BMJ Open

Taking an integrated knowledge translation approach in research to develop a reporting guideline: The example of CONSORT-Equity 2017

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026866
Article Type:	Research
Date Submitted by the Author:	27-Sep-2018
Complete List of Authors:	Jull, Janet; Queen's University, School of Rehabilitation Therapy; Ottawa Hospital Research Institute, Graham, Ian; Ottawa Hospital Research Institute, Kristjansson, Elizabeth; University of Ottawa, Institute of Population Health Moher, David; Ottawa Hospital Research Institute, Ottawa Methods Centre Petkovic, Jennifer; University of Ottawa, Bruyere Research Institute Yoganathan, Manosila; Elisabeth Bruyere Research Institute Tugwell, Peter; University of Ottawa, medicine Welch, Vivian A.; University of Ottawa, Institute of Population Health
Keywords:	health equity, reporting guidelines, CONSORT, integrated knowledge translation, collaborative research, research co-production

Title: Taking an integrated knowledge translation approach in research to develop a reporting guideline: The example of CONSORT-Equity 2017

Janet Jull
Assistant Professor, School of Rehabilitation Therapy, Queens University, Kingston, Ontario, Canada; Affiliate Investigator, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
janet.jull@queensu.ca

Ian D Graham
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute; Professor, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Ontario, Canada
igraham@ohri.ca

Elizabeth Kristjannson
Associate Professor, Centre for Research on Educational and Community Services, School of Psychology, University of Ottawa, Ottawa, Ontario, Canada
kristjan@uottawa.ca

David Moher
Senior Scientist, ,Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Associate Professor, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Ottawa, Ontario, Canada.
dmoher@ohri.ca

Jennifer Petkovic
Coordinator, Campbell and Cochrane Equity Methods Group, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
jennnifer.petkovic@uottawa.ca

Manosila Yoganathan
Coordinator, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
myoganathan@bruyere.org

Peter Tugwell
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Professor, Department of Medicine, Faculty of Medicine, University of Ottawa,

Ottawa, Ontario, Canada; Professor, School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada
ptugwell@uottawa.ca

Vivian Welch
Scientist, Methods Centre, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada,
vwelch@campbellcollaboration.org

AND

Members of the CONSORT-Equity 2017 and Boston Equity Symposium.

Acknowledgements
Collaborating authors who are identified as a member of the CONSORT Equity and Boston Equity Symposium participants are as follows: Rebecca Armstrong, Sarah Baird, Yvonne Boyer, Luis Gabriel Cuervo, Regina Greer-Smith, Anne Lyddiatt, Jessie McGowan, Lawrence Mbuagbaw, Tomas Pantoja, Beverly Shea, Bjarne Robberstad, Howard White, George Wells.

We thank the following individuals for their support and encouragement: Mark Petticrew, Jeremy Grimshaw, Charles Weijer, Monica Taljaard, Yukiko Asada.

Corresponding Author: Dr. Janet Jull, janet.jull@queensu.ca

Abstract

Introduction

Reporting guidelines in health research improve and contribute to an evidence base for health systems decision-making. An integrated knowledge translation (KT) approach engages knowledge users, meaning those whom the research is meant to benefit, with researchers. The aim of this paper is to describe the use of an integrated KT approach to develop a reporting guideline for health equity, CONSORT-Equity 2017.

Methods

A mixed-method study that used an integrated KT approach was conducted to enhance the integration of knowledge user views in six study phases of reporting guideline development. Each study phase was governed by a group of researchers in collaboration with an advisory board populated by knowledge users in an advisory board-researcher collaboration. The 38 member advisory board-researcher collaboration was surveyed for their perceptions of the integrated KT approach.

Results

We describe two essential study stages 1) Establish guiding features, and 2) Engage in research actions. For the first stage there were four key steps: find common ground, form an advisory

board, commit to ethical guidance, and clarify theoretical perspective. The second stage was a multi-phase study bound by the agreed-upon guiding features of the research approach. There were 25 respondents on the advisory board-researcher member survey that reports perceptions of the integrated KT approach. The limitations of the integrated KT approach include those of work, time, distance and communication constraints for knowledge users; strengths include that the integrated KT approach made it possible to build research relationships that include a range of knowledge users.

Conclusions

We describe a process designed to engage knowledge users with researchers to co-create knowledge, in ways that both are likely to define as useful, relevant and applicable. Further work is needed to examine the use of an integrated KT approach in reporting guideline development.

Strengths and limitations of this study

- Reporting guidelines in health research improve and contribute to a robust evidence base for health systems decision-making
- Integrated knowledge translation (integrated KT) is an approach to research that structures the engagement of knowledge users, meaning those for whom the research is meant to ultimately be of use, with researchers in the co-creation of knowledge
- An integrated KT approach was used to engage knowledge users with researchers to develop the CONSORT-Equity 2017 reporting guideline
- A limitation is that the use of an integrated KT approach includes the challenges of work, time, distance and communication constraints for a group of people who hold a range of views, and who are collaborating to achieve study objectives
- An integrated KT approach was found to foster research study processes that prompt deliberation and consensus building among team members in the co-creation of knowledge, and establishes a knowledge base that knowledge users and researchers define as relevant, useful and applicable

INTRODUCTION

Reporting guidelines in health research are important, as they improve and contribute to a more robust evidence base for health systems decision-making. The use of reporting guidelines in health research may improve completeness and transparency of reported evidence from research studies. Further, their importance is reflected in international research policies to deliver impactful research (1, 2). There is a significant amount of avoidable waste in research (3), meaning that potentially useful research findings are disregarded because of inadequate reporting, which better reporting guidelines can help address. Reporting guidelines can also be useful in clarifying how the research was performed, helping to make research more transparent and reproducible. "Integrated knowledge translation" (integrated KT) has been proposed as an approach to address the issues of knowledge production and application (4, 5). Potential guideline knowledge users, meaning those for whom the research is meant to ultimately be of use, may include people from a broad range of disciplines, including patients and members of the public, who are involved in a range of research-related activities. We describe the integrated KT approach designed to engage potential guideline knowledge users with researchers. The participating knowledge users and researchers were interested in better guidance for reporting randomized controlled trials that indicate health equity; specifically, by developing the reporting guideline CONSORT-Equity 2017. An integrated KT approach fosters research study processes that prompts deliberation and consensus building among team members in the co-creation of knowledge, and establishes a knowledge base that knowledge users and researchers define as relevant, useful and applicable.

Potential users of reporting guidelines ("knowledge users") may include people from disciplines such as clinical epidemiology, economics, social science, public health, international development, knowledge translation and patients or patient organizations ("patients") and

members of the public. Knowledge users may be involved in a range of research-related activities, such as research funding, -development, -conduct, -participation, -dissemination, or use of its outcomes for research or making health care decisions. We describe the process designed to engage a group of knowledge users and researchers, who were all interested in better guidance for reporting of randomized controlled trials for health equity. Furthermore, in the process we sought to establish a knowledge base that knowledge users and researchers consider relevant, useful and applicable, and in our example, to support health-equity relevant and focused decision making. In this article, we summarize methods used for engagement of reporting guideline knowledge users with researchers. We report on the perceptions, challenges and strengths in the use of an integrated KT approach for the development of CONSORT-Equity 2017.

Development of a reporting guideline and knowledge translation

Striving for health equity is a matter of social justice and implies that everyone can attain their health potential and that no one is disadvantaged by their social positioning or other socially determined circumstances (6). Randomized controlled trials ("randomized trials") are a powerful design for determining the relative impact of an intervention (7). Nevertheless, for trials to contribute effectively to policies that promote health equity, there remain challenges to overcome (8). For example, poor reporting of equity considerations in trials can have undesired effects on health systems' organizational practices and policies, clinical and public care. Additionally, some interventions can even aggravate and/or undermine health equity (9). Reporting guidelines are needed to support the consideration of equity in the conduct of and communication about randomized trials. While the involvement of knowledge users has been identified as important for clinical guideline development (10, 11), a recent review of clinical guidelines show that there

is evidence for low levels of such involvement (12). Achieving consensus among collaborators on how to report research has been identified as important (13), but there is little information on how consensus can be approached through involvement of inter-disciplinary knowledge users that include patients and members of the public.

"Knowledge translation" (KT) is a term used to refer to processes that bridge the "know-do" gap, and has been defined as the gap between what is learned from research and the implementation by knowledge users, with the aim to improve health delivery systems and health outcomes (14). Understandings of the know-do gap continue to evolve, and today the know-do gap is not seen solely as a problem of knowledge transfer, but also as a knowledge production problem. In other words, addressing the know-do gap requires researchers to begin thinking of KT before knowledge is created (4, 5). "Integrated knowledge translation" (integrated KT) has been proposed as an approach that is more likely to lead to the practical application of knowledge (15, 16) Integrated KT involves a collaborative approach between researchers and knowledge users in the research process to foster and promote inclusion of a range of perspectives (16). This can include developing the research question(s), making joint decisions about methodology and methods, involvement in data collection and tool development, interpretation of findings, and participation in the dissemination of findings (17). The integrated KT process requires that researchers and knowledge users collaborate to address an issue of mutual concern, recognize that each party brings knowledge and values to the research, and that they share a common focus on generation of knowledge for the purpose of its application.

The guideline development example: CONSORT Equity 2017

The internationally recognized Consolidated Standards for Reporting Trials (CONSORT) statement is an evidence-based guideline consisting of 25 items to encourage completeness and

transparency in reporting of randomized trials (18). An equity extension of CONSORT, "CONSORT-Equity 2017", was proposed to influence the reporting of future trials (19). Uptake of CONSORT-Equity 2017 is critical to improve the reporting of trials that contribute health equity-relevant evidence (20). When we developed the CONSORT-Equity 2017, we considered it essential to form partnerships with different types of potential knowledge users, and therefore invited individuals who might be users of the research evidence generated in randomized trials to be involved in a range of research activities. An integrated KT approach was used to foster the development of CONSORT-Equity 2017.

During the development of CONSORT-Equity 2017, potential knowledge users were identified to include people from a range of disciplines; including clinical epidemiology, social science, public health, international development, patients or members of patient organizations; and who identify themselves as involved in the funding, development, conduct, participation, dissemination, or use of outcomes from randomized trials. In this paper, we describe the process of engaging these knowledge users with researchers in ways that contribute to equity-focused decision making. The aim of this paper is to describe the use of an integrated KT approach to develop a reporting guideline, CONSORT-Equity 2017.

METHODS

A mixed-method study that used integrated KT was conducted to enhance the integration of knowledge user views in guideline development (19). It included the following six study phases, based on the guidance for the development of reporting guidelines: (i) identification of the need for the guideline, (ii) review of the literature, (iii) identification of participants, (iv) the conduct of a Delphi study, (v) a face-to-face consensus meeting (13) and (vi) consultation with key informants (19). In addition, each phase of the study was governed by a group of researchers

and conducted in collaboration with an advisory board populated by potential knowledge users. Collectively, they formed an advisory board-researcher collaboration who are acknowledged or listed as coauthors on this paper.

A collaborative framework was used by the advisory board-researcher collaboration to structure the development of CONSORT-Equity 2017 and to foster an integrated KT approach (21). Participatory methods were used to facilitate engagement within the advisory board-researcher collaboration and to build consensus in mutually-agreed upon processes to co-create knowledge and assemble empirical evidence. The advisory board-researcher collaboration was established to function as a partnership throughout the study process to promote inclusion and respect for a multiplicity of perspectives. The collaborative framework structured ongoing negotiations and replicable steps that occurred within the advisory board-researcher collaboration to ensure that the goals of the study were achieved: to conduct research in a collaborative manner that uses consensus-building methods and involves co-creation of knowledge; and, to develop a reporting guideline for equity (CONSORT-Equity 2017) as a contribution to address health systems equity issues. An online survey was used to assess the advisory board-researcher member perceptions on the integrated KT approach and impact on co-creation of knowledge.

Patient and public involvement

Patients and members of patient organizations have been involved in the design, conduct and reporting of the work reported in this manuscript, and are identified as co-authors on the work presented here. Our manuscript reports on the extension of CONSORT for equity and research study processes conducted with knowledge users who include patients and members of patient organization. For this reason, the work that is presented here is an example of how to conduct reporting guideline development in ways that include patient priorities, experiences and

preferences. Patients and members of patient organizations have provided content-related support, and knowledge, skills and experience to the study throughout the multiple stages of the research study process (i.e., the Integrated Knowledge Translation (KT) process) and that includes the planning and conduct of dissemination (road-testing of CONSORT-Equity 2017 with groups that include patient and patient organizations) We thank the participating members of patient and patient organization for their advice and support throughout the work to develop CONSORT-Equity 2017.

RESULTS

Description of the integrated KT approach

We describe two essential stages and associated sub-steps in the conduct of the mixed-method study to develop CONSORT-Equity 2017 (Figure 1):

1) Establish guiding features,
2) Engage in research actions that support the co-creation of knowledge throughout the study processes in the development of a reporting guideline for equity.

Stage 1: Establish Guiding Features (Table 1):

Find Common Ground. For CONSORT-Equity 2017, finding common ground was an iterative three step process: 1) Define knowledge users and their common interests and concerns: Two researcher members (VW, PT) recognized the interest and need to extend CONSORT for equity and engaged others who shared concerns about equity in health systems; 2) researcher members then identified other individuals who held relevant knowledge, and built relationships among other potential interdisciplinary team members; 3) the growing group of interdisciplinary team members then defined parameters of the study relationships to find common ground. The

objectives of a potential research study and study parameters were developed and articulated in a research proposal that was submitted for funding. Following the success of the funding proposal, the 3-step process was engaged in again, expanding CONSORT-Equity 2017 networks, relationships, the study objectives and parameters, and that led to the formation of a CONSORT-Equity advisory board.

Form an Advisory Board. At the start of the study, the importance of collaboration with knowledge user groups during the development of CONSORT-Equity 2017 was identified. An international CONSORT-Equity advisory board of intended users across a range of perspectives were defined and recruited: journal editors, trialists, bioethicists, patients and members of the public, clinicians, systematic review authors, policy makers, and funders. One facilitator was identified to coordinate the advisory board (JJ) and another to facilitate the researcher group (VW) to ensure communication within and between the groups (Table 2). The inclusion of the advisory board created an opportunity to expand on and explore concepts related to health equity.

Commit to Ethical Guidance. The members of the advisory board-researcher collaboration made decisions to structure the study in adherence to ethical guidelines. These agreements structured communication and consensus-building processes (20) with the aim to ensure respect for and representation of a broad range of views.

Clarify Theoretical Perspective. Absent and/or poor-quality evidence about health equity is identified by policy makers as a key limitation of research (22). The lack of consensus on the use of the terms related to health equity, health inequality, and health disparities was identified as an important feature in the development of a reporting guideline to address health inequity.

Therefore, the members of the advisory board-researcher collaboration sought to clarify terminology and the underpinning assumptions, and to relate these understandings in accessible work plans (19, 20). Theory-based assumptions were revisited and reflected upon during the conduct of the study to develop CONSORT-Equity 2017.

Stage 2: Engage in Research Actions

Conduct Study. The multi-phase CONSORT-Equity 2017 study was bound by the agreed-upon guiding features of the research approach and conducted to accomplish its objectives and products over a two-year timeframe. The use of participatory methods promoted consensus building, and resulted in the co-creation of knowledge during the study. The five steps of the study included (i) define (establish guideline need among knowledge user collaborators), (ii) assess (state of the literature, experts on health equity), (iii) develop/adapt (propose and debate adaptation of guideline), (iv) disseminate (develop and execute plan for uptake of guideline), and (v) apply (process of road-testing guideline).

Table 1. Essential phases and associate sub-steps in the development of CONSORT-Equity 2017

Stage 1: Establish Guiding Features	**Example**
1) Find Common Ground	A process to initiate and develop a collaborative work plan that for CONSORT-Equity 2017 was an iterative 3-step process and resulted in a published protocol (19).
2) Form an advisory board	Defined advisory board roles, accessed networks to recruit advisory board members; terms of reference to structure relationships within and between the advisory board-researcher collaboration (Table 2). Consensus building processes promoted engagement in active debate and co-creation of knowledge, for example, to define and validate when a randomized trial is health- equity relevant (20).
3) Commit to ethical guidance	Advisory board-researcher collaboration agreed on study conduct to adhere to ethical guidelines (in Canada, the Tri-Council Policy Statement Version 2 (23) and that could include other research ethics protocols or requirements considered relevant by knowledge user partners, such as the example of research conduct with Indigenous peoples (24, 25)
4) Clarify theoretical perspective	CONSORT-Equity 2017 is premised on understandings of key concepts, their definitions and usage among the advisory board-researcher collaboration: understandings of health equity and agreements among members about underpinning assumptions: the role of social determinants of health theory, a definition of "health equity", a health-equity relevant randomized trial, when is there a health disadvantage (19, 20).
Stage 2: Engage in Research Actions	**Example**
5) Conduct study	The five research study steps in stage 2 are bound by the guiding features of stage 1: i) define, ii) assess, iii) develop/adapt, iv) disseminate, v) apply. Study outcomes are reflected in the success of an invitational study meeting (the 2016 Boston Equity Symposium) and co-authored publications (20, 26-28) and the CONSORT-Equity 2017 checklist elaboration and explanation (27, 29). Work is underway to further disseminate and promote the application of the CONSORT-Equity 2017 guideline.

