QUANTITATIVE APPROACHES TO PATIENT SAFETY

Research in Risk Analysis and Risk Management as Applied to Radiotherapy
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Research in Risk Analysis and Risk Management as Applied to Radiotherapy

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Preface

The Alberta Heritage Foundation for Medical Research (AHFMR) health technology assessment initiative series, commenced in March 2000 with “A Framework for regional health authorities to make optimal use of health technology assessment.” The purpose of this series is to provide policy and decision-makers with the best information available on how to redesign their healthcare structures and processes to effectively improve the outcomes of their healthcare delivery systems. This paper undertakes to introduce and describe an innovative approach to facilitating patient safety – risk assessment and risk management analysis. Although their subject of study is radiotherapy the authors encourage the application of the approach to other healthcare interventions.

Other papers in this series are listed on the inside cover. Copies of these and other reports can be found at: http://www.ahfmr.ab.ca/frames3.html

If you have any comments or suggestions to make on this paper, I would be delighted to receive your feedback.

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ABBREVIATION LIST

US: United States of America
EBDM: Evidence based decision-making
TBCC: Tom Baker Cancer Centre
ACB: Alberta Cancer Board
QA/QC: Quality assurance/quality control
CHR: Calgary Health Region
FMEA: Failure mode and effects analysis
PRA: Probabilistic risk analysis
RCA: Root cause analysis
PRADA: Probabilistic risk and decision analysis
TNM: Tumor size, nodal status, metastasis
QALY: Quality adjusted life-year
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Introduction

“First, do no harm.” Yet, patient harm does occur in healthcare, despite the best intentions of providers and healthcare systems. But, how do we determine whether or to what degree a healthcare provider or system is harming patients? The US Institute of Medicine’s report of 44,000 to 98,000 deaths per year in the US attributable to medical errors (1), and recent estimates for Canada of approximately 185,000 adverse events per year (2) are staggering. How does a healthcare organization effectively assess and manage medical incidents in which patients are subjected to deviations from beneficial pathways of care? Further, as innovation, dissemination, and implementation of medical technologies increase at an exponential rate, the potential exists for new and highly uncertain risks to also be introduced into healthcare at an exponential rate. An implicit assumption is often that new technologies somehow confer a net increase in benefit to patients and organizations simply because they are “new and improved.” This is not necessarily the case.

We use the term incident because some of these deviations may result in harm to patients, and some may not; yet analysis of all can be informative. We are concerned with pathways of care, because patients are often subjected to multiple treatments from multiple providers, sometimes under multiple organizations. Further, many medical treatments result in harm, but the benefits outweigh the harm. For example, taking aspirin relieves a headache, yet may result in stomach bleeding. Determination of the net benefit of a pathway of care or technology, whether or not incidents occur, is clearly important. The appropriate balance of benefit and harm becomes more critical and difficult to identify with complex treatments such as cancer care. Choices are further complicated because resources are limited in healthcare, so the determination of the net benefit of a pathway of care or technology under resource constraints is particularly difficult.

There is no doubt that progress has been made in illuminating some patient safety issues and possible interventions; this qualitative work is the subject of recent reviews (3–5). There is general agreement that proactive, transparent approaches to patient safety (as opposed to reactive, “sweep-under-the-rug” historical approaches) are not only desirable, but essential. In this paper we argue that rigorous, quantitative approaches used in areas outside medicine involving human health risks such as nuclear safety, environmental regulation and food safety are not only applicable
and informative in healthcare, but will likely meet the requirements of a comprehensive and appropriate safety system for use in healthcare.

We argue that such approaches are desirable from several aspects, as discussed in detail later in this paper, but in general the advantages include:

- They are concordant with evidence based decision-making (EBDM), as practiced in clinical care;
- They address multiple objectives of multiple stakeholders;
- They address tradeoffs across the benefits, risks, and costs associated with different medical care alternatives;
- They address changes in technology that may be associated with increased or decreased potential for risk, and associated costs.

This paper summarizes the first steps in a research program designed to inform technology assessment and decision-making associated with radiotherapy (treatment of cancer with ionizing radiation) at the Tom Baker Cancer Centre (TBCC) in Calgary, Alberta. The TBCC is a comprehensive cancer care, education and research facility that is part of the Alberta Cancer Board (ACB) and closely associated with the University of Calgary. The intent of our project is to “raise the bar” in terms of how decisions are made regarding resource allocation for clinical risk management. The TBCC serves as a field test for an ongoing research program approach that may have general applicability in many areas of medicine.
Research Team

The project started with a chance encounter in 2002 between a risk analyst (Lee) and a medical physicist (Dunscombe); both new to the Faculty of Medicine at the University of Calgary. Lee had previously spent many years consulting in risk analysis and risk management in a variety of settings. Dunscombe, although primarily a radiation oncology physicist, had also been active in activity-based costing and health economics in clinical settings for several years. Soon after this informal collaboration began, two radiation oncologists (Kelly and Craighead) joined the group. Craighead, in addition to his clinically oriented research, has worked in the area of health services delivery. More recently, an additional medical physicist and former international management consultant (Newcomb) joined the team. Additional content experts have been consulted on specific aspects of the project.

