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A voice to be heard: patient and public involvement in health technology assessment and clinical practice guidelines in Malaysia

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Perspective

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Abstract

Patient and public involvement (PPI) in health technology assessment (HTA) is widely promoted to ensure that all health-related decisions are made after taking into consideration the viewpoints of important stakeholders. In Malaysia, patients or their representatives have been involved in the development of HTA and Clinical Practice Guidelines (CPG) since 2009 and their influences have been growing steadily over the years. This paper aimed to describe the journey, achievements, challenges, and future direction of the PPI throughout all stages of the development and implementation of HTA and CPG in Malaysia. Currently, in Malaysia, patients or their representatives are mainly involved during the initial development of HTA and CPG drafts as well as during the internal and external reviews. Additionally, they are also encouraged to be involved during the implementation of HTA and CPG recommendations. Although their involvement in this aspect has slowly increased over time, challenges remain in the form of limited representativeness of selected patients or carers, uncertainty on the level of patient involvement allowed during the HTA/CPG development processes, and limited health literacy, which affect their ability to contribute meaningfully throughout the processes. Continuous improvement in these processes is important as patients or their representatives play a pivotal role in ensuring transparency, accountability, and credibility throughout the HTA/CPG development and decision-making processes.

The Journey

Patient and public involvement (PPI) is increasingly important in healthcare decision making to ensure that all decisions made are relevant after considering the opinions of multiple important stakeholders. Thus, it has been suggested that health technology assessment (HTA) should involve patients to incorporate their experience of living with the disease as well as their views, needs, and preferences on the new health technology (1). Patients' involvement is vital to ensure the comprehensiveness of a review that emphasizes important issues pertaining to the patients and the public.

The Malaysian Health Technology Assessment Section (MaHTAS) was established under the Ministry of Health (MOH) in 1995. Patient involvement in HTA and Clinical Practice Guidelines (CPG) processes started in 2009. Following the establishment, the number of patients participating in HTA or CPG development has been growing steadily over the years. Generally, patients or their representatives are involved as members of the Review Committee (RC) for a CPG or included in the Expert HTA Committees for specific HTA topics. They are invited to contribute their testimonials and experiences during the development and implementation stages of a HTA or CPG.

However, at present, patients are not involved in other stages of HTA or CPG development such as the topic prioritization stage for various reasons. Firstly, our current prioritization process is not based on discipline or disease. Therefore, PPI at this stage may require appropriate priority setting processes to manage any differences in research interests and agreed priorities. Secondly, patients in Malaysia may have different expectations on healthcare services based on their socioeconomic status. In view of these expectations, mutual understanding between various stakeholders and an effective involvement system must be established to expand PPI. Therefore, the expansion of PPI to include the topic prioritization stage is expected to be a relatively lengthy process.

This paper aimed to describe the journey, achievements, challenges, and future direction of PPI in Malaysian HTA and CPG processes.

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PPI in HTA

PPI in the development of HTA documents and internal review of HTA drafts is highly dependent on the topics. The recruitment of reviewers is based on the availability of suitable patients or their representatives. The representatives can be identified through experts in the related field or patient society. Once agreed, they will constitute the expert committee members in HTA projects to share their experiences and to provide input on the technology being assessed. They can help provide a better understanding of the health issues being discussed and review the recommendations based on their perspectives.

To date, two completed HTA projects by MaHTAS have included public representatives from the patient society. In the HTA of Prostate Cancer Screening (2010), a public representative was invited from the Malaysian Cancer Society, and he provided his input on the acceptability of the program to, and the perceived impact of the program on patients and society (2). Valuable inputs from this representative facilitated a more holistic and patient-centered evaluation in the HTA. In another HTA project on Computerized Cognitive Behavioural Therapy for Adults with Depression (2011), a representative from the Malaysian Mental Health Association was included as an expert committee member. His perspective as a patient enabled other members to better understand the issues in the management of adults with depression and the potential benefits of the technology in improving patient outcomes (3).

Following the successes of these two projects, MaHTAS went on to elicit the views of patients and carers in the development of an HTA on the predialysis education program (PDEP). The preliminary outcomes obtained from the survey were presented to the expert committee members, including nephrologists and clinical experts involved in the management of chronic kidney diseases. The views and opinions obtained from the patients and carers were very informative and were subsequently used to guide the committee members on the planning of a more holistic PDEP that will be implemented nation-wide later.

PPI in CPG

In the development and implementation of evidence-based CPG, the involvement of relevant stakeholders, especially patients, is important to ensure a comprehensive coverage of the issues at hand to maximize CPG utilization. Patients' views about their disease management are paramount to guide CPG development and to improve the uptake of CPG via a sense of shared ownership.

