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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Pilot for topic identification selection and prioritisation (TISP) – Endpoint evaluation other technologies

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Developed by WP4 lead partner NIPHNO in collaboration with co-lead partner on other technologies LBI-HTA

This document is part of the project / joint action '724130 / EUnetHTA JA3' which has received funding from the European Union's Health Programme (2014-2020).

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1.	19.11.2019	TISP Pilot group on OT	Draft EPER on TISP pilot for OT	Pilot reviewers OT
2.	09.01.2020	TISP Pilot group on OT	Final EPER on TISP pilot for OT	TISP Working group (Authors and reviewers)

EPER = Endpoint evaluation report

1 Executive summary

As part of the EUnetHTA work package 4 (WP) deliverable on Recommendations for Topic Identification Selection and Prioritisation (TISP) this pilot was conducted to explore a workflow for voluntary collaboration on a TISP process for EUnetHTA collaborative and joint relative effectiveness assessment (REA) of medical devices (MDs) and in-vitro diagnostics (IVDs). The process was designed to be as simple as possible and included three steps: identification, selection and prioritisation of possible topics for REA. The pilot was conducted by a pilot group set up by the TISP WP4 work group according to a pre-defined project plan (available here). A three step process was set up were each step resulted in a product/list: A minimal dataset (MDS), a call for collaboration list (CCL) and the EUnetHTA prioritisation list (EPL). The EPL was published on the EUnetHTA web site. The other products were considered internal documents of EUnetHTA WP4. Based on the pilot the following conclusions were made by the Pilot group:

- *A TISP process for collaboration on REA of MDs and IVDs is feasible by collaborative means, but can not be performed on voluntary basis alone*
- *The piloted workflow could be conducted at least once or twice a year and help identify topics of broad interest to the network members*
- *The prerequisite for the process to be successful is the presence of a central acting secretariat and the commitment of network members to share data, commit to production and uptake*
- *An improvement of the workflow would be to set up an agreement with a pre-selected high quality HSS to specifically serve the purpose of the collaboration*
- *The value of the process with regard to increasing the number of voluntary collaborations on REA is uncertain and probably limited, unless the process can be more systematically applied and aligned with national systems of HTA commissions, and there is a clear commitment to engage in production*

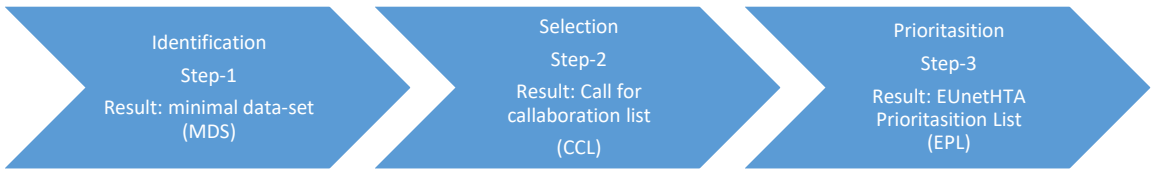
Results of the pilot was used to inform the final recommendations on a TISP system for European collaboration on HTA beyond 2020.

2 Aims of TISP pilot – Other technologies

The aim of the pilot was to explore a workflow for voluntary collaboration on TISP for REA of MDs and IVDs. The process for the pilot was designed to be as simple as possible so that it could be used on a voluntary collaborative basis beyond EUnetHTA Joint Action 3 (JA3). Results of the pilot will inform the final recommendations on Horizon scanning (HS) and TISP for European collaboration on HTA beyond 2020.

In short, the process includes three steps: identification, selection and prioritisation of possible topics. Each step results in a product/list as shown in figure 1.

F1 Steps of the TISP process



3 Methods

The pilot was conducted as outlined below, with details of each step as described in the pilot project plan (available here).

Organisation of work

The WP4 lead partner (NIPHNO) and co-lead on other technologies (LBI-HTA) constituted the pilot working group supported by the EUnetHTA partners AGENAS, NSPHMPDB and NICE as described in the project plan. Shortly, NIPHNO and LBI-HTA acted as a central secretariat organising the TISP process.

Identification (Step-1)

1) EUnetHTA partners sharing data from existing local or regional HS systems (HSS) or TISP lists informing prioritisation of HTA. A questionnaire was sent to all on whether they were able to share data from a regional or national HSS or a TISP list.

