



Advanced Innovation
Health Technology
Assessment

Epposi Advanced Innovation Programme Health Technology Assessment July 2011- November 2012

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1 Question to be addressed and overall timings summary

Epossi is building on the outcomes of work carried out in 2010 in a series of workshops, as well as three focus groups held in 2011 as an integral element of the programme formulation process. It is identifying ways to optimise added-value to patients' organisations, science and industry in the field of health technology assessment as a multi-stakeholder think tank focusing on innovations in healthcare.

1.1 The Big Question

The overwhelming consensus from all those consulted so far is to examine the question:

“How can HTA agencies at national level consider societal benefits as an integral element of the HTA core model which positively contribute not only to the realisation of better health outcomes for EU citizens but also to a smart, sustainable economy?”¹

The examination of the question will build on the work of Epossi members over the course of 2010 and 2011 as well as Epossi and member organisations' published reports, the work of the WHO and OECD. The Epossi study programme will seek to find workable solutions to the following questions:

1. Definition of scope –
 - a. What elements does the Epossi community consider to be key to a societal benefits assessment model - including (but not exclusive) to:
 - How technologies (including therapeutics, ICTs and medical technologies) go beyond the traditional confines of demonstrating the value of technologies within the sphere of healthcare alone. Instead, there is a need to examine how they can they be evaluated using societal criteria
 - Direct and indirect cost of HTA for all stakeholders (patients, payers, science and industry)
 - Non-medical/ clinical elements such as work-related productivity can be taken into account as a clinical outcome
 - b. Does the current definition of HTA adopted by the EUNetHTA network and in some European countries reflect the elements necessary to provide HTA providing societal benefit?
2. In an environment where the trend is towards harmonisation across countries rather than centralisation of HTA policies and practices at EU level, how can all stakeholders (HTA agencies, patients, science, payers and industry) contribute to and benefit from a best practice harmonised HTA system at local and regional (in-country) levels?
3. Is the impact of such a model on the overarching objectives of Europe to be a smart and sustainable knowledge economy with innovative products, services and systems in place?

1.2 Timings summary

Programme phase timings overview

The programme will have short as well as medium term outputs:

- **Applied research into a model for how a societal benefits approach to HTA in Europe can work at national, regional and local level -**
 - **Total duration 14 months (July 2011 – end August 2012)**
- Multi-stakeholder **design and piloting of locally applicable templates and tools** on a societal benefits approach to HTA. The tools will aim at **enhancing the skills and competences** of patients' organisation representatives, health workforce professionals and how industry can better understand how best to interact and support the model.
 - **Total duration – 7 months of design , pilot and finalisation loop (April – October 2012)**

1.3 Expected outcomes

- a. Applied research outcomes
 - i. An in-depth analysis of if and how the scope of the current definition of HTA needs to be amended to effectively represent a societal benefits approach.

¹ http://www.eunetha.eu/Public/About_EUNetHTA/Tools/HTA-Core-Model/

- ii. Research into developing a model and implementation guidelines as to how best to adopt a societal benefits approach to HTA in European countries.
- b. Stakeholder skills enhancement outcomes
 - i. Development of skills enhancement templates for patients and health workforce professionals at local level:

2 Rationale

2.1 The challenge

As a think tank focusing on innovation in healthcare from a non-advocacy, multi-stakeholder perspective, it is Epposi's role to seek out workable solutions to current and upcoming questions on healthcare policy at European and national level.

The challenge identified by a number of different stakeholder groups, patients, health workforce professionals, carers, is that current scientific and economic evaluation elements of the HTA process (being implemented by most national pure HTA agencies) are a narrow interpretation of the broad definition; not only in terms of sectors undergoing HTA (primarily pharmaceutical), but more significantly, the emphasis on cost effectiveness of a technology being almost exclusively judged within the confines of the "siloes" healthcare budget, rather than its total impact on society. Clearly this is an increasingly important oversight given that the indirect societal costs associated with many chronic conditions are greater than those directly incurred and managed by the healthcare budget.

Many stakeholders – governments, HTA agencies, academics, patients and healthcare professionals alike – alike are becoming more critical of the current approach. Some academics² have also started to propose other broader approaches to HTA which are more "grounded in the realities of day to day patient experiences" rather than based primarily on statistical modelling which seems largely to exclude the variables of what is needed to ensure that HTA recommendations produce societal benefits in the wider picture.

2.2 Policy context

Key policy areas which have been taken into account for this programme are:

- a) **EU Cross-border Directive (article 15 and 16)** – national and regional implementation challenges
- b) **EUnetHTA³ Joint Action** – particularly the two objectives of,
 - the Construction of a business model for collaboration addressing the sustainability of the HTA collaboration within EU by the end of 2012 and,
 - identification of areas where methodological guidance is needed and by providing it, suggesting ways to integrate REA⁴ of pharmaceuticals as a special version of the HTA Core Model.
- c) **CAVOD⁵ mechanism** – Using the CAVOD model inverted pyramid which can be termed an "à la carte system", the Epposi societal benefits model could use the "additional evidence generation" layer as inspiration for methodologies for transparent recommendations to Member States for post-marketing evidence generation with a societal impact/ benefits element.

