



BMJ Open TOwards enhancing Paediatric Intensive Care for Children with Medical Complexity (ToPIC CMC): a mixed-methods study protocol using Experience-based Co-design

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ABSTRACT

Introduction Advances in medical technology and postoperative care have led to increased survival of children with medical complexity (CMC). Parents of CMC develop substantial caregiver expertise and familiarity with paediatric intensive care unit (PICU) staff and treatment procedures which may give rise to tensions regarding respective roles, caretaking preferences, treatment goals and expected outcomes. A therapeutic alliance built through strong partnerships constitutes the foundation of patient and family-centred care (PFCC), contributing to improvements in experiences and outcomes. Yet acute care settings continue to struggle with integrating PFCC into practice. This study aims to enhance PFCC for CMC in the PICU using an innovative approach to integrated knowledge translation.

Methods A mixed-method concurrent triangulation design will be used to develop, implement and evaluate PFCC practice changes for CMC in the PICU. Qualitative data will be collected using an Experience-based Co-design (EBCD) approach. Parents, CMC and staff will reflect on their PICU care experiences (stages 1 and 2), identify priorities for improvement (stage 3), devise strategies to implement changes (stage 4), evaluate practice changes and study process, and disseminate findings (stage 5). The quantitative arm will consist of a prepractice and postpractice change evaluation, compared with a control site. Analysis of qualitative and quantitative data will provide insights regarding the impact of PICU practice changes on PFCC.

Ethics and dissemination The McGill University Health Centre Research Ethics Board (Ref. #2019-5021) and the Hospital for Sick Children Research Ethics Board (Ref. #1000063801) approved the study. Knowledge users and researchers will be engaged as partners throughout the study as per our participatory approach. Knowledge products will include a short film featuring themes and video/audio clips from the interviews, recommendations for improvements in care, and presentations for healthcare leaders and clinical teams, in addition to traditional academic outputs such as conference presentations and publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study aims to enhance patient and family-centred care for children with medical complexity in the paediatric intensive care unit (PICU) using Experience-based Co-design (EBCD), an innovative approach to integrated knowledge translation.
- ⇒ This will be the first study to use EBCD to improve patient and family-centred care experiences for children with medical complexity, parents and healthcare professionals in the PICU.
- ⇒ Knowledge users (children, parents, healthcare professionals) will be engaged as partners to identify, codesign and implement practice changes to enhance patient and family-centred care for children with medical complexity, a PICU population that staff may be less familiar with through training, experience or expertise.
- ⇒ Findings will inform healthcare professional training and medical/health sciences education regarding this growing PICU population.
- ⇒ Implementing practice changes in the PICU environment may present challenges; however, to optimise institutional buy-in, key representatives of the institutions and units are engaged as members of the research team.

INTRODUCTION

The growing prevalence of children with medical complexity (CMC) has important implications for paediatric healthcare, and a profound impact on interactions between parent caregivers and healthcare professionals (HCPs) in the paediatric intensive care unit (PICU).^{1–4} Advances in medical technology and postoperative care have led to increased survival of CMC who share four defining features: (1) the presence of one or more complex chronic medical conditions that is severe and expected to be lifelong;

(2) significant functional limitations typically reliant on medical technology; (3) high healthcare utilisation and (4) high healthcare service needs.^{5 6} CMC are three times more likely to have an unscheduled PICU admission than previously well children,⁷ and are at higher risk of prolonged length of stay,^{1 8} frequent readmission,^{8–10} adverse events¹¹ and PICU mortality.¹ In Canada, they constitute approximately 15% of total PICU admissions, yet are estimated to occupy 25%–50% of PICU beds at any given time.¹² The complexity of their care requires a high degree of service coordination and caregiver expertise and has been recognised as a health service priority.¹³ Often, because of the intensity of their baseline care needs, the care given at home surpasses the level of care possible on general wards, and CMC may require intensive care environments for all of their hospitalisations.

There is growing international recognition of the benefits derived from research that incorporates patient experiences in designing and improving the delivery of family-centred healthcare services.^{14–16} Although paediatric institutions across North America are committed to supporting patient and family-centred care (PFCC), there has been limited PICU practice change that aligns with these objectives and approaches. One study found PICU nurses' strict adherence to implicit and explicit unit rules and policies to protect efficient ways of working ran counter to providing PFCC.¹⁷ This despite calls over a decade ago by an American College of Critical Care Medicine Task Force to include the family as an integral part of the ICU team based on evidence that PFCC facilitates timely restoration of health, facilitation of patient and family coping, improved patient care, better patient and family healthcare experiences, reduced staff stress related to family interactions and optimisation of the dying process.¹⁸ Indeed, neglecting to provide PFCC for CMC may negatively impact child and family health outcomes.

Parents of CMC become technologically sophisticated, expert caregivers who know their child's medical condition intimately and can detect subtle changes and responses to medical interventions.^{2 19 20} They challenge the traditional PICU caretaking model where parents assume a relatively passive role, relying heavily on clinician expertise to rescue their child.⁴ Interventions to promote parental involvement at the bedside have been traditionally based on a PICU model of care that assumes parents lack the knowledge and expertise necessary to provide highly technical care.^{21–23} HCPs working within that model often fail to take families' expertise into account despite evidence that parents harbour expectations of a collegial relationship with staff based on continuing negotiation and mutual trust.^{24 25} When parental and HCP perspectives regarding medical treatment options, care priorities and approaches differ, uncertainty, tension, and conflict regarding caregiving practices and treatment goals may arise.^{2–4} This collision of expertise can compromise patient care by creating barriers to establishing mutually beneficial partnerships between patients, parents and HCPs that are at the core

of PFCC, at a time when children and families are particularly vulnerable.

