Study Protocol

Implementation of a Clinical Pathway for Acute Care of Pediatric Concussion: Uptake, Outcomes, and Health Care Impacts

REB18-0405

10.Nov.2021

Implementation of a Clinical Pathway for Acute Care of Pediatric Concussion: Uptake, Outcomes, and Health Care Impacts

Section/item		Description
Administrative information		
Title	1	Implementation of a Clinical Pathway for Acute Care of Pediatric Concussion: Uptake, Outcomes, and Health Care Impacts
Trial registration	2	Clinical Trials…
Protocol version	3	01.Nov.2021 Version 4.0
Funding	4	Brain Canada Foundation Alberta Health Services – Health Outcomes Improvement Fund
Roles and responsibilities	5	Principal Investigator Keith Owen Yeates, PhD, RPsych, ABPP, FCAHS Ronald and Irene Ward Chair in Pediatric Brain Injury Professor and Head, Department of Psychology Adjunct Professor, Departments of Pediatrics and Clinical Neurosciences University of Calgary 2500 University Dr. NW, AD254, Calgary, AB T2N 1N4 kyeates@ucalgary.ca p 403-220-2928 Co-Principal Investigator: Karen Barlow, MD PhD, MBChC, MRCPCH, FRACP Professor of Paediatric Neurology Acquired Brain Injury in Children Research Program Interim Director, UQ Child Health Research Centre, Room 603, Centre for Children's Health Research, South Brisbane, Qld 4101 Australia Department of Pediatrics, University of Calgary 2500 University Dr. NW, Calgary, AB T2N 1N4 k.barlow@uq.edu.au p +61 7 3069 7486 Co-Principal Investigator: Bruce Wright MD, FRCPSC, FAAP Director, Division of Pediatric Emergency Medicine, Stollery Children's Hospital, University of Alberta 3-513 Edmonton Clinic Health Academy (ECHA) 11405 - 87 Avenue Edmonton, AB T6G 1C9 Bruce.wright2@albertahealthservices.ca p 1.780.248.5575

The following Co-Investigators contributed to study design and conception, analysis, interpretation of data, and/or preparation of manuscripts for publication:

Brenda Clark, MD
Associate Professor, Department of Pediatrics, Faculty of Medicine & Dentistry, University of Alberta
116 St & 85 Ave, Edmonton, AB T6G 2R3
Brenda.clark@albertahealthservices.ca p 1.780.735.7921

Alf Conradi, MD
Medical Director, Stollery Children's Hospital, University of Alberta Health Services
116 St & 85 Ave, Edmonton, AB T6G 2R3
Alf.Conradi@albertahealthservices.ca p 1.780.248.5433

David Johnson, MD
Senior Medical Director, AHS Maternal, Neonatal, Child & Youth Clinical Network
Professor, Departments of Pediatrics, Physiology and Pharmacology, University of Calgary
2500 University Dr. NW, Calgary, AB T2N 1N4
David.johnson@albertahealthservices.ca p 1.403.955.7507

Angelo Mikrogiankis, MD, FRCPC
Chair and Professor, Department of Pediatrics, McMaster University
Chief of Pediatrics, McMaster Children's Hospital, Hamilton Health Sciences, & St. Joseph's Healthcare Hamilton
1280 Main Street West, HSC 3A
mikrogia@mcmaster.ca p 1.905.521.2100

Alberto Nettel-Aguirre, PhD, PStat
Associate Professor, Departments of Paediatrics and Community Health Sciences, Cumming School of Medicine;
Statistician, Child Health Research Unit
Alberto.nettel-aguirre@albertahealthservices.ca

Kathryn Schneider, PT, PhD, DipManiPT
Associate Professor, Sport Injury Prevention Research Centre, Faculty of Kinesiology, University of Calgary
2500 University Dr. NW, Calgary, AB T2N 1N4
kjschnei@ucalgary.ca p 1.403.220.5332

Antonia Stang, MDCM MBA MSc
Section Head, Pediatric Emergency Medicine, Alberta Children's Hospital
Associate Professor, Department of Pediatrics, Cumming School of Medicine, University of Calgary
2500 University Dr. NW, Calgary, AB T2N 1N4
Antonia.stang@albertahealthservices.ca p 1.403.955.7070

Ken Tang, PhD
Biostatistician, Clinical Research Unit, Children's Hospital of Eastern Ontario
401 Smyth Road, Ottawa, Ontario K1H 8L1
Ktang@cheo.on.ca

Roger Zemek, MD, FRCPC
Professor, Dept of Pediatrics and Emergency Medicine
Director, Clinical Research Unit, Children's Hospital of Eastern Ontario
401 Smyth Road, Ottawa, Ontario K1H 8L1
rzemek@cheo.on.ca p 1.613.737.7600

Jennifer Zwicker, PhD, MPP
Director of Health Policy, School of Public Policy, University of Calgary
Assistant Professor, Faculty of Kinesiolgy, University of Calgary
Deputy Scientific Officer, Kids Brain Health Network
2500 University Dr. NW, Calgary, AB T2N 1N4
Zwicker1@ucalgary.ca

Dr Antonia Stang and Dr Bruce Wright, along with the above roles, also contributed to study management within their respective emergency departments at the Alberta Children's Hospital and Stollery Children's Hospital.

Study Coordinators, Anh Ly and Heather Godfrey, contributed to study design, data collection, study management, analysis and interpretation of data, and preparation of manuscripts for publication.

