



One Dollar in Seven: Scoping the Economics of Patient Safety

***A Literature Review prepared for the Canadian Patient Safety Institute
by***

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Executive Summary

The safety of patients undergoing treatment in hospital has attracted much policy attention over the past fifteen years, with landmark research in Canada and other health systems around the world, to estimate the clinical impact of untoward events in hospital care.

Until recently, relatively little attention has been directed toward the economic impact of such events. Few studies have attempted to estimate the additional costs of adverse events in hospital care, and fewer still the costs in healthcare settings outside of hospitals.

Controversy surrounds the definition of untoward or ‘adverse’ events, because of a history of trying to apportion blame when health care goes wrong. Estimates of the costs of such events thus vary depending on such factors as the degree of ‘preventability’ of an adverse event, the extent to which particular complications of care can be anticipated, and whether it is possible to separate costs of treating the presenting problem from resources used in treating complications.

Nonetheless, every study analysed here demonstrates that health care-associated injury and ill health adds substantially to the costs of health care. International studies show these add between 13 and 16 per cent to hospital costs alone [Jha, 2009; Jackson, 2008; Ehsani, 2006]; at least ***one dollar in every seven dollars spent on hospital care***. Treatment costs of the sequelae of these events are largely unmeasured. ***We know that adverse events waste money in the healthcare system, but we do not know where to invest the next dollar to reduce this cost burden.*** And, of course, in-hospital events and less well-studied complications of out-of-hospital care entail a large but unmeasured burden of pain and incapacity for patients.

Decision makers face competing claims for additional investment in the healthcare system, despite the oft-cited ‘first do no harm’ imperative of patient safety. Economic considerations should not be the only factor considered in patient safety policy, but when budgets are tight, new interventions will need evidence that they are as good as or better than other investments to improve health.

This paper reports a survey of the international published literature (1999-2009) on the economics of healthcare-related injury and illness, using the widest definition of such terms. The *Methods* section describes the search approach and parameters: it is limited to interventions to improve patient safety, and does not consider the growing literature on facility (particularly hospital) capital improvements that may also improve patient safety, nor studies of the effects of financial incentives on patient safety, nor broader studies of quality of care. The *Results* section analyses the underlying problems in summarizing this literature (why economic answers are hard to find and compare). It identifies three key problems:

- difficulty in defining common measurement parameters (which ‘events’ are worthy of counting?);
- lack of consensus about how cost estimates should be derived (costs to whom? measured how?);
- few reports of program costs (what does it cost to reduce the incidence of ‘events?’).

The *Results* section of the literature survey is structured around tables that summarise the available international estimates of the costs of adverse events in healthcare (**Table 1**), and Canada-specific estimates (**Table 2**); reported program costs for prevention or reduction in the rate of specific types of adverse events (**Table 3**), and cost-effectiveness studies that combine measures of both effectiveness and costs (**Table 4**).

The *Discussion* highlights the main lessons available from this sparse literature, and Canada-specific gaps in the research literature:

- ‘cost of illness’ estimates are useful to motivate change, but not informative about where investments should be made;
- available evidence is not easy for decision-makers to extrapolate to their decision context because definitions of desirable and undesirable outcomes are fraught with controversy and

well-established principles for estimating costs are not routinely used in the patient safety literature;

- the value of common outcome metrics across studies is increasingly recognized in the literature, but not yet well-represented in empirical studies;
- a small number of good quality Canadian studies are available, but reflect the limitations of the international literature;
- patient safety events outside hospitals, including home care, ambulatory medical care and long term residential care, are not well represented in the patient safety economics literature;
- costs of intervention programs are not well-documented.

Beyond vague generalities that improving patient safety should logically reduce costs and improve outcomes of patient care, the literature reviewed here is, on the whole, unsuitable as the basis for specific policy recommendations. The *Conclusion* draws together lessons from the literature survey with the known gaps in Canada-specific research on the economics of patient safety, and sketches broad directions for further research. It argues that:

- cost-effectiveness/cost benefit analyses of patient safety interventions are to be preferred because they recognize and quantify patient benefits;
- more limited ‘business case’ and ‘return on investment’ studies should be used in decision-making to ‘rule in’ but not to ‘rule out’ patient safety investments;
- cost-effective patient safety interventions are less likely to be adopted when the costs and benefits of doing so accrue to different stakeholders in the healthcare system;

- use of simple economic decision-analytic models can combine the information valued by different stakeholders to yield useful information on the incremental cost effectiveness of specific interventions;
- sensitivity analysis can identify the critical variables that affect cost-effectiveness judgments for particular programs, suggesting where additional research could narrow the range of uncertainty for decision makers.

Demonstrated patient harm and documented cost-effectiveness of harm reduction strategies are powerful policy tools in gaining wider acceptance for investment in patient safety. Additional research on the economics of patient safety in Canada following these principles would assist in directing future patient safety investments toward the most cost-effective alternatives.

Introduction

Over the past decade, health systems have become aware of the frequency and additional cost of adverse events in healthcare. A wide range of interventions has been introduced to reduce the incidence of such events. Perhaps because of the medical injunction to ‘first do no harm’, programs to reduce this toll have seldom been subjected to the same scrutiny as other healthcare innovations.

Traditionally patient safety priorities have been set on the basis of clinical judgments about three key variables: Is the ‘event’ frequent? Is it amenable to prevention? Does it cause sufficient harm to patients to make concerted efforts to prevent? These judgments are often implicit ones, with little attempt to compare one intervention/ reduction effort with another in terms of either clinical gain or the costs of any such gains. Government and other funders have become involved in priority setting when public attention to particular events calls into question the performance of the system as a whole; ‘reputational risk’ is increasingly factored into decision making.

