Literature review of Patient Advocacy Group (PAG) involvement in HTA

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BACKGROUND
Patient input is an important part of the assessment process, yet it is sometimes seen as anecdotal and having a low evidence base. Previous work by the authors suggests more research is needed on identifying how the patient group contribution is impacting decision making. HTA can be strengthened by gathering evidence around patient’s perspective and ensuring effective engagement of patients at different levels to create a fair deliberative process.

OBJECTIVE
To review and critically appraise existing publications on PAG involvement in HTA.

METHODS
A search in the Medline, Cochrane and ISPOR databases was undertaken to identify studies on patient or PAG involvement in the HTA decision. The search terms used included “Health Technology Assessment/HTA, patient involvement, participation, public involvement, consumer participation, patient group, vulnerable populations, patient advocacy, framework clinical governance.” The studies were limited to English publications in the past 5 years. Studies were evaluated for relevancy and excluded following review of title and abstracts then review of full-text articles. Two reviewers extracted methodological details, study designs, and outcomes into summary tables.

RESULTS
We identified 18 articles out of a total of 97 studies. Articles covered multiple subject areas. Process improvements were most common (6 studies) followed by current perceptions (5 studies), comparison of patient pathways (4 studies) and specific type of patient input desired (2 studies). The studies used different research methodologies and involved telephone, web-based, interview and survey work. Studies and Stakeholders varied between national & international HTA agencies, experts and patient groups. Three studies involved patient groups and one involved patients. All of the studies informed the role, process and nature of input but did not address the impact on HTA decision-making.

PROCESS IMPROVEMENTS
One of the several challenges related to patients involvement identified in the different studies was linked to the processes used in the decision making. There is currently no general consensus on the optimal processes to ensure patients’ involvement in HTA decision making. However, results highlighted the need for the industry to bring in the patient insight earlier in the development, alongside the continuous development of HTA processes to better facilitate patient involvement, increasing transparency and feedback. Indeed, PAGs provide access to genuine patient perspective and early involvement would help ensure that research is focusing on topics that are relevant to patients. HTA decision making can be strengthened by gathering evidence around the patient perspective and ensuring effective engagement of patients at different levels to create a fair deliberative process. The role of the PAG being seen as an important to access the genuine patient voice. Another key improvement proposed lies in the methodologies used for a low level of patient issues. The findings suggest that there is a lack of a clear methodology within HTA agencies regarding patient involvement. The absence of a coherent methodology makes many agencies reluctant to engage adequately in patient involvement.

CURRENT PERCEPTIONS
HTA is moving towards public involvement but remains cautious about its acceptability. Indeed, no standard process are currently in place and acceptability of this to policy makers is at present unknown; when the process is well developed it will provide a substantial contribution to the overall assessment process. Obstacles to patient involvement include (i) low evidence base (ii) lack of clarity on standardized input approach (iii) lack of awareness on process by patients & PAGs (iv) insufficient explicit evidence collection about patient preference. There is a need for rigorous evidence around HTA decision-making practices in order for this to be taken into account in the HTA decision-making process.

PATIENT PATHWAY COMPARISON
A large variation between HTA models with respect to patient involvement was observed across different studies; varying from comprehensive, patient-focused and interview-based to exclusion. Due to a lack of a common methodology, input of stakeholder involvement cannot be compared from one country to another. This is highlighting the need to reconcile the perspective of payers, manufacturers and patients in order to achieve universal access to innovative and costly technologies. The rationales of improving legitimacy and insights into value judgments appear to be one of the most important and showed the least variation across 3 major European HTA agencies (Germany, France and UK).

TYPE OF PATIENT INPUT
There are disparities on the type of input desired by the different HTA agencies. The finding show that the most common type of patient input is communication and consultation rather than participation. However, if most of the public input is currently qualitative, discrete choice experiments can be used to provide quantitative assessments to patient or public preference for treatment endpoints.

FURTHER INSIGHTS
It is striking that the low level of involvement of the patient groups cited as authors are pursuing patient research or involvement in HTA. The scope of this on the perceived low evidence base of patient input in HTA needs further clarification. Possible explanations for this absence include non peer-reviewed patient group led studies not picked up in our search. Too broad search criteria or simply the results reflecting the reality of very limited involvement of patient groups in research. These results suggest (i) overall more capacity building in scientific skills may be an important approach for patient groups to follow (ii) future work should be restricted to a single disease area (iii) identify specific patient groups with a track record of publications.

CONCLUSIONS
Compared to other HTA areas there is a lack of published material on direct patient involvement. There have been many attempts to provide a framework for patient involvement but so far none has been used in HTA decision-making. Existing data does not help to quantify role of the patient in HTA decision making. Additional research is needed to understand and quantify patient input in HTA decisions.

REFERENCES