An initial major challenge was securing research funding for the project. Capacity was needed to help the team collect information and to model the system. Because many of the approaches that we desire to implement are novel to healthcare, we did not expect to find anyone with direct experience in such approaches, so we sought an individual with general experience in mathematical modeling and decision science methods. Funding was secured from the Canadian Institutes of Health Research, and an engineer with expertise in uncertainty management in intelligent systems (Ekaette) was hired. Additional research funding is being applied for on a continuous basis to recruit additional staff for various aspects of the project. For example, a recent Ph.D. graduate in operations management with many years of safety management experience in industry (Cooke) has been recruited for a postdoctoral fellowship in patient safety. This project, as well as other similar projects, are being conducted under a larger research program called the Health Technology Research Group (HTRG); part of the Department of Community Health Sciences (Faculty of Medicine), the Centre for Health and Policy Studies, and the Southern Alberta Cancer Research Institute at the University of Calgary.
Problem Formulation

3.1 Conceptual process

The conceptual process that we are following is illustrated in Figure 1. This is a generalized framework based on common sense, as well as methods employed in statistical decision theory and strategic planning that have been well established since the 1960s (6). The key to this process is that it is not only qualitative, but that it can be represented by a quantitative model, in the spirit of the following maxim: In order for risks to be effectively managed, they must be quantified. This is a fact that is recognized in nearly every other industry (insurance, financial management, industrial safety, nuclear safety, aerospace, environmental management; to name a few), but remains largely unrealized in healthcare.

Risk is not an abstract concept; rather, it is defined as a function of the probability and severity of adverse events (7-9). If risk is quantified, then reduction in risk by means of risk management can be measured and tracked. However, risks are perceived differently by scientists and engineers as compared to individuals without quantitative training; thus, proper communication of risk is critical (10).

3.2 Patient safety in radiotherapy

This team recognized early on that quantification of risk was desirable, and the first step was to define the decision context and the question. Radiotherapy for cancer is a critical medical procedure that occurs in a complex environment involving
numerous health professions, complex machines and hardware, as well as software. The potential exists for rare incidents that can lead to inappropriate administration of radiation to patients, with potentially catastrophic consequences such as premature death or appreciably impaired quality-of-life.

Catastrophic incidents have occurred in radiotherapy in some jurisdictions (Table 1). We define catastrophic incidents as incidents that result in patient mortality or severe loss in quality-of-life. As one example, in Canada in the 1980s, Atomic Energy of Canada Limited introduced a radically new, progressive design of linear accelerator featuring a large degree of computer control. A design fault resulted in lethal burns for three patients and several others received serious radiation misadministrations (11-15). Incidents involving misadministration can also occur in the opposite direction; i.e. if a patient does not receive adequate therapy, their cancer can progress unnecessarily. Based on media observations (11;15), multiple fatalities or injuries are of greater public interest than individual incidents, and thus reported incidents can be expected to comprise only a fraction of those incidents actually occurring.

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Number of Patients Affected</th>
<th>Cause</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985-87</td>
<td>Canada</td>
<td>6</td>
<td>Faulty design</td>
<td>Death, morbidity</td>
</tr>
<tr>
<td>1988</td>
<td>England</td>
<td>207</td>
<td>Miscalibration</td>
<td>Death, morbidity</td>
</tr>
<tr>
<td>1999</td>
<td>Panama</td>
<td>9</td>
<td>Software bug</td>
<td>Death, morbidity</td>
</tr>
<tr>
<td>1988-99</td>
<td>Japan</td>
<td>254</td>
<td>Technician error</td>
<td>Morbidity</td>
</tr>
</tbody>
</table>

Although quality assurance/quality control (QA/QC) mechanisms are in place in all modern cancer treatment facilities, we feel there is still room for improvement. In particular, we see an increasing need to:

- Predict the probability of such incidents;
- Determine whether current QA/QC mechanisms are truly adequate for risk management (i.e. in terms of reduction of probability/consequences of catastrophic events), and to assess alternative mechanisms;
- Determine whether resources are being expended in the most efficient way to prevent such incidents, while providing high quality patient therapy.
Thus, the fundamental decision objectives or goals of our project can be represented as:

- Maximizing patient quality-of-care;
- Minimizing patient harm;
- Staying within resource constraints.

There are other objectives that may be important, such as maximizing provider satisfaction, minimizing the potential for legal action, and the like; but at the beginning of the risk management process our desire has been to concentrate on the above risk dimensions of the problem.
Challenges Associated with Patient Safety Risk Management in Healthcare

Once it is recognized that quantification of risk is desirable and a problem is roughly defined, then a challenge arises with regard to information. Reliable quantitative risk information in healthcare is often lacking compared with other fields and is subject to large biases (1,16,17). So how can reduction in risk be determined? One way forward is to collect data. This is a major reason for current efforts to implement incident reporting systems and electronic health records. This is likely a reasonable and efficient way to address frequent incidents in a retrospective fashion, but what about proactive management of rare incidents that result in catastrophic consequences (e.g. Table 1)? Such events are rare, but particularly as they may involve multiple patients and/or catastrophic consequences not only associated with the patients themselves, but with diversion of resources, potential litigation, etc., the need for management of both systematic and random incidents becomes apparent. A challenge associated with risk management of rare events lies in prediction of these events, even if they have not occurred. Standard statistical analyses are obviously of little utility in such situations.

