Developing an implementation strategy for post-concussion communication with low health literacy parents in the emergency department

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Please note: Due to the smaller sample recruited we simplified our analytic plan to focus on primary outcomes and no subgroup comparisons.

PROJECT TITLE:

Developing an implementation strategy for post-concussion communication with parents in the emergency department

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Contents

1. Objectives

1.1. Purpose, specific aims, or objectives:

The aims of this project are to:
Aim 1: Engage families and health care providers in: adapting the CDC's Acute Concussion Evaluation Care Guidelines to be readable/useable by families with low health literacy and developing an implementation strategy for communicating about this information and sharing this adapted handout with families who sought closed head injury care for their child in the emergency department (ED).
Aim 2: Assess how treatment-as-usual is being experienced by parents seeking care for their child post-closed head injury in the ED.
Aim 3: Assess the impact of strengthened post-closed head injury communication (as developed in Aim 1) on family adherence to evidence-based concussion management guidelines.
Aim 4: Ensure the study measures used in this study are valid and reliable- including ensuring that participants are not confused by question wording and that responses are correlated with other demographic, behavior, knowledge, and self-efficacy variables in predictable ways (e.g., to assess measure validity).

1.2. Hypotheses to be tested:

Aim 1: This research is qualitative and exploratory; our goal is to understand the perspectives of different stakeholders in order to adapt materials and develop an implementation strategy that better supports family adherence with evidence-based guidelines about post-concussion management following discharge from the ED.

Aims 2 and 3: We expect that families who receive the adapted education toolkit (Aim 3) will report greater understanding of evidence-based guidance and will be more prepared to adhere to evidence-based guidance post-closed head injury as compared to parents in the control condition.

Aim 4: This research is qualitative and exploratory; our goal is to develop and validate measures of concussion-related behaviors, knowledge, and self-efficacy. We aim to get feedback from adults to ensure that the survey questions for Aims 2 and 3 are easily understood and that the measures are valid and reliable.

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

Appropriate concussion management reduces concussion-related morbidity Every year, more than one million U.S. youth are diagnosed with a concussion from sport or recreational activities.[1] The Centers for Disease Control and Prevention's (CDC) recent Report to Congress on the Management of Traumatic Brain Injury in Children[2] emphasizes that appropriate post-concussion management in the home, school and sport settings is critical for minimizing morbidity. During the symptomatic period post-injury, which can range from several hours to months,[26] the brain experiences a metabolic cascade during which there is greater vulnerability to additional injury.[27] Appropriate management is important for minimizing risk of subsequent injury and optimizing quality of life during recovery.[28] Consensus guidelines recommend avoiding activities with a risk of contact or collision (e.g., sport) and, after a brief period of rest, moderating cognitive demands in the school and home setting in response to symptoms, under the guidance of a medical professional.[29] **Parents are key partners in implementing evidence-based guidelines about post-concussion management in the home, school and sport settings.** This includes being observant for symptoms at home, interfacing with medical providers and academic personnel and ensuring the child does not return to sport prematurely

and risk greater injury.[2] However, many parents lack knowledge about post-concussion management[30] and struggle to achieve the necessary communication, decision-making, and planning to support their child's recovery.[6] In part due to differences in post-concussion management behaviors,[5,26] lower socioeconomic status youth are at elevated risk of experiencing poor health-related quality of life post-concussion.[7,32] Consistent with broader patterns in health literacy,[33] components of which include being able to access, understand and apply health-related information,[34] concussion knowledge and information-seeking tends to be greater among more educated, affluent, non-Hispanic white parents.[35,36] **There is thus a critical need to address knowledge translation to low health literacy parents to support post-concussion management behavior. For many families, the initial post-concussion visit in the emergency department (ED) is the sole point of clinical contact post-injury and a critical time for evidence-based knowledge translation.** Youth on Medicaid who seek medical attention post-concussion are most likely to do so in an ED.[9] More than two thirds of pediatric patients seen post-concussion in the ED do not seek follow-up from a concussion specialist or primary care provider,[10] due in part to inconsistent recommendations from ED providers[37] and their lack of a medical home.[12,38,39] This heightens the importance of knowledge translation to parents in the ED. However, there is substantial variability in whether the written discharge instructions parents receive are based on current consensus guidelines.[15,17,18] **Existing evidence-based approaches to knowledge translation post-concussion are currently inadequate without adaptation to meet the needs of parents with low health literacy.** The CDC has developed the Acute Concussion Evaluation (ACE) Care Plan,[3] a two-page handout for healthcare providers to share with families following their child's injury with information about returning to daily activities, return to school and return to sport. Sharing these materials has been recommended as part of an evidence-based clinical pathway for acute pediatric post-concussion evaluation and management[40] and their utilization has been associated with improved youth outcomes.[4] However, the short and densely-written fact sheet does not adhere to best practices for knowledge translation to low health literacy patients, such as giving the most important information first, using visuals where possible, limiting the number of messages and clearly stating the actions the reader should take.[34] Additionally, the readability of the CDC ACE Care Plan handout[3] is at a 10th grade level (Flesch Reading Ease=49.0, Flesch-Kincaid Grade Level=10.0), which is higher than recommended guidelines.[20 41] Finally, these materials have not been translated into Spanish or any other language. **Thus, there is a need to adapt the CDC ACE Care Plan to meet the learning needs of parents with low health literacy and limited English proficiency (LEP). Well-designed written materials alone are not sufficient for effective knowledge translation that supports behavior change.** Among parents, recall of written discharge instructions from EDs post-concussion is greater when they are accompanied by a verbal discussion from nurses in the ED.[21] This is consistent with a broader literature on educational strategies for families in healthcare settings, which recommends a provider-initiated discussion that includes a teach-back component to gauge understanding.[42] Such a discussion can also help parents identify and address barriers to action beyond knowledge, such as how to access additional care if symptoms are not improving.[40] However, only half of youth with sports-related concussion who sought care in the ED report having discussed discharge instructions with a healthcare provider.[22] Such variable implementation disproportionately impacts lower SES families, as racial or ethnic minority families or families with limited education are less likely to ask questions of providers,[23] and are less likely to have a teach-back style of patient education used in their clinical visit.[43] More than half of physicians in ED settings have inadequate knowledge about post-concussion management[16,44,45] and a systematic review of the training provided to ED physicians concluded that there is a need for improved training to optimize the dissemination and implementation of best practices for concussion management in this setting.[46] **Existing approaches for discharge communication can be adapted to support implementation of evidence-based**

parent education about concussion management. The Agency for Healthcare Research and Quality (AHRQ) has developed a Re-Engineered Discharge (RED) Toolkit[19(p2)] to help optimize the discharge process in hospital settings that can be used as a foundation for acceptable and equitable implementation of the CDC ACE Care Plan. Core components of RED guidance related to family-provider communication include: (1) ensuring that written materials are easily understood and available in the family's preferred language, (2) ensuring there is satisfactory explanation of these materials, including an opportunity to ask questions, and (3) providing support in planning next steps for engaging in recommended behaviors[19(p2)]. Ongoing quality improvement efforts at Seattle Children's Hospital have identified important opportunities for implementing RED communication guidelines, such as having nurses work with families to gauge understanding and plan next steps.[47] **To realize improved discharge communication, ED providers (physicians and nurses) require: (1) access to evidence-based information about concussion management to share with parents post-injury and (2) support implementing such materials in their clinical setting.**

2.2. Relevant preliminary data:[1]

See section 2.1

2.3. Scientific or scholarly background:

See section 2.1

2.4. Prior approvals:

N/A

3. Study Endpoints[2]

3.1. Primary and secondary endpoints:

Aim 1: Recruitment of participants will occur until thematic saturation. For each participant, the endpoint will be the conclusion of the interview or focus group.