A new approach to care for CMC is required, in which there is a shift in the existing paradigm towards greater shared expertise models between critical care teams and family caregivers. The educational and practice change interventions designed to implement such a model of care should be rooted in the patient and family experience. The focus of this study is to rigorously determine what the key elements of such a paradigm shift in care, education and practice change ought to be.

Understanding healthcare experiences can yield important insights into care processes. While patient healthcare experiences have become a central indicator of quality healthcare, studies rarely include specific data to guide practice change, resulting in little systematic work in acute care settings to improve those experiences.²⁶ Involving children and parents as knowledge users and equal partners throughout the research process is the central premise of integrated knowledge translation, an approach to enhance research relevancy and maximise the likelihood that findings will be useful to knowledge users, including patients, families and HCPs.^{27 28} This study will advance our understanding of PFCC experiences, establish priorities for enhancing them, and bring knowledge users together to establish and implement practice change to enhance PICU care.

OBJECTIVES OF THE STUDY

This study aims to develop and assess the implementation of PICU practice changes on PFCC for CMC. Specific objectives include:

1. To capture and understand how knowledge users (CMC, parents and HCPs) experience PFCC along its four core dimensions (see the Conceptual framework section), in the PICU.
2. To engage knowledge users as partners in identifying joint priorities for enhancing PFCC.
3. To engage knowledge users as partners in codesigning and implementing PFCC practice changes.
4. To evaluate (A) practice changes along the four core dimensions of PFCC and (B) the Experience-based Co-design (EBCD) process.

CONCEPTUAL FRAMEWORK

This study is guided by the conceptual framework for PFCC developed by the Institute for Patient-Centred and Family-Centred Care.²⁷ This framework is grounded in mutually beneficial partnerships between HCPs, patients and families that are integrated into the planning, delivery and evaluation of healthcare. Four core dimensions are included: dignity and respect, information sharing, participation in care and decision making, and collaboration. Benefits of PFCC include improved healthcare experiences, better health outcomes, improved care coordination, enhanced patient safety, judicious allocation of

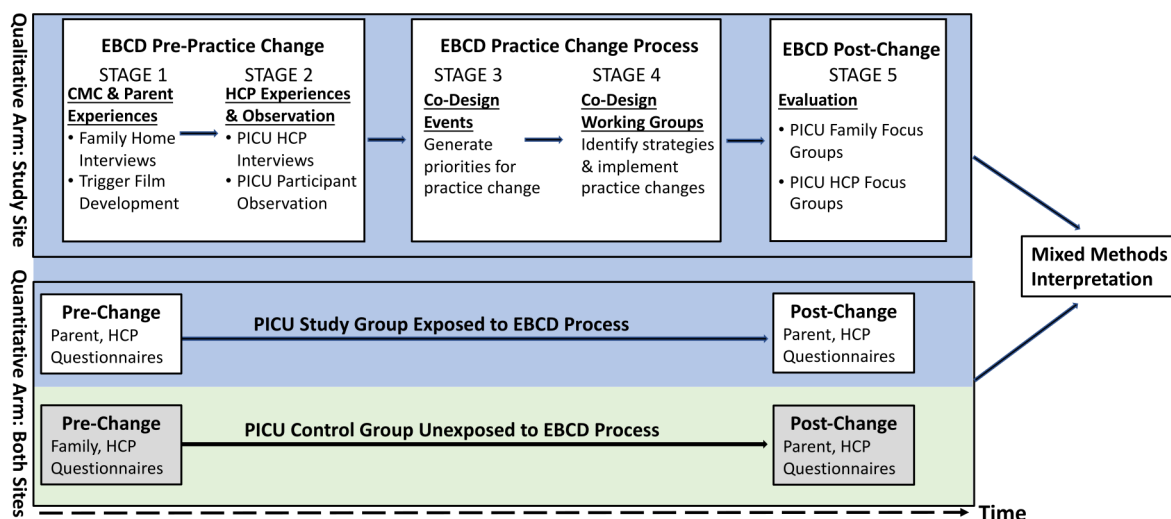


Figure 1 Mixed-methods, concurrent triangulation design: Experience-based Co-design (EBCD: qualitative arm) and difference-in-differences approach (quantitative arm). CMC, children with medical complexity; HCP, healthcare professional; PICU, paediatric intensive care unit.

resources and improved HCP engagement.^{29–32} Despite widespread acceptance in principle, acute care settings continue to struggle with integrating PFCC into practice, and little is known about the establishment of effective caregiving partnerships. This is attributed to the continuation of models of care that position parents as visitors at their child's bedside, rather than integral members of the healthcare team.³³ This study will integrate the four core dimensions of PFCC into our data collection approaches, and use them to guide our codesign events and practice change implementation processes as we seek to enhance parent–child–HCP partnerships.

