

Creating a Flexible Curriculum Tool for Pediatric Palliative Care Rotating Learners

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Protocol Revision History

Protocol Version with Summary of Changes	Version Date
Initial Submission v1	08/27/2025
Revision v2	11/20/2025
Revision v3	11/21/2025
Revision v4	11/24/2025
Revision v5 (for ClinicalTrials.gov to remove personal pronouns)	02/04/2026
Revision v6 (for ClinicalTrials.gov to remove personal pronouns)	02/11/2026

List of Abbreviations

ACGME	Accreditation Council for Graduate Medical Education
DSMB	Data Safety Monitoring Board
GME	Graduate Medical Education
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
OHRP	Office for Human Research Protections
PI	Principal Investigator
RE	Reportable Event

Protocol Summary

Title:	Creating a Flexible Curriculum Tool for Pediatric Palliative Care Rotating Learners
Brief Summary:	The overall objective of this study is to determine if a flexible curriculum tool can improve the experience of rotators with the pediatric palliative care team, measured by their perception that the rotation helped achieve standard and their personal learning objectives. This is a pilot study that will compare rotation evaluations before and after implementing a flexible curriculum tool that uses a database of resources to supplement the clinical rotation education and tailor it to the needs of each learner.
Study Population:	The target population will be a convenience sample of trainees rotating with the palliative care team. This will include physicians in training (hospice and palliative medicine fellows, pediatric subspecialty fellows, pediatric and other residents, medical students), NP students, pharmacy residents, allied health professional students and fellows, research associates, and any other learner who does clinical shadowing. The investigators expect to have about 30 learners over the course of the year, based on 29 last year.
Study Site(s):	Children's National Hospital
Number of Participants:	The investigators anticipate a maximum of 30 participants – 15 for the control group and 15 for the intervention group
Accrual Ceiling:	40 participants
Study Duration:	24 months
Subject Duration:	2-7 months (depending on timing of their rotation compared to the focus group)
Objective(s):	Primary: To evaluate if use of a flexible education tool using a palliative care education database is more effective than standard educational practices in meeting standard learning objectives.

<p>Methodology:</p>	<p>Secondary: To evaluate if use of a flexible education tool using a palliative care education database is more effective than standard educational practices in meeting learner-specific rotation objectives.</p> <p>Unblinded pilot medical education study with convenience sampling and control group to compare to intervention group</p>
<p>Outcome Measures:</p>	<p>Primary: response to the question “I achieved the standard objectives of the rotation (which will be provided to the learner).” It will be quantified using a Likert scale with five choices, 1-5, with 1 set to strongly disagree and 5 set to strongly agree.</p> <p>Secondary: response to the question “I achieved my specific objectives for the rotation (which the learner provided at the start of the rotation).” It will be quantified using a Likert scale with five choices, 1-5, with 1 set to strongly disagree and 5 set to strongly agree.</p>
<p>Study Intervention/Procedures:</p> <p>Statistical Analysis:</p>	<p>This is a single center, unblinded pilot study evaluating the use of a flexible curriculum tool to improve the experience of rotators with the palliative care team, measured by how well the rotation helps them meet standard as well as individualized learning objectives. All learners in the first half of the study period will be in the control group and all learners in the second half of the study period will be in the intervention group. Outcomes will be measured on post-rotation evaluation surveys, sent to each trainee after their rotation is complete. Qualitative data will be further interrogated with a focus group of trainees in the intervention group.</p> <p>Demographic data will be reported using descriptive statistics. A Mann-Whitney U test will be used to compare distribution of responses to Likert scale questions between control and intervention groups and inductive thematic analysis to analyze responses to open-ended survey questions and focus group transcriptions.</p>

Section 1: Key Roles

Principal Investigator	Co-Principal Investigator
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Palliative Care Attending Physician, Hospice and Palliative Medicine Fellowship Program Director	Palliative Care Attending Physician, Hospice and Palliative Medicine Fellowship Associate Program Director
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There are no study leadership committees. The principal investigator will provide oversight of the data. The investigators do not expect to have many adverse or unexpected events (see more in detail below), but they will respond to any complaints or adverse or unexpected events as required by the Children's National OPHS policy on reportable events.