Table 2. Terms of Reference

Role of advisory board membership	-Members to participate in a collaborative process -Members will provide content-related support, and bring knowledge, skills and experience to the working group throughout the multiple stages of the research study process (i.e., the Integrated Knowledge Translation (KT) process including the end-of-grant dissemination)
Method and frequency of communication	-The facilitator (JJ) will provide study background documents -Agendas to be provided in advance of meetings, with identification of key decisions to be made by the advisory board -There will be ongoing opportunities for communication, in a manner that facilitates the function of advisory board members in their roles
Description of workload	-Meeting participation by members -Provision of feedback on key issues will be made in meetings or by email correspondence -There will be opportunities for interested advisory board members to meet authorship criteria (see below "Authorship")
Timelines	-The advisory board involvement is anticipated to begin in June 2015, and end in December 2016 -Meetings and/or updates will occur every 2 to 3 months (3 to 5 meetings/year, and with brief email correspondence)
How advice will be managed	-Advisory board input will be sought and considered along with that of the core research team. -Disagreements on views will be respectfully and collaboratively managed by the advisory board facilitator (JJ)
Authorship	-Criteria outlined by International Journal Committee of Medical Journal Editors (IJCME) will be used to guide publication authorship (30).

Perceptions on the integrated KT approach and impact on co-creation of knowledge

There is little evidence about the experiences of interdisciplinary teams that include patient and members of the public in the development of reporting guidelines. Previous work to investigate perspectives in clinical guideline development concluded that effective engagement requires planning, and the recommendations arising from that work include: the use of smaller

and more diverse groups, with no prior relationships with other members of the team; individual and group preparation for engagement on the team; and, an identified contact person for participants (31). Our work involved interdisciplinary members of the advisory board-researcher collaboration and included patient and members of the public, with 38 members from eight countries. Furthermore, our use of an integrated KT approach meant that there were many opportunities to be fully involved in the entire research process. The members of the advisory board-researcher collaboration were invited to participate in all phases of the reporting guideline development process, and efforts were made to accommodate their participation.

We prioritized the engagement of advisory board-researcher members in the study to improve applicability of CONSORT-Equity 2017. To strive for authentic (that is, ethical, equitable) engagement, deliberate efforts were made to foster partnerships with a broad range of international knowledge users. We purposefully sought a range of views and ideas about the different characteristics and social circumstances of individuals and populations. We failed to engage with one group member due to time constraints around their ability to participate; and it was not possible for every member of the advisory board-researcher collaboration to have their views accommodated so that some members chose to remove themselves from participation either temporarily or permanently (n=2). As well, it was not possible (and indicated as not desirable by respondents) for every member of the collaboration to participate in every step of the guideline development process, although information was always available and shared with the group. As collaboration and consensus-building methods were a central feature in CONSORT-Equity 2017 development, it was also important to understand the study experiences of those who were involved in the reporting guideline development.

The members of advisory board-researcher collaboration were asked to participate in a short survey following the development of the CONSORT-Equity 2017 reporting guideline. In consultation with an integrated KT expert (IDG), an on-line survey was developed, pilot-tested and ethics approval obtained. The brief survey was subsequently administered in July 2017 to the advisory board-researcher members, and their feedback on their experiences with the use of integrated KT approach was sought. There were 38 individuals invited to participate in the survey, with one declining to participate due to time constraints. Of the 37 surveyed members of the advisory board-researcher collaboration, there were 25 respondents (response rate of 67.5%).

The survey was used to gather feedback on the experience with the integrated KT approach, and the response to eight survey questions are presented here. Two questions report on the overarching experience of engagement and satisfaction with the use of an integrated KT approach during the development of CONSORT-Equity 2017. When asked "Overall, how would you rate the extent to which the research team engaged you in the study? (Where 1 is not at all and 5 is completely engaged)", 16/25 (64%) of surveyed respondents indicated being completely engaged: "I had a concrete role in the process and the team was very respectful and considerate of input so it was easy to feel invested". In response to the question "How satisfied are you with the level of your engagement with the research team? (Where 1 is not at all satisfied and 5 is totally satisfied)", 19/25 (76%) of surveyed respondents indicated being totally satisfied: " [I would] be happy (very) if all research teams engaged all participants in the same manner".

In the survey, respondents were asked six questions to learn details about their experience with the integrated KT approach, and frequency counts of the type of responses were recorded and are reported in Table 3. When participants were asked what they perceived as the benefits of an integrated KT approach (question 1), the most common (56%) response described integrated

KT as an approach that allows multiple voices/opinions to be heard and considered. In response to being asked about whether they thought that the team faced any challenges in the study as the result of the integrated KT approach (question 2), many participants (32%) reported that the logistics involved with including lots of people was a challenge, and most (36%) reported that they were unaware of any team challenges. When asked about whether they faced any challenges in the study as the result of the integrated KT approach (question 3), most participants (76%) indicated that they did not face any challenges in the study. Participants were asked what they consider to be the impact(s) of using an integrated KT approach with the study (question 4), and the majority (44%) indicated that an integrated KT approach improved the relevance of the final guideline product. When asked if they would change anything about how the integrated KT approach was used (question 5), most participants (56%) indicated that they would not have changed anything. Finally, when asked for additional comments (question 6), while most (76%) had no comment, some (24%) reported that the integrated KT process was a positive experience.

Table 3. Results of team survey about experience with integrated knowledge translation (KT) approach (n=25)].

Question	Response
1. What do you perceive as the benefits of an integrated knowledge translation (KT) approach to develop a reporting guideline extension of CONSORT for equity?	1) Allows consideration of a range of views: "Capturing a multitude of perspectives, to enhance relevance and acceptability of reporting guidelines across disciplines" (14/25; 56%). 2) Fosters engagement in study processes: "It allows participation and engagement of various stakeholders at all stages of the project for whom the guideline is relevant" (6/25; 24%). 3) Enhance guideline uptake: "Results are more likely to be adopted and applied" (5/25; 20%).
2. Do you think that the team faced any challenges in the study as the result of the integrated KT approach?	1) The logistics of including a range of people in the team: "Takes more time to work with a large and diverse crowd" (8/25; 32%); 2) Management of perspectives: "Because of the wide range of

	different disciplines present, it may have been difficult to engage all participants equally across all issues" (5/25; 20%); 3) Reconciliation of within-team differences: "It is difficult to deal with perhaps conflicting and at times unclear opinions" (3/25; 12%). 4) Unaware of any team challenges: "Not that I'm aware of" (9/25; 36%).
3. Did you face any challenges in the study as the result of the integrated KT approach?	1) No personal challenges faced in the study: "I did not face any challenges. My input and participation had equal standing in the process" (19/25; 76%). 2) The personal experience of challenge related to the pace, number of consultations, and/or to provide informed opinions: "It was slow at times and a bit frustrating. We achieved what we did through patience, persistence and good will of team members" (6/25; 24%).
4. What do you consider to be the impact(s) of using an integrated KT approach with the study?	1) Improves the final guideline product: "I feel that we produced a product that was relevant to all of our team members, and that they can support in their communities" (11/25; 44%). 2) Inclusion of different forms of knowledge: "It ensures that the study is better informed by the expertise, perspectives and needs of the different stakeholders" (11/25; 44%). 3) Unsure/did not notice impact of integrated KT approach: "Not sure" (3/25; 12%).
5. Would you have changed anything about how the integrated KT approach was used in the study? If yes, how?	1) Would not change the use of the integrated KT approach "No change suggested" (8/15; 53.33%). 2) Greater range of participants: "I would have tried to broaden the scope of stakeholders" (3/15; 20%). 3) Narrow the stakeholder focus and seek more intense consultations, such as through in-person meetings: "Smaller reach, deeper consultation" (2/15; 13.33%). 4) More time: "More time is always a benefit to measure the impact" (2/15; 13.33%).
6. Do you have any additional comments**?**	1) No comment (19/25; 76%). 2) Indicated that it was a positive experience: "I would do this again" (6/25; 24%).

Challenges and strengths with an integrated KT approach with guideline development

The challenges of integrated KT approach include work and time constraints for those in the advisory board-researcher collaboration, reliance upon facilitators at one site for fostering regular and productive contacts among international members, and the use of online

communications (versus face-to-face) with many members of the advisory board-researcher collaboration and the subsequent impacts on participation. At times, communication between and within those in the collaboration was a challenge due to the logistics of distance and time zones, the numbers of people, and the range of views to bring together and accommodate to achieve study objectives The strengths of the integrated KT approach include that in the study it was possible to build and/or strengthen research relationships across a range of knowledge users that include patients and members of the public (within or related to research communities). These research relationships were demonstrated by participation in publication co-authorship, attendance at regular meetings, email contacts, and feedback on products.

The success of the longer-term engagement of the members in the advisory board-researcher collaboration was possibly due to the options for regular and ongoing opportunities to re-engage at different stages of the study. The facilitators sought to create inclusive, frequent and varied opportunities for participation in the study processes through scheduled face-to-face and/or telephone calls, and maintained regular email study updates. We also sought more distant engagement with broader networks associated with the advisory board-researcher collaboration. For example, we presented different stages of the work at face-to-face meetings and at conferences; advisory board-researcher collaboration members held discussions within their networks about different aspects of the study. Opportunities for discussion and inclusion of ideas in publications were ongoing and clearly indicated terms of reference structured opportunities for authorship or other forms of acknowledgement and that aimed to be inclusive of many ideas to co-create knowledge. Overall, a committed group of advisory board-researcher collaboration members were involved and integrated in a collaborative effort for the duration of the study and

that resulted in agreed upon objectives and products and that were considered in relation to the context of the knowledge user.

CONCLUSIONS

A previously developed collaborative framework structured and facilitated ongoing negotiations to develop the CONSORT-Equity 2017 reporting guideline. Members of an advisory board-researcher collaboration agreed upon and then made steady and successive achievements in study goals to collaboratively develop the reporting guideline. The use of integrated KT fostered equity in the research study processes using participatory methods to prompt deliberation and consensus building among interdisciplinary team members. Further work is needed to examine the collaborative framework components and its potential applications to other initiatives that engage researchers with knowledge users interested in and seeking to improve research guidance.

[Figure 1. Integrated Knowledge Translation (KT) approach for CONSORT-Equity 2017]

Ethics Approval: Participants gave informed consent before taking part in the study reported in this manuscript (Bruyère REB Protocol # M16-15-042).

Transparency Statement: The lead author and guarantor (JJ) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

Role of funding source: Funding was not received for this study.

Data sharing statement: No additional data available.

Competing interests: All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the previous three years; no other relationships or activities that could appear to have influenced the submitted work, with the following exceptions: 1) Dr. Cuervo reports he works as a Senior Advisor for Health Systems Research to the Pan American Health Organization/World Health Organization. His Organization's Policy on Research for Health calls for the development and use of research reporting standards and improving the value and impact of research for health. His opinions and contributions to this manuscript are his own and do not necessarily reflect the decisions or policies of his employer; 2) Dr. Moher reports that he is one

of the 'inventors' of CONSORT; 3) Dr. Welch reports grants from Canadian Institutes of Health Research, grants from Ontario Early Career Researcher Award, during the conduct of the study.

Contributorship Statement: JJ, IDG, VW conceived and led the design of the work described in the manuscript and were responsible for the first and final drafts of this manuscript. All authors participated in and provided substantial contributions to the analysis and interpretation during development of the work described in the manuscript. JJ led the writing and IDG, EK, DM, JP, MY, PT, VW made contributions to drafts of this manuscript; all authors including the listed members of the CONSORT-Equity 2017 and Boston Equity Symposium have reviewed and revised the manuscript for important intellectual content and approved the final version.

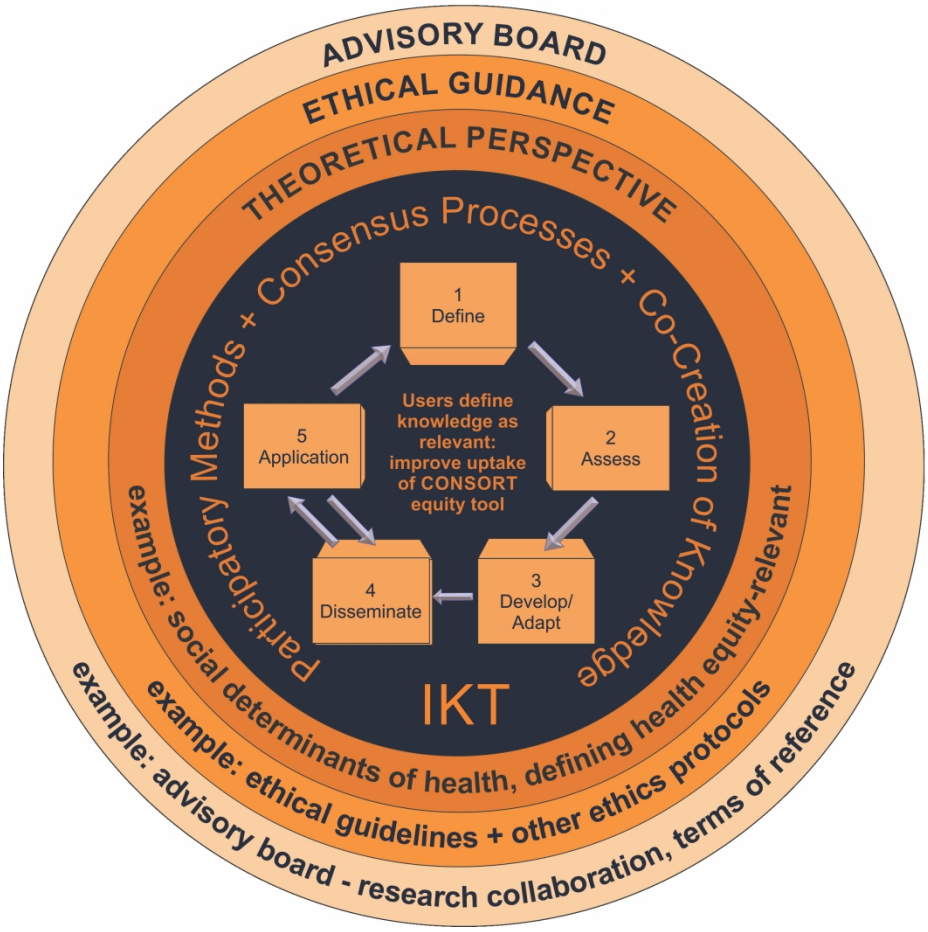
Dr. Janet Jull is the guarantor of the article.

References

1. 63rd World Health Assembly. WHO Strategy on Research for Health; WHO Roles and responsibilities on health research: document WHA63.22 and Resolution. 20 Avenue Appia, 1211 Geneva 27, Switzerland; 2012.
2. Pan American Health Organization, 49th Directing Council, 61st Session of the Regional Committee of WHO for the Americas. Policy on research for health: document CD49/10. Washington, DC: PAHO; 2009.
3. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. Lancet. 2014;383(9913):267-76.
4. Bowen S, Graham I. Integrated Knowledge Translation. In: SE Straus, J Tetroe, ID Graham, editors. Knowledge Translation in Healthcare: moving evidence to practice. West Sussex: Wiley; 2013. p. 14-23.
5. Van de Ven D, Johnson P. Knowledge for theory and practice. Academy of Management Review. 2006;31(4):802-21.
6. Whitehead M. The concepts and principles of equity and health. Int J Health Serv. 1992;22(3):429-45.
7. Sackett D, Rosenberg W, Gray J, Haynes R, Richardson W. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312:71-2.
8. Marmot M, Allen J, Bell R, Goldblatt P. Building of the global movement for health equity: from Santiago to Rio and beyond. Lancet. 2012;379(9811):181-8.

9. Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. J Epidemiol Community Health. 2013;67(2):190-3.
10. Jarrett L, Patient Involvement Unit (PIU). A report on a study to evaluate patient/ carer membership of the first NICE Guideline Development Groups. London: National Institute for Clinical Excellence (NICE); 2004.
11. Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012;156(7):525-31.
12. Armstrong MJ, Bloom JA. Patient involvement in guidelines is poor five years after institute of medicine standards: review of guideline methodologies. Res Involv Engagem. 2017;3:19.
13. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med. 2010;7(2):e1000217.
14. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? J Contin Educ Health Prof. 2006;26(1):13-24.
15. Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge. Implement Sci. 2017;12(1):150.
16. Canadian Institutes of Health Research (CIHR). Guide to knowledge translation planning at CIHR: integrated and end-of-grant approaches 2015 [Available from: http://www.cihr-irsc.gc.ca/e/45321.html.
17. Graham ID, Tetroe J, KT Theories Group. Some theoretical underpinnings of knowledge translation. Acad Emerg Med. 2007;14(11):936-41.
18. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. Syst Rev. 2012;1:60.
19. Welch V, Jull J, Petkovic J, Armstrong R, Boyer Y, Cuervo LG, et al. Protocol for the development of a CONSORT-equity guideline to improve reporting of health equity in randomized trials. Implement Sci. 2015;10:146.
20. Jull J, Whitehead M, Petticrew M, Kristjansson E, Gough D, Petkovic J, et al. When is a randomised controlled trial health equity relevant? Development and validation of a conceptual framework. BMJ Open. 2017;7(9):e015815.
21. Jull J, Giles A, Boyer Y, Stacey D, Minwaashin Lodge. Building and enacting ethical research processes: the example of culturally adapting a decision making strategy. ACME: An International Journal for Critical Geographies. 2016;17(3);671-86.
22. Petticrew M, Whitehead M, Macintyre SJ, Graham H, Egan M. Evidence for public health policy on inequalities: 1: the reality according to policymakers. J Epidemiol Community Health. 2004;58(10):811-6.
23. Panel on Research Ethics. TCPS 2 – Chapter 9. Research Involving the First Nations, Inuit and Métis Peoples of Canada [Available from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/ .
24. First Nations Information Governance Centre (FNIGC). The First Nations principles of OCAP® 2017 [Available from: http://fnigc.ca/ocap.html.
25. Canadian Institutes of Health Research (CIHR). CIHR guidelines for health research involving Aboriginal People. 2007 [Available from: http://www.cihr-irsc.gc.ca/e/29134.html.

