Commission of Inquiry on Hormone Receptor Testing

Volume 2: "Looking Forward…" Policy Papers

The Honourable Margaret A. Cameron
Commissioner

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"Looking Forward…" Policy Papers
Introduction

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Over the past decade, patient safety has emerged as a dominant health policy concern. Regional, national, and international entities have engaged the topic in an effort to develop policies, systems, and technologies to increase patient safety, thus saving lives, reducing injuries, and lessening the burden on health care systems.

Part II of the *Commission of Inquiry on Hormone Receptor Testing* was set within this broad context. Specifically, the mandate of Part II was to look forward and to provide the Commission with information that would assist in the development of recommendations for policy reforms. While Part I of the Commission was focused on the details of the hormone receptor controversy, Part II was designed to tackle questions of broader application. For example, how can we improve the current system so as to reduce the likelihood of similar events in the future? What are the current legal and ethical norms relevant to this issue? And how are other jurisdictions handling patient safety concerns?

The goal was to be constructive, interdisciplinary, and open to a wide variety of perspectives. To this end, a faculty of internationally renowned experts was brought together to provide an overview and analysis of key issues. The faculty included lawyers, ethicists, communications experts, and health care professionals – each an authority in an aspect of patient safety. Some of the faculty were asked to provide background papers, the topics of which were decided upon through a round of discussions with the Commission and faculty members. Upon their completion in the spring of 2008, the papers were made available to the public on the Commission website and were used

as background information for the other key component of Part II of the inquiry: a public symposium, held in St. John's on April 22 and 23, 2008.

The background papers cover a wide range of key issues. Professor Bernard Dickens' paper tackles legal and ethical issues through the lens of government and health authorities. To what degree are these macro-policy-makers responsible and, perhaps, liable for ensuring patient safety and disclosing errors? Dickens concludes that, at a minimum, these entities are politically and ethically responsible for issues of patient safety. At times, they may also be legally responsible for the implementation and operationalization of patient safety initiatives.

Professors Joan Gilmour and Gerald Robertson dig further into the relevant legal obligations and standards–the former exploring broad questions of standard of care and the latter the physician's duty to disclose medical errors. These scholars conclude, *inter alia*, that physicians have a well established obligation to protect the best interests of their patients and, in relevant circumstances, to disclose medical errors.

The Commission also wanted information on emerging international policies and disclosure practices. Papers by professors Thomas Gallagher and Sherry Espin supply this and more. They offer an overview of how various jurisdictions, such as Australia, the UK, New Zealand, and the US, have addressed patient safety issues; they also consider what available evidence tells us about disclosure options and procedures.

Finally, Dr. Philip Hébert's contribution focuses on the ethical dimensions of disclosure, including a historical overview of the evolution of physician disclosure practices. In this regard, we see a shift from paternalistic secrecy toward the current ethos of openness and almost unqualified honesty.

This is a valuable and diverse collection of articles. Each is scholarly and accessible, thorough yet tremendously readable. They serve as a unique policy resource – a "one-stop" set of papers on the

central legal, ethical, and policy issues associated with patient safety, especially as it relates to the practice of disclosure.

Part II - Symposium Agenda

Commission of Inquiry on Hormone Receptor Testing

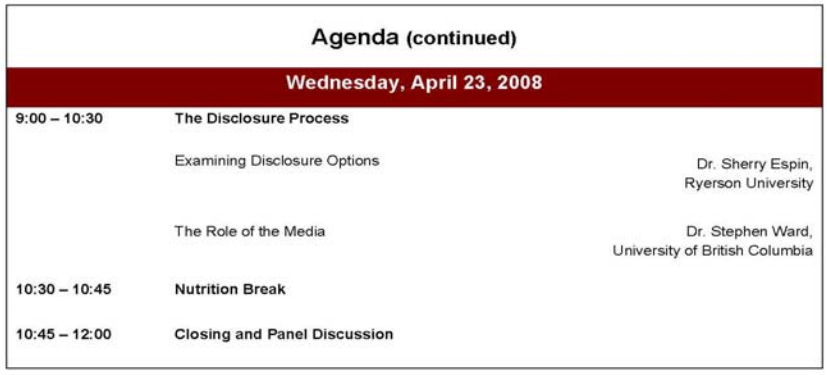
Part II – Symposium: Looking Forward....