5c Brain Canada Foundation provided financial support for the study through a Multi-Investigator Research Initiative grant. They were not involved in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication

Alberta Health Services (AHS) provided financial support for the study through a Health Outcomes Improvement Fund grant. The AHS Maternal, Newborn, Child, and Youth Strategic Clinical Network was instrumental in developing a pediatric concussion working group, from which many members of the study team were drawn. An AHS project manager and an AHS analyst also worked collaboratively as part of the study team. AHS personnel collaborated on study design; management, analysis, and interpretation of data; and writing of the report. They agreed to submission of the report for publication but did not have ultimate authority for that decision or any other study activities.

Introduction

Background and rationale 6a

Pediatric concussion is a significant public health burden, sometimes referred to as a silent epidemic.[1] More than a million children in North America sustain a concussion annually, and the numbers seeking medical care are rising dramatically.[2,3] Children with concussion often report postconcussive symptoms, including somatic (e.g., headache, dizziness), cognitive (e.g., inattention, forgetfulness), and affective (e.g., irritability, dysphoria) complaints.[4] Postconcussive symptoms are most severe acutely, but can persist for weeks to months and result in functional disability and declines in quality of life in 15-25% of children with concussion.[5,6]

Multiple evidence-based clinical practice guidelines (CPGs) have been developed to guide the management of concussion in children.[7-9] However, the implementation of CPGs in clinical settings is spotty, resulting in significant practice variation and knowledge gaps. For instance, among 577 front-line primary care providers in Ontario (i.e., family physicians, emergency medicine physicians, general pediatricians, nurse practitioners, and physician assistants) who diagnose and manage concussion, only 47% recommended an initial period of school absence, only 37% correctly applied return-to-play guidelines, and only 26% reported regular use of standardized rating scales for assessing concussion.[10] Even among emergency medicine physicians from academic medical centers belonging to the Pediatric Emergency Research Canada network, only 64% correctly applied return-to-play guidelines, 60% recommended school absence, and 22% reported regular use of standardized rating scales for assessing concussion.[11]

Two major factors are likely to account for a lack of knowledge translation in the clinical care of pediatric concussion. First, CPGs for pediatric concussion have seldom been translated into clinical pathways (CPs), which operationalize CPGs into accessible and actionable algorithms more readily implemented by health care providers.[12,13] Second, implementation typically relies on passive dissemination, rather than active, planned interventions. Effective implementation interventions require evidence-based, theory-driven approaches, both to systematically assess barriers and facilitators that may affect uptake of CPs and to select implementation interventions that address those barriers and facilitators.[14,15] Recently, the Theoretical Domains Framework (TDF) has shown promise in providing a theory-based approach to implementation interventions.[16] The TDF provides a comprehensive framework of 14 theoretical domains based on 33 behaviour change theories, and provides concrete methods for assessing barriers and facilitators in those domains and choosing evidence-based interventions that address them.[17]

In Canada currently, CPs do not guide the care of children with concussions presenting to acute care settings. In 2015, the Maternal Newborn Child Youth (MNCY) Strategic Clinical Network (SCN) of Alberta Health Services (AHS) identified pediatric concussion as one of its three top priorities, and convened a work group to develop best-practice, evidence-based CPs based on existing CPGs[7-9] to guide the management of pediatric concussion in both emergency department and primary care settings. The CPs are currently being finalized, and will be implemented using theory-driven, evidence-based strategies to optimize integration into daily practice. The goal of the current proposal is to conduct an expanded evaluation of the implementation and impact of the CP for acute care of pediatric concussion across four sites in both Calgary and Edmonton in Alberta.

No published studies have reported an evaluation of CP implementation for the management of pediatric concussion involving a randomized trial design, focus on patient-centered outcomes, and assessment of health economics. One prior study has assessed the impact of CP implementation for pediatric concussion in acute care[33]. The study involved two emergency departments and a simple pre- versus post-intervention comparison without randomization. The evaluation focused on physician uptake of the CP and on parental reports of the provision of care (e.g., % given recommendations on activity), but did not assess children's health outcomes or examine health care utilization or costs. Thus, the proposed project will break new ground in efforts to promote better outcomes for children with concussion and reduce public health burden. The project is especially innovative in its use of technology to assist in CP implementation, as well as to assess relevant patient-centered outcomes. The website portal and text-based reminder system will be scalable and could help transform the care of children with concussion nationally.

The proposed project is a direct outgrowth of the MNCY SCN pediatric concussion workgroup, which consists of health care providers and researchers from a wide variety of disciplines and settings. The PI (Yeates), Co-PIs (Barlow, Wright), and most of the Co-Investigators (Clark, Conradi, Mikrogianakis, Schneider) are members of the workgroup, and have been working together for the past 18 months. They have a long track record of multidisciplinary clinical and research endeavours with children with concussion and their parents, which they will bring to bear in evaluating the CP. Dr. Johnson, Medical Director of the MNCY SCN, has significant experience with implementation science and specifically with evaluation of CPs; he led the evaluation of the Alberta Childhood Asthma Pathway. We have also partnered with Dr. Roger Zemek, from Children's Hospital of Eastern Ontario, who chaired the development of the Ontario Neurotrauma Foundation pediatric concussion guidelines. This linkage will help us to consolidate and unify concussion management not only across Alberta, but also nationwide. The additions of Dr. Ken Tang and Dr. Jennifer Zwicker to the team bring relevant expertise in biostatistics and health economics, respectively. The team has already begun working together via email, videoconferencing, and face-to-face meetings, and will continue in this vein throughout the proposed project.

