A Pragmatic Strategy Empowering Paramedics to Assess Low-Risk Trauma Patients with the Canadian C-Spine Rule and Selectively Transport them Without Immobilization

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Contents

Study Protocol

The information included in this report follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Guidance for recommended items to include and address in a clinical trial protocol (1, 2).

Section 1: Administrative Information

1.1 Study Title

A pragmatic strategy empowering paramedics to assess low-risk trauma patients with the Canadian C-Spine Rule (CCR) and selectively transport them without immobilization.

1.2 Trial Registration and Data Set

The trial has been registered at ClinicalTrials.gov. The ClinicalTrials.gov identifier assigned to this study is: NCT02786966. Table 1 (below) contains information on the recommended items from the WHO Trial Registration Data Set (http://www.who.int/ictrp/network/trds/en/) (1, 2). When items from Table 1 are updated in this protocol, the trial registry at ClinicalTrials.gov will be updated accordingly.

Table 1. C-Spine Study Registration Data Set

Item	Information
Primary registry and trial identifying number	ClinicalTrials.gov, NCT02786966
Date of registration in primary registry	May 31, 2016
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Ontario SPOR SUPPORT Unit (OSSU)
Primary sponsor	Ottawa Hospital Research Institute
Secondary sponsor(s)	none
Contact for public queries	Manya Charette, Study Coordinator, email: mancharette@ohri.ca
Contact for scientific queries	Dr. Christian Vaillancourt, Principal Investigator, email: cvaillancourt@ohri.ca
Public Title	A pragmatic strategy empowering paramedics to assess low-risk trauma patients with the Canadian C-Spine Rule (CCR) and selectively transport them without immobilization.
Scientific Title	Can a strategy allowing paramedics to assess selective low-risk trauma patients with the Canadian C-Spine Rule and transport them without immobilization be safe, cost-effective, and result in significant health service benefits for patients, Emergency Medical Services, and Emergency Departments? – A Cluster Randomized Pragmatic Multicentre Trial.
Countries of recruitment	Canada (Ontario only)
Health condition(s) or problem(s) studies	Stable trauma patients with a potential neck injury requiring assessment by Emergency Medical Services (EMS)
Intervention(s)	Application of a decision rule – CCR – to determine the need for spinal immobilization
Key inclusion and exclusion criteria	Included: consecutive, alert (able to follow commands), stable (normal vital signs) patients evaluated by paramedics following acute blunt trauma (within 48 hours). Excluded: Patients with penetrating trauma, acute paralysis, known vertebral disease, those referred from another hospital and transported between facilities, and those younger than 8 years of age.
Study type	Stepped wedge, cluster randomized trial
Date of first enrolment	*To be determined*
Target sample size	7,200
Recruitment status	Not yet recruiting
Primary outcome(s)	Proportion of patients immobilized Proportion of patients feeling comfortable (co-primary outcome)
Key secondary outcomes	Proportion of patients with a pain score ≤ 4/10 Time from EMS arrival to ED discharge or admission to hospital Patient radiation exposure from diagnostic imaging Number of skin pressure injuries Number of missed c-spine injuries Time spent in the field by paramedics before arrival to hospital Time spend in-hospital by paramedics before transfer of care

	ED length of stay Number of subsequent ED visits within 30 days Number of subsequent clinical/family physician visits within 30 days Frequency of c-spine diagnostic imaging performed within 30 days Incremental cost per one immobilization avoided

1.3 Protocol Version and History of Changes

Any changes to the protocol that are more substantive than simply the correction of typographical errors will be recorded in Table 2. The revised protocol will be given a new version number, and a summary of the revisions made to the previous protocol version will be listed. The current protocol version number and effective date will also be displayed in the footer at the bottom of each page in the protocol and should match the version number on the cover sheet and in Table 2.

Table 2. Description of Protocol Revisions

Protocol Version #	Effective Date	Summary of Revisions
1	March 2016	N/A
2	May 2016	1.2 Trial Registration and Data Set – addition of registry number Table 1 – Trial Registration Information 2.1 Background – addition of ILCOR reference 3 – clarification regarding number of sites 3.2 Eligibility Criteria – clarification of penetrating trauma, modification to stable vital signs Appendix 6 – Paramedic Data Collection Form – new version 6.1 Data Monitoring – additional information on DSMB Appendix 4 – Paramedic Committee Terms of Reference Appendix 8 – addition of DSMB Terms of Reference

1.4 Funding

This study has received funding through the Ontario SPOR SUPPORT Unit (OSSU's) IMPACT Awards competition. OSSU, which receives funding from the Canadian Institutes of Health Research and the Province of Ontario, has agreed to provide funding in the amount of $1,456,990 for the period June 2, 2015 to September 30, 2018. The funding will be used to cover the direct costs required to implement and run this multicenter study. Indirect funding will be provided by the sponsor organization – the Ottawa Hospital Research Institute. Participating EMS Services have all agreed to provide paramedic training time for this study in-kind.

1.5 Roles and Responsibilities in Protocol Development

CV = Dr. Christian Vaillancourt, Ottawa Hospital Research Institute
MC = Manya Charette, Ottawa Hospital Research Institute
MT = Dr. Monica Taljaard, Ottawa Hospital Research Institute
KT = Dr. Kednapa Thavorn, Ottawa Hospital Research Institute
AP = Dr. Amy Plint, Children's Hospital of Eastern Ontario

CV conceived of the study and drafted the IMPACT Awards Application. MC initiated the drafting of the study protocol using the IMPACT Awards Application as a template. MC will be responsible for maintaining the protocol going forward. MT provided statistical expertise into both the Application and the Protocol. KT provided expertise on the Health Economic components of the project. AP is coordinating the pediatric component of the project and provided input on these sections of the Application and the Protocol. All study team members (see Appendix 1. C-Spine Study Team Membership, Roles and Affiliations) contributed to the grant application. Members of the Steering Committee (see section 1.8.1 Steering Committee) reviewed the complete draft study protocol.

1.6 Sponsor Contact Information

Study Sponsor: Ottawa Hospital Research Institute
Contact Name: Dr. Duncan Stewart, Chief Executive Officer; Ms. Nancy Camack, Director, Research Administration; Dr. Dean Fergusson, Director, Clinical Epidemiology Program
Address: 725 Parkdale Avenue, Ottawa, ON K1Y 4E9
Phone: 613-761-4395
Email: info@ohri.ca

1.7 Roles and Responsibilities – Sponsor and Funder

Neither the Sponsor nor the Funder had any role in the design of this study. The Funder will be kept up-to-date on study progress and activities, but will not have any direct role in the execution, analysis, interpretation or publication of study results.

1.8 Roles and Responsibilities – Committees

1.8.1 Steering Committee

Chair: Dr. Christian Vaillancourt

Membership: *(to be confirmed)* Dr. Amy Plint, Elizabeth Hall (patient representative), paramedic representative, Dr. Monica Taljaard, Dr. Kednapa Thavorn, one representative from each OSSU Partner (Ottawa Methods Centre, Institute for Clinical Evaluative Sciences, Ontario Child Health SUPPORT Unit, Women's College Hospital Women's Xchange, OSSU Ontario Francophone Communities Working Group, Clinical Trials Ontario), study support staff

Responsibilities*:*

- Approve the main study protocol and any subsequent amendments
- Monitor and supervise the trial towards interim and overall objectives
- Review relevant information from other sources, including information from related studies that could impact the main study protocol
- Review recommendations and requests from participating Research Ethics Boards, as well as the Data Safety Monitoring Board
- Review activity of study subcommittees, including, but not limited to the Publications Committee, the Paramedic Committee, and the Patient Engagement Committee.

Terms of Reference: appended, please see

Appendix 2. Steering Committee Terms of Reference.

1.8.2 Publications Committee

Chair: Dr. Christian Vaillancourt

Membership*: to be decided*

Responsibilities*:*

- Promote publication of study findings and activities in peer-reviewed, MEDLINE-indexed journals
- Support broad and equitable participation by study team members and investigators in presentations and publications
- Define rules and guidelines for writing group membership for manuscripts
- Review manuscript proposals, assign writing groups and prioritize publications and presentations
- Provide editorial support and timely review of presentations and publications.

Terms of Reference: will be appended to Appendix 3. Publications Committee Terms of Reference when finalized.

1.8.3 Operations Committee

Chair: Dr. Christian Vaillancourt

Membership: Manya Charette, other study support staff

Responsibilities: day-to-day trial logistics and operations

1.8.4 Paramedic Committee

Chair: Brent McLeod, paramedic representative

Membership: one representative from each participating EMS Service and each supporting Base Hospital Program, study Principal Investigator, study support staff

Responsibilities:

- To help develop, review and approve study training materials, data collection forms and study advertisements
- To provide feedback to the Steering Committee on the EMS logistics of proposed study activities and processes
- Review and provide feedback on the main study protocol and any subsequent amendments
- Develop a strategy to communicate the study requirements, activities and study progress to each participating EMS service.

Terms of Reference: appended, please see

Appendix 4. Paramedic Committee Terms of Reference.

1.8.5 Patient Committee

Chair: *to be decided*

Membership: Elizabeth Hall, a second patient representative, a pediatric representative from CHEO, plus others to be confirmed

Responsibilities: *to be finalized following development of Terms of Reference*

Terms of Reference: will be appended to Appendix 5. Patient Committee Terms of Reference.

1.8.6 Data Safety Monitoring Board

Please see Section 6. Methods: Monitoring for details on the study Data Safety Monitoring Board.