Aim 2: Recruitment will continue until 200 families agree to participate. For each family, participation will conclude after completing the two-week post-discharge survey.

Aim 3: Recruitment will continue until 200 families agree to participate. For most families, participation will conclude after completing the two-week post-discharge survey. For a subset of families, participation will conclude at the conclusion of the interview.

Aim 4: Recruitment will continue until thematic saturation. For each cognitive interviewing participant, the endpoint will be the conclusion of the cognitive interview. For each online survey participant, the endpoint will be the conclusion of the online survey.

3.2. Primary or secondary safety endpoints:

There are no primary or secondary safety endpoints for this research project.

4. Drugs, Devices and Biologics[3]

4.1. Manufacturer and name of all drugs, devices and biologics:

N/A

4.2. Description and purpose of all drugs, devices and biologics:

N/A

4.3. Regulatory status of all drugs, devices and biologics:[4]
N/A

4.3.1. Drugs or Biologics:
☐ IND Exempt. Explain:[5] ✍Click here to enter text.
☐ IND.

4.3.2. Devices:
☐ IDE Exempt. Explain:[6] ✍Click here to enter text.
☐ Abbreviated IDE / Non-Significant Risk. Explain:[7] ✍Click here to enter text.
☐ IDE / Significant Risk.

4.4. Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
N/A

5. Procedures Involved

5.1. Study design:[8]

Aim 1: Qualitative methodology, including interviews.
Aims 2 and 3: Consecutive cohort design with randomization.
Aim 4: (1) Cognitive interviewing (one-on-one interviews where participants talk through survey questions and identify challenging/confusing parts), and (2) cross sectional study, with data collected through anonymous online surveys.

5.2. Research procedures:[9]

Aim 1: This aim involves qualitative interviews, following a semi-structured questioning methodology, informed by an interview guide that will be iteratively and flexibly adapted based on emergent participant feedback. Interviews will be digitally recorded and transcribed verbatim, then coded for relevant themes using a thematic analysis approach. We will announce that the interview will be recorded at the beginning of each interview, and that announcement will be recorded. We will conduct a one-on-one interview with each parent and healthcare participant that will last approximately 45 minutes. Parent interviews will be conducted remotely (e.g., by phone or by video conferencing) or in person at SCH or the parent's house or a nearby community location (e.g., private room in public library). Healthcare provider interviews will be conducted remotely (e.g., by phone or by video conferencing) or in person in a private room at SCH. Interviews with parents will be conducted in their native language (English or Spanish). Spanish language interviews will be conducted by a research team member who is fluent in Spanish and is a Certified Bilingual staff member, with consent also obtained by this person. As part of parent data collection for Aim 1, all parents will complete the 3-item Brief Health Literacy Screen as part of a demographic questionnaire given prior to the start of the interview. For remote qualitative interviews, the same procedures will be followed, however, participants will be emailed the demographic questionnaire and information sheet and they will participate via an online platform (i.e. Zoom). Please see timeline (uploaded in "Other Attachments") for more information regarding the timing of Aim 1.

Aims 2 and 3: We will assign participants to the intervention and control groups using a consecutive cohort design with randomization. In the first data collection cohort (Aim 2), all participants will be assigned to the education-as-usual control condition. In the second cohort (Aim 3), participants will be

randomized to either the education toolkit intervention condition or treatment-as-usual control condition in a 2:1 ratio. For participants in the control group (Aim 2 and those randomized to control group in Aim 3), there will be no change to the nature of provider communication with families about closed head injury/concussion. Data will be collected about the experience that family's have seeking care in the ED for their child's closed head injury. For both Aims 2 and 3, survey data will be collected from parents at three time points: at initial ED visit before discharge, one day post-visit, and at 2-week follow-up. As part of parent data collection for Aims 2 and 3, all parents will complete the 3-item Brief Health Literacy Screen at the first time point of survey data collection. Please see timeline (uploaded in "Other Attachments" for more information regarding the timing of Aims 2 and 3.

For Aim 3 participants randomized to the intervention group, the parent education toolkit finalized in Aim 1 will be delivered by the study team. Based on feedback from qualitative interviews in Aim 1, the toolkit will consist of brief education from a member of the ED study team at enrollment, followed by asynchronous phone-based follow-up (audio/ voice and/or text). Parents will receive automated daily educational messages related to how they can provide recovery support to their children during the 2-week study period. Automated messages will be delivered via Twilio, by turning on the "initiate survey as SMS conversation" feature in REDCap. Parents will also receive reminders to schedule a follow-up appointment, with an option to received tailored support from research staff to help with scheduling. A more detailed description and content of each toolkit component can be found in "Aim 3 Parent Education Toolkit Content" uploaded in "Other Attachments".
All patient materials will be available in both English and Spanish. Certified translations will be uploaded prior to use.

For both Aims 2 and 3, survey data will be collected from parents at three time points: immediately post-visit, one day post-visit, and at 2-week follow-up. A purposive subset of parents who complete all three surveys in Aim 3 will be invited to participate in optional one-on-one qualitative interviews. Interviews will be conducted remotely (e.g., by phone or video conferencing) and will be recorded. As part of parent data collection for Aims 2 and 3, all parents will complete the 3-item Brief Health Literacy Screen at the first time point of survey data collection.

Aim 4: (1) Cognitive interviewing: Parents will complete a one-on-one conversation with a research team member in or near the ED. In that conversation, they will be asked to read through a series of survey questions about parent behaviors, self-efficacy, and knowledge related to concussion and concussion management to help develop the final survey instrument for Aims 2 and 3 (a mock up of the cognitive interviewing survey instrument can be found in "Other Attachments"). Participants will then be asked to provide feedback about how they would think about answering these questions, with a particular focus on identifying anything that is confusing about the questions conceptually and any wording that is confusing or ambiguous. They will not be asked to answer questions about their personal health status or the health status of their children. All potential participants will complete the 3-item Brief Health Literacy Screen as part of screening, with stratified purposive recruitment among adequate and low health literacy parents until thematic saturation of survey feedback is reached. (2) Online surveys: Participants will complete online surveys built in REDCap with the survey link posted on the participant recruitment tool Amazon Mechanical Turk (or MTurk). The surveys will consist of behavior, belief, knowledge, and demographic questions that will help us validate the survey measures to be used in Aims 2 and 3. Participants will not be asked to answer questions about their personal health status or the health status of their children. Based on cognitive interview responses, we will post a subset of the survey questions on MTurk with potential corrected wording for clarity based on participant feedback. Participation in the online surveys will be voluntary and anonymous. A mockup of the online REDCap surveys can be viewed in "Other Attachments". Please see the study timeline (also uploaded in "Other Attachments") for more information regarding the timing of Aim 4.

5.3. Data sources that will be used to collect data about subjects:[10]

Aim 1: Data will be derived from qualitative participant feedback (interviews, participatory design sessions and usability feedback). The source records that will be used to collect data from participants (e.g. question guides) are attached to the Click Smartform. The qualitative question guides will change iteratively based on feedback from participants, but themes explored will remain the same, consistent with best practices for qualitative data collection. Please note that all materials will be translated to Spanish and uploaded as an IRB modification prior to recruitment of Spanish speaking participants.