26. Mbuagbaw L, Aves T, Shea B, Jull J, Welch V, Taljaard M, et al. Considerations and guidance in designing equity-relevant clinical trials. Int J Equity Health. 2017;16(1):93.
27. Welch VA, Norheim OF, Jull J, Cookson R, Sommerfelt H, Tugwell P, et al. CONSORT-Equity 2017 extension and elaboration for better reporting of health equity in randomised trials. BMJ. 2017;359:j5085.
28. Petkovic J, Welch V, Jull J, Petticrew M, Kristjansson E, Rader T, et al. How is health equity reported and analyzed in randomised trials: Cochrane Systematic Review Registered Protocol. Cochrane Methodology Review Group. 2017(Issue 8 . Art. No.: MR000046).
29. Simera I, Moher D, Hirst A, Hoey J, Schulz KF, Altman DG. Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. BMC Med. 2010;8:24.
30. International Committee on Medical Journal Editors (ICJME). Defining the role of authors and contributors 2018 [Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.
31. Armstrong MJ, Mullins CD, Gronseth GS, Gagliardi AR. Recommendations for patient engagement in guideline development panels: A qualitative focus group study of guideline-naïve patients. PLoS One. 2017;12(3):e0174329.


ADVISORY BOARD
ETHICAL GUIDANCE
THEORETICAL PERSPECTIVE
Participatory Methods + Consensus Processes + Co-Creation of Knowledge
1 Define
2 Assess
3 Develop/ Adapt
4 Disseminate
5 Application
Users define knowledge as relevant: improve uptake of CONSORT equity tool
IKT
example: social determinants of health, defining health equity-relevant
example: ethical guidelines + other ethics protocols
example: advisory board - research collaboration, terms of reference

BMJ Open

Taking an integrated knowledge translation approach in research to develop a reporting guideline: The example of CONSORT-Equity 2017

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026866.R1
Article Type:	Research
Date Submitted by the Author:	28-Feb-2019
Complete List of Authors:	Jull, Janet; Queen's University, School of Rehabilitation Therapy; Ottawa Hospital Research Institute, Graham, Ian; Ottawa Hospital Research Institute, Kristjansson, Elizabeth; University of Ottawa, Institute of Population Health Moher, David; Ottawa Hospital Research Institute, Ottawa Methods Centre Petkovic, Jennifer; University of Ottawa, Bruyere Research Institute Yoganathan, Manosila; Elisabeth Bruyere Research Institute Tugwell, Peter; University of Ottawa, medicine Welch, Vivian A.; University of Ottawa, Institute of Population Health
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice
Keywords:	health equity, reporting guidelines, CONSORT, integrated knowledge translation, collaborative research, research co-creation

Title: Taking an integrated knowledge translation approach in research to develop a reporting guideline: The example of CONSORT-Equity 2017

Janet Jull
Assistant Professor, School of Rehabilitation Therapy, Queens University, Kingston, Ontario, Canada; Affiliate Investigator, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
janet.jull@queensu.ca

Ian D Graham
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute; Professor, School of Epidemiology and Public Health, University of Ottawa, Ottawa, Ontario, Canada
igraham@ohri.ca

Elizabeth Kristjannson
Associate Professor, Centre for Research on Educational and Community Services, School of Psychology, University of Ottawa, Ottawa, Ontario, Canada
kristjan@uottawa.ca

David Moher
Senior Scientist, ,Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Associate Professor, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Ottawa, Ontario, Canada.
dmoher@ohri.ca

Jennifer Petkovic
Coordinator, Campbell and Cochrane Equity Methods Group, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
jennnifer.petkovic@uottawa.ca

Manosila Yoganathan
Coordinator, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
y.manosilah@gmail.com

Peter Tugwell
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Professor, Department of Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada; Professor, School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada
ptugwell@uottawa.ca

Vivian Welch
Scientist, Methods Centre, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada,

vwelch@campbellcollaboration.org

AND

Members of the CONSORT-Equity 2017 and Boston Equity Symposium.

Corresponding Author: Dr. Janet Jull, janet.jull@queensu.ca

Abstract (299)

Objective We describe the use of an integrated knowledge translation (KT) approach in the development of the CONsolidated Standards Of Reporting Trials extension for equity ("CONSORT-Equity 2017"), and advisory board-researcher members' ("the team") perceptions of the integrated KT process.

Design An observational study to describe team processes and experience with a structured integrated KT approach to develop CONSORT-Equity 2017. Participant observation to describe team processes and a survey were used with the 38 team members.

Setting Use of the CONSORT health-research reporting guideline contributes to an evidence base for health systems' decision-making, and CONSORT-Equity 2017 may improve reporting about health equity-relevant evidence. An integrated KT research approach engages knowledge users (those whom the research is meant to benefit) with researchers to co-create research evidence and is more likely to produce findings that are applied in practice or policy.

Participants Researchers adopted an integrated KT approach and invited knowledge users to form an advisory board-researcher team.

Results An integrated KT approach was used in the development of CONSORT-Equity 2017 and structured replicable steps. The process for co-creating the reporting guideline involved two stages: 1) establishing guiding features for co-creation, and 2) research actions that supported the co-creation of the reporting guideline. Stage one consisted of four steps: finding common ground, forming an advisory board, committing to ethical guidance, clarifying theoretical research assumptions. Bound by the stage one guiding features of an integrated KT approach, stage two consisted of five steps during which studies for consensus-based reporting guidelines

were conducted. Of 38 team members, 25 (67.5%) completed a survey about their perceptions of the integrated KT approach.

Conclusions An integrated KT approach can be used to engage a team to co-create reporting guidelines. Further study is needed to understand the use of an integrated KT approach in development of reporting guidelines.

Strengths and limitations of this study

- Reporting guidelines in health research improve and contribute to a robust evidence base for health systems decision-making
- Integrated knowledge translation (KT) is an approach to research that structures the engagement of knowledge users, meaning those for whom the research is meant to ultimately be of use, with researchers to facilitate the co-creation of knowledge
- An integrated KT approach was used to engage knowledge users with researchers to develop the CONsolidated Standards Of Reporting Trials extension for equity ("CONSORT-Equity 2017") reporting guideline
- Limitations are that the use of an integrated KT approach includes the logistics of including a range of people and the management of views; the strengths include that the integrated KT approach allows consideration and inclusion of a range of views.
- An integrated KT approach can be used to engage knowledge users with researchers to co-create reporting guidelines.

INTRODUCTION

Reporting guidelines in health research are important, as they improve and contribute to a more robust evidence base for health systems decision-making (1, 2). There is a significant amount of avoidable waste in research (3), and part of this waste can be attributed to potentially useful research findings being disregarded because of inadequate reporting, which reporting guidelines can help address. Defined as a tool for use by health researchers to structure manuscript writing, reporting guidelines consist of minimal lists of information to ensure that a manuscript can be understood by a reader, replicated by a researcher, used by a clinician to make a clinical decision and included in a systematic review (4). The use of reporting guidelines in health research may improve completeness and transparency of reported evidence from research studies, and many examples of reporting guidelines can be found at the Ottawa Hospital Research Institute's Centre for Journalology site at http://www.ohri.ca/journalology/docs/guidelines.aspx (5), as well as the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network site at https://www.equator-network.org/ (4).

The internationally recognized CONsolidated Standards Of Reporting Trials (CONSORT) statement is an evidence-based guideline consisting of 25 items to encourage completeness and transparency in reporting of randomized controlled trials ("randomized trials"). CONSORT is in the form of a checklist and flow diagram (6). The checklist focuses on reporting how the randomized trial was designed, analyzed and interpreted and the flow diagram depicts participant progress through the randomized trial processes. Extensions to the CONSORT Statement have been developed for specific issues (for example, pragmatic trials, non-pharmacologic therapies,

and social and psychological interventions) (4), although none report items to assess the effects of an intervention on health equity (7).

Striving for health equity is a matter of social justice and implies that everyone can attain their health potential and that no one is disadvantaged by their social positioning or other socially determined circumstances (8). Randomized trials are a powerful design for determining the relative impact of an intervention (9). Nevertheless, for randomized trials to contribute effectively to policies that promote health equity, there remain challenges to overcome (10). For example, poor reporting of equity considerations for randomized trials can have undesired effects on health systems' organizational practices and policies, clinical and public care. Additionally, some interventions can even aggravate and/or undermine health equity (11). Reporting guidelines are needed to support the consideration of equity in the conduct of and communication about randomized trials.

Engagement is defined here as an arrangement with those who influence, administer and/or who are active users of healthcare systems in the governance of the research process to co-lead research and that leads to co-creation of knowledge (beyond being a research participant) (12). While the engagement of knowledge users has been identified as important for clinical guideline development (13, 14), a recent review of clinical guidelines show that there is evidence for low levels of such engagement (15). Achieving consensus among developers of health research guidelines has been identified as important (16), but there is little information on how to achieve consensus when involving inter-disciplinary knowledge users that include patients and members of the public in reporting guideline development (17).

"CONSORT-Equity 2017"

Wishing to produce the highest quality reporting guideline and recognizing that the uptake of the resulting reporting guideline would be critical to improving the reporting of future trials (18), between 2015 and 2017, an interdisciplinary group of knowledge users and researchers came together as an advisory board-researcher team ("the team") to develop an equity extension of CONSORT, "CONSORT-Equity 2017" (7).

Of particular concern to the group was the need to prompt careful consideration of the knowledge translation issues that might promote uptake of the final reporting guideline product (that is, the equity extension of the CONSORT guideline). "Knowledge translation" (KT) is a term used to refer to processes that bridge the "know-do" gap which is defined as the gap between what is learned from research and the implementation of what is learned by knowledge users, with the aim to improve health delivery systems and health outcomes (19). Initially, know-do gaps (for example, uptake of reporting guidelines) were considered simply a problem of knowledge transfer (20) and with end users only needing to become aware of the knowledge and they would implement it. Understandings of the cause of know-do gaps continue to evolve, and now these gaps are considered to be more of a knowledge production problem (the knowledge being produced does not meet the needs of those who should be using it). Taking this later perspective, addressing the know-do gap requires researchers to begin thinking of KT before knowledge is created (21, 22). Proposed as an approach to address the issues of knowledge production and application (21, 22), "integrated knowledge translation" (integrated KT) is also identified as an approach that is more likely to lead to the practical application of knowledge (20, 23) because knowledge users are involved in co-creating the research which means the findings

are more likely to be useful, useable and used (21, 22). As there are issues with the uptake of reporting guidelines (6) an integrated KT approach is appropriate for the development of reporting guidelines.

Given the presumed benefits of an integrated KT approach and the desire to maximize the quality, usefulness and use of the reporting guideline, the group decided to adopt an integrated KT approach to the development of the CONSORT- Equity 2017 reporting guideline so as to optimize the co-creation of the guideline. In the case of CONSORT-Equity 2017, people from a broad range of disciplines who are involved in research-related activities and disciplines such as clinical epidemiology, economics, social science, public health, international development, knowledge translation, patients or patient organizations ("patients") and members of the public are potential users of the reporting guideline (those for whom the research is meant to ultimately be used by) and so were invited to engage in the research to develop the reporting guideline.

The objective of this paper is to describe the use of an integrated KT approach in the development of the CONSORT-Equity 2017 reporting guideline and team members' perceptions of the integrated KT process.

METHODS

We adopted an observational study design involving participant observation supplemented with a survey of team members to produce a description of team processes and experiences with the structured integrated KT approach used to develop the CONSORT-Equity 2017 reporting guideline (7). The research stages followed in developing the reporting guideline are described in

detail in a published protocol (7). Participant observation is a qualitative and interactive process that connects to human experience through immersion and participation in a particular context (24). The processes to develop CONSORT-Equity 2017 were structured by a framework that depicts integrated KT (25). The framework originally was developed to describe the collaborative processes of work conducted by researchers in full partnership with an Indigenous community to culturally adapt a shared decision making tool through research processes of development, conduct and dissemination (25). The framework consists of two stages that involve knowledge users and researchers agreeing to establish the parameters of the study (forming an advisory body, agreements on the approach to ethics, and theoretical assumptions in the research) and then the conduct of the study with the knowledge users and researchers in full partnership throughout the steps of a series of studies. The collaborative framework describes structured processes of negotiation within the study partnerships and that engages knowledge users as full partners with researchers (25). As engagement of knowledge users throughout the development of CONSORT-Equity 2017 was a priority, the framework was selected as appropriate for use. We describe the study processes of CONSORT-Equity 2017 in relation to the framework that depicts integrated KT.

We used the previously developed framework to guide and organize documented observations and events to describe the development of CONSORT-Equity 2017 (26). At the completion of the study, team members were surveyed about their perceptions of the integrated KT approach.

The survey was developed for team members to gather their feedback on the experience with the integrated KT approach. In consultation with an integrated KT expert (IDG), an eight-question

on-line survey consisting of two Likert and six open-ended questions about experience with integrated KT during the CONSORT-Equity 2017 study was developed, pilot-tested and research ethics approval obtained from the Bruyère Research Ethics Board (Bruyère REB Protocol # M16-15-042). The survey questions were designed to evoke understandings of the team experiences, with the two Likert questions about the extent to which team members felt they were engaged, and satisfaction with engagement. The open-ended questions were aimed at details on the experience with integrated KT during the CONSORT-Equity 2017 study. The team members were asked to participate in a survey following the development of the CONSORT-Equity 2017 reporting guideline. There were 38 individuals invited to participate in the survey, with one declining to participate due to time constraints.

Following a process of informed consent, the survey was administered in July 2017 to the team members. The frequency of the responses to the two Likert questions were tabulated. To analyze participant responses to the six-open ended survey questions, a process of inductive content analysis was used and that involves segmenting responses by topics and into categories. For the analysis of these responses, each question was considered to be a topic and the responses and development of codes defined the content in each category (27). One researcher conducted the content analysis process (JJ) and that was confirmed by a second reviewer (MY).

Patients and Public Involvement

Knowledge users who include patients and members of the public have been involved in the design, conduct and reporting of the work reported in this manuscript to develop CONSORT-Equity 2017, and are also identified as co-authors or acknowledged on the work presented here.

Patient priorities, experience, and preferences informed the development of research questions and outcome measures that are reported in this document to describe the research processes of CONSORT-Equity 2017. Patients were also involved in the design of the study reported in this paper and that is the result of consultation with the knowledge user group about reporting on the experience with an integrated KT approach to develop CONSORT-Equity 2017. Patients were involved in the recruitment to the study reported here and have participated in the development of this document. The membership and roles of knowledge users who include patients and members of the public are reported in the study protocol and final product documents (7, 17, 18, 28). For this reason, the work that is presented here is one example of how to conduct and report on the development of reporting guidelines in ways that include knowledge user priorities, experiences and preferences and that include patients and members of the public (29).

RESULTS

The development of CONSORT-Equity 2017 used an integrated KT approach to structure replicable steps: to conduct research in a collaborative manner that uses consensus-building methods and involves co-creation of knowledge (25); and, to develop a reporting guideline for equity (CONSORT-Equity 2017). The process for co-creating the reporting guideline involved two stages: 1) establishing guiding features for co-creation, and 2) engaging knowledge users and researchers (the team) in research actions that supported the co-creation of the reporting guideline.

Stage 1: Established Guiding Features for Co-creation

Preparation: Finding common ground. Initiating a process to engage researchers with potential knowledge users in the development of CONSORT-Equity 2017 involved: 1) identifying knowledge users' interests and concerns and finding alignment with researchers; 2) building relationships among knowledge users and researchers; 3) defining parameters of team relationships to find common ground through collaboration (25).

Finding common ground was an iterative three-step process of preparation of researchers, knowledge users and resulted in an agreed-upon agenda aimed at identifying their common interests. Two researcher members (VW, PT) recognized the interest and need to extend CONSORT for equity. Next, these researcher members identified other individuals (funders, journal editors, researchers) who held relevant knowledge and who shared concerns about equity in health systems, and so relationships were built among these individuals to form a rudimentary research team. The growing research team defined the objectives of a reporting guideline project and parameters in a proposal that was submitted for funding. Following the success of the funding proposal, the iterative, three-step process was then engaged in again with the recognition of the need to include a broader range of knowledge users.