Section 2. Introduction

2.1 Background

Problem: Ontario Emergency Medical Services (EMS) annually transport half a million patients with a potential neck (cervical/c-spine) injury, from falls or motor vehicle collisions, to local emergency departments (ED). Ninety-five percent of those patients are alert and stable and at low risk of c-spine injury. Less than 1% actually have a c-spine fracture, and even less (0.5%) have a spinal cord injury. Spinal cord injuries result from moderate to severe blunt traumas and not from minor movements occurring during transport to hospital. Regardless, current EMS practice is to transport all such trauma victims (with or without c-spine injury) by ambulance using backboards, collars, and head immobilizers. These patients stay fully immobilized until an ED bed is made available, sometimes for as long as 3 hours. This prolonged immobilization is often unnecessary and increases patient discomfort, contributes to ED crowding, prolongs EMS intervention times, and adds a heavy financial burden to our healthcare system.

Why C-Spine Immobilization of Low-Risk Patients May Be Unwarranted: Not only is immobilization often unnecessary, its potential for clinical adverse effects and discomfort are well documented (3). Chest straps used in immobilization can have a pulmonary restrictive effect, even in healthy non-smokers. Immobilization on a board leads to progressively worse pain in the head, neck, and back area, often resulting in the necessity to perform diagnostic imaging on an otherwise normal spine in the ED. The presence of a c-spine immobilization collar has been associated with hyperextension, actually causing spinal cord injury in patients suffering from ankylosing spondylitis. In addition, c-spine collars can cause neck vein compression and increased intra-cranial pressure for patients with head injury, difficulty swallowing, and local skin necrosis.

We have identified three systematic reviews relevant to c-spine immobilization. Work published by Abram in 2010 (32 studies) (3) suggested there was a growing body of evidence documenting the "*risks and complications of routine spinal immobilization*", and that there was a "*possibility that immobilization could be contributing to mortality and morbidity in some patients."* A more recent review by Sundstrom et al (220 studies) (4) concludes there is limited evidence supporting current c-spine immobilization practices, that large definitive randomized trials are lacking, that the benefit on neurological injury and spinal stability is uncertain, and that there is a growing body of opinions against the use of c-spine collars. The International Liaison Committee on Resuscitation (ILCOR) provides

international guidelines on cardiac arrest and trauma resuscitation. In November 2015, ILCOR published a recommendation not to use routine application of c-spine collars for adult and children with blunt suspected traumatic c-spine injury (based on very low quality of evidence from 29 studies) (5).

Effect on Overburdened EMS Systems, and Crowded EDs: Because trauma victims need to be seen rapidly at the hospital, paramedics are given only 15-20 minutes to evaluate and treat them in the field before transport. Even for minor trauma victims, c-spine immobilization takes greater than 5 minutes to apply, or up to 30% of the allotted field time. Unlike minor trauma victims coming to the ED by their own means of transport and commonly triaged to the waiting room area, minor trauma victims immobilized and transported by paramedics can wait up to 3 hours until an ED stretcher becomes available, also holding up the EMS crew who then become unavailable for the next community emergency. In 2013, the U.S. National Association of Emergency Medical Services Physicians took a position in favor of a judicious immobilization strategy (6).

Once on an ED stretcher, it is not unusual for these patients to remain fully immobilized for several hours until physician assessment and c-spine diagnostic imaging can be performed and interpreted. This consumes valuable time for physicians, nurses, and radiology technicians and distracts them from other urgent responsibilities. These delays compound the burden of our crowded Canadian EDs in an era when they are under unprecedented pressures. The median length of stay for a patient evaluated in the stretcher area is approximately 8-12 hours, whereas similar minor trauma victims arriving without immobilization can be evaluated and discharged in less than 4 hours.

The Canadian C-Spine Rule: We have derived, validated, and implemented the Canadian C-Spine Rule (CCR) to be used by physicians (7-9), triage nurses (10), and paramedics (11) in more than 40,000 alert and stable trauma patients. The CCR (Figure 1) directs that immobilization is unnecessary if the patient has no high-risk criteria, has at least one low-risk criterion, and can voluntarily rotate their neck 45' left and right. Physicians and nurses already use the CCR in the ED to safely remove immobilization devices without the need for imaging and with no documented adverse outcomes. We recently completed a pilot implementation study with Ottawa paramedics where selective patients were transported without immobilization. We have recruited 3,854 patients, and paramedics have identified **all** clinically significant injuries (100% sensitivity) without negative consequence when the CCR determined that immobilization was not required (68% specificity). Approximately 60% of immobilizations were avoided.

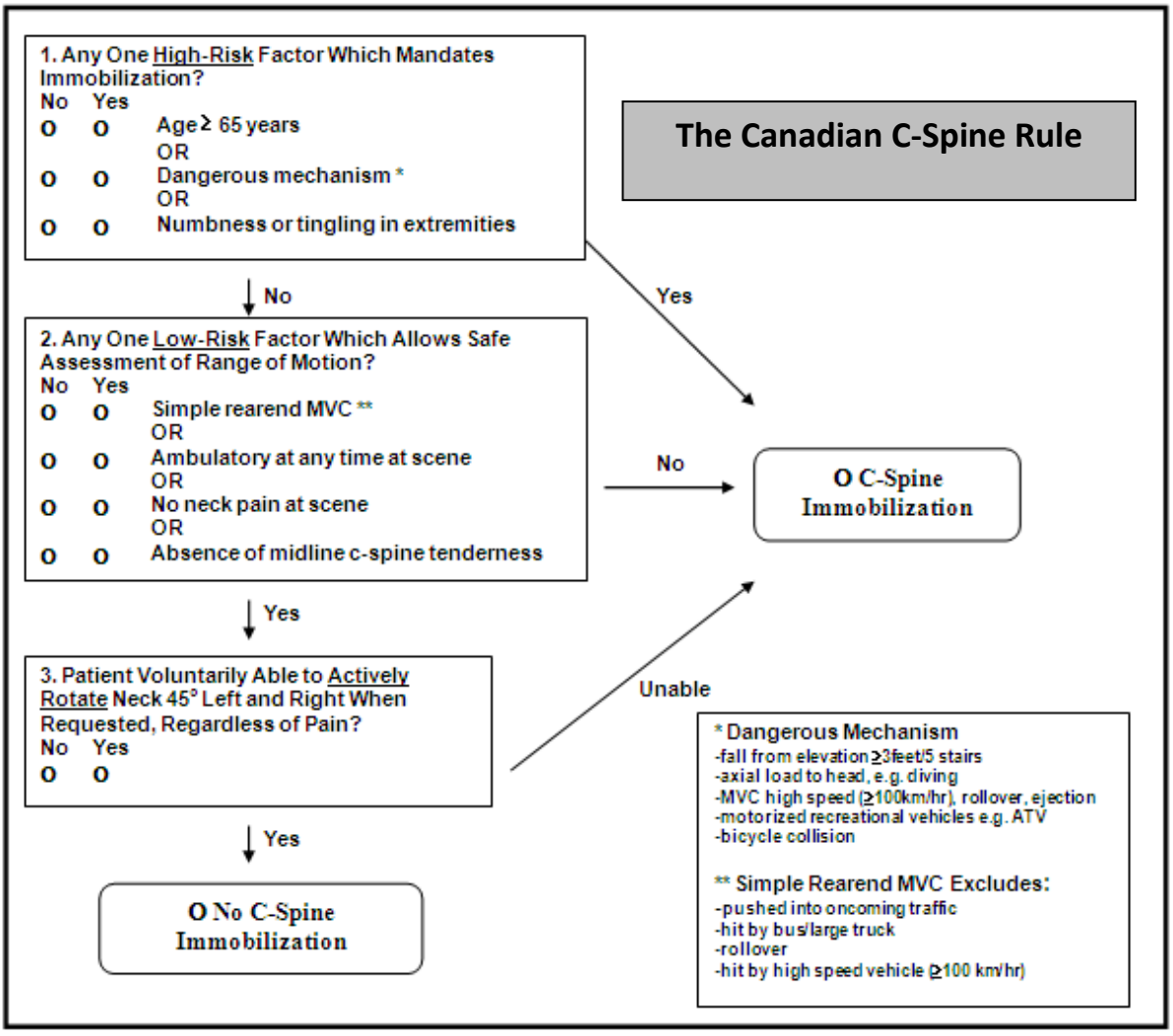
C-Spine Evaluation in Children: The NEXUS decision instrument for use in adults and children was validated in 2,160 children aged 8 to 17 (12) and identified all significant injuries. The CCR's performance was superior to that of the NEXUS decision instrument when prospectively compared in an adult population (13), but has yet to be implemented for use in children. A case-control study of children younger than 16 with c-spine injuries identified 8 risk factors for significant injuries, 7 of which are included in the CCR (14).

Based on information provided by our EMS stakeholders, we estimate there are ≥4,000 children aged 8 to 16 transported with immobilization each year in Ontario. In a survey of physicians, 85% stated they would use the CCR if it were properly evaluated for use in the pediatric population (15).

Rationale for This Study: Minor trauma is very common and these patients are usually transported to the ED by EMS, but rarely do they have a fracture or spinal cord damage. Current immobilization and transport practice guidelines are not evidence-based, and there is a growing body of evidence testifying to the deleterious effects and consequences of this practice on patients, EMS systems, EDs, and the

health care system. We have successfully derived, validated, and implemented the CCR for use by physicians, nurses, and, more recently, by paramedics in a pilot project. Patient groups, EMS stakeholders, ethics board members, and the Medical Advisory Committee for the Ontario Ministry of Health and Long-Term Care Emergency Health Services Branch (MOHLTC-EHS) are all supportive of this multicentre implementation evaluation study. We now need a large pragmatic study to evaluate the feasibility, benefits, and safety of implementing the CCR in geographically and socially diverse prehospital communities. We are encouraged that most EMS services would only participate in the study if we adopted a design that would guarantee, at some point, an opportunity for them to be assigned to the intervention arm and expand the scope of their paramedics' practice.

Figure 1. The Canadian C-Spine Rule Adapted for Use by Paramedics



2.2 Objectives

The overall goals and impacts of this study are to improve patient care and health system efficiency and outcomes by allowing paramedics to assess eligible low-risk trauma patients with the CCR and selectively transport them *without* immobilization to the ED.