METHODS AND ANALYSIS

A mixed-methods, concurrent triangulation design will be used (figure 1).^{34 35} In the qualitative arm, data will be collected at the study site using an EBCD approach.^{26 36} Through a codesign process, participant knowledge users (ie, CMC, parents and HCPs) will reflect on their PICU care experiences (stages 1 and 2), work together to identify priorities for improving PFCC (stage 3), devise strategies to address these priorities and to implement associated practice changes (stage 4), reflect on and evaluate the practice changes and the EBCD process (stage 5). In the quantitative arm, standardised PFCC-related outcomes will be measured at the study site and at a control site for temporal comparison prior to and following EBCD exposure, and analysed using a difference-in-differences approach.³⁷ Findings from the qualitative arm regarding participants' perceptions of the EBCD process and resultant practice changes will be interpreted together with findings from the quantitative arm. The complementarity of the qualitative and quantitative data will provide a comprehensive understanding of the impact of practice changes on PFCC.

Recruitment Setting

All stages of the qualitative arm will take place at the study site, while the quantitative component will take place at both study and control sites. The two Canadian PICUs participating in this study are located in different provinces, and both are located within university-affiliated paediatric hospitals offering Complex Care Services to CMC. In the qualitative arm, child and parent interviews will take place at the family's home to optimise comfort (or preferred location), while HCPs will be interviewed in hospital (or preferred location). To minimise risk during the COVID-19 pandemic, interviews will take place via secure video conference. Codesign events, working groups and project team meetings will take place at the study site or via secure video conference according to public health pandemic recommendations at that time. In the quantitative component, parents and HCPs will complete questionnaires at home or in hospital.

Participants and eligibility criteria

CMC <18 years of age who speak English or French will be included with: (1) one or more severe, complex chronic medical conditions expected to be lifelong; (2) significant functional limitations with reliance on medical technology; (3) daily care needs at home similar to hospital care and (4) high healthcare service utilisation, including one or more PICU visits in the previous year.⁵ Parents of CMC and HCPs who provide direct patient care to CMC in the PICU will be included who speak, read and write English or French.

Quantitative sample

Parents

Prepractice change (time 1), parents of all CMC admitted to the PICU in the 10–12 months preceding the start of practice-change activities will be invited to

complete questionnaires. Postpractice change (time 2), we will use continuous sampling and invite all parents of CMC admitted prospectively over the 10–12 month period postpractice change to complete questionnaires. Time periods are based on prior CMC PICU admission numbers at both sites. To examine parents' perceived changes in PFCC, a sample size of 50 families/group ($n=100$) at each time point will achieve 80% power at a significance level of 0.05 to detect a medium effect size of 0.6³⁸ using a two-sample t-test. We expect at least a medium effect size on the Measure of Processes of Care (MPOC-20), our primary outcome measure, similar to that reported by parents using it to evaluate differences in PFCC services in Canadian healthcare programmes for children with disabilities (see the Measures section).³⁰ Sample size was inflated by 10% as some children will be readmitted and questionnaires will not be independent (based on a 50% readmission rate with a large clustering effect intraclass correlation coefficient=0.15,³⁹ variance inflation factor=1.08).

Healthcare professionals

All PICU and Complex Care staff working with CMC in the PICUs at both sites will be invited to participate during time 1 and time 2.

Qualitative sample

CMC and parents

Maximum variation sampling will be used to select 12–15 CMC and their parents (1 parent/child; $n=24-30$) from the time 1 quantitative sample who indicated their interest (as per earlier consent) in being contacted for a potential interview. We will aim for variation in child and family characteristics (eg, child age, family structure, ethnicity and socioeconomic status), and medical conditions (eg, age of onset, home care needs, PICU admissions). Analysis and data collection will proceed in tandem and recruitment will continue until data saturation is reached.^{40 41}

Healthcare professionals

Maximum variation sampling will be used to select 12–15 HCPs representing PICU and Complex Care staff of varying levels of seniority and disciplines (with proportional representation from those disciplines, for example, nursing (85%), medicine (13%), respiratory therapy (1%), social work (1%).^{36 42} Analysis and data collection will proceed in tandem and recruitment will continue until data saturation is reached.^{40 41}

Data collection and analysis

Qualitative arm

Stage 1: Gathering CMC and parent experiences

For parents and children over 9 years of age who agree to be interviewed, written informed parent consent and child assent will be obtained and an interview scheduled at the families' convenience. A qualitative researcher will conduct video-recorded interviews using a semistructured, narrative approach.^{40 43} From within the interview

narrative, we will seek to identify personal touch points, or key moments during PICU hospitalisation that shaped participants' PFCC experience.^{36 44} Participants will be encouraged to describe their experiences of care including interactions with HCPs from their own perspectives, and based on their own care priorities. Experiences will be explored along the four core dimensions of PFCC (online supplemental appendix 1). To ensure analytical rigour, two members of the research team will independently review the video data and analyse professionally transcribed interviews to identify emergent themes through constant comparison analysis.⁴⁰ They will analyse parent and child data separately when possible. NVivo analytical software (V.12) will be used to support the development of the coding framework, data interpretation and thematic analysis, enhancing the trustworthiness of the data.⁴⁰ Multiple referents (transcripts, video data) will enhance credibility and confirmability.