Section 2: Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

It estimated that 2017, more than 21 million children worldwide would have benefited from pediatric palliative care services, and over 8 million would benefit from pediatric palliative care services delivered by a specialist.¹ Palliative care is accepted as a part of standard of care for children with severe illnesses,² but this need is not being met, partially because of a lack of educational opportunities.³

To that end, there have been many educational interventions developed for education of trainees^{4,5} as well as pediatric specialists in principles of palliative care.⁶ While there are developed standards of education for pediatric palliative care education, by the Accreditation Council for Graduate Medical Education (ACGME) in the United States, as well as by other groups in the United Kingdom,⁷ many learners also have individual goals uniquely suited to their practice needs, especially if they do not primarily practice pediatric palliative medicine.⁸

Some educators in pediatric palliative care have utilized more tailored interventions for learners, but they target balancing the patient versus trainee experience,⁹ not necessarily aligning the trainee experience with their

individualized learning goals, especially within the limitations of clinical rotations in a busy training program.

2.2 Scientific Rationale

The pediatric palliative care team at Children's National Hospital supports learners at various levels, with different experiences and goals during their clinical rotations. Some seek to learn about primary palliative care skills, to learn about palliative care careers, or to develop expertise in pediatric palliative care. The team attempts to tailor educational experiences to standard and individualized learning goals and timeframes on service (half day to a few months). It would be helpful to have a database of resources to support these learners for the time on rotation and afterwards. There are multiple databases that exist to serve as tools for medical education, including PubMed, Cochrane Central, MedEdPORTAL, Embase, and ERIC. They provide access to primary literature and books, supporting evidence-based practice, but do not include podcasts, modules, videos, and lectures that are powerful educational tools. Palliative care clinicians utilize *ad hoc* methods to meet learner goals by providing literature that compliments patient encounters or learner inquiries. Tailoring education to meet individualized learning goals at the appropriate level for the learner and the length of their rotation takes energy and time to execute, so it is difficult to do well.

The purpose of this pilot project is to use the Framework for Flexible Education¹⁰ to develop and evaluate a flexible curriculum tool that permits quick connections to resources for educators and learners that are stored in a bespoke and updatable database. The investigators would like to assess if it improves 1) meeting standard objectives and “elective objectives” and 2) the experience of trainees during their rotation. The hypothesis is that it will improve the ability of the rotation to meet learners’ objectives as measured by Likert-scale-based end of rotation evaluations as well as open-ended questions and a focus group.

The study population is a convenience sample of learners who choose to rotate with the palliative care team. The control condition was chosen to be approximately half of the academic year with the intervention the other half. The palliative care team does not have rotators (outside of the pediatric palliative care fellow) during July, so that month was excluded. This pilot study will be performed over the course of the academic year in order to facilitate the teaching team’s ability to improve education for the next year of learners.

2.3 Potential Risks

Minimal risk to subjects is expected. Survey data will be de-identified. Expected time commitment for survey participants is 5 minutes for survey completion, in addition to possible participation in the focus group. For those who participate in the focus group, there is a risk that information shared in the group will not be kept private by other participants.

2.4 Potential Benefits

There is minimal likelihood of direct benefit to subjects, as they would benefit from the educational intervention whether they participate in the study. Indirect benefits may include laying groundwork for future improvement of palliative care education.

Section 3: Objectives and Endpoints

The overall objective of this study is to determine if a flexible curriculum tool can improve the experience of rotators with the pediatric palliative care team, measured by their perception that the rotation helped achieve standard and personal learning objectives. The hypothesis is that the rotators who rotate when the tool is in use will be more likely to agree or strongly agree that learning objectives will be met.

3.1 Primary Objective(s)

To evaluate if use of a flexible education tool using a palliative care education database is more effective than standard educational practices on the pediatric palliative care team in meeting standard rotation learning objectives.

3.2 Secondary Objective(s)

To evaluate if use of a flexible education tool using a palliative care education database is more effective than standard educational practices on the pediatric palliative care team in meeting learner-specific rotation objectives.

