Training curriculum to help patient representatives participate meaningfully in the development of clinical practice guidelines

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Abstract

Patient participation in the development of clinical practice guidelines (CPGs) is critical for validity and trust. Many guideline panels now include patient representatives. Engagement of these individuals may be improved by training them about the process and their role before they join a guideline panel. To aid patient representatives in engagement in the improvement of guidelines, we developed and implemented a curriculum. The curriculum was developed based on content from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group and readability principles, and was delivered through a webinar followed by a face-to-face half a day workshop. Twenty-four patient representatives were recruited by the American Society of Hematology to serve on guideline panels. Barriers assessment was facilitated by a pre-curriculum survey. The curriculum targeted patient representatives' knowledge, skills and attitudes and was followed by actual engagement in a guideline panel and a post-curriculum survey. Participants reported that the combination of the two training methods was very useful (9/10 on the Likert scale) in increasing their knowledge about guideline development. They agreed that their skills and self-efficacy in developing guidelines improved (8/10). Their attitudes (confidence in their ability to participate) improved by 30% between the webinar and the workshop. They developed a script to use during panel deliberations and an instruction sheet for the guideline panel about how to empower and engage them as active participants in the guideline development process. The benefits of incorporating patients' voice in CPGs are multifold. These benefits may be optimised by providing patient representatives with training that addresses barriers to engagement and tools to increase their knowledge, skills and attitudes required for meaningful participation.

Introduction

Clinical practice guidelines (CPGs) are systematically developed recommendations drawing from best available scientific evidence to assistant clinicians and patients in making medical decisions. The Institute of Medicine has published standards for trustworthy guideline development.[1] These standards suggest patient representatives should be included on guideline panels to ensure that the patient voice and perspective is considered when developing a guideline. The GRADE approach for developing guidelines, a well-defined and commonly used approach, emphasises the need to incorporate patients' values and perspective to determine the importance of outcomes, clarify tradeoffs and inform issues of acceptability and feasibility of recommendations.[2 3]

Patients can enrich the guideline development process by sharing their values, preferences and unique experiences of an illness and by illuminating social and clinical context.[4] This is particularly important when the certainty in evidence is not high, a situation that is common in the biomedical literature. Under the GRADE approach, even when available evidence is high certainty, recommendations may be 'weak' or 'conditional' because of a close balance between benefits and harms that requires the input of patients. Unfortunately, evaluation of a sample of published guidelines showed that the guidelines were 'out of context'. Patients were not included in the guideline development process in 71% of the guidelines and there was a complete absence of incorporating the impact of multiple chronic conditions, socio-personal context and patient preferences in 29%, 39% and 57% of the guidelines, respectively. When mentioned, multiple chronic conditions were considered biologically, but not as contributors of complexity or patient work or as motivation to focus on patient-centred outcomes.[5]

In addition, studies have shown that patient engagement in guidelines and other research can become tokenistic.[6] Patients may also have difficulty in understanding medical and statistical jargon and subsequently limit their contributions.[7 8] Guideline panels composed mainly of experts may be intimidating to patient representatives, inhibiting their participation. Furthermore, guideline panels and methodology teams may be inexperienced with how to engage patient representatives in review of evidence and deliberations around recommendations. A focus group of consumers identified to be potential candidates for guideline engagement has shown preference for pre-meeting reading and training.[9] Numerous other studies have described pre-engagement training as an important tool for meaningful engagement of patient representatives and means to successfully incorporating their values and preferences into the guideline development process.[4 9–11]