Exemplar quotes from the videorecorded interviews that represent key touch points identified through constant comparison analysis will be included in one composite, 30 min trigger film. Participants will review their own interview and provide written consent and assent for selected clips to be used in the trigger film. They will then be invited along with other family participants to validate the trigger film and identify care priorities prior to its presentation at codesign events (stage 3), where it will be used to trigger discussion and identify joint family-HCP priorities for improving PFCC experiences. The trigger film is a key element of a successful EBCD approach, providing staff with a powerful understanding of patient healthcare experiences.³⁶

Stage 2: Gathering HCP experiences and participant observation

Written informed consent will be obtained from HCPs who agree to participate, and an interview scheduled at their convenience. A qualitative researcher will conduct semistructured, audiorecorded interviews exploring HCPs' experiences caring for CMC in the PICU, focusing on the core dimensions of PFCC (online supplemental appendix 1). To ensure analytical rigour, two members of the research team will independently review and analyse verbatim, anonymised transcripts to identify emergent themes through constant comparison analysis.⁴⁰ NVivo analytical software (V.12) will be used to develop the coding framework and support data interpretation and thematic analysis, enhancing the trustworthiness of the data.⁴⁰ Multiple referents (transcripts, observational field notes) will enhance credibility and confirmability. HCPs will be invited (10 HCPs/group maximum) to review and validate the findings and identify care priorities with an experienced facilitator who is not on staff, prior to presenting data summaries at subsequent codesign events.

Participant observation will provide contextual data to complement participants' narratives and subsequent codesign work by revealing relational and social processes that may affect PICU care experiences.⁴⁵ Specific aspects

of PICU care will be observed by research staff trained in qualitative methods, including functional (eg, technical care procedures) and relational aspects (eg, settling the child after a difficult procedure). Written informed consent will be obtained from parents and HCPs who agree to participate; child assent will be obtained when possible. To understand PICU activities and care processes and provide insight into significant touch points in healthcare experiences, CMC, parents and HCPs will be observed interacting with one another.³⁶ Observational notes will be read by two members of the research team, and emergent themes identified through constant comparison analysis.⁴⁰ Thematic summaries will be presented at codesign events to inform discussion of care practices and PFCC priorities.

Stage 3: Codesign events

Parents, children and HCPs who participated in earlier stages of the study and indicated their interest (as per previous consent) will be approached to participate in one codesign event. Should someone decide not to participate, a potential participant will be identified with consideration to maintaining maximum sample variation, and written informed consent or assent obtained. Codesign events will be offered at different time to accommodate participants. CMC, parents and HCPs will view the trigger film together, and an experienced facilitator will then lead discussion of the film and present PFCC priorities identified by families and HCPs in earlier interviews. Smaller, mixed breakout groups will use that information as a springboard to identify joint priorities for enhancing PFCC, focusing on caregiver relationships, information sharing, care coordination and collaboration. Groups will exchange priorities, identify areas of overlap and establish care priorities for CMC. If consensus is lacking across codesign events, a final event with representation from each group will be convened to review differences and determine which priorities to present to the working groups.^{26 36 44 46}

Stage 4: Working groups

Working group participants will be drawn from the codesign events where they will have expressed interest and provided consent to contribute as partners to addressing identified priorities for enhancing PFCC for CMC. Groups will design and implement clinical practice changes. Although it is not possible to identify the precise number of care priorities at the outset of the study, 2–4 working groups (1 group/priority) are anticipated. Each group will consist of 2–3 HCPs, 2–3 parents and 2–3 CMC (9+ years of age). The research team will provide guidance regarding the steps and process and an experienced facilitator will lead one group per care priority to plan a change (plan), coordinate action to implement the change (do), observe and learn from the change (study) and determine required modifications to the change (act) based on the Institute for Healthcare Improvement's 'plan-do-study-act' cycles for creating

practice change.^{47 48} Actions and progress will be documented by a member of the research team assigned to each of the groups to support the process. We anticipate needing approximately three cycles per group to achieve uptake of the desired practice change.

Stage 5: Evaluation

Focused, facilitator-led group discussions will take place to evaluate the extent to which participants perceive that (1) joint priorities for improving the core components of PFCC for CMC were established, and (2) working groups were able to codesign and implement practice changes to address identified care priorities. We will determine what did and did not work during the EBCD process, and explore enablers and barriers to designing and implementing practice change in the PICU. Discussions will be recorded, professionally transcribed and analysed using constant comparison analysis. Key themes identified in the analysis of the data will be reviewed by a subgroup of participants identified in codesign events and working groups to ensure the analysis reflects their experiences.⁴⁰ Complementary data regarding parents' and HCPs' perceptions of engagement in the EBCD process will be collected following stages 3 and 4 using the Public and Patient Engagement Evaluation Tool. This tool was designed to help assess the quality and impact of public and patient engagement activities within health system organisations, and has undergone extensive usability testing.⁴⁹ Data will be summarised using descriptive statistics, reviewed in conjunction with themes generated from the focus group data, and combined using a parallel data analysis approach⁵⁰ to consolidate and facilitate data interpretation.

