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PRACTICAL APPLICATION

Prioritizing Participant and Research Team Emotional Safety During Data Generation and Analysis in Qualitative Patient-Reported Outcome Measure Research: Development of a Framework Informed by the GENDER-Q Youth Study

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Abstract

Conducting applied qualitative health research studies often involves discussion of sensitive topics that may impact the emotional safety of participants and researchers. While generic guidance exists to support researchers in prioritizing participant and researcher emotional safety, specific considerations for conducting virtual qualitative interviews to develop patient-reported outcome measures (PROMs) remain limited. This article provides a framework to support PROM developers in prioritizing participant and researcher emotional safety when conducting virtual qualitative interviews. This framework is informed by the strategies developed and applied in the GENDER-Q Youth study, an interpretive descriptive study to develop a PROM for youth receiving gender-affirming care (GENDER-Q Youth). The GENDER-Q Youth study involved virtual concept elicitation interviews with transgender and gender diverse youth (aged 12 years and older) to understand important care-related experiences and outcomes. The interview data were then used to develop draft scales. Virtual cognitive debriefing interviews were conducted with concept elicitation participants to obtain feedback on the draft scales. Strategies to promote participant and researcher emotional safety were developed and implemented throughout data generation (i.e., concept elicitation and cognitive debriefing interviews) and data analysis. On the basis of knowledge gained from creating and applying safety strategies in the GENDER-Q Youth study, a framework was developed to support researchers in prioritizing participant and researcher emotional safety when conducting their respective virtual PROM development studies. This framework offers considerations to support researchers before data generation (e.g., scheduling interviews when support will be available, should an emotional safety concern arise), during data generation (e.g., conducting check-ins with participants), after data generation (e.g., providing opportunities for the interviewing researcher to debrief), and during data analysis (e.g., conducting check-ins with research team members). This framework can help PROM developers identify threats to emotional safety that may occur before, during, and after virtual data generation and during data analysis and facilitate the development of strategies and plans to mitigate these risks.

1 Introduction

1.1 Background

Conducting qualitative research about participants' experiences of health and health-related concerns can involve the discussion of sensitive and potentially distressing topics, which may affect the emotional well-being of participants [1] and researchers [1, 2]. Concerns regarding emotional well-being have long been central in applied qualitative health research and have been referred to in the literature using various terminology (e.g., emotional distress [3–7] and emotional or psychological safety [1, 2, 8]). This article focuses on the process of promoting emotional safety.

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Key Points for Decision Makers

Conducting applied qualitative health research studies to develop PROMs can impact the emotional safety of all those involved in the research process, including participants and research team members.

This article aims to fill a gap in guidance specific to PROM developers conducting virtual applied qualitative health studies by providing a framework that researchers can use to prioritize the emotional safety of participants and researchers throughout data generation and analysis in their respective virtual PROM development studies.

This framework was built on the strategies developed and implemented during the GENDER-Q Youth study to create a PROM for youth receiving gender-affirming care and is supported by relevant applied qualitative health literature (when available).

Future research should explore considerations when applying this framework within other study contexts (e.g., conducting virtual PROM development studies with other youth populations).

Promoting emotional safety as a process includes: (1) considering the immediate and delayed [8] impacts of the research process on the psychological well-being of participants [1] and researchers [1, 2], (2) intentionally and proactively identifying potential harms to the psychological well-being of those engaged in research [1, 2], and (3) developing and implementing strategies to mitigate harms [1, 2] and create a secure and supportive research environment [1].

There is a growing body of applied qualitative health methodological literature that discusses the importance of prioritizing emotional safety within a person-centered approach to research, which offers a range of considerations for everyone involved in the research process. For example, Dempsy et al. [3] provided a framework for conducting interviews about sensitive topics, which included emotional safety concerns for participants (e.g., developing a distress protocol); Whitney and Evered [5] also provided insight into the development of a protocol for navigating participant distress during applied qualitative health research. Jack et al. [1] included considerations for participant and researcher emotional safety in their framework of data generation strategies in applied qualitative health research. Emotional safety considerations for participants and researchers when conducting applied qualitative health research using a trauma-informed approach were discussed by Alessi and Kahn [9] and Isobel [10]. Bowtell et al. [2] developed guidance for promoting the emotional safety of researchers, which included recommendations that can be used to support researchers when developing emotional safety protocols; guidance about researcher emotional safety was also provided by Silvero et al. [11]. A trauma-informed approach to graduate student researcher emotional safety was offered by Orr et al. [4]. Lastly, McCosker et al. [8] described emotional safety considerations for study participants, researchers, transcriptionists, supervisors, and readers of published research.

Although the cited articles about emotional safety offer valuable guidance for researchers conducting applied qualitative health studies, there are two limitations to note. First, these articles are based on studies with adults or do not provide recommendations specific to research with youth. Although much of the information in these articles can apply to both adult and youth populations, there are unique concerns inherent to working with youth (e.g., consent/assent and confidentiality [12]) that may not be adequately reflected in the abovementioned guidance for researchers. This limitation extends to research with equity-deserving (marginalized) youth populations (e.g., transgender and gender diverse youth), where additional ethical and logistical considerations are needed [12] to ensure youths' emotional safety. Second, these articles are primarily written within the context of conducting in-person research. Therefore, they may miss important emotional safety concerns that exist when conducting virtual research.