An additional challenge is to explicitly evaluate the tradeoffs associated with risk management strategies. All risk management costs something, be it time, money, human, or other resources. Resources spent on risk management may be better spent on other aspects of healthcare. This becomes particularly important in a publicly funded healthcare system, where hospitals or regions operate under a limited budget controlled by government agencies. Indeed, in an integrated system such as the ACB or the Calgary Health Region (CHR) in Alberta, if increased resources are spent on risk management in one healthcare department or hospital, then the care of patients in another hospital or component of the healthcare system may be compromised. In the quality management field, quality is often viewed as being free, as expenditures on quality improvement are often paid back many times by the value realized. It is unclear whether this is the case in healthcare settings, particularly in publicly funded systems. Research of the type described here is likely be informative in this regard.
From another perspective, if a healthcare system mandates a risk management strategy, but has not accounted for the preferences of providers, legal constraints, union issues, and the like, then an obviously suboptimal situation will result. Further, many risk management strategies impose a new set of risks. For example, say a healthcare system implements a new technology, such as an electronic health record system with a major goal of reducing prescribing incidents. What are the risks associated with the electronic system itself (e.g. what happens when, not if, it crashes?). How do these risks compare to the benefits conferred by the new technology, and how can the risks be effectively and efficiently managed? Standard financial and economic analyses do not address these tradeoffs, and are thus of limited utility to decision-makers.

Figure 2: Different types of health technology research activities

Health Technology Research Group

Institutions
- University of Calgary Centre for Health and Policy Studies
- Southern Alberta Cancer Research Institute
- Calgary Health Region
- Alberta Cancer Board

Funders
- Canadian Institutes of Health Research
- Alberta Heritage Foundation for Medical Research
- Health Quality Council of Alberta
- Institute of Health Economics
- Other Funders

Assessment
- Systematic reviews
- Cost studies

Appraisal
- Risk analysis
- Cost-effectiveness analysis
- Benefit-cost analysis
- Multi-attribute decision analysis
- Field evaluation

Implementation
- Risk management
- Operations management
- Priority-setting

Evaluation
- Field evaluation
- Organizational learning

Iterative Research and Applications
Risk management is intimately tied with technology assessment. For example, Canadian cancer treatment programs are considering various forms of stereotactic radiosurgery facilities. Although a literature review and a costing study have been conducted and published by the Alberta Heritage Foundation for Medical Research (18–19), such new technologies potentially introduce a new set of benefits, risks, and costs into a particular setting. An expanded definition of and role for technology assessment in healthcare settings may include the types of activities that we are currently pursuing through the University of Calgary HTRG (Figure 2), which cover the continuum illustrated.

The assessments under health technology assessment typically summarize and synthesize existing technical information regarding clinical effectiveness and financial costs. The analyses under health technology appraisal incorporate explicit consideration of risk, as well as socioeconomic considerations and tradeoffs across different objectives or goals in decision-making. The activities under health technology implementation are oriented toward evaluation of operational considerations and portfolio management. The studies under health technology evaluation are outcomes oriented and relate to program evaluation.

Appreciable challenges exist with regard to EBDM and systems thinking in patient safety, but these challenges are not insurmountable. Innovative approaches are currently being applied by the authors to address quantitative risk analysis and management of rare events in radiotherapy; these approaches are described in detail below. The overall goal of our research program is to provide a quantitative methodology that will inform QA/QC, risk management, and health technology assessment practices in healthcare. As the group’s expertise is primarily in radiotherapy we have chosen this area for our first case study.

We start by describing some other approaches that have been applied to patient safety in medicine, and then discuss and compare our approach to these other approaches.
Current Approaches to Patient Safety
Risk Analysis and Management

We performed a literature review to determine the state-of-the-art in patient safety risk analysis and management. The primary author and others previously conducted a review of risk and decision analysis methods in healthcare in general; the interested reader should consult this article and the references therein for additional information on the state-of-the-art in healthcare evaluation (20).

PubMed and Internet searches using the terms risk assessment; risk analysis; decision analysis; patient safety and medical error (no date limits) identified over 200 documents, for which abstracts or Web summaries were reviewed. Based on our review, the state-of-the-art in healthcare risk assessment and risk management (aside from ad hoc approaches) appears to be represented by approaches such as failure mode and effects analysis (FMEA) (21), which is a semi-quantitative, proactive approach with engineering origins currently employed by providers such as the US Veterans Administration (22). FMEA qualitatively characterizes a system, identifies potential failure points, assigns probability and severity categories, and incorporates this information into a decision matrix/flowchart (we use the term semi-quantitative because FMEA does not model the relationships between system variables, and does not explicitly address uncertainty).

Other qualitative/semi-quantitative approaches used to characterize potential system incidents include root cause analysis (23) and microsystems analysis (24), but neither technique quantitatively estimates probability and severity, and both are typically employed reactively, that is after an event has occurred. However, these approaches and FMEA are reasonable, important steps in identifying sources of potential failures leading to adverse patient outcomes. It is important to characterize human, organizational, technological, and information management sources of failure, because they are the key to identifying risk management alternatives (9).

Despite their utility, the methods outlined above do not completely inform a holistic risk assessment and management strategy in complex, technologically intensive healthcare systems because they do not:

1. Quantitatively model the relationships between events in the system;
2. Identify and track uncertainties associated with the system itself and system variables;
3. Address variability across patients, provider practice, facilities, etc.;
4. Address rare incidents;
5. Address multiple objectives important to a healthcare program, and tradeoffs across objectives;
6. Address resource constraints;
7. Address system changes such as new equipment, new personnel, etc.;
8. Address operational considerations.

