common components for all definitions:

1. ICT use;
2. Geographical distance among participants;
3. Use in the context of health/medicine.

One of the problems that could affect the quality and nature of the conclusions in the material stems from the fact that, like many other innovations in the healthcare field, almost all of the studies from the available literature, assessing the positive and negative impact of telemedicine, focus primarily on the purely economic, technical and clinical parameters, particularly emphasizing on cost reduction and technological efficiency but ignoring the ethical considerations at the same time. The latter, however, is an essential element of any general assessment of a new technology, without whose thorough clarification and its understanding remains impossible further incorporation into future guidelines, standards of care and policies.

While collecting and reviewing specialized literature, another major gap has been found – lack of sufficient empirical studies dealing specifically with the advantages and disadvantages of implementing teletechnologies in clinical practice, with emphasis on just general theoretical philosophical and ethical concepts instead. Therefore, since the exact benefits and harms of telemedicine remain unknown at this stage, they require additional empirical confirmation or denial so that decision-makers could reach a grounded, reasoned decision on the selection of a concrete health technology and its further implementation into routine medical practice.

The available literature is concentrated in two key papers representing meta-analyses of data from randomized controlled trials comparing the two forms of remote monitoring – telemonitoring and structured telephone support in terms of clinical or cost effectiveness indicators[3],[4]. Quite vaguely mentioned has been their acceptability to patients and patients’ level of satisfaction. Also a bias in patient selection has been identified – only persons with skills and affinity to modern communication have been included.

Like the majority of the available empirical material on teletechnologies, ethical aspects have been neglected. A significant disadvantage of the meta-analyses used is their failure to strictly define the scope of the term “structured telephone support”. Despite the operational definition provided, it cannot be codified and equally applicable to all types of structured telephone support; rather, each of the authors of the studies, included in the meta-analyses, gives his/her own understanding of what

is meant by the term and its boundaries. The adjective “structured” implies regularity of telephone contacts with their initiation on the part of healthcare personnel, but the limits of the scope are higly blurred, at times closely approaching each other and even further confusing them by mixing structured telephone support with telemonitoring through the transfer of electronically registered and traceable physiological indicators – all of these made possible by the use of mobile applications. This poses the question of to what extent structured telephone support should be confined to traditional landlines and won’t it be more correct with a view to the overwhelming digital environment for the analyses to be based on data including mobile telephones, as well.

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Organisational aspects

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Summary

ORG1: How does Telemonitoring in home care for patients with chronic cardiovascular diseases affect the current work processes?

As most of the studies are conducted in controlled academic environment or non realistic setting, it might be that additional option should be considered in real setting, like hiring a nurse, use of low cost telephone service, use more time for outcomes dissemination and results discussion in a team. STS can be carried out in very different settings, from primary care to tertiary care. There is little information in the studies on the changes of the workflow – usually for the STS an additional nurse was used who had access to patient data, carried out the STS, monitored the patient, recorded the symptoms and data and reinforced and adapted the plan of care for the patient. The other medical professions did not get involved in STS directly, only indirectly, through the STS nurse, who coordinated all the activities and services around the patient. No study specifically recorded the (decrease or increase of) workload for other specialists in case a STS nurse was involved in the work. One study {6} describes how to manage human resources and the division of roles between nurses. During the 2007 calendar year, there were 1.356 patients visits to the HF clinic and telephone calls accounted for an additional 1.914 patient encounters in 2007. One full-time nurse practitioner, one clinical nurse specialist (working 0,7 of a full-time equivalent), and one registered nurse (vacation replacement) provided the nursing interventions with the telephone visits. Nurse spent 24 % of their working hours doing 1.914 telephone calls in one year.

ORG 2: What kind of patient/participant flow is associated with Telemonitoring in home care for patients with chronic cardiovascular diseases?

STS replaced historical program of doctor's visits for HF patients after discharge. In interventions utilizing STS, the patient is monitored remotely while being at home (including a relative's home, nursing home or residential care home). The patients are contacted in regular time intervals via telephone by either healthcare personnel (e.g. specialized HF nurses) or an automated telephone-based interactive response system. The STS support starts being planned while the patient is in hospital through education and meeting with the HF nurse. Education and practising with the technology follows and the materials are given to the patients as well as explained to the relatives. At the point of discharge the timing of the first call is agreed. The frequency of calls varies greatly among the studies but in common the calls are weekly at least first two weeks after discharge and then get biweekly until two months after discharge. After that they become monthly. It is not clear how long the intervention should last: there are different periods, going from 3 months up to 2 years after the discharge. It is not clear when the effect is biggest, possibly within first 3 months.

ORG3: What kind of involvement has to be mobilized for patients/participants and important others?

Please find the overlapping results also in TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

ORG4: What is the process ensuring proper education and training of the staff?

Proper education and training of the staff is ensured through the courses for nurses on HF (formal HF certification) and on the remote monitoring, which is assured by telemedicine providers in case any devices for home symptoms measurements are included. As far as the STS itself, no specific training were found to be offered to staff in the literature.

ORG5: What kind of co-operation and communication of activities have to be mobilised?

In the heart of communication and cooperation strategy in the studies there is always a nurse. A consistent nurse case manager who cares for the patient and connects family, tries to understand goals and specific outcomes, provides information and monitors patient and communicates and cooperates with other members of health team to help them understand the patient {240}. A published communication strategy is important, including patient support strategy, communication between patient: nurse, patient: medical doctor, patient: pharmacist, the brochures, diaries to record daily control measurements, web pages with disease information and with instructions, instructions for family members to share a best practise.

ORG6: How is the quality assurance and monitoring system of Telemonitoring in home care for patients with chronic cardiovascular diseases organised?

Please find the overlapping results in TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases***?***

ORG7: What are the processes ensuring access to care of Telemonitoring in home care for patients with chronic cardiovascular diseases for patients/participants?

In general, RM including STS provides greater access to care in geographical terms. In most of the studies the problems with accessability to phone line were not reported. Careful planning of STS is necessary among specific population that might have issues in moving around and having lower access to phone lines. Also, the number of telephone contacts per week should not be too high, not even in the first week as this may affect adherence. The problems might arise on the side of physicians as patients might relocate to more developed health care centres with remote monitoring programs posing financial risk for smaller providers.

Speaking in terms of financial accessability, no specific problems were mentioned on the side of the patient. On the side of the provider, the current reimbursement structures basically do not support STS and hence act as a disincentive to providers wanting to offer RM incl. STS to patients sustaining HF. Innovative reimbursement schemes such as coverage with evidence in development are suggested in the literature.

ORG8: What are the likely budget impacts of implementing the technologies being compared?

While some studies reported {2} no statistically significant difference in healthcare costs (either total costs or all-cause hospital costs), other studies reported important and significant reductions in costs. While the average costs of intervention across the studies amounted from $23,6 to $443, the reported savings amounted from $30,9 to $536 per patient per month. The savings across studies were reported in various ways which makes them hardly comparable (percentage reduction in inpatient costs, percentage reduction in overall costs, percentage reduction in total health expenditures, reduction in different currencies per patient, per nurse, per year, per month, per

6 months...). However, more important than this is the method of costs calculation that varies widely across the studies. More or less, only direct costs are included, mostly connected to reduction in hospitalizations. More than 70 % of the studies did not take into account expenses in one of the following categories: healthcare sector, other sectors, patient/family expenses or productivity losses. None of the studies analyzed a shift of cost, from specialits to HF nurse to GP, for instance. In 80% of the studies the source and methods of the evaluations were not clear. Authors mostly focused on direct costs while omitting indirect and intangible costs {310}. Principally, the costs were missing across majority of the studies and those of the intervention overheads, training of personnel, and patient related costs. There is a difficulty in capturing all of the effects of telehealth intervention. Thus the cost effectiveness evidence for specific implementations in the field of telehealth is limited. Problems with telehealth interventions reside in absence of quality data and appropriate measures. The quality of economic data is especially questionnable. The quality of evidence in the scientific literature is poor. More studies on all costs are needed to reach the unbiased conclusion.

ORG9: What management problems and opportunities are attached to Telemonitoring in home care for patients with chronic cardiovascular diseases?

The use of RM has improved as a possible way to improve the management of patients with HF by allowing more frequent assessment of patients without the need for FTF clinical reviews {100}. When planning the introduction of a RM intervention in general, there are several questions that need to be addressed concerning: the choice of patients targeted by these programmes; the parameters that will be monitored; the more efficient way to monitor them; the training of patients and healthcare personnel; how to organize the response of the health care professionals to data obtained from monitoring to optimize patient care {1430}{1}. Possibly management will need to deal with (de)employment of new resources, new information systems, new equipment for STS provisions, new administrative leadership and new group culture that promotes quality improvement {15}{40}.

CUR3 / ORG10: Who decides which people are eligible for Telemonitoring in home care for patients with chronic cardiovascular diseases and on what basis?

Eligibility to new technology depends on an assessment of the general practitioner of a patient’s condition and the patient's willingness and ability to participate. Access to new technologies depends on support of healthcare providers. In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patient is willing to incorporate these technologies into their care or patients at high-risk {40}. Having an access to a touchtone telephone is an essential inclusion criterion {1} . By Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

ORG11: How is Telemonitoring in home care for patients with chronic cardiovascular diseases accepted?

Adherence to STS programs differs in HM to HH STS programs, it seems that interpersonal interaction with a care provider is an important active component of STS (adherence is higher in HH than HM STS) {40}. Adherence is reported from 55,1% to 84% across the studies, adaptation to the technology to 90% or higher, more than 90% of patietns are statisfied with the use of technolgy. Acceptance of automated voice interactive system was poor, mostly due to technical failures. Patients were generally very satisfied with various STS programs across studies.

The clinicians, on the other hand, have several reservations, such as potential increased clinical workload, medicolegal issues, and worries of difficulty of use for some patients due to lack of visual acuity or manual dexterity. The clinicians believed that the telephone interactions is as effective as face-to-face interactions. The clinicians fear that system would result in a significant increase in their workload {91}.

ORG12: How are the other interest groups taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases?

No other interest groups except those mentioned in other assessment elements, are taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases.

Introduction

In this domain we aim to explain the impact of STS on providers (their work processes, education and training of staff, management strategies, acceptance), on patients (patient flow, patient involvement, access to STS, eligibility and acceptance) as well as on health care system (budget impact, quality assurance and monitoring). From oragnizational aspect the most important issue is ensuring optimal organization on the side of provider by assigning a trained heart failure (HF) nurse to carry our STS program through proper communication that assures maximum acceptance, adherence and satisfaction by patients. According to the opinion of medical staff, lack of proper reimbursement in most health care systems makes the management of STS programs challenging. It needs to take into account evidence based findings on best result technology, social and organizational issues to achieve maximum results.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition.

	Target population description Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
G0001	Health delivery process	How does the technology affect the current work processes?	yes	How does structured telephone support (STS) for adult patients with chronic heart failure affect the current work processes?
G0100	Health delivery process	What kind of patient/participant flow is associated with the new technology?	yes	What kind of patient/participant flow is associated with structured telephone support (STS) for adult patients with chronic heart failure?
G0002	Health delivery process	What kind of involvement has to be mobilized for patients/participants and important others?	yes	What kind of involvement has to be mobilized for patients/participants and important others?
G0003	Health delivery process	What is the process ensuring proper education and training of the staff?	yes	What is the process ensuring proper education and training of the staff?
G0004	Health delivery process	What kind of co-operation and communication of activities have to be mobilised?	yes	What kind of co-operation and communication of activities have to be mobilised?
G0012	Health delivery process	How is the quality assurance and monitoring system of the new technology organised?	yes	How is the quality assurance and monitoring system of structured telephone support (STS) for adult patients with chronic heart failure organised?
G0101	Structure of health care system	What are the processes ensuring access to care of the new technology for patients/participants?	yes	What are the processes ensuring access to care of structured telephone support (STS) for adult patients with chronic heart failure for patients/participants?
G0005	Structure of health care system	How does de-centralisation or centralization requirements influence the implementation of the technology?	no	As telemonitoring is provided at patients' home and is monitored by the unit defined in the system, the level of de/centralization has no impact on the implementation.
G0007	Process-related costs	What are the likely budget impacts of implementing the technologies being compared?	yes	What are the likely budget impacts of implementing the technologies being compared?
G0006	Process-related costs	What are the processes related to purchasing and setting up the new technology?	no	Investments in premises and equipment (except phone lines/broadbands) are not necessary and not mentioned in the literature, which clearly follows from TEC domain. This is the reason we find this question irrelevant.
G0008	Management	What management problems and opportunities are attached to the technology?	yes	What management problems and opportunities are attached to structured telephone support (STS) for adult patients with chronic heart failure?
G0009	Management	Who decides which people are eligible for the technology and on what basis?	yes	Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?
G0010	Culture	How is the technology accepted?	yes	How is structured telephone support (STS) for adult patients with chronic heart failure accepted?
G0011	Culture	How are the other interest groups taken into account in the planning / implementation of the technology?	yes	How are the other interest groups taken into account in the planning / implementation of structured telephone support (STS) for adult patients with chronic heart failure?

Methodology description

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain). For some answers (ORG4) an additional handsearch was performed.

Information sources

- Common basic project literature search
- Specific literature search performed together with ECO domain
- Specific literature search performed in SAF, EFF and ECO domain
- Handsearch (additional reference found/ provided)
- Google

Quality assessment tools or criteria

We did not rate the quality of the included studies, but mentioned whether the information was extracted from systematic reviews or single studies (i.e. RCTs) or other resources. The basis for inclusion and exclusion of the studies is described in other domains with whom the search was perfomed and was based on the contents of the abstract (we checked the relevance of topic for our AEs and PICO). Quality assessment of the literature was not performed in ORG domain - however, no separate search was performed within the domain as well. We found the opposing results based on the same articles cited in 2 articles – in such cases the original articles was searched for and the results were checked.

Analysis and synthesis

Three investigators divided the amount of studies among themselves, each scanned one third of the studies and double-checked the other two thirds. The investigators in the further process divided the questions (each investigator 4 questions) and we wrote and wrapped them up based on the findings from the literature. The whole document was checked before sent to internal reviewers. The comments from internal reviewers were divided among investigators according to the separate questions and reacted to accordingly. The whole process was coordinated with ECO, TEC and LEG domain through PI s of each domain. The classification of literature was prepared in other domains and not in Org and is therefore not presented here.

Result cards

Health delivery process

Result card for ORG1: "How does structured telephone support (STS) for adult patients with chronic heart failure affect the current work processes?"

View full card

ORG1: How does structured telephone support (STS) for adult patients with chronic heart failure affect the current work processes?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain). The results are provided in descriptive way.

Short Result

STS can be carried out in very different settings, from primary care to tertiary care. There is little information in the studies on the changes of the workflow – usually for the STS an additional nurse was used who had access to patient data, carried out the STS, monitored the patient, recorded the symptoms and data and reinforced and adapted the plan of care for the patient. The other medical professions did not get involved in STS directly, only indirectly, through the STS nurse, who coordinated all the activities and services around the patient. No study specifically recorded the (decrease or increase of) workload for other specialists in case a STS nurse was involved in the work. Staples et al {6} describes how to manage human resources and the division of roles between nurses. During the 2007 calendar year, there were 1.356 patients visits to the HF clinic and telephone calls accounted for an additional 1914 patient encounters in 2007. One full-time nurse practitioner, one clinical nurse specialist (working 0,7 of a full-time equivalent), and one registered nurse (vacation replacement) provided the nursing interventions with the telephone visits. Nurses spent 24 % of their working hours doing 1.914 telephone calls in one year. As most of the studies are conducted in controlled academic environment or non realistic setting, it might be that additional option should be considered in real setting, like hiring a nurse, use of low cost telephone service, use more time for outcomes dissemination and results discussion in a team.

Result

Standard care of HF patients discharged from an acute care setting, may include patients' follow-up visits to a PCP, participation in a CHF management programme run by a health care provider (for example a clinic), or visits at the patient's home by specialised CHF health professionals. According to one point of view, telehealth can substitute home visits by healthcare professionals or visits by the patient to physicians' offices and clinics {9}, therefore the provision of STS programmes and RM in general can be considered a "reengineering of health care processes" {40}. According to another point of view, RM is rather a different way of systematically organizing effective care and should not be seen as replacement for specialist care or multidisciplinary heart failure clinics {1280}. The heart of the medical practice is the relationship between a care provider (physician, well-trained nurse, etc.) and a patient in focus. New technologies should be viewed as potentially useful adjuncts in selective subgroups and using specific parameters to be defined in good RCTs. They should not be the centrepiece of redesigned health care system on top of UC-technology comes second and the patient-centered relationship between patient and provider comes first {80}.

The STS programs described in the literature present variations. In terms of the various actors involved in the process, all interventions are performed by nurses who have access to patient records, and through the STS intervention can monitor the patient, record symptoms, reinforces the treatment plan and makes adaptations to medications or can refer patients to other healthcare professionals e.g. dietician.

Other healthcare professionals may also be involved in the STS program through various procedures. They can be involved in the development of the STS intervention. Also, during the provision of STS, physicians and pharmacists can be involved via regular monitoring of reports sent by the nurses, supervising of the STS intervention, providing instructions and feedback to the nurses regarding the treatment plan or training nurses on problems that were encountered during the telephone communications with the patients. Healthcare professionals such as nurses, physicians, pharmacists, social workers, dietitians, cardiac rehab specialists and other health care professionals may also be involved in providing patient education before discharge from the hospital.

In STS programs, patients and their family/carers have a more active role as they receive education regarding their illness, symptoms and treatment, and are required to self-monitor and report to the HF nurses, thus constituting important actors in the procedure.

Other actors that were reported in some of the studies include technical staff (when the intervention included videophone); health plans' case managers who communicated with nurses carrying out the STS program and provided information on issues relating to the plan benefits such as durable medical equipment procurement and transportation difficulties; and, the telemedicine providers who offer consulting services that include program support as well as healthcare personnel and patient training to organizations that are implementing or plan to implement STS programs.

In case STS is an add on to same work process and no changes in work process are visible, additional work for nurses as well as physicians is necessary. In most studies, additional nurse (called centralized nurse{230}, registered nurse {230}, nurse case-managers {230}, cardiac nurse {230}, study nurse {1}, HF nurse {200}) specially trained in management of HF, led the STS, monitored patients' status and advised patients.

In the Tele-HF trial the reports were reviewed regularly by physicians and medications were adjusted as necessary {1150}. In another case, the standard care work process after discharge was as follows {1}: medical center staff provided all subjects the usual discharge teaching, also follow up clinic appointments were scheduled in the usual manner for all subjects. UC subjects contacted their primary nurse case manager by telephone if needed. Intervention subjects, on the other hand, contacted their assigned study nurse if needed. Two additional registered nurses conducted all intervention contacts for intervention patients – they reviewed the discharge plan during the first intervention contact and reinforced it during subsequent contacts. When subjects reported symptoms, nurses reviewed the data, reinforced the plan of care and made referrals (eg. dietitian) or contacted physician for care plan adjustment. Study nurses had full access to the subject's medical records through the Computerized patient record system. When STS included videophone, more technical staff needed to be involved due to the fact that 76% of encounters were limited by technical problems, primarily poor video resolution {1}.

In a randomized, controlled clinical trial conducted in the U.S. {2} disease managers were employed by CorSolutions, Inc, which is an established DM company and was contracted for the study. A challenge that arised in such a setting was that physician did not welcome input from disease managers. A small number of potential patients for the trial withdrew from considering participation after they were advised by their physicians they should not enroll, some of whom stated they would no longer see the patient if the patient participated in DM.

In the German HeartNetCare-HF Würzburg study, the heart failure nurse {200} was set in a centre of services provision for the patient. Her working environment was in a hospital and she used a hospital telephone line to carry out STS. Soon a special relationship was established between a nurse and a patient. One nurse could support 100 to 120 patients. She worked under the supervision of cardiologist as well as psychologist. As a nurse could do some work which was done by cardiologist earlier on, the doctors had less workload. However, a special knowledge and additional training is necessary before such nurse can take on additional responsibilities.

In another study {1500} nurses trained in the management of patients with HF based in a centralized calling center contacted intervention patients. Answers to questions were collected using software and analyzed by the system to identify at-risk patients. Nurses contacted a patients' cardiologist as needed during the interventions.

There is a lack of published data about the nature of nursing interventions that are required to provide telephone management for patients with HF. Staples et al describes how to manage human resources and the division of roles between nurses. During the 2007 calendar year, there were 1.356 patients visits to the HF clinic. Telephone calls accounted for an additional 1.914 patient encounters in 2007. One full-time nurse practitioner, one clinical nurse specialist (working 0,7 of a full-time equivalent), and one registered nurse (vacation replacement) provided the nursing interventions with the telephone visits. Nurses spent 24 % of their working hours doing 1914 telephone calls in one year. Nurses initiated 65 % of calls; others were received from patients, family members and other health care providers. When patients called about troubling symptoms (other than HF), non-HF issues, or seeking information on other topics, interventions were required that only the nurse practitioner could provide. The nurse practitioner was usually the only nurse who could make medication changes based on diagnostic test results {6}.

A consistent nurse case manager who cares for the patient and connects family, tries to understand goals and specific outcomes, provides information and monitors patient, can help other members of health team understand the patient and coordinates services. Since most of the studies are completed in academic settings or a specific study setting is created, the clear influence of the implementation of intervention might exist in community based agencies. For example, health care centers in real setting may consider low cost option of nurse run telephone care services or improving fragmented care by employing nurse case manager. There is more time needed for routine dissemination of outcomes data and discussing results with staff {240}.

The work processes due to telehealth might be affected also on the side of the patients. For example, if a patient needs a telephone line to perform STS while at work, his or her workpalce might lack the facilities, privacy and comfort needed. Public, residential and commercial spaces might need to be redesigned to include health kiosks or other appropriate spacesfor STS. Also, providers might need different environment or office to perform STS {3}.

Where primary care services are well developed, the GP and community nurse could be involved in the routine monitoring of the stable patient, although the evidence for this is not secure. UC/STS should be incorporated into the activities of the multidisciplinary team, with timely communication between primary, secondary and tertiary care being vital. This is often not the case {100}. Once a patient is on optimized medication, the PCP and community HF nurse can continue to monitor the majority of patients.

Importance: Critical

Transferability: Completely

Result card for ORG2: "What kind of patient/participant flow is associated with structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

ORG2: What kind of patient/participant flow is associated with structured telephone support (STS) for adult patients with chronic heart failure?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain).The results are provided in descriptive way.

Short Result

STS replaced historical program of doctor's visits for HF patients after discharge. In interventions utilizing STS, the patient is monitored remotely while being at home (including a relative's home, nursing home or residential care home). The patients are contacted in regular time intervals via telephone by either healthcare personnel (e.g. specialized HF nurses) or an automated telephone-based interactive response system. The STS support starts being planned while the patient is in hospital through education and meeting with the HF nurse. Education and practising with the technology follows and the materials are given to the patients as well as explained to the relatives. At the point of discharge the timing of the first call is agreed. The frequency of calls varies greatly among the studies but in common the calls are weekly at least first two weeks after discharge and then get biweekly until two months after discharge. After that they become monthly. It is not clear how long the intervention should last: there are different periods, going from 3 months up to 2 years after the discharge. It is not clear when the effect is biggest, possibly within first 3 months.

Result

Historically, patients with HF were not taught to self-monitor but were reviewed periodically by a doctor working in either primary or secondary care. Even in the high risk period after hospital discharge it was traditional to arrange hospital clinic review some weeks after discharge. During this visit the doctor would assess the patient and determine if changes to treatment were required. In many countries where there were only a few physicians with a special interest in the condition, many patients would be discharged back to primary care review alone. Such a model of patient flow is now considered outdated and substandard.

In interventions utilizing STS, the patient is monitored remotely while being at home (including a relative's home, nursing home or residential care home). The patients are contacted in regular time intervals via telephone by either healthcare personnel (e.g. specialized HF nurses) or an automated telephone-based interactive response system. {40}

There is much that the patient and their family can do to monitor how well the heart failure syndrome is controlled. Professional monitoring should faciltate self-management, where patients adjust their therapy depending on the control of the HF failure recurrence. HF typically affects the elderly and their limited mobility and lack of social support may make hospital clinic attendance problematic. Remote monitoring (inlc. STS) has a role to widen access to care. After hospital discharge the patients in STS receive telephone calls initiated by nurse, aiming to educate, assess compliance with the medications, worsening of symptoms and signs of fluid retention. The nurses could adjust the medication over the phone or organize clinic appointments {100}.