Within the last 5 years, literature to support researchers when conducting virtual qualitative research studies has increased. For example, Gray et al. [13] offered reflections (from the perspectives of participants and researchers) on using Zoom to conduct interviews, and provided recommendations for researchers, most of which pertain to technical (e.g., interrupted internet connections) or logistical (e.g., sharing the meeting link) aspects of virtual interviewing. Carter et al. [14] identified challenges that can arise when conducting virtual qualitative research and offered potential solutions to researchers. They discussed a range of ethical (e.g., obtaining consent), technical (e.g., selecting the platform that will be used), and environmental (e.g., managing microphones and background noise) considerations that researchers may experience when conducting virtual interviews or focus groups. Meherali and Louie-Poon [15] discussed challenges associated with conducting virtual interviews with adolescents about sensitive topics, focused largely on issues related to privacy and confidentiality. Although this literature offers some insights into emotional safety concerns when conducting virtual applied qualitative health research, more research is needed to support researchers in identifying and navigating the range of emotional safety concerns that exist throughout virtual qualitative data generation and analysis.

Emotional safety is especially important to consider when designing and conducting applied qualitative health research studies to develop patient-reported outcome measures

(PROMs). Qualitative PROM development research involves conducting concept elicitation interviews to learn about patients' experiences and discussing a range of topics to understand their perspectives on important health-related outcomes and healthcare experiences [16]. PROM development also involves cognitive debriefing interviews conducted to obtain patients' feedback on PROM scales [17]. Often, both types of interviews require discussion of concepts that may be difficult to talk about, which pose concerns to participants' and researchers' emotional safety. Therefore, in the early stages of study design, PROM developers must think about potential emotional harms and create a plan to promote the emotional safety of participants and researchers. However, there is limited literature to support researchers in prioritizing emotional safety within the unique context of PROM development; this extends to PROM development research that is conducted virtually. More research on emotional safety concerns throughout the virtual data generation process (e.g., concept elicitation and cognitive debriefing interviews) and data analysis is needed to support PROM developers.

1.2 Aim

This methodological article provides a framework informed by the strategies developed and applied in the GENDER-Q Youth study. The framework is intended to support researchers in prioritizing participant and researcher emotional safety when conducting their respective virtual applied qualitative health research studies to develop PROMs.

2 Context: The GENDER-Q Youth Study

2.1 GENDER-Q Youth Study Overview

This article is situated within a multi-step, mixed methods study to develop the GENDER-Q Youth, a PROM to assess gender-affirming care outcomes and healthcare experiences for youth who identify as transgender or gender diverse [18]. The first step to develop the GENDER-Q Youth was a qualitative study using an interpretive description approach [19]. The GENDER-Q Youth qualitative study aimed to: (1) identify gender-affirming care experiences and outcomes that mattered to youth seeking or receiving gender-affirming care, (2) use that data to form a conceptual framework and the GENDER-Q Youth scales, and (3) ensure the content of the resulting GENDER-Q Youth scales was relevant, comprehensive, and comprehensible [18].

Transgender and gender diverse youth from Canada and the USA were invited to participate in a one-to-one virtual concept elicitation interview and complete a pre-interview timeline-based activity about their gender-affirming care journey [20]. Data were used to develop a conceptual framework and draft scales that assess concepts related to experience of care (e.g., healthcare providers and information about hormones), gender practices (e.g., binding and tucking), health-related quality of life (e.g., appearance-related distress and social function), and voice (e.g., sound and voice-related distress). Youth were then invited to take part in a virtual cognitive debriefing interview to provide feedback on the GENDER-Q Youth scales. Youth who completed an interview received a $100 (CAD/USD) e-gift card. Additional information about the GENDER-Q Youth study (and the GENDER-Q Youth scales) is available elsewhere [18].

2.2 Strategies to Promote Emotional Safety in the GENDER-Q Youth Study

When designing and conducting the GENDER-Q Youth study, strategies were created to prioritize participant and research team emotional safety. The strategies included measures to navigate emotional safety concerns before, during, and after data generation and during data analysis. These strategies were especially important given the study population and the nature of the interviews. First, the study population is known to have a higher risk of mental health concerns, including self-harm and suicidality [21]. Second, the interviews contained discussions about potentially distressing topics (e.g., family support, life at school, and psychological distress) and provided space for potential safety-related concerns to be disclosed by participants. Therefore, strategies were needed to ensure that participants were safe while taking part in the study and that the research team was prepared in the event of an adverse outcome (e.g., a participant experienced distress). Strategies were also needed to ensure the emotional safety of the research team when generating and analyzing potentially distressing data or navigating disclosures.

The strategies used in the GENDER-Q Youth study were developed on the basis of knowledge gained from previous research experiences (e.g., approaches used in prior studies conducted with transgender and gender diverse youth), training and learning sessions (e.g., applied qualitative health research courses), and literature. The strategies were refined throughout the conduct of the GENDER-Q Youth study through critical reflection and reflexivity, regular meetings with the research team, conversations with study participants, and institutional guidance (e.g., feedback from local research ethics boards). The strategies are described in Supplementary File A.