All of these considerations are important in our present work. However, fully quantitative risk assessment approaches to patient safety are limited in the literature. An outstanding exception is the work by Pate-Cornell et al. (25;26), who examined anesthesia related risks with probabilistic risk analysis (PRA). PRA was developed in engineering, and has been applied in many scenarios ranging from nuclear safety to environmental assessment (7;8;27). Typically using simulation techniques, PRA estimates the probability and severity of adverse events by identifying potential incidents and propagating the uncertain probability of failure according to system characteristics.

Uncertainty analysis, an integral component of PRA, quantifies what is known and what is not known or incompletely known. Uncertainty, as used here, may be subjective such as the incomplete knowledge on the part of an expert or group of experts, but is always quantifiable in some sense. Uncertainty analysis is important where risk attitude is relevant: for instance where rapidly increasing aversion to increasing levels of risk exists, where uncertain information from different sources must be combined, and where decisions must be made regarding additional resource allocation to reduce uncertainty (28). All these factor into risk management decisions involving patient safety. Estimates of medical incident rates are likely to be undermined by large uncertainties and potential biases (16;17), but this has not been fully explored in the literature. For these reasons application of PRA is a useful direction in patient safety studies.

While PRA is useful in identifying risks and associated uncertainties, it does not directly guide risk management decisions. Decision analysis models (6) can be helpful in this respect, particularly because healthcare decisions involve important tradeoffs (29). Quantitative decision analyses examine comparative utility across different strategies. The utility of a strategy is an aggregated measure of how well that strategy attains decision objectives, which are quantitative representations of individual or organizational
values (30). Examples of objectives in healthcare are maximizing patient survival and quality-of-life, minimizing patient harm, maximizing compliance, and staying within resource constraints. Tradeoffs across multiple objectives are almost inevitable in patient safety risk management.

Based on our literature search, decision analyses addressing medical incident risk management in healthcare are limited. Many decision analyses of pharmaceuticals consider adverse effects without specifically addressing patient safety, typically using cost-effectiveness or cost-utility ratios, or more rarely, net benefit, as the outcomes (29). Provider safety has been addressed by Laufer and Chiarello (31), who examined interventions to prevent needlestick injuries; and AuBuchon and Littenberg (32), who examined cost-effectiveness of a mechanical barrier system to reduce mistransfusion risk. No examples of true multi-objective decision analyses addressing medical failure scenarios were identified.

Table 2 compares the different methods discussed here as well as others commonly in use, incorporating the desirable criteria for a risk assessment and management framework listed above.

Table 2: Comparison of different types of risk assessment and risk management analyses

<table>
<thead>
<tr>
<th>CRITERION</th>
<th>Ad hoc</th>
<th>Descriptive statistics</th>
<th>RCA</th>
<th>FMEA</th>
<th>Microsystems modeling</th>
<th>PRA</th>
<th>Decision analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Proactive/predictive</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>System-oriented</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Quantitative</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>Semi +</td>
<td>Semi +</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Addresses parameter uncertainty</td>
<td>-</td>
<td>Semi +</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Addresses variability</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Can model rare incidents</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Addresses multiple objectives</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Addresses resource constraints</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Addresses changes to the system</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

+ = method addresses this criterion  
- = method does not address this criterion.

Notes on methods:
Ad hoc: although different criteria may be met by an ad hoc process, there is no mechanism for ensuring that the criteria are met.
RCA: root-cause analysis.
FMEA: failure mode and effects analysis.
PRA: probabilistic risk analysis.
Probabilistic Risk and Decision Analysis (PRADA)

Healthcare providers and organizations need proactive, systematic risk management strategies that incorporate quantitative risk analysis, especially for complex scenarios. However, few examples of fully quantitative approaches to patient safety risk management exist in the healthcare literature, and none were located that combined the strengths of the powerful methods of PRA and multi-attribute decision analysis. This contrasts with work in industries with high potential public health or safety impacts (e.g. the nuclear power industry), and is unfortunate because quantitative methods potentially add so much value. The reasons for the limited use of quantitative approaches are unclear, but may relate to healthcare being typically expert or practice driven, as opposed to systems-analysis driven (1). Lack of training in quantitative analysis beyond descriptive statistics among those in the medical field may also be a contributing factor. Texts such as Clemen (6), Cox (7), Haimes (9),
and others referenced here provide useful methodologies and further references.

PRA can potentially characterize highly uncertain probabilities and consequences that influence decision-making. Based on the experience of the authors in quantitative methodologies, we believe that a holistic, multi-attribute probabilistic risk and decision analysis (PRADA) model (Figure 3 on the previous page) could potentially inform patient safety risk management and uncertainty reduction activities in technologically intensive healthcare institutions. FMEA and similar methods may serve as useful “front-ends” for such quantitative approaches in an integrated strategy, but we believe that adopting rigorous, quantitative techniques could advance the field of patient safety and address many of the shortcomings of existing qualitative assessment frameworks. To our knowledge, such a model has not been proposed for application to patient safety to date, and will be discussed in more detail later in this report.
6.1 Case study: process mapping and conceptual models for radiotherapy

Before we could proceed to model the radiotherapy decision, however, additional work was required to specify the radiotherapy system itself, and the variables in that system that may be subject to failure and therefore result in incidents. The qualitative system map that we devised, based upon extensive, iterative discussion among the co-authors, is represented in Figure 4.