Quantitative arm

Changes in PFCC will be evaluated and a Difference-in-Differences approach used to compare parents' and HCPs' perceptions of PFCC at both sites, prepractice and postpractice change (figure 1).³⁷ A letter from the PICU Nurse Manager and Medical Director describing the study will be sent to potential participants via email, along with a personal link to a REDCap secure web platform that will provide study information, a consent form and an online questionnaire. Regular mail will be used to send materials to those who do not have an email address.

Measures

Participants' demographic and hospital baseline data will be collected from the medical charts (online supplemental appendix 2). Parents will evaluate PFCC using the Refined (MPOC-20, primary outcome measure), a 20-item self-report measure of caregivers' perceptions of the extent of family-centredness of the care received by children with disabilities in a healthcare organisation.³⁰ The MPOC-20 is composed of five subscales reflecting the core dimensions of PFCC. HCPs will evaluate PFCC using the 27-item MPOC for Service Providers (MPOC-SP).⁵¹ Both measures demonstrate good reliability and validity

and have been used with parent and HCP caregivers of CMC.

Analysis

Demographic and hospital baseline data will be summarised at each time point using descriptive statistics. Primary analysis will be based on the MPOC-20, and changes in scores from time 1 to 2 will be compared between sites using the following mixed effect linear regression model: $MPOC-20 = \text{site} + \text{time} + \text{site} \times \text{time}$ [+random effect], accounting for within-patients variation in readmitted patients. For the secondary analyses, changes in MPOC-20 scores from time 1 to 2 will be compared between sites, while further adjusting for patient/parent characteristics (child age, previous PICU admissions, length of stay, risk of mortality, parent education), using a mixed effect linear regression model.⁵² MPOC-SP data will be similarly analysed, adjusting for HCP characteristics (years of PICU experience, professional role, education).

Mixed methods data interpretation

PFCC practice changes reflected in group differences in time 1 and time 2 MPOC scores (parents and HCPs) will demonstrate the effectiveness of practice changes in enhancing PFCC across its core dimensions, as reflected in the instruments' subscales. We will use a parallel data analysis approach to consolidate quantitative and qualitative findings.⁵⁰ Quantitative data will be compared and contrasted with themes generated through constant comparison analysis of parent and HCPs interviews. Since qualitative and quantitative data sets both address similar concepts, we do not expect difficulties integrating them. We will use a mixed-method data matrix to determine where the data sets converge, and where (and why) they diverge to provide a comprehensive interpretation of participant engagement and changes in PFCC experiences for CMC in the PICU.^{34 35}

PATIENT AND PUBLIC INVOLVEMENT/PARTICIPATION

This study is based on a participatory action research design that integrates knowledge translation throughout all stages of design and conduct of the research. Families were involved in the development of this study and will continue to be engaged in all EBCD events. Knowledge users and researchers will partner throughout the study process.^{42 53} CMC and their parents will be invited to participate in all EBCD stages in the qualitative arm of this study, and to provide their unique perspectives on PFCC and how it can be fostered in the PICU. The research team will work with the hospitals' Family Advisory Committees to promote knowledge uptake and dissemination (below).

ETHICS AND KNOWLEDGE DISSEMINATION

Ethical approval was granted by the McGill University Health Centre Research Ethics Board (Ref. #2019-5021) and the Hospital for Sick Children Research Ethics Board

(Ref. #1000063801). Participants will receive verbal and written information regarding the study, and be encouraged to ask questions and discuss their decision to participate. Participants will be told they can withdraw from the study at any time without affecting their hospital care or, for HCPs, their employment. Consent and assent will be revisited and reaffirmed at each stage of the study. Prior to screening the trigger film that will feature video clips of children's and parents' interviews, participants will be given an opportunity to view their respective clips and asked to provide written formal consent for their use. No health or safety risks are anticipated; however, participants will be informed that should they experience emotional distress while sharing their experiences and wish to take a break or withdraw from the study, this will be respected. Should they experience ongoing difficulties or concerns after participating and wish to speak with someone, a referral will be made to hospital support staff. Data collection methods respect Federal and Provincial public health regulations regarding COVID-19 restrictions to ensure participants' safety.

Knowledge dissemination activities will occur throughout the study. Progress will be summarised following each stage in a study newsletter and disseminated to participants, PICU and complex care service staff, clinical and institutional leaders. All participants will be invited to a celebration event at the end of the study to discuss the findings and lessons learnt in the EBCD process. A final report of PICU priorities and recommendations for promoting PFCC for CMC will document key lessons learnt, common solutions and core attributes of the EBCD process that could be transferable across hospital and community care settings. By regularly sharing progress and findings with the hospital Family Advisory Committees at both sites, the dissemination of findings will be promoted locally, provincially and across patient support groups; this will also provide opportunities to explore other means for knowledge uptake. The trigger film will be used for medical and nursing education within hospital and university settings. Presentations, workshops and publications will further ensure dissemination of findings through professional and academic networks.

The growing prevalence of CMC together with the demonstrated benefits of engaging patients and families in service delivery and redesign presents opportunities and challenges for paediatric critical care. CMC present with complex illness trajectories along with expert parent caregivers who know their child's medical condition intimately, altering the dynamics and established character of HCP-family relationships. Resulting tensions can negatively impact caregiving partnerships in the PICU at a time when they are needed most. This study will advance our understanding of families' and HCPs' PFCC experiences, establish joint priorities for enhancing care, and bring CMC, parents, and HCPs together to establish and implement practice changes to enhance PICU care for this vulnerable population.