3.3 Primary Outcome Measure(s)

The primary outcome measure is response to the question “I achieved the standard objectives of the rotation (which will be provided to the learner).” It will be quantified using a Likert scale with five choices, 1-5, with 1 set to strongly disagree and 5 set to strongly agree.

3.4 Secondary Outcome Measure(s)

The secondary outcome measure is response to the question “I achieved my specific objectives for the rotation (which the learner provided at the start of the rotation).” It will be quantified using a Likert scale with five choices, 1-5, with 1 set to strongly disagree and 5 set to strongly agree.

Other outcome measures include whether (via Likert scale, scores ranging from Strongly Disagree to Strongly Agree as defined above):

- The learner was provided with a variety of resources to meet their learning objectives
- The education they received matched their level of training
- Their education was appropriate to their previous exposure to hospice and palliative medicine
- The education matched their learning style
- They felt the rotation was valuable

- The clinical educators promoted an open, respectful, and safe environment for discussion, learning, and improvement
- They would recommend this rotation to others

Open-ended feedback will be elicited regarding strengths of the rotation, areas for improvement, and practice changes, both on the survey and during the focus group.

Lastly, learners will be assessed on their confidence in meeting each standard rotation objective, on a Likert scale of 1-5, both before and after the rotation.

All of this allows the team to gather more information to understand why there was benefit for the flexible learning curriculum, if indeed there was one.

Section 4: Study Design

This is a single-center pilot study evaluating the use of a flexible curriculum tool to improve the experience of rotators with the palliative care team, measured by how well the rotation helps them meet standard as well as individualized learning objectives. It will not be blinded.

All learners will be sent a welcome email that will include a pre-rotation self-assessment, identifying type of learner and personal experience with palliative care, self-identified preferred ways of learning, length of time on the rotation, and personal learning goals.

All learners in the first half of the study period will be in the control group, and all learners in the second half of the study period will be in the intervention group. Outcomes will be measured on post-rotation evaluation surveys, one for each trainee, sent to them after their rotation is complete. Qualitative data will be more deeply interrogated with a focus group of trainees who participated in the intervention.

Section 5: Study Enrollment and Withdrawal

5.1 Study Population, Recruitment and Retention

- Target sample size: This will be a convenience sample of learners already scheduled to rotate with the palliative care team. There is an anticipated approximately 20 learners per group screened and hope to recruit about 15 per group
- Anticipated accrual rate: 60-75%
- Training site: Children's National Hospital
- Recruitment site: only those who rotate with the palliative care team at Children's National Hospital
- Restrictions to enrollment: none

- Participation will not be limited based on health, only that they need to be healthy enough to participate in the palliative care rotation for at least ½ day, as the target population is trainees
- Participants will be incentivized to participate in the focus group with a \$20 gift card to a location approved by the IRB to compensate them for their time

5.2 Inclusion Criteria

- Age: Must be an adult, greater than or equal to 18 years old
- Must have rotated with the pediatric palliative care team for at least ½ day during the study period
- Must speak English

5.3 Exclusion Criteria

- There are no exclusion criteria for this study

5.4 Vulnerable Subjects

The purpose of this study is to improve the training and educational process for trainees (students and other learners), who will already be taking part in the palliative care rotation.

Their status as a trainee within the program will not be negatively affected if they decide that they do not want to participate in the study, and they will not be pressured to participate in the study due to their status as a trainee.

5.5 Recruitment

The subject population will come from trainees who have rotated with the palliative care team during the study period. They will not be required to participate in the study to rotate with the team; however, they will be emailed rotation evaluation surveys soon after their rotation. On the first page of the evaluation survey, they can consent to participate in the study. If they participate in the study in the intervention group, they can indicate that they would be willing to participate in a focus group and will be sent a separate link (disconnected from their survey data) to indicate that interest. Subjects who indicate interest will be invited to participate in a focus group. The evaluations will be done using Redcap software to protect the privacy of the learners' responses. Any data that is downloaded for analysis will be de-identified and stored on password protected computers on the Children's National Hospital network. Only authorized study team members will have access to the data.

