The Ethics of Disclosure of Adverse Health Events Caused by Healthcare Management

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Abstract

The disclosure of adverse health events is the imparting, by healthcare providers to patients or their family, of information pertaining to any unexpected health event affecting the patient. Even though both the law and professional codes of ethic require the disclosure of all adverse health events, only a fraction of such events are actually disclosed. This disclosure gap is a reflection of the morally difficult decision about whether and how to disclose adverse events to patients. This thesis examines deontological and casuistic theoretical ethical perspectives on the healthcare professional's duty to disclosure adverse health events. Three case studies with different severities of clinical outcomes are used to demonstrate the differences and similarities between the two theories. The conclusions support the reconciliation of the deontological theory and casuistic reasoning in the decision to disclose adverse events, with recommendations to improve communications skills and disclosure training for healthcare providers.

Abrégé

On entend par divulgation d'événements indésirables dans le domaine des soins de santé, la transmission d'information relative à tout événement indésirable affectant un patient. Cette information est communiquée ou aux patients à leur famille par les prestataires de soins de santé. Bien que la loi et les codes de déontologie exigent la divulgation de tout événement indésirable lié à la prestation des soins de santé, seule une fraction de ces événements est divulguée. Cette déficience en matière de divulgation reflète la nature de cette décision moralement difficile. C'est-à-dire, faut-il divulguer un événement indésirable aux patients et, dans l'affirmative, quelle est la façon de procéder? La présente thèse examine les perspectives déontologiques et casuistiques concernant le devoir éthique des professionnels de la santé de divulguer les événements indésirables. Trois études de cas, dont la gravité des résultats cliniques diffère, sont utilisées pour démontrer les différences et les similitudes entre les deux théories. En plus de favoriser la réconciliation de la théorie déontologique et du raisonnement casuistique dans la décision de divulguer les événements indésirables, la conclusion propose des recommandations visant à améliorer les techniques de communications et la formation sur la divulgation, offertes aux prestataires de soins de santé.

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Chapter I

Introduction

Scientific literature (Baker et al, 2004; Banja, 2005; Benn, 2001; Blais, 2004; Henry, 2005; IOM, 2000; Leap, 1998; Maroudis, 2005; Pani, 2004; Rowe, 2004) and countless news reports (Brown, 2001; Chamberlin, 1997; Fallk, 2009; Gawande, 1999; Guadagnino, 2000) repeatedly demonstrate the prevalence of adverse events within the healthcare environment. According to Gallagher and Levinson (2005), approximately 70% of adverse health events in the United States are not disclosed. Studies conducted in Quebec demonstrate comparable results (Armutlu*, 2006; Armutlu, 2007; Beaudet-Roy, 2008). The reasons most often cited for the failure to disclose is the fear of reprisals. Reprisals may come in the form of lawsuits, the loss of employment, or the disapproval of colleagues. The "train and blame" response to adverse events, that is to train healthcare providers not to make mistakes and punish them when they do, has been found to be counterproductive and has resulted in reduced reporting and to the nondisclosure of adverse events (Leape, 1998; Sibbald, 2001). This culture remains substantially unchanged as demonstrated below.

A systems approach that examines multiple contributing problems within an organization is considered a more effective approach to adverse events (Leape, 1998; Stewart, 2002). This approach considers the individual involved in an adverse event to be one in a number of factors within the system. This paper advances the argument that an

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* The author has extensive work experience within the healthcare milieu and a keen personal and professional interest in adverse events reporting and disclosure. Since 2000, she held the position of Coordinator of Quality and Risk Management for a University Affiliated Teaching Hospital. She is a member of both governmental and non-governmental committees related to patient safety, having played a key role in the development of the provincial adverse events reporting tools and web-based adverse events reporting systems. Some of the materials in this thesis are drawn from the experiences of the author and those of her colleagues. The paradigm cases described in Chapter V are based on a composite of actual cases not involving adverse events and the personal experiences of both the author and her colleagues within the healthcare milieu.

organizational culture based on both a systems approach to adverse events and on respect for patient autonomy is required to ensuring that hospitals consistently take the step necessary for the disclosure of unanticipated adverse outcomes to patients.

1.1 Adverse events

Despite the Hippocratic Oath to "do no harm", medical journals and periodicals are filled with examples of cases where medical care resulted in harm. An adverse health event is defined as an unintended harm or consequence to the patient caused by healthcare management rather than by the patient's underlying disease process (Baker et al., 2004). Adverse events are often referred to in American scientific literature as medical errors. The Institute of Medicine's (Kohn et al, 1999) report titled *To Err Is Human,* brought to the forefront of public attention the problem of adverse events and patient safety by announcing that up to 98,000 patients die in hospitals every year in the United States because of preventable adverse events. The IOM report stressed the importance of changing the culture of patient safety within healthcare institutions and encouraged adverse events reporting and disclosure. This report set forth an international agenda for reducing adverse events and improving patient safety through the design of safer healthcare systems, and the open disclosure of these events to the patient or his family.

Since the 1999 publication of the IOM report, *To Err is Human*, the challenge of enhancing patient safety has become an important public policy issue. Leape (1998) has shown that how healthcare organizations deal with an adverse event can either aggravate an already difficult situation or promote openness, learning and prevention. Leape's recommendations for open disclosure as the most effective way to deal with adverse events was subsequently supported by the Institute for Safe Medication Practices (ISMP) Canada

(Healthcare Papers, 2000), and the Royal College of Physicians and Surgeons of Canada (2003).

1.2 Disclosure of adverse events in Quebec

During the late 1990's Quebec's news media brought to the forefront numerous reports of adverse events with catastrophic consequences occurring within the Quebec healthcare milieu. These reports brought to light the fact that the true nature of these events were not openly reported nor disclosed to the patients or their families. The patients and families were often not supported by the healthcare organization and were left in the dark about what had actually happened, resulting in complaints to the Health and Social Services Ombudsman or in law suits. In 2000, the Quebec Health and Social Services Ministry set up a committee to study adverse events in the province. Under the chairmanship of Mr. Jean Francoeur, the province's first Health and Social Services Ombudsman, the committee made a series of recommendations concerning all aspects of patient safety, including information to patients, management of healthcare facilities, and risk management (Quebec Offical Publisher, 2001 : Comité ministériel sur les accidents évitables dans la prestation des soins de santé).

In 2001, the Groupe national d'aide à la gestion des risques et à la qualité, currently known as the Groupe Vigilance pour la sécurité des soins (Ste-Marie, 2005), was created as a result of the Francoeur Commission report. The Groupe Vigilance is a permanent consultative body to the Quebec Minister of Health and Social Services and is composed of experts in all fields of healthcare and safety. The Groupe Vigilance's mandate is to ensure that priority recommendations from the rapport Francoeur are acted upon, including the

promotion and application of a national policy on patient safety, and the declaration and disclosure of accidents.

In December 2002, the Quebec National Assembly adopted Bill 113 (L.Q. 2002, c. 71), making amendments to the Act Respecting Health and Social Services with regards to the safe provision of health services and social services. Bill 113 stipulates that patients have the right to be informed of any accident having occurred during the provision of healthcare services that has potential consequences for their state of health or welfare, it further defines the healthcare facilities' obligations to report incidents or accidents (all adverse events) and to disclose accidents (adverse events with consequences). These amendments to the Health and Social Services Act, oblige any person working in a healthcare institution to report any adverse event as soon as possible. Every institution is since required to form a risk management committee responsible for seeking, developing and promoting means to ensure patient safety and to reduce the incidence of adverse events and accidents related to the provision of health services and social services. In addition, the Board of Directors of every institution is required to establish and adopt regulations concerning disclosure of all necessary information to the patient as well as measures to prevent the recurrence of such an event. Since 2003, the Health and Social Services ministry requires Healthcare organizations to disclose within their Organization's public annual report patient safety statistics. Included within these statistics are the numbers of reported adverse events.

In 2005 a ministerial committee called the Comité des utilisateurs du système d'information sur la sécurité des soins et des services (SISSS) was established to develop a national registry for reported adverse health events and to revise the existing form for the reporting of these events. The new reporting tool was launched in 2008 in both the paper

and electronic version. A form for the disclosure of adverse events as well as one for the analysis of such events was also developed and launched in 2008.

1.3 Thesis Focus and purpose

Recent policies and regulations requiring the disclosure of adverse events are helpful in attempting to encourage increased openness and truthfulness. American studies however demonstrate that only 30% of such events are actually disclosed (Gallagher and Lucas, 2005). Internal hospital audits conducted in two Montreal institutions (Armutlu, 2006; Beaudet-Roy, 2008) demonstrate a documented disclosure rate of 22% in 2006 and 46% in 2008, thus supporting the premise that, in spite of the noted improvements, disclosure remains difficult despite regulatory requirements and legal obligation to disclose adverse health events. Hingorani et al. (1999) presented evidence that the vast majority of patients prefer to be informed. Brendon et al. (2002), and Rowe (2004), further demonstrate that most clinicians believe that transparency and truth telling is the preferred course when dealing with adverse health events. Why then is it so difficult to disclose an adverse event when all parties seem to agree that it is the preferred thing to do?

This thesis provides a critical analysis of competing casuistic and deontological ethical arguments for and against the disclosure of adverse events. It addresses the question of whether or not all adverse events need to be disclosed to the patient or his family, while supporting the notion that the patient – care provider relationship must to be based on open communication and trust. It further identifies circumstances where non-disclosure may be warranted and situations where disclosure may possibly do more harm than good to the patient, thereby proposing alternative processes for consideration. With the adoption of regulations and development of hospital policy requiring the blanket disclosure of all

adverse events to patients or their families, it becomes imperative that these critical questions are addressed openly and without fear of reprisals. In answering these questions, we are better able to understand the current reluctance to disclose adverse events, demystify the disclosure process for all parties and most importantly make the process less threatening for the care provider.

1.4 Context and Qualifiers

For the purposes of this thesis, "adverse health events" does not include expected consequences due to either standard clinical intervention or health related research intervention, incidents having no consequences, nor clearly reckless or negligent acts. Incidents having no consequences to the patient's health and to his subsequent care plan are reportable; however such incidents do not require disclosure. Reckless or negligent acts must be addressed by means of disciplinary or legal measures. The term "healthcare providers" encompasses all clinicians providing health care, such as physicians, nurses, pharmacists, physiotherapists, inhalation therapists, etc. Healthcare providers constantly face ethical dilemmas during their practice. For example, the principles of patient autonomy and non-maleficence are in conflict when physicians withhold from their patients bad news related to an adverse health event for fear that disclosure may cause the patient anxiety and further harm. This paternalistic approach, usually taken in the best interest of the patient, can potentially undermine both the patient's autonomy and his need to be an active member of the treating team. This thesis examines in more detail the basic ethical principles of respect for autonomy and informed consent as they apply to adverse events disclosure.

Numerous ethical approaches and arguments can be made for or against the disclosure of adverse health events. These include, but are not limited to, an ethics of care, feminist

ethics, virtue-based ethics, utilitarian ethics, rights-based ethics, deontological Kantian ethics and casuistic ethics. For the purposes of this paper, the ethical analyses of adverse events disclosure focuses on Kantian ethics and casuist ethics due to the divergent approaches of these two philosophical theories. Deontological (Kantian) and casuistic ethical arguments are examined using three different case scenarios. In doing so, the author demonstrates how these divergent philosophical approaches when applied to actual cases can converge and lead to conclusions that may be acceptable to both.

A risk / benefit analysis for the disclosure of adverse events is performed, using three case scenarios ranging from serious to minor medical outcomes. Competing ethical arguments based on Kantian and Casuistic ethics for and against disclosure are examined and applied to each case scenario. Ethical rights arguments supporting disclosure through the basic principles of patient autonomy, informed consent, beneficence, non-maleficence and justice are addressed, while competing arguments support the notion of paternalism and therapeutic privilege in the patient-provider relationship thus potentially sanctioning non-disclosure and negating informed consent.

Furthermore, this thesis addresses two key concepts in the study of adverse events and patient safety. These being the establishment of a blame-free environment that encourages reporting and facilitates disclosure of an adverse event, and an approach to the review and analysis of adverse events that takes the focus off the individual and redirects the focus to the root cause of the problem.

1.5 Outline of Chapters

This thesis is accomplished in several steps. Chapter II consists of a review of relevant current literature on the issue of adverse health events as well as the historical legal and political evolution of the concept of disclosure of adverse events. Chapter II also provides a review of the lexicon associated with adverse health events, thus proving definitions for various terms including incidents, accidents, medical errors, and complications. Studies on adverse events, both at the national level and Quebec based, are reviewed with the intent to understand the impact of adverse health events on Canadians and Quebecers. This is then compared to the Institute of Medicine's 1999 report on "medical errors" in the United States, entitled *To Err is Human*. An over-view will be provided of adverse events within healthcare in an attempt to understand the medical, legal and ethical influences that have shaped modern day movement towards the disclosure of healthcare related adverse events. The literature review concludes with a look at the historical evolution of adverse health events disclosure, comprised of a review of the philosophical influences through history, the development of professional codes of ethics, the evolution of morbidity and mortality rounds and finally the development of the Canadian Patient Safety Institute's National Guidelines for Adverse Events Disclosure (Canadian Patient Safety Institute, 2008).

Chapter III reviews current regulatory and legal requirements for the disclosure of adverse events with an examination of case law and relevant legal judgements, as well as the contributions of various governmental reports, laws, and accrediting bodies. Chapter IV describes the traditional culture of blame within health care. The need to change this culture and to move beyond blame, towards a more transparent and non-punitive

environment, is supported. This alternate approach takes the focus away from the individual and places it on the system. A systems approach does not suppose that individuals do not make mistakes nor are never to be blamed. Banja's (2005) and Bosk's (2003) analysis of blamability and punishment is reviewed and discussed in context to adverse events. This paper demonstrates the need for hospital leadership to reject a culture of blame and instead promote a systems approach to the review of adverse health events where transparency is encouraged through adverse events reporting and disclosure.

Chapter V provides an ethical analysis of disclosure with arguments in favour and against disclosure. The ethical analysis will examine the theories of Deontological Kantian ethics and Casuistic ethics while applying the principles of respect for patient autonomy, informed consent, justice, and veracity in arguments for disclosure, with paternalism, professional beneficence, non-malificence and therapeutic privilege used in arguments against disclosure. A resolution of the moral arguments will be proposed. The Kantian and Casuistic ethical approaches are re-examined and compared using three different case scenarios, followed by a pragmatic solution that respects the tenets of the two theories. Recommendations are made for clinicians to evaluate the necessity of adverse event disclosure using a combined Kantian and Casuistic ethics approach.

Chapter VI examines the processes involved in nurturing reporting and truth telling. Here the ethical framework of patient autonomy and the need to keep the patient informed is revisited. The need to report and disclose adverse health events is presented with a description of the patient's and family's perspective, the health care professional's perspective as well as the students and residents' perspective on the issue of disclosure; and the means with which the reporting of adverse events and truth telling can be nurtured from

the perspective of the student, resident, the healthcare professional and the patient and family is thus examined. When considering disclosure, the patient and his family's emotional, cultural and spiritual needs must be taken into consideration. Once it is decided that a disclosure is needed, it is suggested that an ethics of care approach be considered when determining how to proceed with the actual disclosure process. Through this process, we also examine the principles of care ethics, looking more carefully at the need for good communication and justice in the delivery of care. Thereby being attentive and responsive to the needs of our patients, and doing so in a culturally competent and responsible manner. The beliefs, attitudes and behaviours of health care providers, students and medical residents, as well as that of the patient and his family towards the reporting and disclosure of adverse health events are examined through a review of the literature. Chapter VII provides a practical guide for the disclosure of adverse health events if offered, with the introduction of the "5 Rights" for adverse events disclosure. Concluding recommendations are proposed in chapter VIII for possible improvements in both clinical practice and teaching, with suggestions for future research.

Chapter II

Literature review

The importance of autonomy and informed consent for the patient involved in an adverse health event was briefly introduced in Chapter I. There are at times discordance within the healthcare sector on the definitions of adverse events, medical errors, incidents and accidents, as evidenced in recent published research on the subject. In addition to the 1999 Institute of Medicine report, in May 2004 the Canadian Medical Association published "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada" lead by Dr. Ross Baker, and in September 2004 the Groupe de recherche interdisciplinaire en santé (Secteur santé publique, Faculté de mèdicine, Université de Montréal) published the "Incidence d'événements indésirables dans les hôpitaux québécois" lead by Dr. Régis Blais. These two subsequent studies confirmed to some degree the generalizibility of the American IOM report to the situation here in Canada and Quebec. The following sections provide definitions for adverse events, medical errors, accidents and other relevant terms, as well as a brief overview of these three reports.

2.1 Adverse Events - Current Definitions

Cook et al. (2004) conducted a multi-method research study of 29 small hospitals in nine Western states examining the organizational processes used to recognize adverse health events (termed as "medical errors" in the actual article) and assign responsibility for them to resolve patient safety issues. Their research was comprised of seven sub-studies to gather data from nurses, physicians, administrators, pharmacists, and other health care workers. This study showed that the definitions of error presented as a problem in the staff-patient safety survey. When asked whether they were in agreement with the definitions of "error",

about two-thirds (69%) believed that to be the case. But among the 23% who believed that there was not general agreement among their hospital staff on what constitutes an error, the two explanations most frequently given for the discrepancy were a lack of consistent guidelines and definitions that were too narrow.

Health care providers often complain that the guidelines and definitions are too vague and therefore are unable to agree on what to report. As a result, most adverse health events actually go unreported (Henry, 2005). This section provides definitions from the Oxford English Dictionary, the Canadian Council on Health Services Accreditation AIM Glossary (2001), Baker et al.'s (2004) Canadian Adverse Events Study, James Reason (1997), the Quebec Health and Social Services Law L.R.Q., c. S-4.2 ch.71 (2001), and the Canadian Patient Safety Dictionary (2003). There are clearly many terms used as seen from the following definitions.

Adverse health events are defined as an unintended injury or consequences to the patient that is caused by health care management rather than by the patient's underlying disease process. Health care management includes the action of individual staff members as well as broader systems and care processes. This may include acts of omission (e.g. failure to diagnose, failure to treat) as well as acts of commission (e.g. incorrect diagnosis, incorrect treatment, poor performance). According to the Canadian Patient Safety Dictionary (2003), an adverse event may be defined in one of three ways:

1. An unexpected and undesired incident directly associated with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.

Accidents are risk events or circumstances having or that could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person. An accident is an unplanned, unexpected, and undesired event, usually with adverse consequences (L.R.Q., c. S-4.2, 2001). The Canadian Patient Safety Dictionary's (2003) recommended definition of an accident is that of an adverse outcome that was not caused by chance or fate.

Critical Incident is a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service / program. A human or equipment failure that could have led, if not discovered or corrected in time, or did lead, to an undesired outcome, ranging from increased length of hospital stay to death (CCHSA, 2001). The Canadian Patient Safety Dictionary (2003) further defines a critical incident as an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response.

Incidents are risk events or circumstances that do not have consequences for the state of health or welfare of the patient, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances (L.R.Q., c. S-4.2. 2001). The Canadian Patient Safety Dictionary (2003) further defines incidents as including events, processes, practices, or outcome that are noteworthy by virtue of the hazards they create for, or harms they cause, patients.