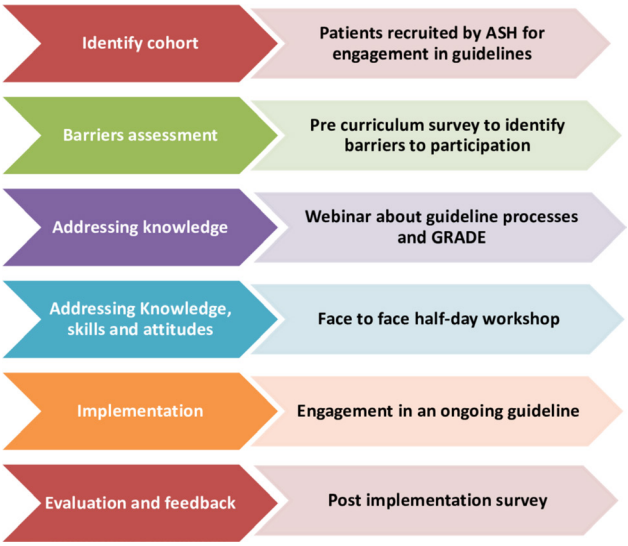

Figure 1 Methods of developing and implementing the curriculum. ASH, American Society of Hematology.

To address these barriers to meaningful patient engagement, we developed and implemented a training curriculum for patient representatives who were recruited to serve as regular voting members on guideline panels formed by the American Society of Hematology (ASH). This paper describes the methods that were taken to develop the curriculum, elements of the curriculum, implementation strategies and feedback for further improvements.

Methods

Participants

We selected a convenience sample of 24 patient representatives from 11 (Management of Immune Thrombocytopenia, Venous Thromboembolism (VTE) Prophylaxis in Medical Patients, Diagnosis of Venous Thromboembolism, Thrombophilia, VTE Treatment, Optimal Management of Anticoagulant Therapy, Cancer-Associated Venous Thromboembolism, Venous Thromboembolism in the Context of Pregnancy, Pediatric Venous Thromboembolism, Heparin-Induced Thrombocytopenia and Sickle Cell Disease) ASH guideline panels. They included individuals with and without prior experience of the guideline topic (ie, illness) as well as caregivers. Among these participants, 15 individuals had been appointed to previous 10 guideline panels (immune thrombocytopenic purpura (ITP)/VTE) and 9 to guideline panels on the management of acute and chronic complications of sickle cell disease (SCD) with whom the curriculum was tested. These patient representatives were involved from the beginning of the process when the systematic review questions were developed and when outcome importance was rated. They attended all the interim teleconference calls for panel discussions and they attended the face-to-face meeting in which the recommendations were made and voted on.

Developing the curriculum

We conducted a pre-survey with a group of patient representatives from the ITP/VTE guidelines to receive feedback on their experience on the guideline panels. The feedback was then used to develop a training curriculum.[12] A post-survey after the implementation of the curriculum was conducted to receive feedback on the training and suggestions for future improvements. Descriptive statistics was used to summarise survey results using Stata V.14. This patient training was approved by the Mayo Clinic Institutional Review Board. The approach of developing, implementing and evaluating the curriculum is depicted in figure 1.

Pre-curriculum survey

An initial survey (see supplementary appendix: Pre-curriculum patient experience survey questionnaire) with the patient representatives from the ITP/VTE guideline panels was conducted to obtain information about their previous experience with guideline development and to identify the barriers to participation for active engagement. The survey included both closed-ended and open-ended questions. A total of six patient representatives responded to the survey. Among them, two (33%) participants had prior experience with other CPGs development, five (83%) did not receive training for active participation, four (67%) felt that they were able to actively participate, three (50%) felt their voice was heard and reflected in the guideline, and three (50%) participants expressed that their overall experience with a different guideline panels that they participated prior to the ITP and VTE was good. In the open-ended questions, the participants described their roles as being able to provide guidance on non-medical issues and treatment suggestions from a patient's perspective. They also identified lack of knowledge, inadequate preparation, difficult medical terminology, lack of education as barriers to successful participation. All of them placed a strong emphasis on training and resources on what to expect or how to be more active. The results and qualitative feedback from the pre-survey were used to develop the content of patient training intervention.