Inco Innovation Centre
Memorial University, St. John's, NL
April 22 – 23, 2008

Agenda

Tuesday, April 22, 2008

9:00 – 10:30	**Introductions**	
	Welcome	Professor Timothy Caulfield, University of Alberta
	The Inquiry	Justice Margaret Cameron, Commissioner
	The Patient Safety Movement	Dr. Peter Norton, University of Calgary
10:30 – 10:45	**Nutrition Break**	
10:45 – 12:30	**Medical Error and the Provider's Disclosure Obligation**	
	The Clinical Experience	Dr. Edward Etchells, Sunnybrook Health Sciences Centre
	Legal Obligations	Professor Gerald Robertson, University of Alberta
	Discussion	
12:30 – 1:30	**Lunch Break**	
1:30 – 3:00	**Disclosure Obligations: When, What and by Who?**	
	Legal and Ethical Obligations of Public Health Authorities and Government	Professor Bernard Dickens, University of Toronto
	Duty of Care and Standard of Care	Professor Joan Gilmour, Osgoode Hall Law School
	Discussion	
3:00 – 3:15	**Nutrition Break**	
3:15 – 4:45	**The Disclosure Trends and Policies**	
	International Trends and Norms	Dr. Thomas Gallagher, University of Washington
	Ethical and Policy Considerations	Dr. Philip Hébert, Joint Centre for Bioethics, University of Toronto
	Discussion	



Agenda (continued)

Wednesday, April 23, 2008

9:00 – 10:30	**The Disclosure Process**	
	Examining Disclosure Options	Dr. Sherry Espin, Ryerson University
	The Role of the Media	Dr. Stephen Ward, University of British Columbia
10:30 – 10:45	**Nutrition Break**	
10:45 – 12:00	**Closing and Panel Discussion**	

Copies of the presentations given during the symposium, as well as the transcripts, are available for a limited time on the Commission's website (www.cihrt.nl.ca).

Six of the individuals who gave presentations also produced papers which are found in this volume.

Legal and Ethical Obligations of Public Health Authorities and Government

Bernard M. Dickens, LLB, LLM, PhD, LLD
University of Toronto

Introduction

Individuals who together compose the population of a province expect the provincial governments they elect to employ the taxes they pay to provide, as a principal duty among other duties, reasonable access to medically necessary health services. Medical services are a major charge on the provincial budget, and governments in Canada accept accountability to manage the resources at their disposal to protect and advance the health of members of their public. The dilemma for provincial governments is that, under conditions of unavoidable scarcity, funds devoted to serve the health needs of one member of the public, through provision for instance of hospital services and health service personnel, will leave another member's needs unmet, or incompletely met.

This paper addresses the legal and ethical settings within which governments and the subordinate agencies to which they lawfully delegate powers tackle the dilemma of allocating usually inadequate resources to serve the medical needs of the population for whose care they are responsible. They must explain how they propose to allocate resources to maximum beneficial effect, and justify their decisions, particularly those that deny patients services indicated for their health protection, or that delay their necessary and even critical care.

Health care agencies of government must also justify decisions about disclosure of health care information, not only to the public at large but also to individual patients affected by their resource allocation decisions. The Supreme Court of Canada has endorsed patients' rights to

make informed decisions about their health care, as an important aspect of their individual self-determination and dignity. Patients have a legal right to know the implications of choices among services offered to them, and an ethical claim to know when allocation decisions, justified as serving the public interest, deny them individual choices.

Accordingly, this paper reviews the legal and ethical accountability of government agencies that are empowered to decide on allocation of medical care resources, and are responsible to explain, at population-wide and individual patient levels, the decisions they have made. This involves interactions among the different branches of government.

Under the classical doctrine of the separation of powers, the legislative, executive and judicial branches of government are independent of each other. In the democratic practice of parliamentary government under the rule of law, however, the exercise of power is often highly interactive. That is, the executive branch of government develops policies, which are given the force of law by enactment through the legislature, in which the political party or parties in government can achieve a majority vote, and laws are assessed under constitutional standards and interpreted by the judiciary. Courts do not rule on the wisdom, practicality or, for instance, morality of government policies, but when policies are given effect through legislation, the courts determine whether the policies are constitutional. They may be found unconstitutional for being beyond the scope of legal authority directly given by the Constitution of Canada, or for being in violation of the Canadian Charter of Rights and Freedoms, which was incorporated into the Constitution in 1982.