Complications are deviations in outcome, anticipated or not, from a planned diagnostic or treatment action that may or may not require additional medical care or affect the patient's outcome. The Canadian Patient Safety Dictionary (2003) defines complication to

be a disease or injury that arises subsequent to another disease and / or health-care intervention.

Error is a generic term encompassing all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some change agency (Reason, 1990).

Medical Errors or **Human Errors** as described by James Reason is defined as the failure of achieving the intended outcome in a planned sequence of mental or physical activities when that failure is not due to chance. According to Reason (1990), human errors are divided into two major categories: (1) **slips** that result from the incorrect execution of a correct action sequence and (2) **mistakes** that result from the correct execution of an incorrect action sequence. The Canadian Patient Safety Dictionary (2003) defines medical errors as being no different from their definition of error, where error is the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim.

Consequence is defined as something that occurs as a result of some previous action, inaction or occurrence, a logical result, or the antecedent. That which follows something on which it depends; that which is produced by a cause; a result (Webster, 1913). Consequences in healthcare by this definition are thus not unexpected.

Negligence is the failure to do something that a reasonable person of ordinary prudence would do in a certain situation or the doing of something that a person would not do (Canadian Patient Safety Dictionary, 2003).

Recklessness in healthcare law is equivalent to carelessness or negligence, not heeding the consequences of one's actions (Canadian Patient Safety Dictionary, 2003).

Fault in health law is a wrongful act, omission, or breach of duty and the determination or fixing of blame. It is also defined as the failure to perform a duty, the lack of care, guilty of error, or of mistake. Use of the term "fault" applies to causality as it implies blame (Canadian Patient Safety Dictionary, 2003).

Blame is to express disapprobation, the imputation of demerit on account of fault or blemish (Canadian Patient Safety Dictionary, 2003).

The Canadian Patient Safety Dictionary (2003) recommends that when discussing patient safety the terms blame, fault and negligence and recklessness not be used. It further stresses the importance of limiting the use of the terms negligence and recklessness to legal proceedings and to the decisions of the courts. This paper will use the term "adverse health events" as described in the definition, and outlined in the next diagram. Expected medical complications, reckless / negligent acts and incidents that have no consequences to the health or welfare of the patient are excluded from the definition of "adverse health events" for the purposes of this paper.

2.2 Current Studies in Adverse Events:

A review of the literature indicates that the numbers of adverse events that occur in patient care are significantly under-reported (Gallagher et al, 2003, Institute of Medicine, 2000, Levinson & Gallagher, 2007, Rowe, 2004, Vincent, 2007). Some studies have indicated that as much as 80% of all adverse events go undetected or unreported (University of Missouri Health Care, 2006). The question one must then ask is what is the true incidence of such events? Most authors agree that more accurate reporting must be

achieved before this question can be answered (Vincent, 2007, and Pietro et al, 2000). Some authors and policy makers suggest mandatory reporting of all adverse events (Sibbald, 2001, Liang, 2002, and Henry, 2005). Others feel that even greater success will come from allowing the reporting of adverse health events to be anonymous (Sibbald, 2001, and Rowe, 2004). It is believed that this will remove many of the barriers associated with the "culture of blame" (Banja, 2005, and Bosk, 2003).

2.21 The IOM Report - Before the Canadian and Quebec studies on adverse events, in 1999 the Institute of Medicine report, *To Err Is Human*, called attention to the problem of adverse events ("medical errors") and patient safety by announcing that between 44,000 and 98,000 patients die in U.S. hospitals every year because of medical errors. The media took this information and used it to question whether anything was being done to improve patient safety (BBC News, 1999; Brown, 2001; Lundberg, 2000; .Millenson, 2002; and Tye, 1999). Healthcare providers and hospital administrators also reacted by attempting to contest the IOM report (Brennan, 2000; and MacDonald, 2000). Governments and public groups on the other hand, called for corrective action to ameliorate the situation (JCAHO, 2003). The 1999 IOM report spurred public concern over hospitals' ability to deliver safe care and eventually lead patient safety and the reporting and disclosure of adverse health events to become an important public issue.

To this day, hospitals in the United States continue to struggle in their attempts to rectify the problems identified in this report (Fallk, 2009). The IOM report (1999) also stressed the importance of changing the culture of patient safety within healthcare institutions, to encourage error reporting and to evaluate systems problems when reviewing an adverse health event ("medical error").

2.22 Canadian Studies - Following the 1999 IOM report, similar to the United States, patient safety received increasing attention in Canada. The Canadian Adverse Events Study (Baker, et al. 2004) looked at the rate of adverse events among hospital patients as an indicator of patient safety. This study sampled a total of 20 hospitals, randomly selecting four acute care non-specialty hospitals each from five provinces. The study showed that an estimated 7.5 % of patients admitted to acute care hospitals in Canada in 2000 experienced one or more adverse health event. Of these, it was found that 36.9% were judged to be highly preventable. In its concluding remarks, this report accentuates the need for leadership to encourage reporting of adverse health events, the continued monitoring of the incidence of these events, the judicious application of new technologies and improved communication and coordination among caregivers.

2.23 Quebec Studies - In the same year, a parallel group of researchers from the University of Montreal's Groupe de recherché interdisciplinaire en santé, lead by Dr. Régis Blais, conducted a Quebec based study titled, *Incidence d'événements indésirables dans les hôpitaux québécois* (incidence of adverse events in Quebec hospitals). This study randomly sampled 20 acute care non-specialty hospitals with a minimum of 1500 admissions per year and with an emergency department open 24 hours per day, seven days a week. The study showed that an estimated 5.6 % of patients admitted to acute care hospitals in Canada in 2000 experienced one or more adverse health event. Of these, it was found that 26.8% were judged to be highly preventable. Unlike the Canadian study, the definition for adverse events used in the Quebec study included cases of readmission following hospitalization. If these cases were removed from the analysis, then the actual incidence of one or more adverse events within Quebec would drop to 4%. This report echoes the same

recommendations made in the Canadian study. It further called for better use of information technologies, enhanced communication systems, and improved coordination between clinicians and interdisciplinary teams. This study further stresses the need for a change in culture toward one of transparency with respect to patient safety issues.

2.3 The Historical Evolution of Adverse Health Events Disclosure

Since antiquity, discussions and moral and ethical arguments have taken place about the conduct of man in society, and in particular about the code of conduct of healthcare providers. Philosophers such as Hippocrates, Plato, Aristotle and Cicero, Kant, Bentham, and Mills, and most recently, Toulmin, have significantly influenced current morbidity and mortality discussions, medical ethics and health care policy development.

2.31 The Influence of Philosophers through History - This section provides an over view of the contributions of four of these theorists and examines existing medical codes of ethics of various medical associations and colleges from the following sources:

- 460 - 377 BC Hippocrates
- 384 - 322 BC Aristotle
- 1724 - 1804 Immanuel Kant
- 1922 - Stephen E. Toulmin
- International Code of Ethics
- American Medical Association
- Canadian Medical Association
- American College of Physicians
- Morbidity & Mortality Conferences
- CPSI – National Guidelines for the Disclosure of Adverse Events

Hippocrates (460 BC–380 BC) was an ancient Greek physician, considered "the father of medicine." The Hippocratic writings introduced patient confidentiality as described under the Hippocratic Oath (Davey, 2001). Hippocrates recommended that physicians record the methods or practices they used and their findings, so that these records

may be learned and employed by other physicians. Davey (2001) explains that the origin of the phrase "First, do no harm" comes from Hippocrate's works, *Epidemics*, where he wrote:

> "Declare the past, diagnose the present, and foretell the future; practice these acts. As to diseases, make a habit of two things—to help, or at least to do no harm."

Medical ethics, as defined by the oath of Hippocrates, requires the interest of the patient be the primary focus of medical practice and override any self-serving interest of the physician. However, with respect to the disclosure of bad news, according to Davey (2001), Hippocrates took a paternalistic perspective and advised physicians to withhold information that may cause patients more harm:

> "Concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and serenity […] revealing nothing of the patient's future or present condition. For many patients […] have taken a turn for the worse [...] by forecast of what is to come." *Davey (2001)*

Aristotle (384 - 322 BC) viewed ethics as an attempt to find out one's highest good. According to Aristotle one's aspirations and desires must have an objective, identified universally as happiness. Unlike Plato's self-existing good, Aristotle believed happiness cannot be found in any abstract or ideal notion, but that it must be something practical and human, as found in the work and life unique to humans (IEP, 2005). According to Aristotle, the human soul has an irrational element which is shared with the animals, and a rational element which is distinctly human. The human ability to properly control desires (such as joy, grief, hope and fear) is called moral virtue, and is the focus of morality. Aristotle argued about the nature of moral virtues (i.e. desire-regulating virtues) that the ability to regulate one's desires is not instinctive, but learned and is the outcome of both teaching and practice (IEP, 2005).

Aristotle's ethics is considered to be **teleological.** For him, the telos of a human life is to live according to reason. This leads to 'happiness' in the sense of human flourishing. According to Kraut (1991) this flourishing is achieved by the habitual practice of moral and intellectual excellences, or 'virtues'. For Aristotle, the excellences are of two types. A moral virtue is an excellence of character, a 'mean' between two vices. One of Aristotle's virtues is courage, a mean between recklessness and cowardice, which are vices. Modern virtue ethic sets itself the task of discerning the virtues for our time. In a healthcare setting what virtues would we like doctors, nurses, etc. to possess - self-control, truthfulness, generosity, compassion, discernment, integrity?

Aristotle also identified a second type of excellences, intellectual virtues, which constitute a preference for truth over falsehood and for clarity over muddle, both in pure reason and in practical affairs (The Ethox Center, 2005). Both the moral and intellectual virtues are, for Aristotle, the expression of reason. Slowther et al. (2004) describe modern virtue ethics as the way one feels is the 'right' way to behave towards patients and to colleagues. For example, a virtuous healthcare provider would take time to explain treatment options to a patient and find out what he wants.

In The Abuse of Casuistry, Jonsen & Toulmin's (1988), site the early writings in book III of the *Nicomachean Ethics,* when describing Aristotle's methodology of listing the features of a situation that have to be considered in order for the moral standing of any action to be properly judged. As explained by Jonsen & Toulmin's (1988), only when all these "circumstances" have been specified, with an eye to the actual situation, is it clear what *kind* of "action" is being considered; and only then can the action be soundly appraised. The circumstances enumerated by Aristotle are:

"Who did it?"
"What was done?"
"To what (or in what context) was it done?"; and, when appropriate,
"Using what (e.g., an instrument)?"
"To what end (e.g., as an act of lifesaving)?" and/or
"In what manner (e.g., gently or violently)?"

Jonsen & Toulmin (1988)

Aristotle's list of factors or "circumstances" was the first of such lists and, as we shall see, assumes great significance to casuist ethics.

Immanuel Kant (1724-1804) was the first advocate of the study of duty, **deontological** ethics. Kant's moral theory is that actions are morally right in virtue of their motives, which must be derived more from duty and not from inclination. The clearest examples of morally right action are those in which an individual's determination to act in accordance with duty prevails over his self-interest and desire to do otherwise. For example, the duty to disclose an adverse event would take precedence and would be deemed morally virtuous over the healthcare provider's concerns about the outcome of the disclosure to both the patient and to himself. On Kant's view, the sole feature that gives an action moral worth is not the outcome that is achieved by the action, but the motive that is behind the action. The categorical imperative is Kant's famous statement of this duty:

> "Act only according to that maxim by which you can at the same time will that it should become a universal law."
>
> *Source: Stanford University (2004). http://plato.stanford.edu/entries/kant-moral/*

Kant's deontological ethical approach is further detailed in Chapter V (section 5.31).

Stephen Edelston Toulmin (1922 -) is a British philosopher renown for his work in the analysis of moral reasoning. Toumlin's work sought to develop practical arguments that can be used effectively in evaluating the ethics behind moral issues. Toulmin questioned

the practical value of theoretical arguments (absolutism) that attempt to resolve moral issues by adhering to a standard set of principles, regardless of context. Toulmin asserts that many of these principles are irrelevant to actual situations encountered by individuals on a daily basis. In contrast to absolutists' theoretical arguments, Toulmin's practical argument focuses on the justificatory function of argumentation, as opposed to the inferential function of theoretical arguments. It was through the revival of casuistry (case-based ethics) that Toulmin attempted to find a reasonable middle ground. In *The Abuse of Casuistry: A History of Moral Reasoning* (1988), Toulmin collaborated with Albert Jonsen to demonstrate the effectiveness of casuistry in practical argumentations. Chapter V (section 5.32) outlines in more detail the casuist ethical approach.

2.32 The Development of Professional Codes of Ethics

i. American Medical Association - Code of medical ethics section 8.12 "Patient Information": The AMA's code of medical ethics states that it is a "fundamental ethical requirement that a physician should at all time deal honestly and openly with patients". Section 8.12 of the AMA's code of medical ethics states:

> "Patients have a right to know their past and their present medical states and be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care […] this obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information."
>
> *Source: Except on the AMA's Code of Medical Ethics, 2004-2005 Edition, as found in, Bhattacharyya and Yeon (2005).*

ii. Canadian Medical Association – CMA Policy: Code of Ethics 2004 revision: The CMA Code of Ethics was prepared by the Canadian Medical Association as an ethical guide

for Canadian physicians, medical residents and students. It is based on the fundamental principles and values of medical ethics. Sections 11, 14, and 21 are related to adverse events disclosure:

> (11) Recognize and disclose conflicts of interest that arise in the course of your professional duties and activities, and resolve them in the best interest of the patient.
> (14) Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.
> (21) Provide your patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of your ability.
>
> *Source: Canadian Medical Association (2004).*

iii. American College of Physicians - Disclosure Statement: The American College of Physicians makes the following recommendations to its members regarding the disclosure of medical errors:

> "To make health care decisions and work intelligently in partnership with the physician, the patient must be well informed. Effective patient–physician communication can dispel uncertainty and fear and can enhance healing and patient satisfaction. Information should be disclosed whenever it is considered material to the patient's understanding of his or her situation, possible treatments, and probable outcomes. This information often includes the costs and burdens of treatment, the experience of the proposed clinician, the nature of the illness, and potential treatments.
>
> However uncomfortable to clinician or patient, information that is essential to the patient must be disclosed. How, when, and to whom information is disclosed are important concerns that must be addressed.
>
> Information should be given in terms that the patient can understand. The physician should be sensitive to the patient's responses in setting the pace of disclosure, particularly if the illness is very serious. Disclosure should never be a mechanical or perfunctory process. Upsetting news and information should be presented to the patient in a way that minimizes distress. If the patient is unable to comprehend his or her condition, it should be fully disclosed to an appropriate surrogate.
>
> In addition, physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may."

Source: American College of Physicians (1998).

In Canada, four provincial Colleges of Physicians have disclosure policy statements, including the College des medecins du Quebec (2002), the College of Physicians and Surgeons of Ontario (2003), the College of Physicians and Surgeons of Saskatchewan (2002), and the College of Physicians and Surgeons of Manitoba (2003).

2.33 Mortality and Morbidity Conferences - The morbidity and mortality (M&M) conference is a form of retrospective peer review. It is one of medicine's most visible forums for discussion of adverse events and errors. According to Pierluissi et al. (2003), cases with adverse events and errors are infrequently presented at morbidity and mortality conferences and, when presented, are discussed as an error only half of the time. In this forum, the physician's failures are presented for all to see and that this is the only occasion in medical training that exists for public and open criticism of the physicians. At the M & M conference, medical adverse events are accounted for professionally, that is, reasons presented for them are formal and technical. One important purpose of M & M conferences is to illustrate that critical adverse events are an inevitable part of medical practice. The goal is to learn from these unfortunate happenings so as not to repeat them.

Discussion of errors with the goal of learning how to prevent them underlies the tradition of the M & M conference. Open discussion of errors may enhance error reporting and, thus, promote patient safety. These conferences are also opportunities to provide residents with experiences that help develop competency including systems-based practice, practice-based learning and improvement, professionalism, and communication (Rosenfeld, 2005). As a profession, physicians are entrusted with monitoring and improving the quality of the medical care they provide. This responsibility includes identifying and remedying

those services and procedures that threaten patient safety. Error discussion is a vital aspect of fulfilling this responsibility. Pierluissi et al.'s (2003) study findings demonstrate important cultural differences between services and missed opportunities for learning to improve patient care. Morbidity and mortality conference leaders have the opportunity to model error acknowledgment and use explicit language in error discussion more frequently and ensure that efforts are clearly linked to education and local improvement activities.

2.34 The CPSI - National Guidelines for the Disclosure of Adverse Events - In 2001 Health Canada established the National Steering Committee on Patient Safety. In 2002 the steering committee published a report called "Building a Safer System." In this report it proposed a national integrated strategy for improving patient safety in Canadian healthcare. One of its key recommendations was the establishment of a Canadian Patient Safety Institute (CPSI), non-regulatory agency, intended to promote innovative solutions and to facilitate collaboration among governments and stakeholders to enhance patient safety. The institute became operational in 2004 as an independent non-profit organization. In May 2008, the CPSI launched the National Guidelines for the Disclosure of Adverse Events. These guidelines were designed to support healthcare organizations and providers in advancing the consistent and effective implementation of the disclosure process across Canada:

> "Disclosure of adverse events to patients should occur routinely and consistently in Canada. A culture of patient safety that includes open communication after an adverse event is essential to this objective. Simply stated, disclosure is the right thing to do for patients, families, healthcare providers, as well as organizations and the healthcare system."
>
> *Source: CPSI – Canadian Disclosure Guidelines (2008)*

Chapter III

Legal and Regulatory Requirements

The ethical principle of respect for the individual requires the sharing of medical information with the patient. The sharing of information helps boost patient autonomy, while fostering trust and facilitating the patient's ability to make appropriate decisions and participate actively in the treatment and care process (Dubler, 2003). In recognition of the need to ensure the provision of adequate information, the legal system has imposed fiduciary obligations for disclosure on healthcare providers. These fiduciary obligations exist when the patient is dependent on healthcare providers for information that is otherwise not available nor accessible to the patient (Vogel and Delgado, 1980).

According to Lamb (2004), patients or their families become angry and mistrust their healthcare providers when adverse events are left unexplained. In this situation, the patient or their family start perceiving the healthcare providers as being dishonest. Their inability to get anyone within the healthcare organization to explain what happened, and the sense among family members that the healthcare providers are uninterested or unwilling to listen to their concerns or questions further increases their anger and frustration. Literature has demonstrated that it is disappointment and anger over unexpected poor clinical outcomes or the discovery of important undisclosed information in and around an adverse event, that are the main contributors to law suits against healthcare providers and institutions (Lamb, 2004; Leibman and Hyman, 2004). While the Canadian legal system acknowledges the non-negligent fallibility of healthcare providers, it nonetheless condemns the dishonesty associated with withholding information (Hebert et al., 2001).

A Canadian study conducted in 2003 by Blendon et al. (2004) found that less than 50% of Canadian organizations have disclosure policies compared to 88% in the US and 74% in the UK. The existence of disclosure policies appear to be directly linked to their legal requirement. To date, the legal requirement for disclosure in Canada has been limited to Quebec (2002) and Manitoba (2006); with Alberta (2007) and Ontario (2008) adopting provincial regulations for disclosure (CPSI, 2008).

