Providing a framework for meaningful patient involvement in clinical practice guideline development and implementation

Abstract

The importance of patient involvement in guideline development is internationally recognised, yet there is a lack of clear methodology for integrating patient preferences and values in guidelines and a need to identify the optimum stages for involving patients in guideline production. European Association of Urology (EAU) guidelines have international reach, a rigorous guideline production process, an established patient information section and existing links with European cancer patient organisations. This makes EAU and genitourinary cancers the ideal setting to test a framework for patient involvement in guideline development. The EVOLVE study is a unique collaboration between a professional society, Guideline Panels, researchers, clinicians and patient organisations, aiming to design a framework for meaningful patient involvement within guideline production. Stages for considering patient preferences and values were identified via systematic review and interviews with key stakeholders, then prioritised by patients and clinicians via an international Delphi study. The final EVOLVE framework will be tested within EAU Guideline Panels and a strategy developed to assess the impact of patient involvement in guidelines.

Clinical practice guidelines help reduce unwarranted variation in clinical practice and improve patient outcomes.[1] At present, European Association of Urology (EAU) guidelines are endorsed by 75 countries worldwide, including all 27 EU member states. Furthermore, European urologists are highly aware of the guidelines, with 17,084 users of the EAU Guidelines app recorded.[2] Despite the international reach of EAU guidelines there are factors that hinder full adherence to the guidelines. One such barrier to adherence, stakeholder involvement, including routine involvement of patients within guideline development, has been identified as an area for improvement.[3,4] The involvement of patients within guideline development has been shown to improve quality of guidelines and associated patient education materials[5] and is particularly important when considering preference-sensitive decisions, where patient preferences take priority when considering the benefits and harms of treatment options. An example of a preference-sensitive decision is the choice of treatment for localised prostate cancer, where the oncological control is similar across intervention types, but the side effects and long-term implications of treatment decisions differ.[6]

Despite international recommendations to include patients within guideline production there is a lack of clear methodology, including a need to identify the optimum stages for patient involvement. Further challenges to patient involvement include 'tokenistic' involvement rather than routine integration of the patient voice, lack of support to help patients understand medical terminology, resistance from some health professionals and lack of resources.[7]

A solution to the problem of when and how to include patients in guideline development is provided in the **giving patients a mEaningful VOice in the design and deLiVery of carE (EVOLVE)** study. EVOLVE is a unique collaboration of a professional society (EAU), researchers, clinicians and patient organisations to improve guideline development and implementation, a core activity of the EAU. The main aim of the EVOLVE study is to develop a framework for patient involvement within guideline development for genitourinary cancers in collaboration with the EAU Guideline Panels for Prostate Cancer, Testicular Cancer, Renal Cell Carcinoma, Non-muscle-invasive Bladder Cancer and Muscle-invasive Bladder Cancer. EAU is a forward-thinking professional society, which has international reach, robust guideline development processes, multi-disciplinary collaboration, an established patient information section and existing engagement with European cancer patient organisations. This makes EAU genitourinary cancer guidelines the ideal setting to test a framework of patient involvement in guideline development and implementation.

Framework development

The EVOLVE framework was developed using an iterative approach, comprising of four phases. First, a systematic review was carried out to evaluate existing models and frameworks of patient involvement in guideline development and to identify potential stages within guideline production for involving patients.[8] Next, interviews were conducted with 23 members from the participating EAU Guideline Panels, including clinicians and patients, to determine barriers and enablers for patient involvement specific to genitourinary cancer guidelines and to identify further stages for patient involvement in guideline production. A shortlist of potential stages for patient involvement was then collated and entered into a Delphi survey. Participants for the Delphi survey included patients with a diagnosis of prostate, renal, bladder or testicular cancer recruited via international patient organisations and clinicians, including urologists, nurses and medical and clinical oncologists, recruited via the EAU and the European Association of Urology Nurses. Participants were asked to rate the importance of patient involvement for each stage within guideline production using a nine-point Likert scale based on the GRADE scoring system. Scoring and feedback to participants was conducted in line with a previous Delphi study.[9] Consensus was defined as ≥70% rating a stage critical for patient involvement and ≤15% rating a stage not important;

and vice-versa. Stages that did not meet consensus following two Delphi survey rounds were discussed and voted on by a consensus panel. Finally, the EVOLVE framework for patient involvement in guidelines was developed based on integrated outputs from the systematic review of patient involvement methodologies, interviews with key stakeholders and the results of the Delphi process.

