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Methodology paper

ETHICAL AND FEASIBLE STAKEHOLDER ENGAGEMENT IN GUIDELINE DEVELOPMENT

Abstract

Background: Stakeholder engagement impacts on the relevance and usability of guidelines.

Consequently, guideline developers are advised to engage with a diverse group of stakeholders. One of the most critical and challenging phases of guideline development is determining the guideline scope, and there is currently scant guidance for how stakeholders can be engaged in feasible and ethical ways.

Aim: This article aims to provide practical guidance for how diverse stakeholders can be engaged to determine the scope of a guideline.

Methods: Supported by previous frameworks and by drawing on experiences from a research project aiming to develop a clinical practice guideline on non-pharmacological approaches for agitation in the intensive care unit, this paper describes a 7-step process for stakeholder engagement. Guideline developers need to consider the aim of their project, identify relevant stakeholders, decide on the level of engagement, plan how to engage in feasible and ethical ways, consider how to increase the trustworthiness of a project, and finally consider how to evaluate the project.

Conclusion: Consultation of diverse stakeholder groups is feasible, but it is essential to plan the activities and be aware of the steps to take to ensure an effective and ethical process.

Summary of Relevance

Problem or Issue:

- Failure to engage relevant stakeholder groups when determining the scope of clinical practice guidelines may result in inadequately addressing existing needs, thus compromising the implementation of the guideline.
- No guidance exists on how guideline developers can involve diverse international stakeholders in feasible and ethical ways.

What is already known:

- Evidence shows that often stakeholder engagement is not done, or not done well.

What this paper adds

- This paper describes the steps guidelines developers can take to increase the likelihood of ensuring ethical and feasible stakeholder engagement.

Keywords Practice Guidelines, Critical Care, Stakeholder Engagement, Knowledge Translation, Patient and Public involvement, Research Ethics, Research Design Stage, Patient-Centred Care

Introduction and background

The implementation of evidence-based practice is challenging (Braithwaite, Glasziou, & Westbrook, 2020). Although guidelines are tools developed to support this process (Steinberg, Greenfield, Wolman, Mancher, & Graham, 2011), the lack of guideline uptake is a major concern internationally (Girlanda, Fiedler, Becker, Barbui, & Koesters, 2017; Heneghan, Perera, Mant, & Glasziou, 2007; Reinecke et al., 2015). Lack of guideline uptake can occur when end-users do not agree with recommendations (Spitaels et al., 2017), when a guideline format is not user friendly (Cahill, Suurdt,

Ouellette-Kuntz, & Heyland, 2010), or when the recommendations are not feasible (Perez, Wisnivesky, Lurslurchachai, Kleinman, & Kronish, 2012). Research has explored ways to improve knowledge uptake and to develop guidelines with a form and content that more easily can be implemented (National Health and Medical Research Council, 2020). Evidence shows stakeholder engagement can have an impact on the relevance and usability of the final guideline (Armstrong, Mullins, Gronseth, & Gagliardi, 2018), thus increasing the likelihood of successful implementation (Health & Excellence, 2015; World Health Organization, 2014). Within guideline development, stakeholders include those who have a legitimate interest in a guideline and/or who may affect, or be affected by it. Stakeholders may include health professionals, patients and their representatives, those financing, managing or monitoring care, employers, and manufacturers (Cluzeau et al., 2012).

Despite emerging evidence for engaging diverse stakeholder groups when developing practice guidelines, often this is not done or not done well (Armstrong & Bloom, 2017; Wyatt et al., 2014). Facilitating ethical and feasible stakeholder engagement can be challenging, and many attempts of engagement have been criticised for being ineffective or tokenistic in nature (Ocloo & Matthews, 2016). Tokenistic engagement means that projects present a false appearance of inclusiveness. Tokenistic engagement occurs when stakeholders are not holding real influence, when their input is underestimated and not taken seriously, and when stakeholders are not allowed to contribute in ways that are meaningful and respectful to them (Romsland, Milosavljevic, & Andreassen, 2019). Determining a meaningful and feasible guideline scope¹ is considered one of the most essential and challenging phases of guideline development (World Health Organization, 2014). Supported by existing frameworks and a clinical example, this paper aims to provide guidance on how diverse international stakeholder groups can be engaged to determine the scope of a clinical practice guideline.