Aims 2 and 3: Parents will complete surveys at three time-points: (1) at initial ED visit before discharge, (2) one day post-visit, and (3) approximately two-weeks post-visit. The first survey will be administered over the phone by the study team member. Surveys will be translated into Spanish using a certified translation service and the research team member involved in parent data collection will be certified to use Spanish or use a professional interpreter. Participating parents will be contacted one day post-visit and two-weeks post-visit to complete the follow up survey by telephone (call or text linking to a survey hosted on REDCap), or by email (linking to a survey hosted on REDCap). [58] Subsequently, a purposively selected subset of twelve parents will be invited to participate in a one-on-one qualitative interview about their experiences with the education toolkit; additional parents may be recruited if necessary to reach thematic saturation. Please note that all materials will be translated to Spanish and uploaded as an IRB modification prior to recruitment of Spanish speaking participants.

Aim 4: (1) Cognitive interviews: Data will be derived from qualitative participant feedback (e.g., cognitive interviews). The source records that will be used to collect data from participants (e.g., question guides) are attached to the Click Smartform. (2) Online surveys: Data will be collected through an online surveys, built in REDCap with the survey link posted on MTurk.

5.4. Data to be collected, including long–term follow–up data:[11]

Aim 1: The goal of the parent interview will be to (1) explore their experiences with communication in the ED following their child's concussion and (2) provide critical feedback on the content and design of the CDC ACE Care Plan.[3] The Cultural Treatment Adaptation Framework[50], will provide the foundation for the open-ended question guide for parents, with questions about the handout focusing on: (1) language and semantics, (2) use of culturally relevant examples, and 3) preferences for material delivery. The goal of the healthcare provider interviews will be to review the CDC ACE Care Plan handout[3] and the RED Toolkit,[19] and provide feedback about (1) barriers and facilitators to implementation in the ED and (2) the type of support (e.g., materials, training) that they believe would be helpful for implementation. CFIR[24] will provide the foundation for the open-ended question guide for healthcare providers, with a focus on individual characteristics (e.g., provider knowledge and self-efficacy), implementation toolkit characteristics, and aspects of the inner setting (e.g., time pressures in the busy ED, compatibility with existing communication networks and tools such as the EHR system) that may constrain implementation success.

Aims 2 and 3: Survey data will be collected from up to 200 parents at three time points: at initial ED visit before discharge, one day post-visit, and at 2-week follow-up. **Primary outcome.** Our primary outcome will be parenting behaviors at 2 week follow-up (emotional support and instrumental support). **Secondary outcomes.** Parent surveys at initial ED visit before discharge, one day post-visit, and two-weeks post visit will assess parent cognitions related to concussion management and proximal cognitions (concussion management knowledge and self-efficacy), parental anxiety related to concussion management, youth outcomes (health-related quality of life, post-concussion symptoms), the nature of provider-parent communication in the ED (e.g., did the parent have an opportunity to ask questions?), and additional

covariates (demographics and environmental conditions). In Aim 3 only, the parent surveys at 2 weeks post-visit will also include questions about their experiences with receiving the education toolkit.

Parent Interviews (Aim 3 only): Based on parents' responses to their experiences with the education toolkit, a purposive recruitment strategy will be used to invite by email 12 parents to participate in one-on-one qualitative interviews. Interview content will be based on the Consolidated Framework for Implementation Research[24]and Communication Accommodation Theory, assessing their experiences implementing content of the intervention, and their affective experience engaging with educators. Following best practice guidance for eliciting qualitative data about implementation barriers and facilitators and communication experiences, the question guide will remain open ended so that interviewers can explore other themes raised by participants.

Aim 4: (1) Cognitive interviews: The goal of the cognitive interview will be to assess understanding of survey questions and receive feedback on survey content. Research assistants will talk through questions with parents and identify 1) if question wording is confusing or challenging in any way, and 2) if questions could be asked in a way that is easier to understand. (2) Online surveys: The surveys will primarily assess parent behaviors, knowledge, and self-efficacy related to concussion management in order to validate our survey tool Additional covariates (such as demographic information, previously diagnosed concussion) will also be collected for the purpose of ensuring the survey tool is valid and reliable for the general population. Survey questions will come from a bank of potential questions, which can be found in the support document "Aim 2 Parent Survey Questions".

6. Data and Biospecimen Banking[12]

6.1. Complete list of the data and/or biospecimens to be included in the bank:[13]
N/A

6.2. Location of data and/or biospecimen storage:[14]
N/A

6.3. List of those with direct access to data and/or biospecimens in the bank:
N/A

6.4. Length of time data and/or biospecimens will be stored in the bank:
N/A

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:[15]
N/A

6.6. How the data and/or biospecimens will be made available for future use:
N/A

6.6.1. Who can request data and/or biospecimens from the bank:
N/A

6.6.2. Format in which data and/or biospecimens will be provided:
N/A

6.6.3. Process for investigators to request data and/or biospecimens:[16]

N/A

6.6.4. Restrictions on future use:[17]
N/A

6.6.5. Plan for providing data results from banked data/biospecimens:
N/A

7. Sharing of Results

7.1. Plan to share results with subjects/others:[18]

Aggregate data will be shared with members of the research team and disseminated via peer reviewed publication. No personal identifiers will be shared.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:

Note: Aims are not numbered in chronological order, however they will be listed below in the order they will be collected.

Aim 4: (1) Cognitive interview: For each parent, the endpoint will be the conclusion of the cognitive interview; (2) Online surveys: For each participant, the endpoint will be the conclusion of the online survey.

Aim 1: For each participant, the endpoint will be the conclusion of the interview. For healthcare providers participation will conclude following completion of a survey and/or qualitative interview.

Aims 2 and 3: In the first data collection cohort (Aim 2), all participants will be assigned to the education-as-usual control condition. In the second cohort (Aim 3), participants will be randomized to either the education toolkit intervention condition or treatment-as-usual control condition in a 2:1 ratio. For each parent in the control group and for most parents in the intervention group, participation will conclude after completing the two-week post-discharge survey. For a subset of parents in the intervention group who agree to participate in a follow-up interview, participation will conclude at the end of a qualitative interview following the data collection period.

8.2. Duration anticipated to enroll all study subjects:

Aim 4: 1 month
Aim 2: 5 months (potentially up to 9 months)
Aim 1: 12 months (potentially up to 18 months)
Aim 3: 5 months (potentially up to 9 months)

8.3. Estimated date for the investigators to complete this study:

Primary analyses will be completed about 2 years after the start of the study

9. Study Population[19]

9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):

Aim 1:
Parents: Parents of children who sustained a closed head injury and sought care in the Seattle Children's Hospital Emergency Department or Urgent Care within the past 2 years.

Children: Children of parent participants chosen for the study using the criteria immediately above. Please note: Children will have no active participation in the study, but private identifiable information about them will be collected.

Medical providers: Medical providers (physicians and nurses) who have provided post-closed head injury care in the Seattle Children's Hospital Emergency Department.

Aims 2 and 3:
Parents: Parents of children who sustained a closed head injury and sought care in the Seattle Children's Hospital Emergency Department or Urgent Care during the study period.
Children: Children aged 5-17 of parent participants chosen for the study using the criteria immediately above.
Please note: Children will have no active participation in the study, but private identifiable information about them will be collected.