5.6 Retention

- All study subjects in the control group will only participate in the study for the extent of one survey
- Study subjects in the intervention group will participate in the study for the extent of one survey

- Subjects in the intervention group will then be recruited to possibly participate in a single focus group
- Participants will be incentivized to participate in the focus group with a \$20 gift card to a location approved by the IRB to compensate them for their time

5.7 End of Participation Criteria and Procedures

Participants are free to withdraw from participation in the study at any time upon request. Their participation in the study is only when they complete their evaluation form and if they choose to participate in the focus group. For those that require evaluations for their training programs, study participation does not affect their ability to participate successfully in a rotation with the palliative care team or receive positive evaluations, since the processes are independent.

Participants may also withdraw during the focus group.

Section 6: Study Procedures

6.1 Informed Consent/Assent and HIPAA Authorization

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study. It continues throughout the individual's study participation. Because HIPAA-protected information will not be collected in this study, a Waiver of Consent Documentation will be requested, and an information sheet will be used to recruit participants.

- All study subjects will be adults who are fluent in English (as they are rotating with the palliative care team), so will provide their own informed consent
- When study subjects receive emails with their evaluation for the rotation, they will also be sent the information sheet attached to the email
- If they choose to participate in the study, they can indicate their agreement by clicking on the evaluation survey link that will be housed on the information sheet
- Subject privacy will be assured as there will be nothing linking their identity to their survey responses
- The evaluation form will be sent to all rotators. That email will also include an information sheet describing the study, and they will be able to decide whether to complete the form and whether to have their data contribute to the study at the point that they fill it out. The information sheet will be written, with no names attached, and it will be sent after their rotation is complete, and their evaluations are sent. They will have four weeks to complete the evaluation survey, so they are able to discuss it with others prior to agreeing to participate. All of this is to minimize any sense of obligation or coercion.
- The participants may withdraw their consent at any time throughout the course of the study.

- A copy of the information sheet will be given to the participants for their records via email
- The rights and welfare of the participants will be protected by emphasizing that the quality of their education will not be adversely affected if they decline to participate in this study. Additionally, they will be consenting post intervention, so they will be receiving education without bias from the faculty.
- Because names and email addresses will be collected for the focus group scheduling and not tied to participants' medical information, HIPAA Section is not applicable.

6.2 Screening Process

All trainees rotating with the palliative care team who are 18 years or older and participated in at least ½ day with the team clinically within the study period are eligible to participate. The program director and associate program director are the two key personnel in this study and have access to the contact information of the trainees. They will all be included and sent an evaluation form for the rotation within two weeks after the last date of their rotation. They choose whether to participate in the study before completing their evaluation form.

6.3 Study Interventions and Follow-Up

Database Development. Initial database development will be done in Microsoft Excel until June 2026. This database will include links to a variety of resources in the following categories, to be used alongside experiential and on-the-fly teaching: didactics (lectures by palliative care faculty, seminars from other sources, online lectures, videos, and podcasts), interactive resources (online modules, interactive websites, simulations), and written resources (books, articles, handouts, and websites or blogs). Topics covered will include palliative care symptom management, communication in different circumstances, diagnostic, prognostic and treatment information, decision making, ethics, active resources for patients and families, hospice, psychosocial and spiritual support of patients and families, end of life care, and well-being and self-care.

Every resource will be characterized based on questions answered in a learning self-assessment, when a trainee begins their rotation. It will ask about standard objectives and elective objectives, level of training, experience in hospice and palliative medicine, learning style, and time on service. Starting in July 2026, for each trainee in the intervention group, a curriculum will be built per their rotation specifications. Following the tailored curriculum, learners will be given an evaluation to evaluate how effective the rotation experience was at meeting the objectives.

Intervention Implementation. Between January – June 2026, the rotation education will continue as normal for the control group. Rotators will be sent an

introductory email with standard rotation goals and learning objectives and resources. They will share their individual learning objectives on the first day of the rotation. Preceptors will provide resources and clinical opportunities in an *ad hoc* manner for learning based on their individual learning objectives, as is the standard right now. Between July – December 2026, learners with the team will be asked to provide answers to the self-assessment approximately one month before the start of the rotation, and the flexible curriculum tool will be used to generate a tailored set of resources for them. Of note, some rotators organize their rotation on a shorter time frame, and for those learners, the self-assessment will be sent when they set up their rotation to be done as soon as possible.

