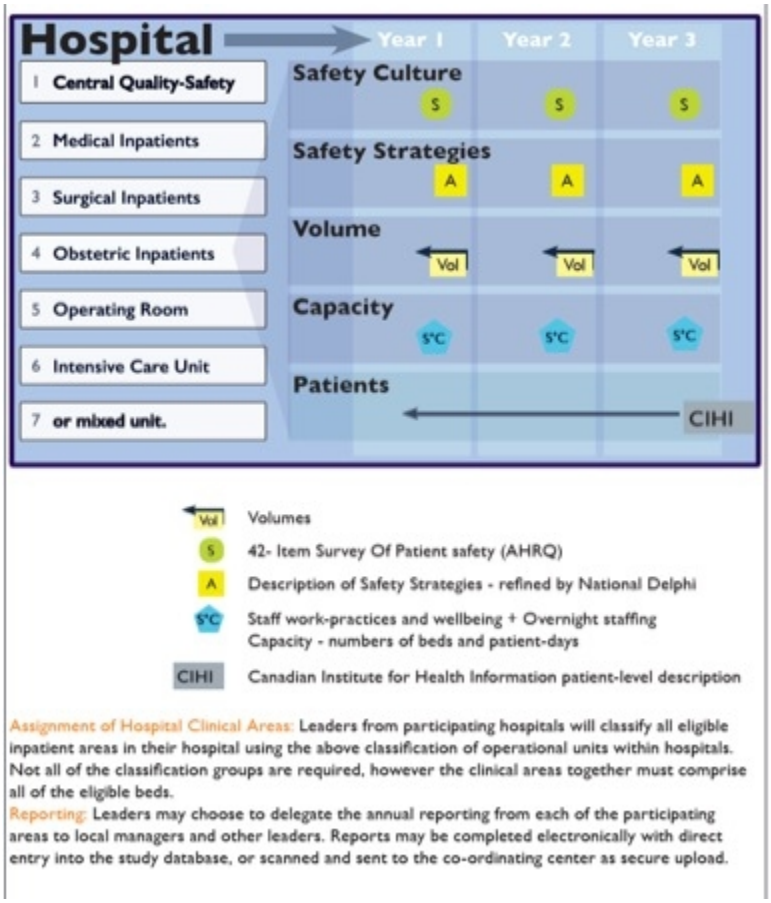
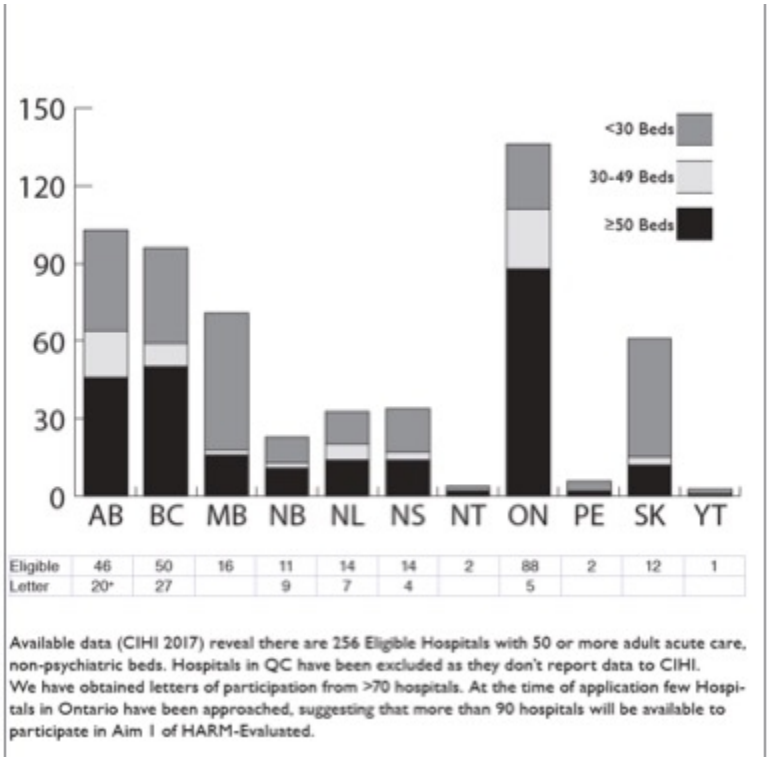