Amongst CHF patients who have previously been admitted to hospital for this condition there is now good evidence that case management type interventions led by a HF specialist nurse reduces CHF related readmissions after 12 months follow up, all cause readmissions and all cause mortality. It is not possible to say what the optimal components of these case management type interventions are, however telephone follow up by the nurse specialist was a common component {68}. The limitation of STS is that the telephone calls are primarily initiated by the professional at preset times (usually protocol driven) and they are thus unable to detect more rapid changes in the condition.

In a RCT reported by Dunagan et al. {10}, patients in both UC and STS arms received educational material with information on the causes of HF, the basic principles of treatment, their role in routine care and monitoring of their condition, and appropriate strategies for managing a HF exacerbation. The intervention group received additional education from study nurses during scheduled telephone contact. During the telephone communication, nurses screened patients on HF exacerbations (administering also a screening instrument for this purpose), and also promoted self-management skills, appropriate diet and adherence to medications. Patients could contact the nurses in case they had questions or were experiencing exacerbation symptoms.

In the Trans-European Network–Home-Care Management System (TENS-HMS) study {9} patients in all arms were given an individualized written management plan that described what pharmacologic treatment they should receive, in what order, and how it should be monitored. The management plan focused on treatment of LV systolic dysfunction according to regional guidelines. For patients assigned to the Nurse Telephone Support, their management plan was sent to their primary care phycisian. In addition, they were contacted by telephone each month by a heart failure specialist nurse to assess their symptoms and current medication. The nurse could provide advice to the patient and feedback to the primary care provider.

In a matched cohort study conducted in the US {11} patients received a customised self-management intervention plan that included risk stratification; formal scheduled nurse education sessions; 24-hour access to a nurse counseling and symptom advice telephone line; printed action plans, workbooks, and individualized assessment letters; medication compliance reminders and vaccination reminders; and physician alerts about symptoms and signs of decompensation, as well as notification to physicians of gaps between patient-reported practice and guideline recommendations.

In HeartNetCare-HF study {200} initial personal contact between HF nurse and patient and his relatives/friends were made during the hospitalization due to HF. Patient would be invited to the education where self monitoring of blood pressure, heartbeat, weight and HF symptoms would be explained and practised. Patients were given materials and calender to monitor the symptoms. They were explained the STS programme and personal talk with HF nurse took place. The timing of the first call was defined at the moment of discharge. The STS had a clear structure and was prepared by cardiologist and clinical psychologist, the nurse was adequately educated on the matter. The call consisted of modules that were defined in advance and set script was followed, which was individually adjusted according to the responses of the patient. Modules for example were: medication, diet, physical activities etc. The results were statistically analysed after the call. The calls were placed 4 weeks after the hospitalization once a week, the length of the talk did not exceed 20 minutes and was documented. On the basis of the information the therapy was adapted and each week the doctor checked the results presented by nurse. Each week the nurses had a specific training with the cardiologist according to the problems that might have occured throughout the week {200}.

The frequencies of the calls and the length of STS support in months varies greatly among the studies. In a study by Kasper et al {240} telephone nurse coordinator and HF nurse placed telephone calls within 72 hours of discharge and then weekly for 1 month, twice in second month and monthly thereafter. Set script was followed. In Krumholz et al {240} nurse phoned patients weekly for 4 weeks, biweekly for 8 weeks and then monthly for total intervention for 1 year. In Galbreath et al study {2} initial call frequency was weekly, with a transition to monthly for the duration of the intervention (18 months). After each call, a call summary was faxed to the patient’s PCP. Information or orders from the PCP could likewise be faxed to the DM. In another study the patients were contacted three times the first week after discharge, and then weekly for 11 weeks (4 contacts over 3 months) {1}. In the study by Dunagan et al. the calls occured weekly for 2 weeks and then according to the patient’s need. By Riegel et al, the frequency of calls was determined by nurses using decision support software {230}. In the U.S. matched cohort study {11} patients were stratified in three categories (low, medium, high risk) and the frequency of scheduled telephone calls by nurses during the 12 month programme was decided on this basis: (low risk - 2 calls; medium risk - 7 calls, and high risk- 16 calls). In DIAL trial {100} the phone calls were made biweekly, after which the frequency was based on the nurse’s assessment of clinical need.

There is a dearth of evidence about how long patients should be supported by STS. It is possible that the greatest benefit in terms of education and medication patterns is accrued within a few weeks and that long-term monitoring is redundant {1180}.

Importance: Critical

Transferability: Completely

Result card for ORG3: "What kind of involvement has to be mobilized for patients/participants and important others?"

View full card

ORG3: What kind of involvement has to be mobilized for patients/participants and important others?

Method

Please find the overlapping results also in TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

Short Result

Please find the overlapping results also in TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

The activities in which patients and important other need to be included are one of utmost importance in STS. Without the preparation activities for self empowerment for the patients and important ones the STS would not be possible. The diagnosis of HF necessitates that patients and families develop self-care skills and adopt lifestyle changes that facilitate controlling symptoms and slowing the progressing of disorder.

The following training/ patient education aspects were adressed:

General heart failure education

- **detection of deterioration**
- **use of medication**
- **diet**
- **physcial activity/ exercise training**
- **Smoking cessation**

Telemonitoring specific training

- **training to use devices (technically)**
- **training to manage the information (empowerment and self-care), interpret the vital signals and efficiently utilize them**

Other training/ education

- **coping with difficult emotions**
- **relaxation and cognitive symptom management techniques**
- **lifestyle aspects: alcohol intake, sexual activity**
- **necessity of vaccinations**
- **capabilities of patients to travel or work**
- **coping with individual problems, often related to comorbid conditions**
- **training of relatives/ caregivers**

How is the training provided:

- **in groups of 10-15 people, where patients can assist and help each other**
- **through leaflets and online manuals, depending on the service**

- home visits
- videophone
- telephone calls or letters to the patient at home
- 1-hours, in-person patient education program with usual discharge care
- by technology through predischarge viewing of an educational CD-ROM
- video to be viewed at home
- predischarge nurse-led intensive education about HF symptoms and treatment followed by 1 telephone to reinforce education

Result

Please find the overlapping results also in TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

Importance: Critical

Transferability: Completely

Result card for ORG4: "What is the process ensuring proper education and training of the staff?"

View full card

ORG4: What is the process ensuring proper education and training of the staff?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain).A qualitative handsearch (google; keywords: structured telephone support, heart failure, telemedicine, telehealth consulting for professionals) was done adding further information for this question. The results are provided in descriptive way.

Short Result

Proper education and training of the staff is ensured through the courses for nurses on HF (formal HF certification) and on RM, which is assured by telemedicine providers in case any devices for home symptoms measurements are included. As far as the STS, no specific training were found to be offered to staff in the literature.

Result

Stork et al claim {200} that education of HF nurses is very important and was carried out at the University of Würzburg. The concept of training followed the strict standardized documented and verbal concept and the content concentrated on pain, sadness, depression and anger. All the modules used in STS calls with patients were worked through. All the contents was discussed with the cardiologists and phsychologist. The training was alo carried out later, at the place of STS provision, where the work of the nurses was supervised and the education was structured, based on discussion of weekly problems that might have arisen.

Nurses typically spend the most time with patients and can best evaluate educational needs as well as identify barriers to learning, and should therefore lead patient education efforts. Therefore, formal HF certification provides nurses with advanced knowledge and demonstrates their commitment to a higher level of care for their patients. In addition, it provides nurses with a sense of accomplishment as well as enhances personal credibility and accountability. Health system support for HF nurses to provide patient education should include {7}:

- Programs that enhance nurses' knowledge of HF self-care through a sound educational curriculum
- Encouragement for nurses to become HF certified
- Provision for adequate staffing that includes sufficient time for discharge teaching
- Evidence based/HF guideline-directed content for HF patient education curriculum
- Ability to provide multimodal education in several languages
- EMR for easy documentation of the education plan and evaluation of learning
- Models that integrate comprehensive patient education as part of overall HF management within a DM structure
- Provision for a multidisciplinary approach to patient education by those who are experts in HF care using nurses, physicians, pharmacists, social workers, dietitians, cardiac rehab specialists and other health care professionals.

As far as the STS itself is included (and not HF), no specific training were found to be offered to staff in the literature.

Browsing the official different telemedicine providers' websites, the following information were found:

The telemedicine providers offer the following to medical professionals {11}:

Consulting:

- Program support
  - Defining your program goals and metrics
  - Program scheduling, operational timeline and logistics planning
  - Inventory management (installation, deinstallation, and cleaning processes)
  - Clinical workflow and business process consulting
- Resource planning
  - Defining the right operational model for your program
  - Evaluating clinical readiness and measurements needed
- Clinical support
  - Defining patient selection criteria for telehealth
  - Patient stratification tools, including surveys on medication compliance, nutrition, depression, etc., to identify patients at risk for hospitalization
  - Reporting for program administrators and physicians
- Training and e-learning:
  - Online CEU courses and telehealth resources
  - Clinical staff education and training on telehealth devices, clinical and administrative software, protocols, best practices, and management of surveys
  - Patient education, user manuals, and training videos
  - Telehealth Certification Program to credential your clinical staff
  - Managed through regional field supervisors.

Importance: Critical

Transferability: Completely

Result card for ORG5: "What kind of co-operation and communication of activities have to be mobilised?"

View full card

ORG5: What kind of co-operation and communication of activities have to be mobilised?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain).. The results are provided in descriptive way.

Short Result

In the heart of communication and cooperation strategy in the studies there is always a nurse. A consistent nurse case manager who cares for the patient and connects family, tries to understand goals and specific outcomes, provides information and monitors patient and communicates and cooperates with other members of health team to help them understand the patient {240}. A published communication strategy is important. It should present patient support strategy, that includes communication between patient and nurse, patient and medical doctor, patient and pharmacist and also the brochures, diaries to record daily control measurements, web pages with disease information and with instructions as well as instructions for family members to share a best practise.

Result

RM through STS is a strategy that builds on a patient's self-monitoring. To be effective, self-monitoring requires the local HF service to be easily accessible to the patient and their family/carer. TM can be useful in this situation and patients may develop expertise through the timely feedback provided by monitored data and from the health professional contact {100}.

A published communication strategy is important, including patient support strategy, communication between patient: nurse, patient: medical doctor, patient: pharmacist, the brochures, diaries to record daily control measurements, web pages with disease information and with instructions, instructions for family members to share a best practise.

In the heart of communication and cooperation strategy in the studies there was always a nurse. A consistent nurse case manager who cares for the patient and connects family, tries to understand goals and specific outcomes, provides information and monitors patient and communicates and cooperates with other members of health team to help them understand the patient. She/he also coordinates services for the patient {240}.

In the matched cohort study of a disease-management heart failure program employing a structured telephonic nursing intervention {11}, communication between nurses (who made the telephone calls to patients) and phycisians and, between nurses and the health plans' case managers occurred usually after each scheduled patient call. In the communication between nurses an phycisians, communication took place via letters, facsimiles and telephone calls. The content of the communication included recommendations for further counseling topics or clarification of patient-reported information. Two-way communication was encouraged. In the comunication between nurses and the health plans' case managers, the communication aimed at resolving or enquiring on information on issues relating to the plan benefits such as durable medical equipment procurement, mental health visit coordination, transportation difficulties, or financial barriers to adhering to physician recommendations.

Findings from TRICARE's disease management programs for asthma, congestive heart failure, and diabetes patients suggest a program cordinated by a care manager {3}:

- an initial 40- to 50-minute baseline assessment by telephone with a care manager;
- monthly follow-up telephone calls to set goals, assess progress toward those goals, and educate patients about their conditions and self-management;
- educational materials specific to the patient's needs (eg, pamphlets, videos, cookbooks); and
- newsletters and Internet-based materials.

Importance: Critical

Transferability: Completely

Result card for ORG6: "How is the quality assurance and monitoring system of structured telephone support (STS) for adult patients with chronic heart failure organised?"

View full card

ORG6: How is the quality assurance and monitoring system of structured telephone support (STS) for adult patients with chronic heart failure organised?

Method

Please find the overlapping results in TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases?

Short Result

Please find the overlapping results in TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases?

The answer was created out of statements in eight of the included studies from the general literature search and an additional handsearch in google for more information.

The studies providing information about the staff qualification mainly contains information on:

- management according to a multidisciplinary/ physicians care plan
- provision of monitoring and reaction in case of abnormities by nurses

The results of the survey with 15 experts in Germany {70} provide a conclusive overview of Expected skills:

- methodological competence (analytical thinking, ability of reflexion, autonomy, linguistic, anamnestic competence, ability of abstraction, ability of reaction)

- social competence (empathy, communication skills, politeness, social sensitivity, authority, motivation skills, kindness)

- professionality (basic medical knowledge, secure technical skills, practical medical experience, knwoledge of basic health legislation, knowledge about the health system, psychological motivational skills, knowledge in quality management)

personal competence (self-knowledge, psychical capacity, steadiness, distress-resistancy, learning motivation, professional distance, IT-skills. The quality assurance seems to be lacking.

Structural quality:

- How telemonitoring or telemedicine is implemented and to whom varies (see also CUR and LEG domain).

Process quality:Marketing authorisation and licensing is partly provided (and discussed in CUR and LEG domains) and differs among health systems and continents. A regulative norm should be able to distinguish between technical and staff-related quality aspects. {15}

Result

Please find the overlapping results in TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases?

Importance: Critical

Transferability: Partially

Structure of health care system

Result card for ORG7: "What are the processes ensuring access to care of structured telephone support (STS) for adult patients with chronic heart failure for patients/participants?"

View full card

ORG7: What are the processes ensuring access to care of structured telephone support (STS) for adult patients with chronic heart failure for patients/participants?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain).A qualitative handsearch (google; keywords: structured telephone support, heart failure, telemedicine) was done adding further information for this question. The results are provided in descriptive way.

Short Result

In general, RM including STS provides greater access to care in geographical terms. In most of the studies the problems with accessability to phone line were not reported. Careful planning of STS is necessary among specific population that might have issues in moving around and having lower access to phone lines. Also, the number of telephone contacts per week should not be too high, not even in the first week as this may affect adherence. The problems might arise on the side of physicians as patients might relocate to more developed health care centres with remote monitoring programs posing financial risk for smaller providers.

Speaking in terms of financial accessability, no specific problems were mentioned on the side of the patient, although we must take into account that the literature is mostly reporting studies and less real time and location STS programs that would be reimbursed regularly by health care system. On the side of the provider, the current reimbursement structures basically do not support STS and hence act as a disincentive to providers wanting to offer RM including STS to patients sustaining HF. Innovative reimbursement schemes such as coverage with evidence in development are suggested in the literature.

Result

Programmes involving RM of patients, including TM and STS, offer the potential of improved access to specialist care for a larger number of patients across a larger geographical area compared to usual care {290}. RM may be of particular benefit to patients who have difficulty accessing specialised care because of geography, transport or infirmity {1280}.

All CHF patients for which STS is provided need access to phone line. In the TIM-HF study it was assured that patients had access to telephone {1150}. Inability to access the patient by telephone is an exclusion criterion in a study {30}. In a study {30} that took place in South Texas, where patients came from urban, suburban and rural settings (general real-world setting), there was no mentioning of access restriction due to phone line accessability. In Riegel's study of Hispanic patients {230}, the authors point out that nurses had difficulty reaching patients at various times during the follow-up period because they were moving among different households or travelling back to Mexico.

In a study {1} for all subjects assigned to the telephone groups, all intervention contacts were conducted using their personal telephone in their home. One reason for the fewer-than-expected contacts is that the study nurses sometimes found it difficult to schedule and complete the planned three contacts in the first week postdischarge. In the same study, some planned videophone contacts were replaced using telephone contacts due to technical issues, such as inability to connect by videophone or transitory problems with video resolution. Although a broadband Internet connection could minimize the problem of slow transmission rates, use of a computer adds a level of complexity that would deter many older patients from participating in this type of intervention. Furthermore, the monthly fee for the broadband services is an expense that some patients could not afford {1}. Based on the results of the subanalysis in a Tele-HF trial {270} it does not seem that interactive voice response technology is an appropriate strategy for comparison of clinical studies of remote monitoring for HF.

For designers and manufacturers, home health monitoring systems occupy a unique niche. As a result, as insurance reimbursement for home telemonitoring evolves, these devices are more cost-sensitive than most other medical devices {12}. The current reimbursement structure is a disincentive to providers wanting to offer DM services to HF patients. Today, physicians reimbursement remains a major concern with a lack of appropriate reimbursement in place in most countries worldwide and as a result limiting an increased use of evidence-based RM {120}. Today's cost containment pressure requires increased reimbursement effort with the burden of proof shifting to medical communities and manufacturers. Innovative reimbursement schemes such as coverage with evidence in development might be a viable option to overcome the current discrimination of RM reimbursement. Based on today's evidence in place, the utilization of RM should not be further limited by discriminative reimbursement policies but should be left to the decision making of doctors and patients to optimize individual patient care {120}. Although many providers and healthcare systems would like to offer DM services to patients with HF, current reimbursement can create a disincentive to provide DM interventions {1500}. The lack of reimbursment has been identified as a significant reason for the limited use of DM by providers. On the other hand, the cost of providing DM services such as additional clinical visits, patient education materials, or additional personnel time has not been well documented. {1500}.

Importance: Critical

Transferability: Completely

Process-related costs

Result card for ORG8: "What are the likely budget impacts of implementing the technologies being compared?"

View full card

ORG8: What are the likely budget impacts of implementing the technologies being compared?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain).The results are provided in descriptive way.

Short Result

While some studies reported {1} {2}{23} no statistically significant difference in healthcare costs (either total costs or all-cause hospital costs), other studies reported important and significant reductions in costs. While the average costs of intervention across the studies amounted from $23,6 to $443, the reported savings amounted from $30,9 to $536 per patient per month. The savings across studies were reported in various ways which makes them hardly comparable (percentage reduction in inpatient costs, percentage reduction in overall costs, percentage reduction in total health expenditures, reduction in different currencies per patient, per nurse, per year, per month, per 6 months...). However, more important than this is the method of costs calculation that varies widely across the studies. In most studies, only direct costs are included, mostly connected to reduction in hospitalizations. More than 70 % of the studies did not take into account expenses in one of the following categories: healthcare sector, other sectors, patient/family expenses or productivity losses. None of the studies analyzed a shift of cost, from specialits to HF nurse to GP, for instance. In 80 % of the studies the source and methods of the evaluations were not clear. Authors mostly focused on direct costs while omitting indirect (i.e., productivity gains and losses) and intangible costs (i.e., relief from pain, lost leisure time for patient or family) {310}. Principally, the costs were missing across majority of the studies and those of the intervention overheads, training of personnel, and patient related costs. There is a difficulty in capturing all of the effects of telehealth intervention. Thus the cost effectiveness evidence for specific implementations in the field of telehealth is limited. Problems with telehealth interventions reside in absence of quality data and appropriate measures. The quality of economic data is especially questionnable. The quality of evidence in the scientific literature is poor. More studies on all costs are needed to reach the unbiased conclusion.

Result

1 of the 16 studies on STS reviewed by Inglis et al. {130} reported the effect of the intervention on the cost of care. Two studies {2}{23} found no statistically significant difference in healthcare costs (either total costs or all-cause hospital costs) in a timeframe of 6-18 months. Three studies {24} {25} {26} reported reductions in cost (either cost per admission or overall reduction in healthcare costs). Results from RCTs where remote monitoring interventions were offered alongside existing services potentially underestimate the interventions' effectiveness and cost-effectiveness in comparison to integrating these services into existing ones {130}. In Wakefield et al {1} the differences in resource use (hospital stays, hospital days, emergency department visits) were not significant. Clark et al {1280} included 14 RCTs on STS or TM in a review. STS included monitoring of symptoms, medicine management, and education and counselling on lifestyle. In 4 studies the effect on cost per patient: in Riegel et al. {26} a 46% reduction in inpatient costs ($p<0,04$) was reported. The costs of intervention amounted to $443 per patient. In Laramee et al {24} $2.482 average reduction per patient was noticed – the costs amounted to $228,52 per patient. In Tsuyuki et al. {28} $2.531 cost reduction per patient was noticed. In Riegel et al. {23} no effect on cost of care were detected. The average costs of intervention in Barth et al. {28} amounted to $23,60 per patient.

Although HF DM improves the quality of care and decreases hospitalization for patients with HF (the primary driver of cost for HF care) in a number of studies, the impact on cost is less certain. Although many of the RCT of HM DM provided personnel costs, few included cost estimates for patients medications (increased utilization of medications), patient time, additional clinic visits potentially generated by the intervention, patient materials, and personnel training. Study of telephone follow up {1500} estimated that training involved 95 hours of personnel time at $ 26,51 per hour, training cost $ 2.518 per case manager. In addition, the increased surveillance of patients by interventions identifies a number of issues that may have gone undetected and subsequently increase physician time. One economic model of HF DM based in the United Kingdom, wich attempted to account for the cost of the interventions, changes in pharmacotherapy, and increases in clinic visits, estimated that 49.000 British pounds per year could be generated for each HF nurse hired to provide a HF DM intervention {1500}.

The study by Chen et al {13} was designed to assess the clinical effect of a home-based telephone intervention in Chinese heart failure patients. A total of 550 Chinese heart failure patients were enrolled into either (i) a group that received the usual standard of care (UC group); or (ii) a group that received a home-based heart failure centre management programme using nursing specialist-led telephone consultations (HFC group). The impact of the home-based intervention on medical costs over 6 months was measured {13}.

Table 2: Financial impact of the different types of follow-up care offered to patients with heart failure: usual

standard follow-up care (UC group) or the home-based Heart Failure Centre management

programme using nursing specialist-led telephone consultations (HFC group)

Financial measure	**UC group n = 275 (USD per patient)**	**HFC group n = 275 (USD per patient)**	**Change (%)**	**Statistical significance**
Out-patient cost, 6 months	321 + 354	510 + 424	+58,9 %	P < 0,001
Total cost of all-cause in-patient heart failure care, 6 months	8.280 + 14.446	5.479 + 12.547	-33,8 %	P = 0,02
Cost of in-patient heart failure care, 6 months	5.332 + 13.276	3.200 + 9.815	-40 %	P = 0,03
Cost of in-patient non-heart failure care, 6 months	2.948 + 7.588	2.279 + 8.446	-22,7 %	NS
Emergency department cost, 6 months	121 + 255	51 + 164	-58,1 %	P < 0,001
Total overall cost, 6 months	8.722 + 14.385	6.040 + 12.500	-30,8 %	P = 0,02
Total overall cost/month	1.454 + 2.397	1.006 + 2.083		
Data show mean + SD. NC not statistically significant (P > 0.005).				

The overall costs per patient for all-cause inpatient care and for in-patient care due to heart failure were both significantly lower for the HFC group compared with the UC group (P = 0,02 and P = 0,03, respectively) (Table 2). In contrast, the overall out-patient cost during the 6 months of follow-up was significantly higher per HFC patient compared with the cost per UC patient (P < 0,001). When considering all of the costs, despite having 58,9% higher out-patient care costs, the HFC home-based intervention still reduced the overall healthcare expenditure by 30,8% compared with the usual care programme.

Table 3: Univariate and multivariate analyses of the impact of disease management with the home-based

Heart Failure Centre management programme using nursing specialist-led telephone

consultations on clinical outcomes and healthcare costs in Chinese patients with heart failure

	Out-patient cost		Cost of all-cause in-patient care		Cost of heart failure in-patient care		Cost of in-patient non-heart failure care		Total overall cost	
	β	Statistical significance	β	Statistical significance	β	Statistical significance	β	Statistical significance	β	Statistical significance
Model 1	0,236	P < 0,001	-0,103	P = 0,016	-0,091	P = 0,033	-0,042	NS	-0,099	P = 0,020
Model 2	0,273	P < 0,001	-0,170	P = 0,001	-0,143	P = 0,004	-0,080	NS	-0,166	P = 0,001
Model 3	0,226	P < 0,001	-0,102	P = 0,043	-0,092	NS	-0,040	NS	-0,100	P = 0,048
NS, not statistically significant (P > 0,05) [a] Model 1, univariate analysis; model 2, multivariate analysis after adjusting for age, gender, left ventricular ejection fraction, coronary artery disease, hypertension, diabetes mellitus, hyperlipidaemia, and smoking; model 3, multivariate analysis as in model 2 but also adjusting for medication use (spironalactone, β-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, diuretics, statins and amiodarone).										