The main path (Assessment, Preparation, Treatment, and Follow-Up) represents the general stages of care that occur once the patient enters the treatment facility. Within this path, specific clinical events occur which result in information or actions performed upon the patient. Decision nodes are indicated by boxes. Information is transferred throughout the process.

Treatment by radiotherapy typically occurs in many fractions over the course of several weeks. Although this system map is specific to radiotherapy in detail, note that the main path is generalizable to many forms of medical treatment. The map is hierarchical or layered in the sense that additional details can be represented to the degree necessary to represent the specific system under study and to inform the decision. The map is also the basis for quantitative evaluation of the benefits, risks, and costs associated with radiotherapy.

As an example of one component of this approach, the variables, decisions, and outcomes associated with the assessment stage (specific to radiotherapy for breast cancer) can be represented as in Figure 5 (see next page).

The assessment stage is represented here as an influence diagram (6) in which variables that have uncertainty associated with them as well as the potential for incidents are represented as ovals (i.e. probabilistic nodes). These variables represent the different sorts of information that are used to determine the “TNM” (Tumor size, Nodal status, Metastasis) classification (33) for a breast cancer patient's disease, which is a common basis for determining whether radiotherapy is appropriate for that patient. The decision to conduct imaging and the decision to pursue radiotherapy itself are represented as rectangles influenced by the probabilistic nodes (arrows). Influences on value of nodes are represented by dark arrows, while timing and/or structure influences are represented by lighter arrows. All information, tests and decisions in this representation have associated costs and health outcomes (positive and negative), represented as a
hexagon. Potential errors can occur throughout, but ultimately may be reflected in the decision to pursue radiotherapy.

This influence diagram structure is important because it is not only a visual, qualitative representation of important decisions at the beginning of the radiotherapy process, but it is the basis for a quantitative, computational model of the decision. Influence diagrams, as built in specialized software, incorporate calculations that are similar to decision trees, which are commonly used in medical decision analysis and economic evaluation (29). These methods can compare across different alternatives to determine which satisfy the objectives in better ways than others. Additionally, the impact that different sources of uncertainty can impose on making informed decisions can be assessed through sensitivity or value-of-information analyses (29).

The other three stages in Figure 4 can be represented in a similar fashion. The process of defining the variables and decisions associated with radiotherapy has been an interactive and challenging exercise for the research group. As in most complex processes, individuals tend to work in “boxes” or “silos;” doing their jobs without necessarily thinking about what other individuals or departments, units, etc. are doing. In a complex care pathway such as this, very few, if any, people can estimate tradeoffs and
rank alternatives “in their heads” in terms of preference. This may or may not be adequate on a day-to-day basis, but it certainly invites systematic failures to creep in. It could be argued that the process of individuals learning from other individuals is one of the most valuable components of the EBDM process as applied here. This is precisely why these tools are being developed; to help inform decisions.

As decisions regarding the benefits, risks, and costs associated with radiotherapy are hierarchical and complex, and we are in the process of defining some of the decisions, we do not describe all the details of modeling in detail here. Rather, we describe the process that we have followed in framing the decisions, and important considerations in methodology.

6.2 Decomposing and modeling the decisions

6.2.1 Uncertainty Assessment
We have expended much effort on different aspects of decomposing and modeling the decision as documented in Figure 1 (page 4). For example, the assessment influence diagram as illustrated in Figure 5 shows a range of different types of tests and procedures that can inform the TNM classification decision and the decision to pursue radiotherapy (for breast cancer, in this case). Each patient may not require all of the tests listed in the diagram. Different combinations of tests and procedures will be chosen based on their initial presentation. Certain standards are in place which help direct the proper assessment of patients while at the same time minimizing risk and satisfying resource constraints. By modeling different alternatives (different combinations of different tests and procedures), we can start to estimate which combinations are most beneficial to the patient in terms of proper assessment, which are associated with minimal risk, and which satisfy resource constraints. We emphasize the critical need to examine the impact of uncertainty.

As an example, consider the information value and potential for errors in a pathology review. Pathology information is critical to establishing the “T” and “N” components of TNM classification. The literature has shown that error rates of 1% to 6% can occur with regard to pathology misdiagnosis (34–36). If such errors are not caught by another individual (i.e., another pathologist, oncologist), then they can be potentially propagated through the treatment system so that a decision to pursue radiotherapy is made on wrong information, thus potentially leading to patient harm. At another level, the information produced by a pathologist essentially amounts to expert opinion. Assuming the same biological specimen, that opinion may vary across pathologists, and indeed within the
same pathologist from day to day (the degree of which is likely dependent on experience). Thus, even if the information is not wrong, it may be uncertain, and that uncertainty can impact a treatment decision.

Uncertainty must be quantified in order to determine its impact. Figure 6 illustrates common statistical representations of uncertainty, or precision, and accuracy, or bias.

“Precision” correlates to “uncertainty” here, and “accuracy” corresponds to “bias.” For example, a bathroom scale that on average displays one’s true weight, but which varies by some amount each time one steps on it, is imprecise and thus its display is associated with uncertainty. If the scale displays one’s weight with little variation each time, but the dial on the scale is set artificially low, then the display is precise but inaccurate, and thus biased.