Overview of study methods and design

135x157mm (72 x 72 DPI)



Number of hospitals with at least 50 adult, non-psychiatric acute care beds in Canada

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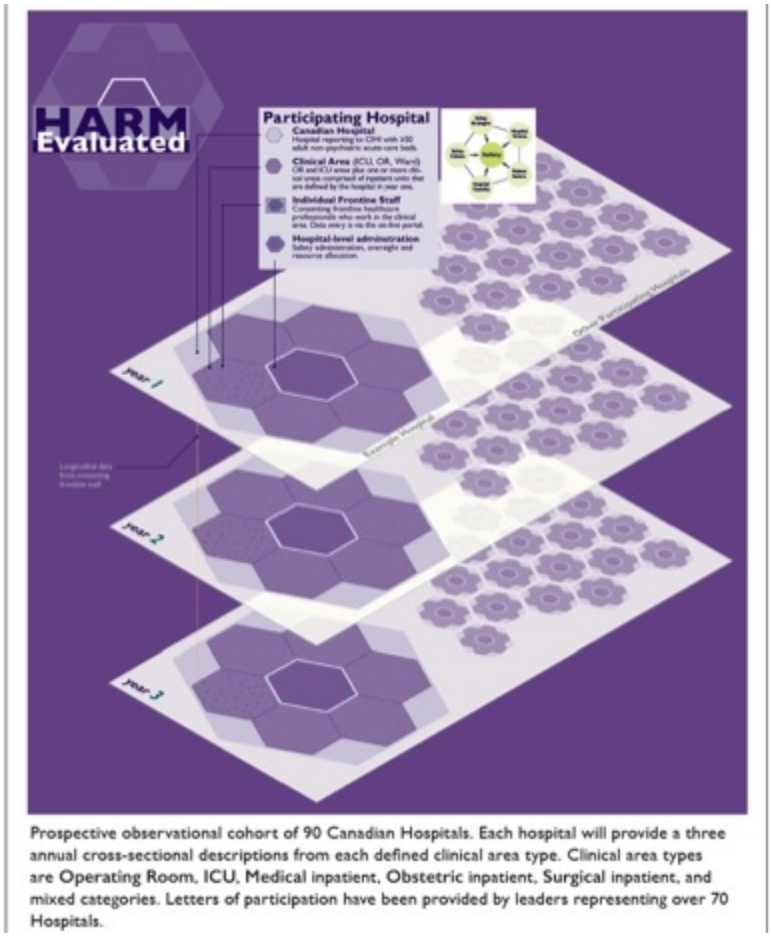

Prospective observational cohort of 90 Canadian Hospitals. Each hospital will provide a three annual cross-sectional descriptions from each defined clinical area type. Clinical area types are Operating Room, ICU, Medical inpatient, Obstetric inpatient, Surgical inpatient, and mixed categories. Letters of participation have been provided by leaders representing over 70 Hospitals.