3 Framework to Prioritize Participant and Researcher Emotional Safety

A framework was created to support researchers in prioritizing participant and researcher emotional safety when conducting their respective virtual PROM development studies. The framework was grounded in the research team's experiences developing and applying safety strategies in the GENDER-Q Youth study. The framework was revised by engaging in critical reflection and reflexivity, having discussions with research team members, and connecting components of the framework to existing research.

The framework includes four components that cover the following research stages: (1) before data generation (Table 1), (2) during data generation (Table 2), (3) after data generation (Table 3), and (4) during data analysis (Table 4). The following sections describe each component of the framework and include examples from the GENDER-Q Youth study. Supporting literature is provided (when available) to give examples of how other researchers described or approached considerations in the associated research stage.

3.1 Research Stage: Before Data Generation

3.1.1 Designing the Data Generation and Analysis Processes

Researchers need to identify potential emotional safety concerns for the participants and research team when designing the study and develop strategies to navigate these concerns [1–3]. Identified concerns and developed strategies should be reviewed by research ethics boards to ensure the research team has considered a comprehensive range of concerns and proposed appropriate strategies to manage these concerns [2]. Providing training or resources to the research team to help them recognize and manage potential emotional safety concerns should also be considered [11]. In the GENDER-Q Youth study, the researcher participated in several pertinent educational sessions (e.g., training about gender-affirming care and working with transgender and gender diverse youth). While the educational sessions helped the researcher identify potential emotional safety concerns, more training on how to respond to emotional safety concerns would have been beneficial.

3.1.2 Recruiting Prospective Participants

When recruiting prospective participants, it is important to consider how this process can impact their emotional safety. When prospective participants provide consent to be contacted by a research team, they should be informed about who their information will be shared with, what information will be shared, and how it will be shared. Prospective participants should also clearly understand the next steps (e.g., who will be contacting them, when they will be contacted, how they will be contacted, and where the research team is located), be asked about their preferences during the recruitment process, and be asked if they have any concerns. Any contact-related constraints or specific procedures (e.g., the researcher initiates contact by email) should also be discussed. When prospective participants contact a research team directly, researchers should think about how the level of burden on prospective participants can be minimized. In addition, researcher safety should be considered during the recruitment process (e.g., "Will researchers use their personal phones or email addresses to contact prospective participants?")

3.1.3 Having an Initial Meeting with Prospective Participants

Researchers also need to think about who is navigating the informed consent process and how informed consent will be obtained. In the GENDER-Q Youth study, written consent to participate in the study was obtained by the coordinating site, and not by the local sites. To ensure participants understood the study details and the study consent forms and were able to ask questions, the researcher held initial meetings with prospective participants. At the end of the initial meetings, prospective participants were asked to review the study forms and share a signed copy with the researcher if they were interested in participating. They were also informed that they could contact the researcher if they had any additional questions after reviewing the forms. Although this process seemed to be sufficient, the researcher had two questions when reflecting upon the initial meetings/informed consent process: (1) "How can it be ensured that prospective participants understood all of the study details?" and (2) "Is there more that can be done to prepare participants for an interview?"

3.1.4 Scheduling Interviews

Lastly, it is important to reflect on the design and implementation of the interview scheduling process. In the GENDER-Q Youth study, interviews were scheduled when a member of the participant's local gender clinic team or a trusted adult could be available. This approach introduced a concern about respecting the participant's time and ensuring the interview process was accessible. Although this strategy was used to ensure the researcher could contact someone in the event of a concern for the participant's safety, it may have impacted the participant's ability to take part in an interview at a time that was preferable or safer for them. Interview scheduling may also affect the research team's safety; if interviews are

Table 1 Framework for prioritizing participant and researcher emotional safety before data generation

Stage	What should I consider?	What can I do?	Supporting literature
Designing the data generation and analysis processes	What are the risks to participants' emotional safety during data generation and analysis? What are the risks to the research team's emotional safety during data generation and analysis? Is there anyone else involved in data generation and analysis who needs to be considered when identifying emotional safety risks? Does the research team require any training or resources to recognize and manage potential emotional safety concerns?	(1) Work with the research team to identify potential emotional safety concerns for everyone involved in data generation and analysis. (2) Develop a plan for managing these concerns and promoting the safety of individuals involved in data generation and analysis. (3) Work with the research ethics board to ensure the plan for promoting emotional safety is comprehensive and appropriate. (4) Work with the research team to ensure they are prepared to identify and respond to potential emotional safety concerns during data generation and analysis.	[2–5, 8, 10, 11, 14]
Recruiting prospective participants	Who is initiating contact between prospective participants and the research team? What are the potential threats to prospective participants' privacy and safety during the recruitment process? What are the potential threats to the research team's safety during the recruitment process?	If prospective participants consent to being contacted by the research team: (1) Ensure they understand what they are consenting to (e.g., the details about sharing their information with the research team). (2) Ask them about their preferences (e.g., how and when they would like to be contacted). (3) Ask them if they have any concerns. (4) Explain any constraints or procedures that impact the contact process. If prospective participants contact the research team directly: (1) Ensure the process for contacting the research team is clearly described (e.g., prospective participants know who to contact and how to contact them). To ensure research team safety: (1) Consider alternatives to using personal phones or email addresses if appropriate and possible (e.g., create a study email address).	[3]
Having an initial meeting with prospective participants	Who is navigating the informed consent process and obtaining consent? Do prospective participants have all the information they need to understand what taking part in the study would involve? Do prospective participants have all the information they need to make an informed decision about consent?	(1) Ensure prospective participants have the information needed to understand the study and review the study consent forms in detail. (2) Provide prospective participants time to review the study consent forms on their own (i.e., without the researcher present). (3) Ensure prospective participants have opportunities to ask questions about the study and the study consent forms.	[3, 14]