3 Programme outline

3.1 The applied research methodology

The applied research elements of this programme which is driving the development of a model and tools for grassroots implementation for the societal benefits approach to HTA will be implemented using **the Epposi 4-step methodology** of:

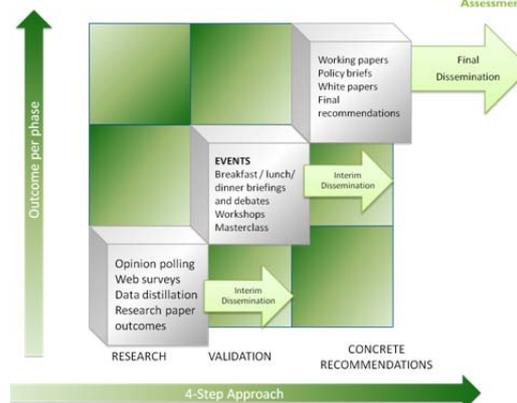
² Appraisal of health care: from patient value to societal benefit, J Public Health (2010) 18:297–302 (Franz Porzolt & Holger Pressel & Carola Maute-Stephan & Ralf Kindervater & Jan Geldmacher & Sigrid Meierkord & Jörg M. Sigle & Martin Eisemann)

³ European network for Health Technology Assessment - EUnetHTA

⁴ Relative Effectiveness Assessment

⁵ Clinical Added Value of Orphan Drugs

- Research
- Hypothesis testing/validation
- Concrete recommendations
- Dissemination



1.4 Governance

To ensure robust governance across all four Epossi Advanced Innovation Programmes (Chronic Conditions Management, Innovation in Healthcare, HTA and Rare Diseases), an Advanced Innovation Programming governance committee (AIPGC) will be set up and chaired by Epossi's Secretary, Prof Jean-Jacques Cassiman. Please [contact the Secretariat](#) for the full Terms of Reference as formally ratified at the Epossi Board meeting of 3 May 2011. The general governance principles are as follows:

- Each programme must maintain a balanced ratio of engagement from patients' organisations, science and industry and each will nominate one representative per stakeholder group per programme to sit on the (AIPGC).
- The role of the (AIPGC) is to ensure continued complementarity of programmes and that they pursue the aims of Epossi as a health innovation think tank as per the mission statement. The (AIPGC) will meet twice a year (Stakeholder Day and Advance Innovation Programming Day) face-to-face with an option to also convene virtually.
- Each programme representative is mandated to liaise between the committee and the rest of the programme members but is not empowered to take decisions without consultation.

2 PROGRAMME CONTENT AND TIMELINE

2.1 Defining the "societal benefits approach to HTA" and detailed project scope

The project will firstly set the definition of "societal benefits" we would like to work towards in the context of HTA. Building on the existing EUNetHTA definition, questions such as:

- *Societal benefits*: Aim to optimise the *societal benefits*.
- *Societal costs*: Determine what the *societal costs* are. Thinking is required on how to re-prioritise the way society looks at costs.
- *Societal needs*: This means looking beyond the economic element. For example, it is important to examine the impact of ill health on mental health, career and aspiration goals and the family element (discussions with, eg, a physiotherapist, occupational therapist are needed). Re-skilling may be an element.
- *Definitions of societal needs*: Example questions: what societal benefits come from 'healthier patients'? e.g., what premium do we afford early diagnosis and therapeutic intervention?
- *Budgetary issues*: "Health is wealth only if you look at it in wider terms than simply health-related budget." Healthier patients afford a much larger benefit to society than just healthcare efficiencies. Examine other possible budgets and their implications.
- *Patient needs*: "Patient needs are not necessarily *per se* societal needs." There could be a conflict between patients' needs and societal needs *unless one looks at health as wealth*.
- *Work Ability*⁶ *as a health outcome*: Should workability be included in our definition of societal benefits derived from healthcare expenditure?

⁶ Work Ability: A measure of self-reported physical or psychological functional capacity which allows an individual to sustain the performance of their normal duties at work (paid employment or other forms of work).

Source: Prof Stephen Bevan, The Work Foundation

2.2 Applied Research

The research phase runs from July 2011 – end August 2012 and is divided into four main phases:

- Phase 1: July – October 2011
 - Project inception
 - Definition scoping exercise (see above)
 - **Breakfast briefing on interim results and opportunity for peer review and consensus – Q4 2011**

- Phase 2: November 2011 – end August 2012
 - Mapping of HTA systems – literature search and qualitative interviews to ascertain where/whether there is a willingness to use a societal benefits approach at national level.
 - **Breakfast briefing on interim results and opportunity for peer review and consensus – Q1 2012**
 - Building and piloting (simulation) of the model with TU Delft
 - **Full workshop on outcomes of pilot and model – end Q2 2012**
 - **Report write up and dissemination**

- Phase 3: April – October 2012
 - Skills enhancement templates development – 4 pilot countries to see how understanding of local HTA systems, by local people and for local stakeholders can best be developed effectively.
 - The roll out of the pilot projects will also allow qualitative research to be carried out in relation to phase 4 (below) on the development of a model and implementation framework for adopting a societal benefits approach to HTA.

- Phase 4: Exact timelines to be specified
 - Using the outcomes from the applied research to produce a model and tools for stakeholder implementation; stakeholders will receive competence-building tools and techniques to help them credibly move their HTA systems to adopting an inclusive societal benefits approach to HTA.

- Ongoing dissemination: Epossi is actively seeking speaking engagements, profile-raising opportunities and peer-reviewed journalistic opportunities to highlight the work of our HTA Programme.

2.3 Validation of the research phase

Validation of the interim research results will be carried out at face-to-face meetings with all programme stakeholders and through testing within the competence-building exercises in country

3.2 Public dissemination

A position paper outlining the approved model and framework for implementation with rationale underpinning the model will be published by the end of 2012.