The final evaluation survey will be sent within two weeks of the last day of their rotation. They will be given four weeks to complete the evaluation.

6.4 Description of Study Procedures/Evaluations

The primary deviation from standard education is described above in intervention implementation. The behavioral intervention is the use of the flexible curriculum tool to systematically tailor rotation resources to each learner. It will be utilized by one of the study personnel who are also the program director and associate program director of the fellowship program and primarily responsible for coordinating rotator education. The tool will output the recommended resources for each learner, which will then be passed along. A description of the tool, as well as a standard operating procedure for its utilization, is attached.

Self-Evaluations: All learners will be sent a self-evaluation describing their level of training and palliative care experience, preferred learning styles, time on the rotation and personalized learning goals.

Rotation Evaluation: Following the rotation, all learners have an opportunity to evaluate the rotation. Individuals not participating in the study can access a separate QR code/link in the body of the first survey email sent to them to provide rotation feedback in RedCap system. The QR code is in the Panda Palliative Care Office on the door and is available for all learners to provide anonymous feedback to faculty. The evaluations are provided at the end of the year to faculty. As standard of practice for the rotation, the program/rotation site director sends an email at the end of the rotation to the trainees with the same QR code as a reminder to complete these evaluations. This information can be found in document called

For those participating in the survey, a separate evaluation process will be utilized. Similar to standard of practice, evaluations will be sent via email and submitted through a different RedCap Survey. It is called “Post Rotation Evaluation.”

The focus group will be organized once all intervention group participants have submitted their evaluations by the end of January 2027. It will take place in February to early March 2027 over Microsoft Teams teleconferencing software and will use the attached focus group guide, developed using best practices.¹¹

As time rotating on the palliative care service can be emotionally distressing in general due to the nature of the work, trainees are offered frequent check-ins with faculty as well as psychosocial colleagues. They are also reminded of resources that they have through their training programs for mental health support, such as EAP, resident counseling, chaplain support, etc. Confidential information can be sent to palliative care administrators, trainee program directors, or CNH graduate medical education (GME) staff. Trainee performance or personal evaluations will not be impacted by their evaluations of the rotation. This will be the same for both control and intervention groups.

6.5 Study Team Training and Intervention Reliability

The intervention will be administered by the key personnel of the study. The flexible curriculum tool and database will not be updated during the intervention period, so all rotators during that period will have the same experience with the tool. It will be standardized, with standard operating procedures, which are attached, so it can be used by any user and yield the same recommendations for each learner based on the answers to their self-assessment.

6.6 Concomitant Interventions and Procedures

Participants are allowed to continue using any other educational tools while on the palliative care rotation. This does not limit their participation in the rotation or in the study.

Section 7: Safety Assessments and Reporting

Rotation with the palliative care team in general can be an emotionally difficult experience; however, there is no anticipated increased risk of adverse events during participation in the study, whether routine, severe, or unexpected and therefore would find no reason for the study to be halted.

Section 8: Statistical Considerations and Analysis

8.1 Statistical and Analytical Plans (SAP)

Because of the simple nature of this pilot study, there will not be a formal Statistical and Analytical Plan (SAP) apart from what is included in the IRB protocol.

8.2 Statistical Hypotheses

Primary Outcome Measure:

- Hypotheses:

- Null: There is no difference (in terms of central tendency) between the two groups in their response (using a Likert scale) to the question, “I achieved the standard objectives of the rotation.”
- Alternative: There IS a difference (in terms of central tendency) between the two groups in their response (using a Likert scale) to the question, “I achieved the standard objectives of the rotation.”

Secondary Outcome Measures:

- Hypotheses:
 - Null: There is no difference (in terms of central tendency) between the two groups in their response (using a Likert scale) to the question, “I achieved my specific objectives for the rotation.”
 - Alternative: There IS a difference (in terms of central tendency) between the two groups in their response (using a Likert scale) to the question, “I achieved my specific objectives for the rotation.”