Table 1 (continued)

Stage	What should I consider?	What can I do?	Supporting literature
Scheduling interviews	How are the interviews being scheduled? What are the potential concerns to participants' safety when scheduling the interviews? What are the potential concerns to the research team's safety when scheduling interviews?	(1) Work with the research team and local care providers to create a plan for scheduling interviews that ensures support will be available to participants if needed. (2) Work with participants to understand their needs and preferences when scheduling an interview. (3) Ensure that the researcher will have support available to them (for both the participants and themselves) at the time of a scheduled interview. (4) Ensure adequate time for rest and recovery is allotted between the scheduling of interviews to protect the researcher's emotional safety.	[1, 3, 8, 11]

scheduled outside of traditional working hours (e.g., during evenings or weekends), strategies need to be developed so that the researcher has the necessary resources and support available to ensure their safety [11].

3.2 Research Stage: During Data Generation

3.2.1 Conducting Pre-interview Introductions

When conducting concept elicitation and cognitive debriefing interviews, the pre-interview introductions are crucial parts of the study that must be carefully planned and delivered. The pre-interview introductions provide the opportunity for researchers to create an environment that prioritizes participant comfort and safety. The pre-interview introductions are also necessary to ensure participants understand what the interview will involve and the options available to them during the interview, and to reaffirm that they consent to taking part in the interview.

In the GENDER-Q Youth study, one challenge that was encountered pertained to understanding the participants' interview spaces. In the pre-interview introductions, the researcher described their environment (e.g., working from a home office, in a private room with the door closed, and wearing headphones) so that participants could understand how their privacy was being protected; they also alerted participants to potential background noises (e.g., dogs may bark) so that participants were not frightened if such noises occurred during the interview. While the researcher asked participants if they were in a space where they felt comfortable talking, the researcher did not ask participants to describe their spaces. As a result, during some interviews, the researcher was surprised to encounter indications that other people may have been present in the participants' spaces. While this was not a concern from the perspective of the participants' emotional safety (i.e., they were welcomed to take the measures needed to feel comfortable during the interview process), it impacted the researcher's comfort and emotional safety during the interviews. In reflecting on these experiences, the researcher had the following questions: (1) "Can the pre-interview introductions be approached differently so that the researcher can get a better sense of participants' spaces without making them feel uncomfortable?" and (2) "If a concern about a participant's space arises during an interview, how can the researcher navigate a conversation about it with the participant without making them feel uncomfortable?"

3.2.2 Conducting Interviews

To promote participant safety when conducting concept elicitation and cognitive debriefing interviews, researchers need to: (1) be clear about what topics may be discussed during

Table 2 Framework for prioritizing participant and researcher emotional safety during data generation

Stage	What should I consider?	What can I do?	Supporting literature
Conducting pre-interview introductions	All interviews: How can a welcoming and safe environment be created for participants? How does camera usage (e.g., camera on or off) impact the creation of a welcoming and safe environment for both participants and the researcher? Do participants have all the information they need to understand the interview process? Do participants have all the information they need to make an informed decision about ongoing consent? Do participants have all the information they need to feel prepared for the interview process?	(1) Be transparent about the interview space and how participants' privacy will be protected during the interview. (2) Ask participants if they have a space where they feel comfortable during the interview. (3) Ensure participants understand the interview process (e.g., what the interview involves). (4) Confirm that participants still consent to taking part in the interview before it begins. (5) Ensure participants have all of their questions asked and answered before initiating the interview.	[1, 9, 10, 13–15]
Conducting Interviews	All interviews: Are there any topics of discussion that pose risks to the emotional safety of participants and/or the researcher? How are the interviews structured? What are the strategies in place to identify potential emotional safety concerns during an interview? (e.g., check-ins) How are check-ins being conducted during interviews? When do potential emotional safety concerns require further action? What are the strategies in place to navigate potential emotional safety concerns that require further action? How does camera usage (e.g., camera on or off) impact the strategies used to identify and navigate potential emotional safety concerns? Cognitive debriefing interviews: How and when will the draft scales be shared with participants? Are there potential risks to participants' emotional safety associated with the scale-sharing process?	When conducting "regular" check-ins with participants during an interview: (1) Ask participants about how they are feeling. (2) Monitor the time and discuss the time with participants. (3) Work with participants to determine how their interview will proceed (e.g., if a break is needed, if they are okay to continue, and which topic(s) will be discussed next). When checking in with participants due to a potential emotional safety concern during an interview: (1) Ask participants about how they are feeling. (2) Determine if further action is needed and work with participants to navigate this process (e.g., contacting a care provider if the participant requires immediate medical attention). (3) If the interview continues, work with participants to determine how they want to proceed (e.g., which topic(s) they want to discuss). During all interviews: (1) Ensure participants understand the range of topics that may be discussed during the interview. (2) Work with participants to understand the topics that are important to them, and to structure the interview in a way that ensures both their needs and the needs of the study are met. (3) Conclude the interview by discussing a positive topic.	[3, 5, 8–10, 14]
Conducting post-interview debriefs	All interviews: How can the interview be concluded in a positive way for participants? Do participants have all the information they need to understand the next steps of the study?	(1) Ask participants how they feel after the interview. (2) Be prepared to provide resources to participants if needed (e.g., contact information for local helplines). (3) Ask participants if they have any questions about the interview or the study. (4) Clearly describe the next steps (e.g., compensation) so that participants know what to expect after the interview.	[1, 10]