We conservatively estimate that, in Ontario, more than 60% of all eligible trauma patients (300,000 annually) could be transported safely and comfortably, without c-spine immobilization devices. This will significantly reduce patient pain and discomfort, EMS intervention times, and ED length of stay, therefore improving access to EMS and ED care. This could be achieved rapidly and with lower healthcare costs compared to current practices (possible cost saving of $36 per immobilization, or $10,656,000 per year).

In addition, this project will facilitate a new paradigm in prehospital research by integrating paramedics and patients actively into the research and knowledge translation process. It will offer the added benefits of consolidating a network of EMS research partners and of facilitating future collaborative projects. It will also make innovative use of data provided by the Institute for Clinical Evaluative Sciences (ICES) to streamline and decrease the cost of conducting prehospital research, and, with the help of our new OSSU partners, foster collaborative efforts to measure and possibly correct health inequities in prehospital care. Lastly, this project could lead to the use of the CCR by paramedics from across Ontario and Canada and to immediate health care benefits/savings on a national scale.

PICOT Question: *Does allowing paramedics to assess selective low-risk trauma patients with the Canadian C-Spine Rule (CCR) and transporting them without immobilization result in significant and immediate health service benefits for patients, Emergency Medical Services, and Emergency Departments, in a safe, cost-effective manner?*

2.3 Trial Design

The multicentre implementation of the CCR by paramedics is designed as a stepped wedge cluster randomized trial with three steps, involving a total of 13 Ontario EMS Services. Our 36-month study will consist of a 12-month set-up and training period (Year 1), followed by the stepped wedge trial (Year 2), and a 12-month period for study completion, analyses, and knowledge translation and exchange (see Figure 2). EMS services in each step will cross from the control condition (usual care) to the intervention condition (CCR implementation) at intervals of 3 months until all communities have crossed to the intervention. Data will be collected on all eligible patients in each EMS service for a total duration of 12 months.

Figure 2: Diagram of the Study and Stepped Wedge Design

Year 1		**Months 1-9**			**Months 10-12**
		Study set-up ePlatform programming for EMS data collection Preparation of study material and site visits			Paramedic training
Year 2	**Step**	**Months 1-3**	**Months 4-6**	**Months 7-9**	**Months 10-12**
	1 (4 EMS services)	Usual Care	CCR	CCR	CCR
	2 (4 EMS services)	Usual Care	Usual Care	CCR	CCR
	3 (4 EMS services)	Usual Care	Usual Care	Usual Care	CCR
Year 3		**Months 1-6**		**Months 7-9**	**Months 10-12**
		Study completion Data linkage with ICES		Data cleaning Data analyses	Reports and manuscripts writing; KTE

Section 3. Methods: Participants, Interventions and Outcomes

3.1 Study Setting

The study will take place in the province of Ontario. Up to 12 new Ontario Emergency Medical Services will participate. Ottawa will also participate, but only provide data for the pediatric cohort, since the CCR has already been implemented within their practice. The 12 new EMS services vary in terms of size, population served and geographical location. A list of the participating EMS Services is located in Appendix 1. C-Spine Study Team Membership, Roles and Affiliations). Each EMS Service in Ontario is affiliated with a Base Hospital. There are eight Regional Base Hospitals in Ontario which provide medical direction, leadership, and advice in the provision of prehospital emergency care. Although the Base Hospital Programs will not be participating directly in the study as separate sites, they will be assisting with start-up, implementation and follow-up. A list of the seven involved Base Hospital Programs is included in Appendix 1. C-Spine Study Team Membership, Roles and Affiliations).

3.2 Eligibility Criteria

All consecutive, alert (able to follow commands), stable patients (normal vital signs) evaluated by the paramedics employed by a participating EMS Service for potential cervical spine injury after sustaining acute blunt trauma (within 48 hours). These are patients for whom standard Ontario EMS trauma protocols usually require immobilization. As in prior CCR studies, patients will be excluded if they do not require immobilization as per the standard Ontario EMS trauma protocol, have a Glasgow Coma Scale score less than 15 or are intubated, or have unstable vital signs (systolic blood pressure < 90 mmHG; respiratory rate <10 or >24 breaths/minute). Patients will also be excluded if: their injury occurred more than 48 hours previously; they have penetrating trauma from stabbing or gunshot wound to the neck, acute paralysis, or known vertebral disease (specifically ankylosing spondylitis, rheumatoid arthritis, spinal stenosis or previous cervical spine surgery); they were referred from another hospital and transported between facilities; or they are younger than 8 years.

3.3 Interventions

Paramedics will be trained in the use of the CCR prior to the start of the trial. We have conducted an Ottawa EMS CCR implementation pilot study and have designed our training program to address barriers identified in the pilot. The training entails one hour of education: 30 minutes of self-review of a teaching video addressing the background and scientific development of the CCR, and a 30-minute in-class teaching video reviewing the specific steps involved in using the CCR, complete with a demonstration and question and answer period with a certified trainer. Paramedics will be "certified" to clear the cervical spine by medical directive if they have: a) successfully completed the initial training sessions, and b) successfully completed (score of ≥80%) a written quiz. Paramedics failing the written quiz would be required to attend a remedial session and review all wrong answers with their certified trainer. Of note, Ottawa paramedics all successfully completed their training.

The stepped wedge trial will begin after paramedic training has been completed (see Figure 2). During the Usual Care phase, paramedics will complete the CCR data collection form for all eligible patients, but will continue to immobilize them all before transport to the receiving hospital. Once a community has crossed to the intervention CCR phase, paramedics will be permitted by medical directive to implement the CCR. Paramedics will then transport selected patients without immobilization according to the CCR. Although following the medical directive will be mandatory for paramedics, they will be encouraged and allowed to immobilize patients if they are uncomfortable with the CCR's recommendation to not immobilize them.

During the study set-up time period (Figure 2), each participating service will designate a local paramedic study champion. These individuals will be in close contact with staff at the Study Coordinating Centre and will receive further information about the study, the methodology and the implementation of the CCR. These individuals will be heavily involved in delivering the study training material at their particular location and will serve as a first point of contact throughout the implementation. Paramedics with questions about specific aspects of the CCR, or the application of the CCR for unusual scenarios will be able to communicate directly with a peer in an effort to promote adherence to the protocol.

Paramedics will be encouraged to ask questions during the training sessions, speak directly with their study champion, add comments to study forms, or communicate with study staff via the study website or through social media. These questions and concerns will be compiled and distributed back to study champions to disseminate to local staff. Staff at the study coordinating centre will regularly provide updates and reminders to study champions.

3.4 Outcomes

The outcomes of interest are divided into three categories: measures of patient and health system benefit, measures of patient benefit and measures of health system benefit.

3.4.1 Measures of Patient and Health System Benefit

a) proportion of patients transported with immobilization (primary outcome of interest)

3.4.2 Measures of Patient Benefit

a) Proportion of patients feeling comfortable (score ≤4 on a 10-point Likert scale) (co-primary outcome of interest),

b) Proportion of patients with a pain score ≤4 on a 10-point Likert scale upon arrival at the Emergency Department (ED),

c) Time from EMS arrival to ED discharge or admission to hospital,

d) Patient radiation exposure (in millisieverts) from diagnostic imaging of the spine,

e) Number of skin pressure injuries, and

f) Number of missed clinically important c-spine injuries. A clinically important c-spine injury includes any injury other than the following defined unimportant injuries which require neither specialized treatment nor follow-up: isolated avulsion fracture of osteophyte, isolated fracture of transverse process not involving the body or facet joint, isolated fracture of the spinous process not involving the lamina, isolated simple compression fracture <25% of body height.

3.4.3 Measures of Health System Benefit

a) Time spent in the field by paramedics before arrival to hospital,

b) Time spent in-hospital by paramedics before transfer of care to the ED team,

c) ED length of stay until discharge or admission to hospital,

d) Number of subsequent ED visits or admission to hospital within 30 days of ED discharge,

e) Number of subsequent clinic/family physician visits within 30 days of ED discharge,

f) Frequency of c-spine diagnostic imaging performed within 30 days of ED discharge, and

g) Incremental cost per one immobilization avoided (including cost of training, equipment, paramedic time, ED utilization, diagnostic imaging, and follow-up visits).

3.5 Participant Timeline

Patients with the potential for a c-spine injury will be enrolled in the study and evaluated with the CCR at the time of first contact with a paramedic. The paramedic documentation, as well as a completed study form will be reviewed by study staff to obtain the necessary information on the outcomes of interest. We will be partnering with the Institute for Clinical Evaluative Sciences (ICES) to obtain information on the initial ED visit, as well as any subsequent health care utilization within 30 days following the initial injury.

3.6 Sample Size

Our sample size for this study is determined mainly by pragmatic considerations: we need a large number of sites from across Ontario to evaluate safety and generalizability of implementation in this multicenter setting, while accounting for between-site differences such as size and setting. Power calculations were carried out for the stepped wedge trial. Using data from a previous study in these communities, we expect approximately 600 patients per EMS service per year (or 150 patients per 3 month time interval). A total of 12 EMS services (7,200 patients) evaluated across 4 time intervals in a stepped wedge design will provide at least 90% power to detect minimally important differences of 10% in our two co-primary outcomes using two-sided tests at the 2.5% level of significance. In particular, for our primary outcome we will have >99.9% power to detect a minimally important absolute reduction of 10% in the proportion of patients immobilized assuming a control arm proportion of 100%. For our co-primary outcome we will have 90% power to detect a minimally important increase of 10% in the proportion of patients feeling comfortable assuming a conservative control arm proportion of 50%. In these calculations, we have assumed a commonly used intracluster correlation coefficient (ICC) of 0.05, added 2 EMS services to account for variation in the number of patients across sites, and a further 2 EMS services to account for potential attrition.

