Title: Improved hospital safety performance and reduced medico-legal risk: an ecological study using two Canadian databases

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ABSTRACT

Background: We sought to determine if there was a relationship between in-hospital patient safety events and medico-legal cases involving physicians in Canada. **Methods:** In this ecological study, we used Poisson regression to compare data from the Canadian Institute for Health Information's Discharge Abstract Database and the Canadian Medical Protective Association's database of medico-legal cases over a 10-year period (April 1, 2005 and March 31, 2015). We identified patient safety events based on 15 Agency for Healthcare Research and Quality patient safety indicators within the Canadian Institute for Health Information and Canadian Medical Protective Association datasets. Subgroup analyses were performed for obstetrical and surgical cases. **Results:** We found a statistically significant positive association between volume changes in patient safety indicator events (*n*= 324,592) and medico-legal cases (*n* = 15,180) (parameter estimate: 1.15; 95% CI, 0-1.9). This association suggests that, on average, a 10% decrease in events would correspond to a decrease of 11% in medico-legal cases. The degree of positive association varied by practice type, with obstetrics (patient safety indicator events: *n* = 97,982; cases: *n* = 865) showing a 25% decrease in medico-legal cases for every 10% decrease in events (parameter estimate: 2.9, 95% CI, 0.5-5.3); and surgery (patient safety indicator events: *n* = 168,886; cases: *n* = 4,568), a decrease of 9% for every 10% fewer events (parameter estimate: 0.9, 95% CI, 0.2-1.7). **Interpretation:** Our findings suggest new, practical uses for medico-legal and patient safety indicator data for improving patient safety and quality of care .

Keywords: malpractice; health care economics and organizations; quality indicators, health care; patient safety; Canada

INTRODUCTION

The number and scope of patient safety and quality improvement initiatives are growing, and these activities are increasingly being tied to incentives such as funding and accreditation. Because of their impact on hospital budgets and provider time, there is a pressing need to identify which safety or quality improvement targets have the potential to produce the greatest benefits. At the same time, there is a drive to simplify the measures through which quality and safety are evaluated. Although administrative data including the Agency for Healthcare Research and Quality's patient safety indicators have been used to measure quality improvement and patient safety, their suitability for these purposes has been debated.(1, 2)

In the field of patient safety, many studies have evaluated the impact of health care system improvements on medical liability, with much of this work focusing on obstetrics.(3-12) Other research has attempted to study the link between the patient experience and various measures of quality and safety, with overall findings of a positive association between patient satisfaction, clinical effectiveness and patient safety.(13) However, to date few empirical studies have attempted to validate the existence of a relationship between medico-legal risk and hospital patient safety performance, or to measure the effects of this association.

In 2010, the RAND Corporation's Institute for Civil Justice evaluated the relationship between patient safety incidents and malpractice claims in California over a 5-year period. That study used the Agency for Healthcare Research and Quality's patient safety indicators to identify patient safety incidents, and found a linear relationship that represented a decrease of 3.7 malpractice claims for every 10 fewer incidents. That study also confirmed that the correlation held true across multiple medical specialties.(14) The objective of our study was to determine and quantify the relationship between in-hospital patient safety events and medico-legal cases involving physicians in Canada.

METHODS

Setting, study design and data sources

We used methods similar to those of the RAND study to analyze 10 years of data from the Canadian Institute for Health Information, an agency that collects and reports on data related to Canada's health care system, and the

Canadian Medical Protective Association, a non-profit mutual defense organization that provides medico-legal advice and assistance to physicians. At the time of this study, over 93,000 physicians were members of the Canadian Medical Protective Association (>95% of practicing Canadian physicians). In this ecological study, improvements in hospital patient safety performance were measured by the annual changes in the frequency of these patient safety indicator events.