Participant recruitment and evaluation

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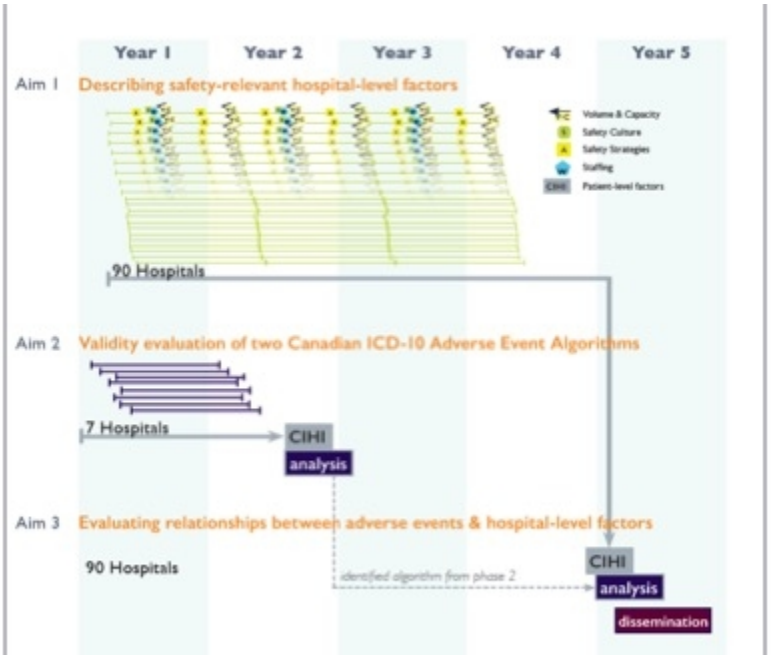

Timelines and evaluation plan

138x114mm (72 x 72 DPI)

What role do hospital characteristics play in patient safety? A protocol for a national cohort study of Hospital safety characteristics and Adverse event Rate Measurement (HARM Evaluated)

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Abstract

Background

Adverse events are a measure of patient safety defined as harm to patients occurring as unintended consequences of healthcare. These events include nosocomial infections, drug reactions and procedural complications. Approximately 9% of hospitalized patients have an adverse event. Beyond the harm of adverse events to the patient, including additional risks of death, these events incur considerable costs to the healthcare system. Substantial expenditures on healthcare safety programs has been justified by their goal to reduce healthcare associated harm, but available evidence suggests these programs have not improved overall safety - adverse event rates over the past four decades are unchanged.

The objective of this study is to identify hospital-level factors that impact patient safety in hospitals.

Methods

Organization-level factors will be explored by surveying 90 (15%) Canadian hospitals on four safety-relevant domains: 1) patient safety culture, 2) safety strategies, 3) staffing and 4) volume and capacity.

Organization-level factors will be evaluated using established scales and a survey co-designed by the study team and hospital leaders. Hospital leaders, clinical unit leaders

and up to 30 front-line staff will complete the surveys once a year for three years. The rate and type of hospital adverse events corresponding to each 1-year survey period will be estimated using national health administrative data.

Interpretation

Analysis of data from this project will describe safety-relevant factors of hospitals nationally and help identify organizational initiatives improving hospital patient safety. Identifying modifiable organization-level factors will allow us to identify existing and novel impactful opportunities to improve hospital patient safety.

Introduction

Hospital-associated harm occurs too frequently – it is estimated that nearly one in ten hospitalized patients experience hospital-associated harm which contributes to 2.8% of hospital deaths and the loss of 4.7 million years of life in good health, globally.[1-3] Healthcare associated harm is often measured as adverse events (AE): unintended, negative consequences of healthcare. AEs increase patients' lengths of stay in hospital, their chances of being admitted to an intensive care unit (ICU), dying in hospital and using more healthcare resources.[3-14] This provides a compelling rationale for the deployment of extensive, resource intensive initiatives to improve patient safety. Unfortunately, the best available data does not support the notion that these efforts are improving patient safety.[15-17] The reasons patient safety efforts have not had a desirable return on investment are complex and multi-faceted, and have not been disentangled nor comprehensively explored.