The present study demonstrated that a home-based intervention led by nursing specialists resulted in a significantly lower admission rate, shorter hospital stay and lower healthcare expenditure. This study demonstrated a mean cost saving of $ 448 per patient per month during the 6-month DM programme. The RM reduced the costs of the treatment of inpatients by reducing the duration and risk of hospitalization. However, they did not analyze the impact of patient's adherence on the cost of telemedicine {13}{250}.

In terms of the economic benefits, a meta analysis by Philips et al. {13} showed that a disease management programme saved $ 359 per patient per month in a non-USA trial, while this type of intervention saved $ 536 per patient per month in a study in the USA {13}.

A study {1000} was set up to estimate the cost-effectiveness of home TM or STS strategies versus UC for adults recently discharged (within 28 days) after a HF exacerbation in England and Wales. A Markov model was used to evaluate a) STS via human to machine (HM) interface, b) STS via human to human (HH) contact,

and c) TM, against d) UC. The results for base case monthly costs per patient were: GBP 27 for UC, GBP 119 for STS HM, GBP 179 for STS HH and GBP 175 for TM {1000}.

In a study by DeBusk and colleagues {15}, UC group of HF patients was compared to intervantion group who received physician-directed, nurse-managed home based program for HF, which included initial educational session, including a videotape, baseline telephone counselling session, nurse-initiated follow up telephone contacts, pharmacologic management and nurse initiated communication with physician. Nurse care managers spent an average of 9 hours per patient during the first year. No statistically significant difference between UC alone and UC supplemented with nurse management was found in the rate of rehospitalization or in the combined outcome of rehospitalization, emergency department visits, or death. This shows a high discrepany in findings and is probably due to the medical attributes of the study sample: other studies usually target high-risk patients whereas in DeBusk et al intervention was for a sample of HMO enrollees out of 5 medical centres in the northern California region, representative of 18 Kaiser Permanente facilities. The authors concluded that a specialized program for patients with mild HF may increase health costs without improving clinical outcomes, such as rehospitalization.

A summary based on a Cochrane review of 14 STS {16} was performed. All-cause hospitalization data were available for 11 STS studies, and STS was effective in reducing the rate of all-cause hospitalization in patients (p<0,02). STS was effective in reducing the hospitalizations for CHF (p<0,0001).One of six studies was significant in terms of reduction in length of stay. Nine studies presented costs for STS – the costs varied accordingly to intensity and technologies used. Studies that reported cost reduction in the cost of care per admission or overall costs reduction due to reduction in hospitalization reported cost savings ranging between 35% and 86%.

Klersy et al {1430} performed a meta analysis of 21 RCTs (5.715 patients). RM was associated with a significantly lower number of hospitalizations for HF, while LOS was not different. Direct costs for hospitalization for HF were approximated by DRG tariffs in Europe and North America. The difference in costs between RM and UC ranged from EUR 300 and EUR 1.000, favouring RM. Estimated costs ranged from 991,2 EUR to 3.207,96 EUR annually, depending on DRG reimbursement rate (from EUR 2.360 to EUR 7.638). A simulation study was performed on a hypothetical cohort of 100 patients observed for 1 year. The initial hypothesis assumed that all patients were treated to UC; then the proportion of these patients followed using an RM management strategy was progressively increased up to 50%. Due to a difference in incidence rate (assumed 0,42 for UC and 0,29 for RM) the adoption of RM strategy entailed a progressive and linear increase in payer/system costs saved. The study concludes that management of HF patients by RM is costs saving driven by a reduction in the number of HF hospitalization. No other costs (like costs of RM etc) or effects (less travel etc) are taken in to account. Authors conclude that the economic data collected in RCTs are scanty.

Analysis of total healthcare utilization as well as CHF-related healthcare utilization {2} showed that in no area, including drug use, office visits, emergency department visits, procedures, or hospitalizations, was there a decrease with the intervention. Moreover, total healthcare cost was not statistically different between groups. Total costs per patient were computed by summing the estimated costs for the 5 resource categories by the three 6-month study periods, and then summing these 3 totals.The costs of administering the intervention were not included. Total costs for 6 months amounted to $3.001,26 for control group and $3.277,05 for intervention group. The difference was not statistically significant. Galbreath et al {2} strongly suggests that widespread application of DM programs for all patients with CHF may have limited impact on healthcare costs. The lack of costs difference persisted even in patients with higher NYHA class, suggesting that the improved survival in sicker patients was not associated with cost savings.

DM will be most useful when there is a marked disparity between the best case management for a disease and the management that is being applied. Earlier DM trials were performed when use of guideline-based therapy was less prevalent that it is currently. In this study {2} 77% of patients were on an ACE inhibitor at the time of enrollment. The startling reductions in hospitalizations and healthcare costs reported by some earlier investigators may not be achievable at present. DM will be most useful when targeted to patients with worse functional class.

One of the latest study by Grustam et al {310} included 15 studies that described a telephone case management. More than 70 % of the studies did not take into account expenses in one of the following categories; healthcare sector, other sectors, patient/family expenses or productivity losses. As a positive example, Wennberg et al (25) estimated the total costs and not just the marginal cost: they included salaries and benefits, training expenses, amortized capital expenditures, data and coaching operations, fulfillment and overhead. None of the studies analyzed a shift of costs from specialist physicians to HF nurse to GP, for instance. In 80% of the studies the source and methods of the evaluations were not clear. Authors mostly focused on direct costs while omitting indirect and intangible costs. Principally, the costs were missing across majority of the studies and those of the intervention overheads, training of personnel, and patient related costs.

Importance: Critical

Transferability: Partially

Management

Result card for ORG9: "What management problems and opportunities are attached to structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

ORG9: What management problems and opportunities are attached to structured telephone support (STS) for adult patients with chronic heart failure?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain). A qualitative handsearch (google; keywords: structured telephone support, heart failure, telemedicine) was done adding further information for this question. The results are provided in descriptive way.

Short Result

The use of RM has improved as a possible way to improve the management of patients with HF by allowing more frequent assessment of patients without the need for FTF clinical reviews {100}. When planning the introduction of a RM intervention in general, there are several questions that need to be addressed concerning: the choice of patients targeted by these programmes; the parameters that will be monitored; the more efficient way to monitor them; the training of patients and healthcare personnel; how to organize the response of the health care professionals to data obtained from monitoring to optimize patient care {1430}{1}. Possibly management will need to deal with (de)employment of new resources, new information systems, new equipment for STS provisions, new administrative leadership and new group culture that promotes quality improvement {15}{40}.

Result

When planning the introduction of a RM intervention in general, there are several questions that need to be addressed concerning: the choice of patients targeted by these programmes; the parameters that will be monitored; the more efficient way to monitor the patients, the training of patients and healthcare personnel; how to organize the response of the health care professionals to data obtained from monitoring to optimize patient care {1430}{1}.

The use of RM has improved as a possible way to improve the management of patients with HF by allowing more frequent assessment of patients without the need for FTF clinical reviews. The technologies and decision systems used vary in their level of complexity. Monitoring can take many forms for a patient with HF: supported self-monitoring, clinic attendance, home visits or RM. Most modern services combine several different approaches, tailoring the care to the needs of the patient and family, and taking account of the local resources and expertise available in both primary and secondary care. Such a tailored approach, matching the model of care to the severity of the condition, is consistent with current healthcare policy in the developed world: most attention is focused on those with more complex needs (case management) built on a platform of good DM in general and with increasingly expert patients who are supported to self-care. {100}

Resources are required to enhance the management of chronic diseases including a clinical information system, a supportive clinical and administrative leadership and a group culture that promotes quality improvement. {15}.

Another parameter to be considered is the cost of the equipment that may be necessary to be purchased by the healthcare provider that is offering the STS programme (for example if the programme includes videophone communication). It can be rented or purchased with advantages and disadvantages in each case {40}.

Another consideration is that provision of these services requires a different approach to the organization of healthcare provision with redeployment of staff being more likely than an increase of the workforce {130}.

With any technology of remote monitoring, the issue of concern is the issue of security and privacy. There is also the question of how to bridge the patient-doctor gap that lies at the root of what telemonitoring strives to solve in the first place. How does one create a product that serves the needs of both the patient, as well as the medical professional, while still upholding a standard of privacy and security? {17}.

Telephonic programs, including the use of home monitoring equipment are the latest approach to improve outcomes for HF patients and several have had acceptable results. To meet this recognized need for improved quality for HF patients, a team of nurses designed a low-cost intervention that was comprehensive and geared toward those who would benefit most (older adults with more severe HF). It was created using the Quality-Caring Model to decrease hospitalization rates while maximize quality of life and satisfaction with services. The Quality-Caring Model indicates that independent (patient-provider) and collaborative (patient-healthcare team) relationships, grounded in specific caring factors, are the foundation for care. In the context of relationship-centered professional encounters, patients and families mutually interact with healthcare providers to advance health. Such relationships promote quality and benefit patients and families, providers, and systems {240}.

The survey results from one Canadian study {210} where clinicians were interviewed in order to expose management barriers and benefits they see from their perspective (Table 1). For example, additional human resources would be required at the clinic, such as a nurse practitioner, to carry out the STS program. Another concern was that there was no method of remuneration for phone interactions with their patients.

Table 1: Perceived benefits and barriers by clinicians {210}

Benefits	Clinical care improvement	Clinicians would be able to monitor their patients closely and would be provided with more information than they previously had to base their clinical decisions on. The information would be particularly useful for medication titration, and could help with false high blood pressure seen in clinic (ie. white coat syndrome). The alerts would be beneficial to inform them when their patients needed their help the most.
Benefits	Self-care improvement	Clinicians thought the system would help reinforce the instructions that were given to their patients in clinic (eg. following reduced salt and fluid intake). A lot of information is thrown at the patients and they probably don't get half of it, so STS can serve as a bit of a security blanket.
Benefits	Reduced clinic visits	Clinic visits by some patients could be reduced if they were closely monitored at home.
Barriers	System not suitable for all patients	Clinicians echoed the concerns expressed by the patients that some would have difficulty using the proposed monitoring system. In addition, they were concerned that patients predisposed to anxiety might not be suitable to use it.
Barriers	Clinical workflow challenges	Clinicians are too busy to respond to the alerts. They were concerned about managing the alerts 24/7, including when they were away on vacation. The most common suggestion was to have a nurse practitioner respond to the alerts. They also commented that there should be a way to financially reimburse physicians for calling patients.
Barriers	Medicolegal issues	There could be legal implications if clinicians did not respond to an alert immediately and the patient's health further deteriorated. They thought that a method to document their actions would be necessary for medicolegal reasons.
Barriers	Security/ privacy	The patient information must be secure, and appropriate technological measures must be taken to ensure patient confidentiality.

Importance: Important

Transferability: Partially

Result card for CUR3 / ORG10: "Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?"

View full card

CUR3 / ORG10: Who decides which people are eligible for structured telephone support (STS) for adult patients with chronic heart failure and on what basis?

Method

Three studies out of the basic literature search provided some information relating the selection of patients for telemonitoring.

Short Result

Three of the reviews reported eligibility and exclusion criteria for patients included in the studies, but there was no answer on who decides or who should decide to use telemedicine for what patient.

One could take the eligibility criteria used in the studies as a surrogate for the decision basis: clinical severity aspects, aspects of positive attitudes towards self-management, and criteria for acceptance and compliance. The used criteria within the studies are listed below.

Several exclusion criteria were used in the studies. Most commonly patients were excluded from the studies in case they:

-had a moderate or serious cognitive, visual, or physical disability {92};

-did not own a phone or who had a life expectancy measured in months rather than years {92};

-were discharged to a long term care facility {42};

-had some form of cognitive impairment or psychiatric disorder {42};

-had a terminal disease or severe co-morbidity {42}.

When determining eligibility criteria, it cannot be denied that some patients appear to benefit more than others. Several studies have suggested that the beneficial effects on state of health are observed mostly among patients:

-whose state of health is considered serious (e.g., the studies by Kwon et al {66} and Trappenberg et al {108}); in {92};

-who want to play an active role in the management of their illness (eg, the studies by Madsen et al {72}, Rickerby and Woodward {97}, DelliFraine and Dansky {18}, and Hopp et al {43}) in {92};

-who are interested in using this type of technological device (eg, the studies by Vähätalo et al {109}, and Madsen et al {72}) in {92};

-with a mean age varied between 56–86 years {42} or 59-82 years {25};

-with a proportion of men from 27–99 % among the studies {42} {25};

-with recorded baseline ejection fractions, with trial means varying from 22–43 % {42};

-with New York Heart Association functional class > II {50} {42} {25};

-with a proportion of patients with coronary artery disease or prior myocardial infarction (MI) ranged from 27 percent to 61 percent in most trials {25}.

In terms of the technology, important acceptance criteria are

-the user-friendliness of the device installed in the home and its nonintrusiveness in the lives of patients, particularly for the youngest patients {92};

-level of technological skill {92};

-level of education {92};

-professional constraints {92} ;

-lifestyle {92};

-having a visual or motor deficit {92}.

Eligibility to new technology depends on an assessment of the general practitioner of a patient’s condition and the patient's willingness and ability to participate. Access to new technologies depends on support of healthcare providers. In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patient is willing to incorporate these technologies into their care or patients at high-risk {40}. Having an access to a touchtone telephone is an essential inclusion criterion {1} . By Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

Result

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-with a mean age varied between 56–86 years {42} or 59-82 years {25};

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-level of technological skill {92};

-level of education {92};

-professional constraints {92} ;

-lifestyle {92};

-having a visual or motor deficit {92}.

Patient self management of chronic conditions, both the disease and the symptoms, is an aged practice that is accelerating and disseminating throughout the world, fueled in part by home-based and portable technologies. Ethically problematic assumptions have the potential to harm some patients and unnecessarily exclude others from self management. A new and higher standard than the current provider-based practice; that readiness to learn, literacy and intact cognitive function are frequently not essential to competent patient self management; that patients, however, are still excluded from it based on apparent defects in these characteristics; and that quality control standards for self management are essential but are not sufficiently rigorous. Barriers to improved outcomes from self management include the virtual absence of objective measures of patient competence to self manage, and of explicit, publicly available and well-argued descriptions of risk and benefit {1450}.

In clinical trials included the selection of patients was made by the researchers on the basis of specific inclusion criteria. For example, in all STS RCTs reviewed by Inglis et al {490}, having access to a touchtone telephone was an essential inclusion criterion. In a RCT of telephone or videophone communication vs. UC {1}, a Mini Mental Status Examination Score above a certain threshold and a phone line at home were among the inclusion criteria. In the clinical trial reported by Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patients are willing to incorporate these technologies into their care or, patients at high-risk could be a main target group for these programmes {40}.

Importance: Important

Transferability: Partially

Culture

Result card for ORG11: "How is structured telephone support (STS) for adult patients with chronic heart failure accepted?"

View full card

ORG11: How is structured telephone support (STS) for adult patients with chronic heart failure accepted?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain). A qualitative handsearch (google; keywords: structured telephone support, heart failure, telemedicine) was done adding further information for this question. The results are provided in descriptive way.

Short Result

Adherence to STS programs differs in HM to HH STS programs. It seems that interpersonal interaction with a care provider is an important active component of STS (adherence is higher in HH than HM STS) {40}. Adherence is reported from 55,1% to 84% across the studies, adaptation to the technology to 90% or higher, more than 90% of patients are statisfied with the use of technolgy. Acceptance of automated voice interactive system was poor, mostly due to technical failures. Patients were generally very satisfied with various STS programs across studies.

The clinicians, on the other hand, have several reservations, such as potential increased clinical workload, medicolegal issues, and worries of difficulty of use for some patients due to lack of visual acuity or manual dexterity. The clinicians believed that the telephone interactions is as effective as face-to-face interactions. The clinicians fear that system would result in a significant increase in their workload {91}.

Result

Acceptance by patients

Pandor et al. {40} included in their systematic review RCTs or observational cohort studies with a contemporaneous control group published from 1999 to January 2012 that evaluated TM or STS programmes compared with usual post-discharge multidisciplinary care for adults who have been recently discharged (within 28 days) from an acute care setting to home (including a relative's home, nursing home or residential care home) after a recent exacerbation of HF. They included 11 studies of STS: 10 used standard telephone equipment and HH contact and one provided support via an automated telephone interactive response system (HM) with an alert system. One study compared both STS and TM to usual care. Their review has overlaps with that of Inglis et al. {490}. In STS programmes regular scheduled telephone contact between patients and healthcare providers was performed usually on a weekly/monthly basis and incorporated telephone-based education and monitoring of signs and symptoms of worsening HF. Studies took place mostly in the US (8), one in Brazil, one in Canada and the rest took place in sites from Germany, Netherlands and the UK. Patient's mean age varied from 63y to 75y. Adherence rates for the interventions were reported in few studies. Adherence for STS programmes ranged from 55.1% to 84%. According to the authors, patient adherence could be related to the type of STS programme (HH or HM). In their review, the low (55%) adherence rate (i.e. use of the system 3 times/week) was observed in the study of HM STS programme (the Tele-HF trial) which could indicate that interpersonal interaction with a care provider is an important active component of STS. In the same trial, 14% of patients in the intervention arm never used the system {40} {960}.

Patient satisfaction was measured in few studies {40}, {490} in which satisfaction among STS patients was higher than among usual care patients ($p < 0.01$).

Inglis et al. {490} reviewed 16 studies of STS and 2 studies that involved both STS and TM as intervention arms. They included only RCTs that evaluated STS programmes compared with usual post-discharge care for adults who have been recently discharged from an acute care setting to home (including a relative's home but not including nursing home or convalescent homes) or have been recruited while managed in the community setting. One study {29} reported patient adherence with STS at 65.8%, adaptation to the technology was measured at 97% and total acceptability of the project as rated by the participants was 76.45%.

In a study by Wakefield et al. {1}, patient satisfaction was relatively high with both telephone and videophone communication. The interventions had high scores in items related to the technologies' potential to save both patients and the healthcare agencies time and money, patients' ability to use the equipment, and the interventions' level of convenience as a form of care provision and a possible addition to regular care. A limitation, however, of the study was the small number (28) of participants.

In a study by Clark et al {1280} only 2 trials on STS (out of 9) reported acceptability of the intervention. In Cleland et al (Ten-HMS study) {9} 4.1% of patients refused to accept technology in their homes, 2.9% of patients asked for equipment to be removed, and 1.8% discontinued recording. Overall patient acceptance was 91.2%. 96% of patients were well satisfied with the system and 97% found the devices easy to use. In Riegel et al. {26} patient satisfaction was significantly higher among people assigned to intervention group compared with UC group ($p<0.01$).

In TELE-HF study {1150} patients in intervention group were assigned to automated voice interactive system and were required to make daily reports on symptoms and weight. The compliance was poor as 14% of patients actually never used the system at all, a further 10% were non-compliant by the end of the first week and only 55% of patients used the system at least three times a week by the end of the study. Perhaps the study reflects the dislike of patients for voice interactive systems.

Holly {16} in her summary found that the adherence to treatment plans was reported in 65.8% of patients in STS groups (three studies). A few elderly patients were unable to adapt to the use of the technology. Adaptation was rated at 96-97% accross 5 studies. Patients were reported to be satisfied with receiving health care for CHF remotely via technology at 57-97% across all studies (14 STS, 9TM, 2 STS and TM).

The medium telephone was well accepted by most patients in a study by Störk et al {200}. It enabled private communication from home environment, but also remote discussion on personal issues. Less than 10% of the respondents withdrew their cooperation throughout the study.The adherence was high and the patients developed healthy life style due to the development of personal relationship between patient and HF nurse through STS exercise.

The objective of one Canadian study {210} was to assess the attitudes of heart failure patients and their health care providers from a heart function clinic in a large urban teaching hospital toward the use of mobile phone-based remote monitoring. A questionnaire regarding attitudes toward home monitoring and technology was administered to 100 heart failure patients (94/100 returned a completed questionnaire). Semi-structured interviews were also conducted with 20 heart failure patients and 16 clinicians to determine the perceived benefits and barriers to using mobile phone-based remote monitoring, as well as their willingness and ability to use the technology. The survey results indicated that the patients were very comfortable using mobile phones (mean rating 4.5, SD 0.6, on a five-point Likert scale), even more so than with using computers (mean 4.1, SD 1.1). Patients and clinicians were willing to use the system as long as several conditions were met, including providing a system that was easy to use with clear tangible benefits, maintaining good patient-provider communication, and not increasing clinical workload.

Acceptance by healthcare providers

In the study by Wakefield et al. {1}, nurses' satisfaction with both telephone and videophone interactions with the patients was high i.e. they believed that the interactions were both effective overall and as effective as face-to-face interactions, and believed that the patients were engaged in the procedure.

As telehealth provides greater access to care in more geographical markets, some physicians may feel financially threatened because patients will be able to access care from other sources, such as distant large health systems with sophisticated telehealth capacities {3}.

The objective of one Canadian study {210} was to assess the attitudes of heart failure patients and their health care providers from a heart function clinic in a large urban teaching hospital toward the use of mobile phone-based remote monitoring. Clinicians cited several barriers to implementation of such a system, including lack of remuneration for telephone interactions with patients and medicolegal implications. Furthermore, the clinicians thought that the proposed remote monitoring system could help them manage their patients' condition by providing timely alerts to worsening health and additional information about their patients that they would otherwise not have. They also believed that the monitoring system could improve their patients' self-care. The clinicians stated that they did not have further capacity to take on duties that would add to their already busy schedule.

One study described that telephone follow up with centralised call-in center addresses issues about the patient-physician relationship can be undermined or circumvented with telephone flow-up interventions. One study found that the lack of personal familiziation between the nurses who called the patients and the physicians involved in the direct care of the patients decreased the benefit of telephone follow-up interventions {1500}.

In a randomized, controlled clinical trial conducted in the U.S. {2} disease managers were employed by CorSolutions, Inc, which is an established DM company and was contracted for the study. A challenge that arised in such a setting was that physician did not welcome input from disease managers. A small number of potential patients for the trial withdrew from considering participation after they were advised by their physicians they should not enroll, some of whom stated they would no longer see the patient if the patient participated in DM.

Feedback from patients already using telemonitoring has been very positive. Here are some of the benefits they have experienced {19}:

- added peace of mind that their condition is being monitored;
- greater understanding of their condition and how to manage it;
- greater freedom to get on with their day-to-day lives without the fear that their condition is deteriorating;
- less risk of unplanned admissions to hospital;
- less need to have contact with a clinician if their condition is stable;
- reduced anxiety for their carers and family.

Importance: Critical

Transferability: Completely

Result card for ORG12: "How are the other interest groups taken into account in the planning / implementation of structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

ORG12: How are the other interest groups taken into account in the planning / implementation of structured telephone support (STS) for adult patients with chronic heart failure?

Method

To answer the questions in the assessment elements we mainly used the basic literature search provided for the whole project. Additionally, two more systematic searches were used: one performed by ORG and ECO domains (described in methodology of ECO domain) and one perfomed by EFF, SAF and ECO domains (described in SAF domain). A qualitative handsearch (google; keywords: structured telephone support, heart failure, telemedicine) was done adding further information for this question. The results are provided in descriptive way.

Short Result

No other interest groups except those mentioned in other assessment elements, are taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases.

Result

No other interest groups except those mentioned in other assessment elements, are taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases.

Importance: Optional

Transferability: Completely

Discussion

ORG1: How does Telemonitoring in home care for patients with chronic cardiovascular diseases affect the current work processes?

As most of the studies are conducted in controlled academic environment or non realistic setting, it might be that additional option should be considered in real setting, like hiring a nurse, use of low cost telephone service, use more time for outcomes dissemination and results discussion in a team. STS can be carried out in very different settings, from primary care to tertiary care. There is little information in the studies on the changes of the workflow – usually for the STS an additional nurse was used who had access to patient data, carried out the STS, monitored the patient, recorded the symptoms and data and reinforced and adapted the plan of care for the patient. The other medical professions did not get involved in STS directly, only indirectly, through the STS nurse, who coordinated all the activities and services around the patient. No study specifically recorded the (decrease or increase of) workload for other specialists in case a STS nurse was involved in the work. One study {6} describes how to manage human resources and the division of roles between nurses. During the 2007 calendar year, there were 1.356 patients visits to the HF clinic and telephone calls accounted for an additional 1.914 patient encounters in 2007. One full-time nurse practitioner, one clinical nurse specialist (working 0,7 of a full-time equivalent), and one registered nurse (vacation replacement) provided the nursing interventions with the telephone visits. Nurse spent 24 % of their working hours doing 1.914 telephone calls in one year.