We selected 15 patient safety indicators from the Agency for Healthcare Research and Quality's *Patient Safety Indicators v5.0,*(15) that could be identified in Canadian hospital data (see Table 1). "PSI 02 Death Rate in Low-Mortality Diagnosis Related Groups (DRGs)" and "PSI 04 Death Rate among Surgical Inpatients with Serious Treatable Conditions" were not included as they could not be identified in the Discharge Abstract Database due to their reliance on diagnosis-related groups, which are not used as a classification system in Canada. "PSI 09 Perioperative Hemorrhage or Hematoma Rate" was not included because it could not be identified in the Discharge Abstract Database due to differences in the ICD coding classification revisions used by the Agency for Healthcare Research and Quality and the Canadian Institute for Health Information for the study period. That is, Agency for Healthcare Research and Quality version 5 patient safety indicators were defined using ICD-9-CM, while the Canadian Institute for Health Information implemented ICD-10-CA coding in 2005.

The Discharge Abstract Database is a key database of the Canadian Institute for Health Information. It captures administrative, clinical and demographic information on hospital discharges. This database contains in-patient discharge data from all Canadian hospitals with the exception of hospitals in the province of Quebec. The database records about 2.5 million in-patient hospitalizations each year. The Canadian Medical Protective Association maintains a national database that contains information on medico-legal cases involving Canadian physicians. Medico-legal cases are coded by a team of professionals with nursing or health information expertise who review the medical issues and legal information in each case. Medical coding follows national standards and in-house developed analytical frameworks.(15) To reduce the risk of misclassification, coders conduct weekly quality assurance reviews of case coding. (17)

For this study, we compared 10 years of data from both databases, from April 1, 2005 to March 31, 2015. To be consistent with the data available to us through the Discharge Abstract Database, medico-legal

cases that occurred in Québec were excluded from the Canadian Medical Protective Association dataset. Medico-legal case volume was represented by the frequency of all medico-legal cases that included not only civil legal actions, but also medical regulatory authority and hospital complaints (Table 2). Because patients or their families may choose different pathways to bring a case forward, we elected to include all three case types to present a fuller picture of the overall medico-legal landscape.

The unit of analysis from both databases was event volume by region and by year. Event volume was represented the number of patient safety indicator events in the Discharge Abstract Database and number of medico-legal cases in the CMPA database. The provinces of British Columbia, Alberta, Ontario, each formed a region on their own, while provinces with smaller population and the territories were combined into one region for measurement stability. For each region, the average number of medico-legal cases across the 10-year study period was used as the denominator, and the medico-legal case volume was standardized by calculating the annual ratio of the case count to the regional average. This standardized value of the medico-legal cases was the response variable in the regression models as illustrated by the following equation:

$$Standard\ Volume_{region,year} = \frac{Annual\ Frequency_{\ region,year}}{10year\ Average_{region}}$$

Similarly, events from the Discharge Abstract Database were standardized by region and by year. This standardized patient safety indicator event volume was used as the main predictor in the regression models.

Obstetrics and surgery are known to be unique practice types, such that they are each more likely to see specific types of patient safety indicator events. Therefore, we built separate models for these subgroups to test for associations between patient safety indicator events and medico-legal cases. Within the same model, if a case from the Discharge Abstract Database was involved in more than one patient safety indicator event, it was counted only once. When a case included events that were related to different models, the case was counted separately in the relevant models.

While the purpose of this study was to examine the relationship of hospital safety and medico-legal risk, there were no unique patient identifiers available to link the cases. As such, it was not possible to perform case-level data linkages between the Discharge Abstract Database discharge records and medico-legal cases.

Statistical analysis

We used Poisson regression analysis with a log-linear link to test the significance of the association between volume changes for patient safety indicator events and medico-legal cases. To distribute expertise and reduce bias, two statisticians (QY and CZ) analyzed the data using SAS software v9.2 (SAS Institute, Cary, NC, USA). Considering the longitudinal nature of the data (i.e. the correlation of repeated measurements from the same region in different years), we used generalized estimating equations to address autocorrelation among responses. We included a set of year and region variables as well as their interaction terms to control for additional variations caused by temporal and regional difference in demographics, health care services, and legal systems. The exponentiated parameter estimates for the patient safety indicator events were the expected effects of changing volume of patient safety indicator events on the volume of medico-legal cases. When the models showed statistical significance in these events, we plotted such effects using the parameter estimates to illustrate the association between the volume of patient safety indicator events and that of medico-legal cases.