Table 3 Framework for prioritizing participant and researcher safety after data generation

Stage	What should I consider?	What can I do?	Supporting literature
Conducting debriefs	What if the researcher has lingering concerns for a participant's well-being after an interview? Are there strategies in place to support the researcher after a distressing interview experience?	(1) Work with the research team to create a plan for supporting the interviewing researcher. (2) Ensure senior research team members (e.g., primary investigators and supervisors) have the training needed to support the research team (both during and outside of meetings). (3) Consider having regular meetings during data generation.	[1–4, 8, 9, 11]

interviews, (2) provide participants with more control over the direction of the interview and topics of discussion, and (3) try to make the interview experience positive for participants. For example, in the GENDER-Q Youth study, ample time was spent explaining the concepts that may be talked about during the interviews; during the interviews, participants were alerted before a potentially distressing topic or scale was introduced. The researcher also tried to provide as much control to participants over the interview process as possible. During the concept elicitation interviews, participants' timelines were used to guide the interview process. These activities helped participants share their experiences; they also facilitated the discussion of potentially distressing topics that were important in participants' gender-affirming care journeys. During the cognitive debriefing interviews, participants were asked which scales they were interested in reviewing at the start of the interview; at the end of the interview, they were asked if there were any other scales they wanted to see. Lastly, the interviews were structured so that they ended with a discussion of positive topics. At times this was challenging when conducting the cognitive debriefing interviews (e.g., if a participant wanted to finish the interview by seeing a potentially distressing scale). However, the researcher tried to end the interview in a way that would positively impact participants and make sure they felt like their voices were being heard (e.g., asking which interview topics were most important to them or if they had any "key messages" to share with the research team).

During the GENDER-Q Youth study concept elicitation and cognitive debriefing interviews, the researcher checked in regularly with participants. During these "regular" check-ins, the researcher typically: (1) asked how participants were feeling, (2) noted the time and asked if they were okay to continue the interview, (3) reminded participants that they could take a break (or have a snack/drink, if needed), and (4) introduced potential topics for continued discussion. Upon reflection about the check-ins, the researcher had the following questions: (1) "How did participants feel during check-ins (e.g., could these check-ins have made them feel self-conscious or embarrassed)?" and (2) "Are there 'right' and 'wrong' ways to approach checking-in with participants (e.g., frequency and content of check-ins)?" When participants had their cameras off during the interviews, navigating check-ins was more challenging for the researcher; they tended to conduct more "regular" check-ins because they could not rely on visual cues from participants to get a sense of how they were feeling or reacting to questions.

When participants seemed upset or disclosed information about a potential concern for their safety, the researcher conducted a more thorough check-in that focused on understanding how the participants were feeling and discussing the next steps (e.g., if the interview would be continued). The researcher had to navigate

Table 4 framework for prioritizing participant and researcher emotional safety during data analysis

Stage	What should I consider?	What can I do?	Supporting literature
Transcribing data	Are there strategies in place to support the transcriptionist if they have a distressing experience while transcribing the interview data?	(1) Work with transcriptionists to create a plan for supporting them while working with potentially distressing interview data. (2) Alert transcriptionists about interviews that contain potentially distressing data. (3) Provide opportunities for transcriptionists to debrief after working with potentially distressing interview data. (4) Conduct check-ins regularly throughout the transcription process.	[1, 8, 10]
Analyzing data	Are there strategies in place to support the research team if they have a distressing experience while working with the interview data?	(1) Work with the research team to create a plan for supporting them while working with potentially distressing interview data. (2) Alert research team members about interviews that contain potentially distressing data. (3) Provide opportunities for the research team to debrief after working with potentially distressing interview data. (4) Conduct check-ins or hold team meetings regularly throughout the data analysis process.	[2, 8, 10]

these check-ins carefully to make sure participants felt supported and safe after disclosing sensitive information, and not like they had overshared or done something wrong. The researcher also had to identify if further action was warranted (e.g., if they were required to contact a care provider or trusted adult). The action(s) taken by the researcher would have been guided by: (1) the participant's needs and preferences for support, (2) the nature of the disclosure, and (3) the researcher's obligations (i.e., as outlined in the study's protocol). At times, however, it was difficult for the researcher to determine if a potential safety concern required further action and what that action would entail. The researcher also felt uneasy when conducting interviews where they would not have the "safety net" of the local care provider to help navigate the concerns and determine an appropriate safety plan.