ORG 2: What kind of patient/participant flow is associated with Telemonitoring in home care for patients with chronic cardiovascular diseases?

STS replaced historical program of doctor’s visits for HF patients after discharge. In interventions utilizing STS, the patient is monitored remotely while being at home (including a relative’s home, nursing home or residential care home). The patients are contacted in regular time intervals via telephone by either healthcare personnel (e.g. specialized HF nurses) or an automated telephone-based interactive response system. The STS support starts being planned while the patient is in hospital through education and meeting with the HF nurse. Education and practising with the technology follows and the materials are given to the patients as well as explained to the relatives. At the point of discharge the timing of the first call is agreed. The frequency of calls varies greatly among the studies but in common the calls are weekly at

least first two weeks after discharge and then get biweekly until two months after discharge. After that they become monthly. It is not clear how long the intervention should last: there are different periods, going from 3 months up to 2 years after the discharge. It is not clear when the effect is biggest, possibly within first 3 months.

ORG3: What kind of involvement has to be mobilized for patients/participants and important others?

Please find the overlapping results also in TEC3: What kind of training and information should be provided for the patient who uses Telemonitoring in home care for patients with chronic cardiovascular diseases, or for his family?

ORG4: What is the process ensuring proper education and training of the staff?

Proper education and training of the staff is ensured through the courses for nurses on HF (formal HF certification) and on the remote monitoring, which is assured by telemedicine providers in case any devices for home symptoms measurements are included. As far as the STS itself, no specific training were found to be offered to staff in the literature.

ORG5: What kind of co-operation and communication of activities have to be mobilised?

In the heart of communication and cooperation strategy in the studies there is always a nurse. A consistent nurse case manager who cares for the patient and connects family, tries to understand goals and specific outcomes, provides information and monitors patient and communicates and cooperates with other members of health team to help them understand the patient {240}. A published communication strategy is important, including patient support strategy, communication between patient: nurse, patient: medical doctor, patient: pharmacist, the brochures, diaries to record daily control measurements, web pages with disease information and with instructions, instructions for family members to share a best practise.

ORG6: How is the quality assurance and monitoring system of Telemonitoring in home care for patients with chronic cardiovascular diseases organised?

Please find the overlapping results in TEC2: What kind of qualification and quality assurance processes are needed for the use or maintenance of Telemonitoring in home care for patients with chronic cardiovascular diseases***?***

ORG7: What are the processes ensuring access to care of Telemonitoring in home care for patients with chronic cardiovascular diseases for patients/participants?

In general, RM including STS provides greater access to care in geographical terms. In most of the studies the problems with accessability to phone line were not reported. Careful planning of STS is necessary among specific population that might have issues in moving around and having lower access to phone lines. Also, the number of telephone contacts per week should not be too high, not even in the first week as this may affect adherence. The problems might arise on the side of physicians as patients might relocate to more developed health care centres with remote monitoring programs posing financial risk for smaller providers.

Speaking in terms of financial accessability, no specific problems were mentioned on the side of the patient. On the side of the provider, the current reimbursement structures basically do not support STS and hence act as a disincentive to providers wanting to offer RM incl. STS to patients sustaining HF. Innovative reimbursement schemes such as coverage with evidence in development are suggested in the literature.

ORG8: What are the likely budget impacts of implementing the technologies being compared?

While some studies reported {2} no statistically significant difference in healthcare costs (either total costs or all-cause hospital costs), other studies reported important and significant reductions in costs. While the average costs of intervention across the studies amounted from $23,6 to $443, the reported savings amounted from $30,9 to $536 per patient per month. The savings across studies were reported in various ways which makes them hardly comparable (percentage reduction in inpatient costs, percentage reduction in overall costs, percentage reduction in total health expenditures, reduction in different currencies per patient, per nurse, per year, per month, per 6 months...). However, more important than this is the method of costs calculation that varies widely across the studies. More or less, only direct costs are included, mostly connected to reduction in hospitalizations. More than 70 % of the studies did not take into account expenses in one of the following categories: healthcare sector, other sectors, patient/family expenses or productivity losses. None of the studies analyzed a shift of cost, from specialits to HF nurse to GP, for instance. In 80% of the studies the source and methods of the evaluations were not clear. Authors mostly focused on direct costs while omitting indirect and intangible costs {310}. Principally, the costs were missing across majority of the studies and those of the intervention overheads, training of personnel, and patient related costs. There is a difficulty in capturing all of the effects of telehealth intervention. Thus the cost effectiveness evidence for specific implementations in the field of telehealth is limited. Problems with telehealth interventions reside in absence of quality data and appropriate measures. The quality of economic data is especially questionnable. The quality of evidence in the scientific literature is poor. More studies on all costs are needed to reach the unbiased conclusion.

ORG9: What management problems and opportunities are attached to Telemonitoring in home care for patients with chronic cardiovascular diseases?

The use of RM has improved as a possible way to improve the management of patients with HF by allowing more frequent assessment of patients without the need for FTF clinical reviews {100}. When planning the introduction of a RM intervention in general, there are several questions that need to be addressed concerning: the choice of patients targeted by these programmes; the parameters that will be monitored; the more efficient way to monitor them; the training of patients and healthcare personnel; how to organize the response of the health care professionals to data obtained from monitoring to optimize patient care {1430}{1}. Possibly management will need to deal with (de)employment of new resources, new information systems, new equipment for STS provisions, new administrative leadership and new group culture that promotes quality improvement {15}{40}.

CUR3 / ORG10: Who decides which people are eligible for Telemonitoring in home care for patients with chronic cardiovascular diseases and on what basis?

Eligibility to new technology depends on an assessment of the general practitioner of a patient’s condition and the patient's willingness and ability to participate. Access to new technologies depends on support of healthcare providers. In real-world settings, patient selection will be critical for the acceptance and compliance with the programme. Patient selection criteria might include the degree to which the patient is willing to incorporate these technologies into their care or patients at high-risk {40}. Having an access to a touchtone telephone is an essential inclusion criterion {1} . By Dunagan et al {10} cognitive or psychologic impairment as well as inability to hear and understand English spoken over the telephone were included as non-eligibility criteria.

ORG11: How is Telemonitoring in home care for patients with chronic cardiovascular diseases accepted?

Adherence to STS programs differs in HM to HH STS programs, it seems that interpersonal interaction with a care provider is an important active component of STS (adherence is higher in HH than HM STS) {40}. Adherence is reported from 55,1% to 84% across the studies, adaptation to the technology to 90% or higher, more than 90% of patietns are statisfied with the use of technolgy. Acceptance of automated voice interactive system was poor, mostly due to technical failures. Patients were generally very satisfied with various STS programs across studies.

The clinicians, on the other hand, have several reservations, such as potential increased clinical workload, medicolegal issues, and worries of difficulty of use for some patients due to lack of visual acuity or manual dexterity. The clinicians believed that the telephone interactions is as effective as face-to-face interactions. The clinicians fear that system would result in a significant increase in their workload {91}.

ORG12: How are the other interest groups taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases?

No other interest groups except those mentioned in other assessment elements, are taken into account in the planning / implementation of Telemonitoring in home care for patients with chronic cardiovascular diseases.

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Social aspects

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Summary

The aspects related to patients' quality of life and satisfaction with STS, patients' views, perceptions and probable improvements in self care allowed by the use of this intervention, are an important part of the success of this technology.

In the studies where quality of life (QoL) is measured with standardised instruments, there is a significant improvement of QoL in the intervention group or no difference between the usual care and the intervention. Pandor's systematic review shows that 4 studies which had quality of life as a secondary outcome and where about STS, reported improvements in QoL, with significant improvements in physical [Angermann, 2011] and overall [Barth, 2001, Wakefiled, 2008] measures, but one study found no significant differences between the groups [Riegel, 2006]. Oher (primary) studies we selected gave scattered results. Dunagan et al. 2005 found that nurse-administered, telephone-based disease management intervention had some impact on functional status and quality of life. Piotrowicz et al. 2015 found that the in the intervention group there was a similar improvement in total QoL index as in the control group. Patients who underwent home-based tele rehabilitation observed an improvement mainly in the mental categories. On the other hand Ramachandran et al, 2007 found and increase in quality of life, as a whole and in many dimensions the intervention group that persisted over time. For Jerant 2003 telenursing at least did not have any large negative impact on patient satisfaction or health status. In the study by Boyne et al. 2014 authors conclusions says that tailored telemonitoring was found to educate patients with HF and to improve their self-care abilities and sense of self-efficacy. Domingues and collegues state that in thier study (2011) the educational nursing intervention performed during the hospitalization period brought improved knowledge of HF and self-care in all patients regardless of telephone contac.

The organisational differences among the variuos STS interventions in the selected studies (programs offering exercise, education and behavioral interventions on patients' psychological outcomes, or monitoring systems of vital signs led by nurses or physician etc.) can help to explain those differences in findings and results and make trasferability and comparability of them difficoult.

To have a deeper understanding about how patients experience the care when it is moved outside of the hospital to their homes with the support of STS, we also selected qualitative studies which allow to highlight perceptions of patients about complex interventions. From this perspective selected qualitative studies show that there can be positive and negative aspects in using telemedicine and its application such as STS. Lynga et al. 2013 interviews to patients who used the intervention showed, that the technology was easy to perform, made patients active in their own care, and increased their self-care activities. However, there were concerns of potential deterioration: transmission of body weight reminded patients of illness, deterioration in their health, increase of diuretic dose (inconvenience in the patient's daily life) and some experienced also a perception of fear that affected their psychological well being.

As regard tro the barriers to the use of the technology, digital divide related to the age or socio-economical status which could avoid patients to use the facilities related to the intervention, we could not retrive definitive and conclusive studies. The qualitative literature that gave an answer to this reaserch question would show digital divide due to age as not being a relevant problem. Seto et al. shows that relatives of those not technology-accustomed would be able to provide support to patient [Seto 2012]. Bond, 2014 finds that most people found the telehealth system easy to use and in the study of Prescher, 2013 most of the patients reported an easy and robust handling of the devices. Nontheless more quantitative studies about the influence of age, gender etc. on the use of STS should be developed to better understand implications of thoses macrosocial variables on the use of STS.

Introduction

Structured telephone support for adult patients with chronic heart failure is an application of telemedicine whose results largely depend on the patients acceptance of this different way of caring for their disease. Its characteristics, such as the indirect or at distance contact that the health professional has with the patient, mediated by the telephone, which does not allow a personal face to face visit, can be seen at the same time as a positive or a negative factor, this depending on the patient's preference. In turn this preference and acceptance can be related to macro social variables as gender, age, literacy, ethnicity etc. and on the patients' own psychlogical structure and personal/social/familiy life.

HF Patients who are telemonitored via STS could positively modify their perceptions of quality of life (both social life and individual well being, by e.g. reducing anxiety and feeling more secure) and their self-care behaviors such as obtaining daily weights, doing physical activity, eating a low salt diet, and being in compliance with medication regimes. Those two aspects can be seen as strictly related according to some authors. Indeed the decrease in QoL for HF patients has been associated mainly to the frequent hospital admissions and this imposes the most relevant personal, social and economic burden [Ferrante et al. 2010]. Since hospital admissions are mainly due to preventable causes (diet, treatment concompliance, inappropriate social support, delayed medical consultation for symptom sof HF progessions) any interventions like telephone support that aim to affect thoses prevenatable causes by enhancing self care behaviors can also enhance quality of life. Quality of life is determined by different components, at individual level and at social level. Anxiety, well being, feeling more secure and monitored, being able to have normal social reletionship at familial, work and firendships level, experiencing a better mental and physical health thanks to any interventions, are some of the aspects that will be analysed in this domain.

According to Paradis et al. 2010 the theory of HF Self-care grounded on the principles that patients are the main actors in health decision making and that they should have the tools to manage their health problems, is based on 3 concepts: the concept of self-care maintenance, which includes symptom monitoring and treatment adherence; the concept of self-care management, which includes symptom recognition and evaluation and treatment initiation and evaluation; and the concept of self-care confidence, which is the patients' perceived capacity to perform self-care. According to the theory, maintenance of self-care will lead to management of self-care, and these two processes will be facilitated if the patient has confidence in performing self-care behaviors. Thus, improving HF patients' conviction and confidence in their self-care capabilities by education, information and STS monitoring, could improve their health.

Including this isues of this domain in the HTA on STS is thus relevant as patient-reported outcomes are to be considered, being integral part of the succes of the technology. What is generally called patient satisfaction is in itself an indicator of quality of care and, e.g., in terms of cost-benefit a satisfied patient can have fewer complaints, fewer second opinions, and fewer repeated investigations, this affecting patients' adherence to medical treatment regimens [Kraii et al. 2011]. Those aspects related to the patients quality of life with STS and its acceptance and views about it, and the comfort with a program of selfcare and information delivered (training program, check of vital signs etc.) are thus the focus of this chapter.

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices
Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home)

	Description Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
H0006	Individual	How do patients, citizens and the important others using the technology react and act upon the technology?	yes	How adult patients with CHF (and their important others) who uses Structured telephone support (STS) react and act upon this technology and how this affects their satisfaction, quality of life, empowerment?
H0004	Individual	What kind of changes may the use of the technology generate in the individual's role in the major life areas?	yes	What kind of changes may the use of Structured telephone support (STS) generate in the patients' social life (changes in work, travel ability, family life, patient/physician relationship)
H0012	Individual	Are there factors that could prevent a group or persons to participate?	yes	Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?
H0003	Individual	What kind of support and resources are needed for the patient or citizen as the technology is introduced?	yes	What kind of support and resources (e.g. ergonomic changes) are needed for the patient as STS is introduced? This imlies a descriptive response.
H0100	Individual	What kind of changes do patients or citizens expect?	no	Selection of H0006 is enough as it includes this question
H0002	Individual	Who are the important others that may be affected, in addition to the individual using the technology?	no	This question just implies for investigators of SOC to list the probable important other that can be affected. This is something that is preliminary when answering to H0006.
H0007	Information exchange	What is the knowledge and understanding of the technology in patients and citizens?	yes	What is the knowledge and understanding of Structured telephone support (STS) in CCD patients?
H0013	Information exchange	What are the social obstacles or prospects in the communication about the technology?	no	Selection of AE H0007 is enough
H0001	Major life areas	Which social areas does the use of the technology influence?	no	This AE is important, but subsumable in H0004. So we exclude this as we alredy selected the H0004. Experinece with the production of other core hTA suggests that it is better to stay strict in the selection of AEs, since at the end of the work you usually find many INTRA domain overlaps.
H0011	Major life areas	What kinds of reactions and consequences can the introduction of the technology cause at the overall societal level?	no	I would stay more focused on the effects of the STS on the CHF patients and important others, and would not deal with overall society/citizens perspective. That is a perspective of people which is not involved in the actual use of this technology.
H0009	Major life areas	What influences patients' or citizens' decisions to use the technology?	no	By selecting AE H0001-H0006-H0012 and H0007 we alreday try to answer to this question (which is very generic) in a more detailed manner (individual/familial/social factors and factors releted to communication/information that can influence the use of STS).

Methodology description

A review of the literature about structured telephone support and the quality of life, self care, emopowerment, acceptance and impact of gender, age, etc. was performed. We aimed at identifying, first good quality secondary literature (HTA reports, quantitative or qualitative systematic reviews) that included the above outcomes and that could be updated. In the absence of existing reviews we identified primary studies, both qualitative and quantitative.

Information sources

Searches have been run on: Medline, Embase, Cochrane Library, PsycoINFO, CINAHL, CRD database. We searched articles in English published from 1995 to 2015 (see Appendix 1 for the Search Strategy). We retrieved 497 references, 17 were doubles We excluded 394 articles on the basis of the abstract and selected 78 studies for the full text reading. Records were read and excluded in double.

Inclusion criteria

We included studies about individuals aged 16 or more with chronic heart failure who have been admitted to hospital at least once for chronic heart failure (excluding recipients of implantable cardiac defibrillators, CRTs or pacemakers), that focussed on structured telephone support and had as an outcome the following domain specific outcomes: patients preferences, views, satisfaction, acceptance, adaptation, adherence, compliance, quality of life, worries, anxiety, confidence,work/family/social life, effect of ethnicity/gender/social and economic status/working status/urban–rural areas on the use of the technology, patient-physician communication/information.

Study Designs

We aimed at including systematic reviews (quantitative) on quality of life with STS and qualitative systematic reviews on patients perceptions/views. We selected primary studies with a quantitative design to update and/or integrate the retrived systematic reviews and selected the relevant qualitative studies for the qualitative part. After the full text reading of the selected articles we excluded 33 studies for the following reasons 1) not our population (5) 2) not our intervention (17) 3) not our outcomes (6) 4) opinions/case/protocols (3) 5) Not in english/not available (2) (see Appendix 2). Studies eventually included were 34 (see Appendix 3. In applying the above general inclusion criteria we needed to be more strict in case of some assessment elements which implied a quantitative response, and less strict (e.g. in the study design) for those assessment elements that allowed more descriptive answers (e.g. reasoning by analogy for tecnhnology and include not comparative study designs etc.). This has been explained in the methods section of each AE's results card.

Quality assessment tools or criteria

We used the quality checklists AMSTAR for systematic reviews, the CONSORT for RCTs, STROBE for observational studies and the Cochrane guidance for assessments for qualitative studies. See Appendix 4 for the included studies' quality assessment.

Analysis and synthesis

For each AE's Results card we gave a qualitative report of the main results of the included secondary and primarty studies that provided an answer to it.

Result cards

Individual

Result card for SOC1: "How adult patients with CHF (and their important others) who uses Structured telephone support (STS) react and act upon this technology and how this affects their satisfaction, quality of life, empowerment?"

View full card

SOC1: How adult patients with CHF (and their important others) who uses Structured telephone support (STS) react and act upon this technology and how this affects their satisfaction, quality of life, empowerment?

Method

Among the secondary literature retrived and selected as relevant, we identified the HTA by Pandor et al. 2013 and the Cochrane Colaboration Systematc Review by Inglis et al. 2010 (which updated the previous systematic review by Clarck et al.) to answer to this research question. This gave a quantitative answer based on studies that used a measurament of quality of life with standardised instruments. We reported the results of those sythesis studies, and added the results of other relevant quantitative primary studies which were not included in those systematic reviews, due to time of publication or because of the qualitative nature of their study design. Futher a synthsis of the qualitative studies that were selected as provided a ”qualitative” answer to assessent elements was also provided.

Short Result

	Main results
Synthsis lit. (HTA)	
Pandor et al. 2013	Four studies were on STS and 2 of them reported improvements in quality of life (Barth, 2001), (Wakefiled, 2008) measures in intervention group. One study found no significant differences between groups (Riegel, 2006). Angerman (2011) measured high adherence in inervention group.
Quantitative studies	
Piotrowicz, 2015	• Similar improvement in total QoL. Different in subscales: in intervention group had improvement in mental categories
Prescher, 2013	• Higher self-care in the intervention group
Domingues, 2011	• No difference between the two groups. Improved knowledge of HF and self-care in all patients regardless of telephone contact after discharge.
Ferrante, 2010	• Some improvement in compliance and selfcare in intevention group
Brandon et al. 2009	• Mean HRQOL had a positive significant change in intervention group. Self care ability impoved in intervention group.
Dunagan et al. 2005	• Modest but significant change in physical dimensions at 6 months
Jearnt, 2003	• Lack of difference between the two groups
Qualitative studies	
Lynga 2012	Patients’ interviews analysis showed that: • Intervention was perceived easy to perform, • Made patients with HF active in their own care, and increased their self-care activities. • Patients perceived that they were safer and well cared • Concerns of potential deterioration in HF related to weight gain
Riley JP, 2013	Patients’ interviews analysis showed that: • Telemonitoring was integrated it into everyday routines easily. • Became more knowledgeable about their heart failure. • Relationship with the telemonitoring nurse perceived a way of having a personalized and additional care.
Seto 2012 and 2010	Patients’ interviews analysis showed that : • Increased Self-Care • improved Knowledge of Heart Failure Condition • increased reassurance and a reduced Anxiety • Increased empowerment and confidence

Result

HTA reports

The HTA report by Pandor A, Thokala P, Gomersall T, et al. is the most recent and good quality secondary study we found as it was published in 2013 (searches of literature are until January 2012). This is about home telemonitoring or structured telephone support programs after recent discharge in patients with heart failure. The authors do not dedicate an ad hoc chapter to patients and families views on those technologies, but do consider quality of life as a secondary outcome in their review of clinical effectiveness (Chapter 3).

Pandor and collegues provide first a brief overview of the evidence from two already existing systematic reviews on remote monitoring programs (Inglis et al. 2008 and Klersy et al. 2009). The methodological quality of both systematic reviews is judged by Pandor to be high, this indicating low risk of bias. Pandor highlights that Klersy et al. did not consider quality of life and acceptability, while Inglis et al did. The latter identified all the studies published before 2008 by updating the previous Cochrane review on the same topic publishes by Clark et al. in 200. Inglis et al.'s review was published in 2010 and included RCTs comparing HF management strategies delivered via STS or TM with usual post-discharge care in HF patients recently discharged from an acute care setting to home or while managed in the community setting (interventions including home visits by professionals personnel for the purpose of education or clinical assessment were excluded) published form 1995 to December 2008. Secondary outcomes included also QoL, and acceptability to patients with HF. Overall, 30 RCTs of STS and TM were identified (25 peer-reviewed publications and five abstracts). Of the 25 peer-reviewed studies, 16 evaluated STS which is the technology of our interest.

Pandor et al. updated this review and their literature searches identified 3060 citations. Of these, 6 RCTs met the inclusion criteria and were added to the 15 trials from the previous systematic reviews. No trials of cardiovascular implanted monitoring devices or observational studies met the inclusion criteria of the current review. Of these, 11 studies evaluated our STS (10 used standard telephone equipment using and one provided support via an automated telephone interactive response system (HM) with an alert system, nine studies assessed TM, and one study assessed both STS and TM compared with usual care. Almost all of the studies used different measures and devices as part of the STS and TM interventions.

Pandor's analysis highlights that quality of life was a secondary outcome measure in 8 of the 21 included studies. These were either a direct comparison between intervention and control groups at study conclusion or a comparison between baseline and study conclusion within the study arm. Since not all the studies included by Pandor were about STS, here after we will focus on describing just those studies that were on STS.

Among the above 8 studies which had quality of life as a secondary outcome, just 4 were on Structured Telephone Support. Three of them reported improvements in quality of life, with significant improvements in physical (p = 0.03) (Angermann, 2011) and overall (MLHFQ, p 0.001) (Barth, 2001), (Wakefiled, 2008) measures. One study found no significant differences between groups in either the MLHFQ or the EQ-5D measure (Riegel, 2006). Pandor's focuses also on the acceptability"and "patient satisfaction" for the systems and only 1 of the 4 studies about STS reported adherence (compliance) rates to the intervention (Angermann, 2011). Adherence was measured at 84.0% for STS by Angermann, 2011.

A range of psychometric measures were used including both generic and HF-specific measures:

- SF-36, 51 (Angermann, 2011).
- Minnesota Living with Heart Failure Questionnaire (MLHFQ) 72 (Barth, 2001), (Wakefiled, 2008).
- European Quality of Life-5 Dimensions (EQ-5D). (Riegel., 2006).

Primary studies

Quantitative studies

In our search we identified and selected 9 further studies that can add some information about quality of life with STS in our population, which were either published after January 2012 (Piotrowitz 2015; O'Neil, 2014; Prescher, 2013; Domigues, 2012) or were published before that date but were not retrived or included in Pandor's HTA (Seto 2010, Ferrante, 2010, Brandon 2009; Ramachadran, 2007 Dunagan, 2005; Jerant, 2003). A description of the main results about quality of life of those studies is reported below.