¹ A guideline's scope sets out what it will and will not cover (NICE, 2015).

Philosophical foundation and theoretical lens

Pragmatism formed the philosophical foundation for this paper. Pragmatism was chosen as it is outcome orientated and focuses on solving practical problems in the real world (Creswell & Clark, 2017; Kaushik & Walsh, 2019). According to pragmatism, researchers can and should use multiple methods and sources of knowledge to solve a problem (Creswell, 2014; Kaushik & Walsh, 2019).

The integrated knowledge translation (IKT) framework was chosen to guide the guideline development process. IKT is "a model of collaborative research, where researchers work with knowledge users who identify a problem and have the authority to implement the research recommendations" (Kothari, McCutcheon, & Graham, 2017, p. 299). IKT aligns well with pragmatism (Nowell, 2015), and is a promising framework to increase knowledge uptake (Straus, Tetroe, & Graham, 2013). Traditionally those who produced knowledge and those who used the knowledge were seen as two separate groups, where knowledge got transferred from production in the first group to implementation in the last (Landry, Amara, Pablos-Mendes, Shademani, & Gold, 2006). IKT aims to bridge these two groups early in the research process with the purpose of making research relevant and useful to its end-users (Kothari & Wathen, 2013). In IKT, researchers and knowledge users work together in all stages of a research project to solve complex real word problems (Kothari & Wathen, 2013). IKT share many similarities with models such as Engaged Scholarship², Participatory Research³ and Co-production⁴ (Kothari & Wathen, 2013). But in contrast to these models with backgrounds in social science, social justice and education, IKT originates from health research and focuses on increasing knowledge use to improve patient care (Kothari & Wathen, 2017; Nguyen et al., 2020).

² Engaged scholarship: Participative research process expanding the capabilities of scholars to gather perspectives of key stakeholders

³ Participatory research: Address community issues in collaborative consultation with people with lived experiences.

⁴ Co-production/co-creation: Active involvement of consumers in the knowledge production process.

IKT brings together researchers and stakeholders such as health care providers and policymakers (Kothari & Wathen, 2013). However, IKT scholars have started exploring the opportunities to engage patients and the public in their research (D. Banner et al., 2019; D. J. Banner et al., 2020).

To our knowledge, no papers have described the step-by-step process for how all relevant stakeholders, including patients and their families, can be engaged in IKT research. To ensure feasible and ethical engagement with a broad group of stakeholders, this study was guided by patient and public engagement scholars, including the International Association for Public Participation (IAP2) and the UK's National Institute for Health Research community engagement program INVOLVE (INVOLVE, 2015).

Steps for stakeholder engagement

Successful stakeholder engagement largely depends on thoughtful planning. To help future guideline developers, we propose seven critical steps for stakeholder engagement. These steps include clarifying the aim, identifying stakeholders and where to find them, considering if Human Research Ethics Committee (HREC) review is required, planning how to engage, ensuring the project's trustworthiness and integrity, and evaluating the project.

A clinical example

The seven steps are illustrated by examples of how we engaged Danish and Australian stakeholders to identify a guideline's scope. The guideline aimed to describe the non-pharmacological management of agitation in the intensive care unit (ICU). Non-pharmacological management is critical to avoid the harmful effects seen from an overuse of sedatives and antipsychotic drugs (Devlin et al., 2018).

Step 1: Clarify the aim of engagement

Guideline developers must articulate a well-defined aim for stakeholder engagement and justify why it is needed (Andrews et al., 2012). By clarifying the aim, clear boundaries and limitations can be set and appropriate methods chosen. The aim will depend on the stage of guideline development. For example, will stakeholders help select a topic, scope the guideline, identify and synthesise the

evidence, develop recommendations and/or disseminate and implement the recommendations? Our project aimed to engage stakeholders to advise on the appropriate scope of a clinical practice guideline. A mixed-methods systematic review indicated the need for a guideline (Adams, Chamberlain, Grønkjær, Thorup, & Conroy, 2021), and systematic searches suggested that no guidelines existed on the topic. The aim of our stakeholder consultation was not to address a research gap.