For the remaining secondary outcome measures evaluated using a Likert Scale, the hypotheses will be like those of the above measures, as they are all evaluated using Likert scales.

For the secondary outcome measures evaluating using Likert Scales at pre- and post-participation time points, the hypothesis is as follows:

- Hypotheses:
 - Null: There is no difference in mean between the two groups in the degree of change between pre- and post-intervention confidence (for each individual objective)
 - Alternative: There IS a difference in mean between the two groups in the degree of change between pre- and post-intervention confidence (for each individual objective)

There are no hypotheses for the analysis of the open-ended survey questions and focus group data, as they will be analyzed using inductive thematic analysis.^{12,13}

8.3 Analysis Datasets

While the flexible education tool and database will be used for all participants in the intervention group to provide them with relevant resources, each individual learner is responsible for utilizing the resources themselves. Therefore, all participating subjects will be included in an intention-to-treat analysis dataset as opposed to per-protocol.

8.4 Description of Statistical Methods

This study is a pre-/post-interventional study; however, different participants will receive the intervention than those that receive the control education because of the nature of the palliative care rotation. Essentially, for the first 6 months of the study period, rotators will receive the control education, and for the next 6

months of the study period, they will receive education using the intervention, the flexible education tool. All evaluations from each 6-month period will be aggregated to preserve anonymity, and there will be no learners who are in both groups.

Demographic data will be collected during the self-assessment and reported using descriptive statistics:

- Level of training (categorically in percentages)
- Amount of experience in hospice and palliative medicine (categorically in percentage)
- Learning style (categorically in percentages)
- Time on palliative care service (categorically in percentages)

For all outcome measures that use Likert scales (ordinal data), the sample size is so small that it is assumed data will not fall within a normal distribution, so a Mann-Whitney U test will be to analyze it and report z-test statistic and p-value, as well as the interquartile range. A p-value of 0.05 will be used for statistical significance.

Individual participant data will not be published.

Confidence ratings will be compared at pre-post time points for significant improvements within each group using a paired t-test. Overall improvement between control and intervention groups will be compared using a student's t-test to compare the change in confidence. A p-value of 0.05 will be used for statistical significance.

Qualitative data, including responses to open-ended survey questions and focus group data, as mentioned in 8.2, will be analyzed using inductive thematic analysis using DeDoose software.

8.5 Sample Size

Because this is a pilot study to improve the education of an existing population on a rotation with a small team, the sample will be a convenience sample of learners who rotate with the palliative care team. It is expected that there will be approximately 20 learners to recruit and screen for each (control and intervention) group and to enroll at least 10 and up to 15 for each group. It is accepted that the statistical analysis may be underpowered, which is why the pilot study will be supplemented with qualitative data.

8.6 Measures to Minimize Bias

Enrollment/Randomization/Masking Procedures

- There will be no randomization, as it is a convenience sample based on when learners have room in their schedule to rotate with the palliative care team

- Based on the way the intervention will be implemented, it is impossible to blind the educators or the rotators as to whether the rotators are in the control or intervention group
- The control and intervention survey data will not be analyzed until after all data is compiled (control data in August 2026 and intervention data in February 2027), and data will have all identifying information (timestamps, etc.) removed.
- Bias will be minimized in the qualitative data using triangulation – independent analysis by multiple personnel as well as comparison of open-ended survey data with focus group data

Section 9: Data Quality and Oversight

Survey data will be de-identified and collected via REDCap. It will be stored in their database until completion and publication of the study. It will be accessible only to authorized users via password. Data downloaded for analysis in an Excel file will have data and timestamps removed.

Focus group data will be de-identified when it is transcribed. It will be conducted over teleconference software (Teams) but recorded via audio recorders outside of the Teams software, so as to not capture visual data. Additionally, participant names will not be used, and they will be referred to as “participant 1”, “participant 2”, etc. Recording will be transcribed using Rev AI transcription software. Recordings and transcriptions will be stored on a password protected shared drive.