3.1 The Common Law Duty to Disclosure:

Canada has two legal systems, federally and in all the provinces and territories except for Quebec, the legal system is based upon the common law system (Gilmore, 2006). In Quebec, a civil law system is in place. Pursuant of the Constitution Act 1867, the responsibility for healthcare is divided between the federal and provincial / territorial governments. The Constitution Act gives the provinces the authority to make and administer laws for the establishment, maintenance and administration of hospitals.

According to Robertson (2002), physicians are under a common law duty to disclose error to their patients. Robertson (2002) explains that this special duty imposed on physicians arises from the doctrine of informed consent and the fiduciary relationship between a physician and a patient. As evidenced in the legal case of *Shobridge v. Thomas* (1999) 47 C.C.L.T., physicians may be liable for increased damages resulting from the failure to disclose, and punitive damages may be imposed as a result of the breach (Robertson, 2002).

According to Dickens (2003), the courts have come to pay increasing attention to whether healthcare providers who detect that an adverse health event occurred in their patients' care have actually informed their patients of the adverse event. If the adverse event

is minor and of no consequence to the patient, the event may not need to be disclosed. Dickens (2003) gives the example of an instrument dropping on the floor during surgery, causing a slight delay while it was autoclaved. In this situation, the patient recovers from the surgery and general anesthesia with no consequences. Even if this error was due to negligence, it may not have to be disclosed as there were absolutely no consequences to the patient. However, if surgery was performed on the wrong tissues, and has to be repeated, disclosure is required as the additional surgery would have consequences on the patient.

Dickens (2003) further explains that a patient consents not simply to a purpose and form of proposed surgery, but also to its performance by a particular surgeon. According to Dickens (2003), the patient may not want to consent to the required repeated surgery being undertaken by the same surgeon who made the error in the initial operation. The lack of true consent may make a subsequent operation conducted by that physician interpreted in the courts as a surgical battery. If an error explains an unsatisfactory outcome of medical care, its disclosure is legally required as an element in an injured patient's informed consent to remedial care.

Moreover, as explained by Dickens (2003), the error to be disclosed is not necessarily that of the physician being sued for negligent nondisclosure. Dickens (2003) points to the 1992 Quebec Superior Court case of *Kiley-Nikkel v. Danais* (1992), 16 C.C.L.T. (2d) 290, where a surgeon relied on a pathologist's report that a biopsy indicated cancer, and performed a mastectomy. The surgeon did not inform the patient when it was later discovered that the biopsy report was incorrect. The patient discovered this fact only six years later, having endured six years of unnecessary cancer treatment. The surgeon was

held legally liable for negligently causing the patient 6 years of anxiety and severe stress from believing she had cancer and fearing its recurrence.

The Canadian legal system recognizes physicians' fiduciary duties to patients. The fiduciary duty requires physicians to use information about patients' care in the patients' best interests. It further requires physicians to make complete and candid disclosure to their patients of matters affecting their health and welfare, and their medical treatment (Dickens, 2003). Patients who were deceived or betrayed though intentional nondisclosure could take legal action against the healthcare provider concerned even in situations where there was no physical, emotional or financial injury. Intentional non-disclosure may be excused only in exceptional situations where "therapeutic privilege" is exercised to save the patient from harm.

3.11 Therapeutic Privilege - Picard and Robertson (2007) site *Riebl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.) and *Hopp v. Lepp* (1980), 112 D.L.R. (3d) 67 (S.C.C.), in describing how the scope of disclosure can be tapered. In these two cases, the courts anticipated a physician having the discretion to vary the information given to a patient to reflect emotional conditions or factors affecting the patient. This is often referred to as "therapeutic privilege", as outlined below by the Chief Justice C.J. Laskin's in *Reibl v. Hughes* (1980) and in *Hopp v. Lepp* (1980):

> "It may be the case that a particular patient may, because of emotional factors, be unable to cope with facts relevant to recommended surgery or treatment and the doctor may, in such a case, be justified in withholding or generalizing information as to which he would otherwise be required to be more specific."
>
> *Reibl v. Hughes (1980)*

> "No doubt, a surgeon has some leeway in assessing the emotional condition of the patient and how the prospect of an operation weighs on him; the apprehension, if any, of the patient, which may require placating; his reluctance, if any, to submit to any operation, which, if the surgeon honestly believes that the operation is necessary

> for the preservation of the patient's life or health, may demand detailed explanation of why it is necessary." *Hopp v. Lepp (1980)*

Picard and Robertson (2007) emphasize that therapeutic privilege should be interpreted very narrowly and applied only to the most exceptional circumstances; otherwise it could obliterate the patient's right to be informed. The courts therefore set strict limits to its defence. Somerville (1981) suggests a doctor should be permitted to invoke therapeutic privilege to justify non-disclosure of material information only where a reasonable doctor in the same circumstances would have believed that "the disclosure, in itself, would physically or mentally harm the patient to some significant degree."

Picard and Robertson (2007) explain that the test by which to measure the patient should be a subjective one. Thus, the question the doctor should consider is whether disclosure would in itself cause significant physical or mental harm to his patient. Canadian courts appear to be adopting this restrictive approach to therapeutic privilege. For example, in the Ontario case of *Pittman Estate v. Bain* (1994), 112 D.L.R. (4th) 257 (Ontario Gen. Div.), a family physician was advised that during surgery five years earlier one of his patients had received a transfusion of blood which was possibly infected with HIV. The physician did not pass this information on to the patient, because he was concerned about the effect which this might have on the patient's physical and mental health. According to Picard and Robertson (2007), the trial judge in the *Pittman Estate v. Bain* (1994) case held that the circumstances did not justify withholding the information. The physician was therefore determined to be negligent. In the Australian case of *Saxon v. Teik Huatt Tai* (1995), 13 S.R. (W.A.) 120 (Dist. Ct.), the physician claimed the defence of therapeutic privilege based on the fact that the patient was very nervous and had a history of depression.

The Court concluded that this was not a sufficient justification for withholding information from the patient, and found the doctor liable (Picard and Robertson, 2007).

3.12 The Professional Disclosure Standard - According to Picard and Robertson (2007), prior to the Supreme Court of Canada decisions in *Riebl v. Hughes* (1980) and in *Hopp v. Lepp* (1980), the question of what risks should be disclosed was determined by asking what a reasonable physician would tell his patient. But the physician would have to take into account the particular patient's intellectual and emotional characteristics, as well as the nature of the relationship with the patient (Picard and Robertson, 2007). This was described as the "professional disclosure" standard. The patient was measured subjectively rather than by an objective "reasonable patient" test. In the court ruling for *Hopp v. Lepp* (1980), Chief Judge Laskin rejected the professional disclosure standard stating:

> "To allow expert medical evidence to determine what risks are material and, hence should be disclosed and correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty. […..] What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment."
>
> *Hopp v. Lepp (1980)*

3.13 The Reasonable Patient Standard - In place of the professional disclosure standard, Chief Justice Laskin in his judgement for *Reibl v. Hughes*, proposed a modified test that focuses on what a reasonable person in the patient's position would want to know. This approach, referred to as the "reasonable patient" test, means that in informed consent cases, evidence of accepted medical practice plays only a small role. In *Ciarlariello v. Schacter* (1993), 100 D.L.R. (4^{th}) 609 (S.C.C.), this issue is further clarified with the statement:

> "The crucial question in determining the issue is whether a reasonable person in the patient's position would want to know of the risk."
>
> *Ciarlariello v. Schacter (1993)*

3.14 The Subjective Standard - According to Downie et al. (2002), the subjective standard of disclosure is the standard used in the Quebec legal system to determine adequacy of disclosure as opposed to most jurisdictions in North America that still use the reasonable person standard of disclosure. As outlined earlier by Picard and Robertson (2007), the appropriate cause of action in non-disclosure cases is negligence. The patient or his family must thereby establish a causal link between the physician's negligence and the injury which occurred. As the alleged negligence is the physician's failure to provide material information, it is this which must be shown to have caused the patient's injury. This would require the patient to prove that he would have declined the treatment if proper information had been disclosed (Picard and Robertson, 2007). If the patient would have consented to the treatment anyway, the physician's negligence cannot be said to have been the cause of the patient's injury. According to Picard and Robertson (2007), this analysis is based on a subjective test of causation, and focuses on whether the actual patient would have declined the treatment if properly informed. In the *Reibl v. Hughes* (1980) case, the Supreme Court of Canada decided that the subjective test was inappropriate, because it placed too much emphasis on the patient's own assessment of what he would have done if there had been adequate disclosure. The criticism against the subjective test of causation is its tendency to over-expose physicians to the patients' hindsight and bitterness (Picard and Robertson, 2007).

3.15 The Patient's Right to Waiver - Picard and Robertson (2007) also describe situations where the patient might want to waiver his right to be informed. This is

acknowledged by Chief Justice C.J. Laskin in the *Riebl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.) case, where he states:

> "It is, of course, possible that a particular patient may waive aside any question of risks and be quite prepared to submit to the surgery or treatment, whatever they be."
>
> *Riebl v. Hughes (1980)*

Picard and Robertson (2007) stress that waiver must be initiated by the patient. It is the patient's right to waiver, but it can only be acceptable in situations where the patient is clearly declining an explanation. There must be evidence of an expressed waiver in circumstances where, from the patient's perspective, the physician was willing and ready to provide an explanation.

The next sections examine the various amendments to the healthcare act, governmental reports and the requirements of regulatory bodies.

3.2 The Francoeur Commission Report

In February of 2001, the Québec Ministère de la Santé et des Services Sociaux published the Rapport du Comité Ministériel (Quebec Official Publisher, 2001), lead by Dr. Jean Francoeur, and titled "La gestion des risques, une priorité pour le réseau: les accidents évitables dans la prestation des soins de santé." Within the health care milieu, this ministerial committee was known as the Francoeur Commission. The Francoeur Commission was established in response to the demands of the public for the government to act in response to the growing number of catastrophic adverse events during the provision of healthcare services. This commission interviewed at length the victims of 10 high profile cases of adverse health events that occurred in the province of Quebec in the 1990's (Quebec Official Publisher, 2001). The report's findings echoed the many concerns originally expressed in the 1999 IOM report, "*To Err is Human*," and has since resulted in

the adoption of various amendments (projet de loi 113) to Quebec's Health and Social Services Law (L.R.Q. s-4.2), thereby requiring by law the reporting of all incidents and accidents, as well as the disclosure of all accidents (these being, adverse health events with consequences to the patient). The obligation to disclose adverse health events became a requirement by law in Quebec, with the adoption in December of 2002, of Bill 113 by the National Assembly.

3.3 Bill 113 (2002) – Amending Quebec's Health and Social Services Act

At the provincial level, patient safety has been actively supported by the Quebec government, with the passing Bill 113 (An Act to amend the Act respecting health services and social services as regards the safe provision of health services and social services R.S.Q., c. S-4.2) in December, 2002.

> 4. Section 8 of the said Act is amended by adding the following paragraphs at the end:
>
> "The user is also entitled to be informed, as soon as possible, of any accident having occurred during the provision of services that has actual or potential consequences for the user's state of health or welfare and of the measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring.
>
> […..] "accident" means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person."
>
> *Quebec Official Publisher- Bill 113 (2002)*

This amendment requires all Quebec hospitals to report adverse events and disclose harm to the patients. The only other Canadian province to pass legislation requiring the disclosure of adverse health events is Manitoba. The Manitoba government passed legislation in 2005 which came into force in 2006 (s. 2 (53.1)) (CPSI, 2006). Since 2006, 24

American states have adopted a mandatory reporting of adverse events law similar to Quebec and Manitoba.

3.4 JCAHO 2009 Patient Safety Requirements

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) issued new standards in 2002 to increase the focus on patient safety in performance standards for healthcare organizations. As part of these standards, hospitals are required to inform patients of outcomes of care, including unanticipated outcomes. In 2003, JCAHO released its initial list of patient safety goals. JCAHO has called for hospitals and all health care delivery systems to develop policies that will inform / disclose to the patient about the care they will and have received. JCAHO further stresses that health care practitioners "clearly explain instances of unanticipated outcomes to patient or family" (RI.1.2.2, JCAHO, 2003). These requirements were developed based on ethical principles of truth and honesty, for disclosing unanticipated outcomes to patients.

3.5 Accreditation Canada

Accreditation Canada 2008 Patient Safety Requirements - The Accreditation Canada's Patient Safety Goals and Required Organizational Practices were developed in 2004, following in the foot steps of JCAHO. Organizations accredited by the Canadian Council on Health Services Accreditation were required to have a disclosure policy (CCHSA, 2004). This requirement stipulates that healthcare organizations implement a formal and transparent policy and process of disclosure of adverse events to patients / families, including support mechanisms for patients, family, and care/service providers. The Accreditation Canada's Required Organizational Practice for patient safety area "Culture" states:

> "Implement a formal and open policy and process of disclosure of adverse events to clients and families, including support mechanisms for clients, family, staff and service providers involved in adverse events."
>
> *Accreditation Canada (2008)*

3.6 Canadian Medical Protective Association

The Canadian Medical Protective Association (CMPA) is a non-profit organization providing medico-legal assistance for physicians who practice in Canada. In 2005 CMPA distributed an Information Sheet to its members titled: "Disclosing adverse events to patients: strengthening the doctor-patient relationship." This information sheet encourages physicians to disclose to patients the occurrence and nature of adverse outcomes, including those caused by adverse events, as soon as it is reasonable to do so. The Canadian Medical Protective Association (CMPA) advises honesty:

> "Physicians are advised to be accurate and factual in their disclosure to patients and avoid discussion of attribution of responsibility. The CMPA can provide assistance to physicians who contact the Association in advance of talking to patients and their families about serious error." *CMPA (2000)*

3.7 The "Sorry Works!" Coalition

Studies consistently show that healthcare providers remain reticent about discussing adverse events, for fear of inadequate legal protection (Green, 2004; Lazare, 2006). This reluctance to report an adverse event impedes efforts to learn from the event and establish preventive measures. In the Unites States, legislation called the American "Sorry works!" Coalition was passed in an effort to encourage and facilitate adverse events disclosure. This law gave physicians legal immunity for their apologies to patients (MacDonald and Attaran, 2009; Wojcieszak et al., 2006). As more studies (Leape, 2006; Lazare, 2006; MacDonald and Attaran, 2009) are demonstrating that patients are less likely to sue when physicians apologize for mistakes, many hospitals now encourage their physicians to disclose their

errors. In the U.S., 35 states have enacted laws excluding expressions of sympathy after accidents as proof of liability (Morse, 2009). In Canada, Saskatchewan, British Columbia, Manitoba and Ontario are the four provinces with similar apology legislation (MacDonald and Attaran, 2009).

Accreditation Canada, the Joint Commission for the Accreditation of Healthcare Organizations, the National Patient Safety Foundation, the Institute of Healthcare Improvement and the Canadian Patient Safety Institute, and numerous other organizations are all calling for and requiring that Canadian and American accredited hospitals be truthful and openly communicate with patients, regardless of outcome. In situation where a reported adverse event is promptly corrected so that the patient's treatment is unaffected with no damage or consequences to the patient, non-disclosure to the patient may be justified if disclosure would, for instance, create undue apprehension and compromise recovery or future care (Dickens, 2003).

Whether or not a patient has to be informed of an error, a physician is obliged to report the error as an adverse event to his senior, the organization's risk manager or hospital administrator and perhaps the medical protective association and the college of physicians. Governments and health care policy makers have a very important role in the transformation of healthcare organizational culture change. Furthermore, laws need to be adopted that protect clinicians from litigation when they come forward with information about an adverse health event. This is a major issue particularly amongst physicians in the United States where law suits have placed physicians into bankruptcy and out of practice. The IOM (2000) report suggests that the focus of mandatory reporting systems be on those serious preventable adverse events. The figure below demonstrates the differences and similarities

between the IOM report and Quebec's Health and Social Services Law with regards to adverse events reporting and disclosure in relation to the severity of the event.

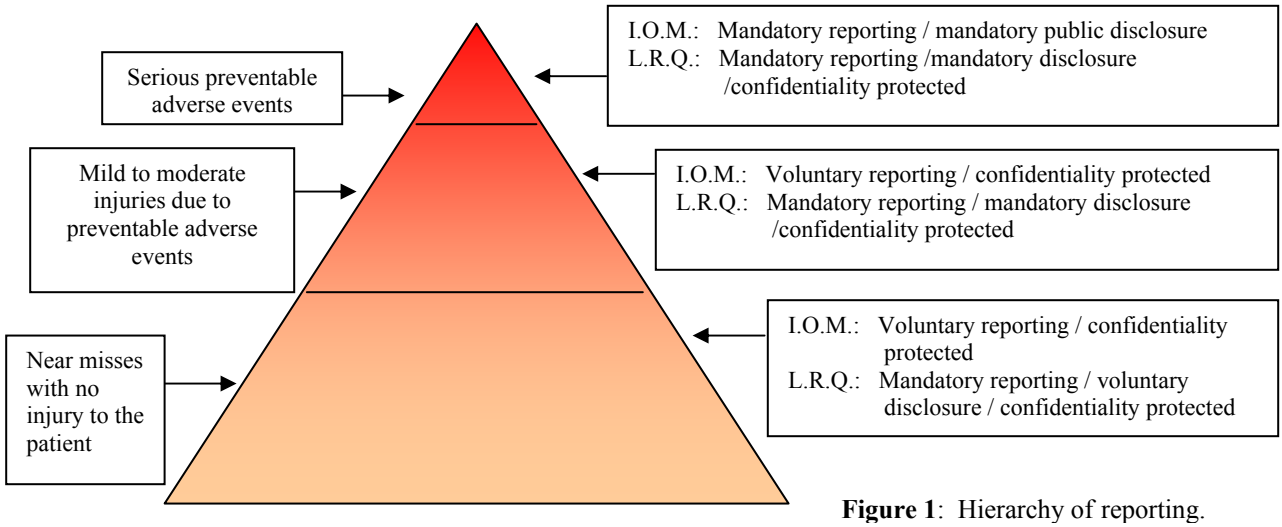

Figure 1: Hierarchy of reporting.

As the healthcare network struggles to maintain public trust and confidence, governments and policy makers can help guide this process through careful thought and practical and effective regulations.

Chapter IV

Patient Safety Culture

> " Fallibility is part of the human condition; we can't change the human condition, but we can change the condition under which people work ."
>
> *Reason (2000)*

Current discourse in Patient Safety Culture distinguishes between system and individual or human failures, attributing most adverse health outcomes to problems in the system and fewer to individual healthcare providers. This approach reflects the thinking that it is almost impossible for one mistake alone to kill a patient in the highly developed intricate world of modern medicine (Dubler, 2003). It is only since the publication of the IOM report (1999) that the health care community has gradually accepted the notion of system-wide interdependent structures and processes within organizations that either allows or prevents adverse health events.