Step 2: Identify all relevant stakeholders

When identifying relevant stakeholders, it is essential to ask the following questions. Who will be directly and indirectly affected by the guideline? Who would want to be involved? Are there any organisations representing the condition that is the focus of the guideline? For example, the UK's National Institute for Health Care Excellence (NICE) invites organisations, representatives of service users and registered stakeholders with specific knowledge of or experience with a condition to comment on the scope of their guidelines. In our project, relevant organisations or representatives of service users did not exist, and therefore we invited previous patients and their families with personal experiences of agitation in the ICU. We also invited ICU clinicians and researchers.

It is also necessary to consider how many stakeholders to engage. Most commonly, the aim of a scoping project is not to make generalisations, and therefore a large number of stakeholders is not necessary. However, guideline developers should have an inclusive approach and ideally seek a range of perspectives from individuals with diverse backgrounds (National Health and Medical Research Council, 2020). We knew that non-pharmacological practices to reduce and manage agitation in ICU varied between countries and within countries. Therefore, we mapped out a variety of stakeholder groups from the different geographical locations. We eventually included around 50 stakeholders, which was manageable while also providing comprehensive information from various people.

Step 3 Consider how to find stakeholders

It is essential to consider how to find stakeholders. The Guidelines International Network (GIN) Public working group, a broad group of researchers, health professionals and consumers, suggests using

either open or targeted invitations or a combination of these (Cowl, Armstrong, Schaefer, & Fielding, 2021). Open invitation means publicly publishing a draft guideline scope and asking anyone to provide feedback. The advantage of this method is that anyone can be involved, and since stakeholders are unknown to the guideline development group, they are unlikely to feel pressured to agree with the group, thus reducing bias. The risk is that nobody provides feedback because nobody feels responsible, or too many provide feedback leaving guideline developers overwhelmed with responses (Cowl et al., 2021). Targeted invitations mean sending out invitations directly to relevant stakeholders. This method can be more effective as it takes less time to find stakeholders, and if they are trained, they will know exactly what is required from them. The disadvantage is that important voices may be lost (Cowl et al., 2021). We used both open and targeted invitations. We contacted researchers directly while also reaching out broadly through professional and patient organisations. These organisations then reached out to their members via emails and newsletters.

We struggled to find previous patients and their family members. The engagement of lay people in projects involving diverse international stakeholder groups has shown to be challenging (Ingoe, Eardley, Rangan, Hewitt, & McDaid, 2020). Ocloo and Matthews (2016) warn that stakeholders can struggle with a lack of confidence and feel they do not have much to contribute. In our project, this was illustrated by one stakeholder who contacted us writing, "I am just an ordinary person with some experiences in this area", and then, unfortunately, withdrew from the project. Like other scholars (Pandya-Wood, Elliott, & Barron, 2019), we believe that meeting individuals and describing the study personally increases stakeholders' trust in the study and their self-confidence, thus encouraging participation. Unfortunately, due to COVID restrictions, we did not have access to post ICU patient support groups which hindered this level of personal contact.

Step 4: Consider if your project requires a Human Research Ethics Committee (HREC) review. Stakeholder consultation should be an integral part of all health research. The Australian National Health and Medical Research Council (2016) states consultation activities are more likely to result in