3.2.3 Conducting Post-interview Debriefs

Like the pre-interview introduction, the post-interview debriefs also require thoughtful preparation and implementation. The post-interview debriefs allow participants to discuss how they are feeling after the interview and share their thoughts about the interview process. Having these discussions is important so that the researcher can provide resources to participants if needed (e.g., contact information for local helplines) and adjust the conduct of future interviews on the basis of feedback about the interview process that participants may share. The post-interview debriefs should also be used to ensure participants have a clear understanding of the next steps. In the GENDER-Q Youth study post-interview debriefs, the researcher re-asked how participants were feeling before they left the Zoom meeting. Although all participants responded that they were "feeling okay", the researcher was left with the following questions: (1) "Are the participants really feeling okay?" and (2) "If the participants were not feeling okay, would they feel comfortable or safe enough to disclose that?"

3.3 Research Stage: After Data Generation

3.3.1 Conducting Debriefs

Strategies should also be developed to support researchers following the interviews [1–3, 8]. In the GENDER-Q Youth study, there were instances where the researcher had lingering concerns about how a participant was feeling after the interview. There were also instances where the researcher needed to talk to someone after a distressing interview experience. In these situations, the researcher contacted a senior research team member. This ad hoc process provided the researcher support when needed; however, it may have been possible that no one was available at the time needed. Establishing a more formal procedure (e.g., the methods used to ensure someone was available for participants if a potential safety concern arose during an interview) would ensure that support was guaranteed to be available to all research team members, and particularly for those conducting the interviews, as needed [2]. In addition, scheduling

regular debriefing meetings (e.g., after interviews or on a weekly basis during data generation) may help the researcher navigate safety-related concerns [2, 11] and facilitate further reflection, which could also have methodological benefits.

3.4 Research Stage: During Data Analysis

3.4.1 Transcribing Data and Analyzing Data

The impact of potentially distressing interview data on the transcriptionist [1, 8] and research team [2, 8] also needs to be considered. Researchers should work with transcriptionists and research team members to develop strategies that prioritize their safety and reflect their unique needs. Such strategies could include: (1) alerting them about interviews that contain potentially distressing content, (2) providing opportunities for them to speak to someone if they have a distressing experience working with the interview data, and (3) conducting regular check-ins with them during the transcription and data analysis processes. Researchers should also be vigilant about maintaining participant confidentiality while supporting transcriptionists and research team members.

4 Discussion

This article provides a framework grounded in research experience and supported by literature (when available) to help researchers identify and navigate emotional safety concerns that the participants and research team may experience when conducting applied qualitative health research to develop PROMs. This framework contains four components (before data generation, during data generation, after data generation, and during data analysis) that are presented alongside reflections from conducting the GENDER-Q Youth study to help researchers contextualize each component and understand how it can be applied when planning and conducting their own research. This article also identifies situations where more guidance is needed to better support researchers.

Researchers must be proactive and develop a plan to promote participant and researcher emotional safety when designing their respective studies [1–3]. In the applied qualitative health literature, there are articles to support researchers in identifying and navigating emotional safety concerns before data generation [1–5, 8, 10, 11, 14], during data generation [1, 3, 5, 8–10, 13–15], after data generation [1, 2, 4, 5, 8–11], and during data analysis [1, 8, 10]. Some of the strategies to support researchers apply to both in-person and virtual research (e.g., structuring interviews in a way that prioritizes the emotional safety of participants); other strategies apply in theory to both types of research but require different approaches when they are implemented during study conduct (e.g., ensuring the emotional safety of participants who experience distress during an interview). Some considerations are unique to virtual research (e.g., identifying and navigating potential concerns for participants' emotional safety when their cameras are turned off). While recent studies are starting to consider how virtual research is designed and conducted, there is a need for more research on emotional safety concerns for participants and researchers during virtual research and guidance to help researchers prioritize emotional safety in their virtual studies. This article contributes to addressing this gap by providing insight into how emotional safety concerns for participants and researchers were identified and navigated while conducting virtual applied qualitative health research to develop the GENDER-Q Youth.

Within the PROM development literature, there is little guidance to support researchers in identifying potential risks to emotional safety and creating strategies to mitigate or manage these risks. While many of the referenced considerations also apply to conducting qualitative PROM development research, more guidance is needed to promote participant and researcher safety during data generation processes unique to PROM development (e.g., considering how and when to share draft scales for cognitive debriefing interviews). Therefore, this article moves the field of PROM development forward by providing a framework that can be used to fill this gap and provide the needed support for PROM developers to prioritize participant and researcher emotional safety.