While the costs of treatment should not replace incidence data, morbidity data or quality of life considerations in making choices and decisions about research or prevention priorities, they should not be ignored

Rigby & Litt, 2000

To date, economic arguments have not featured prominently in decisions about which patient safety programs to initiate. Researchers have aimed to provide estimates of the overall costs of adverse events as a way of motivating support throughout the healthcare system. These ‘cost of illness’ studies have been successful in drawing attention to patient safety issues, but don’t answer the needs of different actors in the system for different sorts of economic information. Foremost of these needs is better information for setting priorities for harm reduction efforts at all levels of the system [Dixon & Shofer, 2006; Warburton, 2005].

Managers of health facilities are concerned with ‘the bottom line’—how improvements in patient safety might reduce costs or shorten average length of stay to enhance the facility’s financial performance. Patient safety advocates are concerned with the efficacy of interventions to improve patient outcomes, and often cite financial estimates of savings to bolster their case. Clinician researchers are primarily concerned with estimates of the patient-effects of adverse healthcare events (rates, degree of injury, risk adjustment and the degree of preventability), and these estimates have direct application to economic questions. Finally, funders and other policy makers are concerned with ‘value for money’ most often expressed as the ‘business case’ for investment in change strategies, or as the cost-effectiveness/cost benefit of changed practices to improve patient welfare.

Economic evaluation of new drugs and devices (often termed ‘health technology assessment’ or HTA) is a relatively well established feature of most modern healthcare systems. Other healthcare interventions or programs of care are less frequently evaluated. In part, this is because outside the drug/device realm, the intervention is less easily defined and operator characteristics or context factors play an important role in determining the effectiveness of interventions.

Patient safety improvement interventions often entail clinical interventions (eg, introduction of safer treatment technologies), but effectiveness may also rely on more complex behavioural change interventions (eg, improved hand hygiene) with similarities to health promotion programs, and management innovation programs.

Some of the important economic questions in patient safety include:

- what is the impact of healthcare-acquired illnesses/injuries on patients' quality of life?
- what are the longer-term impacts on patients' health, their return to the workforce, and their subsequent use of health services?
- what patient outcomes do doctors and other clinicians prioritise for interventions?
- what do adverse events add to the cost of patient care?
- would priorities for harm reduction change if healthcare costs were taken into account?

- would priorities change if compromised patient well-being and/or longer term healthcare costs were taken into account?
- how can the economic and other outcomes of proposed interventions be evaluated prior to widespread adoption across the healthcare sector?
- how can such evaluations be localized to take into account variations in facility-specific effectiveness and costs?

By weighing the additional costs of patient safety interventions against potential gains in patient wellbeing and healthcare costs averted, modeled economic evaluations can be tailored to the needs of specific decision contexts and decision-makers.

This report evaluates the strengths and weaknesses of published reports on economic aspects of improving patient safety, highlighting Canadian work in this area. It identifies a critical path to more effective economic evaluation of proposed interventions, and new standards for studies that quantify financial or economic gains.

Evidence on the costs and effects of most safety improvements is still lacking.
Warburton, 2009

Methods and structure of this literature survey

The field of health economics is not well-suited to the evidence-based medicine paradigm of the randomized controlled trial, systematic reviews and meta-analyses. In part this is because methods and standards in health economic studies are still evolving, but in part it is the nature of health economics that both the ‘effect size’ and any cost estimates will vary from setting to setting, country to country, based on how healthcare is organized and funded. This report was thus conducted as a survey of the international literature, including web-based searches of the grey literature. The report

is intended to provide the Canadian Patient Safety Institute with an overview of what is known about economic losses attributable to adverse events, what methods of research and evaluation are typically used in such studies, and the contextual issues that vary from one health system to another.

It builds on several previous systematic reviews of the literature, including a 2005 study on the return on investment literature in patient safety [Schmidek & Weeks, 2005], and a 2003 report to the UK National Patient Safety Agency on economic issues in patient safety [Gray, 2003]. It does not consider the small but growing literature on the economics of capital construction and refurbishment of healthcare facilities to improve patient outcomes. It also does not review literature on how changes in funding/payment incentive structures might improve patient safety; though this was the subject of a recent UK international review [Christianson, 2008].

The survey has drawn on the author's professional library, assembled through snowball searching that relies on tracking relevant research papers from the reference lists of other relevant papers. Over a period of 9 years (2000 to present), this represents 85 papers where the economics of patient safety were a prominent part of research reports. In addition, the librarian from the Canadian Patient Safety Institute conducted a MeSH term search of PubMed that identified 40 papers. This was used to identify 14 additional studies not retrieved by the snowball search or a web-based search of the grey literature. There was little overlap between the three searches, in part because relevant economic facts are often 'buried' in clinical papers, and in part because search terms are relatively imprecise. Thus, the searches did not use 'systematic' (ie. designed to retrieve *all* potentially relevant information) or reproducible methods, but were reasonably thorough.

The economics of patient safety is a burgeoning area of the literature, and new research reports are appearing weekly. The Institute for Healthcare Improvement's recent white paper, *'Increasing Efficiency and Enhancing Value in Health Care'* [Martin, et al, 2009] was released shortly before this review began, and a UK Health Foundation evidence review on the costs of quality improvement [Øvretveit, 2009] was published just as the current review was concluding.

Results

Results of this review are presented in a series of tables that follow. Synthesis of this literature, however, is difficult because of fundamental differences in the intent of the studies and measures used by study authors. Beyond vague generalities that improving patient safety should logically reduce costs and improve outcomes of patient care, the literature reviewed here is, on the whole, unsuitable as the basis for specific policy recommendations. The review has identified three key problems with the studies reviewed that prevent more robust policy formulation, and these will be elaborated here before findings of the review itself.

What should be counted?