2) The POP-database of planned and ongoing projects. The POP database was for planned projects added within the last 6 months. The record creators were contacted to verify the up-to-datedness of their records and the eligible records were entered into the identification template by LBI-HTA.

3) Input from EUnetHTA partners and stakeholders. An announcement on the EUnetHTA home page (https://eunethta.eu/services/horizon-scanning/) was used to inform partners and stakeholders about the possibility to suggest topics for TISP. Awareness of this announcement was made through the EUnetHTA e-mail list of partners and the EUnetHTA e-mail list of The HTA network Stakeholder Pool (Appendix 1).

The fields of the MDS were completed using the information from the identification list, inspection of information added as hyperlinks by the sources and a web-search. First, as a test the web search was performed including the manufacturers web sites (if found), the FDA medical devices database (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases), clinical trials.gov (www.clinicaltrials.gov) and Google. After testing this approach the following fields were omitted from the MDS: timeline of clinical research and estimated launch. Due to resource restrictions, for the majority of topics, the manufacturers web sites (if found) and the FDA medical devices database was the only web sites searched. Two researchers (one from LBI-HTA and one from NIPHNO) conducted the web-search. If the basic web-search did not yield any results, the search the field was left open. A pre-selection step took place to remove duplicates and topics not considered (MDs or IVDs).

Selection (Step-2)

The selection to include topics for the call for collaboration took place according to the following pre-specified criteria:

1. *only MDs and IVDs*
2. *the product is CE marked or anticipated to be CE marked within 12 to 24 month*
3. *timelines to fit within EUnetHTA WP4 JA3 production.*

In practice, criteria three meant that topics that were not yet CE marked were retained in the MDS to be used in a later CCL. Topics under assessment or recently assessed by EUnetHTA were excluded from the MDS. One researcher (LBI-HTA) conducted the selection based on the above criteria and another researcher (NIPHNO) verified the selection (the excluded as well as the included records). The selection resulted in the CCL.

Prioritisation (Step-3)

The CCL was sent by LBI-HTA to all WP4 OT partners asking them to indicate their interest in the topic. EUnetHTA WP4 partners could express interest in the topic as:

- *expressed interest in the topic as relevant for national/regional setting*
- *expressed interest in national/regional uptake of a EUnetHTA conducted REA*
- *expressed interest to participate in assessment as author, co-authors or reviewers*
- *no expressed interest*

Each yes answer received a score of one, and each no answer or do not know answer/open field received a score of 0. The cut of for entering the EUnetHTA prioritisation list (EPL) chosen in the pilot was:

- *At least four EUnetHTA partners had to express interest in participating in the assessment (no restriction to type of participation)*
- *A cut of to keep the number of prioritised topics to be approximately 20 was pragmatically chosen*[1]

Only topics that fulfilled these criteria were added to the EUnetHTA prioritization list (EPL). The EPL list was published on the EUnetHTA home page. EUnetHTA partners as well as other stakeholders were informed about the list through emails.

Endpoint evaluation

In addition to reporting the timeline of the pilot steps, the endpoint evaluation was, with exclusion of one endpoint (developmental status of topic), performed based on the pre-defined endpoints of the project plan. However, the presentation of the findings have been structured to increase readability. The number of collaborations started based on the EPL was measured approximately four months after publication of the EPL. Partners expressing interest as authors were contacted after three months.

[1] There were 18 responders, each topic could receive a maximum score of 3 from each responder. The maximum score for each topic was 54 (3x18). The highest overall score a topic received was 27, and the lowest overall score a topic received was 8. The cut of chosen was a total score of at least 20 providing prioritised 20 topics (two were excluded from the EPL due to lack of marked availability).

4 Results

Timeline of the pilot

- *The pilot started 1th of February 2019 by sending out the questionnaire on HSS/TISP-lists and the announcement to suggest topics on the EUnetHTA homepage as described above.*
- *The deadline to respond was first 1th of March 2019 and then extended to 15th of March.*
- *The Pop-database was searched 15th of March 2019*
- *The call for collaboration was sent out to EUnetHTA WP4 partners 25th April2019 with deadline to respond until the 16th May, 2019.*
- *The EPL was published on the EUnetHTA homepage on 10th July2019.*
- *The response rate was measured in September 2019 and October 2019*
- *EUnetHTA Partners volunteering as Authors were contacted in September 2019*

In conclusion, each round of a workflow like this (from announcement to suggest topics to publication of the EPL) may take 3-4 months leaving reasonable time for each step to be performed on a voluntary basis. The time line does not include the time needed to initiate assessments (see below under number of initiated assessments) In practice, with a central acting secretariat in place, it should be feasible to conduct a voluntary workflow like this once or twice a year.