Objectives 7

The research has three key objectives:

1) Design an evidence-based, knowledge-user informed, and theory-driven approach to implementation of a clinical pathway (CP) for acute care of pediatric concussion.

Guided by the Theoretical Domains Framework (TDF), we will assess barriers and facilitators likely to influence uptake of the CP in acute care settings. The results of that assessment will inform our implementation strategy design, again guided by the TDF.

2) Evaluate the impact of the implementation of the CP on patient-centered outcomes using a stepped wedge cluster randomised trial.

Within the context of a stepped wedge cluster randomised trial, we will assess relevant process and clinical outcomes to determine whether implementation of the CP results in significant uptake of the pathway, as well as higher patient satisfaction and better health outcomes following acute care for concussion.

3) Determine whether the implementation and use of a CP for acute care of pediatric concussion is associated with changes in health care utilization and associated costs.

Health care utilization and costs associated with care of concussion will be compared before and after the implementation of the CP. Utilization and costs are expected to remain stable or decline following implementation of the CP.

Trial Design 8

Overview. The project will involve a stepped wedge cluster randomised trial to evaluate the implementation of the MNCY CP for the acute care of pediatric concussion.[18] Stepped wedge designs randomise the sequence in which participating sites receive the study intervention, so that each site serves as its own control, but each site starts the intervention at a different time. Data collection continues throughout, so that each site contributes observations during both pre-intervention and post-intervention periods. In this case, each of four participating sites will be considered clusters, and they will be randomised to implement the MNCY CP over 11 months (i.e., after a 2 month lead-in period, implementation will occur at one site and then at the other three sites every 2 months, until implementation has occurred at all four sites, with data continuing to be collected 2 months after the CP is implemented at all sites).

The CP has grown out of the work of the MNCY SCN workgroup on pediatric concussion. It includes several elements, including diagnostic and prognostic tools, discharge instruction forms, information leaflets, and access to an informational website and for patients and parents. To develop the CP, the workgroup reviewed the existing CPGs for concussion diagnosis and management[7-9], and generated a "clinical knowledge topic" document that provides AHS practitioners with information and guidance about concussion care, including care pathways and algorithms. The CP originally incorporated tools such as the Acute Concussion Evaluation (ACE) for identification and diagnosis[19], the PECARN rule for determining the need for CT scan[20], and the 5P rule for predicting risk of persistent symptoms[21]. The CP also was intended to include a parent/patient handout developed by the workgroup and approved by AHS. The CP for the study will based on the most up-to-date evidence and consensus guidelines, as reviewed by the MNCY SCN pediatric concussion workgroup. Although the CP is not expected to change during the study period, it certainly could evolve over time as the evidence base for concussion increases, and consensus guidelines are updated. The goal is to reduce practice variation and improve care by using a CP to align acute diagnosis and management with evidence-based CPGs.[22]

Qualitative interviews and site visits led to iterative changes in the CP to account for practice variations between sites and to enhance clinician buy-in. Initially the ACE tool was chosen as the primary CP tool for physician assessment; however, physicians felt that the ACE overlapped too much with existing assessments and did not direct patient care. Based on this feedback, the 5P rule scoring rubric was chosen instead of the ACE. The 5P risk score was implemented to enable automatic referrals of children at high risk of persistent postconsussive symptoms to a specialty concussion clinic, and also to encourage referral of low and medium risk children for follow-up by primary care providers.

Study Setting 9 The four sites, each of which will be treated as a cluster in the analysis, are Alberta Children's Hospital and South Health Campus in Calgary (treated as a single site because they are staffed by the same group of pediatric physicians), and Stollery Children's Hospital, North East Community Health Center, and Grey Nun's Hospital in Edmonton (each of these Edmonton sites is staffed by different physician groups and will therefore be treated separately). The sites were selected because they represent high-volume centres that account for a significant proportion of children diagnosed with concussion in acute care settings in Alberta. Collectively, they accounted for 2,098 concussion diagnoses over 12 months in 2015-2016, as well as another 1,517 cases with the diagnosis of head injury, unspecified, which is often used in place of the more specific diagnostic code (see Table 1 on next page). Our project team includes the emergency medicine physicians who are the academic and clinical leaders for emergency medicine in both Calgary (A. Stang) and Edmonton (B. Wright).

All four clinical sites have provided enthusiastic letters of support for the proposed project, and will allocate staff time and provide space for project activities as in-kind contributions. More specifically, the operational leads at the sites have agreed to encourage the participation of their physicians and nurses in the project and to provide space needed for project site visits, key informant interviews, and staff training. The participation of the PI, Co-PIs, and all Co-Investigators is strongly supported by their respective academic institutions.

Clinical Sites: Edmonton

The only pediatric emergency facility in central and northern Alberta is at the Stollery Children's Hospital. With its catchment area including the Northwest Territories, Eastern British Columbia, and Western Saskatchewan, the Emergency Department (ED) at Stollery Children's sees approximately 50,000 patients each year. Of those patients, approximately 10% are admitted to hospital. In addition to the Stollery Children's Hospital, children are seen for acute care at several other sites in Edmonton. These include the North East Community Health Center and the Grey Nuns Hospital. Combined, these two sites evaluate approximately 18,000 patients in the Edmonton zone. All three sites have been active in research and have participated in the Alberta Childhood Asthma Pathway implementation, so that they are familiar with CP implementation studies.