Development of the training curriculum

Theory/sources used for the curriculum

We developed the content of the curriculum based on the Evidence to Decision (EtD) approach from the GRADE Working Group materials,[2 3] readability principles for accepted level of literacy for patients[13] and the barriers to participation identified in the survey.

The training curriculum consisted of two components: (a) webinar and (b) face-to-face workshop. Each was developed to better address barriers to participation (identified in the pre-survey) and facilitate patient engagement in the CPGs development process. The specific objectives of the curriculum were:

- To increase knowledge and awareness of the patients living with SCD of their significant role in CPG development.
- To review the challenges that patients may encounter during participation in CPG development.
- To discuss practical strategies that patients may apply during the guideline development to promote relevant and impactful participation in the EtD phase of recommendation.

The descriptions of the webinar and face-to-face workshop are provided below:

Webinar

An interactive online webinar was designed and taught by two experienced instructors (EL and LD) who are experts in guideline development and patient education. The agenda for this webinar was to:

- Increase knowledge of guideline development process.
- Increase knowledge on GRADE recommendations.
- Understand patient role.
- Strategies for active participation.
- Tips of how to bring in patient voice.

The interactive webinar involved discussions on topics such as, why patient active participation is critical, barriers to active engagement and strategies that patient representatives may use

during the recommendation by panel members in order to ensure that their preference and values are reflected in the deliberations.

Face-to-face workshop

A half-day workshop was organised. Patients and their caregivers attended the workshop. Two instructors (EL and LD) led the workshop. The focus of the workshop was on increasing patient representatives' engagement skills and addressing the challenges associated with their involvement.

The agenda for the workshop was to:

- Learn about how guideline panels work and understand the critical role of patients.
- Discuss how to optimise patients' engagement.
- Summarise discussions and develop a strategy based on consensus.
- Develop messages from the patients for the chairs and panels.

The topics addressed in the webinar and the workshop overlapped. However, in the webinar, the focus was on didactics and concepts. In the workshop, the focus was on roleplay and practical issues. To prepare for the workshop, patient representatives were asked to read an article ahead of the workshop.[8] At the beginning of the workshop, during introduction, each patient/caregiver was asked to share an experience they had while living with the disease. The purpose of this strategy was to give them an opportunity to talk about their illness and create a welcoming environment. The workshop included Power Point and use of clip boards for writing major themes raised during the interactive group discussions. At the end of the day, the group developed a series of strategies that patient representatives agreed to use when developing recommendations at guideline panel meetings. They also drafted messages to chairs (see online supplementary document—Table 3) and panel members for the guideline development panels (see online supplementary appendix—Message for Chairs and panel members, for draft that was sent to the panel chairs prior to making recommendations) to inform them of the challenges associated with patient engagement and how to engage patient representatives.

Implementation

The knowledge, skills and attitudes that the patient representatives developed during the webinar and face-to-face workshop, were used by them for engaging in the ongoing guideline deliberations following the workshop. The CPGs panel chairs were informed of the training that the patient representatives were receiving and the messages that were drafted during the workshop were delivered to them so that they were prepared for what to expect from the patient representatives.[12]

Patient representatives used the guiding questions (see online supplementary appendix—Questions/scripts for patient representatives to consider using during recommendation) to assist them with active engagement and to help them vocalise their preferences and values.

Evaluation and feedback

Patients were asked to respond based on a 10-point Likert scale and open-ended questions to give their feedback for future improvement in patient training for CPGs development process. Please see online supplementary appendix for the post-implementation survey questionnaire.