An Advisory Board was formed. Collaboration with knowledge user groups during the development of CONSORT-Equity 2017 was identified as an important feature of the study by the research team, and with a decision to form an advisory board of intended users of the reporting guideline. The importance of collaboration with knowledge user groups during the development of CONSORT-Equity 2017 led to the deliberate defining of roles and recruitment

of nine knowledge users to the advisory board: journal editors, trialists, bioethicists, patients and members of the public, clinicians, systematic review authors, policy makers, and funders. The advisory board is described in detail elsewhere (7). The need to ensure communication within and between the members of the advisory board-researcher groups was identified, and two members of the researcher group were selected as facilitators: one with the advisory board (JJ) and the other with the researcher group (VW).

The facilitator identified to coordinate the advisory board (JJ) worked with the advisory board to define terms of reference and that included expectations (for example, meetings, types of contributions) and opportunities (for example, authorship guidelines) (Table 1). The facilitators (JJ, VW) worked to make plans and schedule events that created opportunities for the advisory board-researcher groups, referred to as "the team", to function in a partnership to promote inclusion and respect for a multiplicity of views in the CONSORT-Equity 2017 study. The engagement between the members of the team created opportunities to explore concepts related to health equity, and are reflected in products (for example, a tool to identify when a randomized trial is health-equity relevant (18)). Finally, the team members defined and agreed upon an agenda for the study and that is published in a protocol (7).

Commitment to Ethical Guidance. The members of the team agreed to collaborate and engage in decisions about how to structure the development of the reporting guideline so that there was adherence to ethical guidelines. The aim was to ensure respect for and representation of a broad range of views through agreements, structured communication and consensus-building processes

(18). The team agreed to adhere to Canadian ethical research guidelines during the conduct of the CONSORT-Equity study(30).

Theoretical Perspective Clarified. Absent and/or poor-quality evidence about health equity is identified by policy makers as a key limitation of research (31). The team identified the lack of consensus on the use of terminology related to health equity concepts and underpinning assumptions as critical to address in the reporting guideline. Therefore, the members of the team sought to clarify terminology and relate these understandings in publications to define the study parameters (7, 18). The team reflected on the underpinning assumptions throughout the reporting guideline development process (for example, a focus on social determinants of health theory, revisiting and reflecting on meanings of health equity et cetera).

Stage 2: Research actions that supported the co-creation of the reporting guideline

Reporting guideline development process. The agreed-upon guiding features of the research approach (Stage 1) were used to structure the multi-phase CONSORT-Equity 2017 study to accomplish objectives and create products over a two-year timeframe (Table 2). The use of participatory methods were used to promote consensus building, and to result in the co-creation of knowledge during the guideline reporting development. Stage two consisted of five steps during which studies for consensus-based reporting guidelines were conducted. The team co-created the CONSORT-Equity 2017 following the methodology for reporting guideline development advanced by Moher et al. (16) and with the innovation of key informant interviews (17). The five steps in reporting guideline development are: (i) define (establish guideline need within knowledge user and researcher collaboration), (ii) assess (state of the literature,

consultation with experts on health equity), (iii) develop/adapt (propose and debate adaptation of the reporting guideline), (iv) disseminate (develop and execute plan for uptake of the reporting guideline), and (v) apply (process of road-testing the reporting guideline).

Role of advisory board membership	-Members to participate in a collaborative process -Members will provide content-related support, and bring knowledge, skills and experience to the working group throughout the multiple stages of the research study process (i.e., the integrated Knowledge Translation (KT) process including the end-of-grant dissemination)
Method and frequency of communication	-The facilitator (JJ) will provide study background documents -Agendas to be provided in advance of meetings, with identification of key decisions to be made by the advisory board -There will be ongoing opportunities for communication, in a manner that facilitates the function of advisory board members in their roles
Description of workload	-Meeting participation by members -Provision of feedback on key issues will be made in meetings or by email correspondence -There will be opportunities for interested advisory board members to meet authorship criteria (see below "Authorship")
Timelines	-The advisory board involvement is anticipated to begin in June 2015, and end in December 2016 -Meetings and/or updates will occur every 2 to 3 months (3 to 5 meetings/year, and with brief email correspondence)
How advice will be managed	-Advisory board input will be sought and considered along with that of the core research team. -Disagreements on views will be respectfully and collaboratively managed by the advisory board facilitator (JJ)
Authorship	-Criteria outlined by International Journal Committee of Medical Journal Editors (IJCME) will be used to guide publication authorship (32).

Table 1. Terms of Reference

Table 2. Stages in the development of CONSORT-Equity 2017 update terms

Stage 1: Establish Guiding Features	**Example**
1) Find Common Ground	A process to initiate and develop a collaborative work plan that for CONSORT-Equity 2017 was an iterative 3-step process to prepare researchers, knowledge users and set an agreed-upon agenda that resulted in a published protocol (7).
2) Form an advisory board	Defined advisory board roles, accessed networks to recruit advisory board members; terms of reference to structure relationships within and between the advisory board-researcher collaboration (Table 1). Consensus building processes promoted engagement in active debate and co-creation of knowledge that resulted in, for example, defining and validating when a randomized trial is health- equity relevant (18).
3) Commit to ethical guidance	Advisory board-researcher collaboration agreed on study conduct to adhere to ethical guidelines (in Canada, the Tri-Council Policy Statement Version 2 (33) and that could include other research ethics protocols or requirements considered relevant by knowledge user partners, such as the example of research conduct with Indigenous Peoples (34, 35).
4) Clarify theoretical perspective	CONSORT-Equity 2017 is premised on understandings of key concepts, their definitions and usage among the advisory board-researcher collaboration: understandings of health equity and agreements among members about underpinning assumptions: the role of social determinants of health theory, a definition of "health equity", a health-equity relevant randomized trial, when is there a health disadvantage and that are reflected in publications (7, 18).
Stage 2: Research actions that supported the co-creation of the reporting guideline. Reporting guideline development process steps.	**Example**: The five reporting guideline development steps in stage 2 are bound by the guiding features of stage 1.
1) Define	Establish guideline need within knowledge user and researcher collaboration: knowledge users were engaged with researchers in a process to determine whether and how they might collaborate to develop an extension of CONSORT for equity. Following funding further work among the team resulted in a published protocol (7) and a tool that determines when a randomized trial is health-equity

	relevant (18) and so should use a reporting guideline for health equity.
2) Assess	Determine the state of the literature (7, 28, 36), consultation with experts on health equity and that included the use of key informant interviews with interdisciplinary knowledge users(17).
3) Develop/Adapt	Propose and debate adaptation of the reporting guideline: Following identification of diverse potential guideline users from high, middle and lower income countries including knowledge users such as patients and methodologists, were invited to participate in an online Delphi study to identify items for the reporting guideline (28), and a consensus meeting (the 2016 Boston Equity Symposium) held to discuss and debate evidence for inclusion in CONSORT-Equity 2017 (28).
4) Disseminate	Develop and execute plan for uptake of the reporting guideline Study outcomes are reflected in the success of an invitational study meeting (the 2016 Boston Equity Symposium) and co-authored publications (17, 18, 28, 36, 37) and the CONSORT-Equity 2017 checklist elaboration and explanation (28, 38).
5) Apply	A process of road-testing the reporting guideline: Work is underway to further disseminate and promote the application of the CONSORT-Equity 2017 guideline.

Extent of knowledge user engagement

The use of the integrated KT approach facilitated engagement within the team by creating structures and opportunities for all team members to offer their views for the development of CONSORT-Equity (17, 28). We failed to engage with one advisory board member due to time constraints around their ability to participate; and it was not possible for every member of the team to have their views accommodated and some members chose to remove themselves from participation either temporarily or permanently (n=2). As well, it was not possible (and indicated as not desirable by members of the team) for every member to participate in every step of the

guideline development process, although opportunities to participate were actively welcomed and sought by the facilitators. For the CONSORT-Equity 2017 study there are publications (see Table 2) that document descriptions of the particular study processes, and that include identification of who and how the team members were involved.

As collaboration and consensus-building methods were a central feature in CONSORT-Equity 2017 development, it was also important to understand the experiences of all those who were involved in the reporting guideline development. An eight-question on-line survey consisting of two Likert and six open-ended questions about experience with integrated KT during the CONSORT-Equity 2017 study was administered to team members. Twenty-four of the 37 team members responded to the first two Likert questions on the survey (response rate of 65%). When asked "Overall, how would you rate the extent to which the research team engaged you in the study? (Where 1 is not at all satisfied and 5 is totally satisfied)" 18/24 (75%) of surveyed respondents indicated "very or totally satisfied". An illustrative quote was: "I had a concrete role in the process and the team was very respectful and considerate of input so it was easy to feel invested". In response to the second Likert question "How satisfied are you with the level of your engagement with the research team? (Where 1 is not at all satisfied and 5 is totally satisfied)", 21/24 (87.5%) of the respondents indicated "very or totally satisfied". An illustrative quote from this response was: "[I would] be happy (very) if all research teams engaged all participants in the same manner".

Table 3. Results of two Likert questions on a team survey about experience with integrated knowledge translation (KT) approach (n=24)

Question	Response category					Illustrative quote from relevant open-ended questions
Overall, how would you rate the extent to which the research team engaged you in the project. (n=24)	1 (not at all satisfied): n=0 (0%)	2 (somewhat satisfied): n=2 (8%)	3 (satisfied): n=4 (16.6%)	4 (very satisfied): n=3 (12.5%)	5 (totally satisfied): n=15 (62.5%)	"I had a concrete role in the process and the team was very respectful and considerate of input so it was easy to feel invested".
How satisfied are you with the level of your engagement with the research team. (n=24)	1 (not at all satisfied): n=1 (4%)	2 (somewhat satisfied): n=0 (0%)	3 (satisfied): n=2 (8%)	4 (very satisfied): n=3 (12.5%)	5 (totally satisfied): n=18 (75%)	"[I would] be happy (very) if all research teams engaged all participants in the same manner".

In the portion of the survey that included six open-ended questions, respondents were asked to provide details about their experience with integrated KT during the CONSORT-Equity 2017 study. Frequency counts of the type of responses were recorded and are reported in Table 3 with example quotes.

When participants were asked what they perceived as the benefits of an integrated KT approach (question 1), the most common (14/25; 56%) response described integrated KT as an approach that allows multiple voices/opinions to be heard and considered. In response to being asked about whether they thought that the team faced any challenges in the study as the result of the integrated KT approach (question 2), many participants (8/25; 32%) reported that the logistics involved with including lots of people was a challenge, but a slightly larger number (9/25; 36%) reported that they were unaware of any team challenges. When asked about whether they faced any challenges during the development of the reporting guideline as the result of the integrated KT approach (question 3), the vast majority of participants (19/25; 76%) indicated that they did not face any challenges.

Participants were asked what they considered to be the impact(s) of using an integrated KT approach with reporting guideline development (question 4), and nearly a majority (11/25; 44%) indicated that an integrated KT approach improved the relevance of the final guideline product. When asked if they would change anything about how the integrated KT approach was used (question 5), few participants provided a response (n=15) and of those that did indicate a response, most participants (8/15; 53%) indicated that they would not have changed anything. Finally, when asked for additional comments (question 6), while most respondents (19/25; 76%) provided no comments, some (6/25; 24%) reported that the integrated KT process was a positive experience (Table 4).

During the CONSORT-Equity 2017 study, team members were found to be more engaged in particular activities in relation to their knowledge, and/or in relation to life events. The

CONSORT-Equity 2017 study was voluntary for most team members – and so was unpaid work – and other duties and personal factors (for example, health issues) meant that participation was not always an option for team members.

Table 4. Results of six open-ended questions on a team survey about experience with integrated knowledge translation (KT) approach (n=25).

Question	Response
1. What do you perceive as the benefits of an integrated knowledge translation (KT) approach to develop a reporting guideline extension of CONSORT for equity?	1) Allows consideration and inclusion of a range of views (14/25; 56%): "Capturing a multitude of perspectives, to enhance relevance and acceptability of reporting guidelines across disciplines". 2) Fosters engagement in study processes (6/25; 24%): "It allows participation and engagement of various stakeholders at all stages of the project for whom the guideline is relevant". 3) Enhance guideline uptake (5/25; 20%): "Results are more likely to be adopted and applied".
2. Do you think that the team faced any challenges in the study as the result of the integrated KT approach?	1) The logistics of including a range of people in the team (8/25; 32%): "Takes more time to work with a large and diverse crowd". 2) Management of views (5/25; 20%): "Because of the wide range of different disciplines present, it may have been difficult to engage all participants equally across all issues". 3) Reconciliation of within-team differences (3/25; 12%): "It is difficult to deal with perhaps conflicting and at times unclear opinions". 4) Unaware of any team challenges (9/25; 36%): "Not that I'm aware of".
3. Did you face any challenges in the study as the result of the integrated KT approach?	1) No personal challenges faced in the study (19/25; 76%): "I did not face any challenges. My input and participation had equal standing in the process". 2) The personal experience of challenge related to the pace, number of consultations, and/or to provide informed opinions (6/25; 24%): "It was slow at times and a bit frustrating. We achieved what we did through patience, persistence and good will of team members".
4. What do you consider to	1) Improves the final guideline product (11/25; 44%): "I feel

be the impact(s) of using an integrated KT approach with the study?	that we produced a product that was relevant to all of our team members, and that they can support in their communities". 2) Inclusion of different forms of knowledge (11/25; 44%): "It ensures that the study is better informed by the expertise, perspectives and needs of the different stakeholders". 3) Unsure/did not notice impact of integrated KT approach (3/25; 12%): "Not sure".
5. Would you have changed anything about how the integrated KT approach was used in the study? If yes, how?	1) Would not change the use of the integrated KT approach (8/15; 53%): "No change suggested". 2) Greater range of participants (3/15; 20%): "I would have tried to broaden the scope of stakeholders". 3) Narrow the stakeholder focus and seek more intense consultations, such as through in-person meetings (2/15; 13%): "Smaller reach, deeper consultation". 4) More time (2/15; 13%): "More time is always a benefit to measure the impact".
6. Do you have any additional comments**?**	1) No comment (19/25; 76%). 2) Indicated that it was a positive experience (6/25; 24%): "I would do this again".

DISCUSSION

The team engaged in mutually-agreed upon processes to co-create knowledge and assemble empirical evidence to develop a reporting guideline, CONSORT-Equity 2017. The team was established to function as a partnership throughout the study process to promote inclusion and respect for a range of views. A structured integrated KT approach was used to organize ongoing negotiations and replicable steps that occurred within the team. The aim was to ensure that the goals of the study were achieved: to conduct research in a collaborative manner that uses consensus-building methods and involves co-creation of knowledge; and, to develop a reporting guideline for equity (CONSORT-Equity 2017) as a contribution to address health systems equity issues.

Perceptions of the integrated KT approach and impacts on co-creation of knowledge

Our study involved an interdisciplinary advisory board-researcher collaboration and included patient and members of the public, with 38 members from eight countries who collaborated in the development of CONSORT-Equity. Details on the team members and study processes are reported in detail elsewhere (7, 28). There is little evidence in the literature about the experiences of interdisciplinary teams that include patients, members of the public, journal editors, trialists, bioethicists, clinicians, systematic review authors, policy makers, and funders. Previous studies that investigate patient perspectives on their involvement in clinical guideline development concluded that effective engagement requires planning, and the recommendations arising from that work include: the use of smaller and more diverse groups, with no prior relationships with other members of the team; individual and group preparation for engagement on the team; and, an identified contact person for participants (39).

Many options exist to facilitate collaboration within research partnerships and that foster democratic approaches to knowledge creation (23, 40-42). Integrated KT was identified as appropriate for our study, as it focuses on the co-creation of knowledge with practical applications (23). Furthermore, we found that an integrated KT approach provided many opportunities to be fully involved in the entire research process and as had been planned for during protocol development (7). Such an approach begins with an iterative process of preparation for participation in research partnerships, a feature reported in other frameworks that structure knowledge user engagement in health research (41, 43, 44). The members of the team were invited to participate in all phases of the reporting guideline development process, and efforts were made to accommodate their participation. Evidence for the value of knowledge user

engagement in reporting guideline development is asserted in a sub-study conducted with interdisciplinary key informants. This study, which engaged key informants in interviews about their views and suggestions for an extension of CONSORT for equity, generated new concepts that contributed to the development of CONSORT-Equity 2017 (17). We prioritized the engagement of team members throughout the CONSORT-Equity 2017 study to improve the likelihood that CONSORT-Equity 2017 would be perceived as useful and applicable in practice. To strive for authentic (that is, ethical, equitable) engagement, deliberate efforts were made to foster relationships among the broad range of knowledge users and researchers.

The success of the longer-term engagement of team members was possibly due to the structured integrated KT approach that fostered processes of negotiation and created opportunities for team members to choose their level of engagement. For example, there were ongoing opportunities for members of the collaboration to engage at different stages of the CONSORT-Equity 2017 study. These opportunities were initially identified during the preparation for the CONSORT-Equity 2017 study. The iterative and prolonged focus on preparation of the researchers and knowledge users led to the development of a shared agenda for the CONSORT-Equity 2017 study. The finding of a focus on iterative preparation is an innovation on the original framework used to guide the integrated KT approach (Figure 1). The opportunity to prepare advisory board members and researchers to engage in the CONSORT-Equity 2017 study and to work together led to opportunities to develop and make shared understandings and agreements explicit. The facilitators of the advisory board and researchers built on the success of the initial engagement of team members in the reporting guideline development, and created frequent and varied opportunities for ongoing participation in the CONSORT-Equity 2017 study processes (for

example, through scheduled face-to-face and/or telephone calls, maintained regular email study updates).