Aim 4: (1) Cognitive interview: Parents of children who sought care (for any reason) in the Seattle Children's Hospital Emergency Department or Urgent Care during the study period; (2) Online surveys: English-speaking parents (age 18 and older)

9.2. Exclusion criteria for each subject population:

Parents: Not fluent in English or Spanish
Medical providers: Not fluent in English

9.3. Populations with special considerations, involved in the study:[20]

☒ Children/Teenagers[21]
Risk assessment specific to this vulnerable population and additional safeguards:[22]
Private and potentially identifiable data will be collected about child patients. Child patients will provide verbal or written assent for study participation in Aims 1, 2, and 3.

☐ Children who are Wards of the State[23]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☐ Adults Unable to Consent [24]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☐ Neonates of Uncertain Viability or Non–Viable Neonates[25]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☐ Pregnant Women[26]
Additional safeguards:
N/A

☐ Prisoners[27]
Additional safeguards:

N/A

☐ Economically or educationally disadvantaged persons[28]
Additional safeguards:
N/A

10. Number of Subjects

10.1. Total number of subjects to be enrolled locally:[29]

Aim 1: We anticipate recruiting and consenting about 20 parents, 20 children and 20 healthcare providers.
Aim 2: We anticipate recruiting and consenting about 200 parents and 200 children
Aim 3: We anticipate recruiting and consenting about 200 parents and 200 children
Aim 4: (1) Cognitive interviews: We anticipate recruiting at least 10 parents for cognitive interviews; (2) Online survey: We anticipate recruiting at least 700 participants for the online surveys.

10.2. Total number of subjects to be enrolled across all participating sites:[30]
N/A

10.3. Number of screened subjects versus the actual number enrolled in the research:[31]

Aim 1: We estimate we will need to screen 60 parents to enroll 20 parent participants, and 25 healthcare providers to enroll 20 participants.

Aim 2: We estimate that we will need to screen 600 families to enroll 200 eligible parents

Aim 3: We estimate that we will need to screen 600 families to enroll 200 eligible parents.

Aim 4: (1) Cognitive interviews: We estimate that we will need to screen 30 families to enroll 10 parent participants; (2) Online surveys: We estimate that we will need to screen 800 parents to enroll 700 parent participants.

10.4. Power analysis:

Aim 1: This is a qualitative study and thus a power calculation is not appropriate.

Aims 2 and 3: With 200 participants per group (Aim 2 and Aim 3), we will have ≥98% power to detect a meaningful 20% difference in the proportion of parents receiving each specific component of the reach measure (Table 1), in Aim 2 vs. Aim 3 groups, after allowing for 10% attrition (alpha=0.05). For Health Literacy subgroup comparisons, we will have ≥80% power to detect a 20% difference, assuming 10% attrition.

Aim 4: This is an exploratory, primarily qualitative study and thus a power calculation is not appropriate.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:

We do not anticipate circumstances under which participants will be withdrawn from the research without their consent

11.2. Procedures for orderly termination:
N/A

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:

Participants may withdraw from the study at any time by notifying study personnel. Once a participant expresses their desire to withdraw, the researcher will terminate data collection. The study team will review, on a case-by-case basis, whether partial data collected will be used in the analysis.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):

This study involves no more than minimal risk to participants. Potential risks include the following:
Testing burden: participants may experience inconvenience associated with answering interview questions
Loss of confidentiality: participants will provide identifiable information about themselves, and in the case of parents, their child.

12.2. Procedures with unforeseeable risks:

N/A there are no procedures that pose unforeseeable risks.

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:

N/A there are no procedures that may have risks to an embryo or fetus should the subject be or become pregnant.

12.4. Risks to others who are not subjects:

N/A There are no risks to others who are not subjects.

12.5. Procedures performed to lessen the probability or magnitude of risks:

N/A- this is a minimal risk study

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:[32]

There is no anticipated benefit of participating in this study. The information from this study could benefit children who sustain concussions in the future.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Aim 1: Qualitative data will be digitally recorded and transcribed verbatim and coded for relevant themes using a thematic analysis approach. This analysis will begin with an intensive review of audio-recordings and coded transcripts by two experienced qualitative coders to identify themes across stakeholder groups

and settings. Coded segments will then be entered into Dedoose© software to facilitate analysis, and themes will be iteratively revised to better represent the overall tenor of the interviews, until a representative sample of themes has been developed that is independently supported by both coders. Interim analyses will be conducted after 5 interviews in each category, and themes that develop will be used to iterate provider support materials. We will explore whether there are emergent differences in groups of parents (e.g., differences by demographic variables) and healthcare providers (e.g., by provider type) and within family dyads. Data analysis will occur on an ongoing basis, with emergent results iteratively informing adaptations to the question guide so as to appropriately clarify and contextualize responses related to the target areas of questioning.

Aims 2 and 3: Primary outcomes. We will compare parenting behaviors (emotional support and instrumental support) at Time 3 between the two groups using chi-squared tests for each behavior and total proportion of behaviors. **Secondary outcomes.** For each group (control and intervention), the percentage of parents reporting receipt of specific discharge components will be calculated and compared. We will also compare rates across specific subgroups, including high vs. low health literacy parents and between parents who speak English at home vs. those who do not. These percentages will be compared across subgroups using chi-squared tests to assess statistical significance. We will also compare characteristics of subjects who (a) agree to participate vs. those who do not, and (b) participate throughout follow-up vs. any lost to follow-up. We will also conduct exploratory analyses of the mean change in parent cognitions related to concussion management (concussion management knowledge[60], parental anxiety, and behavioral self-efficacy[59]) and child well-being scores (child PEDs-QL[62] and PCSI[61]) from Time 1 to Time 3, between the groups using t-tests, and plotting trajectories for each group. We will adjust analyses for child age, sex, baseline post-concussion symptoms/severity, as well as covariates not determined to be effect modifiers, if associated with outcome and distributions vary by treatment group. Missing data will be examined for patterns with covariates, sensitivity analyses used to assess impact of missing data on results and imputation used as appropriate to address missingness. **Parent experiences with enhanced education.** Survey data will be analyzed descriptively, with associations by insurance status, language, and gender assessed. For qualitative data, audio-recorded and transcribed interviews will be coded using a deductive content analytic approach[66,67] using consensual qualitative research methods.[68,69] First, two independent coders will review each interview transcript, applying codes from the CFIR,[24] Communication Accommodation Theory, and USE-EBPI while remaining open to other emergent themes. They will then compare codes and agree on final codes using a process of deliberation and consensus.

Aim 4: (1) Cognitive interviews: Analysis will be conducted by reviewing parents' comments and responses to questions about the survey tool. We will explore if there are any emergent differences in understanding survey questions among groups of parents (low vs. high health literacy). Data analysis will occur on an ongoing basis, with emergent results iteratively informing adaptations to the question guide and the survey itself; (2) Online surveys: Survey responses will be reviewed with a focus on the psychometric properties of items and scales (e.g., how are responses distributed), with the plan to retain only items with adequate variability and normal or near-normal distribution. To limit redundancies in the final survey, we will conduct exploratory analyses to determine which survey questions are correlated. Finally, we will compare responses across key parent characteristics (e.g., age, gender, prior concussion) to determine whether psychometric properties are similar across groups.