RESULTS

A total of 324,592 distinct records from the Discharge Abstract Database were used to construct the standardized values for the models. Because some of these records contain more than one patient safety indicator event, a total of 339,741 patient safety indicator events were found in these records. From the Canadian Medical Protective Association database, 15,180 medico-legal cases were used for the models (Table 2). Figures 1A) and B) show the regional trends of medico-legal cases and the standardized ratios of annual case volume to regional average, respectively. The volume decreases seen in the Canadian Medical Protective Association data in the last few years can be explained by a lag time that exists between when an event occurs and a case is initiated. In general, about 50% of cases are reported within 2 years of the occurrence of the event, while 90% are reported within 4 years. To control for this time effect, we created a variable for year in the models to explain the artificial drop between event occurrence and medico-legal case initiation. As this artificial drop is not always the same across years (e.g., not always a linear decrease, or the speed of decrease changed from year to year) and Year is a continuous interval variable, we also added a second-order term of Year into the models at the beginning of regression process. Figures 1C) and D) show

the regional trends of patient safety indicator events from the Discharge Abstract Database and the standardized ratios of annual incident volume to regional average, respectively.

The modelling results are reported in Table 3. The parameter estimate for the patient safety indicator event volume suggest a significant positive association, (1.15, 95% confidence interval [CI], 0.4–1.9; p = 0.003), between volume changes in patient safety indicator events and medico-legal cases when controlling for region and year.

The annual ratio of patient safety indicator events varied between 0.9 and 1.1, as shown in Figure 1D). When the relationship between patient safety indicator events and medico-legal cases was plotted within this range applying the model results, it appeared to be approximately linear (Appendix A, Figure i). This projects that a region with a 10% increase in patient safety indicator events would see a corresponding increase of 12% in medico-legal cases, or alternatively for a 10% decrease in patient safety indicator events, an 11% decrease in medico-legal cases.

The obstetrical model analyzed 97,982 patient safety indicator events identified in the Discharge Abstract Database (or 97,982 distinct Discharge Abstract Database records that involved an obstetrical patient safety indicator event), and 865 obstetrics-related medico-legal cases. The surgical model analyzed 168,886 patient safety indicator events from the Discharge Abstract Database (or 160,598 distinct Discharge Abstract Database records that involved at least one surgical patient safety indicator event) and 4,568 medico-legal cases. Regional annual change ratios for both patient safety indicator events and medico-legal cases were calculated in the same way as the all-cases model for both specialty models. The obstetrics model showed a 25% decrease in medico-legal cases for every 10% decrease in events; and for surgery, a decrease of 9% for every 10% fewer events, as shown in Appendix A, Figure ii and iii.

Notably, obstetrical medico-legal cases showed the greatest rate reduction when patient safety indicator events decreased, lending weight to the potential benefits of quality interventions in this area. The obstetrical case modelling results are shown in Table 3 and suggest a significant positive association (2.9, 95% CI, 0.5–5.3; p = 0.02). This projects that a region with a 10% decrease in patient safety indicator events would see a corresponding decrease of 25% in medico-legal cases. However, the degree of increase in medico-legal case volume is far greater than that of the patient safety indicator event, with an average of 34% increase for

every 10% of patient safety indicator increase. The surgical case modelling results, shown in Table 3, also suggest a significant positive association (0.9, 95% CI, 0.2–1.7; p = 0.02). This projects that a region with a 10% increase in patient safety indicator events would see a corresponding increase of 10% in medico-legal cases or, alternatively, for a decrease of 10% in patient safety indicator events, a 9% decrease in medico-legal cases.

INTERPRETATION

This comparison of two Canadian databases suggests a relationship between hospital safety performance and medico-legal risk in Canada. The degree of positive association varied by practice type, with obstetrics showing a stronger relationship. This association may reflect the severity of events encompassed by patient safety indicator 17, which include neurological injury to the infant. These types of injuries are a major source of malpractice litigation for obstetricians given the vulnerability of patients and lifelong care costs associated with these events.