Out of nine patient representatives (who took the training) from SCD panel, six responded to the post- implementation survey. The representatives felt that the usefulness of the webinar was eight and the face- to-face workshop was 9.6 out of 10 on the Likert scale for increasing their knowledge in participating in CPGs development. The usefulness of the webinar in skills development for active participation was 7.16 and 9.3 for face-to-face workshop out of 10 on the Likert scale. A total five participants felt that their confidence in their ability to participate increased after attending the webinar and all of them (six participants) felt that their confidence was increased after attending the face-to-face workshop. The combination of the two training methods was very useful (9 out of 10 on the Likert scale) and an increase in their confidence was observed by 30% from webinar to face-to-face workshop. Patient representatives also felt that the overall quality was 'Excellent' and valuable. Some quotes from the open-ended questions are provided below:

> Very advanced but pushed me to learn and research more... –Webinar
> It was very educational...-Webinar
> The session was extremely valuable, especially the demonstration of the GRADE process.....It was also helpful to hear voices of the other patients/family members... -Workshop
> It was just perfect...-Workshop
> Include patients in the process. We want to be at the table always when decisions are being made about us....-Overall
> Thank you... , and thank you to the entire panel. You all make patients like myself feel more hopeful about the future of our healthcare. I feel very fortunate to have been privileged enough to be a part of such a great team. I wish you all the best-Overall

The in-person workshop received better than the webinar due to the nature of face-to-face communication strategy. Patient representatives felt assuring and comfortable after meeting their peers in the in-person workshops thus was more interactive and felt more comfortable sharing their experiences with the group. Patient representatives also reflected on the training as very helpful for them to understand the guideline development process and in increasing their competency in active engagement. They recommended that the training should be delivered prior to the first guideline panel meeting and before the final recommendation deliberation.

Limitations

A few limitations should be considered for the development and implementation of the curriculum. A small sample of patient representatives from eleven guideline panels was recruited to test the curriculum. There were also limitations due to a possible lack of generalizability since these patients may not represent patients at large in their background or education. A large study with representation of patients with different backgrounds and health conditions[14]using patient engagement framework[15] to further develop and test the curriculum may increase the validity and acceptance of the curriculum. Lastly, this curriculum focuses on training patients and their representatives; however, panellists and researchers also require training for proper engagement. Patient engagement in guideline can add some additional costs; although likely not large compared with other costs.[11 16]

Discussion and recommendations

Under the GRADE approach, the patient perspective and experience should inform the direction and strength of guideline recommendations. The GRADE EtD framework structures guideline panel discussions around key criteria that determine a recommendation, with the goal of making patient-centred recommendations.[3] Lack of patient involvement in these

Table 1 Components of webinar

Participants	Patient representatives recruited for guideline development
Length	2 hours
Resources	PowerPoints
Method of delivery	Live webinar presentations and discussions
Topics discussed	► Clinical Practice Guideline process. ► GRADE. ► Shared decision-making. ► Significance of patient role. ► Barriers to patient participation. ► Strategies for patient participation.

Table 2 Components of face-to-face workshop

Participants	Patient representatives recruited for guideline development
Length	Half-day workshop
Resources	PowerPoints, clip boards, handouts and article
Method of delivery	In class interactive discussions
Topics discussed	► Clinical Practice Guideline process. ► GRADE. ► Significance of patient role. ► Barriers to patient participation. ► Strategies for patient participation. ► Develop messages for panel members.

discussions may result in recommendations that do not reflect patients' preference and values and could lead to recommendations that are not trusted or accepted by patients. In this study, a training curriculum was developed to enhance how patient representatives participate on guideline panels. The curriculum aimed to improve knowledge of how guideline panels work, emphasise the critical role of the patient's perspective and voice, teach skills to increase confidence of patient representatives to participate, and provide scripts for use during recommendation deliberations. Though a small sample of patient representatives participated in the training, the curriculum received a high level of acceptance. The combination of online and in-person methods was effective, with the in-person workshop being most favourable to participants. Participants particularly appreciated the experiential learning and roleplay, which gave them tools to use for engagement. It is unlikely that such experience can be provided electronically.

Further research with representations from patients with different backgrounds and health conditions should ensure the generalisability of the curriculum.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval All procedures performed in studies involving patient representatives were in accordance with the ethical standards of the institutional ethical committee. Ethical approval was granted by the Mayo Clinic Institutional Review Board, Rochester, Minnesota.

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