

Final Minutes of the Patient Involvement in EUnetHTA JA3 Meeting

08 March 2017 – 13:00 to 16:30

Meeting Venue: ZIN Offices - Eekholt 4 | 1112 XH | Diemen

Role	Name
Chair	Michelle Mujoomdar (EUnetHTA Directorate)
Present	<p><u>EUnetHTA</u>: Wim Goettsch (Director, WP4 co-lead pharma), Ingvil Saeterdal (WP4 lead), Sabine Ettinger (WP4 co-lead other tech), François Meyer (WP5), Patrice Chalon (WP6)</p> <p><u>European Commission</u>: Karolina Hanslik</p> <p><u>Patient & Consumer Organisations</u>: Valentina Strammiello (EPF), Cristiano Pisani (EMSP), Christoph Thalheim (EMSP), François Houyez (EURORDIS), Francesco Florindi (ECPC), Francesca Cattarin (BEUC)</p>

Item	Final Agenda	Lead
1	Welcome and Introductions	All
2	Overview of principles related to Patient Involvement in EUnetHTA JA3	Wim
3	Debrief on meeting in Dec 2016	EURORDIS, BEUC, EPF, EMSP, and Wim
4	When and how to involve patients in WP activities: Part 1 – Initial thoughts from WP4, 5, and 6	WP LP and Co-LP
5	When and how to involve patients in WP activities: Part 2 – Reflections from Patient Organisations	EURORDIS, BEUC, EPF, EMSP, ECPC, and IAPO
6	Practical challenges (e.g., inclusiveness versus timeliness)	Michelle
7	Action planning	Michelle

1. Welcome & Introductions

Participants were welcomed by the Director of EUnetHTA JA3 (the Director) and introductions were made

2. Overview of principles related to Patient Involvement in EUnetHTA JA3

The Director explained that prior to JA3 patient involvement was limited to participation in the EUnetHTA Stakeholder Forum, in the Stakeholder Advisory Groups, and in the early dialogues (SEED). It was noted that in JA3, the involvement of patients will change because, for example, there is no longer a stakeholder forum. Instead, patients, patient groups, and other stakeholders can participate in the EUnetHTA extranet. In addition, patients and patient groups are invited to participate in the EC/EUnetHTA annual forum where EUnetHTA partners and stakeholders can discuss topics of mutual interest.

In JA3, patients will participate at the individual work package (WP) level to provide specific input to Joint and Collaborative Assessments (WP4) – including any public consultations on deliverables and in Early Dialogues (WP5). In addition, there can be interaction on the level of methodologies, guidelines, and procedures (WP6).

3. Debrief on meeting in Dec 2016

A preliminary meeting between members of the EUnetHTA Directorate and several patient and consumer organisations was held in Dec 2016. Minutes from this meeting will be distributed. Attendees provided a short overview of what was discussed at this meeting. Briefly, the opportunities to increase the involvement of patients in EUnetHTA were discussed. It was suggested to look at the procedures of the EMA as a possible starting point, but it was also noted that it is important to take the experience of national HTA bodies and previous work (e.g., SEED) into consideration.

4. When and how to involve patients in WP activities: Part 1 - Initial thoughts from WP4, WP5, and WP6

WP4:

WP4 outlined a number of principles/criteria for patient involvement in EUnetHTA's joint work. It's preferred that patients are involved rather than patient representatives, recognising that for some technologies, healthy individuals may need to be involved (e.g., screening programmes). To avoid issues related to language and to ensure efficient use of fiscal resources, there should be a focus on local/regional and national patients rather than supranational. Patients should be reimbursed for their travel and time and full disclosure of material and immaterial is necessary. Methods to involve patients should be appropriate and validated; results transparent and open to public access.

Within WP4, patients and other stakeholders can be involved in the scoping phase of joint and collaborative assessments, consultation on draft joint assessments, and in the implementation of EUnetHTA tools and joint products. As yet, there is not an agreed upon framework to guide the involvement of patients/ patient groups – i.e., a synthesis of current approaches around Europe or globally regarding what is being done to involve patients in the HTA process. It was suggested that this is something to consider creating or adapting something that is already available. Action: EUnetHTA Directorate to inquire with several external experts if a mapping of patient involvement in HTA has been conducted.

The Lead Partner (LP) of WP4 noted that training material that provides an overview of EUnetHTA is available on the EUnetHTA website. This material was created in JA2, but it remains valid.