3.7 Recruitment

Based on the volume of immobilized patients transported in each of the 12 new proposed participating centers, we expect there could be 8,129 eligible cases over the proposed 12-month evaluative period (required sample size is 7,200). We are confident that the required sample size can be obtained with the participation of the proposed centers, and we have accounted for unlikely attrition in our study design and sample size calculation.

We also plan to employ a number of strategies during the enrollment phase of the study in order to meet our recruitment goals. We have specifically approached Ontario EMS Services that have previously and successfully participated in prehospital research. These paramedics will be familiar with completing specific study paperwork. We will be approaching the vendors of the software used by EMS Services in order to develop a study form that is easy to access, complete and submit. We will employ a local study champion at each EMS Service who will be accessible to the front-line paramedics to answer questions, deliver updates and reminders and provide feedback regarding certain cases or applications of the CCR.

Lastly, we will develop a study website, and utilize social media to keep the participating EMS Services and their staff engaged in the study.

Section 4: Methods: Assignment of Interventions

The 12 new participating EMS Services will be randomized using the technique of covariate constrained allocation to protect against chance imbalances in the following prognostic factors: catchment area (km^2), number of immobilizations per month, average response time and staff make-up (advanced care paramedics and primary care paramedics) . Due to the relatively small number of allocation units, it is particularly important to use an allocation technique that minimizes the risk of chance imbalances. In the stepped-wedge design, randomization is with respect to the timing of implementation of the intervention. Effective randomization is essential to protect the internal validity of the trial, including the ability to obtain a valid estimate of any secular trend, as well as a valid estimate of the intervention effect. Covariate constrained allocation was selected as it was found to be superior to simple stratification and matching in a recent simulation study (16). In covariate constrained allocation, all possible allocations of sites will be considered (a total of 34,650 possible allocations), and those that are acceptable – in that they meet a set of balance constraints – will be identified. One of the allocations will then be randomly selected from among the set of acceptable allocations. To protect the validity of the randomization, the number of times that any given pair of sites receives the same allocation will be counted and constraints will be relaxaed if the design is found to be overly constrained. The allocation will be performed using a SAS macro developed for this purpose, by an independent statistician not associated with the trial. Allocations will be securely kept by the independent statistician and will be concealed from the study investigators and all participating sites, until one month before the allocated start time of a particular site.

Section 5: Methods: Data Collection, Management, and Analysis

5.1 Data Collection Methods

Once training of paramedic staff has been completed, paramedics will begin evaluating eligible patients with the CCR. Each time an eligible patient is assessed using the CCR, the paramedic treating that patient will complete and submit an electronic CCR (see Appendix 6. Paramedic Data Collection Form). The paramedic will also record patient-reported comfort level and pain level on this form. Staff at the study coordinating centre will receive the electronic EMS-completed CCR, as well as a copy of the Paramedic Care Record (ePCR). Study staff will review the paramedic documentation in order to assess compliance with the study protocol and application of the CCR. Information on patient age, gender, mechanism of injury, field time, offload time and immobilization status are contained in the ePCR and will be recorded from there (see Appendix 7. Study Data Collection Form).

We will link the information obtained from paramedic care records to provincial administrative databases housed at ICES. This linkage will allow us to obtain information related to the initial ED visit, c-spine diagnostic imaging, hospitalization, and subsequent ED/clinic/family physician visits within 30 days of injury.

5.2 Data Collection Methods – Retention

We will employ a number of methods to minimize the number of missed cases and amount of missing information on EMS-completed data forms. We will work closely with local Study Champions to ensure that there are regular study updates, visible study advertisements and electronic reminders. Paramedics

will be able to connect with their local study champion, or remotely with study staff via e-mail, website communication or social media. We will provide feedback to services on aspects of the study that are going well, as well as areas where improvement may be needed. We will provide regular progress reports to participating sites, as well as Base Hospitals. Ultimately though, this study has been designed as a pragmatic trial. We will do our utmost to keep the study at the forefront using the methods described above, but we will not have the time nor the resources to locate and follow-up on missed cases (i.e. those cases where the CCR was not used but should have been).

5.3 Data Management

Data will be entered centrally at the study coordinating centre by trained study staff. Staff will receive training on the study protocol, definition of data elements, application of the CCR and elements of the ePCR. A complete list of data points and definitions will be compiled and included in a study manual for reference. The data will be entered electronically. The data entry screens will resemble the paper study forms approved by the Steering Committee (see Appendices 6 and 7). Where possible, the study database will be designed to ensure that each given variable can only be entered in a certain format, thereby limiting the number of errors in data entry. A certain percentage of cases will be entered in duplicate to ensure accuracy. A small percentage of cases (10%) will also be pulled and compared to the source documents to independently verify the accuracy of the data. We will regularly run range and logic checks to previously-entered data to locate and fix any errors or discrepancies in the data set. We will work closely with staff at the participating Base Hospitals and our local EMS Study Champions to locate promptly identify and locate missing data. Queries about particular cases and situations will be flagged for review by the Research Coordinator. If the Research Coordinator is unable to determine the appropriate course of action, the flagged issue will be brought to the attention of the Principal Investigator who will review the issue and advise. Any resulting changes to data definitions will be noted and dated in the study manual.

The study database will be designed and located on servers housed at the Ottawa Hospital Research Institute. All electronic study documents will be saved on network folders with limited access. The network folders are backed up nightly by the Ottawa Hospital Research Network Information Technology team. Paper files will be stored in locked cabinets in locked offices.

5.4 Statistical Methods

Analyses will be conducted at the level of individual patient data using generalized linear mixed effects regression with a random effect to account for clustering by EMS service, and fixed effects for treatment and time interval to account for the stepped wedge design. The primary and co-primary outcomes will be analyzed using binomial distribution with identity link and the effect of intervention will be expressed as absolute differences with 97.5% confidence intervals. Secondary outcomes will be similarly analyzed using binomial distribution and identity or logit link for dichotomous variables, normal distribution and identity link after log-transformation or gamma distribution and log-link for continuous variables with a skewed distribution, or Poisson or negative binomial distribution with log link for count variables. The effect of the intervention on each secondary outcome will be described using absolute difference, Relative Risk or Odds Ratio with 95% confidence interval. Subgroup analyses (described below) will be conducted by including interactions with time interval and treatment in the regression model.

Our **health economist** will perform a cost-effectiveness analysis from the perspective of the Ministry of Health and Long-Term Care. Trial data will be used to populate the relative costs and outcomes of the use of the CCR by paramedics with usual care (100% immobilization). Resource use will be collected during the trial and obtained from ICES, while unit costs will be obtained from appropriate Canadian

sources, such as Schedule of Benefits for Physician Services. Total cost for each patient includes costs of the intervention and costs of health services, including the follow-up period of 30-days post ED discharge. Cost of intervention covers cost of training and operation. Costs of operating paramedic services include personnel cost (e.g. salaries and employee benefits), service cost (e.g. fuel, maintenance), medical supplies (e.g. an on-board liquid oxygen system, medications, and single-use patient care supplies). Costs of healthcare services will be obtained from ICES and will be estimated by multiplying the unit costs by the volume of healthcare used. We will use mixed-effects regression analyses to estimate the difference in expected healthcare costs and outcomes between the intervention and control groups. The incremental cost-effectiveness ratio will be estimated by dividing a difference in cost by a difference in the number of immobilizations. The 95% confidence interval will be calculated using a non-parametric bootstrapping method. Results from the bootstrapping exercise will also be used to depict a cost-effectiveness acceptability curve (CEAC), which links the probability of a treatment being cost-effective to a range of potential threshold values (λ) that the health system may be willing to pay for an additional unit of effect (17). A CEAC is a graphical representation of the probability that the CCR may be cost effective given alternate dollar values placed on an outcome. This will allow estimation of the probability that the CCR can be considered cost-effective given the available data. In addition, sensitivity analysis will be undertaken to examine the effect of conducting a complete case-only analysis and of varying the cost of the intervention.

We will also conduct a budget impact analysis to estimate the financial consequences of implementing the CCR by paramedics in Ontario. All analyses will be conducted using STATA version 13.0 and Microsoft Excel and Visual Basic for Applications.

Pre-Specified Sub-Group Analyses will be conducted to examine the differential effects (possible inequity) of the intervention on the following groups, defined by:

a) sex,
b) language barrier present vs. not (collected by paramedics on data collection form),
c) long transport times (longer vs. shorter than 15 min),
d) age (adult ≥16 vs. children <16),
e) socioeconomic status and education level (ICES data), and
f) type of backboard used (full board, open-back scoop, or trunk and neck KED devices).

Section 6. Methods: Monitoring

6.1 Data Monitoring

An external, independent Data Safety Monitoring Board (DSMB) will be established to provide a review of study safety while the study is ongoing. The composition and membership is being confirmed and we hope to include: a paramedic researcher, an emergency physician, a nurse familiar with the application of the CCR, a paramedic representative, a statistician and a pediatric emergency physician.

We have developed Terms of Reference for the DSMB, using the guidance provided by OHRI, entitled *Data and Safety Monitoring Guidelines for Clinical Trials,* as well as the Terms of Reference used for our previous single-centre evaluation of the CCR. The Terms of Reference will be reviewed by the Study Steering Committee, before being sent for review and approval to the OHRI's Research Administrative Committee. The most up-to-date version of the Terms of Reference has been appended to the study protocol (see Appendix 8. Data Safety Monitoring Board Terms of Reference).

All members of the DSMB will be required to complete and sign a Confidentiality Agreement, which will be kept on file by the study team. The DSMB members will familiarize themselves with the Study Protocol, as well as the Terms of Reference. The content and information available for review will depend on the availability of outcomes provided by ICES. At a minimum, the DSMB members will be provided with a report including information on accrual, application of the CCR by paramedics, protocol deviations, mechanism of injury and other data points collected from the paramedic documentation. If available for interim analyses, information provided by ICES on imaging and c-spine injuries will be included in the report for review. Due to the short intervention, this information may only be available in a final report.