The experience with varied levels of engagement by team members in the CONSORT-Equity 2017 study led to consideration of the meaning of "engagement" among an interdisciplinary team of knowledge users and researchers. Overall, a committed group of team members were involved in a collaborative effort for the duration of the CONSORT-Equity 2017 study. They met and agreed upon study objectives and this in turn resulted in co-created products. However, during the series of CONSORT-Equity 2017 studies the nature and degree of engagement varied over time and according to the capacity of team members and study tasks. Team members: asking to be kept informed but not wanting to actively participate (for example, one-way direction of information updates on the study such as an email with announcements); being consulted for feedback (for example, responding to an email request for information or feedback on a document); supporting others who provide governance in the CONSORT-Equity 2017 study processes (for example, providing support in a study in response to requests by team leads); sharing in the governance of the study (for example, advising and/or decision making in a co-leading role, such as in development of CONSORT-Equity 2017 study directions or products), to, in some instances and for particular topics, leading the process (for example, knowledge users who are thought leaders on topics taking the lead and directing other members of the team – including researchers – in the study to support their initiatives). The different levels at which knowledge user engagement may occur has been under examination for many years, one of the earliest instances is Arnstein's 1969 ladder of participation and that ranges from non-participation to citizen control (45). Since then there have been many other ways of

conceptualizing knowledge user engagement in research (46-48). During our CONSORT-Equity 2017 study, we accomplished engagement of knowledge users in study governance – and then exceeded this aim with knowledge user leadership. There are documented instances of knowledge users taking the lead during parts of the CONSORT-Equity 2017 study conduct and that occurred during meetings (for example, expert knowledge user leads taking initiative with and guiding sessions at the Boston Equity Symposium) and with study publications (37). The range of engagement that was observed during the CONSORT-Equity 2017 study processes demonstrate that engagement may be more changeable and nuanced –and less able to be anticipated - than is currently described in the literature encouraging knowledge user engagement (12, 47). The use of the structured integrated KT approach allowed members of the team to determine how and in what capacity they would contribute, while also being engaged to co-create a reporting guideline.

Limitations and strengths of the integrated KT approach

The main limitations (challenges) of an integrated KT approach were identified by members of the team on the survey and found to be the logistics of including a range of people in the study, and the management of their views. The facilitators of the advisory board and researchers reflected on the logistics and the challenges of scheduling meetings to accommodate or align with work roles (outside of CONSORT-Equity) and time constraints for those on the team to participate in the study. As well, there may have been impacts on participation of team members due to the reliance upon the facilitators who were based at one site and responsible for fostering regular and productive contacts, and with the use of online communications (versus face-to-face meetings). For example, communication between and within those on the team was a challenge

due to the logistics of time zones, the numbers of people, limitations of technology. These challenges were further complicated by the need to bring views of the group together in consensus to achieve CONSORT-Equity 2017 study objectives. The surveyed members of the team identified the main strength of the integrated KT approach to be the consideration and inclusion of a range of views in the research process. The facilitators of the team reflected on the use of study processes structured by the integrated KT approach that, for the duration of the study, make it possible to build and/or strengthen research relationships initiated at the start of the study and across a range of team members. These research relationships were demonstrated by participation in publication co-authorship, attendance at regular meetings, email contacts, and feedback on products.

Limitations of the study about the integrated KT approach

Limitations of the study reported in this paper include that the work was done with a smaller group of diverse team members, and that all team members shared an interest in the work related to the development of a reporting guideline (CONSORT-Equity 2017). For this reason, the findings about the integrated KT process presented here have not been documented in this way before, and may not be relevant to other teams that consist of a different groups of team members, and that have different team objectives. In addition, the methods we used are observational and not established for use with teams who are engaged in multiple series of studies to develop an end-product (in our instance, a reporting guideline).

CONCLUSIONS

A structured integrated KT approach was successfully used to engage knowledge users with researchers in a mixed-method study to develop a reporting guideline, CONSORT-Equity 2017. The CONSORT-Equity 2017 study was governed by an interdisciplinary advisory board populated by knowledge users and a group of researchers, in an advisory board-researcher collaboration. The use of an integrated KT approach fostered engagement of the advisory board – researcher collaboration in the study processes and prompted deliberation and consensus building among team members. Further work is needed to examine the collaborative framework components and its potential applications to other initiatives that engage researchers with knowledge users interested in and seeking to improve research reporting guidelines.

[Figure 1. Integrated Knowledge Translation (KT) approach for CONSORT-Equity 2017]

Ethics Approval: Participants gave informed consent before taking part in the study of the integrated KT approach used in the development of the CONSORT-Equity 2017 reporting guideline reported in this manuscript (Bruyère REB Protocol # M16-15-042).

Transparency Statement: The lead author and guarantor (JJ) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted. There were no deviations from what was planned.

Role of funding source: Funding was not received for this study.

Data sharing statement: No additional data available.

Competing interests: All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the previous three years; no other relationships or activities that could appear to have influenced the submitted work, with the following exceptions: 1) Dr. Cuervo reports he works as a Senior Advisor for Health Systems Research to the Pan American Health Organization/World Health Organization. His Organization's Policy on Research for Health calls for the development and use of research reporting standards and improving the value and impact of research for health. His opinions and contributions to this manuscript are his own and do not necessarily reflect the decisions or policies of his employer; 2) Dr. Moher reports that he is one of the 'inventors' of CONSORT; 3) Dr. Welch reports grants from Canadian Institutes of Health Research, grants from Ontario Early Career Researcher Award, during the conduct of the study.

Contributorship Statement: JJ, IDG, VW conceived and led the design of the work described in the manuscript and were responsible for the first and final drafts of this manuscript. EJ, DM,JP, MY, PT, VW and members of the CONSORT-Equity 2017 and Boston Equity Symposium coauthors participated in and provided substantial contributions to the analysis and interpretation during development of the work described in the manuscript. JJ led writing of the first version of the manuscript. JJ and IDG revised the manuscript. EJ, DM,JP, MY, PT, VW made contributions to drafts of this manuscript including the listed members of the CONSORT-Equity 2017 and Boston Equity Symposium, and have reviewed and revised the manuscript for important intellectual content and approved the final version of the manuscript.

Dr. Janet Jull is the guarantor of the article.

Acknowledgements
Collaborating authors who are identified as a member of the CONSORT-Equity and Boston Equity Symposium participants are as follows: Rebecca Armstrong, Sarah Baird, Yvonne Boyer, Luis Gabriel Cuervo, Regina Greer-Smith, Anne Lyddiatt, Jessie McGowan, Lawrence Mbuagbaw, Tomas Pantoja, Beverly Shea, Bjarne Robberstad, Howard White, George Wells. Reporting of involvement of patients and public is included here.

We thank the following individuals for their support and encouragement: Mark Petticrew, Jeremy Grimshaw, Charles Weijer, Monica Taljaard, Yukiko Asada.

JJ held a Canadian Institutes of Health Research (CIHR) Postdoctoral Fellowship for a portion of the time she was writing the paper.

IDG is a recipient of a CIHR foundation grant (FDN# 143237).

References- to be finalized

1. World Health Organization (WHO) Assembly. WHO Strategy on Research for Health; WHO Roles and responsibilities on health research: document WHA63.22 and Resolution. 20 Avenue Appia, 1211 Geneva 27, Switzerland; 2012.
2. Pan American Health Organization, DC, 61st Session of the Regional Committee of WHO for the Americas. Policy on research for health : document CD49/10. Washington, DC: PAHO; 2009.
3. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. Lancet. 2014;383(9913):267-76.
4. EQUATOR Network. The EQUATOR Network: Enhancing the Quality and Transparency of Health Research Centre for Statistics in Medicine (CSM), NDORMS, University of Oxford.: UK EQUATOR Centre; n.d. [Available from: https://www.equator-network.org/.
5. Centre for Journalology. Using Reporting Guidelines Ottawa Hospital Research Institute2019 [Available from: http://www.ohri.ca/journalology/docs/guidelines.aspx.
6. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. Syst Rev. 2012;1:60.

7. Welch V, Jull J, Petkovic J, Armstrong R, Boyer Y, Cuervo LG, et al. Protocol for the development of a CONSORT-equity guideline to improve reporting of health equity in randomized trials. Implement Sci. 2015;10:146.
8. Whitehead M. The concepts and principles of equity and health. Int J Health Serv. 1992;22(3):429-45.
9. Sackett D, Rosenberg W, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312:71-2.
10. Marmot M, Allen J, Bell R, Goldblatt P. Building of the global movement for health equity: from Santiago to Rio and beyond. Lancet. 2012;379(9811):181-8.
11. Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. J Epidemiol Community Health. 2013;67(2):190-3.
12. Canadian Institutes of Health Research (CIHR). Patient Engagement: What is patient engagement? Government of Canada 2018 [Available from: http://www.cihr-irsc.gc.ca/e/45851.html.
13. Jarrett L, Patient Involvement Unit (PIU) PIU. Patient Involvement Unit (PIU). A report on a study to evaluate patient/ carer membership of the first NICE Guideline Development Groups. London: National Institute for Clinical Excellence (NICE); 2004.
14. Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. Ann Intern Med. 2012;156(7):525-31.
15. Armstrong MJ, Bloom JA. Patient involvement in guidelines is poor five years after institute of medicine standards: review of guideline methodologies. Res Involv Engagem. 2017;3:19.
16. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med. 2010;7(2):e1000217.
17. Jull J, Petticrew M, Kristjansson E, Yoganathan M, Petkovic J, Tugwell P, et al. Engaging knowledge users in development of the CONSORT-Equity 2017 reporting guideline: a qualitative study using in-depth interviews. Res Involv Engagem. 2018;4:34.
18. Jull J, Whitehead M, Petticrew M, Kristjansson E, Gough D, Petkovic J, et al. When is a randomised controlled trial health equity relevant? Development and validation of a conceptual framework. BMJ Open. 2017;7(9):e015815.
19. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? J Contin Educ Health Prof. 2006;26(1):13-24.
20. Canadian Institutes of Health Research (CIHR). Guide to knowledge translation planning at CIHR: integrated and end-of-grant approaches 2015 [Available from: http://www.cihr-irsc.gc.ca/e/45321.html.
21. Van de Ven D, Johnson P. Knowledge for theory and practice. Academy of Management Review. 2006;31(4):802-21.
22. Bowen S, Graham I. Integrated Knowledge Translation. In: SE Straus, J Tetroe, ID Graham, editors. Knowledge Translation in Healthcare: moving evidence to practice. West Sussex: Wiley; 2013. p. 14-23.
23. Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge. Implement Sci. 2017;12(1):150.

24. Guest G NE, Mitchell ML. Collecting Qualitative Data: A Field Manual for Applied Research. 2013 2019/02/16. 55 City Road, London: SAGE Publications, Ltd; [75-112]. Available from: http://methods.sagepub.com/book/collecting-qualitative-data.
25. Jull J, Giles A, Boyer Y, Stacey D, Minwaashin Lodge. Building and enacting ethical research processes: the example of culturally adapting a decision making strategy. ACME: An International Journal for Critical Geographies. 2016.
26. Jull J, CONSORT-Equity Team. The value of an integrated knowledge translation approach for developing reporting guidelines: engaging knowledge users interested in equity-relevant decision making. Knowledge Translation Canada Scientific Meeting Toronto, Ontario, Toronto, Ontario2016.
27. Morse J, Field P. Nursing research : the application of qualitative approaches. London: Chapman & Hall; 1996.
28. Welch VA, Norheim OF, Jull J, Cookson R, Sommerfelt H, Tugwell P, et al. CONSORT-Equity 2017 extension and elaboration for better reporting of health equity in randomised trials. BMJ. 2017;359:j5085.
29. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. Res Involv Engagem. 2017;3:13.
30. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2018 [Available from: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf].
31. Petticrew M, Whitehead M, Macintyre SJ, Graham H, Egan M. Evidence for public health policy on inequalities: 1: the reality according to policymakers. J Epidemiol Community Health. 2004;58(10):811-6.
32. International Committee of Medical Journal Editors (ICJME). Defining the role of authors and contributors 2018 [Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html].
33. Panel on Research Ethics. TCPS 2 – Chapter 9. Research Involving the First Nations, Inuit and Métis Peoples of Canada [Available from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/].
34. First Nations Information Governance Centre (FNIGC). The First Nations principles of OCAP® 2017 [Available from: http://fnigc.ca/ocap.html].
35. Canadian Institutes of Health Research (CIHR). CIHR guidelines for health research involving Aboriginal People. 2007 [Available from: http://www.cihr-irsc.gc.ca/e/29134.html.
36. Petkovic, Welch V, Jull J, Petticrew M, Kristjannson E, Radar T, et al. How is health equity reported and analyzed in randomised trials: Cochrane Systematic Review Registered Protocol. Cochrane Methodology Review Group. 2017(Issue 8 . Art. No.: MR000046).
37. Mbuagbaw L, Aves T, Shea B, Jull J, Welch V, Taljaard M, et al. Considerations and guidance in designing equity-relevant clinical trials. Int J Equity Health. 2017;16(1):93.
38. Simera I, Moher D, Hirst A, Hoey J, Schulz KF, Altman DG. Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. BMC Med. 2010;8:24.

39. Armstrong MJ, Mullins CD, Gronseth GS, Gagliardi AR. Recommendations for patient engagement in guideline development panels: A qualitative focus group study of guideline-naïve patients. PLoS One. 2017;12(3):e0174329.
40. West JF. Public health program planning logic model for community engaged type 2 diabetes management and prevention. Eval Program Plann. 2014;42:43-9.
41. James S, Arniella G, Bickell NA, Walker W, Robinson V, Taylor B, et al. Community ACTION boards: an innovative model for effective community-academic research partnerships. Prog Community Health Partnersh. 2011;5(4):399-404.
42. May M, Law J. CBPR as community health intervention: institutionalizing CBPR within community based organizations. Prog Community Health Partnersh. 2008;2(2):145-55.
43. Johnson DS, Bush MT, Brandzel S, Wernli KJ. The patient voice in research-evolution of a role. Res Involv Engagem. 2016;2:6.
44. Jinks C, Carter P, Rhodes C, Taylor R, Beech R, Dziedzic K, et al. Patient and public involvement in primary care research - an example of ensuring its sustainability. Res Involv Engagem. 2016;2:1.
45. Arnstein S. A ladder of citizen participation. Journal of the American Planning Association. 1969;35(4):216–24.
46. INVOLVE. NIHR INVOLVE 2001 [Available from: https://www.invo.org.uk/].
47. Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA, panel) Advisory Panel on Patient Engagement. The PCORI Engagement Rubric: Promising Practices for Partnering in Research. Ann Fam Med. 2017;15(2):165-70.
48. Forsythe LP, Ellis LE, Edmundson L, Sabharwal R, Rein A, Konopka K, et al. Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. J Gen Intern Med. 2016;31.

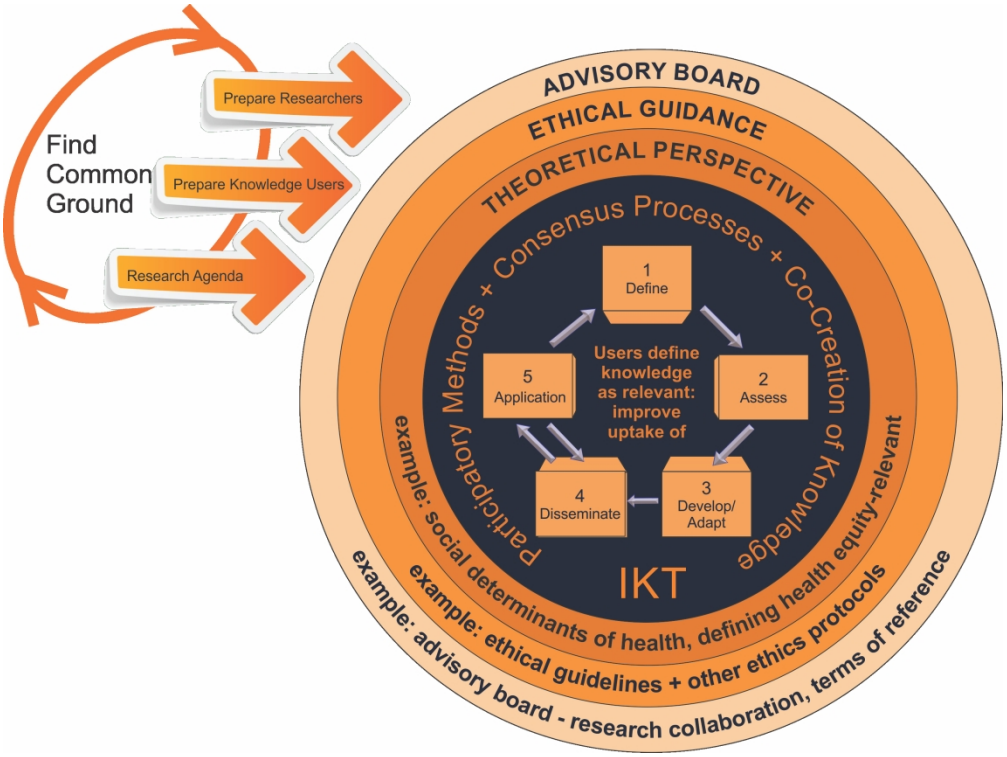

Find Common Ground
Prepare Researchers
Prepare Knowledge Users
Research Agenda
ADVISORY BOARD
ETHICAL GUIDANCE
THEORETICAL PERSPECTIVE
Participatory Methods + Consensus Processes + Co-Creation of Knowledge
1 Define
2 Assess
3 Develop/ Adapt
4 Disseminate
5 Application
Users define knowledge as relevant: improve uptake of
IKT
example: social determinants of health, defining health equity-relevant
example: ethical guidelines + other ethics protocols
example: advisory board - research collaboration, terms of reference

Figure 1.

