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CURRENT OPINION

Patient and Public Involvement in the Development of Healthcare Guidance: An Overview of Current Methods and Future Challenges

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Abstract Clinical guidelines and health technology assessments are valuable instruments to improve the quality of healthcare delivery and aim to integrate the best available evidence with real-world, expert context. The role of patient and public involvement in their development has grown in recent decades, and this article considers the international literature exploring aspects of this participation, including the integration of experiential and scientific knowledge, recruitment strategies, models of involvement, stages of involvement, and methods of evaluation. These developments have been underpinned by the parallel rise of public involvement and evidence-based medicine as important concepts in health policy. Improving the recruitment of guideline group chairs, widening evidence reviews to include patient preference studies, adapting guidance presentation to highlight patient preference points and providing clearer instructions on how patient organisations can submit their intelligence are emerging proposals that may further enhance patient and public involvement in their processes.

Key Points for Decision Makers

The role of patient and public involvement in the development of clinical guidance and standards has grown in recent decades.

A number of issues have been considered in the international literature, including the integration of experiential and scientific knowledge, recruitment strategies, models of involvement, stages of involvement, and methods of evaluation.

A variety of suggestions have emerged considering ways to advance this involvement and make it more meaningful, including acknowledging and addressing barriers and measuring impact.

1 Background

In recent decades, guidelines and health technology assessments have become an increasingly important part of healthcare policy and practice around the world [1–3]. Rising healthcare costs, expensive technologies, variations in service delivery among providers and the intrinsic desire of clinicians to offer the best possible care are all factors that have contributed to this rise. Clinical guidelines are systematically developed statements that are used to guide healthcare decisions across various settings [4, 5]. Health technology assessments are research-based, practice-oriented assessments of healthcare technologies that support policymakers to introduce new technologies to the health system effectively [6]. Quality indicators, meanwhile, are measurable items that facilitate improvement in the quality

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of healthcare practices and services [3]. They all share a common approach of robustly evaluating evidence and expert knowledge to formulate practical recommendations to achieve improvements in healthcare delivery.

In order to support guideline producing organisations to reach these important goals, there has been much international interest in how to improve the quality of guidance through standardised methodologies and critical assessment tools [7]. A systematic review assessed 24 such assessment instruments from eight different countries, concluding that the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was the highest quality overall [8]. A subsequent systematic review in 2012 used the AGREE instrument to assess the quality of clinical guidelines developed in Europe since 2000, finding that there was considerable room for methodological improvements [9].

An aspect of guideline quality that has received particular attention is the extent to which patients and public are involved in the development process. It has been suggested that this involvement has the potential to increase the relevance and acceptability of recommendations as patients are likely to have fewer alliances than healthcare professionals [10]. However, various barriers to meaningful participation have also been cited, including the hierarchical nature of healthcare professions and perceived bias in individual viewpoints [11], leading to limited opportunities for input and influence. The lack of empirical research about the measurable impact of patient and public involvement (PPI) is noteworthy [12], and the diversity of opinion about optimal involvement strategies highlights that although PPI is taking place worldwide in different forms, it remains an emergent field.

This review seeks to summarise the current practice of PPI in healthcare guidance development and highlight future challenges. Database searches and manual reference tracking were used to identify editorials and primary qualitative and quantitative research exploring patient involvement in healthcare guidance. Decisions about literature inclusion and the shaping of key themes were made through consensus meeting of the reviewers.

2 Stages of Involvement

The production of guidance can be a lengthy process, and public involvement can take place at multiple stages. Topic selection is the obvious first step, with input at this stage considered valuable for both clinical guidelines and health technology assessments [13–16]. Similarly, participation in deciding the scope is deemed important as it is an opportunity to "set the agenda and determine the rules and the players" [17]. Involvement in the formation of recommendations is widely advocated [18, 19], along with opportunities to comment on draft versions [15, 18].

Patient and public members may also be included in implementation activities [13, 20–22], including working with the media and promoting guidance at national and regional levels [23]. There is a strong body of support calling for PPI throughout the guideline development process [18, 22, 24, 25].