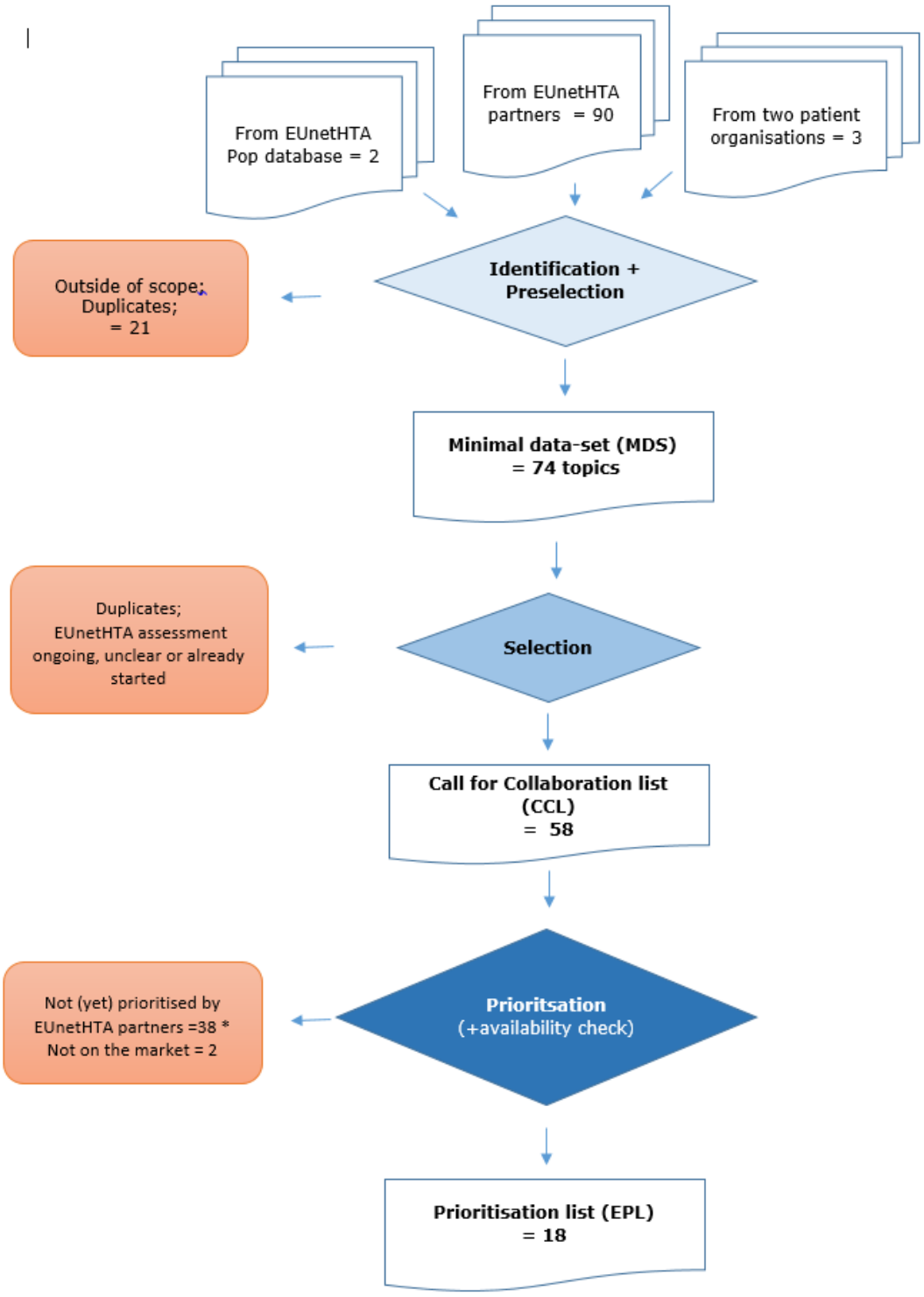
Identification
Availability of data from different sources and barriers for information sharing

1) EUnetHTA partners sharing data from existing local or regional HSS or TISP lists.