The first of these key problems is a difficulty in defining common measurement parameters—that is, which patient safety issues are worthy of ‘counting’? Table 1 uses the term ‘Event Type’ to clarify what kinds of safety incidents each study specifically addresses. The wide variety in this variable can be expected to influence estimates of incidence and costs in a number of ways. Voluntary reports [Paradis, et al., 2009; Cullen, et al., 1995] for example, may identify events at both ends of the severity spectrum. Serious consequences to patients may prompt healthcare personnel to make such reports, increasing estimates of reported economic outcomes. Safety-minded staff may voluntarily report more ‘near misses’ resulting in minimal patient harm, and thus reduce estimates of economic outcomes. Rates of voluntary reporting (and thus incidence of the events reported) vary widely, depending on the organizational climate and any perceived penalties from such reporting. Thus basing economic evaluations on such studies is inadvisable, despite arguments to the contrary [Paradis, et al., 2009].

The variable quality of hospital discharge abstract data (often termed ‘administrative’ data, although it is largely clinical in focus) has been noted by both proponents and critics of the use of these data [Quan, et al., 2008; Romano, et al., 2002; Zarling, et al., 1999; Geraci, et al., 1997]. It is generally agreed that this method of identifying adverse patient safety events undercounts such occurrences

because of the requirement that explicit medical documentation appear in the patient record [Jackson et al., 2006; Forster, et al., 2004; Zhan & Miller, 2003; Quan, et al., 2002; Lawthers, et al., 2000]. Comparison of rates across jurisdictions and between hospitals is unwise because of differing coding standards, differing patient risk profiles, and differing levels of investment in data quality. The method will not identify ‘near miss’ events, nor those with only minor patient consequences, as these are unlikely to be documented or coded, and thus studies using these estimates may overestimate the costs of particular patient safety events because only the most harmful will be identified and costed.

The AHRQ Patient Safety Indicators [Miller, et al., 2001] rely on routinely coded data and have been used as the basis of a number of cost estimation studies [Miller & Zhan, 2004; Zhan & Miller, 2003]. These studies have the advantage of drawing on sets of public-domain definitions of adverse events, and thus lend themselves to comparisons based on similar types of events. They were developed, however, before information about ‘present on admission’ diagnoses was routinely available [Naessens, et al.1991], and thus are limited to a small number of indicators where the hospital is indisputably the place of occurrence.

Chart review studies [Brennan, et al., 1991; Leape, et al., 1991; Wilson, et al., 1995; Thomas, et al., 2000; Vincent, et al., 2001; Schiøler, et al., 2001; Davis, et al., 2002; Baker, et al., 2004; Kobayashi, et al., 2008; Soop, 2009] are currently considered to be the ‘gold standard’ method of identifying rates of adverse events. Because the method relies on multiple clinicians reviewing patient records, agreement amongst them about both the fact of an ‘adverse event’ and its ‘preventability’ is often low. Increasing the number of reviewers has been found to increase the reliability of such identification [Forster, 2007].

Whichever measure is the focus of research, authors frequently distinguish between those events that are ‘preventable’ and those that are not. Making the judgment about preventability is fraught with controversy and inter-rater reliability is typically low when individual cases are assessed by multiple physicians [Hayward, et al., 2001; Lawthers, et al., 2000; Localio, et al., 1996]. Recent US

Medicare payment reforms [Clancy, 2009] have been focused on so-called ‘never’ events (those deemed to be always preventable) thus avoiding dispute about non-payment. The reality, however, is that most complications associated with healthcare are neither 100% preventable nor universally occurring. A more realistic goal is to reduce rates of all events, rather than arbitrarily define many as ‘not preventable’. Studies that report an incidence rate or cost savings only for ‘preventable’ events are thus difficult to compare.

The differing thresholds for identifying events mean that economic comparisons are only meaningful when comparing ‘apples with apples’. The Patient Safety Indicators (PSIs) have dealt with this problem best by offering standard and reproducible event definitions, but they are still open to the criticisms made of routinely coded or ‘administrative’ data. Because they are a subset of all hospital-acquired injury and illness (albeit important patient safety issues), they comprise only 18-20 indicators, and thus economic studies based on them will be limited to these events.

The lack of standard taxonomy, in addition to definitional issues, in large part explains why so little is known about the prevalence, adverse event outcomes and effective prevention of medical injuries.
Zhan, et al., 2003

Recent work for the Australian Commission on Safety and Quality in Health Care (ACSQHC) has resulted in the development of a comprehensive set of markers for ‘hospital acquired conditions’ [Jackson, 2009]. The Classification of Hospital-Acquired Diagnoses (CHADx or ‘chaddix’) uses coded hospital data along with a ‘present on admission’ marker (similar to Canada’s ‘Diagnosis Type 2’ marker) to identify events routinely abstracted from the patient record [Jackson, et al., 2006]. Like the PSIs, CHADx provides standard and reproducible definitions of events; unlike PSIs, CHADx can identify the full range of conditions (distinguishing, for example, hospital-acquired urinary tract infections from pre-existing UTIs). Both systems are limited by the underlying quality of diagnosis coding.

The PSIs, incorporate risk adjustment (rates for specific patient sub-populations), while the CHADx does not, because its primary purpose is hospital-level care improvement efforts rather than external quality comparisons. However, for research purposes, risk adjustment algorithms could be devised. Moreover, comparisons at the jurisdictional level (health region or province), can more readily be assumed to have similar risk profiles [Miller, et al., 2001]. With 144 classes, CHADx allows better understanding of the full range of hospital-acquired conditions, and the ability to estimate the marginal contribution of each of these events to patient treatment costs to aid in priority setting on the basis of system costs [Jackson, 2008].

Tables 1 and 2 demonstrate the varying event definitions used in studies reviewed here.

How should ‘cost’ be measured?

A second key problem found in the literature on the economics of patient safety is the absence of standard methods for defining and measuring costs. Because ‘costs’ are usually presented in numbers, they take on a spurious reality. But as is the case for definitions of patient safety events, ‘costs’ are always a construct, and how they are defined can affect the conclusions reached about the economics of patient safety.

Cost estimation in US studies is frequently based on billed charges as a proxy for costs, despite the known limitations of these as accurate measures of resource use [Ashby, 1993; Finkler, 1982].