3 The Integration of Experiential and Scientific Knowledge

The challenge of incorporating patient perspectives alongside scientific evidence reflects the conceptual conflicts between evidence-based medicine (EBM), which relies on objective and robust data, and PPI, which is intrinsically based on the experiences of individuals. It has been suggested that this may be resolved by providing active support for patient and public members to engage in guidance development. For example, the use of scientific and medical terminology by guideline developers and health professionals has been identified as a particular barrier for patient and public participants [13, 14, 26–30] and there has been reported uncertainty about the extent to which they should be able to interpret scientific evidence [14, 27]. Providing critical appraisal training for patient and public participants has been widely endorsed [15, 17, 18, 20, 21, 23, 27, 30–32], although it has been found to be resource intensive [23, 27]. However, a contrasting perspective is that the unique benefit of PPI comes from experiential learning and therefore academic skills are not relevant [28], and indeed, it has been argued that they actually weaken participation by reducing the uniqueness of "true" patients "in the wild" [33].

Guideline development is typically performed by a group that includes a chair, healthcare professionals from different backgrounds and technical staff from the guideline-producing organisation [34], along with patient and public members. The role of the chair has been widely recognised as being important for effective PPI to occur [20, 23, 29, 35, 36]. Although chairs seem to have discordant opinions on how important active PPI is [36], it has been suggested that they could play an important empowering role, with specific proposals including the use of a psychologist chair to ensure effective group dynamics [29] and a reminder item on the agenda to consider patient perspectives in each meeting [20]. There was some concern that patient and public members may not be actively included in these groups, leading to infrequent and inappropriate contributions [19, 27], although their presence was felt to be vital by others to make discussions less "physician-centric" [24] and keep a focus on the right questions.

There has been considerable interest in understanding how patient preferences can be better incorporated into healthcare guidance. Widening search strategies to include qualitative research [13, 15, 21, 24, 28, 31, 37], developing new methods to synthesise patient preference knowledge [15, 38, 39] and using social scientists to review this evidence [21, 37] have all been widely supported. There is, however, an impression that this type of evidence is deemed less credible by guideline developers and concerns about the extent to which narrative evidence fits into the traditional hierarchy of EBM [16, 23, 24, 35, 40]. An additional related mechanism to include these perspectives is the addition of relevant key questions for guideline development groups to consider.

In the presentation of guidance, a greater openness about uncertain recommendations may help emphasise patient preferences, with calls for less firm recommendations [41] and more use of menus to present multiple possible management strategies [26, 42]. It was also felt that professional versions of guidelines could be improved by signalling recommendations that require shared decision making and providing links directly to decision aids from the guideline [24, 31, 38].

4 Recruitment

There has often been a lack of clarity about whether lay members should be representing themselves or the wider public, with expectations often being unclear [14–16, 33, 36, 38, 43]. Although there have been suggestions that input should be exclusively from an individual or general public perspective [25, 33], there seems to be recognition that in reality, this is a complex distinction to make [36]. Views about the role of patient organisations have been divergent. Whilst there is recognition that they can play a variety of roles, including submitting evidence and nominating or recruiting members [16, 23], concerns have been raised about the fact that some organisations are dependent on industry funding.

The difficulty of recruiting a diverse range of participants has been noted, with challenges to recruit representation across age, gender, ethnicity, education and socioeconomic dimensions [16, 22, 38, 44]. Stigma is an important consideration when recruiting for conditions such as sexual diseases and HIV [45]. Some organisations have opted to produce mini "job descriptions" [23, 38] with description of the role, task and skills needed. Although these have helped to ensure that participants are clear about their roles and have largely been deemed helpful [23], the presence of scientific literacy as a desirable trait has been criticised as a barrier to achieving genuine representation [42].

5 Model of Involvement

In her seminal paper on citizen involvement, Sherry Arnstein conceptualised a ladder of involvement with eight steps representing increasingly significant levels of involvement in decision making [46]. Subsequent adaptations of the model have focussed particularly on flow of information and have distinguished between organisations that use unilateral methods of communication (such as consultation or public information) and those that use the preferable bilateral approaches (such as active group participation) [17, 31]. Although posting guidance online for public comment is a broad and open avenue, it relies on engagement with long documents that contain significant amounts of technical information and jargon.

Public advisory committees such as the Citizen's Council of the National Institute for Health and Care Excellence (NICE) [13, 15, 20, 31, 47] and the Ontarian Health Technology Advisory Committee (OHTAC) [44, 48] in Canada are generally highly regarded, although the lack of direct input and public will to engage have been noted as limitations [13, 47]. Priority-setting exercises are a further means to seek public advice, but their role is limited by the high amount of resources required.