The response rate on country level was 65 % (partners from 19 countries responding out of 29 countries with EUnetHTA members), and on partner level was 35% (28 responding partners out of 81 EUnetHTA partners). Partners from 13 countries stated that they had a national or regional HSS informing HTA and/or list of topics informing prioritisation of HTA. EUnetHTA partners from eight countries stated that there was a HSS or TISP-list informing prioritization of HTA on MDs and IVDs (see table 1). EUnetHTA partners from six countries stated that they were able to share data/topics from the HSS/TISP-list for the EUnetHTA pilot. EUnetHTA partners from seven countries stated that they were able to voluntarily collect and share data from the HSS/TISP- list on a regular basis beyond 2020. The preferred interval for sharing data varied from 1 to 4 times a year. Most of the respondents for MDs and IVDs preferred 2 times a year. The barrier for sharing information was related to confidentiality issues.

T1 *Countries with HSS or TISP-list informing HTA*

Country with HSS or TISP-list informing prioritisation of HTA on MDS and IVDs	EUnetHTA partners able to share for pilot	EUnetHTA partners able to share beyond 2020	Preferred interval for sharing (x per year)
Austria	Yes	Yes	1
Ireland	Yes	Yes	2
Italy	Yes	Yes	2
Norway	Yes	Yes	2-4
Spain	Yes	Yes	1-2
Switzerland	No	Yes	2
United Kingdom	Maybe/yes	Maybe	No answer
Wales	No	No	-



F2 Flowchart of the TISP process for MDs and IVDs

*Based on the cut-of used in this pilot

For the pilot, the following five EUnetHTA partners supplied topics from national or regional HSS/TISP-lists: AGENAS (Italy), Austria (LBI-HTA), Norway (NIPHNO), England (NICE) and Spain (SESCS/FUNCANIS). In addition, EUnetHTA partners from France (HAS), Germany (IQWIG), Denmark (DEFACTUM), Spain (AQUAS), Austria (HVB) and Sweden (SBU) proposed topics by responding to the invitation to propose topics sent to EUnetHTA partners and stakeholders. The total number of topics from the responding EUnetHTA partners was 90.

2) The POP database of planned and ongoing HTA projects.

On 15th March LBI-HTA searched the POP database for planned projects added within the last six months, verified the up-to-datedness of the records and created a list of the eligible projects. Six projects were identified, four were excluded after contacting the record creators to verify the status of their records (the projects had already started). The total number of topics included from the POP database was two.

3) Input from stakeholders.

We received three topics from two stakeholders (i.e. non-EUnetHTA partners: EURORDIS, The Voice of Rare Disease Patients in Europe and The Dravet Syndrome European federation)

Number of identified topics and duplicates
95 topics[2] were identified from the above three sources and assessed for their eligibility to enter the MDS. Four out of the 95 topics were identified by multiple sources, one of which by three sources, the other three by two sources. After excluding these duplicates, 91 topics were further assessed for eligibility.

Selection
The number of topics was reduced in a pre-selection step if they were considered duplicates based on classifying technologies with approximately the same definition as one topic, or to be out of scope (not MD/IVD) and too early for assessment. The final MDS contained 74 topics. During selection from MDS to CCL, 16 topics were excluded due to further deduplication, already being assessed or under assessment by EUnetHTA, topics without a CE marked technology or CE mark unclear (5 topics). A total of 58 topics were included in the final CCL.

Prioritisation
A total of 36% (18/50) WP4 EUnetHTA partners on OT from 12 countries responded to the CCL. Three of the responding partners did not give a comprehensive answer. Two of these replied that they could not answer the questions at all and one could only answer for the topics they proposed, but not for the topics proposed by others. Reasons for this are related to how their national system for HTA works, and that the HTA partner can neither suggest or priorities topics for HTA. Their input was scored as 0. Based on the scoring system suggested by the project plan, each topic could at maximum score 54 points based on 18 responders (3x18). The highest overall score a topic received was 27, and the lowest overall score a topic received was 8. No topic received zero expressed interest in any of the three fields. Interest to participate

The highest overall score for a topic based on interest to participate in assessment was 8/18 and the lowest score was 1/18. The highest overall score for a topic based on interest for national setting was 12/18 and the lowest score was 2/18. The highest overall score for a topic based on interest for

[2] Notably, the definition of a topic was based on highly similar technology definitions, which is similar technologies with approximately the same indication and not a product per se. This implies that the number of individual products was higher than the number of topics.

national uptake was 10/18 and the lowest score was 2/18.