In line with international requirements, MaHTAS actively invites patients, carers, or members from patient associations to join in the RC of a CPG. They will serve as advisors and provide inputs based on their perspectives. They may also be invited as external reviewers. However, they are not expected to draft the initial content of the CPG. They are chosen as RC members or external reviewers based on their knowledge and active participation in patient care to ensure that the CPG content is relevant and reflective of the actual patient experience. For example, a rectal carcinoma survivor and the Hemophilia Society of Malaysia have contributed significantly in CPGs on the Management of Colorectal Carcinoma and Management of Hemophilia, respectively. In addition, the CPG draft will also be uploaded on the public domain and made available for public view and feedback.

Following this, before the official CPG implementation, patients, carers, or patient associations will be involved in the development of the accompanying patient information leaflet (PIL) and the official launch of the CPG. For example, during the launch of the CPGs on Management of Type 1 Diabetes Mellitus and Management of Atopic Eczema, both patients and carers participated in the events and shared their experiences in disease management with the audience. Another good example would be the active involvement of mental health associations in developing the PIL of the CPG for the Management of Major Depressive Disorder. In short, patients, carers, or patient associations are known to be strong advocates for the development and utilization of CPG.

Challenges

Despite some of the successes, MaHTAS has encountered several challenges in incorporating PPI into the HTA and CPG processes over the years. Firstly, there are no formal recruitment criteria for the patients or their representatives. Hence, uncertainty remains on which is the best way to ensure the representativeness of patients who are selected to participate during HTA and CPG development. The existing selection method may lead to information bias and a variable degree of participation from representatives. Some of them are actively involved during the review of evidence in HTA or CPG, whereas others can be more passive. The variation in their socioeconomic backgrounds may also represent different understanding levels of scientific evidence that can affect their degree of participation.

Secondly, we also encounter challenges with regard to the methods applied to encourage patient involvement and the best way to determine the extent of PPI in HTAs and CPGs. A recognizable factor that may contribute to this issue is the insufficient engagement and the lack of relationships with the various patient advocacy groups. Due to the sheer number of such patient groups in Malaysia, continuous efforts must be made to formally engage with them so that they can better understand and embrace their roles in PPI. Furthermore, it is also challenging to balance the different expectations from the perspectives of patients and decision makers during the HTA and CPG development processes.

Certain HTA topics require a direct elicitation of the patient's experience and views. However, this is not being practiced in MaHTAS currently. Thus, an enhanced capacity in conducting primary research should be put in place to further expand PPI in HTA and CPG. On a similar note, the time constraint in completing a review represents another obstacle for PPI. Usually, a review is expected to be completed between 6 and 18 months. Such a tight time line means that it is often not possible to include PPI comprehensively in the process.

Furthermore, there is also uncertainty about the values of patient or public contribution in decision making. Such perceptions can arise from either patients themselves or healthcare providers and are closely interrelated with their understanding of the goals of PPI in Malaysia. Looking at examples of other countries, the formal process for PPI is viewed as a starting point rather than a complete solution to the transparency and accountability issues in the decision-making process (4). Additionally, it is also widely argued that the cultural differences across countries mean that each country is likely to have its values of PPI that best reflect the healthcare system and HTA processes (5).

Way Forward

To a certain extent, PPI has been included in HTA and CPG processes in Malaysia. However, with a limited experience in doing so and faced with the challenges as described above, it is important to undertake consistent efforts in improving PPI within the work processes. Firstly, the processes can be further enhanced by aligning PPI and the strategic plan of MaHTAS to ensure a more rapid establishment of PPI in HTA and CPG. To begin with, an awareness program should be provided to healthcare professionals to improve their understanding of PPI. With this, it is hoped that their perception of the value of incorporating PPI during HTA and CPG development can be changed and that they will instill the necessary changes in their practice culture to ensure better acceptance of PPI.

Secondly, a clear definition of the purpose of PPI in HTA and CPG must be established to streamline the development of formal structures and processes. Staniszewska et al. (6;7) proposed the Guidance for Reporting Involvement of Patient and Public (GRIPP) and GRIPP2 checklists that included important components of PPI for research and report writing. Some of the components highlighted were the level of participation (single vs. multiple stages), methods, and reporting format (7). A well-defined and structured framework based on GRIPP recommendations will help improve the quality, transparency, and comprehensiveness of PPI in Malaysia. Furthermore, a well laid out framework can overcome the challenges in patient selection to widen their involvement in various stages of health technology assessment.

In addition, close collaboration between MaHTAS and the patient representatives or the public can be achieved *via* the formation of the Patient and Public Engagement Committee. This is a vital step toward establishing trust, recognition, and visibility of patients in the decision-making processes of HTA and CPG. For example, in Canada, the formation of the Health Technology Assessment Public Engagement Subcommittee in Ontario opened up several opportunities for PPI to be more involved in the HTA process, such as in the consultation process for draft recommendations (8;9). In line with this, an internal task force can also be set up to develop a framework that is customized to navigate PPI initiatives in local settings. With this task force, capacity building on PPI activities can be strengthened.