ethically conducted patient-centred research. However, the concept of engagement is relatively new, and confusion exists around ethics and the risks involved for stakeholders. Scholars argue that ethics approval is not needed when patients and the public are consulted or involved in developing the processes and scope of projects as opposed to being subjects or participants of research (Involve, 2009). Consultation in guideline development poses a very low risk of harm to stakeholders. This is because being consulted differs from participating in research where data, such as personal information and experiences, are collected, transcribed, analysed, published and stored. Therefore consultation of stakeholders rarely causes ethical concerns (Australian Clinical Trials Alliance, 2021). However, regardless of the nature of their engagement in a project, ethical dilemmas can arise (Pandya-Wood, Barron, & Elliott, 2017; Salerno, Coleman, Jones, & Peters, 2021). Examples of this can be when stakeholders feel pressured to participate; when they provide certain answers due to their relationship with a guideline developer; when stakeholders do not fully understand their role or the aim of a project; or when guideline developers breach confidentiality. Due to these concerns, we recommend following ethical principles for stakeholder engagement (Pandya-Wood et al., 2017; Salerno et al., 2021), while also contacting a relevant ethics committee for advice on local requirements.

Step 5 Plan how to engage

Once the *why* stakeholder engagement is needed and the *who* stakeholders are is clear, it is time to identify *how* to engage stakeholders. It is crucial to make a tailored plan that will suit the project's purpose and the characteristics of the involved stakeholders. Guideline developers should work ethically and recognise the limitations of resources available. Below we describe the importance of considering the level of engagement, what questions to ask the stakeholders, the different forms of engagement, how to ensure clear and effective communication, how to maximise benefits and minimise harm, and finally, how to allocate sufficient time and resources.

Decide on the level of engagement.

IKT projects require varying levels of engagement at various times (Andrews et al., 2012). Guideline developers must be clear about the level of engagement required for their project. The IAP2 Public Participation Spectrum can help to define the exact role of the stakeholders (see levels of engagement Figure 1)

		INCREASING IMPACT ON THE DECISION				
		INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
PUBLIC PARTICIPATION GOAL		To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions.	To obtain public feedback on analysis, alternatives and/or decisions.	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.	To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place final decision making in the hands of the public.
	PROMISE TO THE PUBLIC	We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision.	We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.

Figure 1 IAP2 Spectrum of Public Participation ("IAP2 Spectrum of Public Participation," 2018), published with approval from the IAP2 working group.

The level of engagement ranges along a continuum from informing through to collaborating and empowering. At the lower level of engagement, stakeholders are informed but not able to influence decision-making processes. In contrast, at the higher end, the decisions are fully led by the stakeholders. Levels of engagement may depend on many factors, such as the aim of the project, the financial resources, and the timeframe. In guideline development, *inform* can be used to inform and raise awareness about guidelines and their updates. *Consultation* can be used in different phases but is commonly used to get advice on the guideline's relevance, scope or review tentative

recommendations. *Involvement* and *collaboration* often refer to stakeholders who are members of the guideline development group where they can be review evidence or carry out research. Finally, *empower* refer to stakeholders who help implement and disseminate research.

We decided to consult stakeholders about the guideline scope. While consultation has been criticised for being tokenistic (Arnstein, 2019) and a 'tick box' exercise compared with approaches that collaborate and empower stakeholders, it can be a vital step in international guideline development, allowing a larger group of people to be heard. Consultation suited our aim, and while stakeholders were not able to make final decisions, their advice directly influenced the determination of the final scope, and they were continuously kept informed about the progress of the guideline development.

Decide to engage diverse stakeholder groups separately or simultaneously.

Professionals and laypeople can be engaged separately or simultaneously, and there are advantages and disadvantages to both options. Separately engaged groups may facilitate the development of unique and more directly relevant questions for each group. For instance, Serrano-Aguilar et al. (Serrano-Aguilar et al., 2015) carried out a Delphi study to reach agreement amongst consumers on priorities for a practice guideline and Tong et al. (Tong et al., 2012) invited 30 consumers to participate in two 3-hour workshops to select the topic and outcomes on early-stage chronic kidney disease. While such methods may be effective, they are also resource-intensive. We engaged diverse groups simultaneously to integrate several views into a project with strict time and resource restrictions.

Consider what questions to ask the stakeholders.

A proposed guideline scope, built on the existing literature, should be developed before consultation commences. Guideline developers can then seek input on the proposed questions for the guideline to address, the population, including potential subgroups, end-users, setting, interventions, and meaningful outcomes (Cowl et al., 2021). We also found it helpful to also ask stakeholders about the predicted barriers to guideline implementation.