For 29 topics there was an expressed interest to participate in the assessment from four partners or above (score 4 or above). In four topics it was only one partner who was interested in the topic, in 12 topics it was two partners and in 13 topics three partners indicated they would participate in a EUnetHTA assessment.

For 20 of the 29 topics reaching the four partner interest to participate score, the overall score (participation, national relevance and uptake) was 20 or above. Notably, all topics with a score of 20 or above reached the four partners interested in participation cut-off. Based on this observations, the cut-off for the pilot was chosen to be at least 4 partners interested to participate and at least 20 in overall score. 20 topics fulfilling these criteria were considered the highest prioritized topics for the EPL and made available on the EUnetHTA website (https://eunethta.eu/assessments/eunethta-prioritisation-list-epl-other-technologies/). However, two topics were excluded after prioritisation as they were not available on the market.

The partners were asked to indicate what role (author, co-author or reviewer) in the assessment they could be interested in. Interest in the author role was registered only for four topics. For one of these topics, the overall score was below 20 and the topic was not included in the EPL. Interest in the co-author role was registered for 17 topics with five not included in the EPL. In seven topics, partners were able to take the role of dedicated reviewers only, three of these topics did not reach the overall score of 20.

Information on the topics and information gaps

For five out of 91 identified topics, the CE mark was not applicable because the topic was considered a procedures and not a MD or IVD per se. These topics were excluded from the MDS. For five out of 91 topics information on the CE mark was not found. The lack of information might be due to an early technology readiness level of the topic. The topics were included in the MDS, but not included in the CCL. For all other topics of the final MDS (69/74 topics) there was at least one CE marked product. For some topics with more than one product from different manufacturers, information on CE mark was lacking for one or more individual products. By developmental status we had in mind to describe the status of clinical research (no clinical research, ongoing, completed) and best guess on expected launch. However, for most topics this information was difficult to find and the endpoint was omitted. Where available the information was included in the comment field of the MDS.

The dominating therapeutic areas of the CCL (58 topics) were cardiovascular diseases (7 topics); cancer and palliative care (6 topics); ear, nose and throat (5 topics); musculoskeletal and orthopaedics (5 topics); neurology and neurosurgery (6 topics); respiratory disease (5 topics). The dominating therapeutic areas of the EPL (18 topics) were cardiovascular diseases, cancer and palliative care with four topics each.

Table 2 presents information gaps of the identification list (91 topics after removal of duplicates), and the resources spent to search the information. As the first four fields were mandatory, these were provided by the partners who shared topics. In case of topics identified via the POP database, the name of the products and the name of the manufacturers needed to be identified. For two fields (timeline of clinical research and estimated launch), we decided to omit the data as in most cases this was either not provided, very uncertain or would require resources not available for the pilot. For two fields (hyperlink to information and comments) no searches were made. Information for the remaining fields were searched as described in methods. The total time used for searches (not including time spent for the fields omitted) was 32,5 work hours, corresponding to an average of almost 0,4 hours per topic. The most work intensive field to populate was the regulatory status of the topic in Europe (16 hours). The most difficult information to be found was the class of MD/IVD (lacking in 25 out of 91 after an additional 8 hours of search).

T2 *Information gaps*

Fields of the MDS template	Information gaps after search	Time spent to seek out information in 91 topics
Technology/Topic definition*	0	-
Name of product*	0	3 hour (for 2 topics (those identified in POP)
Manufacturers*	0	3 hour (for 2 topics (those identified in POP)
Indication (anticipated, including age and sex if applicable)*	0	0.5 hour (for 2 topics (those identified in POP))
Therapeutic area	0	1 hour
Type of device according to CE marking (MD class, IVD class)	25/91	8 hours
Timeline clinical research (Information on pivotal trials and trial number(s) if available).	-	We decided to omit this data field as it was very time consuming to search. Where easily found, the information was put in the comments field.
Regulatory status Europe (CE mark) at first entry	10/91 (information lacking in 5 after search and not applicable in another 5)	17 hours
Regulatory status USA (FDA approval) at first entry	9/91 (information lacking in 4 after search and not applicable in another 5)	6 hours
Estimated launch (best guess) at first entry	-	We decided to omit this data field as it was very time consuming to search and country specific. Where easily found, the information was put in the comments field.
Hyperlink to information (if available)	44/91	-
Comments (not obligatory)	71/91 (12 provided comments, but we complemented the comments and added 8 more).	3 hours (including 8 topics were developmental status was checked – this was not done for the rest)
		35,5 h= mean 0.4 h/topic

*Provided by the proposer

Workload connected with each step

An approximately estimate of workload per step is given in table 3.