The meeting frequency has not yet been finalized, but we anticipate the DSMB will meet very shortly after data collection begins, followed by another meeting approximately six months later. The DSMB may also meet to review the final report. Following each meeting, the DSMB will complete a report to be submitted to the Principal Investigator. The report will be presented to the Steering Committee and will also be sent to the REB, as well as OHRI's Research Administration Committee. We will respond to any concerns raised by the DSMB and provide additional information requested. Any corresponding changes to the protocol will be documented in Table 2.

6.2 Data Monitoring – Interim Analyses

The intervention period for this multi-centre study is fairly short - only 12 months long. Because of this, there are no interim analyses planned.

The number of c-spine injuries in eligible patients will be monitored as outcome information is available. We plan to obtain preliminary information on a small subset of study outcomes for safety assurance purposes before the first cluster of centres begin actively using the CCR. We will send the required information to ICES based on the first two months of enrollment following training (see Figure 2). Analysts at ICES will link our data at that time with the information available from the Ontario Health Insurance Plan (OHIP) database, as well as the Canadian Institute for Health – Discharge Abstract Database (CIHI-DAD). This will give us information on which cases had c-spine imaging performed, and of those, whether any c-spine injuries were identified. We will then review these cases to ensure that the CCR was applied appropriately and that no injuries were missed by either the paramedics, or the CCR itself.

The only situation that would trigger an immediate review to consider stopping the trial would be a situation where a spinal cord injury was sustained by an enrolled patient and believed to be a direct consequence of having transported a patient without immobilization resulting from the use of the CCR. In this case, we would notify the DSMB to review the available information and discuss their review and recommendations with the Steering Committee.

We would not consider a missed significant injury sufficient to warrant stopping the study as long as there was no consequence to the patient's safety and health i.e. not resulting in a spinal cord injury that was not already present before transport to the hospital. Any missed significant injury will be reported to both the DSMB and Research Ethics Board in a timely manner.

6.3 Harms

Adverse events will be classified according to the following definitions:

1. Protocol Deviations – this category will include cases where the CCR was applied to the wrong patient population, or situations where the rule was applied inaccurately in the opinion of study staff. These will be included in DSMB reports for review at scheduled meetings.
2. Adverse Events – This category will include transport of patients without immobilization later determined to have an important cervical spine injury. This may include cases where the rule was applied incorrectly by the treating paramedic, or cases missed by the CCR. These cases will be reported to the DSMB and the REB for review and consideration.
3. Serious Adverse Events – This will include patients transported without immobilization who are later determined to have suffered a spinal cord injury with neurological deficit. If such a case was to ever occur, the study would immediately be stopped pending DSMB and REB ruling on whether the study can resume or not. Note: such a serious adverse event has never been observed in more than 36,000 patients evaluated with the CCR in various research studies this far.

6.4 Auditing

We plan to conduct regular site visits with all participating sites. The initial visit will be primarily to go over training material with local study staff, go over study requirements, and ensure local study staff have all the necessary study documentation. The intervention is twelve months in length. We will conduct one subsequent visit to each site during the invention phase to ensure that study documentation is accurate and up to date, and that all study material is accurate and up to date and that local study procedures are being conducted as per the study protocol. If concerns are noted, we will work individually with each site to address the concern and rectify the situation.

Section 7. Ethics and Dissemination

7.1 Research Ethics Approval

The study protocol and all study-related documents (EMS CCR, study data collection) will be submitted to the Ottawa Health Sciences Network Research Ethics Board (OHSN-REB) for review and approval. The OHSN REB has recently become a board of record for Clinical Trials Ontario. As a result, and because this is a multi-centre study, the study protocol will be submitted to the OHSN-REB through Clinical Trials Ontario. All participating sites that have existing agreements in place with Clinical Trials Ontario will be included in the initial REB Submission. We will identify a local site investigator and help coordinate REB submission, review and approval for those sites that do not have agreements with Clinical Trials Ontario.

7.2 Protocol Amendments

Any changes to the protocol including to the study objectives, design, patient population, sample size, or procedures will be first reviewed and approved by the Steering Committee and noted in this document. The amended protocol will then be sent through Clinical Trials Ontario to the OHSN-REB. Once approved, all sites included on the Clinical Trials Ontario application will receive notification of the amendment. We will submit amendments to the additional REBs who are not part of Clinical Trials Ontario.

7.3 Consent

We will be seeking a waiver of informed consent from the OHSN-REB. This was the case in the previous multi-centre prehospital validation of the CCR, as well as the single-centre prehospital implementation study. The study protocol has been reviewed by the Medical Advisory Committee for the Ontario Base

Hospitals Group (MAC – OBHG). The MAC provides advice to the Emergency Health Services Branch (EHSB) of the Ontario Ministry of Health and Long-Term Care. Paramedics employed by EMS Services participating in the study will be allowed via a Medical Directive to use the CCR to evaluate eligible patients instead of the usual immobilization protocols. The Medical Directive will be drafted by the MAC-OBHG and authorized by the EHSB for the duration of the study.

7.4 Confidentiality

Paramedics will evaluate eligible patients using the CCR. They will complete an electronic form that will capture information on the elements of the CCR, as well as pain, patient comfort, and paramedic comfort with using the CCR. The electronic form will not include any information that can identify a patient. Upon receipt of the electronic form, study staff will assign a unique study number. We will also receive the corresponding paramedic documentation electronically that will allow us to capture the remainder of the pre-hospital data required. The paramedic documentation will also be transmitted electronically, stripped of patient identifiers.

In order to link the pre-hospital information with the data housed at ICES, we will need to maintain a list of eligible enrolled patients, including first name, last name, date of birth, sex, postal code, health card number (where available). This list will be generated and maintained by staff at each Base Hospital, or EMS Service if Base Hospital staff are unable to access this information. The information will be stored in a password-protected, encrypted spreadsheet. When this information is required by ICES for linkage purposes, it will be transmitted securely according to their protocols. The linked information that we receive back from ICES will be stripped of personal identifiers before we receive it. All paper study files will be stored in locked filing cabinets in a locked office. All electronic files will be stored on limited-access network folders which are backed up regularly. Any information shared with DSMB Members or other study committees will not include any identifiable information.

7.5 Declaration of Interests

All study members with affiliations to the Ottawa Hospital Research Institute are required to disclose information on competing interests at least once per year. We will require study members to report annually on any real or potential conflicts of interest. This information will be compiled and made available to the entire study team.

7.6 Access to Data

All personal health information will be kept confidential, unless release is required by law. Representatives of government regulators such as Health Canada, representatives of the Ottawa Health Sciences Network Research Ethics Board, as well as the Ottawa Hospital Research Institute, may review the records under the supervision of Dr. Vaillancourt's staff for audit purposes.

Any study information that is shared with participating sites will not have any identifying information. Each study subject will be assigned an independent study number. The link between patient name and independent study number will only be accessible by Dr. Vaillancourt and/or his staff and will be stored separately and securely from the study files.

7.7 Dissemination

There will be multiple opportunities to promote and disseminate various aspects of the study. These activities will be coordinated by the Publications Committee (see section

1.8.2 Publications Committee). We will also work closely with the funding body, OSSU, to capitalize on opportunities to disseminate information related to the study, including but not limited to methodology, results, patient engagement, future directions.

Suggestions for study papers, abstracts and presentations will be brought forward to the Publications Committee. A lead will be identified and will work with the Publications Committee to develop, edit and finalize the material. Authorship for all study-related papers will follow the International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (18).

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Section 9. Appendices

Appendix 1. C-Spine Study Team Membership, Roles and Affiliations

Principal Investigators		
Name		**Institution**
Dr. Christian Vaillancourt		Ottawa Hospital Research Institute
Dr. Ian Stiell		Ottawa Hospital Research Institute
Co-Investigators		
Name		**Institution**
Dr. Dean Fergusson		Ottawa Hospital Research Institute
Dr. Monica Taljaard		Ottawa Hospital Research Institute
Dr. Kednapa Thavorn		Ottawa Hospital Research Institute
Dr. Jamie Brehaut		Ottawa Hospital Research Institute
Dr. Ian Graham		Ottawa Hospital Research Institute
Dr. Lisa Calder		Ottawa Hospital Research Institute
Dr. Tim Ramsay		Ottawa Hospital Research Institute
Dr. Peter Tugwell		Ottawa Hospital Research Institute
Dr. Amy Plint		Children's Hospital of Eastern Ontario
Dr. Sheldon Cheskes		Sunnybrook Centre for Prehospital Medicine
Team Members		
Name	**Role**	**Institution**
Ms. Manya Charette	Study Coordinator	Ottawa Hospital Research Institute
Ms. Lucy Turner	Methods Centre Coordinator	Ottawa Hospital Research Institute
Mr. Brent McLeod	Paramedic Representative	Hamilton Paramedic Service
Mr. Peter Kelly	Paramedic Representative	Ottawa Paramedic Service
Mrs. Elizabeth Hall	Patient Representative	
Dr. Refik Saskin	Collaborator	Institute for Clinical Evaluative Sciences
Dr. Martin Osmond	Collaborator	Ontario Child Health SUPPORT Unit
Mrs. Lisa Nesbitt	Pediatric Coordinator	Children's Hospital of Eastern Ontario
Dr. Colin Macarthur	Collaborator	Ontario Child Health SUPPORT Unit
Dr. Sharon Straus	Collaborator	Provincial KTE Network
Dr. Paula Rochon	Collaborator	Women's Xchange
Dr. Denis Prud'homme	Collaborator	Group de travail sur les communautés francophones de l'Ontario
Dr. Simone Dahrouge	Collaborator	Bruyère Research Institute
Mrs. Susan Marlin	Collaborator	Clinical Trials Ontario
Ms. Penny Price	Ontario Base Hospitals Group Representative	Regional Paramedic Program for Eastern Ontario
Dr. Justin Maloney	Ontario Base Hospitals Group Representative	Regional Paramedic Program for Eastern Ontario
Mrs. Julie Sinclair	Ontario Base Hospitals Group Representative	Regional Paramedic Program for Eastern Ontario
Participating Base Hospital Programs		
Regional Paramedic Program for Eastern Ontario		
Central East Prehospital Care Program		