The composition of guidance producing groups is fundamental, with many organisations including one or two lay members routinely [21, 23, 36, 39]. This direct involvement and opportunity for discussion has been described as an essential feature [24], although contributions can be infrequent and active participation relies on a supportive culture [30]. In addition to direct involvement in groups, the use of structured peer-facilitation and flipcharts has been found useful [30], although such workshops have proven resource intensive [27]. Importantly, the information gathered from these workshops is typically fed back to the guideline working group by a member of the support team, which means there is no direct interaction between the two groups and no means for two-way "knowledge exchange" to occur [19, 49].

Although patient organisations are generally able to submit evidence to inform guidance development [16, 23, 26], there is concern about how it is handled and utilised [13, 40]. These organisations may be able to better use their networks and knowledge if there was a clearer route for them to contribute their data [50]. Interest in using novel ways of engaging the public, such as online platforms and social media is also rising [31]. However, there is not yet a clear mechanism by which these forms of evidence can be quality assured and synthesised into a form that can usefully inform guidance.

6 Evaluation

It has widely been suggested that involvement has intrinsic value by promoting democracy, redistributing power and allowing patients to influence the health system [17, 28, 30, 42, 49]. Thus, PPI may be considered a goal in itself that does not require justification and cannot be opposed, other than on methodological grounds [42]. Others have argued that it is important in order to gain legitimacy [20, 25, 51], increase responsiveness to public need [16] and make guidance easier to implement [30, 49].

Although the lack of formal evaluation of PPI has been criticised [15, 51], there has been recognition that randomised controlled trials (RCTs), for example, would be "very difficult if not impossible" to conduct in this area [28]. Indeed, a Cochrane review in 2006 found no published trials evaluating patient involvement in clinical guidelines [12], and although none appear to have been published since, a more recent cluster RCT across six Canadian communities was promisingly able to demonstrate that patient involvement can change priorities for healthcare improvement at the population level [52]. Of note, there is a lack of published evidence about the experiences of patients and public members involved in healthcare guidance, and this may be an important topic for future research.

Various instruments have been designed to evaluate guidance quality, and although the inclusion of a patient involvement dimension in the AGREE checklist has been welcomed [28], it may not differentiate meaningful involvement from tokenism and has been described as a "blunt instrument" [33] in assessing how patient-centred guidance is. The work of international networks has enhanced patient involvement [51], although even greater international collaboration would allow organisations to further share learning and expertise [38, 53]. Indeed, criticisms of exclusivity and tokenism have also been directed at healthcare research and models of equitable partnership working are currently being developed [54].

7 Conclusions

The concurrent rise in prominence of EBM and patient involvement in health policy in recent decades has been the backdrop to the evolution of PPI in healthcare guidance around the world. The inevitable tensions between these two conceptual paradigms have given rise to complex challenges faced by guideline developers and barriers to designing processes that facilitate meaningful and effective involvement.

The role of a guideline group chair is particularly important, and a greater emphasis on ability to facilitate supportive discussions when electing new chairs may help to improve this. Although there is no consensus on a single involvement strategy, there are circumstances where both individual and broader societal perspectives are beneficial. Areas that require unique perspectives such as clinical guidelines may benefit more from patients or carers with experiences of a particular condition, whereas members of standing committees for health technology assessment or indicators may require public members with societal perspectives.

Widening search strategies in evidence reviews to include patient preference literature has the potential to significantly increase applicability by incorporating a broader collection of perspectives. However, this is likely to require a fundamental change for guideline developers and necessitate developmental work to establish new methods of knowledge synthesis, employment of social scientists to contribute to evidence reviews and significant financial investment. Changing the format of guidance to highlight the relative uncertainty of recommendations and links to decision tools is also an important consideration for the future.

Healthcare guidance and indicators continue to be a key method to improve health systems around the world. Specifically, they improve the quality and experience that patients and the public receive from healthcare, and ensuring their representation in their development is therefore fundamental, whether for reasons of democracy or improved quality. This paper provides policymakers and health guidance producers with a review of current practices and future challenges relating to PPI. Although much progress has been made, further improvements are needed in order to enable guideline production that allows meaningful input through both preference information and direct involvement.

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Compliance with Ethical Standards

Conflicts of interest VT, TS and GL are employed by the National Institute of Health and Care Excellence (NICE), who produce guidelines and quality standards. AR is a clinician in the UK National Health Service who completed a fellowship at NICE in 2015.

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