For instance, in 1988 the Supreme Court of Canada held that the restrictive provisions on abortion in the Criminal Code violated the Charter, because the extent to which they denied women security of the person (Charter s. 7) was not demonstrably justified in our free and democratic society (Charter s. 1), (*Morgentaler*, 1988) and were accordingly unconstitutional and inoperative. When a provincial government proposed legislation to confine abortion procedures to

provincial hospitals in order to threaten sanctions against private abortion facilities for violation of provincial hospital legislation, the legislation was found outside the constitutional authority of a province, because its purpose was primarily penal and the federal government has exclusive constitutional power to create criminal law (*Morgentaler*, 1993).

Policy Decisions and Operational Decisions

The issue of legal liability of public health authorities, acting as agents of government, has arisen with rejection of the historical legal immunity of government, which was based on the ancient pedantry that the Crown could not be sued in the Crown's own courts. In 1989, the Supreme Court of Canada observed that:

> The functions of government and government agencies have multiplied enormously in this century. Often government agencies were and continue to be the best suited entities and indeed the only organizations which could protect the public in the diverse and difficult situations arising in so many fields…. The increasing complexities of life involve agencies of government in almost every aspect of daily living. Over the passage of time the increased governmental activities gave rise to incidents that would have led to tortious liability if they had occurred between private citizens. The early governmental immunity from tortious liability became intolerable. (*Just*, 1989, 704)

Cory J. added, however, that:

> the Crown is not a person and must be free to govern and make true policy decisions without becoming subject to tort liability as a result of those decisions. On the other hand, complete Crown immunity should not be restored by having every government decision designated as one of policy. Thus, the dilemma giving rise to the continuing judicial struggle to differentiate between policy and operation… The dividing line between "policy" and "operation" is difficult to fix, yet it is essential that it be done. (*Just*, 1989, 704)

The doctrine is being increasingly questioned that, while the courts will not intervene in policy decisions that are within the constitutional power of the government and do not offend the Charter, they may scrutinize operational decisions (Sossin 1993, 372). These include decisions on how a policy is implemented. For instance, courts may consider claims that policies have been put into operation negligently, so harming legally protected interests of others. A decision

to incinerate waste products within an area rather than to transport such products elsewhere, for example, will not be open to court challenge, but if incineration causes a nuisance to residents, their action for private nuisance may be heard, with a potential impact on feasibility of the policy itself.

Whether acts are protected from judicial scrutiny on the ground that they are governmental policy, or open to challenge because they are means of putting a policy into effect, may not be self-evident, and their nature may be determined by the persuasiveness of advocacy. For instance, a health department's decision to cease to monitor the quality of a programme may appear as a policy to economize in expenditure of taxpayers' money, or as an element of programme operationalization. If it is the former, courts will not review whether cancellation of the quality assurance programme resulted in injury (*Just* 1989, 704), but if the latter, patients who claim their health was harmed by the lack of ongoing attention to the programme's declining safety may proceed in their legal action, for instance for negligence. Courts may be prepared to address such an issue of private law, but have conventionally been reluctant to assess policy decisions under principles of public law, although this deferential approach may be changing as courts give greater priority to concerns of public safety (Syrett 2005).

It is usually expected that policy decisions are made at a significantly higher administrative level than operational decisions, for instance within a ministerially - directed government department rather than through the management of subordinate officers of an agency. Nevertheless, the Supreme Court of Canada has noted that "a true policy decision may be made at a lower level provided that the government agency establishes that it was a reasonable decision in light of the surrounding circumstances" (*Just* 1989, 707). In a health care setting, for instance, decisions about a population's medical care may be delegated by a Department of Health to Regional Health Authorities, which are empowered to make policy decisions regarding the use of equipment and personnel in the best interests of the populations of their regions as a whole, in contrast to a decision about the care of an individual patient. That is, the regional authority may make a resource allocation decision

that is "a true policy decision" governing the overall duty of care, in contrast to the standard of care a health care practitioner owes to an individual patient within the implementation of that policy.

A practitioner who declines use of available, appropriate diagnostic or other equipment in a patient's care in order to economize in use of resources may be legally liable to the patient if preventable injury results, for negligence and/or for breach of fiduciary duty (*Law Estate*, 1994). However, if such equipment is unavailable due to a policy decision of management to economize, no liability may arise on the part of either the practitioner or the health authority. The former has no control over availability of resources, and the latter, though administratively responsible for care of a specified population as a whole, does not owe a private law duty of care to individual members of that population.

More clearly operational are monitoring and enforcement of professional standards, such as the effectiveness with which medical staff responsible for patients' care communicate with each other. Communications may be direct or mediated by notations on patients' medical files or records, but by whatever means, they should be timely and clear. If the significance of information is not observed, for instance because pathologists' findings are not understood by oncologists, errors in care may occur for which legal liability may arise, such as for breach of a private law duty of care.