4.1 Examples of human and systems failures

In February of 2001, the Québec Ministere de la Santé et des Services Sociaux published the Rapport du Comité Ministériel, lead by Dr. Jean Francoeur, and titled "La gestion des risques, une priorité pour le réseau: les accidents évitables dans la prestation des soins de santé." Within the health care milieu, this ministerial committee was known as the Francoeur Commission. This commission echoed the many concerns originally expressed in the 1999 IOM report, *To Err is Human*, and, as noted above, has since resulted in the adoption of various amendments (projet de loi 113) to Quebec's Health and Social Services Law (L.R.Q. s-4.2), thereby requiring by law the reporting of all incidents and accidents, as

well as the disclosure of all accidents (these being, adverse health events with consequences to the patient).

Within the commission's report, seven true cases of adverse health events were described from the patient / family's perspective. Each case was analyzed with respect to how the health care system handled these events. In each of the seven cases, the true nature of the event was not openly reported nor disclosed to the patient or his family. The following section provides two separate narratives of adverse health events resulting from complex systems problems and individual errors. The first narrative is extracted directly from the Franceour Commission's report and the second account is taken with permission from an actual adverse event occurring in a Montreal hospital. In both cases, all nominative information has been removed to respect both the confidentiality of the information and the privacy of the patient and family.

4.11 Human Failures - An adolescent girl presents to the emergency of a city hospital at 17H45 with a fractured tibia. The following morning, while still in the emergency department, the nurse on duty discovers the patient in a state of cardio-respiratory arrest. A review of her case showed that within a 5 ½ hour interval she had received Demerol, Atarax, Benadryl, Gravol, and two doses of Dilaudid 4 mgm sub-cutaneous. These medications were prescribed to her by three different physicians. The last time her vital signs were checked was at 21H00. The nurse in charge of her care was a float nurse, and the assistant head nurse had been too busy to complete a full round of all the patients during the night, and therefore had not reviewed this particular patient's file. At 9H00 the parents were informed of her death, with the stated suspected cause of death being pulmonary embolism. Eight months later, the family received in the mail, a coroner's

report that clearly stated that the cause of death of their daughter was severe respiratory depression resulting from the multiple medications she had been prescribed and administered while in the emergency department.

4.12 Systems Failures - An elderly female patient is admitted to a general hospital due to ulcerations and cellulites of her leg. Five days following her admission, she is transferred to the intensive care unit of the hospital due to two episodes of severe and uncontrolled hypotension. While in the ICU, the patient received 2.5 mg IV of Lanoxin instead of the intended 0.25 mg, thereby resulting in cardiac arrhythmia and subsequent death. This adverse health event was reported immediately, the patient's family was informed of her death and an immediate investigation of the cause of death was undertaken. Within a week, the treating physician asked to meet with the deceased patient's family in order to disclose to them the actual reasons for the death of the patient, this being an error in the dose of a medication prescribed and administered to the patient. The investigation revealed that the treating physician had specified to his junior resident the name of the medication and the dosage required, this being 0.25mg IV of Lanoxin. The second year resident, not being familiar with this medication wrote out an order for 2.5mg IV of Lanoxin, this being what he thought he heard, without having his house staff approve the order with a co-signature on the order sheet. The treating nurse, having no more than six weeks of experience in the intensive care, then broke five vials of Lanoxin in order to fill the syringe with the 2.5 mg ordered.

The ICU, not having a separate medication room, is a very busy and complex open area with numerous distractions. Medications are often prepared in the midst of an often stressful and chaotic environment. Understandably, environments that are poorly staffed,

complex, highly pressured and stressful are often where the most severe outcomes of adverse health events are realized. This reality applies to the emergency department (where there is often over-crowding), the intensive care unit, the operating room suites, as well as other such specialized areas.

The two cases outlined above, both resulted in the death of patients due to medication errors. However, it is not as simple as that. In the first case, the adverse event can easily be attributed to the lack of adequate nursing care, or to physician inattention to the medical records that would have provided an indication of the numerous sedatives and pain killers the patient had been prescribed and administered. In the second case, can we simply say that it was the nurse's mistake for not verifying or questioning the dose ordered or the resident's mistake for ordering the wrong dose and not having the order co-signed by the staff physician? Pointing fingers at the clinicians closest to the adverse event, that is at the "sharp end", is indeed the easiest thing to do. This however does not solve the grass roots of the problem. One should ask, what are the lacunas in the system that allow for such errors to occur?

4.13 Individual versus Systems Approach - Litigation and health care risk management tend to miss the appropriate target for adverse event reduction in its focus on an individual as being at fault, as adverse events often result primarily from multiple systems failures. The most important aspect of the IOM report is its focus on adverse events resulting from systemic errors. The systemic approach views the individual health care provider as one link in a chain of events that occur within a complicated healthcare situation. The number of health professionals involved in caring for a patient, the size and complexity of the healthcare institution, the complexity of the patient's medical problems, the illegible

doctors' orders, medications with similar names, work schedules, new and unfamiliar technologies or instruments, etc. all play a role in the realization of adverse events. Studies in cognitive psychology and human-factors engineering indicate that safety requires more than reliance on individual carefulness. James Reason (1997) developed the concept of **'latent' errors**, meaning deficiencies in the design, organization, maintenance, training, and management of systems, such as institutional health care systems, that create conditions in which individuals are more likely to make errors.

Dickens (2003) describes management decisions that create excessive workloads, or that designate tasks to improperly trained personnel, such as emergency room physicians or nurses not having time to check administered drugs or dosages, increasing the likelihood of making errors. Correcting systems problems in organizational management may provide the most effective way to reduce human errors, and is suggested by Dickens (2003) to perhaps be the most relevant focus of preventive patient safety and risk management strategies.

According to Reason (1997), human error is the failure of a planned sequence of mental or physical actions to achieve the intended outcome when this failure cannot be attributed to chance. To prevent human error, the system in which humans work must be adapted to their skills, cognitive strengths and weaknesses and must be designed to ameliorate the effects of human error when it does occur. To design such a system, it is critical to understand the underlying mechanisms of adverse health events.

The shift in focus from individual to systemic error also involves a shift from blame and punishment of individual healthcare providers to learning and fixing systemic problems through better use of computer technology, simplification and standardization of procedures, reduction in reliance on memory and the number of handoffs in a system, as well as the

decentralization of decision making, increased communication both within and across disciplinary teams and lines of authority (Rowe, 2004). As more attention is being turned to the disclosure of adverse health events and patient safety, a few different ways of examining adverse events in patient care is emerging. These include the "swiss cheese" model, the "blunt verses sharp end" model, and the "hind-sight" model of analysis.

The **Swiss cheese human error model** was developed by James Reason (Psychologist, University of Manchester, UK.). Reason explains that there are many defences that organizations have in place to prevent errors from reaching the patient. There are enough layers of the defence system that errors rarely penetrate all of the layers. However, any of these defences systems can potentially fail. Occasionally, holes in the Swiss cheese "line up" allowing the error to get past all of the layers of defence. Reason estimates that for an error to get past all layers of the defence, there are between 4 and 5 failures within the defence system.

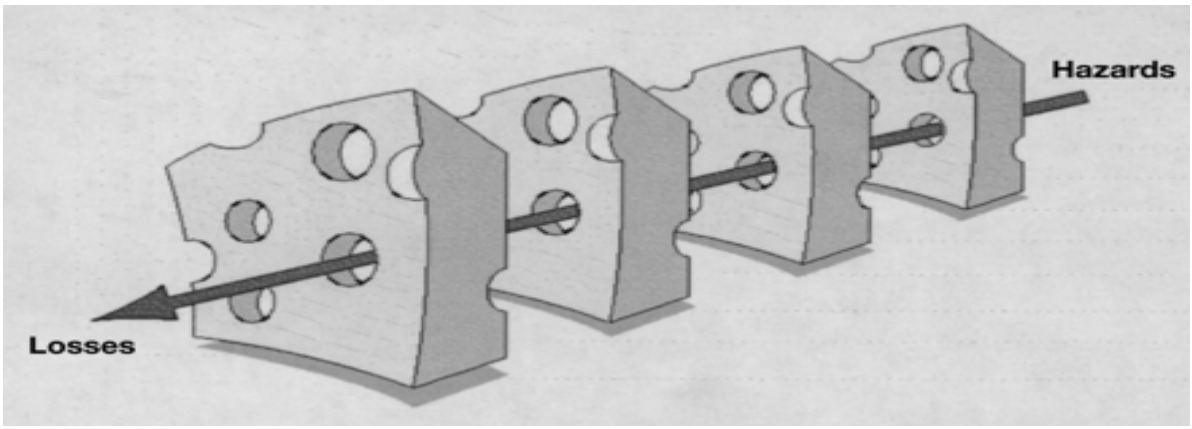

Figure 2: The Swiss cheese model of how defenses, barriers, and safeguards may be penetrated by an accident trajectory. *Reason (2000)*

The **Blunt vs. sharp end** concept was developed by Richard Cook, an anesthesiologist at the University of Chicago. Cook explains that when an error occurs, we

often focus on how the provider delivered care that adversely impacted the patient. MacReady (2000) explains that direct caregivers such as doctors and nurses are the "sharp" end of the delivery of care, interacting directly with patients. Their mistakes, called active failures, are more obvious because they usually have immediate, often serious consequences. However, for the adverse event to take place, one or more failures occurred in the organization's defence system which in this case contributed to the accident instead of preventing it. These factors are the "blunt end" of patient care. The broad blunt end, according to MacReady (2000), consists of managers, administrators, and regulators: the people who set the policies and reinforce the rules. The consequences of poor decisions made at this end are called latent failures, because they can lie dormant for a long time before they become visible. MacReady (2000) suggests that the behaviour of those at the sharp end be viewed in the context of the demands and constraints established by the people at the blunt end. Thorough investigations and analysis of adverse health events consistently reveal that the ability of the people at the sharp end to prevent adverse events depends on a host of factors determined at the blunt end, rather than on isolated acts by any one individual.

Psychologist Baruch Fischhoff developed the concept of **Hindsight bias** in error analysis. While the error's cause might seem quite clear in retrospect, before the error occurred it was not obvious at all. It is important to avoid hindsight bias when investigating errors and attempting to discover the system problems that led to the error (Fischhoff, 1975). In a very general sense, hindsight bias relates to the common expression “hindsight is 20/20.” In the context of safety analysis, according to Fischhoff (1975), hindsight bias refers to the tendency to judge the events leading up to an adverse event as in correct or

erroneous because the bad outcome is known. The more severe the outcome, the more likely the decisions leading up to this outcome will be judged as erroneous. Judging the antecedent decisions as erroneous implies that the outcome was preventable. Those reviewing events after the fact see the outcome as more foreseeable and therefore more preventable than they would have appreciated in real time.

In contrast to the principle of patient autonomy and the ethical duty of full disclosure is the ethical principle of non-maleficence, the historic *Do No Harm* principle. If an error was promptly remedied so that it has no implications for the patient's recovery from treatment or future care, disclosure of how close the patient came to suffering injury may in itself cause the patient unnecessary distress and apprehension. If the healthcare provider was able to effectively identify and correct the adverse events liable to do harm, thereby avoid injury, there may be no ethical duty to inform the patient of the 'near miss.' There may however be an ethical duty, to inform institutional or regulatory officers so that the origins of the error can be traced, for future prevention. What is not noticed can not be reported, and what is not reported can not be corrected and learned from.

4.2 The Culture of Blame

Reason (1997) believed that a "no-blame" culture is neither feasible not desirable. A very small proportion of human unsafe acts are blatantly unacceptable and considered wrong (ie.: substance abuse, reckless non-compliance, sabotage, etc.) and warrant punitive measures. Reason (1997) warns that a blanket amnesty on all unsafe acts would lack credibility within the workforce. Banja (2005) states that at times, a non-blaming, non-corrective response to an error can be grossly irresponsible and morally cowardly. He asks the question whether there are certain acts that are categorically blameworthy yet others that

are not? Banja (2005) proposes the following set of guidelines for assigning blame in relation to their intended or unintended process violations:

Blamability Gradient:	Process Violations:
No Blame / Punishment	- Unintended error not associated with an institutionally articulated process violation. - Unintended error occurred in conjunction with a non-intentional process violation where the institution admits training was insufficient and / or latent system failures significantly facilitated the error.
Modest (if any) blame / Punishment	- Unintentional error occurred in conjunction with an intentional, known process violation, but the professional can identify compelling mitigating circumstances (e.g. system flaws, patient-centered concerns) to explain the violation.
Blame / Punishment Warranted	- Unintentional error occurred in conjunction with an uncomprehending process violation where the professional should have known the standard and no mitigation circumstances are present. - Unintended error occurred in conjunction with an intentional process violation with no mitigating circumstances present.
Severe Blame or Punishment	- Intentional process violation with blatant disregard for the patient's welfare. -Intent to harm the patient, irrespective of whether error or harm occurred.

Table 1: The blamability gradient. *Banja (2005).*

4.21 When Blame is Warranted - The previous table implies that individuals who intentionally harm or who knowingly act contrary to regulations or guidelines regardless of their intent are blameable. However, the health care professional who acts in the best interest of the patient and who unknowingly harms the patient should not be blamed for adverse events in which they are directly or indirectly involved. Does this then mean that the better educated or informed health care professional has a greater responsibility and may be more blame-worthy if involved in an adverse event (as he should have known better) than the less informed professional? What is the incentive then to be informed, as even the most educated and renowned professionals make mistakes? Also, whose responsibility is it to educate or inform these clinicians? It is recommended that this be a joint responsibility of the individual care providers, the schools that graduate them, the health care institutions within which they practice, and the regulating professional orders that award licensure and practicing privileges.

4.22 Moving Beyond Blame - Sometimes it is clearly a mistake or error committed by the health care professional that results in an adverse health event. As Bosk (2003) explains, adverse medical events can occur as a result of a professional's failure to perform competently. This may be due to a failure to apply correctly the body of theoretical knowledge acquired on which the professional practices, known as errors in techniques. Bosk (2003) identifies two varieties of this type of error, technical (skill) and judgmental (critical thinking, reasoning). Then there is the failure to follow the professional's code of ethics. Bosk (2003) calls this a moral failure, and explains that moral errors are often more harshly treated and considered more blame-worthy. This is because a moral error is considered to be a breach of the code of ethics or of a professional's contract with his patient. A health professional who commits a moral error is neither acting in good faith, nor being honest nor providing the amount of care than is reasonably required. As Bosk (2003) explains, the moral system must be nurtured and developed before the technical system can be corrected or controlled.

Cook et al. (2004) and Ramsey, R. (2005), both found that when an adverse health event occurs, it is often the nurse who is blamed. In the second described above (section 4.12), the nurse who administered the incorrect dose of Lanoxin received a reprimand and a temporary suspension. Her return to work was marred by her feelings of guilt, self-blame and insecurity. Within six months of this adverse event, the young nurse quit nursing practice. As for the physician and resident, their involvement was reviewed by the council of physicians, dentists and pharmacists and the Director of Professional Services, and the case was presented at morbidity and mortality rounds.

Cook et al.'s 2004 study revealed that clinicians' understanding of patient safety is heavily influenced by preconceived views of what represents an adverse health event and the role of the health professional. This study further showed that 90% of physicians, administrators, and pharmacists and 96% of nurses perceived patient safety as mainly a nursing responsibility. Only 22% of the respondents said that physicians, nurses, pharmacists, and administrators must equally share accountability for patient care and safety (Cook et al., 2004). This reflects the traditional culture in health care thinking that the clinician closest to the patient (on the sharp end), this being the nurse, carries the greatest responsibility for patient safety and is usually the first to be blamed when something goes wrong. If any progress is to be made in reducing adverse health events and facilitating its reporting and disclosure, the attitudes that have contributed to fostering this culture of blame must first change. This change in culture must be reflected in the various training and mentorship programs as well as through appropriate regulations, hospital policies and government legislation.

Human fallibility must be recognized as being inevitable. Systems failures occur when individuals find themselves in situations that might dispose them to harm causing adverse health events. This may occur, for example, when clinicians are inadequately oriented or trained to work in the area they are assigned. Many adverse health events occur because of errors in the health care management systems. It is undeniable that a "name, blame, and shame culture" (1999, IOM) discourages an open discussion of adverse health events. In moving beyond blame, the health care professional is helped to declare and supported in the disclosure process.

Chapter V

Ethical Analysis

This chapter reviews both ethics and disclosure literature for pertinent information relevant to ethical decision-making and adverse event disclosure. It explores in more detail the tenets of patient autonomy, informed consent, justice, and veracity in favour of disclosure, and paternalism, professional beneficence, non-maleficence, and therapeutic privilege in arguments against disclosure. The healthcare provider's awareness of the patient's need for information and to the amount of "bad news" the patient wishes to receive in the event of an adverse event is addressed. The theories of Kantian deontological ethics and casuist ethics are applied to three cases in an attempt to reconcile the differences in the two divergent theoretical approaches.

The question of whether patients can make autonomous decisions particularly for unplanned interventions following an adverse event is influenced by whether they are provided with appropriate and sufficient information about the event (Post et al, 2006). In the aftermath of an adverse event, similar to many other situations in healthcare, clinicians are faced with the question of how much to tell the patient to allow an informed decision, and at the same time, how much information to withhold to avoid alarming or further harming the patient. The benefits of disclosing information that enhances patient understanding and self-determination are weighed against the potential harms of anxiety and stress that the disclosure may cause. Jonsen et al. (2002) suggest that the healthcare provider might ask:

> "Does the patient really want to know the truth?"
> "What if the truth, once known, causes the patient more harm?"
> "Would deception be more beneficent to the patient by giving him hope or avoiding un-necessary distress?" *Jonsen et al. (2002)*

As will be demonstrated below, the literature reveals ambiguity in the answers to these questions, with some authors favouring truthfulness, while others recommended beneficent deception. This thesis explores both sides of the ethical argument.

5.1 Arguments in Favour of Disclosure

The literature on adverse health events cites ethical, legal and practical arguments in favour of disclosure (Bogardus et al., 1999; Dubler, 2003; Hebert, 2001; Henry, 2005; Post et al., 2006). Dubler (2003) explains that disclosure and truth telling touch the core of trust-based relationships between the patient and his healthcare providers. Withholding disclosure acts as a barrier to open communication and collaboration, and impairs the patient's ability to make decisions about his care and future treatments as his needs change. Post et al. (2006) explain that patients and their legal representatives are ethically and legally entitled to sufficient information to understand the patient's medical condition and prognosis, evaluate the treatment options and make appropriate choices consistent with personal needs, goals and values.

The patient who is the victim of an undisclosed adverse event is dependent on the healthcare provider to understand the nature of the event or even appreciate the fact that an adverse event has taken place. Post et al. (2006) argues that the patient's dependence on the healthcare provider for information that may help him cope with the consequences creates an ethical requirement for disclosure.