9.1 Study Team Quality Assurance and Quality Control

The highest risk for deviations in data quality is in the qualitative data, especially that which will be transcribed from the focus group. The Principal Investigator is responsible for maintaining quality control of the data.

9.2 Data Safety and Monitoring Plan

There is not an anticipated need for a Data Safety and Monitoring Plan considering the minimal risk of adverse events to subjects.

Section 10: Ethical Considerations

10.1 Ethical Standard

The study team will ensure that this study is conducted in full conformity with the Regulations for the Protection of Human Subjects of Research codified in 45 Part 46 of the Code of Federal Regulations, Children’s National Policies and Procedures and Good Clinical Practices.

10.2 Institutional Review Board (IRB)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Children’s National IRB for review and

approval. Approval of both the protocol and the consent form will be obtained before any participant has given consent. Any change to the protocol, consent, recruitment materials and participant information sheets or letters will require IRB approval before implementation and use. The IRB will determine whether previously consented participants need to be re-consented

The IRB will be notified of study team updates via an amendment. Data Safety Monitoring Board (DSMB) Reports will not be submitted at the time of the continuing review or with another applicable IRB transaction due to the minimally risky nature of this study.

Other study events (e.g., protocol deviations, data monitoring reports) will be submitted per the Children's National IRB Reportable Events Module.

10.3 Maintaining Subject Privacy

Initial patient recruitment for the survey portion of the study will be done via email, and their data will be entered in Redcap. It is impossible to fully limit subject privacy during a focus group, so subjects will be informed in the information sheet that there is a risk of loss of privacy of the information they share in the focus group, as the researchers are not able to control the actions of the other participants. However, there will be an explicit expectation of respect for information shared with all participants, and the focus group will be conducted in a private virtual space.

10.4 Maintaining Study Data Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, their staff, the sponsor, and their agents. This confidentiality is extended to cover educational information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The sponsor's representatives and regulatory authorities (e.g., IRB, OHRP) may inspect all documents and records required to be maintained by the investigator. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each study site for internal use during the study. At the end of the study, all research records will be stored in a secure location for the time period dictated by the sponsor and institutional regulations.

The research data will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password

protected. At the end of the study, all study databases will be archived at Children's National.

10.5 Study Support and Conflicts of Interest

Salary support for this study is provided by the Children's National Division of Pediatric Hospital Medicine. REDCap® support is provided by The Clinical and Translational Science Institute (CTSI) at Children's National. Grant support for this pilot project is provided by the Division of Pediatric Hospital Medicine Pilot Grant.

All key study personnel will follow the Human Research Protections Program Investigator, Study Staff, and Family Member Conflicts of Interest (COI) Policy.

Section 11: Data Handling and Record Keeping

11.1 Data Management Responsibilities

Initial survey data will be entered into Redcap via a survey managed by key trial personnel. In August 2026 (control data) and February 2027 (intervention data), the study coordinator will remove identifying information (timestamps, etc.) and compile the data into an Excel file to be saved on a password-protected shared drive.

Statistical analysis will be done using the assistance of a statistician consultant and by the key personnel.

The focus group will be conducted over a recorded teleconference on Microsoft Teams and recording will be transcribed using Rev AI transcription software. DeDoose software will be used to analyze responses to the open-ended survey question and focus group transcriptions.

11.2 Data Capture Methods

The PI is responsible for ensuring the accuracy, completeness, legibility, timeliness and completeness of the data reported.

Research data will be entered into REDCap®, a password protected, secure, Health Insurance Portability and Accountability Act (HIPAA) compliant, web-based electronic database with a built-in audit trail. It will be entered via a survey.

Focus group data will be collected by audio recording of a Teams teleconference focus group.

11.3 Study Record Retention Policy

Study records will be maintained for at least 3 years after study closure. There will be no physical records. Any data that is retained will be de-identified.

Section 12: Publication Policy

Pursuant to receipt of the Pediatric Hospital Medicine pilot grant, authorship, including authorship order, has already been determined. It also requires presentation at local regional meetings as well as submission to national meetings.

Section 13: References

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