Different institutions put different markups on healthcare services, in recognition of which US Medicare discounts charges using its ‘cost to charge ratio’ in estimating Diagnosis Related Groups (DRG) payment rates. Despite the distortions in cost-measurement introduced by billed charges [Friedman, et al., 2002], they are the most accessible estimates available to US researchers.

Differences in methods used to estimate costs, which has been a chronic problem found in economic evaluations, contributes to the wide range of costs reported

Stone, et al., 2005

Alternative cost estimation techniques involve ‘micro-costing’ where costs of patient services are estimated for groups of similar patients, and then compared. The simplest form of micro-costing is also termed ‘protocol costing’ because the clinical protocol (rather than actual treatment) drives the cost estimates. A refinement of micro-costing is computerized ‘clinical costing’, where actual patient utilization of specific services is tracked by hospital costing systems, with standard costs for each service applied to the service bundle used by individual patients [Jackson, 2001; Jackson, 2000].

Where patient-level costs are published, some studies make no allowance for variability in costs due to factors other than the patient safety event of interest. Studies that use regression analysis (or ‘regression models’) to statistically control for the cost-increasing effects of other factors such as comorbidities, patient age, and severity of illness (noted in *Tables 1* and *2*) provide more valid estimates of the marginal costs of patient safety events. Other studies in these tables include matched controls or use DRGs to control for confounders. Adjustment provides a more accurate assessment of the marginal cost of the event, as other cost-increasing factors may be correlated with the event itself.

The use of billed charges, micro-costing, and the cruder method of using average DRG costs, all make extrapolation of findings difficult, as they require currency conversion, adjustment for changes in the value of money over time, and adjustment for differences in factor prices between and within healthcare systems. When reported as percentages, however, such estimates are more amenable to extrapolation to similar institutions or healthcare systems. Japanese researchers have taken a novel approach to the problem by estimating the number of equivalent full time workers required to conduct comprehensive patient safety activities in hospitals surveyed by them [Fukuda, 2008]. Had

this been reported in terms of total hospital staffing (allowing calculation of proportions), it would have been more easily extrapolated.

The simplest form of cost estimation is a count of services used by patient groups being compared, termed ‘healthcare utilization’ in *Tables 1* and *2*. Here, important cost drivers (days of hospital stay, number of ambulatory care visits, etc.) are reported as the economic outcome of a study. This method has advantages and disadvantages. The costs of hospital care over the course of an admission obviously differ: early post-operative days are more labour-intensive and costly than later days of convalescence; costs in the operating room or intensive care unit (ICU) are not well-captured by a simple ‘days of stay’ analysis. For extrapolation to other healthcare systems, however, such estimates have an advantage that they avoid locking in system-specific patterns of capital/labour substitution and more obvious problems of currency conversion and changes in the value of money.

Similarly, changes in the use of ambulatory care may make extrapolations based on the reduction in the number of visits unreliable due to different health system patterns in the use of specialists and hospital-based care, but easier to hold constant price effects from one health system to another.

More fundamentally, cost and benefits differ across stakeholder groups. Patients incur few of the costs of increased patient safety, but gain most of the benefits in terms of improved health status. In contrast, hospital managers bear all of the costs of programs to increase patient safety, and receive few benefits. When hospitals are block-funded, for example, freeing up beds by reducing hospital-acquired injury results in additional work (admissions), but no increase in the hospital’s budget. IHI makes the distinction between ‘light green’ and ‘dark green’ dollar savings from quality improvement initiatives [Martin, et al, 2009], with the former referring to theoretical but undocumented cost savings, and the latter referring to actual, achieved and documented savings. Because of the difficulty in measuring changes in patient safety, reward structures for stakeholders have not, until very recently, included recognition when higher quality care is provided.

So-called ‘pay for performance’ or P4P initiatives in healthcare funding are aimed at changing these incentives. Between these two groups are frontline healthcare workers who bear few of the monetary costs of changes to improve patient safety, but must adapt to what has been termed ‘change fatigue’ [Garside, 2004] to ensure the success of safety interventions. In return, they may receive modest benefits from increased job satisfaction, and affirming their original altruistic motivations for working in healthcare. Thus, studies differ as to *whose* costs and benefits should be considered.

Guidelines for economic evaluation in healthcare [Drummond, et al., 2005; Gold, et al., 1996] have advocated a ‘societal’ perspective, so that decisions based on cost benefit or cost-effectiveness analyses count all effects, even including those falling outside the healthcare sector. A program that has a high cost to the healthcare sector, but large benefits, eg, for the education sector, could be considered cost-effective, using a society perspective. Similarly, such guidelines require that healthcare cost effectiveness judgments not be based on ignoring costs which are shifted onto families or to other economic sectors.

From a societal perspective, the costs would largely be the same [as for a business case analysis], but the benefits would be greater because they would also include benefits to the patient, such as reduced pain and suffering, decreased length of stay, and averted lost income.

Maviglia et al., 2007

Return on investment analyses and business cases, are typically based on profits and losses only to *individual institutions* arising from new investments in patient safety [Weeks, 2003; Oetgen, 2003; Dimick, 2006; Zhan, 2006; Hwang, 2007]. It has been argued that executives violate their fiduciary obligations to their organization by considering benefits that accrue outside the organization [Schmidek & Weeks, 2005], even when these are improved outcomes for patients. Unlike economic analyses, these forms of financial evaluation take into account transfers of resources, such as increased revenues to the organization (including grant income [Brown, 2007]).

Unmeasured costs of interventions have led to a general perception that all safety improvements are cost-saving. Business case analyses typically require a ‘cost saving’ outcome, and thus are better at quantifying the costs of proposed interventions. But cost saving has not been the standard expected as the justification for new treatment technologies; cost effectiveness is based on value for money, not cost-savings.