14.2. Quality control procedures for collected data:[33]

During the start-up phase of this research project, the Principal Investigator will train research assistant(s) on best practices for qualitative and quantitative data collection through workshops, practice interviews, and individual supervision. As an additional quality check, interviews will be audio recorded and reviewed regularly to ensure high-quality data collection methods are used.

15. Confidentiality[34]

15.1. Procedures to secure the data and/or biospecimens during storage, use, and transmission:

During data collection, all research materials (including the audio recording device used for qualitative interviews) containing personally identifiable information will be kept in a locked container while not in use. All interviews conducted online will be recorded via the online platform (Zoom) and all data will be secured on Seattle Children's servers. When conducting interviews online, we will be using the latest version of Zoom, we will make the meetings private, passwords will be required for meeting entry, private chat will be disabled, and consent will be obtained prior to recording. After data is collected, any information which would identify the participant(s) will be removed and code numbers used instead.

All identifiers will be destroyed within 6 months of completion of data collection. If a parent subject chooses not to participate, the both the child and parent identifiers will be destroyed within one week. Transcribed audio-recorded interviews and surveys will be de-identified and stored on the secure Seattle Children's servers, accessible only to the study team; a numeric code will be used to link audio interviews and/or surveys to participants. Only coded segments (without identifiers) of recordings will be entered into Dedoose© software. The link between study code and participant information will be kept in a password-protected file overseen by the Principal Investigator.

All PHI will be stored in password protected REDCap projects, housed at UW and only accessible to members of the study team. The study PIs will be gatekeepers of access. There will not be paper records of PHI. All study databases will use a study ID. We believe this is the best method for protecting identifiers from improper use and disclosure. Once the study is complete, the key that links participant identity to their study ID will be destroyed.

15.2. Location where the data and/or biospecimens will be stored:

Data will be stored on secure Seattle Children's servers and/or in a locked container.

15.3. Length of time data and/or biospecimens will be stored:

Data will be stored for 5 years

15.4. Individuals with access to data and/or biospecimens:

Data will only be accessible to study team members as specified by the PI.

15.5. Process for the transmission of data and/or biospecimens outside Seattle Children's:

15.5.1. List of data and/or biospecimens that will be transmitted:

Interview data and audio recordings, and survey data. Twilio does record information exchanged via SMS conversations, however, the information is removed from their logs after the transaction.

15.5.2. Individual(s) who will transmit data:

If any identifiable data is to be transported, it will be stored in a locked container until it returns to the Seattle Children's Research Institute. Research assistants will make every attempt to remove identifiable information before transporting data. Study team members may transmit de-identified data electronically.

16. Provisions to Monitor Data to Ensure the Safety of Subjects[35]

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:[36]

N/A – this research study involves no more than minimal risk to participants.

16.2. Data reviewed to ensure safety of subjects:
N/A

16.3. Safety information collection procedures:
N/A

16.4. Frequency of cumulative data review:
N/A

16.5. Conditions that trigger an immediate suspension of the research:
N/A

17. Use of Social Media

17.1. Types of social media to be used and how:
N/A

17.2. Measures in place to protect the privacy or confidentiality of subjects:[37]
N/A

17.3. Types of communications that will be submitted to the IRB for review:[38]
N/A

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:
N/A

18. Research Related Injury[39]

18.1. Available compensation in the event of research related injury:

N/A – this research involves no more than minimal risk

19. Recruitment Methods[40]

19.1. When, where, and how potential subjects will be recruited:

Aim 1:

Parents: We will recruit 20 parents of youth who: (1) sought care in the SCH ED or Urgent Care for closed head injury in the past 2 years and during the study period, and were not admitted for inpatient care and (2) were 5-17 years at the time of the concussion-related visit. We will engage our partners in the ED (including the ED research team described below in Aims 2 and 3) to screen for eligible participants via chart review. Every year, SCH ED sees approximately 1500 youth patients with concussion, 1300 of whom are discharged to self-care (not admitted). SCH provides care to patients who are diverse in terms of socioeconomic status and race/ethnicity with financial subsidy for any family with household income <400% of the federal poverty level; approximately 64% of SCH patients are non-Hispanic white, 25% use public insurance and 9% require an interpreter, most often Spanish. Patients will be stratified by type of health insurance (public, private) and then contacted using a random selection process until we have reached 10 consenting parents within each stratum for a total of 20 parent participants. Where possible, we will also stratify by language in which care was sought (English, Spanish) and aim for

representation of both language groups within each health insurance strata. Potential participants will be first provided with a written (mailed) letter, and then subsequently contacted via telephone (call or text message).

Healthcare providers: 20 healthcare providers who work in the SCH ED will be invited to participate in one-on-one qualitative interviews using a stratified randomized recruitment strategy that ensures a representative proportion of participants by provider gender (male, female), and professional role (physician, nurse). Healthcare providers will be invited to participate by email accessible to the SCH research team via internal email address listings. Among physicians, participation will be balanced between pediatric emergency medicine faculty and pediatric emergency medicine fellows. Among nurses, participation will be balanced among registered nurses (RN) and nurse practitioners (ARNP).

Aims 2 and 3: SCH has a team of research assistants physically present in the ED 10 hours per day, 7 days per week to screen and inform families about research studies, and consent eligible and interested parents. This team also has the ability to screen and inform families about research studies who come into the SCH Urgent Care and consent eligible parents. We will engage this team to screen for study eligibility of parents of youth age 5-17 who sought care for a closed head injury and were not admitted for inpatient care. Parents will be eligible for inclusion if they speak English or Spanish. For Aim 3, recruitment and consent will occur prior to randomization.

A purposively selected subset of parents will be invited by email to participate in a qualitative interview..

Aim 4: (1) Cognitive interviews: We will engage the SCH ED research team described in Aims 2 and 3 to screen for parents of youth who sought care for their child in the SCH ED or Urgent Care for any health issue and were not admitted for inpatient care. Parents will be eligible for inclusion if they speak English or Spanish. The research team will approach the parents after their child has been seen by a health professional but before they are discharged. Because study staff will only approach parents whose child has not been admitted to inpatient care, parents will only be approached and informed of the study if their child has a low acuity level; (2) Online surveys: Individuals will be recruited through Amazon Turk (MTurk), an online recruitment platform. Due to the nature of MTurk, only individuals aged 18 and older who identify as parents will be able to view and access the survey.

19.2. Steps that will be taken to protect potential subjects' privacy interests:[41]

Aim 1: All research activities will take place in a private clinic room, telephone or video conference line, or another private location preferred by the participant. Before any research procedures begin, the Research Assistant will explain that participants may choose to skip any questions they do not want to answer and they may discontinue the research study at any time. Research procedures will be conducted in English or Spanish, depending on the preference of the participant. The RA will take steps to make the qualitative interview feel like a conversation, based on supervision and training from the Principal Investigators. All information will be stored on secure servers at the Seattle Children's Research Institute overseen by the Principal Investigators. Study staff will have access to this data as needed for participant contact purposes.

Aims 2 and 3:
Parents: Initial research activities will occur over the phone while the participants are in or near the SCH ED and Urgent Care. Follow-up (at one day post-visit and approximately 2 weeks post-visit) will occur remotely (by telephone—text, or phone call--or email, depending on the participant's preferences). Before any research procedures begin, the study team member will explain that participants may choose

to skip any questions they do not want to answer and they may discontinue the research study at any time. Research procedures will be conducted in English or Spanish, depending on the preference of the participant. All information will be stored on secure servers at the Seattle Children's Research Institute overseen by the Principal Investigators. Study staff will have access to this data as needed for participant contact purposes.
. Subsequent qualitative interviews with parents will be audio-recorded and transcribed verbatim, with all data stored on secure servers at the Seattle Children's Research Institute overseen by the Principal Investigators.