Apart from this, international learning networks such as those initiated by the International Network of Agencies for Health Technology Assessment (INAHTA) and Guidelines International Network (GIN) are also an effective platform for MaHTAS to learn from the experiences of other countries at the different stages of PPI implementation. Apart from enabling us to contribute to our capacity building as reviewers and researchers, continuous sharing of knowledge and active collaboration with our international counterparts will also ensure that MaHTAS stays well informed and updated about the ongoing progress in PPI globally.

Finally, once all of the PPI activities have been well established, further evaluation needs to be conducted to determine their usefulness, completeness, and impact on HTA and CPG. This evaluation can strengthen the quality of PPI. Nevertheless, it is not an easy task to evaluate PPI. Weeks et al. (10) surveyed HTA organizations such as the National Institute for Health and Care Excellence (NICE, UK), the Scottish Medicines Consortium (SMC), and the Canadian Agency for Drugs and Technology in Health (CADTH). They reported a wide variation in the evaluation strategies, thus reflecting the different rationales and approaches to PPI in the HTAs of different countries (10). Some of the challenges that emerged during the evaluation processes included the management of conflicting opinions and expectations of participants, resistance to change, as well as resource constraints on the evaluation and implementation of the recommendations from the participants (10). Furthermore, the stages of PPI, different interpretations of PPI for different types of reviews, and nonidentical goals of PPI among the various stakeholders have also affected the evaluation process (10). To date, no formal evaluation of PPI has been conducted in Malaysia. Therefore, MaHTAS needs to consider these challenges in the process of PPI evaluation in the future.

Conclusion

In short, Malaysia has some experience in implementing PPI in HTA and CPG processes. However, these efforts need to be further strengthened, especially moving toward the direction of value-based health care. MaHTAS is committed to enhancing PPI in Malaysia in the coming years by the establishment of a structured PPI framework and the uptake of more capacity-building activities. In view of its limited experience, MaHTAS has yet to determine the best approach for PPI. Hence, knowledge sharing on challenges and successes from countries that have incorporated PPI into their HTA processes will be useful to guide us in enhancing PPI in Malaysia.

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References

1. **Messina J, Grainger DL**. A pilot study to identify areas for further improvements in patient and public involvement in health technology assessments for medicines. *Patient*. 2012;**5**:199–211.
2. **Sabirin J, Syful Azlie MF, Maharita AR**. Prostate cancer screening. Health Technology Assessment (HTA). Ministry of Health Malaysia; 2010. Report No.: MOH/P/PAK/210.10(TR). Available from: https://www.moh.gov.my/moh/resources/auto%20download%20images/587f10a3253b5.pdf.
3. **Izzuna Mudla MG, Roza S, Zalina A**; Computerised cognitive behavioural therapy for adults with depression. Health Technology Assessment (HTA). Ministry of Health Malaysia. 2011. Report No.: MOH/P/PAK/232.12(TR). Available from: https://www.moh.gov.my/moh/resources/auto%20download%20images/587f112dd18f8.pdf.
4. **Boothe K**. Getting to the table: Changing ideas about public and patient involvement in Canadian drug assessment. *J Health Polit Policy Law*. 2019;**44**:631–63.
5. **Wale J, Scott AM, Hofmann B, Garner S, Low E, Sansom L**. Why patients should be involved in health technology assessment. *Int J Technol Assess Health Care*. 2017;**33**:1–4.
6. **Staniszewska S, Brett J, Mockford C, Barber R**. The GRIPP checklist: Strengthening the quality of patient and public involvement reporting in research. *Int J Technol Assess Health Care*. 2011;**27**:391–9.
7. **Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S et al.** GRIPP2 reporting checklists: Tools to improve reporting of patient and public involvement in research. *Res Involv Engagem*. 2017 2;**3**:13.
8. **Abelson J, Wagner F, DeJean D, Boesveld S, Gauvin FP, Bean S et al.** Public and patient involvement in health technology assessment: A framework for action. *Int J Technol Assess Health Care*. 2016;**32**:256–64.
9. **OHTAC Public Engagement Subcommittee**. Public engagement for Health Technology Assessment at Health Quality Ontario—Final Report from the Ontario Health Technology Advisory Committee Public Engagement Subcommittee [Internet]. Toronto: Queen's Printer for Ontario; 2015 April. p. 57. Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/other-reports/specialreports.
10. **Weeks L, Polisena J, Scott AM, Holtorf AP, Staniszewska S, Facey K**. Evaluation of patient and public involvement initiatives in health technology assessment: A survey of international agencies. *Int J Technol Assess Health Care*. 2017;**33**:715–23.