These differences in perspective will not matter in some circumstances: interventions with a positive return on investment for individual institutions (provided they are not based on shifting costs to other stakeholders), should have a positive ratio of benefits to costs as well. Karnon and colleagues [2008] have demonstrated, for example, that costly interventions such as computerised physician order entry (CPOE) systems, are inevitably cost-increasing when patient benefits are not quantified and included in the analysis.

Predicating safety efforts on the mistaken belief in a short-term return on investments will stall patient safety efforts.

Pronovost, et al., 2008

How much does effective reduction in the incidence of adverse events cost?

In spite of a general movement toward more rational healthcare decision-making, very few patient safety interventions have had formal economic evaluations [Auerbach, et al., 2007]. *Table 3* notes the three studies found in this survey that have tried to quantify costs of an intervention; *Table 4* summarizes five additional studies that compare both costs and benefits of adverse event reduction efforts. Such studies inevitably reflect the other two problems highlighted in this survey of the literature: no agreed outcome measures, and inconsistency in how costs are measured.

No economic studies were identified that tried to quantify the actual or potential costs of actions to avert medical errors or adverse events...
Gray, 2003

Program costs may be similar from one healthcare setting to another where the intervention is technology-based (such as CPOE systems), but vary between settings when a large proportion of the intervention cost is labour. Thus real attention needs to be focused on relative wage rates, overtime arrangements and other labour costs, as well as ‘uptake’ (or ‘buy in’ or ‘compliance’) for behavior change interventions, such as hand washing policies.

When decision-analytic models are used [Hunink, et al.,2001], they give policy makers guidance as to the sensitivity of conclusions to estimates included in the models. These can guide research funding decisions to achieve better (and more local) estimates of critical parameters.

Discussion

This section highlights the main lessons available from this sparse literature, and Canada-specific gaps in the research literature.

Tables 1 and 2 demonstrate that the most common type of economic research on patient safety issues is a ‘cost of illness’ study. Regardless of the metrics used to report on the issues, extrapolation to ‘a 400 bed hospital’ or the entire healthcare system inevitably results in very big numbers being reported. While such estimates may be useful to motivate changed thinking about patient safety, they do not provide information about which problems to focus on: what changes in healthcare delivery are most effective for which type of problem? What costs would such changes incur? What net gains are likely (in terms of both improved patient outcomes and costs of treatment)?

Definitions of desirable and undesirable outcomes are fraught with controversy. Methods such as chart review for identifying changes in outcomes are often prohibitively expensive outside a research

context. Voluntary reports require a high level of trust in an organization to give valid measures, and are unreliable to measure changes over time. Less costly evidence-gathering approaches have not been routinely used in the patient safety literature. The value of common outcome metrics across studies is increasingly recognized in the literature, but not yet well-represented in empirical studies.

Moreover, available evidence is not easy for decision-makers to extrapolate to their decision context. Only a small number of good quality Canadian studies reporting economic outcomes are available, and these reflect the limitations of the international literature. Most of the ‘international’ studies are from the United States. The general features of healthcare are broadly similar to those in Canada, and clinical and program success estimates could be used here, provided ‘uptake’ or health worker ‘buy in’ to safety programs is demonstrated to be similar. But the US higher expenditure per capita and the complexity of the multi-payer environment make cost extrapolation particularly unreliable in Canada. Canadian studies are essential for setting priorities and estimating cost-effectiveness of programs in Canada.

A key to better investment in patient safety is a better understanding of the costs of interventions. Great advances have been made in identifying robust evidence on the efficacy of a range of recommended patient safety initiatives [Shojania, et al., 2001]. Estimating costs of these interventions is much more context specific, and estimates need to reflect relative investments in labour vs capital, staffing profiles, factor prices, and other economic variables that differ between jurisdictions and healthcare systems. All the caveats that apply to costing in cost of illness studies also apply to costing of interventions. Explicit reporting of costing approach, component costs, and costs as a percentage of care per admission or per day of stay would assist decision makers in extrapolating to their own settings.

Although acute care is the single largest expenditure item in Canada, as elsewhere, it is not clear how frequent and how serious patient safety events are outside hospitals, including ambulatory medical care and long term residential care. These settings are not well represented in the patient safety economics literature. Post-discharge acute patients are also not well-represented, and this is of

particular concern with average length of stay (ALOS) declining and a higher proportion of treatments being provided on a same-day basis. These cases have probabilities of adverse events nearly as high as inpatients, but their care is less well-monitored and documented.

Additional research is also needed into the incidence and types of AEs beyond the acute care hospital setting.

Baker, et al., 2004

Conclusion

It is relatively easy to take findings from a cost of illness report and extrapolate to an entire healthcare system. However, such estimates do not answer the economically important question: where should the next dollar be spent?

Cost-effectiveness analysis (and the closely-related cost benefit analysis) attempt to quantify all outcomes in support of decision-making. Cost-effectiveness is more often used in healthcare because of the difficulty in translating benefits (lives saved, infections avoided) into monetary terms, as required in cost-benefit analysis [Drummond, et al., 2005; Gold, et al., 1996]. Increasingly, cost-effectiveness analyses in healthcare uses a composite measure, the Quality Adjusted Life Year (QALY, or variants) to combine *quantity* of life gains with the more intangible *quality* of life benefits provided by healthcare interventions. Few studies were found that quantified patient safety program benefits in terms of QALYs; estimates of the order of magnitude of patient harms (other than mortality rates) would assist the priority setting process. Giving due recognition to the goal of improving patient welfare, cost-effectiveness/cost-benefit analyses provide decision makers with a clearer appreciation of the cost *per health gain*, and allow comparison with other healthcare interventions.

Financial analyses (‘business case’ or ‘return on investment’ studies) are championed in the patient safety literature because they take the perspective of the hospital or other institution that will bear the costs of any program. They generally have the goal of estimating cost savings, or the time to break-even on an investment in patient safety. They frequently include revenue opportunities or other financial benefits that are difficult to extrapolate to other systems, and do not represent true economic benefits.