With a bathroom scale, the degree of uncertainty and bias can be easily determined, but what about a subjective variable such as pathologist opinion? Bayesian statistical methods, which have been used by statisticians, engineers, and other quantitative disciplines for hundreds of years, are designed to quantify subjective uncertainty (6). As an example, say that five pathologists offer their opinion as to the probability that a particular set of biopsy slides indicates a particular type of the tumor. Say that their opinions are: 0.2, 0.3, 0.4, 0.5, 0.6. If this is all the information that exists, then we may start with a uniform distribution (or range of equal probabilities) from 0.2 to 0.6. This is what is known as a uniform prior distribution. This distribution may change if we recruit more pathologists (e.g. five more who all say 0.3), or if we conduct an interactive exercise in which all the pathologists are informed of the initial results. The art and science of formal expert elicitation is often employed in such cases (28).

Scientists and physicians who are trained in “classical” or “frequentist” statistics find this uncomfortable, because frequentist statistics are designed for analyzing data sets, not quantifying expert opinion or multiple sources of uncertainty. In fact, frequentist statistics can be viewed as a subset of Bayesian statistical decision theory; a subset to be used when one...
has adequate data sets (28). In many decision problems, though, like the radiotherapy issue we are evaluating, we have few data sets, and frequentist methods are not useful in terms of informing decisions. Bayesian methods that are designed to evaluate highly uncertain scenarios are more useful.

Proper evaluation of uncertainty is critical for many different reasons, but the most critical are:

1. determination of the driving, or most influential, sources of uncertainty in terms of the results of a model and thus a decision, as well as;
2. determination of the reliability of a model (28;37).

With regard to the first reason, a PRA model, and our proposed PRADA model, are explicitly designed to calculate the impact that each variable that goes into the model has on the outcomes. Referring to Figure 3, there will be a set of uncertain variables that represent the risks, benefits, and costs associated with any particular risk management strategy. Say that Strategy A is current practice, and Strategy B and C are alternatives designed to reduce risk of catastrophic patient harm. One way to calculate the impact of uncertainty is to simply model which variables impact the output of the model the most (using contribution to variance, rank correlation, or other statistical methods); but value-of-information is a more powerful method. In this method, the mean outcome value of each of the strategies (in terms of benefits, risks, and costs) is compared by running all of the model variables through the model using all their possible values. The differences between the outcomes are calculated as these variables are varied in a simulation, and a value for each of the variables can be calculated in terms of uncertainty reduction. In other words, reduction of uncertainty in the most uncertain variables will be most valuable in terms of an informed decision, and this value can be explicitly estimated in dollars, lives, or whatever measure is most informative. This provides direct and transparent information to a decision-maker in terms of where uncertainty reduction will help them make the best decision (6).

The second reason for proper evaluation of uncertainty in a predictive model relates to evaluation of the reliability of the model and its predictions.

6.2.2 MODEL RELIABILITY

Reliability is defined as a measure of confidence in a model’s predictions. Evaluation of the reliability of model predictions involves assessing the magnitude of uncertainty associated with model predictions, and the acceptability of that level of uncertainty in terms of decision-making (37).
Factors that can affect the reliability of model predictions are represented in Figure 7.

Note that this diagram is similar to Figure 1, but more focused on the model itself rather than the decision process as a whole.

Each of the factors in the figure can be associated with different sorts of uncertainty, or bias. For example, if an inappropriate question is asked, an inappropriate answer will result. Uncertainty analysis is usually targeted toward estimation of statistical distributions to be used in the model, but can also be applied to the model itself by examining the impact of different model structures on results.

In the present project, model reliability cannot be completely determined because, to our knowledge, catastrophic events have not occurred at the TBCC. In other words, our model results will always be hypothetical to some degree until such events occur (and of course we hope that they never do). This is not unlike famous failure scenarios such as space shuttle and nuclear power plant disasters, and extreme acts of terrorism such as “9–11.” A national incident report system would of course be useful, but it remains to be seen whether and how such information will be useful for the purpose of quantitative modeling. Regardless, the probability and consequences of such incidents can still be predicted by characterizing and modeling components of the system and thus managing risks, but the results will be
associated with a high degree of uncertainty. The key to a reliable model is capturing and quantifying this uncertainty to the degree possible, and then examining the impact on decisions. Decision-makers who are presented with single estimates of the probability of rare, catastrophic events are essentially being deceived!

Decisions involving management of catastrophic events are of course not only informed by probabilities, but by a number of other factors. Two considerations that are important in risk management are risk aversion, and the tradeoffs associated with resource constraints and other important factors.

### 6.2.3 Risk Aversion

Different levels of aversion to risk exist in any decision situation, according to the situation itself and dependent on the individuals involved. Different levels of risk aversion are shown in Figure 8.