Aim 4: (1) Cognitive interviews: All research activities will occur in person in or near the SCH ED and Urgent Care. Before any research procedures begin, the Research Assistant will explain that participants may choose to skip any questions they do not want to answer and they may discontinue the research study at any time. All information will be stored on secure servers at the Seattle Children's Research Institute overseen by the Principal Investigators. No personal health information about participants will be collected; (2) Online surveys: Prior to accessing the surveys, participants will receive information about the purpose of the study (validating a survey tool to measure concussion related behaviors, knowledge, and self-efficacy) and the eligibility criteria for the study. They will be informed that participation is voluntary and anonymous. No personal health information about participants will be collected.

19.3. Sources of subjects:[42]
Chart screening or provider referral, as described in section 19.1

19.4. Methods that will be used to identify potential subjects:
Chart screening or provider referral, as described in section 19.1.

19.5. Materials that will be used to recruit subjects:[43]
Recruitment materials include a recruitment letter, recruitment script and recruitment text message.

19.6. Recruitment methods not controlled by Seattle Children's:
N/A

20. Consent/Assent Process

20.1. Consent process overview:[44]
Aim 1: All participants will review an information sheet, with parents participating remotely providing verbal consent and parents participating in person providing written documentation of consent All participants participating via Zoom will be informed that the session will be recorded and consent to record via Zoom will be obtained prior to beginning the interview. Children will provide verbal assent. Healthcare provider participants will review an information sheet and provide verbal consent. Participants will be provided with an opportunity to read through all documentation (information sheet/consent form) and to ask questions of the research team member involved in consent.

Aims 2 and 3: All parents in the Aim 2 cohort will be in the education-as-usual control condition. Parents in the Aim 3 cohort will be randomized into control or intervention conditions. For Aim 3, recruitment and consent will occur prior to randomization to intervention or control condition. The ED research team will conduct a full verbal consent conference via phone with a patient's parent or legal guardian and review all elements of the informed consent form prior to enrollment. Though the discussion will take place on the phone, the parent and patient will know that research team member is on site and available to answer questions. Whenever possible, the ED

research team will email a link to an electronic copy of the consent (and when applicable, assent) documents for the potential participant(s) to review during the consent conference. We will also email or mail participants a copy of these documents after enrollment is complete.

Aim 4: (1) Cognitive interviews: All parents will review an information sheet and will have time to ask questions of the research team member conducting the interview before deciding whether or not they will participate; (2) Online surveys: All parents will be informed of the study on MTurk and given information about the contents of the survey (including the amount of time the survey is anticipated to take) before clicking the REDCap link to take the survey. The first page of the REDCap survey will contain an information sheet that participants will review before deciding whether or not to participate. Participants will be informed that by clicking on to take the survey, they are consenting to participate.

20.2. Where the consent process will take place:

Aim 1: This will occur remotely (e.g., over the phone or via video conferencing) or in person at a private location (e.g., community library, SCH conference room) as preferred by the participant.

Aim 2 and 3: The consent process will take place in or near the SCH emergency department or Urgent Care.

Aim 4: (1) Cognitive interviews: An information sheet describing the study will be shared with parents in the SCH Emergency Department or Urgent Care; (2) Online surveys: Participants will review an information sheet about the study online before clicking on to complete the survey.

20.3. Steps that will be taken to protect prospective subjects' privacy interests:[45]

Aims 1, 2, 3, and 4: Before any research procedures begin, the Research Assistant will explain that participants may choose to skip any questions they do not want to answer and they may discontinue the research study at any time. Research procedures will be conducted in English or Spanish, depending on the participants' preferences.

20.4. Waiting period available between approaching a prospective subject and obtaining consent:

Aims 1, 2, 3, and 4: There is no waiting period between consent and research procedures; consent/assent/permission will be obtained immediately prior to conducting research procedures.

20.5. Process to ensure ongoing consent:

If any new information arises that (1) may be relevant to the participant's willingness to continue participation, (2) affects the rights, safety, and well-being of study subjects, and/or (3) has an impact on study conduct and outcomes, the research team will update enrolled participants that are impacted by any of the above and give them the opportunity to withdraw their consent given previously.

20.6. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☒

20.7. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:[46]

20.7.1. Role of the individuals listed in the application as being involved in the consent process:

✍Click here to enter text.

20.7.2. Time that will be devoted to the consent discussion:
✍Click here to enter text.

20.7.3. Steps that will be taken to minimize the possibility of coercion or undue influence:
✍Click here to enter text.

20.7.4. Steps that will be taken to ensure the subject's understanding:
✍Click here to enter text.

20.8. Non-English Speaking Subjects[47]

20.8.1. Anticipated preferred language(s) for subjects or their representatives:
Spanish

20.8.2. Presentation of Research Information and Documentation:

☒ Appendix A-10 of the Investigator Manual will be followed[48]

☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):

☐ Per section 5.5.1

☐ Per section 5.5.2

☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
✍Click here to enter text.

20.8.3. Justification if non-English speaking subjects will be excluded from the research:[49]
N/A

20.9. Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)

20.9.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):[50]

Aims 1, 2, and 3: The age of the child patient will be determined by chart review as part of the parent eligibility screening process (e.g., child below the age of 18 is required for a parent to be eligible to participate in the study).

Aim 4: N/A. All participants in this aim will be ages 18 and older, therefore determining age of consent does not apply.

20.9.2. Parental permission will be obtained from:[51]

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Neither parent.[52]

20.9.3. Process used to determine an individual's authority to consent to each child's general medical care if permission will be obtained from someone other than parents:[53]

Consent will only be obtained from a parent or legal guardian.

20.9.4. Assent will be obtained from:[54]

☐ All children.

☒ Some children. Specify: Assent will be obtained from children ages 13-17.

☐ None of the children. Explain: ✍Click here to enter text.

20.9.5. Procedures for obtaining and documenting assent:

Aim 1: The information sheet will be provided to the child (ages 13-17), and reviewed verbally by the study team member via phone. An opportunity to ask questions will be provided, and the child will have the option of providing verbal assent for their participation. For children consented in Aim 1 in person, written assent will be documented on the consent/assent form.

Aims 2 and 3: When obtaining assent from children ages 13-17, the ED research team will conduct a full verbal consent/assent conference via phone with both the patient and the patient's parent or legal guardian. During the call, they will review all element of the informed consent form prior to enrollment. Children will only be asked to assent after parents or legal guardians consent and give permission.

Aim 4: N/A. All participants will be ages 18 and over.

20.9.6. Plan for re-approaching children who have reached the age of majority to obtain consent:[55]

Aims 1, 2 and 3: Participants who turn 18 during the 2-week maximum period of data collection will be re-approached via their parent to obtain consent. The study team will contact the participant, review the information sheet again, and the participant will verbally consent to continue participation. Participants will not be contacted to obtain consent if they turn 18 during data analysis.

Aim 4: N/A

20.10. Cognitively Impaired Adults/Adults Unable to Consent[56]

20.10.1. Process used to determine whether an individual is capable of consent:

N/A

20.10.2. Individuals from whom permission will be obtained in order of priority:[57]

N/A

20.10.3. Assent will be obtained from:

☐ All of these subjects.