To date, patients have been involved in the scoping and assessment phase of three collaborative assessments of Other Technologies in JA3. The co-LP for other technologies described several examples wherein different approaches (e.g., focus group and providing input on the draft assessment) were used/tested. Two Joint Assessments for the Pharmaceuticals strand are underway. Similar to Other Technologies, several different approaches to involve patients will be tested for the first few Joint Assessments with a view to learn the strength and weaknesses of each approach.

In terms of next steps, the (Action) WP4 LP will start a group to discuss the procedures to involve patients in the joint production activities. Patient and citizen groups will have an opportunity to provide feedback on the proposed procedures.

WP5:

Early Dialogue is also called Scientific Advice by some HTAB. Similar to WP4, there are a number of considerations regarding the inclusion of patients in WP5 activities including the identification of the appropriate patient(s) and training, preparation, and workload for patients. A summary of learnings from SEED was provided in which it was shared that patients highly appreciate having the possibility to participate. The respective role of European networks of associations and national associations should be clarified. The impact of the contribution of patients should be measured and shared.

Resources available for training are limited. There are some training materials available; however, they may need to be customised to fit the purpose. Regarding next steps, (Action) the LP of WP5, in liaison with patient and citizen groups, will develop options for involvement of patients in WP5 activities.

WP6:

WP6 activities are Strand A: Quality management (QM concept paper, overall QM system, process definitions/ SOPs, training activities for the partners). Strand B: Scientific guidelines and tools: methodological guidelines, tools, HTA core model, handbook for HTA doers, POP database, HTA core model online, evidence database, early dialogue stakeholders provide input for both branches at different moments. Challenges for WP6 are resources, confidentiality, training, etc.

Action: WP6, working with WP4 and WP5 will develop an internal standard operating procedure, of how to involve patients in joint work (Joint/Collaborative Assessments and Early Dialogues) and public consultation on deliverables.

5. When and how to involve patients in WP activities: Part 2 – Reflections from Patient Organisations

The issue of centralized patient organisation management was raised: it was suggested that one patient organization could serve as a contact point for other patient organisations. It was stated that it could be more efficient when there is an EUnetHTA intranet so it's easier to manage and contact the patient organisations.

The involvement of patient in collaborative versus joint assessments was discussed. It was noted that collaborative assessments present a challenge because the procedure is driven by the needs of the participating HTABs. There was an open discussion around keeping the umbrella European organisations in the loop (perhaps via the aforementioned group email regarding the type of patient being requested for collaborative assessments. The purpose would be two-fold – one for information, and secondly for support if there is difficulty in recruiting a patient(s).

There was some discussion regarding the advantages of increasing the pool of patients from which perspectives are drawn (e.g., within focus groups). There can be important differences between countries that may not be apparent with a small sample size. It was also noted that there are challenges with involving a large number of patients within a focus group as the resources required to transcribe and synthesise findings are significant. Is there an opportunity to identify situations in which the perspective of patients may differ significantly between

member states - for example, when reimbursement status or clinical practice may vary. It was noted that the goal of involvement of patients isn't to document an exhaustive list of perspectives from patients, but rather, to identify some factors that are important to some patients and that ought to be considered within the joint work processes.

Patient organisations noted several times that they are very willing to assist EUnetHTA in finding the right patients. Sometimes it is difficult to identify patients and find really specific patients. EUnetHTA should consider patient organisations as a support for this activity.

With respect coordination of patient involvement, it was suggested that a general email address be established. When contacting individual patients, this email address can also be Cc'd to allow patient and consumer organisations to be appropriate informed/up-to-date (Action).

6. Practical challenges (e.g., inclusiveness versus timeliness)

Some discussion was had around resources. Resources are limited for both patient organisations and HTABs (HTA bodies). There needs to be a balance between hearing the perspective from numerous patients and the resources available.

7. Action planning

Action Points	Responsible
EUnetHTA Directorate to inquire with several external experts if a mapping of patient involvement in HTA has been conducted.	EUnetHTA Directorate
Establish an internal working group within WP4 to further develop recommendations for patient involvement in joint production activities – provide opportunity for patient and citizen groups to comment on recommendations/draft procedures	WP4 LP
In liaison with patient and citizen groups, develop options for involvement of patients in WP5 activities	WP5 LP
WP6, working with WP4 and WP5 will develop an internal standard operating procedure, of how to involve patients in joint work (Joint/Collaborative Assessments and Early Dialogues) and public consultation on deliverables.	WP6 LP
Establish a general e-mail address as single point of contact for patient groups	EUnetHTA Directorate