5.11 Ethical Principles in favour of disclosure - Grace (2008) describes ethical principles as being useful in helping a clinician identify and uncover important issues, and

validate appropriate actions and decisions in healthcare management. The following section reviews four ethical principles of respect for patient autonomy, informed consent, justice and veracity in favour of disclosure of adverse health events.

i. Respect for patient autonomy - The word "autonomy" comes from the Greek word meaning "self rule" (Merriam-Webster, 2001). Roget's Thesaurus (1980) lists as synonyms for "autonomy" the words liberty, emancipation, privilege, independent, individuality, freedom, unconstrained, spontaneous and unprejudiced. The specific meaning of these terms including that of "respect for autonomy" may vary depending on the context and the perspective adopted. Beauchamp and Childress (2001) define the principle of respect for autonomy with the following statement:

> "To respect an autonomous agent is, at a minimum, to acknowledge that person's right to hold views, to make choices, and to take actions based on personal values and beliefs." *Beauchamp and Childress (2001)*

According to Henry (2005) respect for patient autonomy is the ethical principle that speaks to truth telling and understanding, and it is this principle that is the basis for the development of disclosure policies and organizational culture change. Crone (2006) describes autonomy as the freedom of individuals to make their own decisions, recognizing their capability for self-control, independent thought and actions. Henry (2005) explains that patient autonomy is respected when the healthcare provider discloses information to the patient that will ensure his understanding of the medical situation and thereby allow him to make appropriate decisions.

Depending on the philosophical view point, the literature on autonomy describes differing definitions of autonomy and what constitutes an autonomous act, as noted in the divergent liberal and pluralistic views. Liberal conceptions of autonomy surfaced in the

post-industrial era with an atomistic view of the individual as the dominant unit. Liberal theories believe the autonomous self must be free from the influences of others and that of society (Moody, 1989). Therefore, an autonomous being should be left to himself to decide what is right, to set his own goals and chose his own course of action without interference or influence. Immanuel Kant views the autonomous individual as being very rational by nature and as one who freely chooses one's end in life without regard to one's actual circumstances, assuming that all rational beings will arrive at the same outcome when faced with a moral question (Kant, 1988). Friedman (1997), Sherwin (1998), and Donchin (1995) argue that this conception of autonomy ignores the fact that autonomy changes and evolves over time, and is shaped by the person's emotions, personal and social relations.

Donchin (1995) argues that while traditional liberal conceptions of autonomy are better suited to the impersonal relations, a pluralistic model of autonomy is better suited for today's health care context. Pluralistic conceptions accept the influence of a person's moral and societal relationships, and view the individual in the context of his emotional, physical, personal and psychosocial environment (Friedman, 1997; Sherwin, 1998).

Accepting that a patient's cultural values, and personal or family relations can impact his autonomy, not only affects disclosure, it also promotes, when appropriate, the involvement of significant others in the decision-making process. The pluralistic view of autonomy promotes professionals' awareness of the possible influences others may have on the patient's decisions bearing in mind that these influences may not necessarily constitute coercion or duress if integrated in the person's conception of self. This concept is further examined in section 6.4 with a discussion on transcultural considerations within the context of disclosure.

This thesis supports the pluralistic view of autonomy as perhaps being more appropriate when discussing decision-making related to the disclosure of serious adverse events within critical medical situations. Irrespective of the accepted philosophical conception of autonomy, respect for autonomy is of primary importance within both Canadian culture and law, as indicated in Chapter 7 of the *Canadian Charter of Rights and Freedoms* (Can. Gaz. Part II, 1993) where the right to liberty and security encompass autonomy.

> Chapter 7. "Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."
>
> *Source: Canadian Charter of Rights and Freedoms, Can. Gaz. Part II, 1993.*

Article 10 of the Civil Code of Quebec expresses the importance of the principle of autonomy, inviolability and integrity of persons:

> Art.10. "Every person is inviolable and is entitled to the integrity of his person. Except in cases provided for by law, no one may interfere with his person without his free and enlightened consent."
>
> *Source: Civil Code of Quebec © Éditeur officiel du Québec, 1991.*

The ethical principle of respect for persons requires medical information to be shared in order to foster patient autonomy, increase trust in the healthcare providers, promote rational decision making and ensure active participation in treatment and healthcare. In ensuring respect for autonomy, the healthcare provider must follow certain moral rules that include but are not limited to truth telling and consent for interventions with patients.

ii. Informed Consent - According to Bogardus et al. (1999) all medical interventions regardless of complexity are associated with some adverse risk to the patient. Informed consent is defined as the permission granted by a patient or a patient's legal

representative to the healthcare providers to proceed with a medical intervention after being fully informed about the possible benefits, risks, and alternatives to the intervention. Difficulties arise when healthcare providers sense that their obligations require them to either disclose information that the patient may not want or withhold potentially problematic information, all in the name of promoting the patient's well-being. Dubler (2003) explains that when patients are informed about their medical condition and treatment options, their ability to make appropriate decisions is enhanced. Adequate disclosure for an informed consent is therefore a fundamental right of the patient and a duty of the healthcare provider. Dubler (2003) states that the challenge is trying to determine what the patient should know in order to receive the care he needs.

As noted in the previous section, the principle of respect for autonomy remains central to the doctrine of informed consent. Consequently, any medical intervention, including medical exams, diagnostic tests, administration of antidotes to counter or control the consequences of the error, that are planned as a result of an adverse event demands *a priori* informed consent (Hebert, 2001). When medical errors are not disclosed, the patient's ability to understand the rationale or risks of an additional or alternative procedure or longer hospital stay is impeded; therefore he is no longer capable of giving informed consent (Crone et al., 2006). Failure to disclose may constitute battery and may result in legal proceedings against the healthcare provider and healthcare institution.

As outlined in Chapter III, depending on the jurisdiction and the circumstances, three different standards are used in court to determine if disclosure is adequate, these being the professional standard, the reasonable person standard, and the subjective standard. The **professional standard** of disclosure requires disclosure of information that reasonable and

competent clinicians may determine to be relevant to make informed and rational decisions about an intervention (Katz, 1984). However, the use of the professional standard to assess adequacy of disclosure undermines the autonomy of the patient by leaving the assessment of how much information is relevant to the medical professionals who may be in a conflict of interest and may not be committed to patients making autonomous decisions. For this reason, the professional disclosure standard was rejected in the court ruling for *Hopp v. Lepp* (1980), 112 D.L.R. (3d) 67 (S.C.C.).

The **reasonable person** standard of disclosure is objective in that it is not patient or professional specific. In the judgement for *Reible v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.), the court proposed a modified test that focuses on what a reasonable person in the patient's position would want to know. Therefore, in informed consent cases, evidence of accepted medical practice would play only a partial role.

According to Katz (1984), the reasonable person standard of disclosure assumes a universal response from all individuals confronted with a similar medical situation and disregards differences in opinions and thus still undermines the right of an individual to decide for him/herself. Katz (1984) further warns that the reasonable person standard may tempt physicians to introduce their own subjectivity into the disclosure process by allowing them to believe that what information they, as "reasonable persons", would require is necessarily the information that any reasonable person would need.

The **subjective standard** of disclosure endeavors to determine what information should be disclosed according to the specific patient's needs and circumstances. It requires professionals to clarify the patient's particular situation, his personal values and preferences. The use of the subjective standard to determine adequacy of disclosure encourages

physicians to communicate with the patient in an attempt to determine what information the patient requires to make an informed decision. Usually, this would involve prior discussions with the patient, exploration of the patient's values and beliefs, and confirmation following the disclosure that the patient's informational needs have been satisfied (Downie et al., 2002).

Use of the subjective standard of disclosure complements the pluralistic conception of autonomy, taking into consideration the patients' specific context, his circumstances, his personal and cultural values, and beliefs (Katz, 1984). The nature of the physician-patient relationship and the approach to decision-making influences a patient's ability to exercise autonomy and provide informed consent both prior to initiating any treatment and for an intervention subsequent to an adverse event. According to Picard and Robertson (2007), the subjective standard of disclosure focuses on whether the actual patient would have declined the treatment if properly informed. Studies conducted by Bernstein et al.(2004), Gallagher et al. (2003), Schattner and Tal (2002), etc., have shown that patients who feel informed about their health status and who maintain good open communication with their healthcare providers are less likely to take legal action following disclosure against their care providers

iii. Justice - The principle of justice entails fairness, impartiality, and justness. Justice is defined as

> "…the establishment or determination of rights according to the rules of law or equity; the quality of being just, impartial, or fair; the principle or ideal of just dealing or right action; conformity to this principle or ideal; the quality of conforming to law; conformity to truth, fact, or reason; correctness "
>
> *Merriam-Webster (2001)*

The most fundamental principle of justice, as was first defined by Aristotle, is the principle that "equals should be treated equally and unequals unequally." Velasquez et al. (1990) expressed this principle as follows:

> "Individuals should be treated the same, unless they differ in ways that are relevant to the situation in which they are involved." *Velasquez et al. (1990)*

There are many differences that can be deemed as justifiable criteria for treating people differently (Velasquez et al., 1990). For example, one may think it is fair and just when a patient arrives in the Emergency department of a hospital with chest pain is seen immediately while another patient having arrived three hours earlier with musculoskeletal pain continued to wait. However, within the principle of justice, there are also situations and criteria that prohibit or do not justify giving people different treatment. Distributive justice refers to the extent to which society's institutions ensure that benefits and burdens are distributed among society's members in ways that are fair and just. Our Canadian medical system is one example of distributive justice where all citizens have the right to medical care regardless of income, race, age, etc.

Immanuel Kant (1988) explains how human beings are all equal in that they all have the same dignity, and in virtue of this dignity they deserve to be treated as equals. Whenever individuals are treated unequally on the basis of characteristics that are arbitrary and irrelevant, their fundamental human dignity is violated. Justice, then, must be given due consideration when evaluating any moral decision. However, when a patient suffers consequences as a result of healthcare management errors then that patient should receive priority treatment for any ailment that is a direct result of the adverse event.

A second important kind of justice is retributive or corrective justice. Retributive justice refers to the extent to which punishments are fair and just. According to Velasquez et

al. (1990), punishments are generally determined to be just when they take into account relevant criteria such as the seriousness of the crime and the intention of the criminal. If a patient suffers serious consequences due to a preventable adverse health event possibly due to a negligent act, but is made to think that his deteriorated health status was not preventable and was due to his pre-morbid health status, the clinician involved, having withheld the disclosure of the mistake, unlawfully avoids potential retributive justice.

A third important kind of justice is compensatory justice. Compensatory justice refers to the extent to which people are fairly compensated for their injuries by those who have injured them (Velasquez et al., 1990). Just compensation is often proportional to the harm imposed on an individual. In the same scenario as outlined earlier due to the withholding of information and subsequent ignorance of the fact that his medical decline is a result of an adverse event, the patient is further denied compensatory justice for the injuries that he suffered.

iv. Veracity - According to the Merriam-Webster's Dictionary (2001), veracity is defined as the devotion to the truth or truthfulness, or the conformity with truth or fact. Beauchamp and Childress (2001) name the notions of honesty and trustworthiness as core values derived from the moral obligation of veracity. According to Beauchamp & Childress (2001), veracity within the health care setting, means a comprehensive, accurate, and objective transmission of information alongside the fostering of the patient's understanding of that information.

Dubler (2003) explains that fidelity and promise-keeping requires that there is honesty and commitment to the spoken word, these being fundamental to the fiduciary relationship between patient and healthcare provider. According to Dubler (2003), fruitful

therapeutic exchanges between patient and healthcare provider are dependant on the honest management of information. This may include the safe guarding of patient confidences, the security of medical records, in addition to the disclosure to the patient of information relevant to their care. Good healthcare provider-patient relationships depend on the sharing of accurate and complete information about the patient's medical status, the treatment options, and prognosis. It is through this process that confidence is cultivated and the patient is assured that the care plans as explained to him will be followed and his wishes will be honoured (Dubler, 2003).

Henry (2005) explains how the communication between healthcare providers and patients must be truthful and statements must be factual; and any form of deception (by lying or by omission) must be avoided. According to Reckling and Welsh (2001), the principle of veracity requires particular attention in relation to adverse events disclosure because of its association with the "duty to disclose." Beauchamp and Childress (2001) note that veracity, or truthfulness, is based on the principle of respect for others, and it is clear that adherence to the tenets of veracity is essential if the healthcare providers hope to foster trust.

Shinn et al (2001) explains that untruthful or insufficient disclosure violates respect for the patient and hinders a trusting therapeutic relationship. However, similar to informed consent, veracity inherently deals with the transfer of information. Once again, it is the meaning and extent of the information to be transferred that healthcare providers find difficult to ascertain. In order to avoid further harm, valid questions are frequently asked about the appropriate quantity and quality of information to be disclosed in any given situation. Beauchamp and Childress (2001) warn that while the intention may be to not be

deceptive, but rather to avoid alarm, any withholding of information may be perceived as violating a duty to disclose.

5.2 Arguments against Disclosure

Wu (1997) states that non-disclosure of adverse events may occur in unusual circumstances when there is good reason to forfeit patient autonomy. Wu (1997) cites as an example a case where an already severely depressed patient would be incapacitated by the disclosure. A common disclosure predicament, as explained by Dubler (2003), concerns the withholding of information from patients who have not made a request to not receive bad news, but may be justified by professional obligations to protect patients and not inflict harm. Whenever physicians consider withholding information, especially from capacitated patients, they need to question who is being protected and whether the protection is truly warranted.

Pressure also comes from families asking not to share information with the patient. Schattner and Tal (2002) examined the assumption that all patients want to be well informed and to be active participants in health care decision making. They studied 104 elderly patients in a large, referral teaching hospital in Israel. Schattner and Tal (2002) suggest that having patients give an advance directive about truth disclosure may be a means of resolving this issue. When withholding information is suggested, the physician should start by determining the patient's capacity, understanding of the clinical situation and desire for information.

5.21 Ethical Principles against Disclosure:

Ethical principles of paternalism, professional beneficence, non-maleficence, and therapeutic privilege can be used for arguments against the disclosure of adverse events.

These principles are often co-dependent and redundant, and do not stand alone with the same force as the four outlined earlier in favour of disclosure.

> "You want the truth? You can't handle the truth!"
> *Jack Nicholson, A Few Good Men.*

i. Paternalism - The underlying assumption of the paternalistic model of decision-making is that the physician knows best what is in the patient's interest. With respect to the disclosure of bad news, according to Davey (2001), ancient medicine took a paternalistic perspective and advised physicians to withhold information that may cause patients more harm:

> "Concealing most things from the patient while you are attending to him. […] revealing nothing of the patient's future or present condition. For many patients […] have taken a turn for the worse [...] by forecast of what is to come."
> *Hippocrates in Davey (2001).*

Traditional medical practice remained paternalistic in nature, with information being given or withheld from the patient as the physician thought best. In situations where a patient may be seriously ill, depressed or psychotic, determining the true wishes of the patient may not always be possible. In these situations, with the absence of a legal representative, the physician is required to use his own judgement to determine what is in the best interest for the patient (Kalantri, 2003). Consequently, physicians may avoid giving information to patients, thus fulfilling the requirements of beneficence but simultaneously neglecting to respect patient autonomy. This paternalistic approach is threatened by the requirement of disclosure. In their arguments against disclosure, physicians claim that reporting an error may distress the patient unnecessarily and erode the patient's trust in his physician (Kalantri, 2003).

According to Kettle (2002), strong paternalism is dangerous because of the risk of its potential misuse. However, Kettle (2002) and Ashcroft et al. (2007) explain that a narrow

range of strongly paternalistic acts may at times be ethically justifiable. Ashcroft et al. (2007) explain that theoretically, both beneficence and respect for autonomy are *prima facie* binding and their respective weights can only be determined in specific situations. In asking what conditions need to be met in justifying strong paternalistic actions that infringe the principle of respect for autonomy, Aschcroft et al. (2007) outline the following six conditions:

1. A patient is at risk of a significant, preventable harm.
2. The paternalistic action will probably prevent the harm.
3. The paternalist action is necessary to prevent the harm.
4. The anticipated benefits of harm prevention to the beneficiary outweigh the risks of the intervention to the beneficiary.
5. The anticipated benefits of the harm prevention to the beneficiary outweighs the principle of respect for autonomy in this case.
6. The paternalistic action involves the alternative that least restricts the beneficiary's autonomy while still securing the benefits for him or her.

Aschcroft et al. (2007)

Even though a paternalistic model of decision-making may be appropriate under specific circumstances, routinely adopting such an approach on the disclosure of adverse events is ill advised and does not promote decisions that are autonomous. It may also in some circumstances be illegal.

ii. Professional Beneficence - For advocates of patient autonomy, the healthcare provider's disclosure obligations to the patient and the obligation to seek consent are established above all within the principle of respect for autonomy. Others however view the principle of professional beneficence to be the primary duty to the patient. The concept of serving the best interests of the patient is a key element of the professional relationship. If a healthcare provider believes that a particular intervention or treatment would not be in the best interests of his patient then he would be duty-bound, as a healthcare professional, to refuse it. The

resulting conflict between what a patient may request regarding his treatment options and the healthcare provider's perception of the patient's best interests, is perceived as a conflict between patient autonomy and professional beneficence. Whether respect for the autonomy of patients should have priority over professional beneficence remains an ongoing debate within biomedical ethics.

According to Beauchamp and Childress (2001), the healthcare provider's primary duty is to determine a course of action or intervention that would benefit their patient's health or medical status, and not necessarily to promote autonomous decision-making. However, over the years the principle of autonomy rights have evolved to become so prominent that it is now difficult to find clear support for professional beneficence (Beauchamp and Childress, 2001).

Kettle (2002) relates the debate between the autonomy model and the beneficence model to the failure to differentiate between two different views of principles of beneficence. Kettle (2002) describes beneficence as being inclusive of the patients' autonomous choices, "in the sense that the patient's preferences help to determine what counts as a medical benefit." In the context of disclosure of adverse health events, one must ask, should patients always be informed, or are there situations where nondisclosure may be therapeutically beneficial and, therefore, morally justified? One must also ask whose needs are being served by non-disclosure; the needs of the healthcare provider or that of the patient?

A healthcare provider's decision to limit or withhold disclosure must be made based on the benefit or harm to the patient, as well as on the issue of preserving trust (Reckling and Welsh, 2001). Reckling and Welsh (2001) stress the importance of sound professional

judgment when considering full disclosure. The decisions taken and their outcomes will make the difference between unnecessarily distressing families and enriching the healthcare provider-patient relationships.

iii. Non-Maleficience - Non-maleficence is the avoidance of actions that may cause harm. Beauchamp and Childress (2001) describe most treatments as involving some harm, even if minimal; however, the harm must not out weigh the benefits of the treatment. The principle of non-maleficence runs through from the Hippocratic Oath to current versions of medical ethics. Davey (2001) quotes the phrases within the Hippocratic Oath that serve as a guide to physicians in respect of non-maleficence:

> "I will follow that system of regimen, which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel." *Hippocratic Oath, in Davey (2001)*

iv. Therapeutic Privilege

> "Your patient has no more right to all the truth than he has to all the medicine in the physician's saddlebag … He should only get so much as is good for him."
> *Oliver Wendell Holmes, 1871, in Bernstein and Brown (2004)*

Therapeutic privilege is based upon the belief that the undesired effects of truth telling might outweigh the good effects. Hebert (2001) explains that healthcare professionals may rationalize nondisclosure with concerns about increasing patient anxiety or confusing the patient with complicated information. Nondisclosure for these reasons may be considered within the realm of therapeutic privilege.

Therapeutic Privilege, as outlined by Picard and Robertson (2007) and described in chapter III is also a legal term. In the cases of *Riebl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.) and *Hopp v. Lepp* (1980), 112 D.L.R. (3d) 67 (S.C.C.), the courts anticipated a

physician having the discretion to vary the information given to a patient to reflect emotional conditions or factors affecting the patient.