T3 *Workload*

Step	**Description**	**Anticipated workload (7 h= one day)**
Identification	From Identification list to draft MDS (Including checking the Pop database, and quality check)	28h = 4 days
Selection	From draft MDS to CCL (including information searches described above, quality check and sending out the CCL)	50h = 7 days
Prioritisation	Receiving the results, sorting the results and preparing the EPL.	14h = 2 days
Total	From identification to EPL	92 = 13 days

In total, we anticipate that the workload with the process may be approximately 10-14 person days per cycle if the cycle is repeated twice a year with approximately the same amount of identified topics (95). Notably, the process might be more efficiently performed per time, however repeating the cycles would also include keeping track of the MDS, and re-checking the status.

Number of assessments initiated after the publication of the EPL

Per November 15th 2019, two assessments of topics from the EPL was initiated. For the remaining topics LBI-HTA has contacted the partners who had expressed interest to be authors. These partners could (at the time connected) not commit to be authors. The reasons are connected to how their national commission system works.

5 Discussion

We have explored a simple three step TISP process to support supranational voluntary collaboration on REAs within the framework of EUnetHTA JA3 and beyond. The only selection criteria was technology type and timeline with regard to the CE mark process. The only prioritization criteria was EUnetHTA partners interest in the topic for national setting, national uptake of HTA or participating in HTA.

The results have revealed that it is possible, to set up a system based upon voluntarily sharing of information, and to use this information to extract a list of topics based on the collaborating partners expressed interest in the topic. The workflow may be conducted within approximately 3-4 months leaving enough time for each step. Resources needed correspond to approximately 13 person days based on the number of identified topics are within the same range. This is restricted to the work performed by the central acting secretariat. The resources needed for partners sharing information and partners prioritising is not included in this calculation.

For 18 out of 58 topics identified to be within the scope for a call for collaboration there was substantial interest to participate in assessment, relevance of topic in the national setting and relevance for national up-take. However, the interest to be an author as well as the commitment to follow up the interest was low measured as initiated assessments four months after the publication of the EPL. This may at least in part be due to national or regional processes not being aligned with the collaborative TISP process (see below). Therefore, the value of the process with regard to increasing the number of voluntary collaborations on REA is uncertain and probably limited, unless the process can be more systematically applied and aligned with national systems of HTA commissions and there is a clear commitment to engage in production.

Identification and selection

Identification should assure that relevant topics in scope of the TISP process are identified in a timely manner to ensure that the TISP process contributes to collaboration on the most relevant HTAs. Selection should assure that the identified topics are within the scope of the TISP process. In addition, selection was used to identify duplicates and complete the MDS and CCL. Time line was the main selection criteria.

We explored three sources of identification: EUnetHTA partners sharing data from existing HSS/TISP-lists or suggesting topics of value for their agency, the EUnetHTA Pop database and stakeholders proposing topics.

According to a report from 2017, nine European countries (Scotland, Ireland, Norway, Sweden, Estonia, France, Belgium, Italy and Spain) had HSSs supporting prioritization of HTA of technologies other than pharmaceuticals (ref WP7 report). We found, based on 28 responding EUnetHTA partners from 19 countries, that EUnetHTA partners from six countries were able to share information from their HSS or TISP-lists, five partners from five countries did so as part of the pilot. Additionally, four partners proposed topics to this pilot.

The number of responders to the questionnaire on country level was 65 %, but only 35 % based on EUnetHTA partners. Notably, not all EUnetHTA partners are HTA organisations and only EUnetHTA partners are involved in EUnetHTA WP4 activities. In addition only a few EUnetHTA agencies perform HS and only five agencies replied that they were able to share lists of identified or prioritized topics. It should be noted that, based on the background information identified as part of the TISP work, we are not aware of any publicly available European HSS that have not been explored in this pilot and non-responding partners with a HSS in place may not be able to share data. The number of topics identified were substantial (95) with relatively low level of overlap. This might reflect that the list is far from exhaustive with regard to a very wide scope. Notably, for the responding partners, we are uncertain to whether the processes that lead up to the identification lists are lean and based on

exhaustive searches. Furthermore, we are uncertain to how the national selection criteria have influenced the shared lists. We anticipate that a similar number or even larger number of new topics may be identified twice a year.