Regrettably, we did not ask stakeholders to rank outcomes and interventions. Such information is essential for conducting relevant systematic reviews that will inform the guideline recommendations, and therefore, we recommend future guideline developers do this during the scoping phase.

Insert Table 1

Offer different forms of consultation.

Consultation can take different forms and can occur online or face-to-face, through workshops, meetings, open online discussions, or submission of written feedback. Traditional research methods such as surveys, interviews and focus groups may also be appropriate if the aim of a project is not to get input on a proposed scoping document but to answer a specific research question (Del Campo, Gracia, Blasco, & Andradas, 2011; Tong et al., 2012). For example, research questions could be "what are the lived experiences of patient agitation in ICU?" or "what are the views of agitation management in ICU"?

To maximise opportunities for stakeholder input, we offered three different modes of online engagement, including workshops, one-on-one meetings and the opportunity to provide written feedback. There are several advantages of online patient engagement (Grant et al., 2018). Overall, the modes allowed us to hear the voices of multiple people at their convenience, regardless of time, geographical location, educational levels, income and ethnic backgrounds. Providing a diversity of methods for input and feedback also offered environments where stakeholders could feel safe and comfortable speaking up. We believe that by providing these modes, our strategy was as inclusive and flexible as possible. We have summarised the perceived advantages and disadvantages of each method in Table 2.

Insert table 2

Although there are several advantages of online consultation, there are also disadvantages. These include not being able to ensure stakeholders fully understand the tasks required from them (Grant et al., 2018) and not being able to reach homeless people, people with mental or chronic illnesses, people from lower socioeconomic backgrounds without a computer and internet connection, and those with poor reading or communication skills. These people may have a greater need for health care than the wider population (Ocloo & Matthews, 2016). Reaching these groups would have been valuable and potentially uncovered equity issues. However, this would have required meeting people face-to-face rather than online, which was not possible in our project due to the geographical distance between stakeholders. We suggest guideline developers are aware of the limitations of online engagement and consider if and how barriers can be mitigated.

Ensure clear and effective communication.

While collaboration across borders has become increasingly popular, it can be challenging to ensure clear and effective communication with people speaking different languages (Dusdal & Powell, 2021). Translation of documents and other material can be a lengthy process and researchers, therefore, often restrict themselves to their native language (Alkhaffaf et al., 2021; Berk, Jorm, Kelly, Dodd, & Berk, 2011). We believe this can become a significant limitation of a project and can lead to important voices being lost. We advise guideline developers working with multinational groups to accurately translate all recruitment material and conduct meetings in stakeholders' native language.

It is essential that stakeholders are fully informed before agreeing to be involved (Andrews et al., 2012; IAP2, 2017; Wright, Foster, Amir, Elliott, & Wilson, 2010). When stakeholders do not feel clear about what is expected from them, this can hinder engagement (Ocloo & Matthews, 2016). We developed a bilingual online platform for people with different literacy competencies to ensure all stakeholders were fully informed. The platform offered several videos and text describing the purpose of the guideline development and how stakeholders could be involved. We developed participant information sheets describing the project's purpose and expectations to stakeholders. We advised stakeholders that participation was voluntary and that they could withdraw at any time

without consequences. We pilot tested all material on individuals from Denmark and Australia, including health professionals, a participatory disability researcher, 'lay' people and members of minority groups. We highly recommend testing all material, as this process encouraged us to make several changes. For instance, we realised that two different information sheets were necessary to accommodate different audiences. We developed an *easy read* and a *standard* version, and participants could choose which version they preferred. In the *easy read* version, we were conscious about using plain inclusive language without medical terminology and jargon and infographics when possible. The *standard version* contained more detailed background information without infographics.