The prospective randomized controlled trial by Piotrowicz et al 2015 had as intervention the home-based telemonitored cardiac rehabilitation system while comparator was outpatient-based standard cardiac rehabilitation. It involved 131 patients: 56 were in standard care, while 75 had home-based telemonitored cardiac rehabilitation (HTCR). Satisfaction was measured via the Polish version of the Medical Outcome Survey Short Form 36 (SF-36) questionnaire. The vast majority of patients in both groups were satisfied with the support which they received during each training session. According to author this demonstrated that in heart failure patients HTCR provided a similar improvement in total QoL index as standard care (SCR). Yet it differed in QoL subscales. Patients who underwent home-based tele rehabilitation observed an improvement mainly in the mental categories. Patients in SCR Group improved their general physical well-being. There were no statistically significant differences between the groups regarding the improvement in total QoL index, PCS (physical component summary) score (PF- physical function, RP- role limitation caused by physical problems, BP- bodily pain) or MCS (mental component summary) score (MH- mental health, RE- role limitation caused by emotional problems, VT- vitality). Groups differed in terms of sense of GH (general health) and SF (social function). An improvement in SF (social function) was observed only in standard care Group. Both groups achieved significant improvement in total QoL index, PCS (physical component summary) score, MCS (mental component summary) score. In the subscales evaluating physical well-being, in SCR Group, improvement was observed in three (PF physical function, RP physical problems, BP bodily pain) out of four subscales. In comparison with the baseline examination findings, patients after trainings reported fewer PF restrains, found it less difficult to function socially because of better physical fitness and complained less of BP. HTCR patients improved in PCS in only one out of four subscales. They perceived their PF as better after rehabilitation. The other subscales (RP, BP, GH) did not change significantly. In the subscales assessing mental well-being, in SCR Group, an improvement was observed in three (SF mental health (MH), role limitation caused by emotional problems (RE), vitality (VT) out of four subscales. The results showed that SCR patients reported fewer limitations in their social functioning; moreover they had a better sense of mental health and vitality after rehabilitation completion. HTCR patients improved in MCS in two (MH, VT) out of four subscales after the rehabilitation cycle was completed. The role limitation caused by physical problems did not change significantly in both groups. There were no statistically significant differences between the groups regarding the improvement in total QoL index, PCS score (PF, RP, BP) or MCS score (MH, RE, VT). Groups differed in terms of sense of GH and SF. An improvement in SF was observed only in SCR Group. Cardiac rehabilitation did not have a significant effect on the sense of GH in both groups. The difference between the groups in the analysis is due to the fact that in terms of this parameter the groups differed before the beginning of the rehabilitation.

The study by Prescher et al 2013 has an observational design and does not have any control arm. Patients (n=710) underwent the Telemedical Interventional Monitoring in Heart Failure (TIM-HF). Of them 228 patients originally included answered a quality of life questionnaire (author do not explicit which kind of questionnaire was used). Of the surveyed patients, the 85,5% (n=195) declared to feel more confident in dealing with their disease than before. The additional information about their disease was considered as reasonable by the patients (86,6%; n=198). In the supplementary notes the patients emphasized that the program had given them safety and support in handling their chronic disease (n=17), especially by the monitoring and the contemporary feedback by the telemedical centers of their transmitted vital parameters. The daily 24h/7d accessability of the telemedical center was reported as important by the patients (84,6%, n=193). Only 5,7% (n=13) rated this opportunity as unimportant and 9,7% (n=22) rated this as neutral or did not answer this question.

The brasilian study by Domingues et al, 2011 is a randomized clinical trial. They study adult HF patients with left ventricle ejection fraction who could be contacted by telephone after discharge. Authors evaluated HF awareness through a standardized questionnaire which also included questions regarding self-care knowledge, which was answered during the hospitalization period and three months later. The HF patients were 120 of them just 58 had a telephone contact and were randomised in the Intervention group. The others became automatically the controls. For patients in the IG group contacts were made using phone calls and final interviews were conducted in both groups at end of the study. Forty-eight patients were assigned to the IG and 63 to the CG. Mean age (63 ± 13 years). Scores for HF and self-care knowledge were similar at baseline. Three months later, both groups showed significantly improved HF awareness and self-care knowledge scores (P<0.001). Other outcomes were similar. According to Domingues et al, results show that the educational nursing intervention performed during the hospitalization period brought about improved knowledge of HF and self-care in all patients, regardless of any telephone contact after their discharge from the hospital. There was no difference in the frequency of visits to the emergency room, rehospitalizations and deaths in the three-month period between the intervention and control groups.

Ferrante et al. 2010 is a follow up study of the DIAL study (Grancelli, et al. 2003) which aimed to monitor the long term results after a telephone intervention in HF pateints, some data can be found aboput compliance with therapy and if this increases after STS. In the original study (DIAL) patients had been assigned to the intervention group received an explanatory booklet at randomization and were followed up with a telephone intervention by specialized nurses. The objectives of the intervention were to improve diet and treatment compliance, to promote exercise, to regularly monitor symptoms, weight, and edema, and to promote early visits if signs of clinical deterioration were detected. Nurses could adjust diuretic dose and suggest unscheduled visits to the attending cardiologist. Patients were initially called every 14 days, and after the fourth call, the frequency could be adjusted according to the severity of each case and patient compliance. Subjects in the control group continued treatment with their cardiologist in the same manner as the intervention group, except for the phone calls and the explanatory. In Ferrante et al 2010, of 760 patients in the intervention group, 69(9.1%) did not improve compliance during the first 45 days, 296 (38.9%) improved only in 1 indicator (diet, weight control, or medication), 277 (36.4%) improved 2 indicators, and 118 (15.5%) improved in all 3 indicators. Overall, 82.8% improved in medication compliance, 40.7% improved in diet compliance, and 34.9% improved in daily weight control. Considering the primary end point after 3 years of follow-up, the cumulative incidence in the control group was 57.5% (n _ 436), 65.2% (n _ 45) in the intervention groups with no improvement in compliance, 57.4% (n _170) in the intervention group with improvement in indicator, 52.3% (n _ 145) in the intervention group with improvement in 2 indicators, and 53.4% (n _ 63) in the intervention group with improvement in all 3 compliance indicators (log-rank test p _ 0.041). Differences were more significant when admission for HF was considered as an end point: control group, 35.1%; intervention without improvement, 33.3%; with 1 indicator, 33.1%; with 2indicators, 27.1%; and with all 3 indicators, 17.8% (log-ranktest p _ 0.0009) . These differences persisted after being adjusted by other potential confounders in the Coxregression analyses (sex, age, New York Heart Association functional class, diabetes mellitus, previous admissions,chronic obstructive pulmonary disease, systolic dysfunction):the HR for the intervention group categorized by compliance versus the control group for HF admission according to compliance improvement were as follows: no improvement, HR: 0.91 (95% CI: 0.59 to 1.40, p _ 0.67); 1 indicator improvement, HR: 0.87 (95% CI: 0.69 to 1.10,p _ 0.25); 2 indicators improvement, HR: 0.71 (95% CI:0.55 to 0.92, p _ 0.012); and 3 indicators improvement,HR: 0.44 (95% CI: 0.28 to 0.69, p _ 0.001)..

Brandon et al study (2009) has a pretest–posttest experimental design in which participants were randomly assigned to either an experimental group, who would receive the APN (advanced practice nurses) led telephone intervention, or a control group, who would receive the usual care provided by their cardiologist. the results for the advanced practice nurses intervention on self-care behaviors revealed a significant interaction (p b .001), indicating that the intervention group improved significantly more than the control group. There was an improvement in the mean self-care behaviour scores for the intervention group whereas the control group's mean score did not change. The intervention group reported more improvement in overall Quality of Life, and the control group reported a decrease. The mean pretest score for total QoL for the intervention group was 52.1 and their posttest score for total QoL was 33.4, indicating an improvement in perceived QoL overall. The control group's pretest score for total QoL was a mean of 51.1 and the posttest score for total QoL was a mean of 57.7, suggesting a decrease in perceived QoL overall.. The results of the physical and emotional dimension score revealed no statistical signification between the groups, but with a slight trend for better values of the physical dimension for the intervention group. For the emotional dimension both groups reported significant improvement over time. Authors highlight that an interesting factor was that, among all participants, QoL was consistently poor for those ranked at Level III on the NYHA HF classification, and the Class III HF participants were the only participants in the intervention group who did not report an improvement in QOL upon posttesting (NYHA level IV has only 1 participant so this level could not be evaluated). The self-care ability improved from a relatively good level of 65% to a higher level of 88% in the intervention group.

The prospective, randomized clinical trial by Ramachandran et al, 2007 recruited 50 consecutive patients with heart failure in a clinic in India to assess the impact of a comprehensive telephone-based disease management programme on quality-of-life in patients with heart failure. The HRQOL was evaluated both subjectively and objectively at the end of the 6-month period (mean [SD]: 188 [12] days). It was assessed subjectively by scoring the KCCQ (Kansas City Cardiomyopathy Questionnaire), physical examination and NYHA class. Objective assessment was done by the 6-minute walk test. There was no significant change in the mean HRQOL score of the control group during the study period (62.2 [22.6] to 63.4 [21.9]; p=0.69). However, there was a significant change in the intervention group (60.0 [23.6] to 76.3 [17.3]; p<0.05, see (Fig. 2 from the study by Ramachandran et al, 2007). A part of the questionnaire assessed the patient's ability to carry out activities of daily living and strenuous activities. While there was no significant change in the control group (p=0.9), there was a significant change in the intervention group (baseline score 53.9 [21.3] v. follow up score63.3 [16.2]; p<0.05;). The symptom scores (assessing the frequency and severity of symptoms of heart failure) also showed a significant change in the intervention group (p<0.05) but no change in the control group. The difference in scores between the intervention and control groups at follow up was also significant (p=0.02). Another part of the questionnaire assessed the presence and degree of depression, and the interference caused by the disease in the social functioning of the patient. The control group showed no significant change (p=0.66) but the intervention group did (baseline score 49.3 [22.8] v.follow up score 64.5 [18.9];p<0.05). There was a significant difference in the scores of the two groups at follow up (p=0.001).See Table IV from the study by Ramachandran et al, 2007. Six-minute walk test. There was a difference in the results in the intervention group (p<0.02) but not in the control group (p=0.5).

Dunagan et al. 2005 RCT was performed in USA. Authors show that there were modest but statistically significant changes in physical functioning scores on both the SF-12 and the MLHF questionnaire at 6 months, but not at 12 months. Changes in scores for the SF-12 mental functioning scale, MLHFQ emotional health subscale, and BDI were not significantly different at 6 or 12 months. There were no significant differences between the groups in terms of changes in scores for any of the questions concerning patient satisfaction with care or confidence in their knowledge of and ability to manage their illness. They found that nurse-administered, telephone-based disease management intervention that included judicious use of “rescue” diuretic therapy and patient education about signs and symptoms of HF and self-monitoring, had minimal impact on changes in measures of functional status and quality of life.

(results continue in the "comment" section)

Comment

In the Jerant et al. study 2003, patients were randomised into three groups: usual care, video based telecare and just telephone care with scheduled calls by a nurse. All groups experienced slight reduction in MLHFQ scores, indicating less emotional and physical burden due to CHF after the intervention. Similarly, SF-36 mental component scores increased slightly for all groups during the intervention, indicating slightly improved mental health status, and SF-36 physical component scores also increased slightly for the telecare and telephone groups, indicating somewhat improved physical health status. However, none of the differences between the groups at either baseline or 60 days and non of the within group pre- and post- intervention differences were statistically significant. No clinically meaningful or statistically significant changes in CSQ scores for any of the groups occurred as a result of the intervention. Authors highlight that their study was probably not of adequate power to detect small differences in health status or satisfaction scores. The lack of significant differences in MLHFQ, SF-26 and CSQ scores between groups suggests that telenursing at least did not have any large negative impact on patient satisfaction or health status. It is also possible that the existing instrument we used to measure satisfaction and health status are not sensitive enough to detect differences in these outcomes due to varying the communication medium by which home nursing care is delivered. For example, in contrast to the lack of significant differences in measured health status and patient satisfaction between groups, the study nurse and several subjects informally commented that home telecare resulted in a greater feeling of “collectedness” and security than standard telephone calls. Therefore, health status and patient satisfaction measurement tools to evaluate the impact of differing processes of providing home nursing care should be developed and validated.

Qualitative studies

In their qualitative study (which was the qualitative part of an RCT, involving six centres in Sweden by Lyngaº et al., 2012. Authors developed a typology of the patients focussed on the different reactions to the telemonitoring system they could detect from interviews. Their aim was to describe how individuals in the group experienced and understood the TM. Patients in the intervention group were asked to weight themselves daily and measurements were automatically transmitted to an HF clinic. If a weight gain was detected the patients were contacted by telephone and asked questions based on the RCT study protocol. If there were signs of deterioration in the patients the dose of diuretics was temporally increased.

Authors interviewed 20 patients among the ones in the intervention group. The analysis of the interviews brought to identify five metaphoric categories of understanding the intervention.

- The habitual patient: this way of reacting contained perceptions that the transmission of BW and the daily weighting was easy to do and became a routine. The procedure was described as stressful because of concerns that they would forget to weigh themselves each morning; however, this was a temporary condition that transformed and turned into a routine.
- The concerned patient: described concern in relation to the transmission of BW. One perception that was described was the fear to forget to carry out the daily activity of weighing oneself as well as assuming that they did something
- The technical patient: patients had different experiences of the equipment. There were indications that when the system did not work as expected, the patients' enthusiasm decreased and they got weary of using the electronic scale.
- The secure patient: some patients felt to be looked after and a sense of security emerged. The patients had constant contact with the HF clinic and t healthcare professionals and was perceived as receiving good, being under a positive control
- the self-caring patient: patients described being active, wanting responsibility, and fully cooperating with the study nurses.

The authors conclude that the patients the intervention was easy to perform, made patients with HF active in their own care, and increased their self-care activities. Patients perceived that they were safe and well cared for and got a better understanding of their own bodies. However, there were concerns of potential deterioration in HF related to weight gain which should be considered in clinical care. However, there were concerns of potential deterioration in HF related to weight gain which should be considered in clinical care.

In the qualitative study by Riley JP et al 2013 authors aimed at exploring the extent to which telemonitoring in patients with heart failure empowers them to selfcare. Patients used a stand-alone telemonitoring system that required them to take measurements daily. They recorded physiological data using a weighing scale, automated blood pressure cuff and pulse oximeter. The telemonitoring equipment was connected to the normal home telephone line and the information was automatically transmitted to a secure base station for review by a cardiac trained nurse who triaged and responded to data indicative of clinical change. Riley interviews with 15 patients allowed mean age 74 to identify four key themes related to self-care: the experience of symptoms; use of the technology; heart failure self-care maintenance activities; and heart failure self-management. Patients in Riley's study were old, with more than 50% aged over 75 years (and more than 33% aged over 80 years). According to Riley's conclusions interviews showed that they used the telemonitoring daily and integrated it into their everyday routines easly, became more knowledgeable about their heart failure over the six month period of using telemonitoring but in this, according to Riley, what helped was the relationship with the telemonitoring nurse whom they perceived provided them with specific and personalized information. It emerged the importance of the relationship between the patient and telemonitoring nurse suggesting a possible role for telemonitoring in facilitating self-care but with the presence, also at the telephone, of a professional.

Two studies by Seto et al. published in 2010 and 2012, gave some insight on their patients' attitudes toward phone-based telemonitorinhg (2010) and later on their actual perceptions a with it (2012). In the first study about attitudes (that is patients did not yet experience the intervention), the willingness to use a mobile phone-based remote monitoring was under evaluation. Patients as a whole seemed to be confident in their ability to Use Mobile Phone-Based Remote Monitoring and when, knew they were not accustomed to the technology, stated that they would be able to receive help from family members (eg, their spouses and children). The interviews indicated that patients were comfortable using mobile phones and computers, and were confident that they could learn to look up health information on both mobile phones and computers. Most patients perceived that monitoring their weight and blood pressure was important to help manage their heart failure condition. Several interviewed patients volunteered and said they would be willing to try using the proposed remote monitoring system. Nontheless authors highlight that the remote monitoring system was acceptable under some conditions. Patients expressed their need to see it as something added to the relationship with their clinician at the heart function clinic, that is the system should not be a replacement of face to face interactions. More over patients would adhere to taking daily measurements long-term if they perceived clear tangible benefits and asked for the system to be as easy to use as possible and requested appropriate training and to get technical support if needed.

In the second study by Seto et al they interviewed patients after the actual use of the intervention. A perception of increased Self-Care emerged. The telemonitoring system enabled patients to appropriately modify their lifestyle behaviors (eg, salt and fluid restrictions, diuretic dose, and exercise). IT improved Awareness and Knowledge of Heart Failure Condition as Patients expressed becoming more aware of their heart failure condition and their own body, because they were taking their physiological measurements and symptoms daily. Patients expressed also feelings of an increased reassurance and a reduced substantial anxiety prior to using the telemonitoring system, especially those who were newly diagnosed or those who recently had an acute cardiac episode. Many patients referred to the telemonitoring system as a "security blanket" and it was "like almost having a doctor right beside you". Increased empowerment and confidence and self-care motivation were also another factors that according to Seto et al. came out from interviews. Patients expressed feelings of more in control, confident, and accountable, because they could directly observe the effects of their lifestyle choices on their health and become active participants in their own health. Authors conclude that patients did not want remote monitoring to result in a decrease in communication with health care providers, and thought that they would continue remote monitoring only if there were clear andtangible benefits to their doing so.

Importance: Important

Transferability: Partially

Result card for SOC2: "What kind of changes may the use of Structured telephone support (STS) generate in the patients' social life (changes in work, travel ability, family life, patient/physician relationship)"

View full card

SOC2: What kind of changes may the use of Structured telephone support (STS) generate in the patients' social life (changes in work, travel ability, family life, patient/physician relationship)

Method

We used the domain specific search (described above in the Domain Methodology section) including studies relevant to this outcomes but with no restriction of the study design and broader crtieria (technology, population). The results are given in a descriptive way summarising the text contents of the studies that gave information specifically on what kind of changes STS generate in the patients' social life.

Short Result

	Positive aspects in social life	Negative aspects in social life
Patient	Better daily routine [Martinez 2006] Continue to function in daily life [Cui 2013] Decreased travelling [Clark 2007] Got the daily weight measure easily into daily routine [Lynga 2013] Feeling secure with being monitored [Lynga 2013] [Bond 2014] Having immediate self-care and clinical feedback [Seto 2012]	Social isolation no contact with health professionals (Achelrod 2014)

Result

Reviews

In the Achelroad et al's review [Achelrod et al. 2014] The telemedical intervention with STS was a challenge for the patients' health literacy, especially for older ones, and was felt as social isolation due to not seeing a doctor anymore. The revieew by Martinez et al. [Martinez et al. 2006] shows that home monitoring in general, not STS, lead to a better daily routine for the HF patients thanks to continuous remote vital signs monitoring and adjustment of pharmacological treatment, dietary control, blood pressure balance.

Quantitative studies

In Cui et al.2013 the results of evaluating the *Health Lines program* (nurses were available on the telephone to provide suggestions about the patient's daily management of the disease) showed improvement in self-maintenance so that patients can continue to function in daily life (which include social relationship). One study [Clark 2007] reports about the satisfaction with the interaction between the nurse and the relatives or supportive others of the patients. This wider effect of the intervention is also described in other studies [Riegel et al. 2006]. Patients were also satisfied with the improved accessibility to specialist care and decreased travelling (reducing travel to healthcare services was a very important issue for our rural patients), which was discussed to be similar in the review of Mair &Whitten P. 2000. [Clark 2007]

Qualitative studies

Seto et al study showed that some patients had access to a computer and many already owned a mobile phone, but the others not technology-accustomed reported that they would be able to get support from their family members (eg, their spouses and children). Interviewed patients thought that older and less technologically experienced patients could have trouble operating the small buttons of a mobile phone, however, none of the interviewed patients thought that they themselves would have significant problems using the equipment this showing that they rely on their familial or important others relationship [Seto 2010].

Two years later Seto (2012) published a study with qualitative interviews of patients and concluded that mobile-phone based telemonitoring enabled patients to change their lifestyle behaviors in a positive manner, reduced anxiety and improved their quality of life. The major aspects were having immediate self-care and clinical feedback, being easy and quick to use, and providing tangible benefits to the end-users (ie, the patients). [Seto 2012]

In the qualitative evaluation of Bond (2014) also most people found the telehealth system (this was a computer equipment that automatically send data to healthprofessionals) easy to use. One group of patients were happy that the nurse could 'keep an eye' on them and intervene if necessary [Bond 2014].

Importance: Critical

Transferability: Partially

Result card for ETH11 / SOC3: "Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?"

View full card

ETH11 / SOC3: Are there socio cultural factors that could prevent a group CHF patients (defined by e.g. age, ethnicity, income, geographic area, working staus, geneder etc.) to use Structured telephone support (STS)?

Method

We used the domain specific search (described above in the Domain Methodology section) including studies relevant to thisoutcomes but with no restriction of the study design and broader criteria (technology, population) as evidence on that question was poor and scarce. The results are given in a descriptive way summarising the text contents of the studies that gave some information specifically on age, ethnicity, income, geographic area, working staus, gender etc. to use Structured telephone support (STS)?

Short Result

Age-related technical illiteracy, more severe health status, ethnic minority with language problems were find to be reported as possible barriers to access for telemonitoring. No primary study on STS was found to have as a primary outcome the realtionship among the use of STS and the above social variables. In some studies the participation to study- and control group showed differences in terms of income, employness, education or income status. For the being elderly barriers and age illiteracy it has been highlighted that common use of the new technologies such as the internet etc. started about 20 years ago and has rapidly spread among the

population so that in the future the elderly will more and more be less digitally illiterate, this allowing the age-barrier being less and less relevant. More studies focussed on understanding the actual existence and the effects of those barriers, are needed.

Result

1. Yes, as already mentioned, some ethnic groups (cultural or religious), though unlikely, might refuse such interference;
2. In rare cases there is a risk of damaging the socially disadvantaged segments of the population, leading in turn to a prerequisite for social discrimination by making telemedicine a potential new form of access discrimination;
3. In comorbid older patients, having more or slightly pronounced mental deficiency, handling smartphones would pose some difficulties due to the need of specific technical knowledge and skills. This technology may prove inaccessible to other groups, as well, particularly those with visual or auditory impairments.

From SOC Domain Team:

Primary studies

A lack of effect for the intervention could be the cohort of HF patients which is usually older and has a special experience with their nature of illness. These are not the baby boomers more experienced with technology and with more sophisticated means of monitoring their health as they age. [Schwarz 2008] In opposite to this the study of Lind [2014] asked for the experiences in using the telemonitoring structure for daily reporting of the health status and patients answered that they quickly were able to manage it and felt empowered and increased their own participation. Fourteen patients (11 men, mean/median age 84/83 years at inclusion) diagnosed with HF, NYHA class II-IV, with a median of two previous hospital admissions during the last 12 months were included in the study. Authors analysis of the interviews allowed to focus on the fact that technology in general, including computers and mobile phones, was regarded at the beginning as “not interesting” and “a bit scaring” but digital illiterate patients expressed admitted that they were going to miss a lot of information this way. During the study the patients began using new daily routines for the reporting of assessments and measurements, and they thought that handling the equipment digital pen was an easy task. According to Lind et al. the HF patients in their study had no experiences of using the internet but quickly accepted and managed to handle the digital pen technology for daily reporting of their health status, making them more empowered and increased their own participation. The study shows that, „given that technologies are tailored to specific patient groups, even “the digital illiterate” may use“ them. [Lind 2014].

In thier qualitative study Lynga et al. did a typology of the patients and linked their habitual status to the telehealth results. There were different ways in understanding the telemonitoring in a dominating or non-dominating way. The five women show a higher summary of points (1 or 2 crosses on table 1) in the habitual category than the 15 men (7/5 versus 12/15, respectively) leading to the assumption that they got the daily weight measure easily into daily routine.

The study of Seto [2010] mentioned the young average age of their study participants and the possible bias by positive attitudes towardas telehealth, „however, the participation refusal rate was very low, which suggests that the bias was minimal. Finally, the mobile phone-based remote monitoring system that was proposed to the participants had functionality that was beyond what is available in current best practice“. [Seto 2010]

Seto [2012] also mentioned the lack of continuity for telemonitoring patients going on vacation without bringing the monitoring equipment with them. On average, every phone call was associated with an increase in perceived health, indicating that the overall process was responsible for the improvement of participants’ health states. Considering the fact that there were significantly more contacts for participants with poorer initial perceived health, it was suspected that there is an effect of severity (NYHA stage) on the outcome variables. However, there wasn’t any evidence for a negative impact of NYHA status on participants’ development over the course of counseling. [Boehme 2012]. The study participants in the study of Brandon 2009 all (100%) had annual income levels < 20.000 $ (median income in this county = 30.952 $), were mainly (7/10 in the intervention group, 8/10 in the control group) high school (with or without degree) or lower level, only 30% of the participants had some college or postgraduate study. In the intervention group 70% were female. There was also an option for cardiac rehabilitation education after discharge from hospital only for those patients who had access to transportation. [Brandon 2009]

Importance: Important

Transferability: Partially

Result card for SOC4: "What kind of support and resources (e.g. ergonomic changes) are needed for the patient as STS is introduced? This imlies a descriptive response."