Sunnybrook Centre for Prehospital Medicine
Southwestern Ontario Regional Base Hospital Program
Centre for Paramedic Education and Research
Centre for Prehospital Care, Health Sciences North
Northwest Region Base Hospital Program
Participating Emergency Medical Services
Ottawa Paramedic Service
Frontenac Paramedic Service
Peterborough County/City Paramedics
Durham Region EMS
York Region EMS
County of Simcoe Paramedic Services
Hastings-Quinte Paramedic Service
Hamilton Paramedic Service
Niagara EMS
Middlesex-London EMS
Essex-Windsor EMS
Greater Sudbuy EMS
Superior North EMS

Appendix 2. Steering Committee Terms of Reference

Multicentre Paramedic C-Spine Study Steering Committee

Terms of Reference

Current Members (pending approval/confirmation):

- Christian Vaillancourt (chair) (Ottawa Hospital Research Institute)
- Amy Plint (Children's Hospital of Eastern Ontario)
- Elizabeth Hall (patient representative)
- Brent McLeod (paramedic representative, Hamilton Paramedic Service)
- Monica Taljaard (Ottawa Hospital Research Institute, Ottawa Methods Centre)
- Kednapa Thavorn (Ottawa Hospital Research Institute, Ottawa Methods Centre)
- Additional representative from OMC?
- Refik Saskin (Institute for Clinical Evaluative Sciences)
- Lisa Nesbitt (Ontario Child Health SUPPORT Unit)
- Paula Rochon/Robin Mason (Women's College Hospital Women's Xchange)
- Denis Prud'homme (l'Hôpital Montfort, OSSU Ontario Francophone Communities Working Group)
- Eddy Nason (Ontario SPOR SUPPORT Unit Coordinating Centre)
- Manya Charette (ex-officio) (Ottawa Hospital Research Institute)

Responsibilities

- Approve main study protocol and any subsequent amendments
- Monitor and supervise the trial towards interim and overall objectives
- Review relevant information from other sources, including information from related studies that could impact the main study protocol
- Review recommendations and requests from participating Research Ethics Boards, as well as the Data Safety Monitoring Board
- Review activity of study subcommittees, including, but not limited to the Publications Committee, the Paramedic Committee and the Patient Engagement Committee

Accountability:

- The Steering Committee (SC) will provide a report of its activities and disseminate its meeting minutes to the Ontario SPOR SUPPORT Unit as appropriate

Governance

- The quorum will be established as 50% of the membership. Most decisions should be reached by way of consensus. Should an item be deemed urgent, in cases where quorum is not met and where a vote is perceived to be necessary, an email vote with a time-sensitive deadline will be sent to all members of the SC. A 50% response rate within the allotted time-frame will be considered acceptable by the SC.
- 2/3 majority vote will be required for decision making in cases where a vote is required.

Membership

- Membership on the SC will be determined by the Chair

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- The membership should include a representative from all collaborating OSSU centres, as well as a patient representative, a paramedic representative and members of the study Operations Committee as deemed appropriate by the chair
- Membership terms will be the length of the study (maximum three years)

Subcommittees

- Time-limited subcommittees of the SC will be struck for specific projects/tasks as necessary

Meetings

- Virtual (web or teleconference) meetings will be held every other month
- One face-to-face meeting of the SC will be organized each year of the project
- Agenda items will be determined by the Chair with input from SC members and as required by larger project/OSSU business
- Minutes will be kept for all meetings and circulated to the membership within two weeks of each meeting. Once approved, they will be posted to a restricted-access location on the study website (a link will be included when available).
- Communications between SC members will be largely via email or telephone. All official email related to SC business will be copied to the Chair and Study Coordinator (Manya Charette)
- A webpage detailing the activities and responsibilities of the SC will be incorporated into the main study website, where guidance material, meeting minutes and other resources will also be found.

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Appendix 3. Publications Committee Terms of Reference

To be appended once developed and finalized

Appendix 4. Paramedic Committee Terms of Reference

Multicentre C-Spine Study Paramedic Committee (C-Spine PC)

Terms of Reference

Current Members (pending approval/confirmation):

- Brent McLeod (chair) (Hamilton Paramedic Service)
- Christian Vaillancourt (Ottawa Hospital Research Institute)
- Don Oettinger (Peterborough County-City Paramedics)
- Kristy Smaggus (Centre for Paramedic Education and Research)
- Bryan Laviolette (York Region EMS)
- Shannon Leduc (Ottawa Paramedic Service)
- Dave Mokedanz (Durham Region EMS)
- Kristen Gilmartin (County of Simcoe Paramedic Services)
- Andrew Dillon (Superior North Emergency Medical Services)
- Gale Chevalier (Frontenac Paramedic Services)
- Adam Dukelow (Southwest Ontario Regional Base Hospital Program)
- Susan Kriening (Southwest Ontario Regional Base Hospital Program)
- Julie Sinclair (Regional Paramedic Program for Eastern Ontario)
- Jay Loosely (Middlesex-London EMS)
- Jim Harris (Central East Prehospital Care Program)
- Michael Franklin (Niagara Emergency Medical Services)
- Cathie Hedges (Essex Windsor EMS)
- Melissa Roney (Greater Sudbury Emergency Services)
- Sylvie Michaud (Health Sciences North Centre for Prehospital Care)
- Marcia Broughton (Northwest Region Base Hospital Program)
- To be determined (Sunnybrook Centre for Prehospital Medicine)
- Paul Bradford (Southwest Ontario Regional Base Hospital Program – Windsor)
- Manya Charette (ex-officio) (Ottawa Hospital Research Institute)

Responsibilities

- To help develop, review and approve study training materials, data collection forms and study advertisements,
- To provide feedback to the Steering Committee on the EMS logistics of proposed study activities and processes,
- Review and provide feedback on the main study protocol and any subsequent amendments,
- Develop a strategy to communicate the study requirements, activities and study progress to each participating EMS service.

Accountability

- The C-Spine PC will provide a report of its activities and disseminate its meeting minutes to the Study Steering Committee as appropriate.

Governance

- The expectation is that most decisions will be made by consensus. When a consensus cannot be reached on an item and a vote is deemed to be necessary, the quorum will be established as 50% of the membership. Should an item be deemed urgent, an email vote with a time-sensitive

Version 3 – April 2016

deadline will be sent to all members of the C-Spine PC. A 50% response rate within the allotted time-frame will be considered acceptable by the C-Spine PC.
- 2/3 majority vote will be required for decision making
- The committee will advise and make recommendations to the Steering Committee.

Membership
- Membership on the C-Spine PC will be determined by the Chair
- The membership should include a representative from each participating EMS Service, as well as a representative from each corresponding Base Hospital Program and members of the study Operations Committee as deemed appropriate by the chair
- Membership terms will be the length of the study (maximum three years)

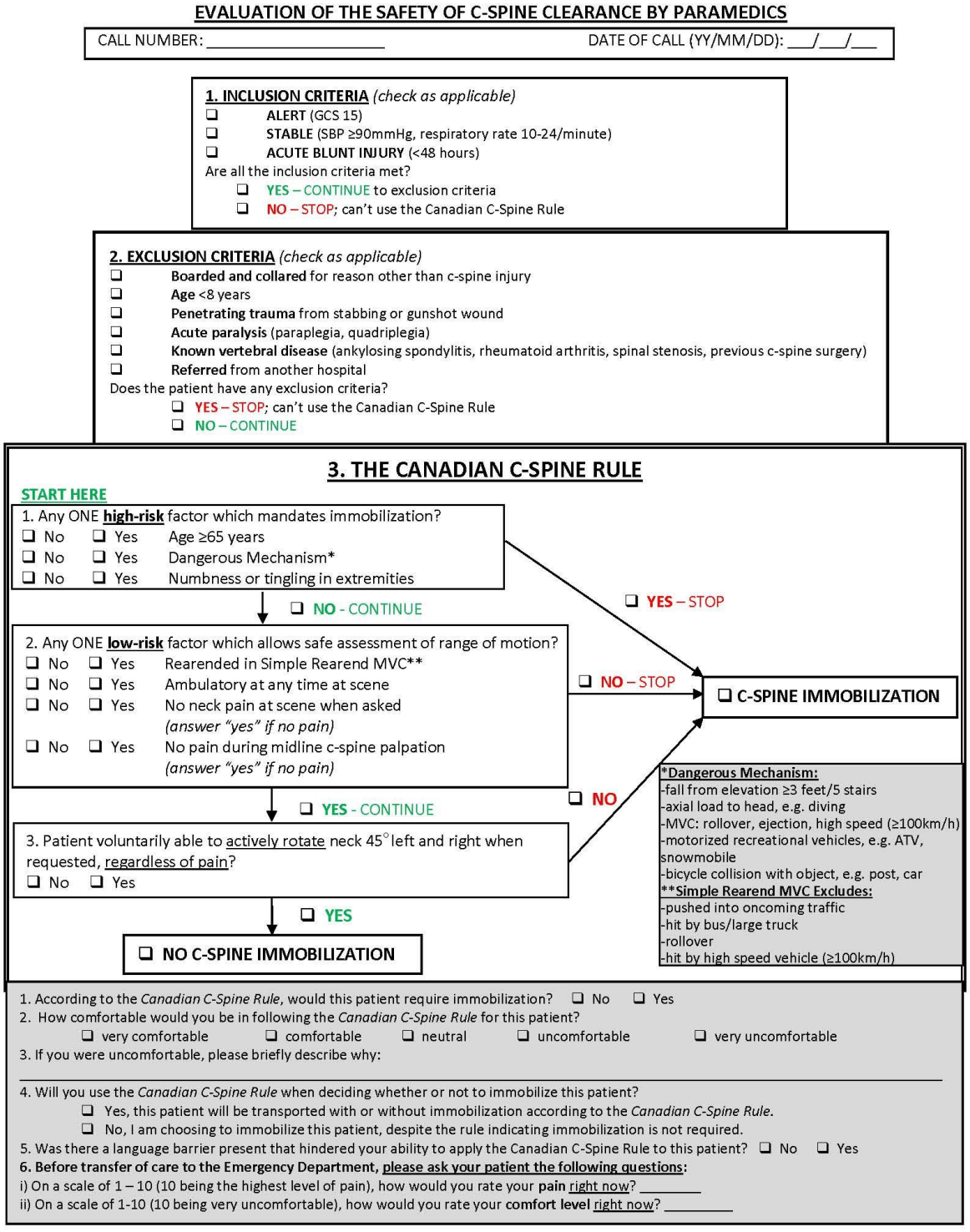
Subcommittees
- Time-limited subcommittees of the C-Spine PC will be struck for specific projects/tasks as necessary

