GENERAL METHODOLOGICAL GUIDELINES

EUNETHTA WORK PACKAGE 7 – SUBGROUP 3

Background

- Agreement on basic methodological standards and their application in projects and pilots has been an integral part of the EUnetHTA collaboration in Joint Action 1 (2010-2012) and in Joint Action 2 (2012-2015)
- EUnetHTA guidelines (JA 1 – WP 5) for rapid Relative Effectiveness Assessments (REA) of pharmaceuticals have been available since 2013 at **www.eunethta.eu/eunethta-guidelines**, and have encompassed a range of topics including: clinical endpoints, surrogate endpoints, safety, internal validity of RCTs, applicability, as well as health-related quality of life and utility measures

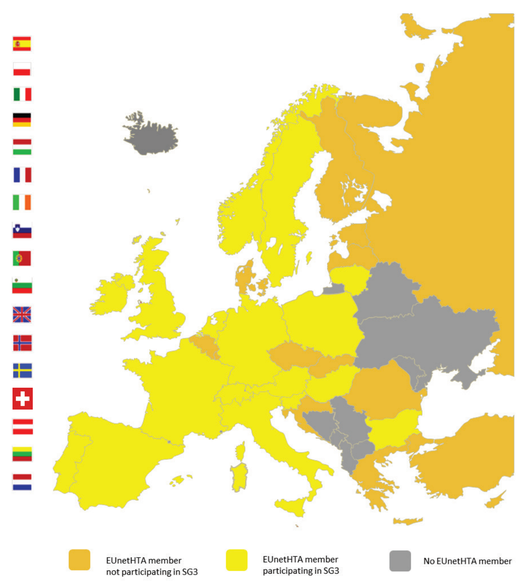
Objectives and deliverables

- Development of new, general guidelines (drugs and other technologies), see table
- Revision of JA1 guidelines including adaptation to the assessment of non-drug technologies (e.g. Medical Devices)
- Final process description (Manual) for development and updating of guidelines in EUnetHTA

SG3 - Participants

22 organisations / agencies from 18 countries (yellow in map)

AETSA – ES	AHTAPol – PL
AIFA – IT	G-BA – DE
GYEMSZI – HU	HAS – FR
HIQA – IE	IACS – ES
IER – SI	INFARMED – PT
IQWIG – DE	NCPRMP – BG
NETSCC – UK	NICE – UK
NOKC – NO	OSTEBA – ES
SBU – SE	SNHTA – CH
UH A. Gemelli – IT	UMIT – AT
VASPVT – LT	ZIN – NL



Target groups of guidelines

Main target group: HT-Assessors in the EunetHTA member organisations
Purpose: Guidance in coping with the methodological challenges encountered while performing relative effectiveness assessments of pharmaceuticals, medical devices and other health technologies

Secondary target groups: decision makers, researchers, industry, other stakeholders
Purpose: Information on what is deemed

- good quality of study design and conduct,
- less biased, reliable and applicable evidence,
- good reporting and synthesis of evidence,
- and good practice of statistical data analysis within the context of HTA

Stakeholder advisory group (SAG) involvement

- Input collection (guideline topics)
- Consultation on draft guidelines (standard) and guideline concept (case-by-case)

External collaborations

- Cochrane Collaboration – NRS Methods Group

  and FP 7 projects *AdvanceHTA* and MedtecHTA

Poster developed by SG3 coordinator: Institute for Quality and Efficiency in Health Care (IQWiG) – Germany

Revised process of guideline development

- Introduction of a concept phase and three defined roles: first author, draft group member, dedicated reviewer
- Intensified communication from the outset and close collaboration in draft group
- Reduction of internal reviews and reduced timeframe (14 months “M”)

Figure: Revised Guideline Development Process

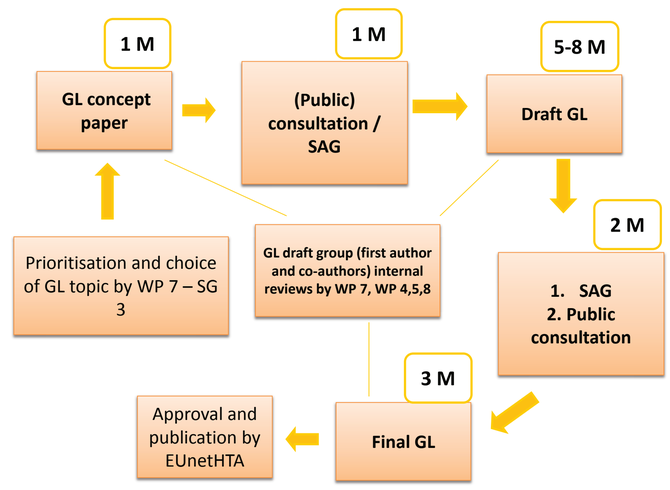


Table: JA 2 topics for methodological guidelines [GL] or position papers [PP] and status of work

Topic	First author	Draft group members	Status
Development period 2013 – 2014			
[GL] Internal validity of non-randomised studies (NRS) on interventions*	IQWiG – DE	NOKC – NO SNHTA – CH	GL under internal review
[GL] Meta-analysis of diagnostic test accuracy studies*	HIQA – IE	IQWiG – DE	Finalised + published
[GL] Economic evaluations*	SBU – SE	HAS – FR IER – SI IQWiG – DE	GL ready for SAG / Public consultation
Development period 2014 – 2015			
[GL] HTA of therapeutic medical devices	UMIT – AT	G-BA – DE IQWiG – DE OSTEBA – ES	Concept under internal review
[PP] Personalised medicine	IQWiG – DE	HAS – FR OSTEBA – ES	Concept under internal review
[GL] Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness*	IQWiG – DE	AETSA – ES NOKC – NO	GL under internal review
*** further information in parallel slide show**			

Experiences so far

Observations

- Considerable diversity of guideline projects (topics, teams, collaborations)
- Variety of methods (e.g. systematic literature search, preceding surveys, cooperation with external experts, piloting of assessment tools)

Improvements

- Introduction of a guideline concept phase
- Early and intensive collaboration of first author and draft group

Requirements

- More flexibility (timelines) for the guideline development process
- Central coordination and support of guideline teams

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