Study setting Cont'd	9	*Clinical Sites: Calgary* The ED at Alberta Children's Hospital (ACH) provides care for over 77,000 patient visits per year. The department serves as the pediatric tertiary medical and trauma referral center for Southern Alberta, Eastern British Columbia, and Western Saskatchewan, and is the primary pediatric ED for the local area. The ED at ACH is actively involved in concussion clinical care and research. It was a central recruitment site for the local 4C study (Barlow, PI) and the national 5P concussion (Zemek, PI) and PLAYGAME (Barlow, PI) studies, and is currently recruiting for the national A-CAP (Yeates, PI) concussion study. The South Health Campus ED opened in January 2013 and serves as a satellite pediatric ED care setting to ACH. The same group of pediatric emergency medicine physicians staff the South Health Campus ED 12 hours per day (noon to midnight), to better serve the children and families of south Calgary and the rural communities to the south. Annually, 15,000 children are cared for in the South Health Campus ED.
Eligibility criteria	10	*Participants.* The individual hospital sites and their acute care teams will be the focus of the CP implementation. Participants at each site will include acute care physicians and nurses, as well as hospital administrators with responsibility for the acute care settings. For the purposes of evaluating the impact of the CP on health outcomes, participants will be children 5 to 18 years of age diagnosed with concussion, as well as their parents. Children 4 years of age and younger are excluded because measures of post concussive symptoms and other clinical outcomes have not been validated for those ages. We will standardize the identification of concussion to include all patients diagnosed with ICD code S06.0 (concussion). We also will include all patients diagnosed with S09.9 (head injury, unspecified) in a sensitivity analysis, and work with AHS analytics to determine whether to recode such cases to code S06.0 when appropriate.
Interventions	11a	*Intervention strategy.* Our first objective is to develop an intervention strategy that promotes uptake of the CP at each site. Because our choice of intervention strategy depends on input from each site, we cannot fully design the intervention until the study begins. However, we have provisionally chosen three core intervention components based on previous CP implementation efforts: (1) a local champion team at each site; (2) a reminder system (i.e., placement of the 5P sticker, information leaflets, and website flyer onto patient charts); and (3) a patient and parent website that provides important information about concussion recovery (see Table 2 on next page); (4) regular teleconferences with site champions to discuss progress; and (5) teaching sessions for physicians and nurses at each site prior to rollout.[23-25] These components address health professional, acute care team, and organizational (site) issues. Based on site input, we may refine these strategies or add others. In general, though, the implementation strategy will be designed to work within existing hospital resources, to ensure feasibility and sustainability, minimize reliance on study support and infrastructure, and assess implementation in a realistic context.

11b *Theory-based design with knowledge user input.* Our intervention strategy will be based on the TDF, which provides an evidence-based, theory-driven approach to informing intervention design.[16,17] Prior to implementing the CP, a TDF-based structured interview guide will be used to elicit barriers and facilitators to implementation from relevant stakeholders through site visits and key informant interviews. Site visits also will be used to assess organizational issues, such as flow of pediatric patients, health provider roles, and experience with CPs in the acute care setting.[26] During each visit, we will interview physicians and nurses to elicit clinical or procedurally important barriers and facilitators to implementing the CP. In addition, one administrator at each site will be interviewed to determine readiness for change, as well as barriers and facilitators, at the organizational level. Site visit interviews will be audiotaped and transcribed for subsequent analysis. The site visit process will promote understanding of site-specific issues and increase project engagement.

11c *Table 2: Core components of implementation strategy*

Core component	**Description**
Local site champion teams	-Nurse educator or emergency nurse -Emergency medicine/acute care physician
Pre-implementation site visits	-Assessment of local ED/acute care attitudes, organization, and feedback on CP usability
Ongoing site support	-Monthly teleconferences with site teams -Weekly emails to all clinical teams for pathway utilization
Reminder systems for health care providers	-CP specific tools for physicians assessing patients (eg. 5P sticker on patient charts) -Referral to concussion clinic for children at high risk of persistent postconcussive symptoms -Reminders to use CPs in patient care areas
Patient and parent engagement	-Family handout given at discharge with concussion care instructions and reminders to access the web portal -Patient and parent-friendly website to provide tools to track recovery and information about concussion recovery and care
Site commitment	-Facilitation through site approval processes -Prioritization within other site initiatives

11d *Intervention mapping*. Information derived from the site visits and key informant interviews will be used to design site-specific intervention strategies. We will match appropriate behaviour change strategies to identified barriers, using known taxonomies of behaviour change techniques, and will select the best delivery mode for each to create a multifaceted intervention strategy.[27,28] To ensure that the implementation succeeds, feasibility and practicality will be key criteria for choosing interventions. The full project team will participate in intervention design via teleconference, and site partners will provide additional input at our launch meeting.

Outcomes

12a *Evaluation and outcomes.* A process log will be maintained by the study coordinator throughout the trial to qualitatively document and assess variability and fidelity in implementation of the CP across the four sites. The process log will be used to capture issues related to site customization of documents, barriers and delays, training workshop attendance and interest, ease of use, and degree of uptake. Components of the log will include workshop participant feedback and facilitator observation forms, brief twice-monthly feedback from site champion teams, and progress with target dates for implementation.