Patient characteristics have been extensively examined as risk factors for safety incidents because of their important association with AEs. Those having surgical procedures, with multimorbidity, greater severity of illness and who are older are each at increased risk of experiencing AEs.[3, 12-14, 18] However, patient characteristics constitute only one of several risk factors for AEs. Organization-level factors also play an important role in patient safety, but have been less prominently explored.[19-26] Safety-relevant hospital-level factors can be conceptually grouped into four broad domains: [1] patient safety culture, [2] patient safety strategies, [3] staffing and [4] hospital volume/capacity.[19-21] [27, 28] Evidence suggests these domains and the factors within

each contribute to patient safety and may even be better predictors of patient safety.[19-21, 23, 29-34]

Most safety improvement strategies to date have had a narrow focus on specific patient characteristics, types of AEs or clinical practices and have not resulted in a meaningful change in the rate of AEs. Effective strategies to prevent hospital AEs are needed to ensure that hospital care is safe. Hospital-level organization factors present a unique/innovative target for safety improvement initiatives but their association with the rate of hospital AEs is not well understood – studies to date have been small, had single cross-sectional designs and have studied only a few organization/hospital factors in specific clinical areas (e.g., ICU or emergency departments). Therefore, appropriately powered, high-quality studies are needed to inform organizational decision making about hospital care. Our objective is to identify hospital-level factors that impact the rate of hospital AEs.

Methods

We will survey 90 hospitals once a year for three-years across Canada (Figure 1). We will use this cohort of hospitals to describe safety-relevant domains within each hospital.

Setting: Ninety Canadian hospitals, representing 15% of Canadian acute care hospitals, will be included in the study. Canadian hospital care is provided through a universally accessible healthcare system that is publicly funded by provincial and federal governments. Eligible hospitals in this study are those that: provide inpatient acute care

to adults (>18 years old), have at least 50 non-psychiatric hospital beds and provide patient-level data to the national health information agency (Canadian Institute for Health Information, CIHI). National data for 2017-2018 suggests there are 258 such hospitals (Figure 2).

The 90 hospitals will be sampled from all Canadian provinces, (except Québec as these hospitals do not provide data to CIHI), and will be a representative mix of urban, tertiary academic hospitals and community hospitals.

Participants: The most responsible hospital-level decision-maker of eligible hospitals will be invited to participated on behalf of their hospital. There are three distinct groups of participants within the participating hospitals: 1) hospital-level decision-makers or delegates, 2) leaders of clinical areas within each hospital (e.g., department or division heads, medical director, unit executive directors) or delegates (e.g., quality improvement leads, clinical unit managers) and 3) front line staff. The hospital-level decision-maker (or delegate) will be identified by our research team; they will then nominate the most appropriate leader within each clinical area to participate. the Up to 30 front line staff from each clinical area (e.g., doctors, nurses, respiratory technicians, dieticians, pharmacists, etc.) will be asked to participate and complete surveys. Written consent will be obtained for each participant. See Figure 3 for participant recruitment and evaluation plan.

Organization-level (outcome) variables: Organization-level factors will be described in four broad categories: 1) safety culture, 2) safety strategies, 3) staffing and 4) hospital

volume and capacity. These organization-level factors will describe hospitals and relevant clinical areas which may include: ICUs, general medical units, specialty medical units, general surgical units, specialty surgical units, operating rooms and the medical response teams (as determined by the hospital leaders).

[1] Patient safety culture. Patient safety culture will be assessed using the validated Canadian Patient Safety Culture Survey Tool (Can-PSCS).[35, 36] The Can-PSCS is a 23-item survey that asks participants to rate their perceptions and opinions of patient safety using a five-point Likert Scale (Strongly Agree to Strongly Disagree). The Can-PSCS was developed based on the United States' Agency for Health Research and Quality (AHRQ),[37] the Patient Safety Climate in Healthcare Organizations (PSCHO) survey,[38] and the Error Climate Scale.[39] The Can-PSCS was chosen because of its sound psychometric properties based on validation across several settings, the fact that it is theory-based and it is specifically tailored to the Canadian context and as such has been adopted by Accreditation Canada (the accrediting body for healthcare organizations in Canada).[35] The Can-PSCS overall score will be a primary descriptor of patient safety culture.