View full card

SOC4: What kind of support and resources (e.g. ergonomic changes) are needed for the patient as STS is introduced? This imlies a descriptive response.

Method

We used the domain specific search (described above in the Domain Methodology section), in a systematic review method, including studies relevant to the social outcomes, no restriction of the study design. The quality assessment is summarized for all included studies for the social domain in the appendix. The results are given in a descriptive way summarising the text contents of the studies

Short Result

Patients need

- Education
- Empowerment
- Technical introduction
- Tangible benefits from measuring

- Acceptance of the program/ system and trust in function
- Still contact to their physician
- Some programs need patients to already have the appropriate telephone devices and telephone lines

For health outcome

- Action has to be initiated (monitoring is no treatment effect)
- The more severely ill, the more phone calls are necessary and the lower the outcome

Unsolved issues

- institutional feasibility
- the appropriate support package which guarantees the expected outcome-results

Result

Systematic reviews

Remote monitoring is a part of a complex package of support which does not have any impact if no action is dictated. The whole package includes education and empowerment of the patient, early detection of deterioration and pharmacological intervention if necessary. Remote monitoring is not simple data-gathering, it is a system, so that a reduction of mortality or a reduction of hospitalisation are not solely attributed to one format of RM intervention or another [Pandor 2013]. The appropriate features of the STS intervention to guarantee positive outcomes has not yet been established, although reduced service utilization and improved clinical outcomes were found in research [Garcia 2007] referring to Cleland 2005 (1) , Benatar 2003 (2), Goldberg 2003 (3), Galbreath 2004 (4). The best medical practices such as training of health professionals, staffing or regularity of monitoring and follow-up, remain to be developed [Achelrod 2014]. The acceptability (institutional feasibility) of HF-monitoring by health authorities is more or less unknown yet. [Martinez 2006].

RCTs

Patients need appropriate introductions on technical issues for proper use of the telephone support system [Wakefield 2009, Jerant 2013], special health education concerning their disease status, i.e. about exercise recommendations, low sodium intake, medication regimen, increased swelling or shortness of breath [Seto 2012, Brandon 2009], and need to learn how to measure the required data (i.e. weight, blood pressure) correctly [Jerant 2013].

Observational study

Participants with lower initial perceived health received significantly more calls than did participants with higher initial perceived health. The negative and significant coefficient + 11 shows that for any additional call, the slope of the growth curve becomes slightly flatter, indicating that those participants who were more strongly impaired showed a weaker improvement over time despite receiving significantly more calls than did participants with less severe impairment [Boehme 2012]

Qualitative studies

Patients wish that the monitoring system is adjunct to their relationship with their clinician at the heart function clinic. It should not be a replacement. They would take their measurements even for longterm, if they perceive clear tangible benefits from it or if their heart condition ever worsened. [Seto 2010, Lynga 2013]

The support system should be easy to use, supported by appropriate training and technical support if needed. [Seto 2010, Sander 2012]

Clinicians would like a remote monitoring system if it would not result in a significant increased workload, especially during nights, weekend,vacations. They also mentioned concerns about the legal situation in case if they did not respond to an alert and the patients' health worsened as a result. The patients' instructions needed to be appropriate and safe. [Seto 2010]

Patients' positive engagement in telehealth service is a crucial factor for the success of the service and understanding how patients perceive telehealth can influence its acceptability and diffusion. Several barriers had been identified to affect the level of telehealth uptake by patients with HF and COPD, including preference for one-to-one with their healthcare professionals, technology anxiety, technical problems, the belief that telehealth to be unnecessary,[Obeh 2015] referring to Gorst 2014 (5)8

- Cleland JG, Louis AA, Rigby AS, Janssens U, Balk AH. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network- Home-Care Management System (TEN-HMS) study. J Am Coll Cardiol 2005;45:1654–64
- Benatar D, Bondmass M, Ghitelman J, Avitall B. Outcomes of chronic heart failure. Arch Intern Med 2003;163:347–52
- Goldberg LR, Piette JD, Walsh MN, et al. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. Am Heart J 2003;146:705–12
- Galbreath AD, Krasuski RA, Smith B, et al. Long-term healthcare and cost outcomes of disease management in a large, randomized, community-based population with heart failure. Circulation 2004;110:3518–26
- Gorst SL, Armitage CJ, Brownsell S, Hawley MS. Home Telehealth Uptake and Continued Use Among Heart Failure and Chronic Obstructive Pulmonary Disease Patients: a Systematic Review. Annals of Behavioral Medicine. 2014; 48(3): 323–336.

Importance: Important

Transferability: Completely

Information exchange

Result card for SOC5: "What is the knowledge and understanding of Structured telephone support (STS) in CCD patients?"

View full card

SOC5: What is the knowledge and understanding of Structured telephone support (STS) in CCD patients?

Method

As with the other SOC AEs

Short Result

The knowledge of the patients about their HF self-management is important. Active patients are higher motivated and perceive better health increase.

Result

In one study [Sander 2012] it was observed that patients could easily misinterpret the information given to them in verbally description, especially when using ”modern” terms like ”bluetooth” or ”broadband” to older people. Seto [2010] asked the patients what they know, and „most“ of the patients perceived that monitoring their blood pressure and weight helps them to manager their HF condition, but there were also patients who questioned the necessity of daily monitoring because their blood pressure had been stable [Seto 2010].

Boehme [2012] measured different modules of HF-management like medication adherence, fluid intake or physical activity separately. They concluded that those patients who completed those modules had an increase in perceived health *(+ 12=0.03; p=.045)*, but this observation was not significant for the modulenutrition“. [Boehme 2012]

To be active in their own care of HF increased the self-care activities and the feeling of being save and well cared with a better understanding of the own body [Lynga 2013]

Comment

One also has to be critical in reading the perceived studies about the knowledge and understanding of the patients about their telehealth support and their disease, especially in looking at the study concepts. If i.e. ethical minorities, unemployed persons or persons with private health insurance are unequally distributed with the study- and the control group as in O’Neil 2014 one has to be careful with the interpretation of results.

Importance: Important

Transferability: Completely

Discussion

There was a high focus within the included studies on quality of life for the participants within STS projects.

Nontheless evidence is scattered about improvements in QoL and Self-care abilities and sense of self-efficacy in the intervention group: some studies show a significant improvement, others found no difference. Differences in interventions characteristics and organisational factors ca explain this. For the impact of age, economic status, ethnicity and other macrosocial variables on patients perceptions of STS we could not find definitive conclusions. Qualitative literature suggests that digital divide due to age is not a relevant problem, above all in near future as new generations, who are accustumed to new technologies, get older and enter the HF more at risk age. In depth understanding of pateints perceptins of this interventions highlights some positive and negative aspects of the intervention: perceptions of being safer and well cared, easy intergartion of selfcare activities and telemonitoring in everyday life, increased empowerment but also, for some patients, increase awarness about their daily health (e.g. weighting everyday) made increase concerns of potential deterioration in HF.

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Appendices

APPENDIX 1 – Search strategy for the Social Domain

Searches has to be run on: Medline, Embase, Cochrane Library, PsycINFO, CINAHL, CRD database. English only. Time: 1995-2015

Keywords for Population and Disease

P: Adults with chronic heart failure (with previous hospital stay due to chronic heart failure)

I/C: telemonitoring via structured telephone support (non invasive telemonitoring via structured telephone support human to human or human to machine) VS standard of care

Keywords for outcomes/AEs:

- Patients preferences/views/satisfaction/acceptance/ Acceptability/ Adaptation/Adherence/compliance/quality of life/Health Related Quality of Life/worries/anxiety/confidence/
- Travel abilities/work/family life/social life/leisure time/lifestyle/daily activities/ patient's everyday life/changes in daily routines
- Access, accessibility ethnicity/gender/social and economic status/working status/urban–rural areas
- Patients information/communications/patient-physician communication/information

Design: SR, HTA, RCTs, Qualitative studies (interviews, focus groups), observational studies, Patient Related Outcomes studies

3th june 2015 (date for latest updating)

Cochrane

Heart Failure, MESH descriptor explode all trees. Entry terms:	AND	"Remote Sensing Technology", MESH descriptor Explode all tree: Entry terms:	AND	MESH descriptor: "quality of life" OR MESH descriptor: "activities of daily living" OR MESH descripto: "leisure activities" OR	NOT	ehealth OR web-based OR

• Cardiac Failure • Heart Decompensation • Decompensation, Heart • Heart Failure, Right-Sided • Heart Failure, Right Sided • Right-Sided Heart Failure • Right Sided Heart Failure • Myocardial Failure • Congestive Heart Failure • Heart Failure, Congestive • Heart Failure, Left-Sided • Heart Failure, Left Sided • Left-Sided Heart Failure • Left Sided Heart Failure OR Heart AND (Failure OR Attack) OR CHF OR HF OR congestive heart failure		• Remote Sensing Technologies • Technologies, Remote Sensing • Technology, Remote Sensing OR “telemedicine” MESH descriptor Explode all tree. Entru terms: • Telehealth • eHealth • Mobile Health • Health, Mobile OR MeSH descriptor “home care services” this term only OR • MeSH descriptor” Home Care Services, Hospital-Based” this term only • OR “remote monitoring” • OR Telemonitoring • OR “Home monitoring” • OR teleconsultation • OR tele-monitoring • OR “distance monitoring” • OR “telemedicine system” • OR “home care” OR Tele*: (title/astract/keyword) AND (monitoring OR contact OR support OR homecare) (title/astract/keyword Telephone-monitoring: title/astract/keyword OR Telephone-support: (title/astract/keyword OR Telephone-contact* (title/astract/keyword OR “Post-discharge monitoring” : (title/astract/keyword OR “tele-watch” :title/astract/keyword OR “tele home care”title/astract/keyword OR “tele homecare” : title/astract/keyword OR smartphone: title/astract/keyword OR smartphone-based: title/astract/keyword OR telecardiology: title/astract/keyword OR telecoaching: title/astract/keyword		MESH descriptor: “Return to work” OR MESH descriptor: “Physician-Patient Relations” OR MESH descriptor: “Patient Satisfaction” OR "length of stay" Ricerca in [Title/Abstract/keyword] per “quality of life” OR QoL OR HRQOL “patient* preferences OR satisfaction OR worries OR anxiety OR comfort (Patients AND (“travel abilities” Or freedom OR “family life” OR “social life” OR “leisure time” OR lifestyle OR “daily activities”)) OR (Patients AND (preferences OR views OR satisfaction OR worries OR acceptance OR acceptability) OR adaptation OR adherence OR confidence OR compliance OR “social and economic status” OR “working status” OR un-employement OR “employement status” OR “working status” OR “patient’s everyday life” OR “changes in daily routines” OR Access OR accessibility OR ethnicity OR gender OR OR “urban areas” OR “rural areas” OR information OR communications OR information OR comfort OR Social Support		"web based" OR internet OR web OR computer OR internet-based

MEDLINE

Heart Failure, MESH descriptor, explode all trees. Entry terms: • Cardiac FailureHeart Decompensation • Decompensation, HeartHeart Failure, Right-Sided	AND	“Remote Sensing Technology” MESH descriptor Explode all tree: Entry terms: • Remote Sensing Technologies • Technologies, Remote Sensing • Technology, Remote Sensing OR	AND	MESH descriptor: “quality of life” OR MESH descriptor: “activities of daily living” OR MESH descripto: “leisure activities” OR MESH descriptor: “Return to work” OR MESH descriptor: “Physician-Patient Relations” OR MESH descriptor: “Patient Satisfaction” OR "length of stay"	NOT	ehealth OR web-based OR "web based" OR internet OR

• Heart Failure, Right Sided • Right-Sided Heart Failure • Right Sided Heart Failure • Myocardial Failure • Congestive Heart Failure • Heart Failure, Congestive • Heart Failure, Left-Sided • Heart Failure, Left Sided • Left-Sided Heart Failure • Left Sided Heart Failure OR heart adj6 failure OR cardiac adj6 failure OR Heart AND (failure OR attack) • OR CHF • OR HF • OR “Cardiac Failure” • OR “Heart Decompensation” • OR “Decompensation, Heart” • OR “Myocardial Failure” • OR “Congestive Heart Failure” • OR “Heart Failure, Congestive”		“telemedicine” MESH descriptor Explode all tree. Entru terms: • Telehealth • eHealth • Mobile Health • Health, Mobile OR MeSH descriptor “home care services” this term only OR MeSH descriptor” Home Care Services, Hospital-Based” this term only • OR “remote monitoring” • OR Telemonitoring • OR “Home monitoring” • OR teleconsultation • OR tele-monitoring • OR “distance monitoring” • OR “telemedicine system” • OR “home care” • OR teleconsultation • OR tele-consultation OR "cell phone"[MeSH Terms] OR "telephone"[MeSH Terms] OR Tele*: title/astract AND (monitoring OR contact OR support OR homecare) Telephone-monitoring: title/abstract OR Telephone-support: title/astract OR Telephone-contact* : title/astract OR “Post-discharge monitoring” : title/astract OR smartphone OR smartphone-based: “tele-watch” : title/astract OR “tele home care” : title/astract OR “tele homecare” : title/astract OR Telecardiology: title/astract OR Telecoaching: title/abstract OR		Ricerca in [Title/Abstrac] per “quality of life” OR QoL OR HRQOL “patient* preferences OR comfort (Patients AND (“travel abilities” Or freedom OR “family life” OR “social life” OR “leisure time” OR lifestyle OR “daily activities”)) OR (Patients AND (preferences OR views OR satisfaction OR worries OR acceptance OR acceptability) OR adaptation OR adherence OR confidence OR compliance OR “social and economic status” OR “working status” OR un-employement OR “employement status” OR “working status” OR “patient’s everyday life” OR “changes in daily routines” OR Access OR accessibility OR ethnicity OR gender OR OR “urban areas” OR “rural areas” OR information OR communications OR information OR Social Support		web OR computer OR internet-based

EMBASE

“Congestive heart failure”/exp OR “heart failure” /exp OR ‘congestive cardiomyopathy’/exp OR CHF OR HF OR “cardiac failure”/exp	AND	• 'telemonitoring'/exp • OR Teleconsultation/exp • OR Telemedicine/exp • OR telecommunications/exp • Or telecare$.tw • OR telecardiol$.tw. • OR telemonitor$.tw. • OR teleconsult$.tw • OR telecare$.tw • OR homecare$.tw • OR home care$.tw OR "cell phone" OR telephone OR Telephone-monitoring OR telephone-support OR telephone-contact OR “Post-discharge monitoring” OR smartphone OR smartphone-based OR	AND	EMTREE TERM: 'quality of life'/exp OR EMTREE TERM: work capacity/exp OR EMTREE TERM: 'life satisfaction'/exp OR EMTREE TERM: 'patient satisfaction'/exp OR EMTREE TERM: 'patient information'/exp OR EMTREE TERM: 'social aspects and related phenomena'/exp OR "length of stay" “quality of life” OR QoL OR “Travel abilities” OR recreation or work or “family life” OR “social life” OR “leisure time” OR lifestyle” OR “daily activities” OR “patient* preferences OR satisfaction OR worries OR anxiety OR “working staus” OR un-employment” OR employment OR –“SF-36 mental score” OR “SF-36 physical score” OR (Patients and (“travel abilities” Or freedom OR word OR “family life” OR “social life” OR “leisure time” OR lifestyle OR “daily activities”)) OR (Patients AND (preferences OR views OR satisfaction OR worries OR anxiety OR religion OR ethnic OR gender OR “social and economic status” OR “working status” OR un-employement OR “employement status” OR “working status” OR ((urban or rural) and patients) OR i((nformation OR communication OR information) AND (patients OR physician)	NOT	ehealth OR web-based OR "web based" OR internet OR web OR computer OR internet-based

OR “cardiac insufficiency”/exp		“tele-watch” OR “tele home care” OR “tele homecare” OR Telecardiology OR Telecoaching OR tele* .		OR Self-Care OR comfort OR Social Support		

Cinhal

(MH“Congestive heart failure”) OR (MH “heart failure”) OR “congestive cardiomyopathy” OR cardiomyopathy OR CHF OR HF OR cardiac and (failure or insufficiency)	AND	"cell phone" OR telephone OR Telephone-monitoring OR telephone-support OR telephone-contact OR “Post-discharge monitoring” OR smartphone OR smartphone-based OR “tele-watch” OR “tele home care” OR “tele homecare” OR Telecardiology OR Telecoaching OR tele*	AND	(MH "Quality of Working Life") OR (MH "Employment Status") OR (MH "Job Satisfaction") OR (MH "Job Re-Entry") OR (MH "Self Employment") OR (MH "Work Experiences") OR (MH " OR "quality of life" OR QoL OR HRQOL) OR preferences OR views OR satisfaction OR worries OR anxiety OR religion OR ethnic OR “social and economic status” OR “working status” OR un-employement OR “employement status” OR Patients AND (urban or rural) OR information OR communication OR "leisure activities" OR "work retun" OR 'social aspects" OR “social activities” OR “rural areas” OR "length of stay"		

Psychinfo

Congestive heart failure OR heart failure OR congestive cardiomyopathy OR CHF OR HF OR cardiac and (failure or insufficiency)

AND

"cell phone" OR telephone OR Telephone-monitoring OR telephone-support OR telephone-contact OR “Post-discharge monitoring” OR smartphone OR

smartphone-based OR “tele-watch” OR “tele home care” OR “tele homecare” OR Telecardiology OR Telecoaching OR tele*

AND

quality of life OR preferences OR job satisfaction life OR satisfaction working OR social OR employement OR worries OR anxiety OR communicationOR information OR social status OR working status OR urban areas OR rural areas OR social aspects or leisure activities

APPENDIX 2 List of excluded studies with reasons

Excluded not our population

Barlow J, Singh D, Bayer S, Curry R. A Systematic Review Of The Benefits Of Home Telecare For Frail Elderly People And Those With Long-Term Conditions. 2007;13(4):172-9.

Barnason S, Zimmerman L, Nieveen J, Schmaderer M, Carranza B, Reilly S. Impact of a home communication intervention for coronary artery bypass graft patients with ischemic heart failure on self-efficacy, coronary disease risk factor modification, and functioning. Heart Lung. 2003;32(3):147-58.

Bekelman DB, Hooker S, Nowels CT et al. Feasibility and acceptability of a collaborative care intervention to improve symptoms and quality of life in chronic heart failure: mixed methods pilot trial. J Palliat Med 2014; 17(2):145-5

O'Neil, Hawkes A.L. Atherton J.J. et al. Telephone-delivered health coaching improves anxiety outcomes after myocardial infarction: The 'ProActive Heart' trial. Eur J Prev Cardiol. 2014;21(1):30-8.

Keeling A.W., Dennison P.D. Nurse-initiated telephone follow-up after acute myocardial infarction: A pilot study. HEART LUNG J. CRIT. CARE 1995; 24(1):45-9.

Excluded not our intervention

Blum K, Gottlieb SS. The effect of a randomized trial of home telemonitoring on medical costs, 30-day readmissions, mortality, and health-related quality of life in a cohort of community-dwelling heart failure patients. J Card Fail 2014; 20(7):513-21

Boyne JJ, Vrijhoef HJ, Spreeuwenberg M, De Weerd G, Kragten J, Gorgels AP. Effects of tailored telemonitoring on heart failure patients' knowledge, self-care, self-efficacy and adherence: a randomized controlled trial. Eur J Cardiovasc Nurs. 2014;13(3):243-52

Cardozo L, Steinberg J. Telemedicine for recently discharged older patients. Telemed J E Health. 2010;16(1):49-55.

Clark AP, McDougall G, Riegel B, Joiner-Rogers G, Innerarity S, Meraviglia M, et al. Health Status and Self-care Outcomes After an Education-Support Intervention for People With Chronic Heart Failure. J Cardiovasc Nurs. 2014.

Dansky KH, Vasey J, Bowles K. Use of telehealth by older adults to manage heart failure. Res Gerontol Nurs 2008; 1(1):25-32.

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APPENDIX 4 – Quality Assessment of included studies

For the quality assessment of the included studies we used

- The AMSTAR guideline for systematic reviews {1}
- The CONSORT 2010 checklist for RCTs {2}
- The STROBE checklist for observational studies {3}
- The Cochrane guideline for critical appraisal of qualitative studies {4}

The different checklists were merged by using the percentage rates of „yes“, „no“ or „n.a.“ of the checklists divided per number of items.

Results

Green – low bias risk, yellow – unclear bias risk, red – high bias risk

Basic list to the graph about the **Quality assessment of included studies for SOC domain STS for patient with CHF 2015**

	checklist used	yes	no	n.a.	total	yes %	n.a. %	no %
Achelrod 2014	AMSTAR	5	4	1	10	50,0	10,0	40,0
Martinez 2006	AMSTAR	10	1	0	11	90,9	0,0	9,1
Ciere 2012	AMSTAR	7	2	2	11	63,6	18,2	18,2
Garcia 2007	AMSTAR	4	7	0	11	36,4	0,0	63,6
Inglis 2011	AMSTAR	10	0	1	11	90,9	9,1	0,0
Kraii 2011	AMSTAR	6	5	0	11	54,5	0,0	45,5
Pandor 2013 (24)	AMSTAR	10	1	0	11	90,9	0,0	9,1
Pandor 2013 (23)	AMSTAR	10	1	0	11	90,9	0,0	9,1
Cui 2013	CONSORT	22	10	5	37	59,5	13,5	27,0
Clark 2007 (d314)	CONSORT	24	2	11	37	64,9	29,7	5,4
Brandon 2010	CONSORT	17	11	9	37	45,9	24,3	29,7
Piotrowitz 2015	CONSORT	24	8	5	37	64,9	13,5	21,6
Domingues 2011	CONSORT	22	10	5	37	59,5	13,5	27,0
Dunagan 2005	CONSORT	29	7	1	37	78,4	2,7	18,9
Ferrante 2010	CONSORT	35	1	1	37	94,6	2,7	2,7
Lynga 2013	Cochrane Guidance for qualitative studies	6	0	1	7	85,7	14,3	0,0

Seto 2010	Cochrane Guidance for qualitative studies	1	6	0	7	14,3	0,0	85,7
Prescher 2013	Cochrane Guidance for qualitative studies	0	6	1	7	0,0	14,3	85,7
Lind 2012	Cochrane Guidance for qualitative studies	2	3	2	7	28,6	28,6	42,9
Riley 2013	Cochrane Guidance for qualitative studies	4	0	2	6	66,7	33,3	0,0
Seto 2012	Cochrane Guidance for qualitative studies	4	0	2	6	66,7	33,3	0,0
Bond 2014	Cochrane Guidance for qualitative studies	3	1	2	6	50,0	33,3	16,7
Boehme 2012	STROBE obs.	29	3	0	32	90,6	0,0	9,4
Wakefilked 2009	CONSORT	14	18	0	32	43,8	0,0	56,3
Ramachandran 2007	CONSORT	19	11	0	30	63,3	0,0	36,7
Jerant, AF 2003	CONSORT	13	17	0	30	43,3	0,0	56,7
Sanders C. 2012	Cochrane Guidance for qualitative studies	3	1	2	6	50,0	33,3	16,7
Lind L. 2014	Cochrane Guidance for qualitative studies	3	1	2	6	50,0	33,3	16,7

[1] http://amstar.ca/Amstar_Checklist.php

[2] http://www.consort-statement.org/Media/Default/Downloads/CONSORT%202010%20Checklist.doc

[3]http://www.google.at/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0CDUQFjADahUKEwi7zO6o7aDIAhUCPRQKHXInBck&url=http%3A%2F%2Fbmjopen.bmj.com%2Fsite%2FAbout%2FBMJ_Open_cohort-studies.doc&usg=AFQjCNHsziTBKuZyCAO88GQJVuP7hTT0HA

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Legal aspects

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Summary

LEG 1 about marketing authorisation, registration is answered within the CUR domain, we did not do it twice.

LEG 2 about intellectual property right:

According to the Directive 2004/18/EC there are some aspects where the property rights regulation cannot be sufficiently precise, these areas have to be solved using the rules for governing open or restricted procedures.