These curves represent utility functions, utility representing the amount of value that different people would place on different outcomes, given a risky gamble or bet (38). In the case of the figure, a risk-averse physician may place decreasing value on incremental increases in life expectancy given an incrementally risky procedure; that is the physician may bet that she can give the patient one year of life expectancy, but probably not ten years if the risk is higher. Conversely, a risk-loving physician may bet that she can give the patient ten years with a highly risky procedure. Surprisingly little empirical work has been done with healthcare providers and organizations (39); but depending on the discipline, they likely span a wide spectrum of risk aversion. In another example, the business of high-risk financial trading where risk is defined as incorporating a two-tailed distribution of consequences (one can win big or lose big) likely attracts risk-neutral to risk-loving people; risk-averse people would get ulcers!

Government organizations such as environmental and traffic safety agencies tend to be risk-averse: they err on the side of safety. Regardless, it is important to capture risk aversion in any decision scenario, as the outcomes of risk management decisions may vary radically depending upon the individual or organization involved, as well as the context. For example, the ancillary risk of litigation in the US healthcare system is much higher than the risk in the Canadian system; thus risk-averse behavior may be more prevalent in US organizations and risk management practices to date may have differed (but this has not been empirically studied, to our knowledge).
In the present project, we are explicitly including risk aversion in assessing different alternative risk management strategies. As risk aversion is incorporated into the concept of utility, we feel it is important to assess the sensitivity of decisions to different degrees of risk aversion.

6.2.4 MULTI-ATTRIBUTE UTILITY

Risk aversion for a single utility outcome, life expectancy, is illustrated in Figure 8. Utility outcomes as decision objectives are quantified by attributes; in this case, the attribute is years of life gained as a result of some medical intervention (30). A decision in healthcare usually involves some level of maximizing years of life, degree of health, etc. However, a procedure that increases longevity may not necessarily increase quality of life; thus a tradeoff exists.

There are other important considerations in healthcare. Healthcare costs money and takes manpower, therefore there are resource constraints. There may be yet other constraints that would limit choices, such as laws or union rules. There may be other utility outcomes that are important to providers, such as maximizing physician or nurse satisfaction within an organization and with working conditions. These sorts of utility and constraint considerations need to be accounted for in important decisions, but they add a measure of complexity, because, in nearly all cases, a gain in health utility results in a loss of something else. This introduces the concept of multi-attribute utility, in which different objectives are traded off against each other, with the intent of finding an alternative that satisfies the most objectives in the best way possible.

For example, say we want to maximize the health benefit of radiotherapy, minimize the risk of patient harm, and stay within financial constraints. Health benefit is commonly measured by quality adjusted life-years (QALYs) gained, which is generally viewed as a preferable measure to “raw” life expectancy in that it can partially correct for the tradeoff mentioned above (28). Minimizing patient harm can also be measured by QALYs, or on another scale. Financial constraints can be measured by dollars. All attributes that quantify these objectives can be incorporated into a multi-attribute utility function. This function can be used in a decision model (e.g. going back to Figure 3) to compare across alternatives. Single attributes, such as QALYs or money, can be assessed, but in a complex healthcare decision these do not tell the whole story. Tradeoffs exist, so they should be assessed.

A common means of assessing the tradeoffs across health-related utility and resource constraints is the cost-effectiveness ratio; that is what is the incremental cost per unit of health utility gained by one alternative compared to another? There is a rich literature on cost-effectiveness...
analysis (e.g. references in (29)), and in many cases cost-effectiveness can be quite informative (say, in making allocation decisions across similar types of interventions in the same department of a healthcare organization). However, there are many conceptual and theoretical problems associated with cost-effectiveness as a decision criterion (40–42); thus we have chosen to use more rigorous and generalizable multi-attribute methods. Multi-attribute outcomes are also easily converted into measures of net benefit (as in benefit-cost analysis) if this seems to be informative.

6.3 Where are we now?

We are now in the process of risk and decision modeling as described above. This particular project is expected to be completed in 2006, and is expected to inform decision-makers with regard to risk and risk management as applied to radiotherapy in the TBCC as our first case study. However, we are exploring simultaneous and subsequent projects as part of a larger research program. Some of these projects are in Section 7.3 (page 27).
Additional Research

7.1 Resource allocation considerations

Radiotherapy programs employ a variety of quality control procedures not only aimed at assuring that currently accepted treatment tolerances are routinely met but also to act as filters in identifying major incidents that may occur in the complex series of processes involved in the treatment of a patient. Although such procedures consume significant resources in any advanced radiotherapy program, the distribution of these resources is generally based on historical evolution over many years rather than a systematic and quantitative study of possible incidents in the total radiotherapy process. We believe that a PRADA model of radiotherapy, such as discussed in Section 6, can lead to a more effective distribution of those quality control resources targeting the avoidance of rare, catastrophic incidents.

The resource implications of alternative risk management strategies is the issue. The resources are almost entirely human and thus knowledge of the time taken and remuneration of the various professional groups involved constitute a reasonably accurate basis for the evaluation of resource consumption. An activity-based costing approach is an appropriate means of doing this (43).

All those interventions that could lead to a reduction in the probability and severity of untoward events concerning patients need to be evaluated. These include, for example, pathology review rounds, quality control of treatment equipment, redundant checking of laboratory reports and treatment plans. In many cases such activities take place routinely and estimating their costs is relatively straightforward. Technological advances, such as the introduction of multi-leaf collimation in radiotherapy, also have resource implications as well as potential safety-related benefits(44). Any risk and decision model that does not become quickly obsolete will need to be flexible enough to accommodate such future developments.