This study joins a small body of research that has found relationships between patient safety indicator events and increased medico-legal risk,(16) lower safety culture scores(17) and patient ratings of physicians and nurses,(18) and poorer performance on other measures of safety and quality.(19, 20) Our results are consistent with those of studies that have shown that improved safety and quality is associated with decreased medico-legal risk.(3-12)

At the system level, longitudinal medico-legal data trends can be used to clearly illustrate the institutional impact of quality improvement and patient safety initiatives for frontline providers. Therefore, our results may support efforts to position patient safety at the forefront of medical malpractice reform by demonstrating that reduced medico-legal liability could be a secondary benefit to improved patient safety. Although researchers have questioned the use of patient safety indicators and other administrative data sources for quality improvement purposes on the basis of inadequate reliability(1) and clinical relevance,(2) this study suggests that the current set of indicators may represent a more consistent measure of patient safety than previously argued.

Limitations

This study also had limitations. Because the patient safety indicators are acute care–related, they do not reflect the full spectrum of clinical care. Also, while the Discharge Abstract Database includes all in-patient health event data, Canadian Medical Protective Association data include only those cases that involved a physician. It

is important to note that although the Canadian Medical Protective Association represents most physicians in Canada, members report hospital and regulatory authority complaints to the Canadian Medical Protective Association at their own discretion, and therefore these cases do not represent a complete picture of all such cases in Canada. Furthermore, to ensure comparability between datasets, medico-legal cases from the province of Québec were not included in this analysis, as data from the province were not available from the Canadian Institute for Health Information. Therefore, our results do not represent a complete picture of Canada.

Sample sizes for medico-legal cases were relatively small for obstetrical cases at the regional level, and the confidence intervals for the parameter estimates were wide. This is explained in part by the fact that because obstetrical cases often concern patients of minority age, they have longer limitation periods (generally when the plaintiff reaches age 18 years plus 2 years) resulting in longer lag times between event occurrence and medico-legal case initiation. Complaints to hospitals and regulatory authorities represented a significant portion of the medico-legal cases included in this analysis. The characteristics of these types of cases may differ from those of legal actions. For example, while the majority of legal actions relate to allegations of harm, hospital and regulatory authority complaints often involve communication, manner, and administrative issues. It should be noted that even those cases not directly associated with harm from healthcare delivery may nonetheless reflect important elements of patient safety culture.

Conclusion

Although the reasons why medico-legal cases arise are often complex and multifactorial, the statistically significant positive association between patient safety indicator events and medico-legal cases quantifies a relationship between patient safety and medico-legal risk in Canadian hospitals. These findings challenge critiques about the suitability of the Agency for Healthcare Research and Quality's patient safety indicators as measures of safety and quality and suggest new practical uses for both medico-legal and patient safety indicator data in system-level quality improvement efforts.

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Tables and Figures

Table 1. Selected Patient Safety Indicators reported in the Discharge Abstract Database, 2005–2015

Patient safety indicator	Number of incidents (*n* = 339,741)	Model	
		Surgical (*n* = 168,886)	Obstetrical (*n* = 97,982)
PSI 02 – Death rate in low-mortality diagnosis related groups	–		
PSI 03 – Pressure ulcer rate	38,136		
PSI 04 – Death rate among surgical inpatients with serious treatable conditions	–		
PSI 05 – Retained surgical item or unretrieved device fragment count[†]	1,979	✔	
PSI 06 – Iatrogenic pneumothorax rate	21,343		
PSI 07 – Central venous catheter–related bloodstream infection rate	13,394	✔	
PSI 08 – Postoperative hip fracture rate	16,848		
PSI 09 – Perioperative hemorrhage or hematoma	–		
PSI 10 – Postoperative physiologic and metabolic derangement rate	12,009	✔	
PSI 11 – Postoperative respiratory failure rate	5,453	✔	
PSI 12 – Perioperative pulmonary embolism or deep vein thrombosis rate	32,066	✔	
PSI 13 – Postoperative sepsis rate	7,450	✔	
PSI 14 – Postoperative wound dehiscence rate	5,781	✔	
PSI 15 – Accidental puncture or laceration rate	87,132	✔	
PSI 16 – Transfusion reaction count	168	✔	
PSI 17 – Birth trauma rate – injury to neonate	15,827		✔
PSIs 18 and 19 – Obstetric trauma rate – vaginal delivery with or without instrument	82,155		✔

Source: Agency for Healthcare Research and Quality. Patient Safety Indicators Version 5.0.
Note: Within the same model, if a case from the Discharge Abstract Database involved more than one patient safety indicator event, it was counted only once. Some records involved multiple indicator events for different models and were counted separately for different models.