☐ Some of these subjects. Specify: ✍Click here to enter text.

☐ None of these subjects. Explain: ✍Click here to enter text.

20.10.4. Process for obtaining and documenting assent:[58]

NA

20.11. Waiver or Alteration of Consent Process

20.11.1. Reasons for requesting a waiver or alteration of informed consent:[59]

We are requesting a waiver of consent for participants who turn 18 during the study period, outside of data collection windows.

20.11.2. Consent Waiver/Alteration Criteria justifications:[60]

20.11.2.1. The research involves no more than minimal risk to the subjects because:

Adolescent participants will have no active participation in the study. The procedures that their parent or guardian will be involved in are low-risk, such as responding to surveys.

20.11.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:[61]

Participants will have already assented to be part of the study and have received written study information for all procedures. None of the information we are collecting would alter or affect the participants' care, and they will be informed of this prior to agreeing to participation.

20.11.2.3. The research could not practicably be carried out without the waiver or alteration because:[62]

After the maximum 2-week period of data collection is complete, we will not have any further contact with families. We may not be able to locate and therefore get in contact with all families again once the child reaches the age of majority since it may be far removed from study participation, and all eligible participants must be included in the study for results to be meaningful.

20.11.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because:

Identifiable information for the research is needed to track data collection over time and carry out various research procedures (for example, in order to contact families for follow up phone contact).

20.11.2.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

While we do not anticipate this, we will provide subjects with additional pertinent information after participation, whenever appropriate.

20.11.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make it determinations:[63]
✍Click here to enter text.

21. Process to Document Consent in Writing

21.1. If consent will be documented in writing (check one):

☐ "SOP: Written Documentation of Consent (HRP-091)" will be followed.

☒ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:[64]

Aim 1: Consent will be obtained verbally if individuals are participating remotely
Aims 2/3: Consent will be obtained verbally after a full consent conference via phone with a study team member.
Aim 4: (1) Cognitive interviews: Consent will be obtained verbally after individuals review an information sheet; (2) Online surveys: Consent will be obtained by participants clicking on to take the REDCap survey after reviewing an information sheet at the beginning of the survey.

21.2. If consent will not be documented in writing (check all boxes that apply):[65]

☒ A written statement/information sheet describing the research will be provided to subjects.[66]

☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: ✍Click here to enter text.

☐ A consent script will be used.[67]

22. HIPAA Authorization and RCW Criteria

22.1. HIPAA Authorization (check all boxes that apply):

☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).[68]

☒ HIPAA authorization will be obtained as part of a signed consent form.

☒ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). *See 21.2 below for required HIPAA waiver/alteration criteria*.

☒ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. See 21.2 below for required *HIPAA alteration criteria*.[69]

☐ Other. Explain:[70]
✍Click here to enter text.

22.2. HIPAA Waiver/Alteration Criteria: Explain why:

22.2.1. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:

22.2.1.1. An adequate plan to protect the identifiers from improper use and disclosure:

Aims 1, 2,3, 4: The PI affirms that there is an adequate plan in place to protect identifiers from improper use and disclosure during recruitment. All study data will be stored on secure servers requiring password access. Participant names will be stored in a separate password protected file accessible only to study staff under the supervision of the Principal Investigator.

22.2.1.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

Aims1, 2,3, 4: All PHI and identifiers will be destroyed at the earliest opportunity consistent with the research protocol. We anticipate that this will mean destroying PHI of the child subjects prior to the end of recruitment. If a parent subject chooses not to participate, the child's identifiers will be destroyed within one week.

22.2.1.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

Aims 1, 2,3, 4: The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required

22.2.2. The research could not practicably be conducted without the waiver or alteration of authorization:

Waiver of HIPAA authorization for recruitment (all aims): We are requesting a waiver of HIPAA for recruitment purposes because we will not obtain HIPAA authorization prior to collecting a limited set of information about potential participants' children to be used to determine whether or not they meet study eligibility criteria, It is not practicable to get HIPAA authorization prior to accessing records for screening because we would be unable to target the children who have previously suffered closed head injuries and do not return to sports. We are also requesting a waiver of HIPAA authorization to collect email addresses of interested participants prior to obtaining consent so that we may share an electronic version of our consent form.

Alteration of HIPAA authorization (removal of the signature requirement) (aim 1 subjects participating by phone):
We anticipate that most data collection for Aim 1 will occur remotely (e.g., by phone); we want to allow for broad participation by families who sought care from SCH—including families who live in rural communities, communities far from Seattle (e.g., Yakima) and among families who have limited resources (e.g., computer access). Requiring a signature would mean traveling to families (limiting our ability to recruit families from outside of the Seattle region) or requiring that they document consent electronically, which our prior experience suggests limits the ability and willingness of individuals with fewer resources and/or lower technological literacy to participate.

Alteration of HIPAA authorization (removal of the signature requirement) (aims 2,3):
We request an alteration of HIPAA to remove the signature requirement. We have previously been granted a waiver of documentation of consent and assent and alteration of HIPAA for this study, with the stipulation that we ask participants to electronically sign the consent and assent forms (including HIPAA language) using the REDCap electronic consent tool.

Given the hospital-wide shortage of personal protective equipment and call to action to use phones as the primary method of communicating into rooms of patients, the ED research team has transitioned to enrolling participants without entering or opening the door to the patient room, when possible. To do this, the ED research team has been calling the patient's parent/guardian on the patient room phone and verbally reviewing all elements of the informed consent form. Then, the study team has then been passing a study iPad through a small "pass through" door typically utilized to pick up paper from a printer sitting outside the room, so the parent may document their consent electronically in REDCap, and pass the iPad back to the study team. However, concerns remained from both clinical leadership as well as research team members about the ability to minimize or control infection risk when team members are still passing materials back and forth through the pass-through door. There is much that is unknown about how long the SARSCoV2 pathogen can live on surfaces like an iPad. We also don't know the infection risk from passing materials back and forth with a family member when the research team is not donning respiratory protection.

In response to the ongoing emergency operations and PPE shortage related to SARSCoV2 circulation and COVID-19 disease, we request to fully utilize the power of our IRB waiver of documentation to mean that no consent or HIPAA documentation, written or electronic, is required at the time of study enrollment.

Alteration of HIPAA authorization (removal of the signature requirement) (aim 4)

The data will be linked to the MTurk ID, which can be linked to identifiers, but per MTurk policy, collection of personally identifiable information is not permitted (e.g. asking for a worker's name, email address, or phone number) therefore requiring a signature would violate that policy. Also, the study team will have no contact with subject's who participate through Mechanical Turk, so obtaining a written signature would not be possible.

22.2.3. The research could not practicably be conducted without access to and use of the PHI:[71]

Aims 1, 2, and3: The PHI collected during screening activities is necessary for the research. The research cannot be practicably conducted without the alteration because access to and use of PHI is necessary for screening purposes.

23. Payments/Costs to Subjects[72]

23.1. Amount, method, and timing of payments to subjects:[73]

Aim 1: A $20 gift card will be provided to each interview participant in Aim 1
Aims 2 and 3: A $10 gift card will be provided to each parent participant at each of the following two timepoints (T1 and T3). A $50 gift card will be provided to each interview participant in Aim 3.
Aim 4: (1) Cognitive interviews: A $10 gift card will be provided to each parent participant; (2) Online survey: Each participant who completes a survey on the MTurk platform will be reimbursed $1.00 by MTurk.