This article also fills an important gap in providing a framework that was developed on the basis of the experience of conducting an applied qualitative health research study with youth. However, because of the unique nature the GENDER-Q Youth study population (i.e., transgender and gender diverse youth) and the institutions involved in the GENDER-Q Youth study (e.g., local research ethics boards), some considerations presented in the framework (and the subsequent reflections on the components of the framework) may not be applicable to working with other youth populations or within other institutions. Future research is needed to understand how this framework can be applied in other study contexts. Furthermore, transgender and gender diverse youth were not involved in the design or conduct of the GENDER-Q Youth study, including the development and application of the strategies presented in this article. Future research is needed to understand how youth experience emotional safety during virtual data generation and analysis and to build on the framework presented in this article to ensure that youths' experiences are being captured. Researchers should also consider involving youth when creating and implementing strategies to promote emotional safety in their respective studies. Youth engagement may help researchers balance

the need to safeguard participants' emotional safety and the need to respect participants' autonomy, and ensure that the strategies are appropriate for and resonate with participants.

5 Conclusions

This article offers a framework to help researchers make decisions that promote participant and researcher safety when designing and conducting virtual applied qualitative health research to develop PROMs. This framework can help identify threats to emotional safety that may occur before, during, and after data generation and during data analysis, and it can facilitate the development of strategies and plans to mitigate these risks. Ultimately, this framework can be used by PROM developers to ensure the emotional safety of the participants and research team throughout virtual data generation and analysis.

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Conflict of interest Anne F. Klassen provides research consulting services to the pharmaceutical industry through EVENTUM Research (Hamilton, ON, Canada). The other authors declare that they have no conflicts of interest.

Ethics approval Research ethics board (REB) approval was obtained from the coordinating site in Canada (Hamilton Integrated Research Ethics Board; project ID #11103) and a collaborating site in Canada (the Children's Hospital of Eastern Ontario Research Ethics Board; project ID #22/41X). Local REBs determined that the two collaborating sites in the USA did not require local approval.

Consent to participate Written consent was obtained from all participants before data generation and verbal consent was obtained at the time of data generation. Parental consent was also obtained when required.

Consent for publication Not applicable.

Availability of data and material Not applicable.

Author contributions Shelby L. Kennedy: conceptualization, formal analysis, investigation, methodology, project administration, writing—original draft, writing—review and editing. Susan M. Jack: conceptualization, methodology, supervision, writing—review and editing. Natasha Johnson: methodology, supervision, writing—review and editing. Jennifer Couturier: supervision, writing—review and editing. Charlene Rae: conceptualization, methodology, supervision, writing—review and editing. Anne F. Klassen: conceptualization, funding acquisition, methodology, project administration, supervision, writing—review and editing.

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SUPPLEMENTARY FILE A

Strategies to Promote Emotional Safety in the GENDER-Q Youth Study

Research Stage: Before Data Generation

Designing the Data Generation and Analysis Processes

Before initiating the data generation process, the researcher attended learning sessions related to gender-affirming care and working with transgender and gender diverse youth. The researcher also had training and experience conducting qualitative and PROM research and continued participating in relevant learning sessions throughout the study process. These sessions allowed the researcher to: (1) build on the knowledge gained through their previous research experiences, (2) develop a better understanding of the unique perspectives of transgender and gender diverse youth and how to create a safe environment when conducting research with them, (3) identify potential emotional safety concerns for the participants and research team, and (4) develop strategies to navigate these concerns.

Recruiting Prospective Participants

During recruitment, several steps were taken to consider the emotional safety of prospective study participants who were informed of the study by a member of their local gender-affirming clinic team and provided consent to be contacted by the coordinating research team. First, interested youth were given specific details about the researcher who would be contacting them about the study (e.g., name and affiliation); youth recruited through clinics in the United States were also informed that the researcher may contact them from a Canadian phone number. Second, youth were asked about their preferences regarding contact methods; for contact by phone call, youth were asked additional questions (e.g., what name to use when contacting them, when to contact them, and if a voice mail could be left). These steps were important to: (1) help youth feel more

comfortable during the recruitment process, (2) mitigate their potential unease when being contacted by someone they have not met to talk about their gender-affirming care, and (3) protect their privacy (e.g., not outing them to unknowing or unsupportive family members). These steps did not apply to youth who contacted the research team directly to learn more about the study (e.g., youth recruited through a community group or snowball sampling).

Having an Initial Meeting with Prospective Participants

Interested youth were invited to an initial meeting by the researcher to learn more about the study and review the study consent forms. The initial meeting took place by phone or Zoom (Version 5.8.4) and youth could choose to have a parent/caregiver present. This meeting was important for several reasons: (1) to ensure youth understood what their participation in the study would involve, (2) to address any questions or concerns they had about participating in the study (e.g., how would their information be used and what topics would be discussed during the interviews), and (3) to begin building rapport and trust with the researcher. Those interested in participating in the study were asked to share a signed copy of the consent form with the researcher. Parental consent was also obtained when required; parental consent requirements varied depending on the recruitment source (e.g., consent policies varied between institutions).

Scheduling Interviews

When scheduling the concept elicitation and cognitive interviews, the researcher used one of two approaches, depending on how the participants were recruited. For participants recruited from gender clinics, a member of their local gender-affirming clinic team was informed when an interview was scheduled. Participants not connected to a recruiting gender clinic were asked to provide the name and contact information of a responsible and trusted adult who could be available during the interview. These approaches were used so that if a potential safety concern arose or a

disclosure was made, the researcher could contact the care provider or trusted adult to establish a plan to ensure the participant's safety.