The number of relevant planned topics entered to the POP-database the last six months within the scope of this project was six. After checking the status of assessments, four were excluded as national assessments were found to already be initiated. This was due to the lack of updating the database by the partners. Nevertheless, we do believe that a more active and systematic use of the POP database in a TISP process could be further explored.

The number of topics suggested by stakeholders was only three. The HTA network stakeholder pool is broad and this could at least partly be due to the short deadlines of the pilot and lack of awareness of the pilot. A higher number might be expected if the system is established and more well known. However, also for this purpose it would be better to suggest topics through an HSS with lean procedures to assure the relevance of the topics.

Improvements of the process could involve stricter inclusion criteria stating that the topics should have been nationally or regionally prioritized topics, and not yet assessed. This would demand a process more aligned with national or regional processes of commission. To do so would require a larger commitment on the level above the individual EUnetHTA partner to express a clear interest in at least some topics being assessed in a collaborative REA. Another improvement would be to set up a collaborative agreement with pre-selected HSS with lean procedures to serve to purpose of the collaboration. This would probably be resource demanding and not possible on a complete voluntary basis.

The time spent to search for information was substantial and some fields (timeline with regard to clinical research and launch) of the MDS had to be omitted. More precise information may be achieved by introducing a step between identification and selection involving input from developers or manufacturers to provide information on their topics. However, this was not in the scope of the pilot and would add to the resource need. In addition, developers might consider the information commercially sensitive and not shared without an agreement of confidentiality. Such agreements can only be made by a professional HSS.

Prioritisation

Prioritisation should ensure that only the most relevant topics are prioritised. In this pilot, prioritisation criteria were limited to expressed interest in topics at the national level, potential participation in production and national uptake of a European HTA.

The number of responding EUnetHTA partners in the call for collaboration was 18 out of 50. The low response rate could partly be due to the fact that not all WP4 partners are HTA agencies, that only a few partners have volunteered to participate in assessments as authors and co-authors and that there is limited resources left to perform any assessments within the framework of JA3. In one case the responding partner stressed they could not answer as they are not an HTA agency, but a research institute. This partner is not an isolated case in EUnetHTA WP4 OT. The number of partners expressing interest to volunteer as an author was only four. This can be explained by the fact that most EUnetHTA partners do not have the ability to prioritise topics that have not been commissioned. Several EUnetHTA partners also expressed that the ability to collaborate depends very much on the available resources in JA3. Thus, a commitment to volunteer as author cannot be given unless the topics are nationally or regionally prioritized. Thus, authorship will depend on the national or regional processes and the value of the EPL and repeating the workflow with regard to increasing the number of collaborative REAs is uncertain.

In general, the EUnetHTA partners who replied to the call for collaboration indicated that they had difficulty to answer and therefore they tried to give a best guess. Where this was commented on, the

reason given was either related to national settings, including the process for topic commission, timelines, type and depth of information needed and resources available to perform assessment. These factors could also influencing the response rate.

Detailed feedback on the commissioning process was received from five partners (from Italy, Norway, Austria, Spain and Scotland). In Italy the topics are commissioned by, a steering committee within the Ministry of Health which includes regional representatives. Topics are prioritised according to a set of criteria. Assessments are initiated within collaboration agreements between the EUnetHTA partner and the Ministry of Health. Regarding the TISP pilot, the time given was too short to submit the CCL to the steering committee. Likewise in Norway, a central commissioner forum decides on the topics suggested by regional health authorities and specialists/clinicians. The HTA body may come up with suggestions through a horizon scanning-like process by producing alerts that can be submitted to the forum. The decision is made on pre-set dates. The process takes some time (at least two months after the suggestion is handed in) as several instances and experts need to be consulted. Thus, in reference to the piloted TISP process, the time given to feed into the CCL list is too short. Also in Spain, the system is similar. The topic is commissioned if hospital managers express their interest in a topic and formally request it. The request has to comply with the regional filtration/prioritization criteria. In Austria, if there is a submission/application for inclusion of a medical device into the benefit catalogue, an assessment is needed urgently. There is no system in place, which would forecast this. In Scotland, clinicians were consulted about the relevance of the topics, and the given time period was too short to obtain information.