Table 2. Distribution of CMPA cases used in modelling by type; *n* = 15,180

Case type	Model; number of cases		
	All cases	Obstetrical	Surgical
Legal	3,639	521	1,820
Regulatory authority complaint	3,757	270	1,200
Hospital complaint	7,643	73	1,527
Other*	141	1	21

*Includes human rights complaints, inquests, and privacy investigations.
CMPA = Canadian Medical Protective Association.

Table 3. Modelling results

Parameter	Model; estimate (95% CI)		
	All cases	Obstetrical	Surgical
Intercept	–1.20 (–2.00 to –0.40)	–1.72 (–3.74 to 0.29)	–1.15 (–1.85 to –0.45)
PSI event volume	1.15 (0.4 to 1.90)	2.91 (0.53 to 5.28)	0.92 (0.17 to 1.67)
Region			
Alberta	–0.15 (–0.18 to –0.13	–0.43 (–0.50 to –0.37)	0.20 (0.18 to 0.21)
British Columbia	–0.11 (–0.12 to –0.09	–0.61 (–0.92 to –0.31)	0.12 (0.003 to 0.24)
Ontario	0.09 (0.08 to 0.09)	–0.23 (–0.40 to –0.07)	0.22 (0.21 to 0.23)
Rest of Canada	—	—	—
Year	0.09 (0.03 to 0.15)	–0.24 (–0.31 to –0.17)	0.22 (0.17 to 0.28)
Year^{2} *	–0.01 (–0.02 to –0.004)	—	–0.03 (–0.03 to –0.02)
Region*Year			
Alberta*Year	0.03 (0.02 to 0.03)	0.10 (0.08 to 0.11)	–0.04 (–0.04 to –0.03)
British Columbia*Year	0.02 (0.02 to 0.02)	0.12 (0.06 to 0.18)	–0.02 (–0.04 to –0.001)
Ontario*Year	–0.02 (–0.02 to –0.01)	0.05 (0.02 to 0.09)	–0.04 (–0.05 to –0.04)

Rest of Canada*Year	—	—	—

*The higher-order year variable (year^2) was not significant and was thus removed from the final model. Note: These parameter estimates can as alternately be depicted as equations:

Log(medico-legal case volume) = 1.15 * PSI event volume + (Intercept + control variables), for the overall model

Log(medico-legal case volume) = 2.91 * PSI event volume + (Intercept + control variables), for the obstetrical model

Log(medico-legal case volume) = 0.92 * PSI event volume + (Intercept + control variables), for the surgical model