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REFERENCES

- Edwards JD, Houtrow AJ, Vasilevskis EE, *et al.* Chronic conditions among children admitted to U.S. pediatric intensive care units: their prevalence and impact on risk for mortality and prolonged length of stay*. *Crit Care Med* 2012;40:2196–203.
- Graham RJ, Pemstein DM, Curley MAQ. Experiencing the pediatric intensive care unit: perspective from parents of children with severe antecedent disabilities. *Crit Care Med* 2009;37:2064–70.
- Klick JC, Ballantine A. Providing care in chronic disease: the ever-changing balance of integrating palliative and restorative medicine. *Pediatr Clin North Am* 2007;54:799–812.
- Rennick JE, Childerhose JE. Redefining success in the PICU: new patient populations shift targets of care. *Pediatrics* 2015;135:e289–91.
- Cohen E, Kuo DZ, Agrawal R, *et al.* Children with medical complexity: an emerging population for clinical and research initiatives. *Pediatrics* 2011;127:529–38.
- Canadian Association of Paediatric Health Centres (CAPHC). Definitions, guidelines, and resources. 2016. Available: <https://ken.childrenshhealthcarecanada.ca/xwiki/bin/view/Management+of+Medically+Complex+Children+and+Youth+Across+the+Continuum+of+Care/Definitions,+Guidelines,+and+Resources>
- Burns KH, Casey PH, Lyle RE, *et al.* Increasing prevalence of medically complex children in US hospitals. *Pediatrics* 2010;126:638–46.
- Namachivayam P, Shann F, Shekardemian L, *et al.* Three decades of pediatric intensive care: who was admitted, what happened in intensive care, and what happened afterward. *Pediatr Crit Care Med* 2010;11:549–55.
- Berry JG, Agrawal RK, Cohen E. *The landscape of medical care for children with medical complexity*. Alexandria, VA: Children's Hospital Association, 2013.
- Halfon N, Houtrow A, Larson K, *et al.* The changing landscape of disability in childhood. *Future Child* 2012;22:13–42.
- Matlow AG, Baker GR, Flintoft V, *et al.* Adverse events among children in Canadian hospitals: the Canadian paediatric adverse events study. *CMAJ* 2012;184:E709–18.
- Razack S. PICU Medical Director, Montreal Children's Hospital [MCH], J. Hutchison, Intensivist, The Hospital for Sick Children [SickKids], Toronto, D. Garros, Intensivist, Stollery Children's Hospital, Edmonton. Personal communication 2017.
- Major J, Steward D, Amaria K. *Care in the long term for youth and young adults with complex care needs*. Ottawa, ON: Canadian Foundation for Healthcare Improvement, 2014.
- Clarke D, Jones F, Harris R, *et al.* What outcomes are associated with developing and implementing co-produced interventions in acute healthcare settings? a rapid evidence synthesis. *BMJ Open* 2017;7:e014650.
- Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013;3:e001570.
- Zieband S, Coulter A, Calabrese JD. *Understanding and using health experiences: improving patient care*. Oxford: Oxford University Press, 2013.
- Baird J, Davies B, Hinds PS, *et al.* What impact do hospital and unit-based rules have upon patient and family-centered care in the pediatric intensive care unit? *J Pediatr Nurs* 2015;30:133–42.
- Davidson JE, Powers K, Hedayat KM, *et al.* Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of critical care medicine Task force 2004–2005. *Crit Care Med* 2007;35:605–22.
- Trowbridge K, Mische-Lawson L. Families with children with medical complexity and self-management of care: a systematic review of the literature. *Soc Work Health Care* 2014;53:640–58.
- Carnevale FA, Alexander E, Davis M, *et al.* Daily living with distress and enrichment: the moral experience of families with ventilator-assisted children at home. *Pediatrics* 2006;117:e48–60.
- Melnyk BM, Small L, Carno M-A. The effectiveness of parent-focused interventions in improving coping/mental health outcomes of critically ill children and their parents: an evidence base to guide clinical practice. *Pediatr Nurs* 2004;30:143–8.
- Johnston CC, Rennick JE, Filion F, *et al.* Maternal touch and talk for invasive procedures in infants and toddlers in the pediatric intensive care unit. *J Pediatr Nurs* 2012;27:144–53.
- Rennick JE, Stremmer R, Horwood L, *et al.* A pilot randomized controlled trial of an intervention to promote psychological well-being in critically ill children: soothing through touch, reading, and music. *Pediatr Crit Care Med* 2018;19:e358–66.
- Dixon DM. Unifying Concepts in Parents' Experiences with Health Care Providers. *J Fam Nurs* 1996;2:111–32.
- Thorne SE, Robinson CA. Guarded alliance: health care relationships in chronic illness. *Image J Nurs Sch* 1989;21:153–7.
- Robert G. *Participatory action research: using experience-based co-design to improve the quality of healthcare services*. In:

- Understanding and Using Health Experiences*. Oxford University Press: Oxford; 2013.
- 27 Institute for Patient- and Family-Centered Care. Patient- and Family-Centered care, 2010. Available: <https://www.ipfcc.org/about/pfcc.html> [Accessed 10 Jan 2022].
 - 28 Canadian Institutes of Health Research. Knowledge translation and Commercialization, 2016. Available: <https://cihr-irsc.gc.ca/e/29418.html#1> [Accessed 27 Apr 2022].
 - 29 Dennis C, Baxter P, Ploeg J, *et al*. Models of partnership within family-centred care in the acute paediatric setting: a discussion paper. *J Adv Nurs* 2017;73:361–74.
 - 30 King S, King G, Rosenbaum P. Evaluating health service delivery to children with chronic conditions and their families: development of a refined measure of processes of care (MPOC–20). *Children's Health Care* 2004;33:35–57.
 - 31 Stone BL, Murphy NA, Mundorff MB, *et al*. Children with chronic complex medical illnesses: is inpatient care family-centered? *J Pediatr Rehabil Med* 2008;1:237–43.
 - 32 Institute for Patient- and Family-Centered Care. BI measuring monitoring outcomes, 2014. Available: <https://www.ipfcc.org/resources/BI-Measuring-Monitoring-Outcomes.pdf>
 - 33 Carnevale FA, Campbell A, Collin-Vézina D, *et al*. Interdisciplinary studies of childhood ethics: developing a new field of inquiry. *Child Soc* 2015;29:511–23.
 - 34 Creswell J, Clark VP. *Designing and conducting mixed methods research: second edition*. 2nd ed. edition. Los Angeles: Sage Publications, 2010.
 - 35 Creswell JW, Creswell JD. *Research design: qualitative, quantitative, and mixed methods approaches*. Sage publications, 2017.
 - 36 Donetto S, Tsianakas V, Robert G. Using experience-based Co-design (EBCD) to improve the quality of healthcare: mapping where we are now and establishing future directions. *Lond King's Coll Lond* 2014;5–7.
 - 37 Dimick JB, Ryan AM. Methods for evaluating changes in health care policy: the difference-in-differences approach. *JAMA* 2014;312:2401–2.
 - 38 Cohen E, Lacombe-Duncan A, Spalding K, *et al*. Integrated complex care coordination for children with medical complexity: a mixed-methods evaluation of tertiary care-community collaboration. *BMC Health Serv Res* 2012;12:366.
 - 39 Thompson DM, Fernald DH, Mold JW. Intraclass correlation coefficients typical of cluster-randomized studies: estimates from the Robert wood Johnson prescription for health projects. *Ann Fam Med* 2012;10:235–40.
 - 40 Lincoln YS, Guba EG. *Naturalistic inquiry*. Newbury Park, CA: Sage, 1985.
 - 41 Coyne IT. Sampling in qualitative research. purposeful and theoretical sampling; merging or clear boundaries? *J Adv Nurs* 1997;26:623–30.
 - 42 The King's Fund. Experience-Based Co-Design toolkit, 2017. Available: <https://www.kingsfund.org.uk/projects/ebcd> [Accessed 10 Jan 2022].
 - 43 Beck CT. Phenomenology: its use in nursing research. *Int J Nurs Stud* 1994;31:499–510.
 - 44 Tsianakas V, Robert G, Maben J, *et al*. Implementing patient-centred cancer care: using experience-based co-design to improve patient experience in breast and lung cancer services. *Support Care Cancer* 2012;20:2639–47.
 - 45 Carnevale FA, Macdonald ME, Bluebond-Langner M, *et al*. Using participant observation in pediatric health care settings: ethical challenges and solutions. *J Child Health Care* 2008;12:18–32.
 - 46 Piper D, Iedema R, Gray J, *et al*. Utilizing experience-based co-design to improve the experience of patients accessing emergency departments in New South Wales public hospitals: an evaluation study. *Health Serv Manage Res* 2012;25:162–72.
 - 47 Institute for Healthcare Improvement. Science of improvement: testing changes, 2017. Available: <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx> [Accessed 10 Jan 2022].
 - 48 Deming WE. *The new economics for industry, government, education*. 2nd ed. Cambridge, MA, USA: MIT Press, 2000.
 - 49 Abelson J, Li K, Wilson G, *et al*. Supporting quality public and patient engagement in health system organizations: development and usability testing of the public and patient engagement evaluation tool. *Health Expect* 2016;19:817–27.
 - 50 Östlund U, Kidd L, Wengström Y, *et al*. Combining qualitative and quantitative research within mixed method research designs: a methodological review. *Int J Nurs Stud* 2011;48:369–83.
 - 51 Dyke P, Buttigieg P, Blackmore AM, *et al*. Use of the measure of process of care for families (MPOC-56) and service providers (MPOC-SP) to evaluate family-centred services in a paediatric disability setting. *Child Care Health Dev* 2006;32:167–76.
 - 52 Zar JH. *Biostatistical analysis*. Englewood Cliffs, N.J.: Prentice-Hall, 1984.
 - 53 Parry D, Salsberg J, Macaulay AC. A Guide to Researcher and Knowledge-User Collaboration in Health Research - CIHR. Canadian Institutes of Health Research Government of Canada, 2012. Available: <https://cihr-irsc.gc.ca/e/44954.html> [Accessed 10 Jan 2022].