Recommendations

The systematic review and interviews with key stakeholders identified three domains considered essential for patient involvement in guidelines and these have been incorporated into the EVOLVE framework:

- Domain one is commitment to involving patients, made at a strategic level within the organisation and evidenced by a formal strategy, resource allocation and established links with patient networks.
- Domain two is acceptance of patient involvement as part of the organisational culture and establishment of a patient role, training opportunities and a supportive environment to enable effective involvement in guideline production.
- Domain three is patient engagement and involvement within the relevant stages of guideline development as defined in the EVOLVE Delphi study (see Figure 1). Patient involvement was considered important throughout the technical stages of the guideline development process from prioritising questions and outcomes to instigating guideline updates. One area where patient involvement was not considered a priority was the technical stage of conducting a systematic review. Furthermore, patient involvement was considered important for stages related to guideline development including research prioritisation and consensus meetings. Patients can also play a key role in disseminating guidelines, including co-designing educational materials such as patient information, patient decision-aids and patient versions of guidelines and helping to disseminate these via patient networks to improve awareness and uptake of guidelines.

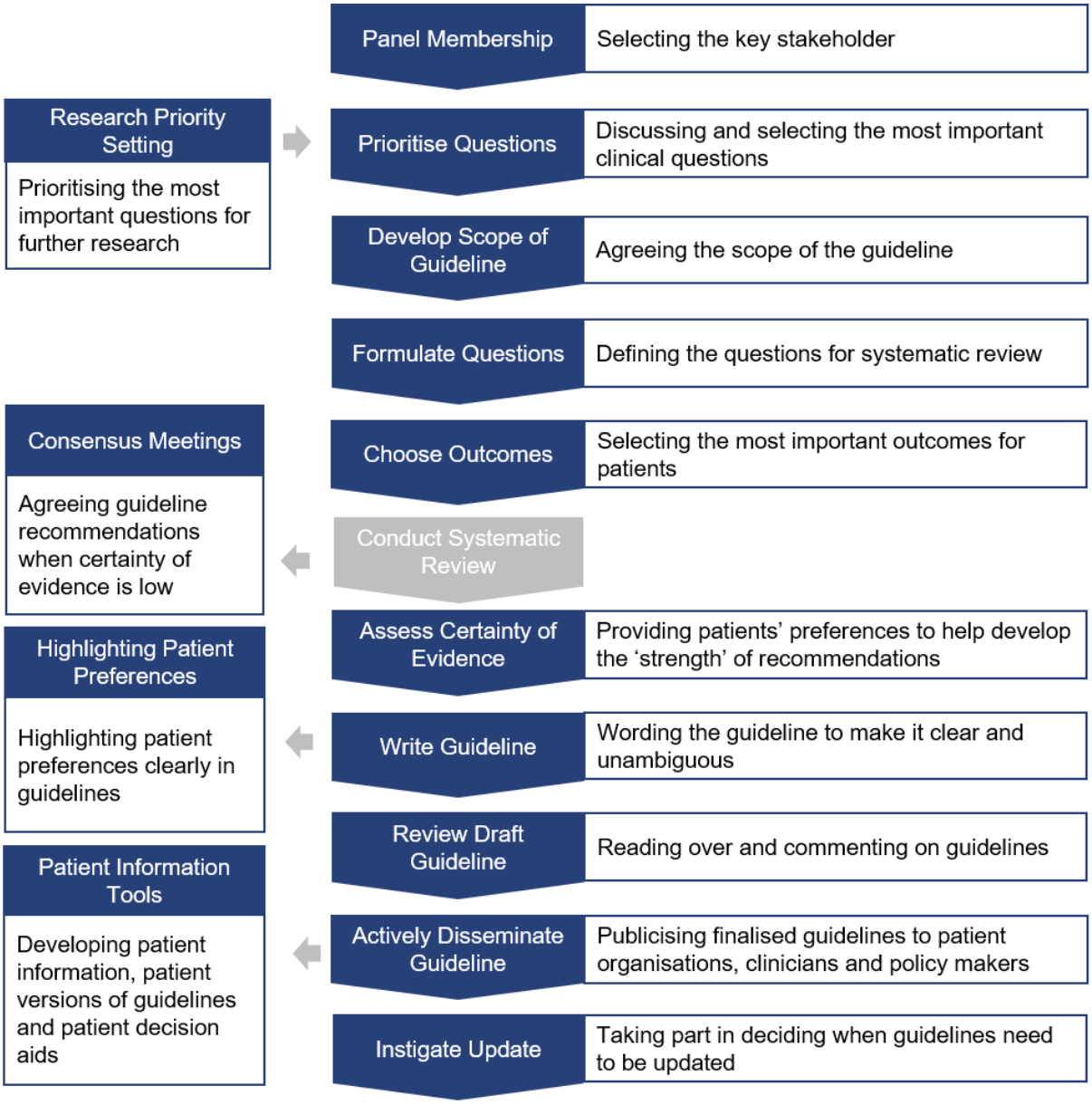

FIGURE 1. Stages for considering patient preferences and values within guideline development and implementation (stages highlighted in blue were included and stages highlighted in grey excluded).

How is the EVOLVE framework being implemented in the EAU's guideline production process?

In the next phase of the EVOLVE study, the Consolidated Framework for Implementation Research (CFIR)[10] will be used to evaluate the implementation of the EVOLVE framework within guideline development for genitoutounary cancers. The EVOLVE framework will be adjusted to address any identified barriers to implementation and the framework will then be trialled for additional guidelines including functional urology. Finally, an evaluation strategy for assessing impact of patient involvement in guideline production will be developed.