BMJ Open

Taking an integrated knowledge translation approach in research to develop the CONSORT-Equity 2017 reporting guideline: An observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026866.R2
Article Type:	Research
Date Submitted by the Author:	29-May-2019
Complete List of Authors:	Jull, Janet; Queen's University, School of Rehabilitation Therapy; Ottawa Hospital Research Institute, Graham, Ian; Ottawa Hospital Research Institute, Kristjansson, Elizabeth; University of Ottawa, Institute of Population Health Moher, David; Ottawa Hospital Research Institute, Ottawa Methods Centre Petkovic, Jennifer; University of Ottawa, Bruyere Research Institute Yoganathan, Manosila; Elisabeth Bruyere Research Institute Tugwell, Peter; University of Ottawa, medicine Welch, Vivian A.; University of Ottawa, Institute of Population Health
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice
Keywords:	health equity, reporting guidelines, CONSORT, integrated knowledge translation, collaborative research, research co-creation

Title: Taking an integrated knowledge translation approach in research to develop the CONSORT-Equity 2017 reporting guideline: An observational study

Janet Jull
Assistant Professor, School of Rehabilitation Therapy, Queens University, Kingston, Ontario, Canada; Affiliate Investigator, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
janet.jull@queensu.ca

Ian D Graham
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute; Professor, School of Epidemiology and Public Health, University of Ottawa, Ottawa, Ontario, Canada
igraham@ohri.ca

Elizabeth Kristjansson
Associate Professor, Centre for Research on Educational and Community Services, School of Psychology, University of Ottawa, Ottawa, Ontario, Canada
kristjan@uottawa.ca

David Moher
Senior Scientist, ,Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Associate Professor, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Ottawa, Ontario, Canada.
dmoher@ohri.ca

Jennifer Petkovic
Coordinator, Campbell and Cochrane Equity Methods Group, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
jennnifer.petkovic@uottawa.ca

Manosila Yoganathan
Coordinator, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada
y.manosilah@gmail.com

Peter Tugwell
Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; Professor, Department of Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada; Professor, School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada
ptugwell@uottawa.ca

Vivian Welch
Scientist, Methods Centre, Bruyère Research Institute, Bruyère Continuing Care and University of Ottawa, Ottawa, Ontario, Canada,

vwelch@campbellcollaboration.org

AND

Members of the CONSORT-Equity 2017 and Boston Equity Symposium.

Corresponding Author: Dr. Janet Jull, janet.jull@queensu.ca

Abstract (299)

Objective We describe the use of an integrated knowledge translation (KT) approach in the development of the CONsolidated Standards Of Reporting Trials extension for equity ("CONSORT-Equity 2017"), and advisory board-research team members' ("the team") perceptions of the integrated KT process.

Design An observational study to describe team processes and experience with a structured integrated KT approach to develop CONSORT-Equity 2017. Participant observation to describe team processes and a survey were used with the 38 team members.

Setting Use of the CONSORT health-research reporting guideline contributes to an evidence base for health systems' decision-making, and CONSORT-Equity 2017 may improve reporting about health equity-relevant evidence. An integrated KT research approach engages knowledge users (those for whom the research is meant to be useful) with researchers to co-create research evidence and is more likely to produce findings that are applied in practice or policy.

Participants Researchers adopted an integrated KT approach and invited knowledge users to form a team.

Results An integrated KT approach was used in the development of CONSORT-Equity 2017 and structured replicable steps. The process for co-creating the reporting guideline involved two stages: 1) establishing guiding features for co-creation, and 2) research actions that supported the co-creation of the reporting guideline. Stage one consisted of four steps: finding common ground, forming an advisory board, committing to ethical guidance, clarifying theoretical research assumptions. Bound by the stage one guiding features of an integrated KT approach, stage two consisted of five steps during which studies for consensus-based reporting guidelines

were conducted. Of 38 team members, 25 (67.5%) completed a survey about their perceptions of the integrated KT approach.

Conclusions An integrated KT approach can be used to engage a team to co-create reporting guidelines. Further study is needed to understand the use of an integrated KT approach in development of reporting guidelines.

Strengths and limitations of this study

- Reporting guidelines in health research improve and contribute to a robust evidence base for health systems decision-making
- Integrated knowledge translation (KT) is an approach to research that structures the engagement of knowledge users, meaning those for whom the research is meant to ultimately be of use, with researchers to facilitate the co-creation of knowledge
- An integrated KT approach was used to engage knowledge users with researchers as a team, to develop the CONsolidated Standards Of Reporting Trials extension for equity ("CONSORT-Equity 2017") reporting guideline
- Limitations are that the use of an integrated KT approach includes the logistics of including a range of people and the management of views; the strengths include that the integrated KT approach allows consideration and inclusion of a range of views
- An integrated KT approach can be used to engage a team to co-create reporting guidelines.

INTRODUCTION

Reporting guidelines in health research are important, as they improve and contribute to a more robust evidence base for health systems decision-making (1, 2). There is a significant amount of avoidable waste in research (3), and part of this waste can be attributed to potentially useful research findings being disregarded because of inadequate reporting, which reporting guidelines can help address. Defined as a tool for use by health researchers to structure manuscript writing, reporting guidelines consist of minimal lists of information to ensure that a manuscript can be understood by a reader, replicated by a researcher, used by a clinician to make a clinical decision and included in a systematic review (4). The use of reporting guidelines in health research may improve completeness and transparency of reported evidence from research studies. Many examples of reporting guidelines can be found at the Ottawa Hospital Research Institute's Centre for Journalology site at http://www.ohri.ca/journalology/docs/guidelines.aspx (5), as well as the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network site at https://www.equator-network.org/ (4).

The internationally recognized CONsolidated Standards Of Reporting Trials (CONSORT) statement is an evidence-based guideline consisting of 25 items to encourage completeness and transparency in reporting of randomized controlled trials ("randomized trials"). CONSORT is in the form of a checklist and flow diagram (6). The checklist focuses on reporting how the randomized trial was designed, analyzed and interpreted and the flow diagram depicts participant progress through the randomized trial processes. Extensions to the CONSORT Statement have been developed for specific issues (for example, pragmatic trials, non-pharmacologic therapies,

and social and psychological interventions) (4). No extension has yet been developed to report items to assess the effects of an intervention on health equity (7).

Striving for health equity is a matter of social justice and implies that everyone can attain their health potential and that no one is disadvantaged by their social positioning or other socially determined circumstances (8). Randomized trials are a powerful design for determining the relative impact of an intervention (9). Nevertheless, for randomized trials to contribute effectively to policies that promote health equity, there remain challenges to overcome (10). For example, poor reporting of equity considerations for randomized trials can have undesired effects on health systems' organizational practices and policies, clinical and public care. Additionally, some interventions can even aggravate and/or undermine health equity (11). Reporting guidelines are needed to support the consideration of equity in the conduct of and communication about randomized trials.

"Knowledge users" are those who influence, administer and/or who are active users of healthcare systems, and who for our study were identified as potential holders of expertise about or relevant to health, research and/or reporting guidelines. "Engagement" is defined here as an arrangement with knowledge users in the governance of the research process to co-lead research and that leads to co-creation of knowledge (beyond being a research participant) (12). While the engagement of knowledge users has been identified as important for clinical guideline development (13, 14), a recent review of clinical guidelines show that there is evidence for low levels of such engagement (15). Achieving consensus among developers of health research guidelines has been identified as important (16), but there is little information on how to achieve

consensus when involving inter-disciplinary knowledge users that include patients and members of the public in reporting guideline development (17).

"CONSORT-Equity 2017"

Wishing to produce the highest quality reporting guideline and recognizing that the uptake of the resulting reporting guideline would be critical to improving the reporting of future randomized trials (18), between 2015 and 2017, an interdisciplinary group of knowledge users and researchers came together as an advisory board-researcher team ("the team") to develop an equity extension of CONSORT, "CONSORT-Equity 2017" (7).

Of particular concern to the team was the need to prompt careful consideration of the knowledge translation issues that might promote uptake of the final reporting guideline product (that is, the equity extension of the CONSORT guideline). "Knowledge translation" (KT) is a term used to refer to processes that bridge the "know-do" gap which is defined as the gap between what is learned from research and the implementation of what is learned by knowledge users, with the aim to improve health delivery systems and health outcomes (19). Initially, know-do gaps (for example, uptake of reporting guidelines) were considered simply a problem of knowledge transfer (20) and it was thought that end users only needed to become aware of the knowledge and they would then implement it. Understandings of the causes of know-do gaps continue to evolve, and now these gaps are considered to be more of a knowledge production problem (the knowledge being produced does not meet the needs of those who should be using it). Taking this later perspective, addressing the know-do gap requires researchers to begin thinking of KT before knowledge is created (21, 22). Proposed as an approach to address the issues of knowledge production and application (21, 22), "integrated knowledge translation" (integrated

KT) is also identified as an approach that is more likely to lead to the practical application of knowledge (20, 23). The engagement of knowledge users in co-creating the research means the findings are more likely to be useful, useable and used (21, 22). As there are issues with the uptake of reporting guidelines (6) an integrated KT approach is appropriate for the development of reporting guidelines.

Given the presumed benefits of an integrated KT approach and the desire to maximize the quality, usefulness and use of the reporting guideline, the team decided to adopt an integrated KT approach for the development of the CONSORT- Equity 2017 reporting guideline. In the case of CONSORT-Equity 2017, potential knowledge users of the reporting guideline were identified from a broad range of disciplines. These knowledge users are involved in research-related activities and disciplines such as clinical epidemiology, economics, social science, public health, international development, knowledge translation, patients or patient organizations ("patients") and members of the public and so were invited to engage in the research to develop the reporting guideline.

The objective of this paper is to describe the use of an integrated KT approach in the development of the CONSORT-Equity 2017 reporting guideline and team members' perceptions of the integrated KT process.

METHODS

We adopted an observational study design involving participant observation supplemented with a survey of team members. We produced a description of team processes and experiences with the

structured integrated KT approach used to develop the CONSORT-Equity 2017 reporting guideline (7). The research stages followed in developing the reporting guideline are described in detail in a published protocol (7). Participant observation is a qualitative and interactive process that connects to human experience through immersion and participation in a particular context (24). The processes to develop CONSORT-Equity 2017 were structured by a framework that depicts integrated KT, called the Collaborative Research Framework ("framework") (25).

The framework was selected as appropriate for use as engagement of knowledge users with researchers throughout the development of CONSORT-Equity 2017 was a priority. The framework was originally developed to describe the collaborative processes of work conducted by researchers in full partnership with an Indigenous community to culturally adapt a shared decision making tool through research processes of development, conduct and dissemination (25). The framework consists of two stages that involve knowledge users and researchers agreeing to establish the parameters of the study (forming an advisory body, agreements on the approach to ethics, and theoretical assumptions in the research) and then the conduct of the study with the knowledge users and researchers in full partnership throughout all the steps of a series of studies. The framework describes structured processes of negotiation within the study partnerships. It stresses the importance of engaging knowledge users as full partners with researchers in a team (25). We describe the study processes of CONSORT-Equity 2017 in relation to the framework that depicts integrated KT.

We used the framework to guide development of CONSORT-Equity 2017 and to organize documented observations and events that describe the development of CONSORT-Equity 2017

(26). At the completion of the study, a survey was conducted with team members about their perceptions of the integrated KT approach.

A survey was developed for team members to gather their feedback on the experience with the integrated KT approach. In consultation with an integrated KT expert (IDG), an eight-question on-line survey consisting of two Likert questions with an option for an open-ended comment, and six open-ended questions about experience with integrated KT during the CONSORT-Equity 2017 study was developed and pilot-tested. Research ethics approval was obtained from the Bruyère Research Ethics Board (Bruyère REB Protocol # M16-15-042). The survey questions were designed to evoke understandings of the team experiences, with the two Likert questions about the extent to which team members felt they were engaged, and their satisfaction with engagement. The open-ended questions were aimed at soliciting details on the experience with integrated KT during the CONSORT-Equity 2017 study. The team members were asked to participate in a survey following the development of the CONSORT-Equity 2017 reporting guideline. There were 38 individuals invited to participate in the survey, with one declining to be invited to participate due to their personal time constraints.

Following a process of informed consent, the survey was administered in July 2017 to the team members. The frequency of the responses to the two Likert questions was tabulated. To analyze participant responses to the six-open ended survey questions, a process of inductive content analysis was used, which involves segmenting responses by topics and into categories. For the analysis of these responses, each question was considered to be a topic and the responses and

development of codes defined the content in each category (27). One researcher conducted the content analysis process (JJ) and that was confirmed by a second reviewer (MY).

Patients and Public Involvement

Patients (that is, patients and members of the public) were members of the team involved in the design, conduct and reporting of the work to develop CONSORT-Equity 2017. As patients were members of the CONSORT-Equity 2017 team, patient priorities, experience, and preferences informed the development of research questions, design of the study, and the outcome measures that are reported in this document to describe the research processes of CONSORT-Equity 2017. Patients are also identified as co-authors or acknowledged on the work presented here. The roles and membership of the team are reported in the study protocol and final product documents (7, 17, 18, 28). For this reason, the work that is presented here is an example of how to conduct and report on the development of reporting guidelines in ways that include patients and which reflects their priorities, experiences and preferences (29).

RESULTS

The development of CONSORT-Equity 2017 used an integrated KT approach to structure replicable steps: to conduct research in a collaborative manner that uses consensus-building methods and involves co-creation of knowledge (25); and, to develop a reporting guideline for equity (CONSORT-Equity 2017). The process for co-creating the reporting guideline involved two stages: 1) establishing guiding features for co-creation, and 2) engaging knowledge users and researchers (the team) in research actions that supported the co-creation of the reporting guideline (Figure 1).

Stage 1: Establishing Guiding Features for Co-creation

Preparation: Finding common ground. Initiating a process to engage researchers with potential knowledge users in the development of CONSORT-Equity 2017 involved discussions with individuals and meetings: 1) determining if and how knowledge users' interests and concerns align with those of researchers; 2) building relationships among knowledge users and researchers; 3) defining the parameters of a team relationship for knowledge users and researchers to find common ground and collaborate as a team on a project to develop CONSORT-Equity 2017 (25).

Finding common ground was an iterative three-step process that involved the preparation of a research team. The research team consisted of researchers and knowledge users who chose to work together to produce an agreed-upon research agenda.. Two researcher members (VW, PT) initially recognized the interest and need to extend a reporting guideline, CONSORT, for equity. Next, these researcher members identified potential research team members who shared concerns about equity in health systems, and so relationships were built and a rudimentary research team was formed. The members of the growing research team defined the objectives and parameters of a reporting guideline project in a proposal that was submitted for funding. Following the success of the funding proposal, the iterative, three-step process was then engaged in again by the research team to ensure inclusion of team members with a broad range of skills and expertise.

An Advisory Board was formed. Collaboration with knowledge users during the development of CONSORT-Equity 2017 was identified as an important feature of the study by the research team,

and a decision was made to form an advisory board consisting of the intended users of the reporting guideline. There was a deliberate effort to define roles and recruit nine members to the advisory board: journal editors, trialists, bioethicists, patients, clinicians, systematic review authors, policy makers, and funders. The advisory board is described in detail elsewhere (7). The need to ensure effective communication within and between the members of the advisory board and research team was identified, and two members of the research team were selected as facilitators: one with the advisory board (JJ) and the other with the research team (VW).

The advisory board facilitator (JJ) worked with the advisory board members to define terms of reference and that included expectations (for example, meetings, types of contributions) and opportunities (for example, authorship guidelines) (Table 1). The facilitators (JJ, VW) worked to make plans and schedule events that created opportunities for the advisory board-research team(collectively referred to as "the team") to function in a partnership to promote inclusion and respect for a multiplicity of views in the CONSORT-Equity 2017 study. Engagement between team members created opportunities to explore concepts related to health equity, and the results were reflected in products (for example, a tool to identify when a randomized trial is health-equity relevant (18)). Finally, the members of the team defined and agreed upon an agenda for the study which was published in a study protocol (7).

Commitment to Ethical Guidance. The members of the team agreed to collaborate and engage in decisions about how to structure the development of the reporting guideline so that there was adherence to ethical guidelines. The aim was to ensure respect for and representation of a broad range of views through agreements, structured communication and consensus-building processes

(18). The team agreed to adhere to Canadian ethical research guidelines during the conduct of the CONSORT-Equity study(30).