As shown in Table 3 on the next page, we have planned a comprehensive evaluation of both process and clinical outcomes to fulfill our second objective. Clinical outcomes will include four patient-centered outcomes, and process outcomes will include five measures of adherence to the CP (e.g., physician provision of discharge instructions; patient/parent adherence to key interventions as recommended by the CP). Physicians and nurses in the ED will distribute a concussion handout at discharge. The front page will advise the family to go to the RECOVER web portal for more information, and the last 4 pages will provide concussion education and advice, including about return to learn and return to play. Prior to CP implementation, the website will provide parents with tools to help track recovery; after CP implementation, it will also supply evidence-based information about how to promote recovery and obtain appropriate concussion care. Both prior to and after CP implementation, the website interface will ask patients and parents to rate their satisfaction with their care in the ED within 3 days of their visit, as well as their comprehension of and adherence to physician discharge recommendations, including those regarding return to school and return to play. They also will report on whether they perceive the patient to have returned to pre-injury status, and provide ratings of the patient's post-concussive symptoms and quality of life. Parents and patients will be blinded to site allocation. They will be able to provide their responses anonymously, or they can elect to provide informed consent to enable us to link their responses on the website to identifying information and medical data.

12b The primary outcome will be the time to symptom resolution based on weekly reports of whether the patient has returned to pre-injury status. Secondary patient-centered outcomes will include ratings of satisfaction with ED care and post-injury ratings of post-concussive symptoms and quality of life. The latter two outcomes will be assessed using the Health and Behaviour Inventory[30] and the PedsQL[31], both of which are measures included in the NIH Common Data Elements for pediatric traumatic brain injury[32] (see Surveys and Questionnaires in appendices).

Secondary outcomes also will include measures of physician adherence, the number of unique website hits per IP address, the proportion of patient- and parent-reported adherence to physician discharge recommendations, the proportion of diagnosed concussions per visit (predicted to increase as physicians identify and code the injuries correctly), and the proportion of CT scans ordered per diagnosed concussion (predicted to decrease because the CP will include prediction rules for CT scanning in concussion).

12c *Table 3: Process and clinical outcomes*

Outcome measure	**Description**	**Details**
Primary clinical outcome	Time to symptom resolution	Weekly ratings by patients and parents of whether patient has returned to pre-injury status
Secondary clinical outcomes	Postconcussive symptoms	Weekly ratings on Health and Behaviour Inventory
	Quality of life	Weekly ratings on PedsQL
	Satisfaction with care	Post-visit rating of overall satisfaction with acute care
Primary process outcome	Physician adherence	Proportion of completed discharge forms per diagnosed concussion[1]
Secondary process outcomes	Patient/parent adherence	Proportion of patient and parent reports of adherence to physician discharge recommendations involving rest, return to school, and return to play
	Patient/parent adherence	Number of unique website hits per IP address
	Physician adherence	Proportion of diagnosed concussions per visit
	Physician adherence	Proportion of CT scans ordered per diagnosed concussion

[1]Qualitative interviews and site surveys resulted in the discharge form being replaced by the 5P risk score sticker. To assess adherence, the study team recorded the number of 5P assessments completed by each site over the course of data collection.

12d *Health care utilization.* We will assess the impact of the implementation of the CP on health care utilization using data from the National Ambulatory Care Reporting System (NACRS). Relevant outcomes will include acute care length of stay and return visits within 72 hours following acute care discharge. Appropriate procedures will be used to link administrative and health data. Use of NACRS data allows efficient capture of return visits, regardless of whether the patient returns to the index site. We will also use administrative data from AHS to assess health care utilization for pediatric patients with concussion. For each concussion diagnosed at the target sites, we will track the duration of stay in the ED, number of subsequent outpatient visits, and number of referrals to other health care services.

Healthcare costs. Payer costs associated with acute care for pediatric patients with concussion will be accounted for, based on ED visits, return visits, and physician fees, as well as subsequent outpatient care, which will be determined from the AHS administrative database. Costs for ED visits will be based on standard methodologies using resource intensity weightings (RIWs). Physician fees associated with ED and outpatient visits, including those for laboratory and diagnostic imaging services, will be captured through associated AHS billings. Cost data will be presented in Canadian dollars for the standard price year of 2014.

Participant timeline 13a *Project phases*. As shown in the Project Timeline below, the project will be divided into four phases. During the pre-implementation phase, which will last 12 months, we will complete site visits and key informant interviews, develop the intervention strategy, seek site approvals for the planned intervention, conduct a launch meeting, and complete randomization. The implementation phase will take place over the next 10 months. According to the stepped wedge design, data collection will occur continuously from 2 months prior to implementation at any site until 2 months after the CP is implemented at all four sites. Data collection will include the monitoring of outcomes, which are described below, during the course of the stepped wedge trial, which will last about 10 months.

The third phase of the project will involve data analysis, which is expected to take 6 months. The final phase will involve dissemination of the study findings to all study sites and associated stakeholders, as well as to broader clinical and scientific audiences through conference presentations and journal publications. Within the context of the broader MNCY concussion workgroup, we also will begin planning for the scaling up of CP implementation on a province-wide level. The complete study is expected to take 3 years.

13b

	Project Year						
Project Activity	**1**			**2**		**3**	
Hire & train personnel							
Pre-implementation							
Project site visits							
Key informant interviews							
Intervention mapping & design							
Site approvals							
Launch meeting & site training							
Randomization							
Implementation							
Collect data							
Data analysis							
Dissemination							
Study site presentations							
Stakeholder presentations							
Conference presentations							
Journal publications							
Plan implementation							

Sample size

14 *Analysis Strategy*. Characteristics of patients and sites will be summarized by exposure status (i.e., control versus intervention) to allow for consideration of possible selection biases. Relevant comparisons will include the number of pediatric patients with concussion at each site before and after the implementation of the CP, site characteristics such as total patient volume, and important patient characteristics, including age and sex.