The TRIPS agreement regulates trade-related aspects of intellectual property rights, including ideas, procedures, methods of operation or mathematical concepts, which also means software programs or source codes. Not included is the data or material itself. Members of TRIPS (=states) may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

Within the patent database EPO – European Patents registration one document was found about Telemedical expert service provision for „telemedicine“ / „telemonitoring“, which seems to be an ongoing negotiation.

For the implementation of telemonitoring one has to look at least for existing property rights on the used system, the implemented software, existing patents, and to secure/regulate the permission for use.

LEG 3 about the voluntary participation of patients:

Basic human rights include respect for integrity and right to fundamental freedom with regard to the application of medicine. The interest of the human being shall prevail over the sole interest of society or science, people have the right to equal access on healthcare of appropriate quality according to their needs. An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

For structured telephone support as a telemonitoring approach for patients with chronic heart failure there is a need of patient-cooperation which implies the will of the patient to take this kind of healthcare.

LEG 4 about patients’ enough time to consider their decisions:

The necessary time for consideration is not legally regulated. It is a matter of individual appropriateness. This Assessment Element is updated and no longer within the legal domain of the HTA Core model 2.1

LEG 5 about securing patient data

Data networks and data communication between providers of tele-healthcare and patients have to secure and protect data sources according to legal data protection regulations.

There is existing data protection regulation on international level which is already adapted and integrated in all of the countries in EU, Norway, Switzerland. There are two additional recommendations for data protection of medical data and protection of private data within telecommunication services which have to be taken into account when implementing a telemonitoring service with STS.

In any case the data protection should be on awareness, especially with low-level support via usual telephone or cell phone line. The informed consent with the patient and the (written) agreement are necessary.

LEG 6 about guarantee of equal access:

Convention for the Protection of Human Rights, Article 14 – Prohibition of discrimination: The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

- Everybody has the basic right to health care at the state of the art ("best care"). It can be discussed whether “structured telephone support” counts as “state of the art”
- There are no exclusions/ special protection declarations for gender equality, prisoners, disabled, regional equalities
- The level of quality is included into the right of good care, but there is a need of legal regulation about a minimum defined quality level to provide equal preconditions for everyone
- Limited access to structured telephone support as a telemonitoring service for special persons are based on the balance between evidence of best outcome rates, economic calculations for the costs and reduction of possible disadvantages due to i.e. lack of compliance. The decision for inclusion/ exclusion into a structured telephone support service has to be transparent

LEG 7 about health-care tourism

Usually there is no health care tourism expected for structured telephone support for chronic heart failure patients. In case of (emergency) treatment abroad and re-transfer into the home-country the appropriate information and continuity of care has to be guaranteed. The routine provision of structured telephone support across borders (in our outside Europe) is expected to be limited by language.

LEG 8 about national/EU register

Due to overlaps with TEC domain we refer to the answer of TEC11

LEG 9 about product safety requirements:

There seem to be no major differences in product safety aspects comparing structured telephone support with usual care. The product safety and responsibility duties have to be followed in both settings. If telemonitoring/ stuctured telephone support is newly implemented there should be appropriate awareness for the safety structure to be equal/similar (or better) as in ”usual care”

LEG 10 about additional licensing fees:

Overlaps with patent binding. We refer to LEG 2.

LEG 11 about depth and length of the providers’ guarantee:

Within structured telephone support provided by a physical person (like a nurse) and/or a group of professionals evaluating deterioration from the collected data by STS, the guarantee for quality can be given via the professional licencing regulations as it is handled within hospitals.

LEG 12 about Regulation of the market

The Directive on public contracting assures price control of servies in case of contracting the whole STS service or in case of material purchasing for HF patients at home. Pricining within reimbursement system for STS (like DRG) is subject to national legislation. The pricing within DRG system must therefore take into account all national legislation and regulation, like national policy on wages or depreciation. However, when the material costs are built into DRG, again the procedures for the public contracting is important, in case of STS it oculd apply to the telephone lines and various equipment that is given to HF patients to monitor their health status at home (scales, meters for circumference of ankles etc).

LEG 13 about acquisition regulation:

If the provider of the telemonitoring by STS is a public organisation the acquisition control has to take place and is usually known and followed by the provider. For contracted parts within or connected with the STS telemonitoring the acquisition regulation could be relevant if a certain amount of costs (i.e. for software, for a company providing the whole package including structured telephone support) is reached. A bottom-up provision of structured telephone support using certain tools or a kind of subcontracted professional team should be aware of the existing acquisition legislation.

LEG 14 about marketing:

The marketing of medical devices is regulated within the Directive 93/42/EEC and has to be taken into account if non-implantable medical devices (like blood pressure devices) are used in connection with STS. This means, the device has to follow the CE regulations.

For the marketing of a special device or product within a provided service one should be aware about the definition of corruption.

Within medical services and/or medical devices advertising is regulated by local governments to prevent misinterpretation about the device or service.

LEG 15 about the coverage of regulation:

There is still legal uncertainty within the provision of structured telephone support for patients with chronic heart failure in terms of

- Cross border healthcare services
- Funding aspects
- Reimbursement
- Procurement

- Sustainable business models
- Data protection via telephone line
- Provider responsibilities

LEG 16 about liability issues:

For the provision of telemedical services/ STS several different legal regulations have to be followed, like:

- Occupational laws
- Hospital legislations
- Good clinical practice
- Health telematic law
- Data protection law
- E-government law
- Consumer protection law
- Signature law
- E-commerce-law
- Telecommunication law
- Copyright/ patent protection
- Media law

(list not exhaustive)

This means that there is uncertainty which liability limitations exist for what kind of service provision.

Due to the different involved system partner within tele-medicine/ STS there has to be a clear business plan to create a legal background and to fulfil different legal regulations. The core of this business plan could be the patients' contract to only one contract partner, which is coordinating the different involved partners.

Introduction

This section provides some thoughts about different legal aspects within STS. Telemonitoring is an upcoming topic including high expectations about potential advantages, and with some already piloted bottom-up solutions in different settings. The legals aspects following the HTA core model structure aim to provide an overview of different aspects that have to be taken into account when bringing STS into action. In some aspects we did a broader view than just the focus on STS. This is caused by the variation of different telemonitoring approaches where STS is not always the only content but a combination of different approaches is done. A certain combination of telemonitoring can also be provided as a whole service-package by a company and is then maybe related to copyright-issues.

Recommendation: non-binding act

Directive: legal act of the European Union which requires member states to achieve a particular result

Regulation: legal act of the European Union that becomes immediately enforceable as law in all member states simultaneously

Treaty: agreement under international law entered into by actors in international law, namely sovereign states and international organizations

Convention: international treaty

Methodology

Frame

The collection scope is used in this domain.

Technology	Structured telephone support (STS) for adult patients with chronic heart failure **Description** Telemonitoring via structured telephone support with focus on patient reported signs (symptoms of congestion, peripheral edema, pulmonary congestion, dyspnea on exertion, abdominal fullness), medication adherence, physiological data (like heart rate, blood pressure, body weight – measured by the patient with home-device), activity level; done in regular schedules using risk stratification (with fixed algorithm by call center staff or experience-based by specialized staff); done by dedicated call centers, center-based staff, nurses, AND reduced visits to a GP or heart center
Intended use of the technology	Prevention Remote transmission of information to alleviate symptoms, relieve suffering and allow timely treatment for chronic heart failure **Target condition** Chronic cardiac failure **Target condition description** Heart failure is a condition in which the heart has lost the ability to pump enough blood to the body's tissues. With too little blood being delivered, the organs and other tissues do not receive enough oxygen and nutrients to function properly. **Target population** *Target population sex*: Any. *Target population age*: adults and elderly. *Target population group*: Patients who have the target condition. **Target population description** Patients with chronic heart failure (CHF; defined as I50 http://www.icd10data.com/ICD10CM/Codes/I00-I99/I30-I52/I50-/I50) AND hospitalization due to heart failure at least once AND without implanted devices

Comparison	Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) **Description** Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist; patient has to move (≠ at home)
Outcomes	Mortality (disease specific and all cause) progressions, admissions, re-admissions, QoL or HRQoL, harms

Assessment elements

	Topic	Issue	Relevant	Research questions or rationale for irrelevance
I0015	Authorisation and safety	Has the technology national/EU level authorisation (marketing authorisation, registration, certification of safety, monitoring, qualification control, quality control)?	yes	Has Structured telephone support (STS) for adult patients with chronic heart failure national/EU level authorisation (marketing authorisation, registration, certification of safety, monitoring, qualification control, quality control)?
I0019	Ownership and liability	Does the technology infringe some intellectual property right?	yes	Does Structured telephone support (STS) for adult patients with chronic heart failure infringe some intellectual property right?
I0002	Autonomy of the patient	Is the voluntary participation of patients guaranteed properly?	yes	Is the voluntary participation of patients guaranteed properly?
I0004	Autonomy of the patient	Is it possible to give future patients enough time to consider their decisions?	yes	Is it possible to give future patients enough time to consider their decisions?
I0003	Autonomy of the patient	Are there relevant optional technologies that future patients should be allowed to consider?	no	We did not restrict the technologies, so this question would be irrelevant. Alternatives in management of the disease are answered in CUR domain
I0005	Autonomy of the patient	Is it possible to obtain an advance directive on the use of the technology?	no	it is assumed that telemedical devices can only be used with patients' cooperation
I0009	Privacy of the patient	Do laws/ binding rules require appropriate measures for securing patient data?	yes	Do laws/ binding rules require appropriate measures for securing patient data?
I0010	Privacy of the patient	What levels of access to which kind of patient information exist in the chain of care?	no	We subsum this in I0011
I0011	Equality in health care	Do laws/ binding rules require appropriate processes or resources to guarantee equal access to the technology?	yes	Do laws/ binding rules require appropriate processes or resources to guarantee equal access to Structured telephone support (STS) for adult patients with chronic heart failure?
I0014	Equality in health care	Is health-care tourism expected from/to other European countries?	yes	Is health-care tourism expected from/to other European countries?
I0012	Equality in health care	Is the technology subsidized by the society?	yes	
I0013	Equality in health care	Is there a wide variation in the acceptability of the technology across Europe?	no	Accepatbility is an ethical or social aspect, not a legal one (see update of the legal domain)
I0016	Authorisation & safety	Does the technology need to be listed in a national/EU register?	yes	Does Structured telephone support (STS) for adult patients with chronic heart failure need to be listed in a national/EU register?
I0017	Authorisation & safety	Does the technology fulfil product safety requirements?	yes	Does Structured telephone support (STS) for adult patients with chronic heart failure fulfil product safety requirements?
I0018	Authorisation & safety	Does the technology fulfil tissue safety requirements?	no	no tissues involved
I0020	Ownership & liability	Does the introduction of the technology presume some additional licensing fees to be paid?	yes	Does the introduction of Structured telephone support (STS) for adult patients with chronic heart failure presume some additional licensing fees to be paid?
I0021	Ownership & liability	What are the width, depth and length of the manufacturers guarantee?	yes	What are the width, depth and length of the manufacturers guarantee?
I0022	Ownership & liability	Is the user guide of the technology comprehensive enough?	no	This question is based on pharmaceuticals
I0023	Regulation of the market	Is the technology subject to price control?	yes	Is Structured telephone support (STS) for adult patients with chronic heart failure subject to price control?
I0024	Regulation of the market	Is the technology subject to acquisition regulation?	yes	Is Structured telephone support (STS) for adult patients with chronic heart failure subject to acquisition regulation?
I0025	Regulation of the market	Is the marketing of the technology to the patients restricted?	yes	Is the marketing of Structured telephone support (STS) for adult patients with chronic heart failure to the patients restricted?
I0026	Legal regulation of novel/experimental techniques	Is the technology so novel existing legislation was not designed to cover its regulation?	yes	Is Structured telephone support (STS) for adult patients with chronic heart failure so novel existing legislation was not designed to cover its regulation?
I0027	Legal regulation of novel/experimental techniques	How the liability issues are solved according to existing legislation?	yes	How the liability issues are solved according to existing legislation?
I0028	Legal regulation of novel/experimental techniques	Are new legislative measures needed?	no	This will be covered in I0026
I0029	Legal regulation of novel/experimental techniques	Is the voluntary participation of patients guaranteed properly?	no	This is double with I0002

Methodology description

The methodological guidelines and suggestions for legal documents within the HTA Core Model [1]were used as a basic.

The different legal documents (directives, recommendations, etc) were read – mainly on international level, because the EU legislations are ratified or at least guidance for the single countries. National legislation cannot be followed for all EU member states and Norway and Switzerland due to language restrictions. Were national legislation has to be taken into account this is mentioned and could be worked out among a national adaptation.

For the questions not sufficiently answered by official legislative documents on EU level or examples from national level a google search was added and/ or an expert opinion was taken as a base for the discussion.

The main literature search for the WP4_3 topic of STS was scanned for legal aspects mentioned within medical studies/ systematic reviews.

Quality assessment tools or criteria

The authors worked with a work/check/re-check method solving discordant aspects by discussion.

The usual review process was provided by one WP4_3 internal reviewer without legal background.

Analysis and synthesis

The results are provided by citations of legal articles/paragraphs either in full wording or in own conclusion. Some aspects could only be discussed due to lack of regulation.

Disclosure: the authors are not professional lawers but working within health technology assessment framework/ health system legislation. This report cannot be taken as a legal proof, but just as a support for what has to be taken into account for structured telephone support provision.

Result cards

Authorisation and safety

Result card for LEG1: "Has Structured telephone support (STS) for adult patients with chronic heart failure national/EU level authorisation (marketing authorisation, registration, certification of safety, monitoring, qualification control, quality control)?"

View full card

LEG1: Has Structured telephone support (STS) for adult patients with chronic heart failure national/EU level authorisation (marketing authorisation, registration, certification of safety, monitoring, qualification control, quality control)?

Method

It is answered within the CUR domain, we did not do it twice.

Short Result

See CUR15

Result

This question is answered within the CUR domain, we did not do it twice.

Importance: Important

Transferability: Unspecified

Ownership and liability

Result card for LEG2: "Does Structured telephone support (STS) for adult patients with chronic heart failure infringe some intellectual property right?"

View full card

LEG2: Does Structured telephone support (STS) for adult patients with chronic heart failure infringe some intellectual property right?

Method

Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. The document was searched for „property right“ and „intellectual“, articles includig these terms are listed.

A Search was done within the EPO – European Patents registration using the keywords „telemedicine“ and „telemonitoring“

Agreement on Trade-Related Aspects of Intellectual Property Rights The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

Short Result

According to the Directive 2004/18/EC {2} there are some aspects where the property rights regulation cannot be sufficiently precise, these areas have to be solved using the rules for governing open or restricted procedures.

Within the patent database EPO – European Patents registration {5} one document was found about *Telemedical expert service provision* for „telemedicine“ / „telemonitoring“, which seems to be an ongoing negotiation, and several other documents about disease management systems, telemedicine systems, interfaces, corresponding methods, etc. This as a result of the legal aspects means, that a provider is on the saver side when checking for patents before implementing STS as telemonitoring. There might be some features not allowed to be copied.

There are some companies providing a full package of telemonitoring including structured telephone interview. If STS is planned to be implemented, the provider has to be aware of possible patents, especially for a certain structure and/or the implemented questionnaire and the risk-calculation-model.

The use of a patent-binded source (or parts out of it) without permission could result in penal costs.

A search within the patent database can help to find out existing patents.

For the implementation of telemonitoring one has to look at least for existing property rights on the used system, the implemented software, existing patents, and to secure/regulate the permission for use, and be in line with the Directive 2004/18/EC.

Result

1. Patents (search in EPO {5}. A list of possible relevant patents is provided in appendix 1. This list is not exhaustive! (links checked on 13th May 2015)

General provisions

- **Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts {2}**

This applies to public contracts concluded by a contracting authority in sectors for: supplies services; and public work contracts. It depends on the context of the provision of structured telephone support for patients with chronic heart failure whether this directive has to be taken into account.

Art 30 (c) ”...in the case of services, inter alia services within category 6 of Annex II A, and intellectual services such as services involving the design of works, insofar as the nature of the services to be provided is such that contract specifications cannot be established with sufficient precision to permit the award of the contract by selection of the best tender according to the rules governing open or restricted procedures“

- **The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994. {4}**

TRIPS in connection to telemonitoring/ telemedicine could be relevant for the definitions and interventions listed in TEC_5 (out of the studies from the basic search) (selected narratively):

Part II Article 9 (2)

”Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.”

Part II Article 10 (1)

”Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).”

Part II Article 10 (2)

”Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.”

Part II Article 27

According to Article 27 1. patents shall be available for any interventions, products and processes. But there is an option to exclude patentibility in 2.:

” 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

”3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

Part II Article 31

”Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:”

”(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;”

Importance: Important

Transferability: Unspecified

Autonomy of the patient

Result card for LEG3: "Is the voluntary participation of patients guaranteed properly?"

View full card

LEG3: Is the voluntary participation of patients guaranteed properly?

Method

Convention on Human Rights and Biomedicine CETS No: 164 (including the Explanatory report to Biomedicine convention).

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

Short Result

The Convention on Human Rights and Biomedicine includes respect for integrity and right to fundamental freedom with regard to the application of medicine. The interest of the human being shall prevail over the sole interest of society or science, people have the right to equal access on healthcare of appropriate quality according to their needs. An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. {6}

In a situation of cross-border healthcare (i.e. a patient was treated at a heart center in EU member state A and want's to participate in the recommended telemonitoring by structured telephone support) a cross-border communication, transfer and/ or reimbursement can be the case. Then the regulations of data protection, data transfer and the need for prior authorisation have to be clarified. {7}

For structured telephone support as a telemonitoring approach for patients with chronic heart failure there is a need of **patient-cooperation** which **implies the will of the patient** to take this kind of healthcare. The voluntary participation is guaranteed with the will of cooperation.

Result

General provisions

- **Convention on Human Rights and Biomedicine CETS No: 164 (including the Explanatory report to Biomedicine convention) {6}**

Chapter I – General provisions

Article 1 – Purpose and object

"Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention."

Article 2 – Primacy of the human being

"The interests and welfare of the human being shall prevail over the sole interest of society or science."

Article 3 – Equitable access to health care

"Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality."

Article 4 – Professional standards

"Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards."

Chapter II – Consent

Article 5 – General rule

"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time."

Chapter III – Private life and right to information

Article 10 – Private life and right to information

1. "Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient."

- **Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. {7}**

Chapter II *Article 5* Responsibilities of the Member State of affiliation

"The Member State of affiliation shall ensure that:

1.

1. the cost of cross-border healthcare is reimbursed in accordance with Chapter III;

2. there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;

3. where a patient has received cross-border healthcare and where medical follow-up proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided on its territory;

4. patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC."

Directives 95/46/EC regulates the data protection, 2002/58/EC regulates the processing of personal data and the protection of privacy in the electronic communications sector.

National contact points for Cross border healthcare can be found here: http://europa.eu/youreurope/citizens/health/help-from-the-pharmacy/prescription/index_en.htm#!lightbox-uid-0

Comment

- Important

Importance: Important

Transferability: Unspecified

Result card for LEG4: "Is it possible to give future patients enough time to consider their decisions?"

View full card

LEG4: Is it possible to give future patients enough time to consider their decisions?

Method

Comment

Result

The necessary time for consideration is not legally regulated. It is a matter of individual appropriateness. This Assessment Element is updated and no longer within the legal domain of the HTA Core model 2.1 {8}

[8] EUnetHTA Joint Action 2, Work Package 8. HTA Core Model ® version 2.1 (Pdf); 2015. Available from http://www.corehta.info/BrowseModel.aspx.

Importance: Optional

Transferability: Unspecified

Privacy of the patient

Result card for LEG5: "Do laws/ binding rules require appropriate measures for securing patient data?"

View full card

LEG5: Do laws/ binding rules require appropriate measures for securing patient data?

Method

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Recommendation R (97) 5 of the Committee of Ministers to Member States on the protection of medical data.

Frame

Structured telephone support provides a special topic for data security. The usual telephone line is usually not privacy protected.

Short Result

Data networks and data communication between providers of tele-healthcare and patients have to secure and protect data sources according to legal data protection regulations.

There is an existing data protection regulation on EU-level {9}, which is already adapted and integrated in all of the countries in EU, Norway, Switzerland. {7} There are two additional recommendations for data protection of medical data {10} and protection of private data within telecommunication services {11} which have to be taken into account when implementing a telemonitoring service with STS.

Result

There are clear regulations in data protection on EU level {9} which are adapted accordingly in the members states

- Directive (2011/24/EU) on Patients' Rights in Cross-border Healthcare states {7}: “(d) patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.”

- **Recommendation R (97) 5 of the Committee of Ministers to Member States on the protection of medical data {10}:**

*“*Recalling the general principles on data protection in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (European Treaty Series, No. 108) and in particular its Article 6 which stipulates that personal data concerning health may not be processed automatically unless domestic law provides appropriate safeguards;

Aware of the increasing use of automatic processing of medical data by information systems, not only for medical care, medical research, hospital management and public health but also outside the health-care sector;”

The recommendation gives clear advice how to understand and act regarding to the protection of medical data.

Within the use of structured telephone support it is relatively easy to ask the patients’ agreement for data transmission and intended use.

- **Recommendation No.R (95) 4 on the protection of personal data in the area of telecommunication services, with particular reference to telephone services {11}:**

“2. Respect for privacy

2.1. Telecommunications services, and in particular telephone services which are being developed, should be offered with due respect for the privacy of users, the secrecy of the correspondence and the freedom of communication.

2.2. Network operators, service providers and equipment and software suppliers should exploit information technology for constructing and operating networks, equipment and software, in a way which ensures the privacy of users. Anonymous means of accessing the telecommunications network and services should be made available.

2.3. Unless authorised for technical storage or message transmission or for other legitimate purposes, or for the execution of a service contract with the subscriber, any interference by network operators or service providers with the content of communications should be prohibited. Subject to Principle 4.2 the data pertaining to the content of messages collected during any such interference should not be communicated to third parties.

2.4. Interference by public authorities with the content of a communication, including the use of listening or tapping devices or other means of surveillance or interception of communications, must be carried out only when this is provided for by law and constitutes a necessary measure in a democratic society in the interests of:

a. protecting state security, public safety, the monetary interests of the state or the suppression of criminal offences;

b. protecting the data subject or the rights and freedoms of others”

[...]

“4. Communication of data

4.1. Personal data collected and processed by network operators or service providers should not be communicated, unless the subscriber concerned has given in writing his express and informed consent and the information communicated does not make it possible to identify called parties. The subscriber may revoke his consent at any time but without retroactive effect.”

[...]

“6.1. Network operators and service providers should take all appropriate technical and organisational measures to ensure the physical and logical security of the network, services and the data which they collect and process, and to prevent unauthorised interference with, or interception of, communications.

6.2. Subscribers to telecommunications services should be informed about network security risks and methods for subscribers to reduce the security risks of their messages.”

[...]

“7.20. When providing and operating a mobile telephone service, network operators and service providers should inform subscribers of the risks for secrecy of correspondence which may accompany the use of mobile telephone networks, in particular in the absence of encryption of radiocommunications. Means of offering encryption possibilities or equivalent safeguards to subscribers to mobile telephone networks should be found.”

Comment

Theoretically, in case if no data security takes place, what were the consequences of unprotected data for the patient?

- Harm in dignity: propably no. Heart failure is usually not stigmatized
- Social harm: probably no. No one else will be directly affected by the heart failure of the patient
- Harm as decreased chances on market: Jobmarket - propably not for Persons aged 65+. Privat (health) insurance market - (higher contributions, refusal of contract) propably not in the age above 65
- Potential of misuse from the provider according to civil law (like purchased life annuity)

Theoretically, in case of too much data security or incompetent (no availability of results for other provider, i.e. the patients' local GP) use of documented data, what are the consequences for the patient?

- results or suspicions are not available for other health care provider with could mean double examinations for the patient and/or missed information (i.e. overseen deterioration)
- missed advantages of provider-networking

Importance: Critical

Transferability: Unspecified

Equality in health care

Result card for LEG6: "Do laws/ binding rules require appropriate processes or resources to guarantee equal access to Structured telephone support (STS) for adult patients with chronic heart failure?"

View full card

LEG6: Do laws/ binding rules require appropriate processes or resources to guarantee equal access to Structured telephone support (STS) for adult patients with chronic heart failure?

Method

The allocation of (limited) resources needs to select the most benefiting patients without discrimination. In case of structured telephone support for patients with chronic heart failure the decision process is to be made transparently and to follow objective indicators like regional distance, compliance, absence of relatives, etc. – despite the medicinal criteria.