Appendix 1. Parent and Child Interview Guides

PARENT

Preamble Statement

The goal of this study is **to improve the care** that children with complex medical care needs and their families receive in the pediatric intensive care unit (PICU). You have a great deal of knowledge and experience that we can learn from.

For this part of the study, we would like to better understand your thoughts and feelings about the care [child's name] and your family received in the PICU. I will ask you some questions about [that/those] care experience[s]. There are no right or wrong answers; we are trying to understand and learn from **your experiences**. (Please try to speak to me, and not to the camera.)

Interview Questions:

1. Tell me about [child's name]. What are his/her care needs at home. (Probes: Who provides [child's] care at home? What is [child's] typical care routine?)
2. Can you describe for me why [child] was last admitted to the PICU? (Probes: What was it like when she/he was in the PICU?)
3. As a parent, you are used to providing your child's care at home. In the PICU, the staff provides some of that care. How were you involved in [child's] care in the PICU? How would you like to have been involved? (Probes: Do you think that being involved/more involved in [child's] care is/would be helpful for you? For [child]?)
4. How are decisions made about your child's care when in the PICU? (These can be small decisions, such as who does what, or more significant goals of care decisions.) (Probes: Who is involved in decision-making? How do you feel about your role in the decision-making process?)
5. How would you describe your interactions/communication with staff in the PICU? (Probes: With nurses, with doctors, with other health care professionals working in the PICU? How have communication and relationships evolved over time?)

6. Can you tell me about a time when partnership with staff went well? (Probes: What made the situation feel positive? What was it that worked well?)
7. What could PICU staff do to better to support you and [child]? (Probes: How can staff work together with you to care for [child]? Were there things staff did during a previous admission that you found helpful?)
8. If you could change something about the care your child and family received while in the PICU, what would it be? Why?
9. If a parent of a child with similar care needs was preparing for a PICU admission and asked you what to expect, and how to prepare – what would you tell that parent?

Did you expect me to ask questions that I did not ask today? What would those be?

THANK YOU for accepting to meet with me. Your participation is very valuable to our research and will contribute to improving patient and family care in the PICU.

CHILD

Toolkit

- **Role play with puppets** (if the child has a favorite toy/toys that this could be acted out with – a toy that was also ‘in the hospital’ with them)

We will pretend that 'toy 1' is a nurse, and that 'toy 2' wakes up in intensive care after a surgery he/she had.

Toy 1 (interviewer), Toy 2 (interviewee)

Interviewer: Hello 'toy 2', I'm going to come and check your vital signs and bandage from your surgery. Today I would like you to get out of bed and sit in your chair. I know it might hurt a little bit, but I could give you some medicine to make it hurt less before you get in the chair. What do you think about that?

- **Photo elicitation**

We're going to pretend that this is an intensive care hospital room.

1. If you were in the hospital room here in Intensive Care, where would you be? What would you be doing?
2. Who is there with you? What are they doing? (use specific term/language she uses to describe people who would be present).
3. What are they saying?
4. Who would be in the room with you? Who would you like to have in the room with you? Who wouldn't you like to have in the room with you? Why wouldn't you like to be in the room with you?
5. What kinds of things does your mommy do for you when you are in the hospital that make you feel better? Does the nurse/RT/doctor do these things? Would you like them to do them?
6. How would you feel if the staff did 'things' the way your mom does them? (Fill in the blank of whatever she replies for the above question)

- **Vignette**

I would like to tell you a story about Charlotte. This is Charlotte in the picture here. She is 9 years old, and she has [medical condition], just like you. Charlotte is in the hospital in the intensive care unit after a surgery she had, and she is resting. Her nurse goes into the room and wakes Charlotte up to take her vital signs and check her dressing from her surgery.

1. What do you think Charlotte is going to tell the nurse when she goes into her room?
2. How do you think Charlotte will feel when the nurse enters the room?
3. How do you think Charlotte will communicate with the nurse if she needs something? (Prompts: As if she has a dry mouth, or needs to be sucked on, or change positions)
4. Do you have a story like Charlotte's?

Appendix 2: Participant Demographic and Hospital Descriptive Data

Child	Parent	HCP
Age	Age	Age
Gender	Gender	Gender
Previous PICU Admissions	Highest Level of Education	Highest Level of Education
Previous Hospital Admissions	Occupation	Professional Role
Home care needs	Relationship to child	PICU Experience
Hospital Descriptives: <ul style="list-style-type: none"> • Admitting Diagnosis • Co-Morbid Diseases • Length of Stay • Invasive Procedures Score* • Pediatric Risk of Mortality (PRISM-III) Score* 	Marital status	Hospital Experience
	Other Children	
	Caregiving Support	
	Ethnic/Cultural Origins	

*Rennick et al (2002)... Rennick, J. E., Johnston, C. C., Dougherty, G., Platt, R., & Ritchie, J. A. (2002). Children's psychological responses after critical illness and exposure to invasive technology. *Journal of Developmental & Behavioral Pediatrics*, 23(3), 133-144.

**Pollack et al... Pollack, M. M., Patel, K. M., & Ruttimann, U. E. (1996). PRISM III: an updated Pediatric Risk of Mortality score. *Critical care medicine*, 24(5), 743-752.