It is likely that computational risk models such as those discussed here will suggest alternative strategies for risk management that are not currently implemented at the Tom Baker Cancer Centre or elsewhere. Estimating the cost of such strategies is associated with more uncertainty than those of existing procedures. Thus, clearly the acknowledgement of uncertainty
in cost estimates is as essential as those in risk estimates and comprises a significant component of any systematic study of patient safety and risk management.

7.2 Incident learning

Previous research by Cooke (45) and others suggests that while accidents in complex socio-technical organizations are normal, risk can be reduced by the implementation of an effective management system for learning from incidents. Such systems have been successfully implemented in high-risk industries such as chemicals manufacturing and aviation, but their potential to reduce accidents in the healthcare industry has not been fully explored. McFadden et al. (46) have suggested that the critical success factors for controlling and managing hospital incidents will be similar to those found in the aviation industry.

One hypothesis is that patient safety in a complex healthcare system can be improved by implementing an effective system for learning from incidents. Such a system will act as a continuous improvement process, potentially reducing the probability and severity of incidents and leading to improved patient safety and more reliable healthcare performance over time.

Research questions that may be addressed include the following:

1. What information on actual and potential incidents is required to characterize those incidents and how might such information most effectively be collected?

2. How can the information so obtained be collated and analyzed so that it can be fed back into the patient care system?

3. Does a system for learning from incidents lead to significant improvements in measures of patient safety and operational effectiveness?

Our proposed incident learning system will be fully aligned with the process model under development (Figure 3, page 13). The proposed incident learning process will enhance and extend the decision analysis approach described earlier by providing a framework for gathering incident information, disseminating knowledge from the incident investigation, enabling corrective actions to be taken and informing risk management decisions. The underlying quantitative nature of this approach will greatly facilitate objective assessment of the effectiveness of the incident learning system.

The methodological approach will be similar to that of McAfee (47) who studied the impact of enterprise information technology adoption on
operational performance at a manufacturing company. This project will employ a case study design and a natural experiment. The case study design will document typical radiation oncology and medical physics operations before, during, and after the implementation of an incident learning system. The natural experiment will compare incident data and other safety metrics for a period before system implementation to similar data post-implementation. There will be an action research component to the project because Dr. Cooke will be advising on system design and implementation. Westbrook (48) advocates action research as an approach that may be relevant to practitioners “because real world operations often face unstructured problems, which cannot be modeled, but must be managed.”

Expected outcomes from this component of the project will be a case study to inform decision-makers in healthcare with regard to the value of an incident learning system and an agreed-upon design for implementation of such a system. The overall incident learning project is expected to take 2–3 years to implement locally, with the first year being focused on the design of methods for the acquisition, analysis and feedback of information. If the incident learning case study and pilot project is judged to be of value locally, it is expected that similar systems would be suitable for implementation at other provincial healthcare institutions and ultimately at a national level.

7.3 Future projects

The previous discussion focuses on projects that are ongoing. Productive areas of research that are part of a larger research program include:

- Establishing the value of the model over time in terms of decision facilitation at the TBCC, and modification of the model as appropriate.
- Explicitly addressing patient values, objectives, and risk aversion in the analysis.
- Use of continuous-risk utility assessment for stakeholder values.
- Evaluation of the reliability of the PRA model by implementing a tracking/reporting system for failures.
- Establishing the reliability of the model over time in longitudinal studies in terms of reduction of probability and/or consequences of failures.
- Developing and applying operational simulation models (integrated with the PRADA model) to inform optimization of treatment strategies.
- Generalizing the approach to all forms of cancer treatment conducted in the TBCC. In particular, a comparative analysis of the risks, benefits, and
costs of radiation oncology as compared with surgery and chemotherapy, as well as combined approaches, will be informative.

- Evaluation of changes to technology and the resultant impact on the potential for failures. Radiation therapy technologies, like most areas of medicine, are rapidly changing; the flexible framework presented here will be amenable to evaluations of the impact of new technologies.

- Conducting stakeholder (especially patients) surveys and elicitation exercises to refine outcome dimensions, using methods such as contingent valuation and willingness-to-pay/accept.

- Exploration of learning as a result of use of the PRADA model by employing statistical process control methods.

- Exploring stochastic effects (i.e. cancer) that are potentially associated with radiotherapy.

- Development and dissemination of a user-friendly spreadsheet tool to facilitate use of the approach by analysts and decision-makers.

- Applying the approach to non-cancer healthcare, for example intensive care, pharmacy, etc. Interest in such an approach has been already expressed by Department heads and senior management in the Calgary Health Region, an integrated health region serving 1.3 million people with an annual budget of $1.8 billion. Application of the approach for informing patient safety decisions in such a large healthcare setting would potentially have large implications for patient care and resource allocation.

- Applying the approach in non-Canadian healthcare settings. Examples may be private systems such as US health maintenance organizations, and publicly funded systems such as the US Veteran’s Administration, the United Kingdom, the European Union, and Australasia.
Opportunities

In this report we have discussed the issues and reviewed the current state-of-the-art in proactive structured patient safety/risk management programs. We see a major role for quantitative methods in this vital area of health systems operations and have suggested what form such methods might take. In concluding, we further suggest that an appropriate model of the type described here for the radiotherapy case study, coupled with a rigorous analysis and decision framework, could inform a comprehensive patient safety/risk management program in many areas of healthcare.
Reference List