Power calculation. Power calculations for the primary outcome, time to symptom resolution, were computed using standard methods for two-group survival analyses (i.e., children who received care before versus after implementation of the CP). We conservatively assumed a sample size of 1,575, based on a total of 2,100 concussions per year across sites, a 50% rate of web site usage, and 18 months of recruitment. If we assume equal numbers of cases in the pre- and post-implementation phases, a median time to symptom resolution of 4 weeks, non-informative censoring because follow up will continue for 3 months, and no clustering effects, then the minimum hazard ratio that we can detect with .80 power at a significance level of .05 would be 1.20, which would represent at 20% higher likelihood of symptom resolution at any given time post-injury after implementation of the CP. Analyses will treat the randomised crossover from control to intervention as having occurred at the planned time, irrespective of any delays in actual implementation of the intervention, although secondary analyses will explore the effects of the actual timing of the crossover should any delays occur. All sites have provided written commitment to the study. Therefore, barring exceptional circumstances, no sites will be lost to follow-up.

Randomization

15 A study statistician will use a computerized algorithm to select a randomly generated order of implementation for the four sites.

Recruitment	16	Recruitment will rely on ongoing support and communication with clinicians. To avoid having implementation become stalled or displaced by other priorities, we will conduct monthly teleconferences with site champions to discuss progress and sustainability. Teleconferences will allow sites to discuss best practices and local solutions to common barriers. Additionally, the study coordinator and PI will be available for more informal consultation by email or phone.

Methods: Data collection, management, and analysis

Data collection methods	17a	Administrative data will be provided to the research team by the AHS data analytics team in either anonymous format (for diagnosed concussions where a parent did not use the web portal or chose to do so anonymously) or a format where personal identifiers are stripped after linkage (for parents who used the web portal and provided consent for linkage). To log in to the web portal, parents and children will provide an email address, password, and the child's name to create an account. This information will not be retained by the study team and investigators will not have access to that information. The web portal may also be used anonymously. Web portal content will be targeted to specific age cohorts: 1) primary pathway for youth age 6-13; 2) secondary pathway for adolescents age 14-17; and 3) caregiver pathway for parents/guardians. Thus, age of the child is required when accessing the web portal. To determine whether the implementation of the CP leads to changes in healthcare utilization (e.g., greater use of outpatient care and less reliance on care in emergency departments), and whether such changes are linked to better child outcomes, healthcare numbers will be obtained by willing families. Once data collection is completed, the research coordinator will destroy any identifying information. The Health and Behaviour Inventory (HBI) and Pediatric Quality of Life (PedsQL) questionnaires will be voluntarily completed by families through the web portal. No data will be entered by the study team. The HBI is a 20-item scale commonly used to assess the frequency of cognitive and somatic pediatric concussion symptoms on a Likert scale of 0 (never) to 3 (often). The PedsQL is a valid and reliable, 23-item model designed to measure the core dimensions of health as delineated by the World Health Organization, as well as role (school) functioning. 4 scales (physical, emotional, school and social functioning) are used to measure health-related quality of life in healthy children and adolescents and those with acute and chronic health conditions.
	17b	The web portal will send email reminders to participating families to complete serial symptom inventories. No contact will be made by the study team unless families reach out voluntarily. Ideally, symptom data will be collected until participants fully recover, however, participants can stop entering data, or leave the study at any time.

Data management	18	The study team will not directly access AHS databases or systems. Administrative data will be accessed externally by an AHS MyChild analyst. The variables collected will be obtained for all children diagnosed with concussion at any of the participating AHS facilities during the conduct of the stepped wedge clinical trial. The data will be de-identified, except for children whose parents have consented to linkage of web portal responses with health records. Individual data entered through the web portal by parents and children will download into the secure REDCap database. The database servers will be located under Canadian jurisdiction and be administered by the Clinical Research Unit of the University of Calgary. These servers are part of the CRU infrastructure and maintained in accordance with strict security and privacy controls. Results from the project will be reported in aggregate format. If individual materials are presented, all personal identifiers will be removed. These safeguards should maintain confidentiality and minimize any risks associated with participation in the project.
Statistical methods	19a	Statistical analyses will involve comparisons of primary and secondary outcomes prior to versus after CP implementation. Children will fall into either the pre-CP or post-CP group because their care (including the version of the website and text messaging they receive) will be based strictly on when they present for acute care (i.e., prior to or after CP implementation at their respective site). Time to symptom resolution will be the primary outcome, and will be examined using survival analyses. First, Kaplan Meier estimates of the curves will be created, to obtain crude comparisons; Cox proportional hazards models will then be used to adjust for other variables. Apart from reporting hazard ratios, we also will present median time to symptom resolution (if reached) for pre- versus post-CP implementation. Other outcomes will be examined using mixed models with random effects for cluster, to adjust for clustering by site, and fixed effects for the test of CP status (pre/post implementation). Linear models will be used for continuous outcomes, Poisson for counts, and logistic regression models for binary outcomes. Exploratory analyses will examine whether the impact of implementation changes as sites gain more experience with the CP, by including the amount of time since the CP was implemented as a fixed effect in the model. Similarly, heterogeneity in intervention effects will be explored using testing interactions of CP status (pre/post) with site.