23.2. Reimbursement provided to subjects:[74]

N/A

23.3. Additional costs that subjects may be responsible for because of participation in the research:[75]

N/A

24. Setting

24.1. Site(s) or location(s) where the research team will conduct the research:

Seattle Children's Hospital Emergency Department and Urgent Care. Data collection will occur in in a private room in or near the ED or Urgent Care, another location or over the phone, dependent on participant preference.

24.2. Composition and involvement of any community advisory board:

The study will occur in consultation with an advisory board comprised of three Seattle Children's Hospital (SCH) ED physicians, three SCH ED nurse practitioners and six parents. Healthcare providers will be invited through a random selection process, with email and telephone contact. A chart review will be used to identify patients who during the past year: (1) sought concussion care in the SCH ED and were not admitted for inpatient care, (2) were between the ages of 5-17, and (3) who sought care using public insurance (e.g., Medicaid). Their parents will subsequently be contacted by telephone using a random selection procedure and screened to only include English speaking individuals. Board members will meet four times, with compensation of $50 per meeting. The role of the advisory board will be to provide feedback about the material development and implementation strategy development process.

24.3. For research conducted outside of the organization and its affiliates:[76]

24.3.1. Site-specific regulations or customs affecting the research:

N/A

24.3.2. Local scientific and ethical review structure:

N/A

25. Resources Available

25.1. Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:[77]

The Principal Investigator is an Assistant Professor at the University of Washington, with expertise in concussion management and concussion education program development. She has experience with qualitative analyses, staffing, institutional review board management, budgeting, and setting up effective collaborations. Dr. Fred Rivara and Dr. Sara Chrisman are investigators at Seattle Children's Research Institute with extensive experience of concussion and will be co-investigators on the study, providing assistance with planning, and interpretation of de-identified data. Co-investigator Dr. Casey Lion is a Seattle Children's Research Institute-based physician-scientist with expertise in research with low health literacy and limited English proficient patients and families. Dr. Eileen Klein is the research director of the Seattle Children's Hospital Emergency Department and will be a key co-investigator, responsible for protocol implementation in the ED. Research assistants from Dr. Kroshus' team who have experience with recruitment, consent, qualitative interviewing and qualitative analysis will also be key members of the study team.

All study staff will be located at Seattle Children's Research Institute and/or Seattle Children's Hospital Emergency Department. A Research Assistant will oversee the daily operations of the project including recruitment, data collection, data management, and IRB communication with oversight from the PIs. The RA will stay up-to-date on all required trainings, including human subjects research training, HIPAA compliance, and good clinical practice.

25.2. Other resources available to conduct the research:[78]

The project coordinator will devote 30% of their time to recruitment, consent, data collection and analysis, with flexibility to increase that time allocating to meet study targets. The PI will devote 20% of her time to this project, with flexibility to increase as needed to support the RA and meet study targets. Research will be conducted at Seattle Children's Research Institute and/or Seattle Children's Hospital Emergency Department, where there are secure computers and servers, private rooms for conducting recruiting phone calls and interviews, and institutional resources (e.g., senior advisory personnel) to help facilitate good clinical practice. The team of RAs located at the Seattle Children's Hospital ED will help facilitate recruitment and data collection. All persons assisting with the research will have completed required ethics training, the CITI Good Clinical Practice module, and will review the study protocol and research procedures and meet with the study PI about their duties and functions on a bi-weekly basis.

26. Coordinating Center Procedures

26.1. Coordinating center institution:

N/A

26.2. If Seattle Children's is the coordinating center:

26.2.1. Process to ensure communication among sites:[79]

N/A

26.2.2. Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:

N/A

26.2.3. Process to ensure all required approvals are obtained at each site:

N/A

26.2.4. Process to ensure all sites are informed of any problems and/or interim results:

N/A

27. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

27.1. If you have committed to conducting the described study per ICH-GCP, check this box: ☐[80]

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
- **If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.**

[1] Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application.

[2] In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

[3] Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that mobile medical applications may meet the definition of a device – see FDA Guidance.

[4] See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

[5] Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See "HRP-306: Drugs" for more information.

[6] Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See "HRP-307: Devices" for more information.

[7] Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

[8] Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

[9] Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

[10] Attach all surveys, scripts, and data collection forms to the "Supporting Documents" page.

[11] Include information about the frequency of data collection.

[12] See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here.

[13] If applicable, include a list of identifiers that will be banked.

[14] Be general (e.g., researchers' lab, clinic, etc.)

[15] Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

[16] Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

[17] You can allow for use for broad purposes

[18] This includes putting results and/or data in the subject medical records.

[19] If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

[20] If you check a box below, be sure to include the additional safeguards associated with the population.

[21] Refer to HRP-416 CHECKLIST: Children.

[22] If the study is minimal risk, explain why. Must also include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable).

[23] This population may be wards of the state or any other agency, institution, or entity. Refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

[24] This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

[25] Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

[26] Refer to HRP-412 CHECKLIST: Pregnant Women.

[27] Refer to HRP-415 CHECKLIST: Prisoners

[28] Indicate how you will ensure that there is no coercion or undue influence

[29] A subject is considered "enrolled" when they consent to be in the study.

[30] Only applicable for multisite studies.

[31] i.e., numbers of subjects excluding screen failures.

[32] Payment for participation is not considered a benefit.

[33] For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

[34] If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

[35] Applicable for studies that present more than minimal risk.

[36] Include information about who (describe in terms of role or group) will review the data.

[37] This should be specific to the social media you are using for the research.

[38] All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

[39] Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

[40] If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

[41] "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

[42] For example: medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

[43] Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

[44]Include how you will ensure that subjects and/or their parent/legally authorized representative have sufficient opportunity to discuss and consider whether or not to participate in the research. .

[45] "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

[46] This section describes the way(s) in which the processes for this study will not follow Seattle Children's SOP.

[47] See HRP-090, HRP-091, and Investigator Manual HRP-103 for more information.

[48] Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

[49] Seattle Children's IRB prohibits the exclusion of non-English speaking populations from research unless there is sufficient justification for the exclusion. See Investigator Manual HRP-103 for more information.

[50] For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children." The age of majority in Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the

study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[51] For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

[52] If parental permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

[53] See HRP-013 for more information.

[54] The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent): please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

[55] See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

[56] See "HRP-417 Cognitively Impaired Adults" for further information.

[57] For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[58] The IRB may allow the person obtaining assent to document assent on the consent document.

[59] For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

[60] The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

[61] Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

[62] Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

[63] See "HRP 419: Waiver of Consent for Emergency Research" for further information.

[64] This section describes the ways in which the procedures will not be following Seattle Children's SOP.

[65] See "HRP-411: Waiver or Written Documentation of Informed Consent" for further information.

[66] An information sheet template can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

[67] The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

[68] PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

[69] If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see RCW 19.34.300).

[70] For example: altering HIPAA elements for international research.

[71] Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

[72] See "HRP-316: Payments" for further information.

[73] Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

[74] Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

[75] This could include things like fuel/transportation costs, parking, and/or childcare.

[76] Type N/A if this section does not apply.

[77] Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

[78] For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and

completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research. (5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

[79] Including communication between sites of current study document versions and modifications.

[80] If you check the box, you are required to conduct your study according to the principles outlined at https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html.