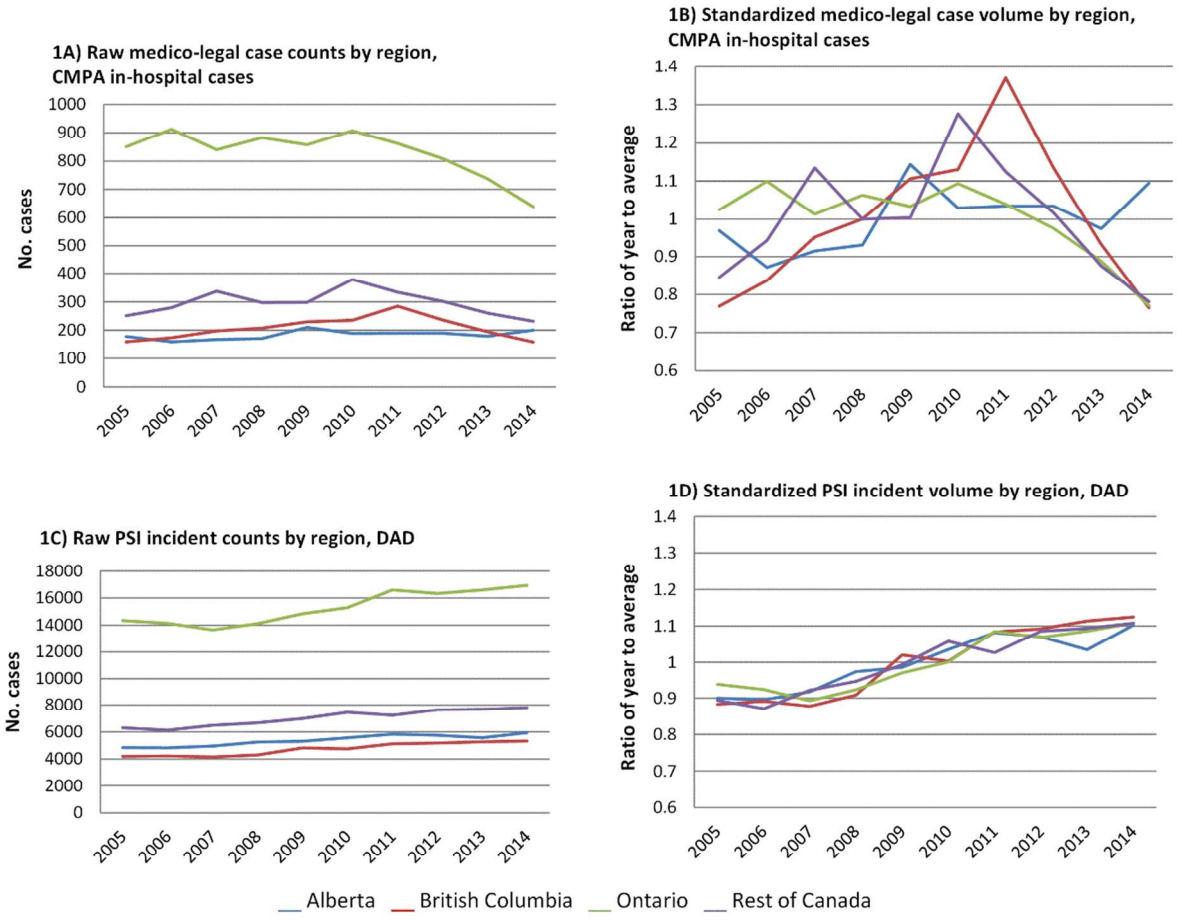
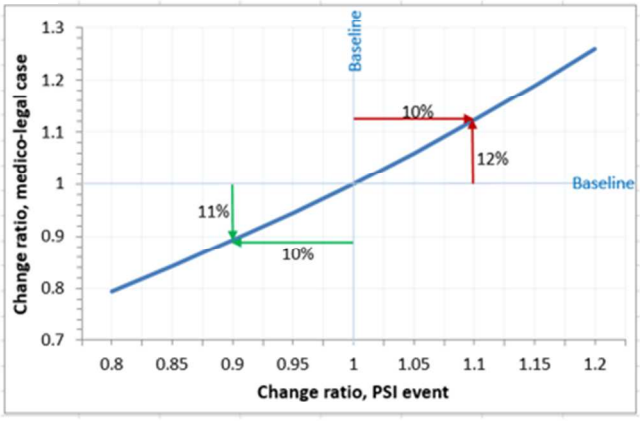


Figure 1. Actual and standardized medico-legal case and PSI incident counts by region

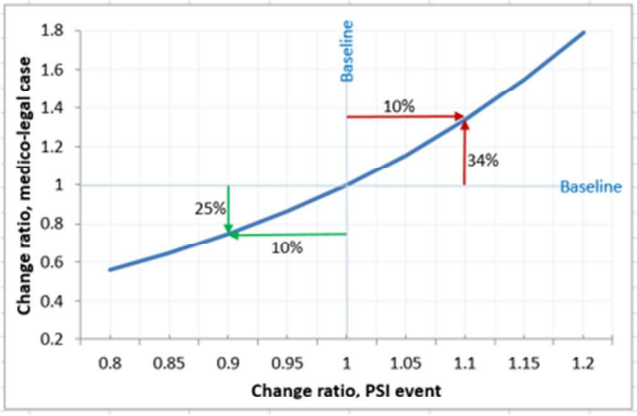
CMPA = the Canadian Medical Protective Association; PSI = patient safety indicator; DAD = discharge abstract database.

APPENDIX A: MODEL RESULTS FOR RELATIONSHIP OF CHANGES OF PSI EVENT AND MEDICO-LEGAL CASES

i) All-specialty model results



ii) Obstetrics model results



iii) Surgical model results