One partner stated that the provided information in the CCL was too scarce. This partner would have preferred an even more filtered list and the use of prioritization based on pre-defined criteria. One partner stated that resources are limited and that they have to be very selective to ensure the topic is highly relevant to the national setting. For one partner it did not matter what the topic was, but the timing needed to fit with their other projects. The same partner said they would use the EUnetHTA report in the national setting only if it is commissioned.

In 14 out of the 18 (78%) prioritised topics of the EPL more partners indicated they would use the EUnetHTA report (uptake) than the number of partners who would participate in producing the assessment. For some topics, there was a mismatch between the number of partners who indicated their willingness to participate and the number of partners who indicated their willingness or ability to use the EUnetHTA report in the national setting. This can be explained by the fact that some partners expressed interest in collaboration to learn the EUnetHTA processes without having a structured national HTA process in place, and therefore not being able to express interest in uptake.

EUnetHTA collaborative assessments of MDS and IVDs are restricted to CE marked and market available products. If an EUnetHTA collaborative assessment is to be considered, the CE mark and marked availability of the products needs to be confirmed with the manufacturer.

6 Conclusions

A TISP process for voluntary collaboration on REA of MDs and IVDs is feasible by collaborative means. The piloted workflow could be conducted at least once or twice a year and help identify topics of broad interest to the network members. The prerequisite for the process to be successful is the presence of a central acting secretariat and the commitment of network members to share data, commit to production and uptake. An improvement of the workflow would be to set up an agreement with a pre-selected high quality HSS to specifically serve the purpose of the collaboration. This is probably not possible on a complete voluntary basis. The value of the process with regard to increasing the number of voluntary collaborations on REA is uncertain and probably limited, unless the process can be more systematically applied and aligned with national systems of HTA commissions and there is a clear commitment to engage in production.

Appendix 1 Contacted stakeholders

ORGANIZATION	CATEGORY
Bureau européen des unions de consommateurs-BEUC	CONSUMERS
Health Action International-HAI	CONSUMERS
European Cancer Patient Coalition-ECPC	PATIENTS
European Federation of Allergy and Airways Diseases Patients' Association-EFA	PATIENTS
European Institute of Womens Health-EIWH	PATIENTS
European Rare Disease Organisation-EURORDIS	PATIENTS
European Patients Forum-EPF	PATIENTS
European Multiple Sclerosis Platform-EMSP	PATIENTS
European Public Health Alliance-EPHA	CONSUMERS/PATIENTS/NGOS/HCP
International Diabetes Federation European Region-IDF	PATIENTS
European Organisation for Research and Treatment of Cancer - EORTC	RESEARCH
International Association of Mutual Benefit Societies-AIM	PAYERS
European Social Insurance Platform-ESIP	PAYERS
Council of European Dentists -CED	HCP
Standing Committee of European Doctors-CPME	HCP
The European Association of Hospital Pharmacists-EHAP	HCP
European Union of General Practitioners/ Family Physicians UEMO	HCP
European Society of Medical Oncology-ESMO	HCP
European Forum for Primary Care-EFPC	HCP
European Public Health Association-EUPHA	HCP
European Hospital and Healthcare Federation-HOPE	HCP
European Society of Cardiology-ESC	HCP
Pharmaceutical Group of the European Union-PGEU	HCP
Association of the European Self-Medication Industry-AESGP	INDUSTRY
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry-COCIR	INDUSTRY
European Association for Bioindustries-EuropaBio	INDUSTRY
European Confederation of Pharmaceutical Entrepreneurs-EUCOPE	INDUSTRY
European Federation of Pharmaceutical Industries and Associations-EFPIA	INDUSTRY
Medicines for Europe*	INDUSTRY
MedTech Europe (Eucomed)	INDUSTRY
MedPharmPlast Europe, a sector group of the European Plastics Converters-MPPE	INDUSTRY
Plasma Protein Therapeutics Association Europe AISBL-PPTA Europe	INDUSTRY
European Diagnostic Manufacturers Association (EDMA)**	INDUSTRY
ISPOR	RESEARCH

* Medicines for Europe is the former European Generic Medicines Association (EGA)
HCP = Health Care Professional