Withholding information on the grounds that disclosure would inflict considerable and permanent harm to an already unstable patient is a rationale that must be employed with caution. Even though Henry (2005) has demonstrated that when there is uncertainty about a clinical course and prognosis of a patient, many healthcare providers revert to nondisclosure in the hopes of protecting the patient from unnecessary anxiety; Parascandola et al. (2002) argue that patients can manage information about uncertainty. Parascandola et al. (2002) warn against therapeutic privilege, stating that it can create an environment where the patient is no longer a partner in the decision making process, thus undermining the patient's trust. Even when therapeutic privilege is determined to be appropriate at the time of the accident, the healthcare provider must be able to give good reason for his decision, and the question of whether or not to disclose should be revisited when the patient returns to a more stable medical condition.

Tomlinson (1994) describes the principle-based approach as inadequate to sustain the explanations, interpretations and decisions that must be made in applying ethical principles to cases. Grace (2008) further describes ethical principles as being useful in helping healthcare providers identify the important issues, clarify important factors, uncover hidden assumptions, and affirm appropriate actions. Principles alone however cannot solve healthcare problems because, as demonstrated earlier, two or more principles pertinent to a situation can offer conflicting direction. Principles alone, as explained by Grace (2008), tend to be too theoretical and imprecise to be practical. For example, hospital patients are never completely autonomous, as they are influenced by multiple external pressures (Grace, 2008).

The next sections examine divergent theoretical approaches to the disclosure of adverse health events.

5.3 A Review of Divergent Theoretical Approaches:

Different theoretical approaches may be applied in resolving arguments for and against disclosure. These theories include, but are not limited to, virtue ethics, ethics of care, case-based casuistry, consequentialist, act or rule utilitarianism, and the deontological approach. However, as explained by Dubose and Hamel (1995), no single approach can on its own reflect the depth and variability of complex healthcare issues. There are comparisons in the literature of utilitarian and deontological approaches to disclosure related decisions (Henry, 2005; Wu et al., 1997); with the evidence overwhelmingly supporting the deontological approach (Bernstein and Brown, 2004; Henry, 2005; Mavroudis et al, 2005). In spite of the casuistic case based approach to actual medical practice (Jonsen, 1991), the casuist approach has never been examined in the literature as a means to review ethical cases involving disclosure of adverse events. This section examines Immanuel Kant's deontological ethics and compares and contrasts it to casuist ethics in the context of adverse events disclosure.

5.31 Kantian Deontological Rights-Based Theory - Immanuel Kant's moral theory is considered by many to be the underpinning of modern bioethics (Mavroudis et al., 2005; Andre and Valesquez, 1990; Bernstein and Brown, 2004). Kant's theory is based on the primary importance of autonomy and dignity of the individual. For Kant, morality can exist only by virtue of our autonomy as rational beings. Deontological Kantian ethics places greater emphasis on the ethical fiduciary duties of healthcare providers to their patients than

on any negative consequences that the healthcare provider may experience, particularly when it upholds the rights of patients (Kant, 1988).

Kant's main thesis on the moral worth of an act is that it results from a sense of duty or obligation, and is not related to the outcome it brings. Duty is described as the action to which someone is bound; and the consequences of an action, according to Kant do not matter. What matters is that the act itself is right and one does one's duty. Kant believed that one's actions should be ruled by the following imperative:

> "I should never act except in such a way that I can also will that my maxim should become a universal law" *Bernstein and Brown (2004)*

According to Kant, all duties are either duties of right or duties of virtue. As explained by Kant (1988), every act has to stand on its moral virtue and be judged as if it were to become a universal law of nature. Kant does not condone lying for any reason because to do so violates the principle of the "categorical imperative" (Kahn, 2005). Therefore, actions must be such that they are generalizable to all other like situations and to all other moral agents so to be moral, all human beings must act consistently and similarly in all cases.

According to Mavroudis (2005), Kantian ethical theory best supports full disclosure of adverse events in a straightforward and clear manner. Mavroudis (2005) explains that a physician is duty bound to maintain the interests of his patients and his profession over his own personal interests. According to Mavroudis et al. (2005), the withholding of information about error from a patient can be considered as treating him only as a means to an end, which is usually for the self-protection of the healthcare provider. Mavroudis et al. (2005) goes further to state that the healthcare provider's withholding of disclosure serves to avoid the possible embarrassment associated with admitting to an adverse event, and the consequent negative perceptions of their patients or peers.

Bernstein and Brown (2004), however, look at disclosure from a broader deontological perspective. They explain that for some patients, in whom a significant adverse event has caused no impact on outcome and who would be overly distraught or could not properly comprehend the meaning of the error, it might be more beneficent to not disclose. According to Bernstein and Brown (2004), this is reflected in Kant's (1988) writings where he states:

> "morality is a law for us only as rational beings […] duty must therefore hold for all rational beings," *Bernstein and Brown (2004)*

This statement provides for different treatment of irrational beings (ie. those with psychiatric illnesses or altered cognition).

Typically, ethicists draw on a variety of moral theories in analyzing a case, as some approaches are more suited to a given problem than others. For example, according to Hughes (2005), utilitarianism may seem the more appropriate approach when tackling questions of resource allocation, whereas an ethics of care approach may be utilized in planning a disclosure process. In *The Abuse of Casuistry*, Jonsen and Toulmin (1988) describe the case based approach to ethics and moral reasoning, known as casuistry. The next section describes the casuist approach to the disclosure of adverse events.

5.32 Casuist Case – Based Ethics - Case-based reasoning, also known as casuistry, has become one of the primary means of validating decisions in clinical ethics. Similar to the methods used in medical practice, casuists rely on analogical reasoning and use paradigm cases to review and evaluate complex cases. Jonsen and Toulmin (1988) in their book titled *The Abuse of Casuistry* define casuistry as:

> "the interpretation of moral issues, using procedures of reasoning based on paradigms and analogies, leading to the formulation of expert opinion about the

> existence and stringency of particular moral obligations, framed in terms of rules or maxims that are general but not universal or invariable, since they hold good with certainty only in the typical conditions of the agent and the circumstances of the action." *Jonsen and Toulmin (1988)*

When faced with a moral question or decision, Jonsen and Toulmin (1988) explain, the casuist will review on all the characteristics of the case and compare these characteristics to a paradigm case; that is a case where there is established social consensus about the right course of action.

Jonsen and Toulmin (1988) outline three steps to casuistic moral reasoning. The first step consists of a complete description of the case and its relevant maxims, and is called the "morphology." In this first step, the casuist must attend to "four topics", as described below, that Jonsen et al. (2006) believe are basic to and consistently present in any ethical problems that may present themselves in clinical cases. Dubose and Hamel (1995) describe the second step in casuistic moral reasoning as taxonomy. Dubose and Hamel (1995) explain that in this step the case in question is matched with morally unambiguous cases. These are referred to as paradigm cases. With the information gained in steps one and two, the casuist is able to make an analogical judgment about which paradigm case most resembles the case at hand, this in turn helps determine how best to proceed (Dubose and Hamel, 1995).

i. The Four Topics - Jonsen et al. (2006) explain that clinical medicine is very practical. It consists of individual cases, with each one consisting of a wide variety of medical facts, conditions and values. Jonsen et al. (2006) believe that clinicians need a straightforward method of sorting out the important facts of any case into an orderly pattern that facilitates the discussion and resolution of ethical problems.

Jonsen et al (2006) suggest that every clinical case, especially those raising an ethical problem be analyzed by means of the "four topics." Jonsen et al. (2006) describe the four

topics as medical implications, patient preferences, quality of life, and contextual features (social, economic, legal and administrative context). They further explain that even when the facts of individual cases differ, these four topics, as outlined in the table below, remain relevant to every case, and help clinicians understand how ethical principles connect with the circumstances of the clinical case.

The "Four Topics" Approach to Clinical Ethics

MEDICAL INDICATIONS	**PATIENT PREFERENCES**
Diagnosis, Knowledge about the disease, Prognosis, Treatment modalities, Risks / benefits, Goals of intervention, etc. 1. What is patient's medical problem? history? diagnosis? prognosis 2. Is problem acute? chronic? critical? emergent? reversible? 3. What are goals of treatment? 4. What are probabilities of success? 5. What are plans in case of therapeutic failure? 6. In sum, how can this patient be benefited by medical and nursing care, and how can harm be avoided?	Patient's present quality of life, Patient's probable future quality of life. 1. What has the patient expressed about references for treatment? 2. Has patient been informed of benefits and risks, understood, and given consent? 3. Is patient mentally capable and legally competent? What is evidence of incapacity? 4. Has patient expressed prior preferences, e.g., Advance Directives? 5. If incapacitated, who is appropriate surrogate? Is surrogate using appropriate standards? 6. Is patient unwilling or unable to cooperate with medical treatment? If so, why? 7. In sum, is patient's right to choose being respected to extent possible in ethics and law?
QUALITY OF LIFE	**CONTEXTUAL FEATURES**
Competent patient's wishes, Values, Beliefs, Character traits, Lifestyle, Decisions about proxy decision-makers, - bases for their judgment, - suitability of surrogates, etc. 1. What are the prospects, with or without treatment, for a return to patient's normal life? 2. Are there biases that might prejudice provider's quality of life? 3. What physical, mental, and social deficits is patient likely to experience if treatment succeeds? 4. Is patient's present or future condition such that continued life might be judged undesirable by them? 5. Any plan and rationale to forgo treatment? 6. What plans for comfort and palliative care?	The individuals and institutions that are positively or negatively affected by the decisions - psychological, - economic, - emotional, - legal, - scientific, - educational, - religious. 1. Are there family issues that might influence treatment decisions? 2. Are there provider (physicians and nurses) issues that might influence treatment decisions? 3. Are there financial and economic factors? 4. Are there religious, cultural factors? 5. Is there any justification to breach confidentiality? 6. Are there problems of allocation of resources? 7. What are legal implications of treatment decisions? 8. Is clinical research or teaching involved? 9. Any provider or institutional conflict of interest?

Table 2: The four topics to clinical ethics. *Jonsen, Siegler, and Winslade (2006)*

According to Dubose and Hamel (1995), within the analysis of each topic one may uncover maxims, resulting in a morally biased topic worthy of ethical consideration. For example, maxims related to autonomy would be appropriate to the discussion of patient preferences (i.e. the patient indicates that he prefers to be informed of all information related to his care).

ii. The Paradigm Case – This next step in casuistic moral reasoning is taxonomy. Dubose and Hamel (1995), explain that in this step the case in question is matched with morally unambiguous cases, referred to as "paradigm cases". These are generally published cases in scientific journals or legal cases where the outcome influences subsequent case law. The outcomes of these cases are generally accepted as examples of correct conduct. The accepted moral perceptions applied in a paradigm case can then be used to determine what should be done in a new case being reviewed.

The casuist identifies the paradigm cases most applicable to the case being reviewed. An individual case is then compared and contrasted with the paradigm case. As Dubose and Hamel (1995) explain, if a case is identical to the paradigm case, moral decisions can be made rather rapidly using the ethical and moral principles advocated in the paradigm case. If the case in question differs from the paradigm case, the differences and similarities are evaluated in order to arrive at a reasonable and rational claim.

The casuistic theoretical approach requires the development of an inventory of paradigm cases with general consensus to their outcome. The difficulty in taking a casuist approach is finding the paradigm cases that reflect all possible outcomes (eg. full disclosure, partial disclosure, and nondisclosure of adverse events). The pressure has been towards open disclosure of all adverse events as reflected in the array of new legislations across

North America. Furthermore, thus far, case law has consistently ruled in favour of full disclosure; and these being the types of cases that reach the courts, they are also often the ones cited in the literature. Due to the discomfort of clinicians to speak openly about cases of adverse events where they believe disclosure is not required, paradigm cases for adverse events disclosure are one-sided, with over-whelming numbers of cases that confirm the duty to disclosure. The lack of variety in available paradigm cases can serve to limit the possible outcomes of the casuist approach, thus putting out of reach the variety of possible outcomes within the spectrum of disclosure discourse. The challenge then is to encourage transparency through a non-blame systems approach; and in doing so, develop a balanced inventory of paradigm cases.

The following section will provide paradigm case examples for situations of full disclosure, partial disclosure and non-disclosure. As there are no documented paradigm cases for partial or non-disclosure, paradigm case #2 and #3 are descriptions of adverse events with non-disclosure (#2) and partial disclosure (#3) based on a composite of actual cases not involving adverse events and the personal experiences of both the author and her colleagues in the healthcare milieu.

Paradigm case #1

An elderly female patient is admitted to a general hospital due to ulcerations and cellulites of her leg. Five days following her admission, she is transferred to the intensive care unit of the hospital due to two episodes of severe and uncontrolled hypotension. While in the ICU, the patient received 2.5 mg IV of Lanoxin instead of the intended 0.25 mg, thereby resulting in cardiac arrhythmia and subsequent death. This adverse health event was reported immediately, the patient's family was informed of her death and an immediate investigation to the cause of death was undertaken. Within a week, the treating physician asked to meet with the deceased patient's family in order to disclose to them the actual reasons for the death of the patient, this being an error in the dose of a medication prescribed and administered to the patient. The investigation revealed that the treating physician had specified to his junior resident the name of the medication and the dosage required, this being 0.25mg IV of Lanoxin. The second year resident, not being familiar with this

medication wrote out an order for 2.5mg IV of Lanoxin, this being what he thought he heard, without having his house staff approve the order with a co-signature on the order sheet. The treating nurse, having no more than six weeks of experience in the intensive care, then broke five vials of Lanoxin in order to fill the syringe with the 2.5 mg ordered.

Paradigm case # 1 was first introduced in Chapter IV (page 47). The principles of veracity and justice point to the need to disclose this event to the patient's family members at the earliest opportunity. Full disclosure is also supported by the deontological perspective with the family being actively involved and representing the deceased patient as the "rational being." In this case, the adverse event was disclosed to the patient's family with positive outcomes. The disclosure was clearly very difficult for the healthcare providers involved. In spite of the catastrophic outcome of this error, and the initial tension and stress amongst the care providers involved in the case, the family was welcoming of the organizations transparency and used this experience to help the team come to terms with the mistake, to learn from it and to put into place systems to avoid a similar adverse event in the future.

Paradigm Case #2:

A 16 year old girl is brought into the emergency of a trauma center in critical condition following a motor vehicle accident. She is unconscious with multiple injuries and significant blood loss. A search of her personal belongings reveals her name, home address and phone number. She is rushed into surgery while the OR clerk calls her home in an attempt to reach her family. A message is left for the family to call back the hospital as soon as possible. A blood transfusion is deemed necessary and is administered. The surgery takes 5 hours. Three hours into the surgery, the mother calls back the hospital. Upon hearing of the unfortunate circumstances of her daughter's condition and the surgery being performed, she immediately informs the clerk that her daughter is a Jehovah's Witness and there must be no transfusion of blood. The clerk in her search for the patient's identification did not come across a Jehovah's Witness Identification Card. This is mentioned to the mother. A nurse then comes on the phone to speak to the mother to inform her that it would be impossible at this point to stop the transfusion. The mother was asked to contact the patient's father and to come to the hospital as soon as possible. Both parents present to the hospital within 30 minutes of the call. They are very concerned about their daughter and upset about the fact that she is being transfused. Her parents are very conflicted about disclosing the transfusion

to their daughter for fear that she will feel violated and may be shunned by her family and friends within their religious order. After considerable deliberation, upon the parent's request, the team reluctantly agrees to withhold disclosure of the transfusion from the patient for the duration of her stay within the intensive care unit.

The parents understood that it was impossible to stop the transfusion during surgery. They were however very conflicted about whether or not to tell their daughter about the transfusion, and wondered why she did not have in her wallet her Jehovah's Witness Identification Card. The healthcare team and her parents wondered whether it was lost or if its absence was an indication of the patient's lack of conviction to tenets of her religion. From the casuist perspective, it would be important to have a good appreciation of this patient's preferences, religious convictions and her critical medical state. The patient remained in critical condition following surgery and was transferred to the ICU in critical post surgery. In an attempt to keep her from further distress, and help her through the difficult recovery process, the parents requested that the fact that she had been transfused be withheld for the duration of her stay within the ICU. The parents has originally requested that as long as their daughter remained a Jehovah's Witness, that she not be informed of the transfusion. The healthcare providers involved in this case disagreed with the parents and informed them that the patient would be informed once she stabilized and that her family physician would eventually receive a discharge summary report indicating that she had received a transfusion during her hospitalization.

Paradigm Case # 3:

A unilingual 96 year old Chinese female patient with 5 children is diagnosed with breast carcinoma. The oldest son who is the patient's and family's spokesperson requests that all negative information be withheld from his mother and a palliative approach to treatment be taken due to the patient's advanced age. A Chinese nursing assistant working on the unit speaks to the patient and confirms her wishes for her son to be her spokesperson, and to have all medical information presented directly to him. Due to the patient's age and the potentially detrimental effects of cancer treatment on the quality of her remaining life, the

patient's physician agreed with the son's request. The patient does not understand English nor French but responds appropriately to Cantonese. She is oriented to the three spheres (person, place and time) and is considered to be competent by the healthcare team. There are, however, observed periods of mild confusion. On the patient's second day of admission, the patient received chemotherapy for her breast cancer in spite of the documented level of care indicating she was palliative. The chemotherapy resulted in her feeling very poorly (increased confusion, fatigued, diarrhea, nausea, etc.). The patient asked her nurse for the reason why she was given a medication that was making her feel ill. This error and its consequences on the patient were disclosed to the patient's son. Due to the patient's inquiries, the team struggled with the option to disclosure the error. However, full disclosure would require transparency about her diagnosis and prognosis. The patient's son reiterated his request to keep the patient palliative and not give the patient the any bad news including information about the adverse event.

As verified by Cantonese interpreters, the patient had no desire to exercise her personal autonomy while she was a patient, with full confidence in her son to act in her best interest. She requested that all medical information be given to her son who will in turn make the appropriate decisions on her behalf. The patient's inquiries about the medication that made her feel ill was addressed with the patient being told that she would no longer receive that particular medication. In this case, the patient herself did not receive a disclosure of the adverse event due to the concerns and requests of the family members. The casuist approach helps the healthcare providers appreciate the four topics as they apply to this case. This approach helps in the care providers understand the complex cultural norms at play, the role of the family, the impact of bad news on the elderly patient. Cultural and moral values and beliefs were respected in accordance to both the patient's and her family's wishes. Professional beneficence and non-malificence takes precedence in this case. The patient is also exercising her autonomy in her decision not to receive information and by appointing her son as her representative. In spite of the decision to not inform the patient, the patient's legal representative (the son) must be informed of any adverse events.

iii. The Analogy – The final step in the casuist approach is the analogy. With the information gained in steps one and two, the casuist makes an analogical judgment about which paradigm case is most similar the case being reviewed, which in turn would inform the healthcare providers about how to proceed (Dubose and Hamel, 1995).