Methods: Monitoring

Data monitoring	20a	Administrative data will be collected retrospectively using de-identified datasets with permissions from AHS. Patient data will be self-entered electronically, without study team involvement. The same study coordinator will be assisting with clinical implementation at all sites for consistency. Because the intervention in this trial is the implementation of a clinical pathway a data monitoring committee will not be required.
Harms	21	Monthly teleconferences will alert study staff to any concerns. Patient adverse events are not a risk with this trial. If the implementation of the CP leads to significantly longer recovery based on the primary outcome at any of the sites, the study protocol will be stopped.
Auditing	22	The investigator will be in contact with the study coordinator consistently throughout the trial and monthly teleconferences will be a form of qualitative audit with each site.

Ethics and dissemination

Research ethics approval	23	Approval will be obtained by the Conjoint Health Research Ethics Board at the University of Calgary.
Protocol amendments	24	Amendments will be submitted to the research ethics board.
Consent or assent	25a	Consent will be obtained from sites through signed agreements. Participant consent will be passively collected when families voluntarily access the web portal and provide electronic consent.
Confidentiality	26	Confidentiality will be maintained by assigning all participants who use the web portal with an identification number. All data collected during the study will use that number for identification purposes. Computer databases will use the identification number for designation purposes, and will not contain participant names. Results from the project will be reported in aggregate format. If individual materials are presented, all personal identifiers will be removed. These safeguards should maintain confidentiality and minimize any risks associated with participation in the project.
Declaration of interests	27	There are no declarations of interest to disclose on behalf of the investigators.
Access to data	28	The final dataset will only be accessible to the study team and will not include patient identifiers.
Dissemination policy	30a	The proposed evaluation of the CP for acute care of pediatric concussion will be an important step in improving the outcomes of children with concussion. We expect that the study will yield critical knowledge regarding the success of CP implementation at multiple levels: uptake of and adherence to the CP among front-line staff, as well as adherence by patients and parents; effects on clinical outcomes, including patient satisfaction and health outcomes; and impact on health care utilization and costs. Standardizing care via the successful implementation of the CP should result in significant benefits to patients, while reducing the burden on the health care system posed by concussion. In summary, the project will advance knowledge about CP implementation and outcomes; build capacity by involving students and early career investigators; inform clinical decision-making by assisting health care providers involved in the acute care of pediatric concussion; improve the health of children with concussion; and reduce the public health and socioeconomic burdens of concussion.

The MNCY SCN pediatric concussion workgroup is working closely with the AHS Clinical Knowledge & Content Management (CKCM) group in the development of its clinical guidelines and CPs. CKCM is a key component of the AHS Provincial Clinical Information System (CIS) initiative, which will support a single integrated electronic health system. The CKCM group is assisting in the development of physician order sets, clinical documentation, and other tools that will facilitate implementation of the CP. With CKCM's leadership, the CP will be placed in a provincial repository to be used and adopted by the provincial CIS, as well as the existing legacy electronic systems until a provincial CIS is fully implemented. This will simplify access to a single provincial clinical standard for concussion. Further, as the provincial CIS design and build begins in late 2017, concussion will be included in the system design, facilitating implementation by inclusion in the electronic CIS. CKCM can also assist in the identification of data elements and measures, and facilitate study linkage to the AHS provincial data warehouse for data reporting and analytics. The AHS Analytics program draws data from a number of information systems, and reports this data to national databases such as NACRS (national ambulatory care reporting system). The available data elements are available on the AHS website, including demographics information, symptom/presenting complaint, arrival/admission and discharge date from ED, and consult information.

30b We anticipate three major project deliverables:

(1) A summary report that includes several key components: study rationale; study design; findings from site visits and key informant interviews; planned intervention strategies; results of the CP implementation; and a plan for dissemination.

(2) A website that facilitates patient and parent engagement in CP implementation by providing them with evidence-based information about concussion recovery and management, along with tools to track recovery across time.

(3) Widespread scientific and professional dissemination through presentations to pediatric acute care providers in multiple settings and at professional and scientific conferences, as well as through peer-reviewed publications in clinical and scientific journals.

30c Knowledge sharing and translation is an integral part of our project, which by definition involves the translation of evidence-based guidelines into clinical practice. We will seek ongoing input from multiple stakeholders during all phases of the study. During the pre-implementation phase, when co-constructing the intervention strategy for implementing the CP, we will draw on the collective expertise of the study team, many of whom are acute care clinicians, as well as on input from physicians, nurses, and administrators at each of the participating sites. During the implementation phase, we will remain in frequent communication with the site champions, to obtain their feedback, troubleshoot local issues, and promote sustainability.

We will involve patients and their parents in the project by inviting study participants to provide feedback on the care they receive and to report on patient-centered outcomes. We have invited two persons with a history of concussion to collaborate on the project by providing ongoing feedback on the CP and its implementation. Throughout the project, we plan to engage a variety of community partners (e.g., Parachute, Brain Injury Canada, Public Health Association of Canada), research networks (e.g., Pediatric Emergency Research Canada, Translating Emergency Knowledge for Kids [TREKK]), and other health provider groups (e.g., sports medicine physicians from the AMSafe clinic at the North East Community Health Center in Edmonton and the Acute Sport Concussion Clinic at the University of Calgary), both to obtain their input about the CP and to assist in its dissemination and implementation. We will also interview families who were referred to concussion clinics via the CP to solicit their feedback on what they found helpful and what would have worked better during their child's concussion experience.

