

Feedback on process: patients' insight

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Principles of patient engagement in HTA agreed by ESCo

of the Stakeholder Pool, presented to the HTA meeting

INCLUSION

- Patients and Consumers shall be included in

Clinical experts acknowledged, DoI published. Not for patients though

Modalities by HTAR CG and subgroup, no co-definition

LEGITIMACY

- Once accepted, Patients and Consumers should be involved with equal

TRANSPARENCY/VISIBILITY

- Possibility to recognise that someone who represents Patients and

Contribution by patient's experts: wait for JCA reports. No transparency on which experts are involved.

PUBLICITY

- HTA procedures (and conclusions) should be clearly understandable, accessible and

Wait for JCA reports and their summaries

RELEVANCE

- The information on which the assessment is based must be able to justify the conclusion

Wait for national uptake

APPEAL/REVISABILITY

- Provide for a mechanism to ensure the possibility of an appeal on the procedure (if n

Wait for JCA reports & updated reports. Unclear if developer can review reports before publication

RESPONSIBILITY

- Playing by the rules: when Patients and Consumers are consulted in an appropriate manner,

Wait for appraisal

ENFORCEABILITY

- The procedure should assure that the prior conditions are met

Stages of patient involvement

2

Find experts

Call: → Disseminate the call or contact people / organisations (and select the right people?) **200 for 10-12 JCAs-JSCs**

Prepare experts

Explain the procedure → what is expected from expert + administrative tasks (Conflicts of interest, confidentiality...). Conversation (phone, video-meeting...)

Involve experts

Achieve the interaction (meetings / questionnaires / interviews / focus groups / aggregated data / Patient Preference Elicitation Studies...) – Same basis for all experts. **Ratio: 200 / 40 – OR: 1 satisfied / 4 not so...**

Elaborate Input

Adjustment and insertion in reports. **Wait for JCA reports**

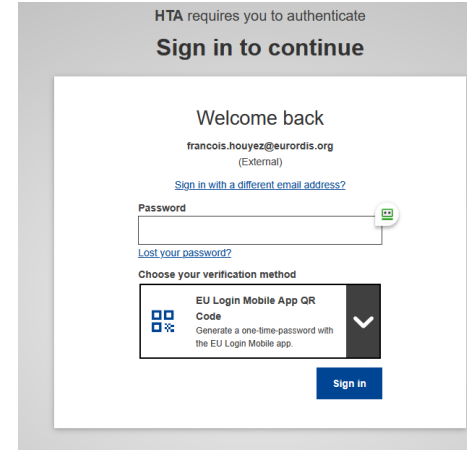
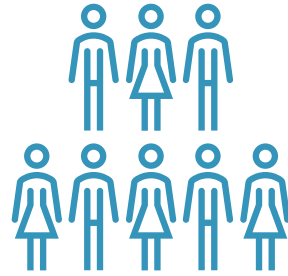
Acknowledge Input

Feedback – Measurement – Visibility & acknowledgement
Where?

Selection and Col

3

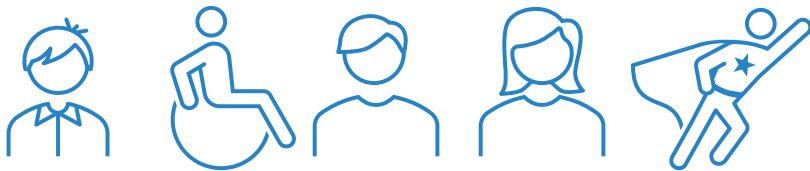
EC request: a certain number of potential experts identified (3 weeks), contact details sent to EC



Before any conversation with someone, by phone or email, they receive a link to something like this

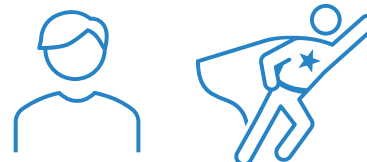
After others gave up, 5 register and fill-in forms

3 proposed to the JCA subgroup



Of whom 2 are selected. Criteria? Explanation provided?

EC assesses Col, not the profiles



What if these 2 have better profiles, eg involved in treatment guidelines?
Why not balance expertise and conflicts?
Why not let the JCA subgroup decide who to involve among all 5?

Anne Glover, Chief Scientific Adviser to the President of the European Commission, 2013

"I was surprised when I began working at the Commission to find I was presumed to be guilty until I could prove I was innocent.

At first, I thought it was a bit of a joke, but when you feel you are constantly trying to prove you are trustworthy, it has a big impact on you.

I have worked with industry, I even set up a company. Are we saying that because of this involvement with industry I am fundamentally untrustworthy, that I am suspicious?

Surely if we reject someone with broad interests because of those broad interests, we will lose out".



Best expertise vs conflicts of interests: Striking the right balance, Report from the public workshop hosted by the EMA in London, on 6 September 2013

https://www.ema.europa.eu/en/documents/report/workshop-report-best-expertise-vs-conflicts-interests-striking-right-balance_en.pdf

How it's done

and questions

Bulk request

- Now 3 weeks
- JSC and JCA mixed
- 30 min to explain JSC + 30 min to explain JCA
- Message is “untrustworthy by default or by nature”
- Industry' views?

List sent to EC

- Total: 19 (2 bulk requests)
- All agreed to take part
- EURORDIS as back office to help with process

Dol / confidentiality

- Not balancing expertise and possible conflicts
- Experts unaware until when confidentiality applies

If accepted

- Input on consolidated PICO's?
- Adapted to cognitive issues (eg Alzheimer?)
- Divergences with patients at national level?
- If patient opposes one or more PICO's, reflected in letter to developer? Elsewhere?
- Taking part in meeting with developer?

Identification

- 4,500 experts in database, 20+ years
- Including rare cancers
- Full-time activity, high turn-over
- 1,115 patient groups, 24 ERNs
- Orphanet, EMA PA/SA, CHMP ED
- Direct conversation: a must

Contacted by EC

- No conversation
- Link to EC IT platform, complex, untested and unfriendly registration procedure

If rejected

- Rejection letter not reviewed
- Clarity? Some rejected after Dol accepted, no explanation
- 200 applied, 40 selected
- 160 frustrated? Ratio 1/4

After involvement

- No public acknowledgement
- Dol not public unlike clinicians
- Are patients sub-citizens?
- GDPR: special rules for public authorities, same as for EMA

KPIs: meaningful engagement? Or?

More the quality of the engagement than the quantity

• Engagement

- In all meetings, f2f or online
- Ample time (for administrative procedures, for input)
- Mentoring in place for new-comers
- More than 2 patients
- Documents in advance
- Same documents as other experts
- Take part whole discussion ± decision
- Point taken (Question to developer, minutes...)
- Experts publicly acknowledged
- Balancing expertise and CoI
- Evaluation: from the perspective of patients and of HTA experts

Quality of the involvement

• More tokenism-like

- Via a questionnaire
- Time not adjusted
- Remotely, not with other experts
- 1 or 2 patients
- Documents last minute
- Only part of the documents
- Only supposed to answer questions
- No input on final document / report / letter, can't check if point taken
- No acknowledgement, no visibility
- Systematic exclusion if CoI
- Evaluation: more a satisfaction survey than a real evaluation
- Numbers of patients involved

Are other hospitals getting more referrals?

Lucas, osteogenesis imperfecta
EURORDIS photo contest 2015

Thank you for your attention



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