According to Boyle (2004), the casuist analogy may misrepresent or oversimplify an otherwise complex issue. In addition, although court cases often receive national attention, Boyle (2004) warns the full details of legal cases are not known as they are usually sealed by the court. Beauchamp and Childress' (2001) caution against casuistry is that casuists have no clear methodological resources to prevent a biased development of cases. To avoid this there needs to be a bank of paradigm cases that reflect divergent outcomes and decisions. This is difficult within the context of adverse events disclosure due to the prevailing culture of secrecy significantly narrowing the variety of available paradigm cases.

This being said, casuistry focuses attention to the case at hand; and underscores the importance of attending to the details of the case. Dubose and Hamel (1995) maintain that the four topics model (Medical Indications, Personal Preferences, Quality of Life, and Contextual Features / External Socioeconomic factors), as described earlier, may contribute to a more complete description and understanding of the case and to a consideration of the full range of values and maxims at issue.

5.4 Ethical Analysis – A Resolution of Moral Arguments:

Due to its focus being on the case and its relevant topics, Casuistry may be more attentive than the deontological approach to the uniqueness of the needs of the patient, family and healthcare providers involved, as it would take into consideration their religious,

spiritual and cultural norms. The next sections will provide three case examples, of varying degrees of severity, where the deontological and casuist theoretical approaches are applied to the decision to disclose or withhold information about adverse event events.

5.41 Case Reviews – Three cases for ethical review and argumentation:

This section introduces three summarized fictitious cases of adverse health events for the purpose of analysis and determination of the best course of action regarding disclosure. The cases are presented in a narrative and then compared to an appropriate paradigm case (previously presented in section 5.32-ii) along with an analysis of the relevant ethical principles. They are presented by their severity and transparency of outcome. A tabular schema is then provided with an indication of the action taken and the reason for the action for either one of two approaches (casuistry vs. Kantian deontological ethics). There are three possible actions, these being: Tell the patient /family, delay telling the patient / family, and do not tell the patient / family. During the analysis, whenever possible ethical principles relevant to the particular case are examined. The three cases have differing outcomes with varying degrees of consequences to the patient involved:

i. Case 1: Geriatrics - Serious obvious error (Mr. J. B.)

Mr. J.B. is an 87 year old male living in a public nursing home. He is mobile yet dependent in most of his activities of daily living due to a decreased mental capacity. He is incompetent and he has a history of dementia of Alzheimer's type, with no advanced directives. Mr. J.B. is under public curatorship, having no living relatives who have shown any interest in his well-being. He was transferred to an acute care hospital due to an acute onset of pneumonia, with respiratory difficulty, and admitted to a medical ward. While on

the medical unit, a medication error resulted in the patient's sudden deterioration. He was transferred to the intensive care unit where he subsequently died.

Case synopsis: Mr. J. B.

Theory	Action	Reason
Deontology (Kantian)	**Tell patient / family** or Delay telling patient / family or Do not tell patient / family	**Send a copy of the completed AH-223 report to the public curator**
Casuist Ethics	**Tell patient / family** or Delay telling patient / family or Do not tell patient / family	**Send a copy of the completed AH-223 report to the public curator**

In the case of Mr. J.B., the public curator is the patient's legal representative and as such needs to know the cause of death. A copy of the completed incident / accident report should be sent to the public curator for his information. From the deontological perspective, the organization has a duty to report the cause of death to the public curator and this can be done through the completed AH-223 Incident / Accident Report. From the casuist stand point, this case is similar to paradigm case #1. Where there are no family members available, the public curator represents the patient's family and is deemed the patient's legal representative. The disclosure then is given to the public curator in the form of a completed AH-223 report as required by provincial regulation. Of the four topics (medical indications, patient preferences, quality of life, external socioeconomic factors) established by Jonsen et al. (2006) for the analysis of cases, only the external socioeconomic factor specific to hospital and legal regulations would apply. A full disclosure which includes the expression of sympathy and an outline of preventative and supportive measures would not be necessary

as the public curator has no personal ties to the patient. However, it is the author's belief that even in this case, there must be internal reporting and full disclosure of the events, through M & M rounds and risk management committee reporting, and of the systems failures contributing to Mr. J.B.'s death. Such an internal process would facilitate organizational learning and promote safer patient care.

ii. Case 2: Oncology - Serious hidden error (Mrs. B.M.)

Mrs. B.M. is a 42 year old married female with two teenaged children. She was admitted to the hospital with an advanced stage of metastatic colon cancer. Her level of care was determined to be palliative, with only a few weeks life expectancy. Prior to her illness, she was a manager of a successful chain of retail stores specializing in health and beauty products. She has a notarized advanced directive giving her husband power of attorney. Mrs. B.M. is competent and alert, but is being sedated for comfort and pain control. Due to the high doses of pain killers, she is slightly confused at times, with increasing drowsiness over the past few days. An error in the dose of sedatives administered to Mrs. B.M. results in severe respiratory depression and her untimely death. Mrs. B.M.'s family (husband, children, parents, and siblings) were all prepared for her death but did not expect it to happen so quickly. They felt both very guilty and distressed at not being with the Mrs. B.M. during her final hours.

Case synopsis: Mrs. B.M.

Theory	**Action**	**Reason**
Deontology (Kantian)	**Tell patient / family** or Delay telling patient / family or Do not tell patient / family	**Disclose adverse event to family ASAP**
Casuist Ethics	Tell patient / family	**Disclose adverse event to family ASAP**

or

Delay telling patient / family
or

Do not tell patient / family

In spite of Mrs. B.M.'s imminent death she continued to play a very important role in the lives of her husband, children, parents and siblings. Mrs. B.M. was a very autonomous individual whose inner strength, spirituality, and personal beliefs helped her through very difficult periods during her illness. From a deontological perspective, the patient's husband would be considered the rational being whose autonomy must be respected. The organization therefore has a duty to disclose the adverse event to Mrs. B.M.'s husband at the earliest opportunity. From a casuist perspective, this case is similar to paradigm case #1. In both cases, the patient dies due to an error in medication and there is a loving and involved family available. The turmoil that the family members are feeling is largely a result of the adverse event. The disclosure of this adverse event may very well turn the family's guilt into feelings of anger towards the organization and the healthcare providers. Veracity and justice dictate that the husband must be informed. The fact that a good therapeutic relationship existed between Mrs. B.M., her husband, and the treating team may facilitate the very difficult disclosure process. Similar to paradigm case #1, and to the deontological approach, disclosure should occur as soon as possible.

iii. Case 3: Psychiatry - Insignificant hidden error (Ms. S. R.)

Ms. S.R. is a 39 year old schizophrenic patient who lives alone in a low income housing unit. She is well known to the psychiatric unit of the hospital with a history of schizophrenia, bipolar affective disorder and non-compliance to her medications resulting in numerous admissions over the past 10 years. When she is well, Ms. S.R. works at the local

library on a part-time basis. Ms. S.R. was admitted to the psychiatric ward in a manic state with delusions of persecution and visual hallucinations. The second day of her admission, she was given the wrong dose of an anti-psychotic medication (Haloperidol) meant for a male patient in the next room. This medication error resulted in Mrs. S.R. feeling lethargic, causing her to miss her meals and remain in her bed for most of the day. By the next day, she was significantly more alert, able to participate in her activities of daily living and interact with her care providers. Ms. S.R. had no recollection of the previous day's events and no idea that there was an error in her medications; her manic tendencies and delusions once again became apparent to her care providers.

Case synopsis: Ms. S. R.

Theory	**Action**	**Reason**
Deontology	Tell patient / family	
(Kantian)	or	
	Delay telling patient / family	**Delay disclosing to patient until she is well**
	or	
	Do not tell patient / family	
Casuistic Ethics	Tell patient / family	
	or	
	Delay telling patient / family	
	or	
	Do not tell patient / family	**Do not disclose to patient but report error and review in detail with team.**

In this particular case, while Ms. S.R. remains in her psychosis, she is considered to be an incompetent and irrational person. Kant's deontological duty however applies to rational beings. Therefore from a deontological perspective, the organization would have to wait for Ms. S.R.'s condition to stabilize (with rational thinking clear of delusions and manic tendencies) before disclosing the adverse event to her. However, from a casuist

perspective, with the absence of a similar paradigm case, the patient's personal preferences, quality of life, medical condition, and external socio-economic factors must be taken into consideration. Disclosing this error to Ms. S.R. may further damage her fragile mental state, annihilate the precarious relationship she has with her treating team, and most likely contribute to further non-compliance to her medications, loss of her job and exacerbated psychiatric illness.

From a casuist perspective, this case contains elements similar to paradigm cases # 2 and #3. In paradigm case #2, the patient is too unstable to receive the information. However the treating team feels that they have a duty to inform her as soon as she stabilizes. In paradigm case #3, the patient requests that all information related to her care be given to her son. In this case, it was decided to withhold disclosure from the patient in order to facilitate her recovery and help the patient maintain a quality of life. With all the four topics analyzed (with the consideration of the patient's unstable medical condition, her preferences, contextual factors and quality of life), it may be determined that disclosure of this adverse event to Ms. S.R. is not recommended as it would have a detrimental effect on Ms. S.R.'s quality of life, medical condition and socioeconomic status. The casuist approach aligns itself in this particular case with the principle of professional beneficence. This may also be viewed as paternalistic, and taking a beneficience / non-maleficience principled approach. Regardless, this event must be reported and analyzed internally to ensure corrective and preventative systems measures are put in place.

The above cases and the corresponding paradigm cases demonstrate the need to take a reconciliatory pragmatic approach to resolving ethical problems involving adverse events disclosure.

5.42 A Pragmatic Solution

Reconciliation of ethical arguments - Casuist / Deontological Approach

As seen earlier and illustrated through the case examples, no single philosophical approach can reflect the variability of human experiences. Through the review of the four topics, casuistry provides a more in-depth perspective of the patient, thus leading to a more knowledgeable dialogue about ethically appropriate courses of action. However, casuistry by itself should not be regarded as the alternate model of moral reasoning preferable or superior to the Kantian or principle-based approaches in medical ethics.

In the context of adverse events disclosure, due to the lack of sufficiently diverse paradigm cases, the casuist approach will lack appropriate normative cases on which to base an analogy. If employed on its own, the casuist approach can lead to indecisions or erroneous decisional outcomes. For this reason, it is recommended that when reviewing cases involving the disclosure of adverse events, casuistry should be used in conjunction to the Kantian deontological theoretical approach with an examination of the ethical principles that apply to each topic being considered.

Generally speaking, the deontological approach should be accepted as the default approach as most patients want a better understanding their medical situation; they want more information about the adverse event, what went wrong, what will be done to help their situation and how the event will be prevented in the future. Therefore, in all cases where the patient is competent and alert, unless the patient has given prior directives to the healthcare organization to withhold any form of bad news, there must always be complete and open disclosure of the adverse event. The question to ask is when is an individual deemed incompetent or not a rational being? In situations where the patient is psychotic or acutely

ill and therefore unable to comprehend the information or participate in decision making, the information should be shared with their legal representative or surrogate whenever possible. In such situations it is the patient's legal representative or surrogate who is considered to be the "rational being." As soon as the adult patient's condition stabilizes and the patient is able to participate in a discussion and comprehend the information being shared, then the patient once again is considered the rational being and the disclosure information is shared directly with the patient. It is in situations where the patient is not able to participate or there is no family available, or where the team believes the patient or family is unable to handle bad news at that particular point in time, or where complex cultural norm are introduced, that the casuist approach is integrated into the analysis.

Healthcare providers must therefore attempt to understand their patients' values, beliefs, and other personal factors in order to determine what is in the best interest of their patients. Following these discussions, it is possible that the patient states a strong preference not to be informed of bad news or delegates his decision making authority to a family representative (as illustrated in paradigm case #3, section 5.31-ii). Patients have both the right to receive information and the right not to receive it. As demonstrated in the case examples, some patients who may be elderly, anxious, easily confused or from cultures that do not value individual autonomy, may find it burdensome or frightening to learn about their conditions. Dubler (2003) explains that for these individuals autonomy is expressed in their request to not be informed of bad news. Casuistic ethical arguments are therefore made using the experiences of past cases for the withholding of information if it can be shown that patient's autonomy would be undermined by disclosure, thus causing the patient more harm

than good. Thus, a decision-making model that promotes patient involvement and open communication between the patient and their healthcare providers is recommended.

To summarize, it is not always in the patient's best interest to apply the patient autonomy principle or deontological theory without consideration of the individual factors or patient preferences that impact the patient or situation at hand. When determining whether an adverse event should be disclosed to the patient or to his family, a reconciliation of the deontological and casuist approach is suggested with the deontological approach used for straightforward cases, and the casuist approach employed as an adjunct in the more complex cases. In either scenario, ethical principles are considered upon review of the moral questions that arise from the individual cases and their subtopics.

The concerns of the healthcare provider, student, and patient involved in an adverse event must be addressed in order to be able to facilitate and nurture the reporting and full disclosure of adverse events. The next chapter addresses these concerns.

Chapter VI

Nurturing Reporting and Truth Telling

Work environments need to strive towards being more supportive and less punitive with their staff. This approach needs to be reflected and supported within the schools and by clinical supervisors, senior clinicians, and hospital administrators. As addressed previously in Chapter IV, organizations that evaluate the systemic problems contributing to adverse events resist blaming the adverse event on the clinician. When an adverse event occurs, these organizations will have mechanisms in place to facilitate the reporting process and help the involved healthcare providers manage their feelings of guilt or inadequacy. Once an adverse health event is acknowledged and reported, and the involved healthcare providers counselled as appropriate, a disclosure conversation can then follow. In order for this to happen, the clinical and academic environments must promote the reporting of adverse events and truth telling. This chapter addresses the approaches needed to nurture reporting and truth telling.

6.1 The Resident / Student's Perspective and the Academic Challenges

According to Moscowitz et al. (2007), most physicians make their first mistake leading to an adverse event as medical students. These experiences, combined with their consequences, can influence long-term attitudes and behaviours with regard to the reporting and disclosure of health care related adverse events. Mazor et al. (2005) stress the need for medical students as well as students from para-medical professional fields to be well informed about adverse events and patient safety. The literature suggests that these young professionals, while in training, often receive mixed messages about adverse events (Green,

et al., 2000; Hevia and Hobgood, 2003; Mazor et al., 2005; Moscowitz et al, 2007; and Rhodes and Cohen, 2003). Clinical supervisors or professors often focus on maintaining the self-esteem of medical students, potentially leading to an inflated sense of mastery and a culture of silence about adverse events. In addition, by responding ambiguously when students exhibit problematic behaviours, clinical supervisors may lead their students to misinterpret or even ignore feedback. On the other hand, the use of formal disciplinary procedures may discourage students from reporting adverse events in the fear that the learning opportunity will become punitive. For example, it might not be surprising to find that a nursing student who received a low grade after making a serious mistake in a rotation would be reluctant to report errors in the future. Green (2000) reports that 5% of internal medicine residents would lie to cover a mistake, for fear of reprisals or of being ridiculed. Wu (1991) found that 50% of residents informed their attending of errors; and less than 25% of these disclosed the event to the patient or family. Moskowitz et al. (2007) suggest that more attention needs to be given in the schools and during training programs to the issue of adverse events reporting and disclosure and that of patient safety. Moskowitz et al. (2007) go further to suggest that this topic be added to the curriculum as a required course.

Schools that train future health care professionals need to help develop individuals who are able to communicate well with other team members and their patients (Trumble et al, 2006). These schools need to help their students understand and appreciate the fact that mistakes can happen. Starting in the classroom, students need to be taught that it is better to report and discuss mistakes with their colleagues and supervisor than to conceal it. Instructors, supervisors and the house staff should encourage their students, interns and residents to openly discuss incidents of adverse health events (e.g. missed diagnoses,

incorrect prescriptions, etc.) and be mindful not to ridicule them (Hevia and Hobgood, 2003).

When dealing with patients, students, residents and healthcare providers need to regard each patient as an individual and viewed within his own context, particularly when communicating bad news (Trumble et al, 2006). This approach needs to be taken from the onset in the training of healthcare clinicians.

6.2 The Healthcare Professional's Perspective

> "Give Me Standard Patients and I'll Practice Standard Medicine"
> *James S Todd, MD. AMA Executive Vice President, 1990-1996*

The disclosure of adverse events causing serious harm or death can be one of the most difficult experiences that a health professional encounters in his career. Banja (2005) describes how physicians in particular as take pride in their attentiveness to detail and success, and want to be needed or admired among their peers and patients. They will therefore have an extremely difficult time disclosing adverse events (Banja, 2005).

Bayliss (1997) explains the physician's inability to cope with or acknowledge the negative outcomes of adverse events to be due to the belief that he must be the "perfect healer", that is infallible and completely in control. This narcissistic image is developed within the medical schools, and then nurtured throughout the physician's medical careers.

Banja (2005) further describes how physicians, when involved in an adverse event, often blame their subordinates, but also privately "name, blame, and shame" themselves, as they feel that they have failed to adhere to the principle *primum non nocere.* Krishnamoorthy and O'Rourke (2004) go further to explain that when a mistake does occur, it is common for physicians to experience emotions of shame, guilt, or failure for years after

the event. Liebman and Hyman (2004), warn that if healthcare providers are not given the opportunity to process their emotions, they will have difficulty attending to the needs of the patient or family, and may not be able to consider what can be learned from the event to improve patient safety.

The most significant barriers to disclosure was identified by a number of studies to be the fear of lawsuits, the threat to the patient-healthcare provider relationship, the threat to the reputation of the healthcare provider, concern about whether the information might harm patients, and discomfort with how to share the information (Gallagher et al., 2003; Gallagher and Levinson, 2004; Henry, 2005; Wu, 2000; and Wu, 1991). Wu (2000), reflecting on his own experiences as a physician, states:

> You feel singled out and exposed—seized by the instinct to see if anyone has noticed. You agonize about what to do, whether to tell anyone, what to say. Later, the event replays itself over and over in your mind. You question your competence but fear being discovered. You know you should confess, but dread the prospect of potential punishment and of the patient's anger. You become overly attentive to the patient or family, lamenting the failure to do so earlier and, if you haven't told them, wondering if they know. *Wu (2000)*

Gallagher et al. (2003) found that American physicians want to apologize to patients but fear that the apology would lead to increased lawsuits. Krishnamoorthy and O'Rourke (2004) recommend timely and honest responses to errors as an imperative to reducing the enduring emotional and medical consequences of adverse events on the healthcare providers and facilitating constructive changes in medical practice.

Henry (2005) identifies the healthcare providers' own personal uneasiness in dealing with patients or family in emotional distress as yet another reason for withholding disclosure, thereby staying clear of emotionally difficult situations. A 2006 study by Gallagher et al. on how physicians would disclose harmful medical errors to patients,

demonstrates only 42% of respondents stated they would provide a full disclosure stating that an error has occurred; whereas 56% would only provide a partial disclosure (mention of the adverse event but not the error) and 3% would not disclose the error at all, making no reference to the adverse event nor the error. Systems must therefore be put into place to both facilitate the reporting of adverse events and support clinicians who come forward with their honest mistakes.

According to Wu (1991), physicians would prefer that discussions with colleagues about medical errors or adverse events become a part of hospital culture. Eighteen years later, hospitals are bringing reported medical errors and adverse events into interdisciplinary morbidity and mortality discussions. Liebman and Hyman (2003) suggest that in responding to news of an adverse event, senior medical staffs should openly discuss their own past mistakes. Such openness on the part of the senior medical staff would be an important source of support for younger physicians, residents and students. Liebman and Hyman (2003), explain that healthcare providers who feel emotionally supported by their peers and supervisors are more likely to feel comfortable talking to patients after an adverse event, answering questions, and expressing regret.