Frame

The allocation of (limited) resources needs to select the most benefiting patients without discrimination. In case of structured telephone support for patients with chronic heart failure the decision process is to be made transparently and to follow objective indicators like regional distance, compliance, absence of relatives, etc. – despite the medicinal criteria.

Short Result

- Convention for the Protection of Human Rights and Fundamental Freedoms {12}, Article 14 – Prohibition of discrimination:

"The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status." {12}

- Everybody has the basic right to health care at the state of the art ("best care"). It can be discussed whether "structured telephone support" counts as "state of the art"
- There are no exclusions/ special protection declarations for gender equality, prisoners, disabled, regional equalities {13,14,15,16,17,18,19}
- The level of quality is included into the right of good care, but there is a need of legal regulation about a minimum defined quality level to provide equal preconditions for everyone
- Limited access to structured telephone support as a telemonitoring service for special persons are based on the balance between evidence of best outcome rates, economic calculations for the costs and reduction of possible disadvantages due to i.e. lack of compliance. The decision for inclusion/ exclusion into a structured telephone support service has to be transparent ({12}, Article 14 – Prohibition of discrimination

Result

There are several regulations and statements on EU- and international level for securing equal access to health care in Europe.{13,14,15,16,17,18,19} It implements that usual care for all persons is provided.

The limits of healthcare should be implemented in a balance between the right of access and the patients' right for human dignity, right to life, right to the integrity of the person, prohibition of torture and inhuman or degrading treatment or punishment; and respect for private and family Life. Transparency is one method to provide prohibition of discrimination as required in the Convention for the Protection of Human Rights {12}.

Especially in the field of e-health *It is essential to discuss, among others, aspects relating to safety and confidentiality; professional accountability; technical standards relating to digital recording, storage, and transmission of clinical data; copyright; authorization from professional regulatory bodies; and licensing for the remote*

practice of medicine. (Rezende 2010) {20}

Responsibility:

Legal issues can be solved easily when responsibilities of parties concerned have been established and documented. Loeber 2008 {21}

Importance: Important

Transferability: Unspecified

Result card for LEG7: "Is health-care tourism expected from/to other European countries?"

View full card

LEG7: Is health-care tourism expected from/to other European countries?

Method

- See LEG3

Short Result

Currently there is no health care tourism expected for structured telephone support for chronic heart failure patients. In case of (emergency) treatment abroad and re-transfer into the home-country the appropriate information and continuity of care has to be guaranteed. The routine provision of structured telephone support across borders (in our outside Europe) is expected to be limited by language.

Result

Cross border healthcare directive – relevant regulations see LEG3

Importance: Optional

Transferability: Unspecified

Authorisation & safety

Result card for LEG8: "Does Structured telephone support (STS) for adult patients with chronic heart failure need to be listed in a national/EU register?"

View full card

LEG8: Does Structured telephone support (STS) for adult patients with chronic heart failure need to be listed in a national/EU register?

Method

Due to overlaps with TEC domain we refer to the answer of TEC11

Short Result

Please take the answer at TEC11

Importance: Optional

Transferability: Unspecified

Result card for LEG9: "Does Structured telephone support (STS) for adult patients with chronic heart failure fulfil product safety requirements?"

View full card

LEG9: Does Structured telephone support (STS) for adult patients with chronic heart failure fulfil product safety requirements?

Method

OECD ICT read for basic ideas within this AE [32]

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Discussion

Frame

What kind of uncertainties are upcoming? Who is responsible for (what kind of) safety?

- Safety challenge 1: data transfer (i.e. continuous telephone WLAN/ energy support guaranteed?) – compare with „usual care“ and „safe transport to the physician“
- Safety challenge 2: Identification and authentication (is the right patient on the phone? Are the documented data of the right patient?)
- Safety challenge 3: timely reaction in case of emergency – compare with „usual care“
- Safety challenge 4: Safety of the (medical) devices used by the patient at home (i.e. blood pressure device)

Short Result

There seem to be no major differences in product safety aspects comparing structured telephone support with usual care. The product safety and responsibility duties have to be followed in both settings. If telemonitoring/ stuctured telephone support is newly implemented there should be appropriate awareness for the safety structure to be equal/similar (or better) as in ”usual care”

Result

Ad safety challenge 1 ”data transfer”)

There is the possibility that the WLAN system or the energy system brakes down (i.e. due to heavy storm or snow) and that the patient at home cannot reach for support. Compared to usual care there is no difference – in such a situation there would be no possibility to reach the physician by usual transport (i.e. car).

Ad safety challenge 2 ”identification and authentication”)

Via telephone there is an incraesed possibility to have a wrong authentication or identification of the patient, meaning that the health porvider calling does not necessarily know the voice to identify the patient correctly. This could lead to a misinterpretation of the communication, especially if compared to an existing (symptom-) trend.

This safety challenge should be easy to solve by re-asking the patients identiy in the beginning of the call by the provider. There are Identification and authentication challenges in hospital too, the rules and solutions how to cope with it (controlling/ cross-check, re-asking) can be adapted.

In a hospital the organisation is in duty for harms due to safety-failure-events. In a physicians practice the physician is in duty for the safety aspects. For structured telephone support it depends who is calling among what kind of organisation structure.

Ad safety challenge 3 ”timely reaction”)

The timely reaction to an upcoming deterioration or emergency situation could be different in the face-to-face contact compared to telephone contact. The advantage of the face-to-face contact is the additional visual aspect (i.e. to see certain symptoms like skin colour, sweat, leg-edemas). Structured telephone support works by trend and staff-experience. The responsibility for an undetected deterioration has to be solved within the working-contract of the health-provider. The role of the patient is unclear – does he/she have to report the symptoms correctly? Is he/she able to detect the symptoms correctly and to report uncertain signs? The face-to-face contact adds visual information even without correct symptom-reporting. A voice-recording system along the telephone-support-call could help to clarify such situations. In „usual“ care there has to be a kind of documentation system about the kind of treatment and care. This documentation should provide appropriate information about unclear responsibility. A documentation is also required for telephone support, and it provides safety awareness for both, patient and provider.

Ad safety challenge 4 ”devices safety”)

Medical devices:

- Have to follow the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices {22}
- The current legal provisions and the structure of Eudamed will not allow Eudamed to provide a complete picture of the EU market for medical devices, the number of devices entered is therefore not representative of the Union's medical device market {23}

Other devices:

- Have to follow Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

Importance: Optional

Transferability: Unspecified

Ownership & liability

Result card for LEG10: "Does the introduction of Structured telephone support (STS) for adult patients with chronic heart failure presume some additional licensing fees to be paid?"

View full card

LEG10: Does the introduction of Structured telephone support (STS) for adult patients with chronic heart failure presume some additional licensing fees to be paid?

Method

Overlaps with patent binding. See LEG2

Short Result

See LEG2

Importance: Unspecified

Transferability: Unspecified

Result card for LEG11: "What are the width, depth and length of the manufacturers guarantee?"

View full card

LEG11: What are the width, depth and length of the manufacturers guarantee?

Method

- We changed the word ”manufacturer” into ”provider” and looked at the duties of the providers of structured telephone support to guarantee appropriate quality
- Search for professional licencing regulations in the context of one member state (Austria) exemplarily

Short Result

Within structured telephone support provided by a physical person (like a nurse) and/or a group of professionals evaluating deterioration from the collected data by STS, the guarantee for quality can be given via the professional licencing regulations as it is handled within hospitals. {25} The qualification requirements are regulated at national/regional level.

Result

The qualification of the provider within the structured telephone support should be transparent and according to the national professional standards (i.e. medical professionals’ law/Medizinberufegesetz, physicians’ law/Ärztegesetz, law for healthcare professionals/Gesundheits- und Krankenpflegegesetz, etc., in Austria).

If a national registration for medical professionals is required it should be the same for the providers of the telephone support, especially if treatment advices are given or symptoms are collected and asked for. {1}

The patient should be informed about the identity and the profession of the person calling. (no legal requirement, content of patient information standards)

The documentation of the data within health records requires the identification of the healthcare provider (who did what, when and how)

Importance: Important

Transferability: Unspecified

Regulation of the market

Result card for LEG12: "Is Structured telephone support (STS) for adult patients with chronic heart failure subject to price control?"

View full card

LEG12: Is Structured telephone support (STS) for adult patients with chronic heart failure subject to price control?

Method

Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts {2}

Use of the common search results by the project manager for this HTA on STS for chronic heart failure patients:

Galbreath AD, Krasuski RA, Smith B et al. Long term health care and cost outcomes of disease management in a large, randomized, community based population with heart failure. Circulation 2004;110:3518-3526. {35}

Staples P; Earle W. The nature of telephone nursing interventions in a heart failure clinic setting. Canadian Journal of Cardiovascular Nursing. 18(4):27-33, 2008. {36}

Short Result

STS for adult patients with chronic heart failure might be a subject to price control whenever the services included in STS fall under the public contracting legislation/ reimbursement schemes. This might happen in different degrees, up to various level. In a randomized, controlled clinical trial conducted in the U.S. {Galbreath} disease managers were employed by CorSolutions, Inc, which is an established disease management company and was contracted for the study to carry out the structured telephone support. In such case, the whole service would be contracted and subject to contracting.

Directive 2004/18/EC (11) defines »framework agreement" as an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged.

The criteria on which the contracting authorities base the award of public contracts can be either:

(a) various criteria e.g. quality, price,technical merit, aesthetic and functional characteristics, environmentalcharacteristics, running costs, cost-effectiveness, after-sales service and technical assistance, delivery date and delivery period or period ofcompletion, or

(b) the lowest price only.

[Directive 2004/18/EC, Article 53 1.]

Usually, however, for the STS an additional nurse was used who had access to patient data, carried out the STS, monitored the patient, recorded the symptoms and data and reinforced and adapted the plan of care for the patient. The other medical professions did not get involved in STS directly, only indirectly, through the STS nurse, who coordinated all the activities and services around the patient. No study specifically recorded the (decrease or increase of) workload for other specialists in case a STS nurse was involved in the work {Staples}.

In such cases, the medical personnel reimbursement remains a major concern with a lack of appropriate reimbursement in place in most countries worldwide and as a result less STS is introduced by providers {33}. As usual setting for STS is hospital (after patients are discharged from hospitals) it is to be expected that a specific DRG (or similar) needs to be formed to finance the STS service. As pricing is national level task, the national legislation applies and the only price control would be contracts conducted between the provider and payer in accordance with national health policy. The pricing within DRG system must therefore take into account all national legislation and regulation, like national policy on wages or depreciation. However, when the material costs are built into DRG, again the procedures for the public contracting is important, in case of STS it oculd apply to the telephone lines and various equipment that is given to HF patients to monitor their health status at home (scales, meters for circumference of ankles etc).

Result

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Comment

- Critical

- **Important**
- Optional

Importance: Unspecified

Transferability: Unspecified

Result card for LEG13: "Is Structured telephone support (STS) for adult patients with chronic heart failure subject to acquisition regulation?"

View full card

LEG13: Is Structured telephone support (STS) for adult patients with chronic heart failure subject to acquisition regulation?

Method

(Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

Frame

Decision about which technology is provided?

Short Result

If the provider of the telemonitoring by STS is a public organisation the acquisition control has to take place and is usually known and followed by the provider. For contracted parts within or connected with the STS telemonitoring the acquisition regulation could be relevant if a certain amount of costs (i.e. for software, for a company providing the whole package including structured telephone support) is reached. A bottom-up provision of structured telephone support using certain tools or a kind of subcontracted professional team should be aware of the existing acquisition legislation.

Result

Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts {2}

For public services the Directive 2004/18/EC provides clear regulation for service exceeding an amount of € 162.000 or € 249.00 or € 6.242.000 (Art 7) for services not excluded from the regulation (Art 10, 11, 12, 18). Central purchasing bodies involvement is regulated within Art 11. Providing exploit public telecommunication networks or telecommunication services is excluded within Art 13. This Directive shall not apply to service concessions as defined in Article 1(4) (see Art 17). Article 44 regulates the choice of the participants and the follwoing articles regulate choice characteristics (personal, economic, suitability, pürofessional ability,quality, environment, operational certification, for the participating service contents or mechanisms (Art 45-52).

The Directive 2004/18/EC is possibly more detailed in respective/implemented national law. For Austria i.e. this would be the procurement law (Bundesvergabegesetz 2006) {26}

Importance: Important

Transferability: Unspecified

Result card for LEG14: "Is the marketing of Structured telephone support (STS) for adult patients with chronic heart failure to the patients restricted?"

View full card

LEG14: Is the marketing of Structured telephone support (STS) for adult patients with chronic heart failure to the patients restricted?

Method

Directive 93/42/EEC of 14 June 1993 concerning medical devices.

National laws

Frame

For medical services the direct marketing towards the patient is always restricted due to the connection with health needs.

Short Result

The marketing of medical devices is regulated within the Directive 93/42/EEC and has to be taken into account if non-implantable medical devices (like blood pressure devices) are used in connection with STS. This means, the device has to follow the CE regulations.

For the marketing of a special device or product within a provided service one should be aware about the definition of corruption.

Within medical services and/or medical devices advertising is regulated by local governments to prevent misinterpretation about the device or service.

Result

Directive 93/42/EEC of 14 June 1993 {22} regulates the use of non-implantable medical devices. The rules have to be followed if such devices are used in combination with STS. (CE mark or at least information of the competent authorities is required for a certain class of medical devices).

Within the field of marketing of medical products/ services one should always be aware of the definition of corruption:

Illegality; a vicious and fraudulent intention to evade the prohibitions of the law. The act of an official or fiduciary person who unlawfully and wrongfully uses his station or character to procure some benefit for himself or for another person, contrary to duty and the rights of others. {27}

Advertisement has the potential to create expectations and powerfully influence the belief in a medical device's capabilities. It is important, therefore, that medical device marketing and advertising are regulated to prevent misrepresentation of a medical device and its performance. (...) Whether to grant local marketing rights to a medical device remains a local government decision, which may rest on local socioeconomic considerations and technology assessment information. {28}

In Austria i.e the physicians' law includes a paragraph about advertisement limitation and prohibition to earn a commission {29}

Importance: Important

Transferability: Unspecified

Legal regulation of novel/experimental techniques

Result card for LEG15: "Is Structured telephone support (STS) for adult patients with chronic heart failure so novel existing legislation was not designed to cover its regulation?"

View full card

LEG15: Is Structured telephone support (STS) for adult patients with chronic heart failure so novel existing legislation was not designed to cover its regulation?

Method

Search among EU websites and in google for legal regulations of telemonitoring/ STS, literature from the common project search.

Used:

COMMISSION STAFF WORKING DOCUMENT eHealth Action Plan 2012-2020

OECD – ICT document

Dubner et al. 2012

Short Result

There is still legal uncertainty within the provision of structured telephone support for patients with chronic heart failure in terms of

- Cross border healthcare services
- Funding aspects
- Reimbursement
- Procurement
- Sustainable business models
- Data protection via telephone line
- Provider responsibilities

Result

- The COMMISSION STAFF WORKING DOCUMENT eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century Accompanying the document COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century /* SWD/2012/0413 final */ {30} states Legal uncertainty in deploying eHealth (cross border) services, ineffective funding, reimbursement, procurement and sustainable business models

(paragraph 3) and describes remaining challenges like the ”creation of a framework for greater legal certainty of eHealth products and services and the provision of online services in telemedicine and ePrescription by the majority of European health organisations and regions*”* (3.1). Within paragraph 4.5 is written: ”Clinical and healthcare workflows, care models, and business processes are significantly more complex than equivalents in other sectors of the economy and less amenable to standardisation and streamlining by conventional eBusiness systems. Below, the results of the public consultation and the available evidence demonstrate other reasons and barriers for slow uptake of eHealth solutions including: the lack of awareness of, and confidence in, eHealth solutions among patients, citizens and healthcare professionals; lack of interoperability between eHealth solutions; limited large-scale evidence of the cost-effectiveness of eHealth tools and services; lack of legal clarity for health and wellbeing mobile applications and the lack of transparency regarding the utilisation of data collected by such applications; inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services and the high start-up costs involved in setting up eHealth systems.” One of the recommendations therefore includes to ”Create a legal framework and space to manage the explosion of health data. This needs to put in place the safeguards that will allow citizens to use health apps with confidence that their data is handled appropriately and subsequently it will create the conditions for the integration of user-generated data with official medical data so that care can be more integrated, personalised and useful for patients.”

There are Good Practive Guidelines existing for Chronic Patients with Cardiovascular disease {31}, which include legal aspects (3.2.5):

*”*Healthcare via telemedicine is like any other care delivered by a health service . It requires

- quality standards of care including the use of appropriately certified
- equipment
- evidence-based medicine
- healthcare professionals to act within their scope of professional practice and statutory/regulatory framework
- due regard for patient safety and wellbeing
- clinical and research governance
- ethical behaviour.”

As concerns are expressed:

- the security of transfer of information from home monitoring equipment via the Internet and/or mobile telephone networks
- specific clinical responsibilities within healthcare professionals providing telemedicine service
- not clearly defined others’ roles

- **OECD – ICT document {32}**

There are many aspects requiring legal governance ”ranging from professional and organisational accountability to means of quality measurement and quality assurance, including those which look at the totality of interagency care, as well as cross-agency leadership and co-ordination.” (p85)

- **Dubner 2012 {33}** states an important comment: Every system with wireless capability has to be assessed to be secure against hackers and other unauthorized access to personal information stored in web-based servers .

Importance: Critical

Transferability: Unspecified

Result card for LEG16: "How the liability issues are solved according to existing legislation?"

View full card

LEG16: How the liability issues are solved according to existing legislation?

Method

Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013)

Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (especially (4), (6), Art 13 (1., 3a, 3b).

used as basic documents for a

discussion with experts

Frame

For the provision of telemedical services/ STS several different legal regulations have to be followed, like:

- Occupational laws
- Hospital legislations
- Good clinical practice

- Health telematic law
- Data protection law
- E-government law
- Consumer protection law
- Signature law
- E-commerce-law
- Telecommunication law
- Copyright/ patent protection
- Media law

(list not exhaustive)

This means that there is uncertainty which liability limitations exist for what kind of service provision.

Short Result

The 1926/29006/EC is used as a basic document, especially due to the aim (Art 2) for regulating the consumer aspects. Its not a regulation.

Directive 2001/20/EC was used as a basic document for the discussion due to the ”liability” of member states for any investigantional medicinal products.

The liability issues require a certain business plan for the provision of (any) tele-healthcare service, including telephone support.

This means that the patient has to have one single partner to be ”contracted” with. In the usual face-to-face contact with the primary care physician (general practitioner) the care-contract exists between the patient and the physician.

Within a telehealth-structure there are many possible contracts like telephone line company, energy support, software involved, the staff providing the telephone support, a possible company providing a package of structured support including telephone calls, the physician providing the data check/ medication change/other medical services, the server hosting company for the data storage, etc...

Within this structure there is an additional challenge in many countries, which implies a direct (face-to-face) medical care required from the phyiscian and/or other healtcare staff., and which is per definition not the case for any kind of telemedical service. Also the hospitals are responsible to provide the care within the hospital environment.

A national health system or a social insurance could be able to provide telemedicine as a ”service” meaning the provision of being the ”contract head” for all different included services (as listed above). The patient, the GP, the hospital, the software/telecom/other companies are contracted with the health system (national /community government, or social insurance) within a kind of structured program regulating the rights and duties of the contracted partners.

Such a service of the health system could be provided everywhere, even if the patient is abroad (i.e. for holidays), because it is not a direct medical treatment, but a service package including different aspects.

Hardisty et al.{34} point out that *There is a fundamental lack of clarity regarding the location of decision making responsibility when the service is spread across multiple providers. This issue has not been addressed in work to date and may require changes in how services are designed and managed, impacting medico-legal frameworks.*

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Importance: Critical

Transferability: Unspecified

Discussion

Structured telephone support ist not a single drug or device or intervention, but includes different aspects of care and organisational structure. Therefore the legal aspects extend the usual frame for drug or device intervention.

The structural basics like property rights, marketing authorisation, patent binding, registries, providers guarantee as well as reimbursement include some tricky legal expanding due to the fact that STS is a package of different providers using possible devices and infrastructure with different regulation aspects. There are i.e. data protection issues, property rights to follow for the used software, patent bindings for a used questionnare, marketing authorisation necessary for medical devices used, and reimbursement issues due to DRG regulation or within contract binding.

In terms of patient right the easiest part is the voluntary participation, because for STS the patient-participation is part of the phone call. Appropriate information is usually part of the package of STS and selfmanagement support within STS, and there is always the opportunity for the patient to ask back. The more tricky legal aspect is the acces to STS and who decides it on what purpose. STS is a healthcare service and not a strict intervention, which can lead to the interpretaion of ”team structure” with compliance required from the patient. Data protection to secure privacy aspects is clearly regulated, so for the use of phone lines and internet connections they have to be followed accordingly by the provider.

There are some uncertain legal aspects due to Cross border healthcare which are usually limited by language, funding aspects with no clear solutions elsewhere, reimbursement aspects with no clear solutions elsewhere, procurement issues, and data protection via normal telephone line. Sustainable business models need to have one central coordinator who coordinates the different legal requirements – like in a hospital setting.

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Appendices

Existing patents	Code	Name	Link
DISEASE MANAGEMENT SYSTEM USING PERSONALIZED EDUCATION, PATIENT SUPPORT COMMUNITY AND TELEMONITORING	WO2012071354 (A2) — 2012-05-31	SANITAS INC [US]; PARTOVI NASER [US]	http://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2012071354&KC=&locale=de_EP&FT=E
TELEMEDICINE SYSTEM FOR REMOTE CONSULTATION, DIAGNOSIS AND MEDICAL TREATMENT SERVICES	WO2014163475 (A1) — 2014-10-09	ESPINOSA ESCALONA FERNANDO PABLO JOSÉ [MX]; IGLESIAS RAMOS CARLOS GUILLERMO [MX]; MORALES MEDEL ALAN [MX] +	http://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2014163475&KC=&locale=de_EP&FT=E
TELEMEDICINE METHOD FOR REAL-TIME REMOTE MONITORING OF MEDICAL PROCEDURES	WO2014094095 (A1) — 2014-06-26	UNICAMP [BR]; UNIV ESTADUAL DO OESTE DO PARANÁ UNIOESTE [BR]; MACHADO RENATO BOBSIN [BR]; CHUNG WU FENG [BR]; LEE HUEI DIANA [BR]; COY CLÁUDIO SADDY RODRIGUEZ [BR]; FAGUNDES JO O JOSÉ [BR]; NUNES MACIEL JOYLAN [BR]; VOLTOLINI RICHARDSON FLORIANI [BR]; MALETZKE ANDRÉ GUSTAVO [BR]; LEAL RAQUEL FRANCO [BR]; AYRIZONO MARIA DE LOURDES SETSUKO [BR]	http://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2014094095&KC=&locale=de_EP&FT=E
MODULAR TELEMEDICINE ENABLED CLINIC AND MEDICAL DIAGNOSTIC ASSISTANCE SYSTEMS	WO2014063162 (A1) — 2014-04-24	TAWIL JACK [US]; TAWIL MARGARET [US]; SANDBERG DOV [US] +	http://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2014063162&KC=&locale=de_EP&FT=E
GRAPHICAL USER INTERFACES INCLUDING TOUCHPAD DRIVING INTERFACES FOR TELEMEDICINE DEVICES	EP2852881 (A1) — 2015-04-01	INTOUCH TECHNOLOGIES INC [US]; IROBOT CORP [US] +	http://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2852881&KC=&locale=de_EP&FT=E
Electrical household system performing telemedicine and/or telecare functions, and corresponding method	EP2592508 (A1) — 2013-05-15	INDESIT CO SPA [IT] +	http://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2592508&KC=&locale=de_EP&FT=E
MULTIFUNCTIONAL MEDICAL DEVICE	EP2630628 (A2) —	3M INNOVATIVE PROPERTIES CO [US] +	http://worldwide.espacenet.com/publicationDetails/biblio?

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METHOD FOR DERIVING AND EVALUATING CARDIOVASCULAR INFORMATION FROM CURVES OF THE CARDIAC CURRENT, IN PARTICULAR FOR APPLICATIONS IN TELEMEDICINE	EP2059163 (A2) — 2009-05-20	TELOZO GMBH [AT]	http://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2059163&KC=&locale=de_EP&FT=E
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