Meetings
- Virtual (web or teleconference) meetings will be held every other month at a minimum, or more frequently when required due to upcoming deadlines
- Agenda items will be determined by the Chair with input from C-Spine PC members and as required by larger project/OSSU business.
- Minutes will be kept for all meetings and circulated to the membership within two weeks of each meeting. Once approved, they will be posted to a restricted-access location on the study website.
- Communications between C-Spine PC members will be largely via email or telephone. All official email related to C-Spine PC business will be copied to the Chair and Study Coordinator (Manya Charette)
- A webpage detailing the activities and responsibilities of the C-Spine PC will be incorporated into the main study website, where guidance material, meeting minutes and other resources will also be found.

Appendix 5. Patient Committee Terms of Reference

To be appended once developed and finalized.

Appendix 6. Paramedic Data Collection Form



EVALUATION OF THE SAFETY OF C-SPINE CLEARANCE BY PARAMEDICS

CALL NUMBER: _____ DATE OF CALL (YY/MM/DD): ___/___/___

1. INCLUSION CRITERIA *(check as applicable)*

- ❑ **ALERT** (GCS 15)
- ❑ **STABLE** (SBP ≥90mmHg, respiratory rate 10-24/minute)
- ❑ **ACUTE BLUNT INJURY** (<48 hours)

Are all the inclusion criteria met?

- ❑ YES – CONTINUE to exclusion criteria
- ❑ NO – STOP; can't use the Canadian C-Spine Rule

2. EXCLUSION CRITERIA *(check as applicable)*

- ❑ **Boarded and collared** for reason other than c-spine injury
- ❑ **Age** <8 years
- ❑ **Penetrating trauma** from stabbing or gunshot wound
- ❑ **Acute paralysis** (paraplegia, quadriplegia)
- ❑ **Known vertebral disease** (ankylosing spondylitis, rheumatoid arthritis, spinal stenosis, previous c-spine surgery)
- ❑ **Referred** from another hospital

Does the patient have any exclusion criteria?

- ❑ YES – STOP; can't use the Canadian C-Spine Rule
- ❑ NO – CONTINUE

3. THE CANADIAN C-SPINE RULE

START HERE

1. Any ONE **high-risk** factor which mandates immobilization?
   - ❑ No ❑ Yes Age ≥65 years
   - ❑ No ❑ Yes Dangerous Mechanism*
   - ❑ No ❑ Yes Numbness or tingling in extremities

❑ YES – STOP

❑ NO - CONTINUE

2. Any ONE **low-risk** factor which allows safe assessment of range of motion?
   - ❑ No ❑ Yes Rearended in Simple Rearend MVC**
   - ❑ No ❑ Yes Ambulatory at any time at scene
   - ❑ No ❑ Yes No neck pain at scene when asked *(answer "yes" if no pain)*
   - ❑ No ❑ Yes No pain during midline c-spine palpation *(answer "yes" if no pain)*

❑ NO – STOP → ❑ C-SPINE IMMOBILIZATION

❑ YES - CONTINUE

3. Patient voluntarily able to actively rotate neck 45° left and right when requested, regardless of pain?
   - ❑ No ❑ Yes

❑ NO → ❑ C-SPINE IMMOBILIZATION

❑ YES

❑ NO C-SPINE IMMOBILIZATION

*Dangerous Mechanism:
-fall from elevation ≥3 feet/5 stairs
-axial load to head, e.g. diving
-MVC: rollover, ejection, high speed (≥100km/h)
-motorized recreational vehicles, e.g. ATV, snowmobile
-bicycle collision with object, e.g. post, car
**Simple Rearend MVC Excludes:
-pushed into oncoming traffic
-hit by bus/large truck
-rollover
-hit by high speed vehicle (≥100km/h)

1. According to the *Canadian C-Spine Rule*, would this patient require immobilization? ❑ No ❑ Yes
2. How comfortable would you be in following the *Canadian C-Spine Rule* for this patient?
   ❑ very comfortable ❑ comfortable ❑ neutral ❑ uncomfortable ❑ very uncomfortable
3. If you were uncomfortable, please briefly describe why:

_____

4. Will you use the *Canadian C-Spine Rule* when deciding whether or not to immobilize this patient?
   - ❑ Yes, this patient will be transported with or without immobilization according to the *Canadian C-Spine Rule*.
   - ❑ No, I am choosing to immobilize this patient, despite the rule indicating immobilization is not required.
5. Was there a language barrier present that hindered your ability to apply the Canadian C-Spine Rule to this patient? ❑ No ❑ Yes
6. **Before transfer of care to the Emergency Department, please ask your patient the following questions:**

i) On a scale of 1 – 10 (10 being the highest level of pain), how would you rate your **pain** right now? _____

ii) On a scale of 1-10 (10 being very uncomfortable), how would you rate your **comfort level** right now? _____

Version 3,May 2016

Appendix 7. Study Data Collection Form

Multicentre Evaluation of the Canadian C-Spine Rule by Paramedics

Data Collection Form

(To be completed by designated staff at the Study Coordinating Centre)

SUBJECT #: _____

Paramedic Run Number: _____ **Event date (yyyy/mm/dd):** ____/__/__

Service: _____ **Study Phase (Usual/CCR):** _____

Age (years): _____ ☐ **Unknown** **Gender:** ☐ **Male** ☐ **Female** ☐ **Unknown**

Transported: ☐ **No** ☐ **Yes** ☐ **Unknown**

- **According to the "Canadian C-Spine Rule" would this patient require c-spine immobilization?**
  ☐ **No** ☐ **Yes** ☐ **Indeterminate**
- **Was this patient transported with c-spine immobilization?**
  ☐ **No** ☐ **Yes** ☐ **Unable to determine**
- **If yes, please check all immobilization devices applied to patient:**
  ☐ **C-Collar** ☐ **Full Backboard** ☐ **Scoop** ☐ **KED** ☐ **Other (Specify):** _____

Mechanism of Injury (check all that apply):

☐ Motor vehicle collision (if yes, see below)
☐ Motorcycle crash
☐ Other motorized vehicles
☐ Pedestrian struck & thrown
☐ Pedestrian struck
☐ Fall from standing
☐ Fall from sitting
☐ Fall from elevation >10ft/15 stairs
☐ Fall from elevation ≥ 3-10ft/5-15 stairs
☐ Fall from elevation < 3ft/5 stairs
☐ Diving
☐ Fall onto head (axial load)
☐ Contact sports (axial load)
☐ Heavy object onto head (axial load)
☐ Other Sports
☐ Bicycle struck
☐ Bicycle collision
☐ Other bicycle
☐ Assault blunt object
☐ Assault fist or feet
☐ Head struck by other object
☐ Hit head on an object
☐ Other (specify): _____

If **"MVC"**, speed?
☐ Stopped ☐ City speed (<60 km/hr) ☐ Highway speed (60-100 km/hr) ☐ High speed (>100 km/hr)
☐ Unknown speed

Ejection from vehicle?	☐ No	☐Yes	☐ Unknown
Rollover?	☐ No	☐Yes	☐ Unknown
Seatbelt use?	☐ No	☐Yes	☐ Unknown
"Head-on" collision?	☐ No	☐Yes	☐ Unknown
Simple rearend?	☐ No	☐Yes	☐ Unknown
If **"bicycle"**, helmet use?	☐ No	☐Yes	☐ Unknown

Times

Arrive to Patient (HH:MM): _____

Depart Scene (HH:MM): _____

Arrive Destination (HH:MM): _____

Transfer Care (HH:MM): _____

Field Time (DS-AP) (MM): _____

Transport Time (AD-DS) (MM): _____

Hospital Time (TC-AD) (MM): _____

Pain and Comfort

Pain Medication Administered by Paramedics: ☐ **No** ☐ **Yes** ☐ **Unable to Determine**

If yes:

Type	Dose	Route	Frequency

Completed by: _____

Date Initiated (yyyy/mm/dd): ____/__/__

Date completed (yyyy/mm/dd): ____/__/__

Data collection form, Version 1, February 2016

Appendix 8. Data Safety Monitoring Board Terms of Reference

A PRAGMATIC STRATEGY EMPOWERING PARAMEDICS TO ASSESS LOW-RISK TRAUMA PATIENTS WITH THE CANADIAN C-SPINE RULE AND SELECTIVELY TRANSPORT THEM WITHOUT IMMOBILIZATION

DATA SAFETY AND MONITORING BOARD (DSMB) TERMS OF REFERENCE

The following document has been prepared as a guide for members of the DSMB for the *Multicentre Paramedic C-Spine Study*. It has been developed, with some modifications, using the document "Data and safety monitoring guidelines for clinical trials" prepared by the Ottawa Hospital Research Institute and the Ottawa Hospital.