The following is from Ryan Sidorchuk and the Canadian Patients for Patient Safety Perspective on the Disclosure of Adverse Events from the Draft National Guidelines for the Disclosure of Adverse Events, CPSI (2007):

> "Disclosure is a process of open communication and dialogue rather than a one-time conversation. **[…..]** Disclosure should be delivered by providers trained in disclosure, capable of effectively managing not only their own emotional responses, but also attendant to the needs of the patient / family as well as the healthcare providers involved in the event. These conversations are some of the most difficult conversations that people can be involved in throughout the course of their lifetimes, and support in the form of training, debriefing, peer and inter-professional support,

> and ongoing professional development is essential for the effective evolution of a comprehensive disclosure program throughout the organization. Strong support from the executive leadership of the institution / health region cannot be overstated if an event is to be transparently disclosed to a patient / family in an empathetic and apologetic manner. Disclosure is always the right thing to do."
>
> *Canadian Patients for Patient Safety – CPSI (2007)*

As Henry (2005) explains, the codes of ethical behaviours for physician, nurses and other health care professionals alike, speak to being "forthcoming with patients, preserving integrity, and telling the truth" when an adverse event has occurred. The new organizational culture of healthcare institutions must therefore be based on transparency, open communication, truth telling, and no blame.

6.3 The Patient / Family's Perspective

Numerous studies reveals the disparity between what patients want and what healthcare providers offer following an adverse health event (Gallagher, et al., 2003; Liebman and Hyman, 2004; Mavroudis et al, 2005). According to Liebman and Hyman (2004), patients want the facts about the event, assurances that they will be compensated for any additional medical fees, an apology, and the assurance that corrective measures are being put in place to prevent of similar events in the future.

Buckman and Kason (1992) state that patients faced with unexpected bad news want to feel "acknowledged, heard, and validated". The literature demonstrates that patients tend to respect and forgive healthcare providers who are honest with them about mistakes (Christensen, et al, 1992; Finkelstein, et al 1997; Reckling and Welsh, 2001).

Gallagher and Lucas (2005) performed an extensive literature review and a meta-analysis of studies on adverse events disclosure, and have found that over a 12 years period,

7 studies have stressed patients' preferences for error disclosure and have found patients want to be told about virtually all medical errors in their care. The Mazor et al. (2004) study surveyed 990 members of a New England health plan and found that nearly all (99%) wanted to be told of an error that resulted in any degree of harm as soon as it was discovered. This study found that between 88% and 92% of patients would even want to know about near misses in their care (Mazor et al., 2004). The findings confirmed that when an adverse health event occurred, most patients wanted detailed explanations, a sincere apology, and assurance that steps will be taken to prevent recurrences.

In another study, Gallagher et al (2003) conducted focus groups about medical errors with 52 patients, all of whom wanted to be told about harmful adverse events and expressed particular interest in the details of why and how the adverse event happened. Hobgood et al's 2002 study showed that 88 % of patients in an emergency department would want to know everything about a mistake, while 12% responded that they only wanted to know about a mistake if it potentially affects their health. Furthermore, 76% of the emergency patients questioned wished to be informed of the adverse event as early as possible. Witman et al. (1996) conducted a survey of internal medicine patients on how patients want physicians to handle mistakes, and found that 98% of outpatient internal medicine patients desired disclosure for even minor errors.

Gallagher and Levinson (AHRQ, 2004) explain that there are essentially four things that patients want when a harmful error takes place:

1. An explicit, jargon-free statement that an error occurred and a basic description of what the error was and why it happened, and they object to evasive explanations.
2. An understanding of the implications of the adverse event for their health and how their health care providers will attenuate the consequences.

3. How the physician, other health care workers, and the health care system will learn from the event.
4. An apology from the healthcare provider, demonstrating that the physician genuinely cares about what happened. *AHRQ (2004)*

The patient, who suspects a "cover-up" and only later finds out what actually happened, is likely to become much more upset and angry than he or she would have been after a straightforward explanation and apology. The disclosure conversation if not handled well, often leaves the patient feeling ill informed and more distressed, leading to a break in the patient - care provider relationship. Literature has shown that the most common reason patients sue their healthcare provider is to get information about what happened.

Ethics of care theory focuses on the importance of maintaining the patient-healthcare provider relationship. According to the ethics of care, the most important expression of care is in the actions taken, and the relationship maintained between the patient and care providers. The commitment must be to maintaining a relationship that honors the particular needs of the patient. This is not possible without mutual trust and honesty. Therefore, error reporting and disclosure must be done in a way that best serves the individual patient.

How does one proceed with a disclosure? There are many factors to consider when faced with a disclosure situation, including the cultural, moral, religious, medical and personal needs of the patient and his family. The next section examines the transcultural considerations during the disclosure process.

6.4 Transcultural Considerations

The literature (Berger, 1998; Carrillo et al, 1999; Jecker at al, 1995; Surbone, 2004; Turner, 2001) successfully demonstrates the existence of cultural definitions to maintaining, regaining or attaining good health. Culture is an important part of the context within which

all people, including healthcare providers, understand their world and make decisions about how to act (Berger, 1998). Cultures, as described by Kagawa-Singer and Kassim-Lakha (2003), are "dynamic, responsive, coherent systems of beliefs, values, and lifestyles that have developed within particular geographic locations", and are influenced by prevailing technologies and economic conditions. Cultures are therefore not homogeneous, undergoing constant change, and transforming over time in response to changing conditions (Kagawa-Singer and Kassim-Lakha, 2003). Kagawa-Singer and Blackhall (2001) warn that misunderstandings resulting from a lack of cultural sensitivity can lead to undesired clinical outcomes and poor interactions with patients and their families at critical point during the provision of healthcare.

Kagawa-Singer and Blackhall (2001) suggest that these ongoing modifications through time are influenced by numerous factors, thereby rendering the cultural group different from the original group. In a multicultural society as Canada, there would be greater influences toward variations within cultural groups, than in a more homogenous population. Varying levels of acculturation, assimilation, age, education, income, family structure, gender, geographic location, wealth, immigrant status all modify the degree to which one's cultural group membership may influence health practices and health status. Within North America, and particularly the dominant white population, patient autonomy is a primary focus of decision making in healthcare. Blackhall et al. (1995) explain patient autonomy as emphasizing the rights of patients to be informed about their condition, its treatment, and their ability to choose or refuse life-prolonging medical care.

Blackhall et al. (1995), further argue that although the patient autonomy model founded on the idea of respect for the person, "people live, get sick, and die while embedded in the

context of family and culture and inevitably exist not simply as individuals but in a web of relationships." One may continue to respect the commitment to individual autonomy as well as the ethical requirements of informed consent, while permitting patients to use a family-centered decision making style. These two methods are clearly not mutually exclusive. Blackhall et al. (1995), suggests a broadened views of patient autonomy so that respect for persons includes respect for the cultural values that the patient and family may bring with them to the decision making process.

Patients from different cultural backgrounds, as well as from within the same culture, bring to the medical encounter a multitude of languages, religious beliefs, and means of receiving or accepting bad news (Kagawa-Singer and Blackhall, 2001). In 2003, Kagawa-Singer and Kassim-Lakha very eloquently described culture using the metaphor of weaving:

> "The multiple elements of culture are woven into an integrated whole fabric. The metaphor of weaving is useful to understand cultural variations. The technique of weaving is universal, but the patterns that emerge from each group are culturally identifiable. The symbols and metaphors used in the weavings express the ethos of each culture and the place of the individual within the cosmos. The two functions of culture are analogous to the warp and woof or the perpendicularly woven thread of a tapestry: the integrative and the prescriptive. The integrative function provides individuals with the beliefs and values that provide meaning in life and a sense of identity, and the prescriptive are the rules for behavior that support an individual's sense of self-worth, and maintain group function and welfare. Specific, discrete beliefs and behaviors are like the threads in the tapestry. A single thread of one cultural tapestry can be taken out and compared across groups for its inherent characteristics (such as postpartum rituals), but the usefulness and integrity of the thread as representative of the entire tapestry cannot be judged unless seen within the pattern of the entire cultural fabric within such behaviors were meant to function. Taken out of context, a single thread, like a belief or behavior, may be misinterpreted or even disregarded as unnecessary or maladaptive, especially if evaluated against a standard appropriate to another culture."
>
> *Kagawa-Singer and Kassim-Lakha (2003)*

The process of disclosure should be approached with sensitivity to the patient's cultural norms and beliefs. No studies have specifically investigated cultural differences in attitudes towards error disclosure. According to Surbone (2006), some cultures believe difficult information about prognosis or diagnosis should be shared with the family and not the ill patient. It is however not known whether similar cultural variations exist regarding the disclosure of medical errors to patients (Gallagher and Lucas, 2005). Kuczewski and McCruden (2001) assert that the notion of autonomy is a product of western culture. As patients in North American hospitals are from cultures that hold differing beliefs concerning individual autonomy and self-determination, Kuczewski and McCruden (2001) argue that the healthcare system must not abandon patient autonomy but must be fundamentally aware that culture will play a role in the understanding of what truth means to all individuals involved in the discussion.

Being culturally competent involves having a basic knowledge of how certain ethnic populations may prefer to communicate and involve themselves in patient care, what their perceptions are of medicine, what their beliefs and practices are, and how they handle bad news. For example, the response of some Chinese individuals to a question may be "yes" to indicate that they have heard what was said, not necessarily that the information was understood or that they agree (Jecker et al, 1995). In the Japanese culture there may be a hesitancy to ask questions because of their perception of physicians as authority figures. The Russian culture tends to be adverse to giving bad news to patients. In Asian cultures the proper protocol to giving bad medical news is to first inform the eldest male child, whereas in Latin cultures this information is first given to the spouse (Hern, 2001). Hern (2001) stresses the need for awareness of certain cultural characteristics and values as being

important to ensuring that patients and family of diverse ethnic backgrounds are treated in a manner that is respectful of their cultural norms. However, irrespective of the cultural background, all patients need to be approached with sensitivity and respect, with an honest attempt to provide disclosure information.

For ethnic minorities, while the language barrier remains a fundamental issue in access to healthcare, outcomes in adverse events disclosure are also strongly related to communication between the clinician and patient. Avoiding the use of medical jargon and checking for understanding are two easy ways to reduce misunderstanding with patients of any culture. When the patient speaks a language not understood by the physician or treating team, the use of translation services is very important. Larson and Tobin (2000), stress the importance of active listening and empathy. They suggest asking several open-ended questions, to involve family members as much as possible, and keep family informed throughout the care process.

Medical care and conversations need to be family-centered and address the common concerns while working with both patients and their families or legal representatives. However, the Schattner and Tal (2002) study conducted in an Israeli medical center found family members to be poor surrogates in determining what the patient wished to know. Schattner and Tal (2002) suggest that having patients give an advance directive about truth disclosure may be the most truthful means to answering this question.

A review of the literature (Blackhall et al., 1995; Crawley et al., 2002; Doescher et al., 2000; Kagawa-Singer, M. and Kassim-Lakha, 2003) demonstrates clearly that many clinicians lack the information to understand how culture influences the clinical encounter and the skills to effectively bridge potential differences. This points to the need for new

ways to enrich medical training in order to adequately address culturally discordant encounters among physicians, their patients, and the families. Any and all of these three players (patient, family or healthcare provider), may have different concepts regarding the nature of the adverse event and the expectations for further treatment, and methods of appropriate communication.

While ethical principles call on healthcare providers to respect the uniqueness, dignity, and autonomy of each patient, Jack et al. (2006) explain that it also calls for the acknowledgement of their relatedness; that is, that sense of community, shared values, and the common good which lends itself to an ethics of care, compassion, and concern for others in the disclosure process.

Chapter VII

Guidelines For the Disclose of Adverse Health Events

Once it is determined that an adverse event must be disclosed, the disclosure conversation needs to be carefully planned and carried out (Leibman and Hyman, 2004). Healthcare organizations must determine who should be involved in the disclosure process, how much information to disclose, and how to proceed with the disclosure process. The following section outlines procedures to facilitate effective communication between healthcare providers and patients following an adverse event.

Nancy Dubler (2003) explains that the feelings of fear, anxiety, and embarrassment can cause the health professional to omit crucial information, minimize the gravity of the situation, or ignore questions asked by the patient or his family. This can lead to a poorly handled and insensitive disclosure process. The disclosure of an adverse event to a patient or to his family must therefore be well planned. Choosing the right time, place, people, information, words and approach are all conducive to a positive disclosure experience.

Prior to the disclosure, the individuals leading the disclosure process within an organization must gather all the facts through a review the patient's medical records and an in-depth analysis of the adverse event. The physician participating in the process should be prepared to answer questions about the patient's treatment and prognosis. The questions or concerns that may be raised by the patient or the family must be anticipated, with prepared answers to the anticipated questions.

7.1 Right Time - The initial disclosure discussion should take place at the earliest practical opportunity and preferably within one to two days after discovery of the adverse event, even if the analysis of the root causes of the event has not completed. Subsequent

disclosure discussions should also occur in a timely fashion. In situations the patient or his family suspect the occurrence of an adverse event, Leibman and Hyman (2004) explain that a delay in disclosure can result in feeling of increased anxiety and abandonment.

7.2 Right Place - The choice of settings and location for disclosure discussions is important. The discussion should be conducted in person, at a location and time convenient to the patient or his family. The confidentiality and privacy of the disclosure conversation should also be considered when determining the location. Ideally disclosure conversation should occur in a private office or small conference room where interruptions can be avoided.

7.3 Right People – The choice of who will be part of the initial disclosure process will vary with the seriousness of what has occurred and is influenced by the setting, type of adverse event, and local policy. At a minimum, the medical staff responsible of the care of the patient and the manager of the clinical unit or service should be involved in the disclosure conversation. Other healthcare providers may be in attendance at disclosure discussions. Their role would be to provide support and information to the patient. The total number of individuals should be limited to 3 or four, as too many can be overwhelming to the patient. If the patient is unable to participate due to the gravity of illness or in capacity, then his legal representative must invited to the disclosure meeting. The patient or his legal representative should also have the option of having one or two support persons at the disclosure meeting.

7.4 Right Information - The initial disclosure discussion should include the facts of the adverse event and its actual and potential consequences to the patient. It should also include the measures taken to alleviate or control the harm to the patient, and the new

treatment options being recommended subsequent to the adverse event. A brief overview must be provided of the on-going investigation, with offers of practical and emotional support, such as spiritual care services or counselling. It is important to avoid speculation, or attribution of blame; to avoid identifying a particular individual as being responsible, even when asked for this information. A systems approach to adverse events disclosure is about honest communication of facts and providing support, and not about assigning individual blame.

7.5 Right Words – Gallagher's 2004 study found that overwhelmingly patients want an apology following a harmful error. The expression of an apology demonstrates to the patient and his family the care providers' and institution's recognition of the significance of what has happened and its consequences to the patient. In every initial disclosure discussion, the healthcare provider who is leading the discussion is encouraged to express regret for what has happened. It is recommended that words be chosen carefully, and used with sensitivity to reflect a caring nature. When patients feel they have received a sincere statement of apology, they feel respected, and their trust in their healthcare providers is often restored (MacDonald and Attaran, 2009).

Effective communication strategies are essential for the disclosure process. This includes the avoidance of medical jargon, and the use of layman terms and words that are more likely to be understood by the patient. The disclosure process must not be rushed, and the patient or his family must be permitted adequate time for questions. Healthcare providers involved in the disclosure process must be sensitized to the patient's cultural and language needs, and should verify with the patient or his family whether the information relayed during the disclosure was understood. The patient and family should be given the

name and contact information of the service manager or hospital representative who can be reached for any questions or concerns. Literature has shown that when full disclosure is done well and is coupled with an appropriate apology, lawsuits are prevented, and the patient or family members become active partners in the struggle to improve patient safety (Wu, et al. 1997).

> "The task of breaking bad news is a testing ground for the entire range of our professional skills and abilities. If we do it badly, the patients or family members may never forgive us; if we do it well, they will never forget us."
>
> *Buckman and Kason (1992)*

Effective disclosure of adverse events will never be easy; however, as noted by Buckman and Kason (1992), it is the right thing to do.

Chapter VIII

Conclusion

Numerous ethical approaches and arguments can be made for or against the disclosure of adverse health events. These include, but are not limited to, an ethics of care, feminist ethics, virtue-based ethics, utilitarian ethics, rights-based ethics, deontological Kantian ethics and casuistic ethics. This paper performed an ethical analysis of adverse events disclosure focusing on Kantian ethics and casuist ethics due to the divergent approaches of these two philosophical theories. Deontological (Kantian) and Casuistic ethical arguments were examined using three different case scenarios. In doing so, the author demonstrated how these divergent philosophical approaches when applied to actual cases can converge and lead to conclusions that can be acceptable to both. As demonstrated, the outcome is not consistently in favour of the absolute duty to disclose all adverse events. Reconciliation between the deontological theory and casuistic reasoning in the decision to disclose adverse events is suggested.

Healthcare professionals have an ethical obligation to tell patients about significant medical errors when such disclosure would benefit the health of the patient, would demonstrate respect for the patient's autonomy, or would be called for by principles of justice. This thesis further demonstrated that if a system failure is at the root of the adverse event, then a "blame and train" response to the adverse event diminishes the chance that the event will be reported and furthers the probability that the system failure will remain unchanged. In a systems approach, it is assumed that errors will occur, and that even the most skilled and experienced healthcare provider will sometimes make errors. A change in

safety culture that encourages adverse events reporting and disclosure is only developed through the use of systems thinking. It is also through the application of ethical principles that assists patients in making their own choices, that acknowledges the patients' views, and recognizes their personal and cultural beliefs that will result in positive organizational culture change. It is expected that this change will result in an organizational shift from an environment of closed protectionism to one of open communication and trust.

Adverse events disclosure, like any other communication skill, requires training and practice. This training must start in the schools and continued within the hospital setting. There is a demonstrated need for new ways to enrich the training of healthcare providers in order to adequately address culturally discordant encounters among clinicians, their patients, and the families. Any and all of these three players (patient, family or healthcare provider), may have different concepts regarding the nature of the adverse event and the expectations for further treatment, and methods of appropriate communication. Healthcare organizations must reinforce such training and insure that their policies support healthcare providers in disclosing adverse events to patients.

Based on these findings, recommendations are made to improve communication skills, transcultural sensitivity and disclosure training for clinicians at every level. Finally the impact of adverse events on both the healthcare providers involved in adverse events and the patient needs to be acknowledged and addressed within the healthcare milieu and the classroom. There is a need for future studies specifically investigating cultural differences in attitudes towards error disclosure, from both the patients' and healthcare providers' perspectives.

Disclosing an adverse health event calls for an enormous amount of courage particularly when the healthcare provider feels personally responsible. Students, residents, and other healthcare professionals privileged to observe a disclosure conversation are often inspired by the courageous act, which leaves upon them an everlasting impression. As these acts are observed with greater frequency, they become the norm and not the exception.

Aegroti salussuprema lex.

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