That said, many are conducted with an implicit goal of improved patient outcomes (that is, recognizing though not quantifying wider benefits to patients rather than strictly the financial well-being of the hospital or institution). So long as economic transfers are not included on the benefits side, such financial analyses closely resemble a cost-effectiveness study. Because individual institutions currently bear all the costs of improved patient safety (and with fixed budgets, none of the benefits), business case analyses will continue to be of interest to institutional decision makers. Beyond the individual institution, they can be useful in ‘ruling in’ particular interventions, but should not be relied on to ‘rule out’ patient safety investments when patient benefits are not explicitly considered.

Some interventions may be cost-saving, and some may also meet a business case criterion, but they are likely to be a very small subset. Using only a business case approach would imply that the willingness to pay for health gain was zero.
Gray, 2003

This survey of the literature has not addressed the question of pay for performance or other funding innovations that seek to share the costs of patient safety improvement among stakeholders in the healthcare system. There is a growing literature on how routine hospital funding and reimbursement of healthcare providers can be modified to encourage and reward harm reduction efforts [McNair, et al., 2009; Clancy, 2009; Christianson, et al., 2008; Zhan, et al., 2006]. These have developed alongside more conventional approaches such as grant programs from government or other funders to

encourage providers to adopt specific patient safety practices. Until the benefits of improved patient safety accrue to those who bear the costs, widespread adoption of effective patient safety interventions is less likely. There are many ways in which this consonance in goals can be achieved (activity-based funding of hospital care, pay for performance arrangements, etc.), but precise recommendations are beyond the scope of this report.

Whoever is the ‘decision-maker’, they will need practical tools to make judgments about how to spend scarce healthcare dollars. Competing priorities arise every day and patient safety is only one of many claims on the healthcare budget. Use of simple economic decision-analytic models can combine the information valued by different stakeholders to yield information on the incremental cost effectiveness of specific interventions [Graves, et al., 2007]. Simple online tools to facilitate such analysis could be developed (see [AHRQ, 2009] for an example of such a tool for estimating the return on investment of better asthma control in different populations). Intervention costs will still be weighed against the marginal funds available, and risks inherent in not funding the various alternatives. Demonstrated patient harms and documented cost-effectiveness of harm reduction strategies are powerful policy tools in gaining wider acceptance for investment in patient safety.

The use of decision-analytic modelling techniques to assist in answering questions about comparative effectiveness and cost-effectiveness in healthcare is well established for drugs and devices [Hunink, et al., 2001; Drummond, et al., 2005]. They allow combining data from different sources, rather than requiring single studies that quantify all the key variables.

Conventional economic evaluation entails combining estimates of:

- hospital or other healthcare costs that can be attributed to adverse events
- estimates of patient welfare losses attributable to adverse events
- evidence of the effectiveness of patient safety programmes
- estimates of program costs of efforts to avoid or ameliorate such events.

These variables are assigned values available from published sources (or plausible estimates when no published sources are available, as will be the case for many patient safety interventions). In particular, little work has been done to measure program costs or patient outcomes other than mortality. Typically a model will consider a hypothetical cohort of patients experiencing the therapeutic alternatives. Comparisons can be between two alternative interventions or between an intervention and ‘normal care’ or other minimal/no intervention alternative.

While models that rely on ‘plausible estimates’ are not strictly evidence based, they could be made more rigorous than the current basis of decision-making on patient safety interventions. Moreover, sensitivity analysis using decision-analytic models can identify the critical variables that affect cost-effectiveness judgments for particular programs, suggesting where additional research could narrow the range of uncertainty around these key variables. When conclusions change if the value of key variables is varied across a plausible range (typically using the best estimate as a base case, and high and low estimates to test sensitivity), the findings are said to be sensitive to assumptions about the value of those variables. Such evaluations can be included as part of the planning of interventions to highlight which features of a proposed intervention are economically important.

Canada has considerable expertise in evaluation of new technologies and drugs in healthcare. The Canadian Agency for Drugs and Technologies in Health (CADTH) provides Canada’s federal, provincial and territorial healthcare decision makers with impartial advice and evidence-based information about the incremental cost effectiveness of drugs and other health technologies. Canada’s research strength in evidence-based medicine is founded on multiple provincially-based research centres with expertise in comparative effectiveness and cost-effectiveness research.

This survey of the literature on the economics of patient safety has identified a number of problems that reduce the usefulness of evidence from published studies. The first is that the strongest evidence is ‘cost of illness’ evidence: there is no doubt that adverse events in healthcare increase treatment costs significantly. What is missing is good comparative evidence on which practical decision making can be based. Researchers and policy makers have not agreed on standard

definitions of reduction-worthy ‘events’ and how they should be measured. Most measurement techniques are labour-intensive and thus expensive. Most entail definitions that cover only a small portion of the spectrum of patient harm during healthcare, or rely on distorted voluntary reporting of such events.

Research attention has focused on hospitals, where it is likely that the largest potential for patient harm arises, and the largest proportion of health budgets is spent. But because other healthcare settings (particularly ambulatory prescribing and long term care) have been so infrequently investigated, it is not possible to say where the largest burden of patient injury, illness and health system cost lies.

Cost estimation is a particular weakness of the cost of illness and cost of intervention studies reported here: estimates come largely from studies in the United States, where overall healthcare costs are higher, and patterns of spending are likely to be different to those in Canadian healthcare. ‘Costs’ are most often estimated using billed charges, and these are known to distort estimates because hospital markups on services differ between service lines, and between institutions.

More strategic investment in patient safety in Canada can only be based on knowing the effectiveness of interventions in the context of Canadian health services, and equally importantly, on the costs incurred in treatment of adverse events and in the reduction of incidence in the Canadian healthcare system.