Maximise benefits and minimise harm

Guideline developers should ensure maximum benefits for stakeholders and minimal harm (Salerno et al., 2021). It may be appropriate to reimburse stakeholders for their participation, as limited resources, for example, caring responsibilities, time, money for transport, limited internet access etc can hinder participation (Ocloo & Matthews, 2016). We required participants to have access to a computer with an internet connection and spend a significant amount of time (more than one hour) reading and answering several questions. Since reimbursing consumers in consultation projects aligns with the principles of patient and public involvement (Hayes, Buckland, & Tarpey, 2012 (updated 2021)), we decided to provide a small reimbursement (AU\$30 voucher) for all participants. However, we advise offering incentives carefully, in particular when there is a risk that a large group of stakeholders will register their interest. Guideline developers can state that only a limited number of stakeholders will receive a voucher on a 'first come, first served' basis to avoid exceeding budget limits. Guideline developers can also decide only to reimburse certain stakeholder groups such as patients and family members. We experienced that health professionals participated during their working hours, were able to claim hours spent on the project as professional development hours and found a few health professionals described feeling uncomfortable receiving reimbursements.

Considering the differences in resource access and reciprocity, we believe guideline developers should prioritise reimbursement of patients and family members over healthcare professionals.

Stakeholders must be able to provide advice without feeling any undue burden (Salerno et al., 2021), and guideline developers must work sensitively to avoid or minimise potentially emotionally upsetting situations (Pandya-Wood et al., 2017). In our project, we knew that thinking back to their time in the ICU could be uncomfortable for some stakeholders. To moderate this, we carefully developed questions that focused on the purpose of the project (see Table 1). We did not ask in-depth questions such as '*what do you feel about it?*' or '*how was your emotional reaction to that?*'.

We anticipated that focusing on the specific questions would minimise the risk of participants finding the involvement emotionally burdening. Although stakeholders are unlikely to become distressed during a meeting, we had a backup plan in case it would happen. Participants were always able to contact the principal investigator for a debrief, and we had a list of free online counsellors available, as suggested by the literature (Pandya-Wood et al., 2017; Wright et al., 2010).

To align with principles of respect in public involvement, stakeholders must also feel appreciated and respected (INVOLVE, 2015; Pandya-Wood et al., 2017). Researchers and guideline developers are encouraged to promise stakeholders feedback on how their participation influenced decision-making ("IAP2 Spectrum of Public Participation," 2018). Therefore, all stakeholders in our project received a summary of our findings, a description of how their feedback contributed to the final scoping document, and rationales for why some feedback was not incorporated. We also asked stakeholders if they would like to be publically acknowledged for their participation in future publications.

Guideline developers must be conscious of how they handle personal and sensitive information (Pandya-Wood et al., 2017). For instance, recording meetings and conversations may be preferable since notetaking can interrupt the flow of discussions. However, the reasons for recording must be clear and permissions obtained. Unless the aim is to carry out research, it is not necessary to transcribe recordings word by word, and personal information, such as names and institutions,

should not be written down. All recordings must be destroyed promptly after notetaking, as storing such data involves risks for the stakeholders and may require ethics approval. Due to the nature of workshops, it is not possible to guarantee confidentiality. However, participants can be advised to leave their video off and leave out their real names if they prefer. They must also be reminded to respect the privacy of fellow stakeholders and not repeat sensitive information outside the workshop.

Allocate sufficient time and resources

It is important to allocate sufficient time and resources for an IKT project (Andrews et al., 2012).

Guideline developers need to allocate money for reimbursements. They also need to allocate time to develop materials and for stakeholders to read through the material and think about it before giving feedback. Insufficient time may result in inadequate feedback and stress for stakeholders (Pandya-Wood et al., 2017). We gave stakeholders between two to three weeks to review the scoping documents, with additional time available to any participant who requested it.