Theoretical Perspective Clarified. The poor-quality or absence of evidence about health equity is identified by policy makers as a key limitation of research (31). The team identified the lack of consensus on the use of terminology related to health equity concepts and the importance of underpinning assumptions as critical to the development of the reporting guideline. Therefore, the members of the team sought to clarify terminology and relate these understandings in publications to define the study parameters (7, 18). The team reflected on the underpinning assumptions throughout the reporting guideline development process (for example, a focus on social determinants of health theory, revisiting and reflecting on meanings of health equity et cetera).

Stage 2: Research Actions that Supported the Co-creation of the Reporting Guideline

Reporting guideline development process. The agreed-upon guiding features of the research approach (Stage 1) were used to structure the (Stage 2) multi-phase CONSORT-Equity 2017 study to accomplish objectives and create products over a two-year timeframe (Table 2). The use of participatory methods in the form of facilitated on-line and in-person team meetings was used to promote consensus building among team members, and that resulted in the co-creation of knowledge in the form of a reporting guideline.

The team co-created the CONSORT-Equity 2017 following the methodology for consensus-based reporting guideline development advanced by Moher et al. (16) and with the innovation of

key informant interviews (17). The five steps in reporting guideline development are: (i) define (establish guideline need within the team, (ii) assess (state of the literature, consultation with experts on health equity), (iii) develop/adapt (propose and debate adaptation of the reporting guideline), (iv) disseminate (develop and execute plan for uptake of the reporting guideline), and (v) apply (process of road-testing the reporting guideline).

Table 1. Terms of Reference

Role of advisory board membership	-Members to participate in a collaborative process -Members will provide content-related support, and bring knowledge, skills and experience to the working group throughout the multiple stages of the research study process (i.e., the integrated Knowledge Translation (KT) process including the end-of-grant dissemination)
Method and frequency of communication	-The facilitator (JJ) will provide background documents -Agendas to be provided in advance of meetings, with identification of key decisions to be made by the advisory board -There will be ongoing opportunities for communication, in a manner that facilitates the function of advisory board members in their roles
Description of workload	-Meeting participation by members -Provision of feedback on key issues will be made in meetings or by email correspondence -There will be opportunities for interested advisory board members to meet authorship criteria (see below "Authorship")
Timelines	-The advisory board involvement is anticipated to begin in June 2015, and end in December 2016 -Meetings and/or updates will occur every 2 to 3 months (3 to 5 meetings/year, and with brief email correspondence)
How advice will be	-Advisory board input will be sought and considered along with

managed	that of the core research team. -Disagreements on views will be respectfully and collaboratively managed by the advisory board facilitator (JJ)
Authorship	-Criteria outlined by International Journal Committee of Medical Journal Editors (IJCME) will be used to guide publication authorship (32).

Table 2. Stages in the development of CONSORT-Equity 2017 update terms

Stage 1: Establish Guiding Features	**Example**
1) Find Common Ground	A process to initiate and develop a collaborative work plan that for CONSORT-Equity 2017 was an iterative 3-step process to prepare a research team.
2) Form an advisory board	Defined advisory board roles, accessed networks to recruit advisory board members; terms of reference to structure relationships within and between the advisory board-research team members ("the team") (Table 1). Set an agreed-upon agenda that eventually resulted in a published protocol (7). Consensus building processes promoted engagement in active debate and co-creation of knowledge that resulted in, for example, defining and validating when a randomized trial is health- equity relevant (18).
3) Commit to ethical guidance	The team agreed on study conduct to adhere to ethical guidelines (in Canada, the Tri-Council Policy Statement Version 2) (33) and that could include other research ethics protocols or requirements considered relevant by team members, such as the example of research conduct with Indigenous Peoples (34, 35).
4) Clarify theoretical perspective	CONSORT-Equity 2017 is premised on understandings of key concepts, their definitions and usage by the team: understandings of health equity and agreements among team members about underpinning assumptions: the role of social determinants of health theory, a definition of "health equity", defining a health-equity relevant randomized trial and when there is a health disadvantage, and that are reflected in publications (7, 18).
Stage 2: Research actions that supported the co-creation of the reporting guideline. Reporting guideline development process steps.	**Example**: The five reporting guideline development steps of Stage 2 are bound by the guiding features of Stage 1.
1) Define	Establish guideline need with the team: team members were engaged in a process to determine whether and how they might collaborate to develop an extension of CONSORT for equity. Following funding, further work among the team members resulted in a published protocol (7) and a tool that determines when a randomized trial is health-equity relevant (18) and so should use a reporting guideline for health equity.

2) Assess	Determine the state of the literature (7, 28, 36): Consultation with experts on health equity and that included the use of key informant interviews with interdisciplinary knowledge users(17).
3) Develop/Adapt	Propose and debate adaptation of the reporting guideline: Identification of potential guideline knowledge users from high, middle and lower income countries that include, for example, patients and methodologists; and who were invited to participate in an online Delphi study to identify items for the reporting guideline (28). Then, a consensus meeting (the 2016 Boston Equity Symposium that included guideline knowledge users) was held to discuss and debate evidence for inclusion in CONSORT-Equity 2017 (28).
4) Disseminate	Develop and execute plan for uptake of the reporting guideline Outcomes are reflected in the success of an invitational study meeting (the 2016 Boston Equity Symposium) and co-authored publications (17, 18, 28, 36, 37) and the CONSORT-Equity 2017 checklist elaboration and explanation (28, 38).
5) Apply	A process of road-testing the reporting guideline: Work is underway to further disseminate and promote the application of the CONSORT-Equity 2017 guideline.

Extent of knowledge user engagement

The use of the integrated KT approach facilitated engagement within the team by creating structures and opportunities for all team members to offer their views for the development of CONSORT-Equity (17, 28). We failed to engage with one advisory board member due to time constraints around their ability to participate; and it was not possible for every member of the team to have their views accommodated and some members chose to remove themselves from participation either temporarily or permanently (n=2). As well, it was not possible (and indicated as not desirable by members of the team) for every team member to participate in every step of the guideline development process, although opportunities to participate were actively welcomed

and sought by the facilitators. For the development of the CONSORT-Equity 2017 reporting guideline there are publications (see Table 2) that document descriptions of the particular study processes, and that include identification of who and how the team members were involved (7,18,28,36,37).

As collaboration and consensus-building methods were a central feature in CONSORT-Equity 2017 development, it was important to understand the experiences of those who were involved in the reporting guideline development. An eight-question on-line survey consisting of two Likert questions with an option for an open-ended comment, and six open-ended questions about the experience with an integrated KT approach during the CONSORT-Equity 2017 study was administered to team members. Twenty-four of the 37 team members responded to the first two Likert questions on the survey (response rate of 65%). When asked "Overall, how would you rate the extent to which the research team engaged you in the study? (Where 1 is not at all satisfied and 5 is totally satisfied)" 18/24 (75%) of surveyed respondents indicated "very or totally satisfied". An illustrative quote was: "I had a concrete role in the process and the team was very respectful and considerate of input so it was easy to feel invested". In response to the second Likert question "How satisfied are you with the level of your engagement with the research team? (Where 1 is not at all satisfied and 5 is totally satisfied)", 21/24 (87.5%) of the respondents indicated "very or totally satisfied". An illustrative quote from this response was: "[I would] be happy (very) if all research teams engaged all participants in the same manner".

Table 3. Results of two Likert questions on a team survey about experience with integrated knowledge translation (KT) approach (n=24).

Table 3. Results of two Likert questions on a team survey about experience with integrated knowledge translation (KT) approach (n=24)

Question	Response category					Illustrative quote from open-ended comments
Overall, how would you rate the extent to which the research team engaged you in the project. (n=24)	1 (not at all satisfied): n=0 (0%)	2 (somewhat satisfied): n=2 (8%)	3 (satisfied): n=4 (16.6%)	4 (very satisfied): n=3 (12.5%)	5 (totally satisfied): n=15 (62.5%)	"I had a concrete role in the process and the team was very respectful and considerate of input so it was easy to feel invested".
How satisfied are you with the level of your engagement with the research team. (n=24)	1 (not at all satisfied): n=1 (4%)	2 (somewhat satisfied): n=0 (0%)	3 (satisfied): n=2 (8%)	4 (very satisfied): n=3 (12.5%)	5 (totally satisfied): n=18 (75%)	"[I would] be happy (very) if all research teams engaged all participants in the same manner".

In the portion of the survey that included six open-ended questions, respondents were asked to provide details about their experience with the integrated KT approach during the development of the CONSORT-Equity 2017 reporting guideline. Frequency counts of the type of responses were recorded and are reported in Table 4 with illustrative quotes.

When participants were asked what they perceived as the benefits of an integrated KT approach (question 1), the most common (14/25; 56%) response described integrated KT as an approach that allows multiple voices/opinions to be heard and considered. In response to being asked about whether they thought that the team faced any challenges in the study as the result of the integrated KT approach (question 2), many participants (8/25; 32%) reported that the logistics involved with including lots of people was a challenge, but a slightly larger number (9/25; 36%) reported that they were unaware of any team challenges. When asked about whether they faced any challenges during the development of the reporting guideline as the result of the integrated KT approach (question 3), the vast majority of participants (19/25; 76%) indicated that they did not face any challenges.

Participants were asked what they considered to be the impact(s) of using an integrated KT approach with reporting guideline development (question 4), and many (11/25; 44%) indicated that an integrated KT approach improved the relevance of the final guideline product, and (11/25; 44%) reported that the work to develop CONSORT-Equity 2017 was better informed. When asked if they would change anything about how the integrated KT approach was used (question 5), few participants provided a response (n=15) and of those that did indicate a response, most participants (8/15; 53%) indicated that they would not have changed anything.

Finally, when asked for additional comments (question 6), while most respondents (19/25; 76%) provided no comments, some (6/25; 24%) reported that the integrated KT process was a positive experience (Table 4).

During the development of CONSORT-Equity 2017, team members were found to be more engaged in particular activities in relation to their knowledge, occupational roles, and in relation to life events. For example, some team members were found to play a larger role when the team activities required expertise held by team members (for example, expertise about health equity, the conduct of randomized trials et cetera). The development of the CONSORT-Equity 2017 reporting guideline was voluntary for most team members – and was unpaid work – and so other employment or volunteer commitments may have influenced the ability of team members to participate in meetings. As well, personal factors (for example, health issues, family events, travel plans) had impacts on participation of team members in the development of CONSORT-Equity 2017.

Table 4. Results of six open-ended questions on a team survey about experience with an integrated knowledge translation (KT) approach (n=25).

Question	Response
1. What do you perceive as the benefits of an integrated knowledge translation (KT) approach to develop a reporting guideline extension of CONSORT for equity?	1) Allows consideration and inclusion of a range of views (14/25; 56%): “Capturing a multitude of perspectives, to enhance relevance and acceptability of reporting guidelines across disciplines”. 2) Fosters engagement in study processes (6/25; 24%): “It allows participation and engagement of various stakeholders at all stages of the project for whom the guideline is relevant”. 3) Enhance guideline uptake (5/25; 20%): “Results are more likely to be adopted and applied”.

2. Do you think that the team faced any challenges in the study as the result of the integrated KT approach?	1) The logistics of including a range of people in the team (8/25; 32%): "Takes more time to work with a large and diverse crowd". 2) Management of views (5/25; 20%): "Because of the wide range of different disciplines present, it may have been difficult to engage all participants equally across all issues". 3) Reconciliation of within-team differences (3/25; 12%): "It is difficult to deal with perhaps conflicting and at times unclear opinions". 4) Unaware of any team challenges (9/25; 36%): "Not that I'm aware of".
3. Did you face any challenges in the study as the result of the integrated KT approach?	1) No personal challenges faced in the study (19/25; 76%): "I did not face any challenges. My input and participation had equal standing in the process". 2) The personal experience of challenge related to the pace, number of consultations, and/or to provide informed opinions (6/25; 24%): "It was slow at times and a bit frustrating. We achieved what we did through patience, persistence and good will of team members".
4. What do you consider to be the impact(s) of using an integrated KT approach with the study?	1) Improves the final guideline product (11/25; 44%): "I feel that we produced a product that was relevant to all of our team members, and that they can support in their communities". 2) Inclusion of different forms of knowledge (11/25; 44%): "It ensures that the study is better informed by the expertise, perspectives and needs of the different stakeholders". 3) Unsure/did not notice impact of integrated KT approach (3/25; 12%): "Not sure".
5. Would you have changed anything about how the integrated KT approach was used in the study? If yes, how?	1) Would not change the use of the integrated KT approach (8/15; 53%): "No change suggested". 2) Greater range of participants (3/15; 20%): "I would have tried to broaden the scope of stakeholders". 3) Narrow the stakeholder focus and seek more intense consultations, such as through in-person meetings (2/15; 13%): "Smaller reach, deeper consultation". 4) More time (2/15; 13%): "More time is always a benefit to measure the impact".
6. Do you have any additional comments**?**	1) No comment (19/25; 76%). 2) Indicated that it was a positive experience (6/25; 24%): "I would do this again".

DISCUSSION

A team engaged in mutually-agreed upon processes to co-create knowledge and assemble empirical evidence to develop a reporting guideline, CONSORT-Equity 2017. The team was established to function as a partnership throughout the study process to promote inclusion and respect for a range of views. A structured integrated KT approach was used to organize ongoing negotiations among team members and used replicable steps to develop a reporting guideline. The aim was to ensure that the team's agreed upon goals were achieved: to conduct research in a collaborative manner that uses consensus-building methods and involves co-creation of knowledge; and, to develop a reporting guideline for equity (CONSORT-Equity 2017) as a contribution to address health systems' equity issues.

Perceptions of the integrated KT approach and impacts on co-creation of knowledge

Our study involved a 38-member interdisciplinary team from eight countries that included patients, and who collaborated in the development of CONSORT-Equity 2017. Details on the team members and processes are reported in detail elsewhere (7, 28). There is little evidence in the literature about the experiences of interdisciplinary teams that include journal editors, trialists, bioethicists, patients, clinicians, systematic review authors, policy makers, and funders. Previous studies that investigate patient perspectives on clinical guideline development concluded that effective engagement in the development process requires planning, and the recommendations arising from that work include: the use of smaller and diverse groups, with no prior relationships with other members of the team; individual and group preparation for engagement on the team; and, an identified contact person for participants (39). In our study, we

prepared an interdisciplinary and international team to work together in the development of a reporting guideline.

Many options exist to facilitate collaboration within research partnerships and that foster democratic approaches to knowledge creation (23, 40-42). An integrated KT approach was identified as appropriate for our team and its' proposed development of a reporting guideline, as it focuses on the co-creation of knowledge with practical applications (23). Furthermore, we found that during the development of the reporting guideline, an integrated KT approach supported many opportunities for team members to be fully involved in the entire research process as planned during the CONSORT-Equity 2017 protocol development (7). The integrated KT approach began with an iterative process of preparation of team members for participation in a research partnership, a feature reported in other frameworks that structure engagement of knowledge users with researchers in health research (41, 43, 44). The members of the team involved in the development of CONSORT-Equity 2017 were invited to participate in all phases of the reporting guideline development process, and efforts were made by facilitators to accommodate their participation.

The value of knowledge user engagement during the reporting guideline development is asserted in a sub-study that was conducted with interdisciplinary key informants. This study, which engaged key informants in interviews about their views and suggestions for an extension of CONSORT for equity, was found to generate new concepts that contributed to the development of CONSORT-Equity 2017 (17). We prioritized the engagement of team members throughout the development of CONSORT-Equity 2017 to improve the likelihood that CONSORT-Equity

2017 would be perceived as useful and applicable in practice. To strive for authentic (that is, ethical, equitable) engagement, deliberate efforts were made to foster relationships within a team that consisted of knowledge users and researchers.

The successful engagement of team members was possibly due to the structured integrated KT approach that fostered processes of negotiation and created opportunities for team members to choose their level of engagement. For example, there were ongoing opportunities for members of the team to engage at different stages of the CONSORT-Equity 2017 study. These opportunities were initially identified during the preparation for the development of CONSORT-Equity 2017. The iterative and prolonged focus on preparation of team members led to the development of a shared agenda for the work to develop CONSORT-Equity 2017. The finding of a focus on iterative preparation of team members is an innovation on the original framework used to guide the integrated KT approach (Figure 1). The opportunity to prepare team members to engage in the CONSORT-Equity 2017 study and to work together led to opportunities to develop and make shared understandings and agreements explicit. The team facilitators built on the success of the initial engagement of team members in the reporting guideline development, and created frequent and varied opportunities for ongoing participation in the CONSORT-Equity 2017 study processes (for example, through scheduled face-to-face and/or telephone calls, maintained regular email study updates).

The experience with varied levels of engagement by team members in the CONSORT-Equity 2017 study led to consideration of the meaning of "engagement" among an interdisciplinary team consisting of knowledge users and researchers. Overall, our team consisted of a committed

group of team members who were involved in a collaborative effort for the duration of the work to develop CONSORT-Equity 2017. Team members met and agreed upon objectives and this in turn resulted in co-created products. During the series of studies to CONSORT-Equity 2017 studies the nature and degree of engagement varied over time and according to the capacity of team members and study tasks. Team members asked to: be kept informed but did not want to actively participate (for example, one-way direction of information updates on the study such as an email with announcements); be consulted for feedback (for example, responding to an email request for information or feedback on a document); play a supportive role for others who provide governance in the CONSORT-Equity 2017 study processes (for example, providing support in a study in response to requests by team leads); share in the governance of the study (for example, advising and/or decision making in a co-leading role, such as in development of CONSORT-Equity 2017 study directions or products. The different levels at which knowledge user engagement may occur has been under examination for many years and one of the earliest instances is Arnstein's 1969 ladder of participation and that ranges from non-participation to citizen control (45). Since then there have been many other ways of conceptualizing knowledge user engagement in research (46-48).