1.0 Responsibilities

The DSMB is responsible for assuring that study participants in *A Pragmatic Strategy Empowering Paramedics to Assess Low-Risk Trauma Patients with the Canadian C-Spine Rule and Selectively Transport them without Immobilization (Multicentre Paramedic C-Spine Study)* are not exposed to unnecessary or unreasonable risks, and that the study is being conducted according to the highest scientific and ethical standards. In order to carry out this responsibility, the DSMB will:

- Familiarize themselves with the DSMB's Terms of Reference, study protocol, data collection forms, and other relevant study materials
- Review semi-annually descriptive reports and interim analyses provided by the Principal Investigator and Research Team

And if the situation emerges:

- Provide recommendations for or comments regarding change(s) to the design or methodology of the study
- Provide feedback on ancillary studies proposed by the Study Team
- Alert investigators regarding emerging procedural or ethical issues
- Comment on the relevancy of new external published data from other studies that may impact on patient safety or efficacy of the study treatment

At the request of the Principal Investigator or the study Steering Committee, the DSMB may be called upon to:

- Provide recommendations to the Principal Investigator and the Steering Committee in order to facilitate the timely completion of the trial
- Advise the Principal Investigator of any and all factors (e.g. subject recruitment, protocol adherence) that could potentially threaten the inferences that may be drawn from the final results of the trial
- Provide recommendations for trial termination or adjustment of sample size or to comment on the results of a futility analysis

2.0 Autonomy

- The DSMB is a standing and independent committee of the *Multicentre Paramedic C-Spine Study* and shall remain independent in the conduct of its operation and the formulation of its recommendation.
- The DSMB will set its own internal rules of operation, including nominations for additional membership, requests for consultation and voting rules. The DSMB shall meet at least semi-annually, by conference call or in person, at the discretion of the

Committee Chair, in order to monitor the cumulative safety data and adverse events during the period where participants are being enrolled in the study.
- The DSMB will meet to review interim analysis data, and when important matters arise such as unexpected adverse events or the occurrence of new external data that could affect the continuation of the study as planned.
- The Chair of the DSMB will set meeting times and agendas.

3.0 Confidentiality

- The DSMB may hold Open Sessions with the Principal Investigator and Steering Committee to discuss generic safety data concerns, or to obtain further clarifications on the reports provided by the Research team.
- Any information presented at Closed DSMB Sessions will not be revealed to the Principal Investigator, Research Team, or Study Investigators except as explicitly authorized by the DSMB Chair.
- It is the duty of each member of the DSMB to protect the confidentiality of the trial and the results of monitoring.
- All participating members of the DSMB will sign a confidentiality agreement to be kept on file by the Principal Investigator with a copy sent to the Ottawa Health Science Network Research Ethics Board (OHSN REB).
- The members of the DSMB acknowledge that the data emerging from this trial is the collective property of the Principal and Study Investigators.
- No member of the DSMB shall have the right to present the data or information derived from this study at a symposia, national or regional professional meeting, or to publish in journals or in any other publication without the explicit permission of the Principal Investigator.

4.0 Reporting

- The DSMB will provide written reports to the Principal Investigator and Research Team of the *Multicentre Paramedic C-Spine Study.* A suggested reporting format is included in Appendix A.
- The Principal Investigator will circulate the DSMB's recommendations to the Steering Committee, OHSN REB, the Chair of the OHRI/TOH Clinical Research Monitoring Committee, and Financial Sponsors.
- In the event of a DSMB recommendation to continue the study following an interim analysis, no other information shall be provided to the Principal Investigator.
- In the event of a DSMB recommendation to terminate the study, the DSMB will provide a full report to the Principal Investigator including rationale for study termination.
- Copies of both the Open and Closed Session Minutes of the DSMB will be provided to the Principal Investigator and Research Team at the completion of the study.
- In the event of an unresolved conflict between the Principal Investigator and the DSMB, the DSMB may contact the OHSN REB directly to elaborate on concerns and make recommendations.

5.0 DSMB Recommendations

- Should the DSMB wish to provide a recommendation to the Principal Investigator for protocol modification(s) or early termination of the study for slow accrual, patient

safety, or for ethical or scientific integrity issues, the Chair of the DSMB must do so in writing and in a timely manner.

- Upon receipt of a DSMB recommendation to modify or terminate the study, the Principal Investigator will call an urgent meeting of the Steering Committee to review the recommendations.
- If in agreement with the recommendations of the DSMB, it is the responsibility of the Principal Investigator and Steering Committee to determine the appropriate course of action.
- It is also the responsibility of the Principal Investigator and the Steering Committee to inform the OHSN REB of any decision to modify or terminate the trial.

6.0 Conflict

- In the event that the Principal Investigator and/or Study Investigators disagree with the DSMB recommendation(s) to modify or to terminate the trial, a third party arbitrator may be called upon. The Chair of the OHRI/TOH Clinical Research Monitoring Committee must be immediately notified if this situation arises.
- A third party arbitrator, selected by both parties, will be an individual possessing the requisite knowledge and experience to make a final decision in the matter.
- The selection of the third party arbitrator will be made by mutual consent of both the Principal Investigator and the Chair of the DSMB.
- It is the responsibility of the Principal Investigator to notify the OHSN REB of any recommendation to stop the study.

7.0 Conflict of Interest

- Recognizing that an institutional monitoring system must at times utilize its own faculty and research staff members to enable the system to function, there is a potential for a conflict of interest to exist. No one who has an indirect or direct relationship to the study being monitored should serve on the DSMB. Individuals invited to serve on a DSMB are responsible for disclosing any potential, real or perceived, conflicts of interest. Individuals who are invited to serve on a DSMB are responsible for disclosing, 1) those significant financial interests that would reasonably appear to be affected by or to affect their research or education activities, and 2) any significant financial interests in entities whose financial interests would reasonably appear to be affected by or to affect the person's performance of his or her OHRI/TOH/University duties, including participation in a DSMB. DSMB members will in many cases know the Study Investigators and must consider this relationship to ensure they perform their duties with the highest integrity in this context.
- Decisions concerning whether an individual with a conflict of interest or the appearance of conflicts of interest may participate on the DSMB will be made at the discretion of the DSMB Chair.

8.0 Responsibilities of the Principal Investigator

- It is the responsibility of the Principal Investigator and his designates to provide regular, descriptive reports to the DSMB (e.g. on a semi-annual basis).
- Study data provided to the DSMB will include, but may not be limited to the following:
    - A summary of monthly enrollment and cumulative enrollment
    - A summary of the status of enrolled participants
    - A summary of baseline characteristics of enrolled patients

- A summary of outcomes where available
- A summary of adverse events where available. Please see Appendix B for a description of how adverse events will be defined and reported for this study.

- All necessary reports will be provided to the Chair of the DSMB at least seven days prior to the scheduled DSMB meeting.
- It is the responsibility of the Principal Investigator and his designates to provide complete statistical analyses for the scheduled interim reports.
- It is the responsibility of the Principal Investigator and Study Investigators to provide the DSMB with the results of any relevant, external published data for its review.

9.0 Quorum

- The DSMB will make decisions by consensus.
- Decisions require input and consultation from a minimum of 3 Committee Members.
- In the event of a split vote, the Chair of the DSMB may obtain opinions regarding recommendations outside scheduled meeting from members who were not in attendance, or the assistance of a third party may be requested.

10.0 Committee Membership *(to be confirmed)*

Chair:
Jan Jensen, Paramedic Research Leader,
Emergency Health Services, Nova Scotia
e-mail: Jan.Jensen@emci.ca

Suggested Membership (to be confirmed by the Committee Chair):

Alix Carter MD MPH FRCPC
Medical Director, Research
Medical Oversight Physician
Emergency Health Services Nova Scotia
Assistant Professor, Emergency Medicine, Dalhousie University
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Calgary, AB T3B 6A8
Phone : 403-955-7493
e-mail : asstang@ucalgary.ca

APPENDIX A – SUGGESTED FORMAT FOR DSMB REPORTS

Multicentre Paramedic C-Spine Study – DSMB Meeting Report

Date: _____

Date of Meeting: _____

Dates Covered by DSMB Report: _____

Protocol Number: **CTO 0769**

Principal Investigator: **Dr. Christian Vaillancourt**

Recommendations:

- ☐ **Continue the study without modification.**
- ☐ **Accrual:**
  - ☐ Recommend the study be closed because of slow accrual.
  - ☐ Continue to monitor study, but consider closure because of slow accrual
- ☐ **Recommend study is amended/changed:**
  - ☐ For patient safety reasons
  - ☐ To extend accrual because of an event rate slower than expected.
- ☐ **Other:**

  _____
  _____
  _____

Name - Chair Data Safety Monitoring Board

_____

Signature – Chair Data Safety Monitoring Board

_____

APPENDIX B – ADVERSE EVENTS CLASSIFICATION AND REPORTING

Adverse events will be classified according to the following definitions and reported to the DSMB:

1. Protocol Deviations – this category will include instances where the Canadian C-Spine Rule was applied to the wrong patient population, or the rule was applied inaccurately in the opinion of study staff. These will be included in DSMB reports for review at scheduled meetings.
2. Adverse Events – This category will include transport of patients without immobilization later determined to have an important cervical spine injury. This may include cases where the rule was applied incorrectly by the treating paramedic, or cases missed by the Canadian C-Spine Rule. These events will be reported to the OHSN REB and the DSMB for review and consideration.
3. Severe Adverse Events – This will include patients transported without immobilization who are later determined to have suffered a spinal cord injury with neurological deficit. If such a case was ever to occur, the study would immediately be stopped pending DSMB and REB ruling on whether the study can resume or not.