Research to support such strategic investment would entail studies that:

- provide better *Canada-specific information* on a comprehensive range of healthcare-acquired harms (rather than focusing on indicators designed for public reporting);
- support *validation studies* of routinely collected hospital and other healthcare data (including data on costs) to make these sources more credible in patient safety research and routine monitoring;

- investigate data sources for health care ***beyond acute hospital care***, to ensure that research gaps for these treatment settings (home care, ambulatory medical care and long term care) are addressed;
- use ***data linkage*** to better understand the sequelae of hospital-acquired illness and injury (including post-discharge utilization of healthcare services), and longer term care issues for out-of-hospital healthcare harms;
- quantify losses due to the ***full range of healthcare-acquired harms*** to set more rational priorities for effectiveness and cost-effectiveness studies;
- support only those intervention studies that included a means of ***estimating the costs of the intervention*** and comparative information about the costs of usual care;
- develop ***tools to make routine cost-effectiveness analysis*** an integral part of program planning, program evaluation and future priority setting for research;
- pilot ways in which ***information on the costs and benefits of interventions*** can be routinely reported back to healthcare teams to motivate continuing effort to reduce adverse events in their healthcare setting.

Preventing medical errors can result in greater access to the health-care system. Until this relationship between patient safety and access to care is acknowledged, attempts at reform will remain focused on increasing supply of services rather than decreasing demand, in part, by decreasing error rates.

Morgan, 2004



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Table 1: Overview of International (non-Canadian) studies with reported economic outcomes (1999-2009)

<i>First Author</i>	<i>Publication Year</i>	<i>Health System</i>	<i>Event Type</i>	<i>Costing Approach</i>	<i>Estimate denominator</i>	<i>Published Cost Estimate*</i>	<i>Estimate for Extrapolation</i>	<i>Notes</i>
Hospital Inpatient Events								
Jha	2009	US	Preventable portion of 10 'major adverse event' types	Literature review of US-based studies	Modelled at risk inpatient populations	+16.6 bil \$US extrapolated to whole population +40.5 bil \$US ('ideal' including currently non-preventable)	+5.5% \$US national inpatient costs +13.5% \$US ideal (all adverse events)	53.2% deemed 'preventable'
Paradis	2009	US	Voluntary reports of 'patient safety events'	Billed charges	Events	+22% days LOS +17% \$US	+22% LOS +17% \$US	
Hoonhout	2009	Netherlands	Adverse events and 'preventable' adverse events	Reviewer estimates of attributable days and surgeries * 'standardized costs'	Patient (incl. multiple admissions)	+9.1 (10.3) days LOS +4,555 (5,286) EURO	+3% beddays +1% national health care costs	40% deemed 'preventable'
Jackson	2008	Australia	CHADx (hospital-acquired diagnoses)	Patient-level measured costs	Events	+14.6% \$AU	+14.6% \$AU	Regression-based adjustment for confounding
Ehsani	2006	Australia	Routinely coded 'hospital acquired diagnoses'	Patient-level measured costs	Discharges	+10.1 days LOS +\$6,826 \$AU	+15.7% \$AU	Regression-based adjustment for confounding
Zhan	2003	US	18 AHRQ Patient Safety Indicators (PSIs)	Billed charges	Events	0- 10.9 days LOS 0-57,727 \$US	Cost and LOS of control patients not reported	Regression-based adjustment for confounding; LOS and \$ only for individual indicators
Brown	2002	New Zealand	Adverse events	Overseas patient tariffs	Discharges	+9 days LOS +10,264 \$NZ	+30% \$NZ	67% deemed 'preventable'
Vincent	2001	UK	Adverse events	Reviewer estimates of attributable days	Events	+8.4 days LOS	LOS of control patients not reported	
Rigby	2000	Australia	12 'preventable' iatrogenic injury types	DRG-based	Discharges	2-3% of costs	+2-3% \$AU	

Table 1: Overview of International (non-Canadian) studies with reported economic outcomes (1999-2009) cont'd

<i>First Author</i>	<i>Publication Year</i>	<i>Health System</i>	<i>Event Type</i>	<i>Costing Approach</i>	<i>Estimate denominator</i>	<i>Published Cost Estimate*</i>	<i>Estimate for Extrapolation</i>	<i>Notes</i>
Adverse Drug Events								
Karnon	2008	UK	Preventable Adverse Drug Events (pADEs)	US charges converted to £ using PPPs	drug orders	+ 1,387 £	Cost and LOS of control patients not reported	Modelled on 400 bed hospital from US incidence & costs
Maviglia	2007	US	Preventable Adverse Drug Events (pADEs)	Microcosting	drugs dispensed	+4,600 \$US (from Bates, 1997)	Cost and LOS of control patients not reported	Net benefit 3.5\$US mil after 5 years
Transfusion Events								
Zilberberg	2008	US	Transfusion-attributable acute respiratory distress syndrome	Costs modelled on published reports	Discharge	+14 days LOS +\$35,291 \$US	Cost and LOS of control patients not reported	
Surgical events								
Jacobsen	2007	US	Major procedural complications	Billed charges	PCI procedures	+4.5 days LOS +6,984 \$US +15,586 \$US (unadjusted*)	+237% LOS +127% \$US	Disease staging and generalised linear modelling adjustment of confounding
Zerey	2007	US	Clostridium difficile in surgical patients	Billed charges	General surgical discharges	+16 days LOS +77,483 \$US	Cost and LOS of control patients not reported	Regression-based adjustment for confounding
Thompson	2006	US	Hospital-acquired pneumonia	Billed charges	Intra-abdominal surgery discharges	+11 days LOS +28,161 \$US	+182% LOS +75% \$US	Regression-based adjustment for confounding
Ehsani	2006	Australia	Cardiac surgery complications	Measured patient level costs	Cardiac surgical discharges	+7.33 days LOS +5,751 \$AU	+ 27.5% to cardiac surgery costs	Regression-based adjustment for confounding
Kozlow	2004	US	Aspiration pneumonia	Billed charges	Surgical discharges	+9 days LOS +22,000 \$US	Cost and LOS of control patients not reported	Regression-based adjustment for confounding