In summary, a framework for meaningful patient involvement in guideline development and implementation for genitourinary cancers has been developed. The EVOLVE framework can help guideline developers involve patients at the optimum stages of guideline production to ensure patient preferences and values are routinely embedded within guidelines, which may improve the quality and relevance of guidelines.

References

1. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: A systematic review of rigorous evaluations. *The Lancet*. 1993;342(8883):1317-1322.

2. European Association of Urology. EAU guidelines analytics report. 2019:1-2.

3. MacLennan SJ, MacLennan S, Bex A, et al. Changing current practice in urology: Improving guideline development and implementation through stakeholder engagement. *Eur Urol*. 2017;72(2):161-163.

4. van den Bergh R,C.N., Ost P, Surcel C, et al. Are clinical guidelines designed according to guidelines? cross-sectional assessment of quality and transparency of clinical guidelines in urology. *World J Urol*. 2018;36(9):1489-1494.

5. Díaz Del Campo P, Gracia J, Blasco JA, Andradas E. A strategy for patient involvement in clinical practice guidelines: Methodological approaches. *BMJ Qual Saf*. 2011;20(9):779-84.

6. Hamdy FC, Donovan JL, Lane JA, et al. 10-year outcomes after monitoring, surgery, or radiotherapy for localized prostate cancer. *N Engl J Med*. 2016;375(15):1415-1424.

7. Ocloo J, Garfield S, Franklin BD, Dawson S. Exploring the theory, barriers and enablers for patient and public involvement across health, social care and patient safety: A systematic review of reviews. *Health Research Policy and Systems*. 2021;19(1):8.

8. Björkqvist J, MacLennan SJ, MacLennan S, Yuan C. An evaluation of existing models of patient and public involvement in the development of clinical practice guidelines: A systematic review. 2018 CRD42018116712.

9. Lam TBL, MacLennan S, Willemse PM, et al. EAU-EANM-ESTRO-ESUR-SIOG prostate cancer guideline panel consensus statements for deferred treatment with curative intent for

localised prostate cancer from an international collaborative study (DETECTIVE study). *Eur Urol*. 2019;76(6):790-813.

10. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*. 2009;4(1):50.