During our CONSORT-Equity 2017 study, we accomplished the engagement of team members that included knowledge users in study governance – and then exceeded this aim with knowledge user leadership. There are documented instances of varied team members taking the lead during the CONSORT-Equity 2017 study conduct and that occurred during meetings (for example, expert knowledge user leads taking initiative with and guiding sessions at the Boston Equity Symposium) and with study publications (37). The range of engagement that was observed

during the CONSORT-Equity 2017 study processes demonstrate that engagement may be more changeable, nuanced, and less able to be anticipated than is currently described in the literature encouraging knowledge user engagement (12, 47). The use of the structured integrated KT approach allowed members of the team to determine how and in what capacity they would contribute, while also being engaged to co-create a reporting guideline.

Limitations and strengths for use of an integrated KT approach to develop a reporting guideline

The surveyed team members identified the main limitations (challenges) of an integrated KT approach to be the logistics of including a range of interdisciplinary team members in the study, and the management of team views. The team facilitators reflected on the logistics and the challenges of scheduling meetings to accommodate or align with team member commitments (outside of CONSORT-Equity 2017) and time constraints for those on the team to participate in the study. As well, there may have been impacts on the participation of team members due to the reliance upon the facilitators who were based at one site and responsible for fostering regular and productive contacts, and with the use of online communications (versus face-to-face meetings). For example, communication between and within those on the team was a challenge due to the logistics of time zones, the numbers of people, limitations of technology. These challenges were further complicated by the need to bring team member views together in consensus to achieve CONSORT-Equity 2017 study objectives.

The surveyed team members identified the main strength of the integrated KT approach to be the consideration and inclusion of a range of views in the research process. The facilitators of the

team reflected on the use of study processes structured by the integrated KT approach that, for the duration of the study, made it possible to build and/or strengthen research relationships initiated at the start of the study and across a range of team members. These research relationships were demonstrated by team member participation in publication co-authorship, attendance at regular meetings, email contacts, and feedback on products.

Limitations and strengths of the study to evaluate an integrated KT approach

The limitations of the study about the use of an integrated KT approach reported in this paper include that the work to evaluate the use of an integrated KT approach (the observational study) was done with a smaller group of interdisciplinary team members, and that team members already shared an interest in the taking an integrated KT approach in the development of a reporting guideline (CONSORT-Equity 2017). For this reason, the findings about the integrated KT process presented here may not be relevant to other teams that consist of a different groups of team members, and that have different team objectives. In addition, the methods we used are observational and not established for use with teams who are engaged in a multiple series of studies to develop an end-product (in our instance, a reporting guideline). The strengths are that we used a previously developed framework (25) to structure our reporting about the use of an integrated KT approach. As well, we successfully engaged an interdisciplinary team throughout the guideline development process and were able to evaluate the process.

CONCLUSIONS

A structured integrated KT approach was successfully used to engage an interdisciplinary and international team to develop a reporting guideline, CONSORT-Equity 2017. The use of an

integrated KT approach fostered engagement of the team in the study processes and prompted deliberation and consensus building among team members. Further work is needed to examine and better understand the use and potential applications of an integrated KT approach to other initiatives seeking to improve research reporting guidelines.

[Figure 1. Integrated Knowledge Translation (KT) approach for CONSORT-Equity 2017]

Ethics Approval: Participants gave informed consent before taking part in the study of the integrated KT approach used in the development of the CONSORT-Equity 2017 reporting guideline reported in this manuscript (Bruyère REB Protocol # M16-15-042).

Transparency Statement: The lead author and guarantor (JJ) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted. There were no deviations from what was planned.

Role of funding source: Funding was not received for this study.

Data sharing statement: No additional data available.

Competing interests: All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the previous three years; no other relationships or activities that could appear

to have influenced the submitted work, with the following exceptions: 1) Dr. Cuervo reports he works as a Senior Advisor for Health Systems Research to the Pan American Health Organization/World Health Organization. His Organization's Policy on Research for Health calls for the development and use of research reporting standards and improving the value and impact of research for health. His opinions and contributions to this manuscript are his own and do not necessarily reflect the decisions or policies of his employer; 2) Dr. Moher reports that he is one of the 'inventors' of CONSORT; 3) Dr. Welch reports grants from Canadian Institutes of Health Research, grants from Ontario Early Career Researcher Award, during the conduct of the study.

Contributorship Statement: JJ, IDG, VW conceived and led the design of the work described in the manuscript and were responsible for the first and final drafts of this manuscript. EK, DM,JP, MY, PT, VW and members of the CONSORT-Equity 2017 and Boston Equity Symposium coauthors participated in and provided substantial contributions to the analysis and interpretation during development of the work described in the manuscript. JJ led writing of the first version of the manuscript. JJ and IDG revised the manuscript. EK, DM,JP, MY, PT, VW made contributions to drafts of this manuscript including the listed members of the CONSORT-Equity 2017 and Boston Equity Symposium, and have reviewed and revised the manuscript for important intellectual content and approved the final version of the manuscript.

Dr. Janet Jull is the guarantor of the article.

Acknowledgements
Collaborating authors who are identified as a member of the CONSORT-Equity and Boston Equity Symposium participants are as follows: Rebecca Armstrong, Sarah Baird, Yvonne Boyer,

Luis Gabriel Cuervo, Regina Greer-Smith, Anne Lyddiatt, Jessie McGowan, Lawrence Mbuagbaw, Tomas Pantoja, Beverly Shea, Bjarne Robberstad, Howard White, George Wells. Reporting of involvement of patients and public is included here.

We thank the following individuals for their support and encouragement: Mark Petticrew, Jeremy Grimshaw, Charles Weijer, Monica Taljaard, Yukiko Asada.

JJ held a Canadian Institutes of Health Research (CIHR) Postdoctoral Fellowship for a portion of the time she was writing the paper.

IDG is a recipient of a CIHR foundation grant (FDN# 143237).

References- to be finalized

1. World Health Organization (WHO) Assembly. WHO Strategy on Research for Health; WHO Roles and responsibilities on health research: document WHA63.22 and Resolution. 20 Avenue Appia, 1211 Geneva 27, Switzerland; 2012.
2. Pan American Health Organization, DC, 61st Session of the Regional Committee of WHO for the Americas. Policy on research for health: document CD49/10. Washington, DC: PAHO; 2009.
3. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. *Lancet*. 2014;383(9913):267-76.
4. EQUATOR Network. The EQUATOR Network: Enhancing the Quality and Transparency of Health Research Centre for Statistics in Medicine (CSM), NDORMS, University of Oxford.: UK EQUATOR Centre; n.d. [Available from: https://www.equator-network.org/.
5. Centre for Journalology. Using Reporting Guidelines Ottawa Hospital Research Institute2019 [Available from: http://www.ohri.ca/journalology/docs/guidelines.aspx.
6. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. Syst Rev. 2012;1:60.
7. Welch V, Jull J, Petkovic J, Armstrong R, Boyer Y, Cuervo LG, et al. Protocol for the development of a CONSORT-equity guideline to improve reporting of health equity in randomized trials. *Implement Sci*. 2015;10:146.
8. Whitehead M. The concepts and principles of equity and health. *Int J Health Serv*. 1992;22(3):429-45.
9. Sackett D, Rosenberg W, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312:71-2.
10. Marmot M, Allen J, Bell R, Goldblatt P. Building of the global movement for health equity: from Santiago to Rio and beyond. *Lancet*. 2012;379(9811):181-8.

11. Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health*. 2013;67(2):190-3.
12. Canadian Institutes of Health Research (CIHR). Patient Engagement: What is patient engagement? Government of Canada 2018 [Available from: http://www.cihr-irsc.gc.ca/e/45851.html.
13. Jarrett L, Patient Involvement Unit (PIU) PIU. Patient Involvement Unit (PIU). A report on a study to evaluate patient/ carer membership of the first NICE Guideline Development Groups. London: National Institute for Clinical Excellence (NICE); 2004.
14. Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P, et al. Guidelines International Network: toward international standards for clinical practice guidelines. *Ann Intern Med*. 2012;156(7):525-31.
15. Armstrong MJ, Bloom JA. Patient involvement in guidelines is poor five years after institute of medicine standards: review of guideline methodologies. *Res Involv Engagem*. 2017;3:19.
16. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. *PLoS Med*. 2010;7(2):e1000217.
17. Jull J, Petticrew M, Kristjansson E, Yoganathan M, Petkovic J, Tugwell P, et al. Engaging knowledge users in development of the CONSORT-Equity 2017 reporting guideline: a qualitative study using in-depth interviews. *Res Involv Engagem*. 2018;4:34.
18. Jull J, Whitehead M, Petticrew M, Kristjansson E, Gough D, Petkovic J, et al. When is a randomised controlled trial health equity relevant? Development and validation of a conceptual framework. *BMJ Open*. 2017;7(9):e015815.
19. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof*. 2006;26(1):13-24.
20. Canadian Institutes of Health Research (CIHR). Guide to knowledge translation planning at CIHR: integrated and end-of-grant approaches 2015 [Available from: http://www.cihr-irsc.gc.ca/e/45321.html.
21. Van de Ven D, Johnson P. Knowledge for theory and practice. *Academy of Management Review*. 2006;31(4):802-21.
22. Bowen S, Graham I. Integrated Knowledge Translation. In: SE Straus, J Tetroe, ID Graham, editors. Knowledge Translation in Healthcare: moving evidence to practice. West Sussex: Wiley; 2013. p. 14-23.
23. Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge. *Implement Sci*. 2017;12(1):150.
24. Guest G NE, Mitchell ML. Collecting Qualitative Data: A Field Manual for Applied Research. 2013 2019/02/16. 55 City Road, London: SAGE Publications, Ltd; [75-112]. Available from: http://methods.sagepub.com/book/collecting-qualitative-data.
25. Jull J, Giles A, Boyer Y, Stacey D, Minwaashin Lodge. Development of a Collaborative Research Framework: The Exampe of a Study Conducted by and with a First Nations, Inuit and Metis Women's Community and Their Research Partners.. *ACME: An International Journal for Critical Geographies*. 2018; 17(3), 671-86..
26. Jull J, CONSORT-Equity Team. The value of an integrated knowledge translation approach for developing reporting guidelines: engaging knowledge users interested in equity-relevant decision making. Knowledge Translation Canada Scientific Meeting Toronto, Ontario, Toronto, Ontario2016.

27. Morse J, Field P. Nursing research : the application of qualitative approaches. London: Chapman & Hall; 1996.
28. Welch VA, Norheim OF, Jull J, Cookson R, Sommerfelt H, Tugwell P, et al. CONSORT-Equity 2017 extension and elaboration for better reporting of health equity in randomised trials. *BMJ*. 2017;359:j5085.
29. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *Res Involv Engagem*. 2017;3:13.
30. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2018 [Available from: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf].
31. Petticrew M, Whitehead M, Macintyre SJ, Graham H, Egan M. Evidence for public health policy on inequalities: 1: the reality according to policymakers. *J Epidemiol Community Health*. 2004;58(10):811-6.
32. International Committee of Medical Journal Editors (ICJME). Defining the role of authors and contributors 2018 [Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html].
33. Panel on Research Ethics. TCPS 2 – Chapter 9. Research Involving the First Nations, Inuit and Métis Peoples of Canada [Available from: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/].
34. First Nations Information Governance Centre (FNIGC). The First Nations principles of OCAP® 2017 [Available from: http://fnigc.ca/ocap.html].
35. Canadian Institutes of Health Research (CIHR). CIHR guidelines for health research involving Aboriginal People. 2007 [Available from: http://www.cihr-irsc.gc.ca/e/29134.html.
36. Petkovic, Welch V, Jull J, Petticrew M, Kristjannson E, Radar T, et al. How is health equity reported and analyzed in randomised trials: Cochrane Systematic Review Registered Protocol. Cochrane Methodology Review Group. 2017(Issue 8 . Art. No.: MR000046).
37. Mbuagbaw L, Aves T, Shea B, Jull J, Welch V, Taljaard M, et al. Considerations and guidance in designing equity-relevant clinical trials. *Int J Equity Health*. 2017;16(1):93.
38. Simera I, Moher D, Hirst A, Hoey J, Schulz KF, Altman DG. Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. *BMC Med*. 2010;8:24.
39. Armstrong MJ, Mullins CD, Gronseth GS, Gagliardi AR. Recommendations for patient engagement in guideline development panels: A qualitative focus group study of guideline-naïve patients. *PLoS One*. 2017;12(3):e0174329.
40. West JF. Public health program planning logic model for community engaged type 2 diabetes management and prevention. *Eval Program Plann*. 2014;42:43-9.
41. James S, Arniella G, Bickell NA, Walker W, Robinson V, Taylor B, et al. Community ACTION boards: an innovative model for effective community-academic research partnerships. *Prog Community Health Partnersh*. 2011;5(4):399-404.
42. May M, Law J. CBPR as community health intervention: institutionalizing CBPR within community based organizations. *Prog Community Health Partnersh*. 2008;2(2):145-55.
43. Johnson DS, Bush MT, Brandzel S, Wernli KJ. The patient voice in research-evolution of a role. *Res Involv Engagem*. 2016;2:6.

44. Jinks C, Carter P, Rhodes C, Taylor R, Beech R, Dziedzic K, et al. Patient and public involvement in primary care research - an example of ensuring its sustainability. *Res Involv Engagem*. 2016;2:1.
45. Arnstein S. A ladder of citizen participation. JAm Plann Assoc. 1969;35(4):216–24.
46. National Institute of Health Research. INVOLVE 2001 [Available from: https://www.invo.org.uk/].
47. Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA, panel) Advisory Panel on Patient Engagement. The PCORI Engagement Rubric: Promising Practices for Partnering in Research. *Ann Fam Med*. 2017;15(2):165-70.
48. Forsythe LP, Ellis LE, Edmundson L, Sabharwal R, Rein A, Konopka K, et al. Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med*. 2016;31.

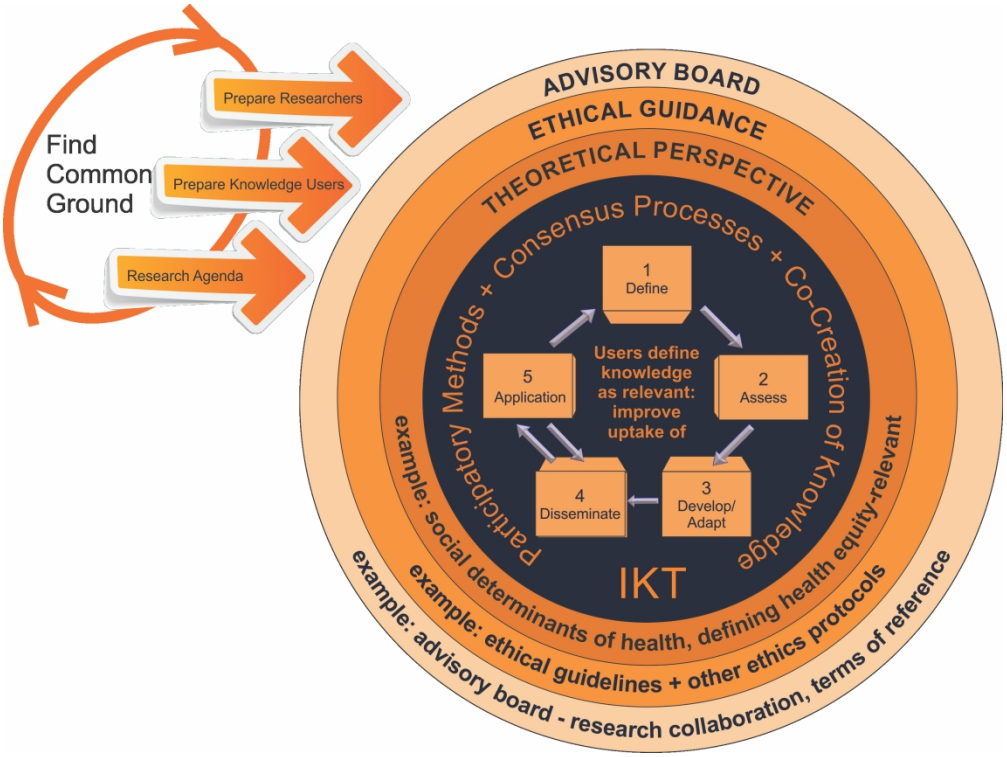

Find Common Ground
Prepare Researchers
Prepare Knowledge Users
Research Agenda
ADVISORY BOARD
ETHICAL GUIDANCE
THEORETICAL PERSPECTIVE
Participatory Methods + Consensus Processes + Co-Creation of Knowledge
1 Define
2 Assess
3 Develop/ Adapt
4 Disseminate
5 Application
Users define knowledge as relevant: improve uptake of
IKT
example: social determinants of health, defining health equity-relevant
example: ethical guidelines + other ethics protocols
example: advisory board - research collaboration, terms of reference

Figure 1.