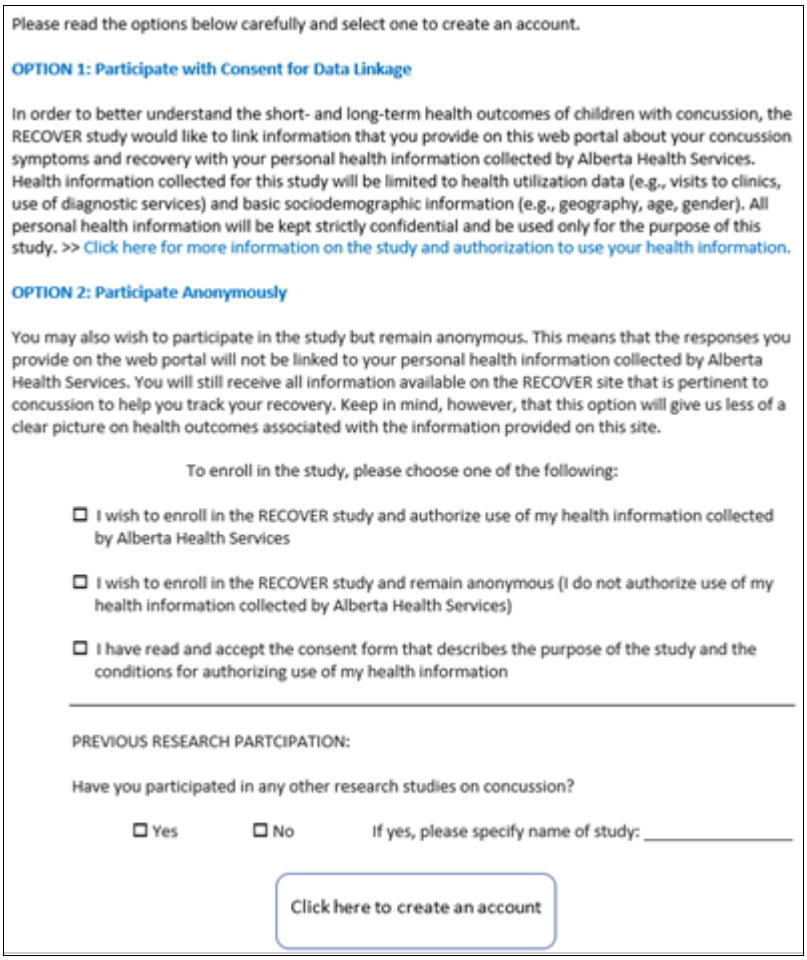
In the dissemination phase, the study team and the site champions will share our findings through interactive education sessions with pediatric acute care providers at AHS sites. Additionally, we will make presentations at national professional and scientific conferences and publish peer-reviewed papers in clinical and scientific journals. The findings will be highlighted on the MNCY SCN website. In conjunction with the MNCY pediatric concussion workgroup, we will seek to spread and scale up the implementation of the CP to all pediatric acute care settings across the province.

30c We also plan to disseminate the project's findings more broadly, outside of Alberta. We are ideally situated to do so given our team's extensive links to important concussion and brain injury initiatives both nationally and internationally. Our team includes investigators who sit on the Federal working group for sport concussion guidelines, the Canadian Concussion Collaborative, the Canadian Traumatic Brain Injury Research Consortium, the Center for Disease Control Mild Traumatic Brain Injury Workgroup, the International Concussion in Sport Group, and the International Initiative in Traumatic Brain Injury Research (IntBIR). We will disseminate our findings to all of these groups, which include clinicians, researchers, sporting bodies, professional organizations, and research funding agencies.

Finally, we will develop a plan for data sharing, to insure the data from the project are available to other qualified investigators. This will likely take the form of a website that allows interested investigators to request data for specific planned analyses, subject to a University-approved data sharing agreement. The website will describe the parent project and provide a data dictionary that can be used to choose specific data elements to be included in requested datasets.

Appendices

Informed consent materials 31



Please read the options below carefully and select one to create an account.

OPTION 1: Participate with Consent for Data Linkage

In order to better understand the short- and long-term health outcomes of children with concussion, the RECOVER study would like to link information that you provide on this web portal about your concussion symptoms and recovery with your personal health information collected by Alberta Health Services. Health information collected for this study will be limited to health utilization data (e.g., visits to clinics, use of diagnostic services) and basic sociodemographic information (e.g., geography, age, gender). All personal health information will be kept strictly confidential and be used only for the purpose of this study. >> Click here for more information on the study and authorization to use your health information.

OPTION 2: Participate Anonymously

You may also wish to participate in the study but remain anonymous. This means that the responses you provide on the web portal will not be linked to your personal health information collected by Alberta Health Services. You will still receive all information available on the RECOVER site that is pertinent to concussion to help you track your recovery. Keep in mind, however, that this option will give us less of a clear picture on health outcomes associated with the information provided on this site.

To enroll in the study, please choose one of the following:

☐ I wish to enroll in the RECOVER study and authorize use of my health information collected by Alberta Health Services

☐ I wish to enroll in the RECOVER study and remain anonymous (I do not authorize use of my health information collected by Alberta Health Services)

☐ I have read and accept the consent form that describes the purpose of the study and the conditions for authorizing use of my health information

PREVIOUS RESEARCH PARTCIPATION:

Have you participated in any other research studies on concussion?

☐ Yes ☐ No If yes, please specify name of study: _____

Click here to create an account