[2] Patient Safety Strategies. There are no established measures of safety strategies therefore a *de novo* survey to measure patient safety strategies is needed. We will co-develop a safety strategy survey with hospital leaders using standard survey development methodology informed by existing materials.[40-42] The survey variables will include: [a] number of dedicated staff and FTE acting in safety jobs, [b] safety budget, [c] number of ongoing patient safety strategies according to the list developed in collaboration with hospital leaders, [d] organizational membership in safety

organizations (accreditation, other) and [e] existence of audit and feedback of safety incidents (e.g., reporting and learning systems). Participants will also be asked to rate adoption and fidelity of these strategies to literature on effective safety practices.

[3] Staffing. Staffing variables will include: [a] nurse to patient ratios, [b] total numbers of staff and FTEs, [c] staff turnover, [d] physician to patient ratios, [d] overnight physician staffing and type and [e] availability of medical emergency team. Staff wellbeing will be measured using the established Moral Distress Survey-Revised (MDS-R).[43]

[4] Volume and Capacity. National data available through CIHI will be used to capture the number of funded beds, occupancy, the number and type of specialty units, the number of admissions, the number of deferred patients and resource intensity used to treat patients within each hospital.

Data sources & measurement: Organization-level variables will be measured once a year for three years in each hospital. Hospital leaders of eligible hospitals will be approached to participate and asked to identify a representative sample of clinical areas and to provide contact information for the leaders of these clinical areas. Clinical area leaders and frontline staff will then be asked to participate. This approach has resulted in a 91% response rate in previous studies.[42] Frontline staff consenting to participate will be assigned a unique study identification number and will be asked to complete the Can-PSCS and the MDS-R every year for the duration of the study (three time points). Similar methods have been used to evaluate patient safety.[44] Clinical area leaders or delegates will be asked to complete patient safety strategies survey yearly for the

duration of the study (three time points). Staffing measures (nurse to patient ratios for day shift and night shift) will be collected intermittently as guided by clinical area leaders, but on at least two randomly selected days each month each year for the three years of the study. Hospital-level data will be collected from CIHI and will be used to compare participating hospitals to non-responding hospitals. See Figure 4 for timelines and data collection plan,

Data analysis: The unit of analysis will be the hospital. Composite scores for each of the safety-relevant domains will be used to distill multiple questions within each domain using principal component analysis and multiple correspondence analysis. Means (standard deviation) and proportions (interquartile range) will be used to describe the domains for each of the three cross-sectional outcome measurements within the study. Differences between measurement periods will be measured to examine temporal trends and stability over time.

Interpretation

This study will describe organization-level factors relevant to hospital patient safety in Canada. There has been little improvement in the rate of hospital AEs over time despite a call to arms by the Institute of Medicine and a surge in evidence around patient safety.[15] While the reason for the stagnant rates of AEs requires further investigation, one potential factor might be that patient safety initiatives to date have largely focused on the same, non-modifiable patient-level variables and limited safety strategies. Regardless of the reason it is clear that innovative approaches to improve safety among

hospitalized patients are needed if we are to improve care. Organization-level factors represent an untapped, potentially modifiable means to improve the safety of hospital care.

This study will provide a robust profile of safety-relevant hospital-level factors and a catalogue of safety activities adopted in Canadian hospitals. The findings of this study in conjunction with a complementary study being conducted by our group looking at AE rates in Canadian hospitals can help prioritize implementation of effective safety strategies and discontinuation of resource intense, yet ineffective programs. The rich, high-quality data from this study will inform key decisions influencing the safety of care in our hospitals and will inform future research aimed at designing, implementing and evaluating hospital-level safety initiatives including those safety strategies currently being used in Canadian hospitals.

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Figure 1. Overview of study methods and design

Figure 2. Number of hospitals with at least 50 adult, non-psychiatric acute care beds in Canada

Figure 3. Participant recruitment and evaluation

Figure 4. Timelines and evaluation plan