Research Stage: During Data Generation

The concept elicitation interviews involved an in-depth exploration of participants' gender-affirming care journeys to understand important outcomes and experiences, which informed the development of scales. The cognitive debriefing interviews involved obtaining feedback on the GENDER-Q Youth study scales [1] (e.g., instructions, response options, and items). Many of the strategies described below were applied to the conduct of both interviews; strategies unique to each interview are identified and discussed.

Conducting Pre-Interview Introductions

All interviews began with an introduction that was not recorded. During the introduction, the researcher reviewed the purpose of the study, talked about what the interview would involve, obtained verbal consent, collected demographic and clinical information, and answered questions. Several topics related to emotional safety were also discussed during this time. First, the researcher described where they were conducting the interview and how they would protect participants' privacy. Participants were asked if they had a space where they felt safe talking and were encouraged to do what they needed to do to make the interview experience comfortable (e.g., have a snack or drink). Second, the researcher talked about topics that may come up during interviews and what would happen if participants became upset or there was a potential concern for their safety. The researcher also emphasized that participants did not have to talk about anything they did not want to talk about. Third, participants were told they could have their cameras off during the interview and adjust their interview settings (e.g., change their displayed name). Fourth, participants were informed that they could choose to have a parent/caregiver present for all or part

of the interview. Lastly, participants were told that they could ask to pause the interview recording or stop the interview at any time. Discussing these topics was important to: (1) be transparent about the interview process, (2) create a safe environment where participants could feel comfortable sharing their experiences, and (3) provide participants with control over the interview and the information they chose to share.

Conducting Interviews

During the concept elicitation interviews, participants were asked to talk about their timelines (if completed) [2] or provide an overview of their gender-affirming care journeys. From that starting point, a range of topics were discussed depending on the concepts identified by youth in their timelines or their journey overviews and the interview guide. The researcher conducted frequent "check-ins" with participants to see how they were feeling; these were typically conducted before shifting to a new topic of discussion. Check-ins were also conducted if participants appeared upset or shared something that seemed to be difficult to talk about. Depending on the response to the check-in, the interview may have been paused or stopped, and the care provider or trusted adult may have been contacted. These measures were also taken if the participant disclosed a potential safety concern.

During the cognitive debriefing interviews, the researcher shared their screen with the scales open to facilitate the feedback process. Participants were not sent the scales in advance of the interview in case they became distressed by the content of the scales. A table of contents was created with the name of each scale so that participants could see the different concepts covered in the GENDER-Q Youth. Participants were asked which of the scales they were most interested in reviewing; this was done to ensure that participants' voices were respected during the interview process. Additional scales were also reviewed depending on study needs (i.e., if more feedback

was needed on a certain scale) and time availability. Participants were informed about the nature of the scale before being shown the scale. Then, participants were shown a scale in its entirety and asked to glance over the scale to determine if they were comfortable talking more about the scale. After reviewing each scale, a check-in was conducted to see how participants were feeling. The check-ins were more thorough after reviewing a scale the researcher felt could be potentially distressing to the participant. The same safety strategies used in the concept elicitation interviews were in place for the cognitive debriefing interviews (e.g., being able to contact a care provider or trusted adult if a potential safety concern was disclosed). At the end of the interviews, participants who did not review all scales were asked if there were any additional scales that they wanted to see and/or provide feedback on; this was important to make sure that participants were able to see as much of the GENDER-Q Youth as they were interested in. Participants were also asked questions about the overall PROM, their thoughts about its implementation into clinical practice, and their overall experience being involved in the GENDER-Q Youth study.

Conducting Post-Interview Debriefs

All interviews concluded with a debrief that was not recorded. The primary purpose of the debrief was to see how participants were feeling. They were asked if they had any questions or things they would like to share about the interview process. Next steps and compensation were also discussed.

Research Stage: After Data Generation

Conducting Debriefs

Post-interview debriefing was used to ensure researcher emotional safety. If an interview was upsetting for the researcher or the researcher felt the need to talk with someone, they contacted senior research team members (e.g., the primary investigator) following the interview to schedule a meeting. These meetings took place as soon as possible after the interviews via phone or Zoom.

Research Stage: During Data Analysis

Transcribing Data

Interview data were audio-recorded and transcribed by the researcher or a professional transcriptionist who had experience working with the research team. For the interviews transcribed by the professional transcriptionist, the researcher informed the transcriptionist when sharing the interview files if an interview involved the discussion of potentially distressing topics. The transcriptionist was also invited to contact the researcher if they wanted to talk to someone while transcribing the audio file. These steps were important to ensure that the transcriptionist was aware of sensitive topics before listening to an audio file and to support them if they felt upset throughout the transcription process.

Analyzing Data

A similar process was used to support the research team members analyzing the interview data. Listening to the interview audio files and repeatedly reading interview transcripts were parts of the data analysis process. The researcher informed the research team of interviews that contained potentially distressing content; reminders were also included through a title page added to interview transcripts. The research team was invited to contact the researcher if they wanted to talk to someone while analyzing the interview data. In addition, check-ins were conducted with the research team during data analysis meetings. These steps were important to alert the research team to the discussion of sensitive topics and ensure support was available if needed.

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