Table 1: Overview of International (non-Canadian) studies with reported economic outcomes (1999-2009) cont'd

<i>First Author</i>	<i>Publication Year</i>	<i>Health System</i>	<i>Event Type</i>	<i>Costing Approach</i>	<i>Estimate denominator</i>	<i>Published Cost Estimate*</i>	<i>Estimate for Extrapolation</i>	<i>Notes</i>
Hospital acquired infections								
Kilgore	2008	US	Nosocomial infections	Measured clinical costs	Discharge	+5.4 days LOS +7,007 \$US	+94.1 % LOS +89.5% \$US	Regression-based adjustment for confounding
Pirson	2008	Belgium	Hospital acquired sepsis	Measured clinical costs	Infection	+16,709 € (adj) +19,301 (unadjusted) +29.8 days LOS +6.1 days ICU/LOS		Adjustment for admitting diagnosis (DRG) only
Sparling	2007	US	Surgical site infections in Paediatric patients	'Costs from hospital financial systems'	Discharge	+ 10.6 days LOS + 27,288 \$US	+107% \$US	Matched case adjustment
Roberts	2003	US	Hospital acquired infections	Microcosting	Infection	+10.7 days +18,300 \$US	+249% LOS +175% \$US	Regression-based adjustment for confounding
Plowman	2001	UK	Hospital acquired infections	Microcosting	Discharge		+209% £	
Kollef	2005	US	Health care associated pneumonia	Billed charges	Discharge	+1.3 days LOS for HCAP* +7.7 days LOS for HAP* +15.5 days LOS for VAP*	+2,429\$US for HCAP* +40,074 \$US for HAP* +125,023 \$US for VAP*	* Increased LOS and costs reported in comparison with Community Acquired Pneumonia only; HCAP= health care associated pneumonia; HAP=hospital acquired pneumonia; VAP=ventilator associated pneumonia; calculated from Table 5.
Brilli	2008	US	Ventilator associated pneumonia in a paediatric ICU	Daily measured patient cost	Discharge	+8.7 days LOS +51,157 \$US	+48.9% LOS +48.7% \$US	

Table 2: Overview of Canadian studies with reported economic outcomes (1999-2009)

<i>First Author</i>	<i>Publication Year</i>	<i>Event Type</i>	<i>Costing Approach</i>	<i>Estimate denominator</i>	<i>Published Estimate</i>	<i>Estimate for Extrapolation</i>	<i>Notes</i>
Hospital Inpatient Events							
Baker	2004	Adverse events	Reviewer estimates of attributable days	Patients	+6 days LOS	+177.5% days	<i>Calculation from Table 4</i>
Emergency department							
Forster	2007	Adverse events	Health care utilisation only	Patients sent home from ED	+62.5% patients return for further treatment	+62.5%	
Intensive care unit							
Forster	2008	Adverse events	Health care utilisation only	ICU admissions	+15 days ICU LOS + 31 days LOS		19% deemed preventable
Computerised Pharmacy Order Entry							
Wu	2007	Adverse drug events	Event rate, equipment purchase and support costs only	None	No utilisation estimates used in model	No utilisation estimates used in model	Cost-effectiveness conclusions based only on reduction in rates; health and healthcare utilisation effects not included.
Surgical events							
Khan	2006	Non-cardiac surgery complications	DRG-based	Non-cardiac surgical discharges	+7.1 days LOS +3,037 \$CDN	+101% LOS +110% \$CDN (+71% adj \$CDN from Table 2)	Regression-based adjustment for confounding; calculated from tables

Table 3: Reported program costs for prevention of specific types of adverse events (1999-2009)

<i>First Author</i>	<i>Publication Year</i>	<i>Health System</i>	<i>Event Type</i>	<i>Costing Approach</i>	<i>Estimate denominator</i>	<i>Published Estimate*</i>	<i>Notes</i>
Hospital Inpatient Events							
Fukuda	2008	Japan	All hospital activities to prevent adverse events	Microcosting converted to \$US	Patient day	9.86 \$US	
					Equivalent full time staff/yr	26	
Bar Coded Drug Dispensing							
Maviglia	2007	US	Adverse drug events	Microcosting	Averted ADE	+1,976 \$US (yrs 1-4) +873 \$US (yr 5 onward)	Net benefit after 5-10 years (depending on assumptions)
Surgical Events							
Egorova	2008	US	Retained surgical instruments	Measured clinical costs	CABG surgeries with discrepant counts	932 \$US	Questions cost-effectiveness of materials counts in theatre

Table 4: Studies reporting incremental cost-effectiveness or net benefit (1999-2009)

<i>First Author</i>	<i>Publication Year</i>	<i>Health System</i>	<i>Intervention</i>	<i>Event Type</i>	<i>Type of Sensitivity Analysis</i>	<i>Variables tested</i>	<i>ICER/ Net cost:benefit</i>
Computerised Physician Order Entry (CPOE)/Bar Coding							
Maviglia	2007	US	Bar Coding	Preventable ADEs	1-way, 2-way and Monte Carlo simulation	All	Net benefit after 5-10 years (depending on assumptions)
Karnon	2008	UK	CPOE, bar coding, employment of additional pharmacists	Preventable ADEs	Hi/Low; Monte Carlo holding intervention cost at one of two levels	All	Net costs when health benefits not included; net benefit of £31.5 mil over 5 years when lost health is assigned a monetary value and included.
Wu	2007	Canada	CPOE and administration system	ADEs	1-way	5 most uncertain variables	ICER: 12,700 \$US (converted from \$CND) per ADE avoided
Ventilator-associated Pneumonia (VAP)							
Shorr	2009	US	Silver coated endotracheal tubes	Ventilator associated pneumonia (VAP)	Multivariable	All	Cost-saving when tubes <388 \$US
Blood stream infections							
Hochenhull	2008	UK	Anti-infective central venous catheters	Blood stream infections	Multivariable	All	Cost saving (£138.20 per patient treated with an AI-CVC)

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