Step 6: Consider how you will increase the trustworthiness and integrity of your project

Using rigorous research methods may not be necessary for engagement activities (Doria et al., 2018), but can increase the quality and integrity of a study. We experienced that dealing with data from multiple stakeholders from different countries required a systematic approach. We used the software program Nvivo (QSR International, 2021) to organise the notes from the meetings. These notes were then analysed using content analysis. Content analysis is a research method that is suitable when combining different types of data. It is a method that is particularly suited when dealing with descriptive, focused and narrow questions that do not require deep and complex interpretation (Liamputtong, 2009). To ensure transparency, guideline developers are also encouraged to feed back the results to stakeholders with a description of how the final decisions were made. To support the integrity of our project, all stakeholders were encouraged to declare any conflicts of interest, such as financial or other interests that could potentially influence considerations on the topic. If significant conflicts of interests were found, stakeholders would be

asked to withdraw from the project. This was important since potential conflicts of interest of guideline developers can damage people's trust and confidence in the guidelines (National Health and Medical Research Council, 2020).

Step 7: Evaluating the project and assessing the impact of engagement.

While stakeholder input is essential to the development of quality guidelines, few studies demonstrate the impact of engagement. Such evaluation is essential to support future engagement projects and secure funding (Andrews et al., 2012). Evaluating the impact of engagement is also important to stakeholders who want to know if their contribution made a difference (Hardavella, Bjerg, Saad, Jacinto, & Powell, 2015). Several tools exist to evaluate the impact of engagement (Boivin & Abelson), yet, much evidence in this area has been criticised as being weak and anecdotal (Russell, Fudge, & Greenhalgh, 2020). Due to resource issues, we did not assess the impact of our project. However, we recommend that future guideline developers use robust methods to evaluate their project and recognise that robust assessment must be planned early on as it is time-consuming and may require ethical approval.

Insert Table 3

Discussion

By critically reflecting on stakeholder engagement, this paper offers a seven-step framework for how to plan and operationalise feasible and ethical stakeholder engagement (see Table 3) when determining a guideline scope. Since we engaged our stakeholders in 2021, some principles for IKT engagement in spinal cord injury research have been developed. (Hoekstra et al., 2022; The University of British Columbia). When mapping the IKT principles to our 7-step process, we notice that our project reflects seven of the eight principles. Principle two states, "partners share in decision making". We consulted stakeholders, and therefore they did not hold the power to make final decisions on what should be included in our guidelines. However, we believe that each level of engagement in the IAP2 spectrum of public participation is equally beneficial at different stages of a research project. With more than 50 international stakeholders involved in the early stage of

guideline development, shared decision making was not feasible. To allow stakeholders more influence on the final scope, consensus methods may be useful (French et al., 2019; McMillan, King, & Tully, 2016), although they require considerably more time and resources (Trevelyan & Robinson, 2015).

While we did not have the resources required to accurately measure the impact of the engagement process, it was clear that the engagement significantly impacted the development of the guideline. To provide one example, stakeholders believed that the guidelines should be for the multidisciplinary team, not just for nurses, as was initially proposed. They stated that developing recommendations only for nurses would hinder implementation and complicate multidisciplinary collaboration. This finding changed the draft scope, the design of further guideline development and most likely the implementability of the guidelines. We also experienced that stakeholder consultation resulted in outcomes that we had not expected. These included important networking with stakeholders and between stakeholders, which could positively influence later stages of guideline development and implementation.

Conclusion

There is no consensus on best practices for consulting diverse stakeholder groups simultaneously in a knowledge translation project. This paper describes a starting point for guideline developers through a practical example and existing frameworks. While getting advice from stakeholders may seem straightforward, developing well-founded guideline scopes in ethical ways requires several considerations.

In our study, we experienced that the consultation of international stakeholders greatly impacted the final guideline scope and highlighted areas that the research team had not considered. Overall, we believe the process made a significant contribution to the development of an effective and implementable guideline. Consultation requires additional resources in terms of time and finances. Still, it is feasible even for novice guideline developers, and unlike other types of engagement

projects, we believe this can be done without additional training of researchers and stakeholders.

Ethical engagement is feasible, valuable and should be incorporated into the development of all clinical practice guideline projects.

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6 Ethical Statement

The project that formed the basis of this manuscript was exempted from ethics review. This decision was based on advice from the Flinders University Ethics committee, as the stakeholders were acting as specialist advisors in the planning and designing of a guideline scope, thus not directly participating in research.

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