Private Law Duties of Care

The arrival in Canada of new viruses, such as the West Nile virus and the coronavirus responsible for the Severe Acute Respiratory Syndrome (SARS) outbreak, has triggered litigation, by individuals and classes of litigants, claiming governmental breach of legal duties and standards of care owed to individuals in a private capacity. Some preliminary motions by municipal and provincial governments to dismiss such claims by affected private parties, as disclosing no legal cause of action, have failed, judges finding it premature to rule that no private law duty of care could be owed to the plaintiffs by such defendants, although the federal government has succeeded in removing itself from claims. However, in 2006, a provincial Court of Appeal

rejected a claim, brought by family members, of provincial liability for failure to prevent the West Nile virus infection of which their relative died. The Court found it "plain and obvious" that there was no private law duty of care owed to an individual by the government to prevent such infection, and that public health priorities should be based on the general public interest without the fear or threat of lawsuits brought by or on behalf of private individuals (*Eliopoulos*, 2006).

The background law is expressed in an English House of Lords decision of 1978 (*Anns*, 1978) which the Supreme Court of Canada has adopted and applied in a succession of cases since 1984 (*Kamloops*, 1984). A leading case in 2001, Cooper v. Hobart (*Cooper*, 2001), concerned whether a statutory regulator was liable in negligence for failing to oversee conduct the regulator licensed, resulting in lost investments. Finding that "[t]he question is whether the [regulator] owes a private law duty of care to members of the investing public giving rise to liability in negligence for economic losses," the Court immediately noted both that "[s]uch a duty of care is as yet unrecognized by Canadian courts," and that "this is not a proper case in which to recognize a new duty of care" (*Cooper*, 2001, 196). This leaves open whether a different case or loss, such as of health or survival itself, would be a proper case in which to find a private law duty of care.

The Court in *Cooper* observed that:

> In brief compass, we suggest that at this stage in the evolution of the law, both in Canada and abroad, the *Anns* analysis is best understood as follows. At the first stage of the *Anns* test, two questions arise: (1) was the harm that occurred the reasonably foreseeable consequence of the defendant's act? and (2) are there reasons, notwithstanding the proximity between the parties established in the first part of this test, that tort liability should not be recognized here? The proximity analysis involved at the first stage of the *Anns* test focuses on factors arising from the *relationship* between the plaintiff and the defendant. These factors include questions of policy, in the broad sense of that word. If foreseeability and proximity are established at the first stage, a *prima facie* duty of care arises. At the second stage of the *Anns* test, the question still remains whether there are residual policy considerations outside the relationship of the parties that may negative the imposition of a duty of care. (*Cooper* 2001, 203).

Accordingly, issues of policy pervade the recognition, or non-recognition, of private law duties of care that may be owed to individuals, or classes of individuals, by governments and governmental agencies in their implementation of their policies.

The Supreme Court of Canada cases that have considered, and uniformly rejected, private law duties of care have concerned regulation of such matters as economic interests (*Cooper,* 2001), house construction (*Kamloops*, 1984), highway maintenance (*Just*, 1989, *Swinamer*, 1994 and *Brown*, 1994) and lawyers' trust accounts (*Edwards*, 2001). These are matters in which individuals may exercise defensive strategies, such as commercial insurance or taking independent professional advice, for instance from building surveyors or investment counsellors. Courts may in time have to consider whether regulation of health care services is comparable, or distinguishable. It is often appreciated that, even with improved education and access to electronic sources of medical and related information, patients cannot take responsibility for health care strategies except to choose among selected options their health service providers offer. They may have no access to physicians outside the facilities that serve them, and in many jurisdictions cannot acquire private insurance for health services covered by their provincial health insurance plans (*Chaoulli,* 2005). Employment of health care resources depends on the expertise of health facility administrators and medical professional judgment. In the Supreme Court of Canada *Just* judgment, Cory J. cited with approval the Australian equivalent of the Supreme Court, the High Court, in the *Sutherland* case (*Sutherland*, 1985), where Mason J. wrote that:

> a public authority is under no duty of care in relation to decisions which involve or are dictated by financial, economic, social or political factors or constraints…But it may be otherwise when the courts are called upon to apply a standard of care to action or inaction that is merely the product of administrative direction, expert or professional opinion, technical standards or general standards of reasonableness. (*Just*, 1989, 706)

Courts may be called on to consider whether medical professional decisions on the testing or re-testing of patients' tissue samples, or on providing patients with information that becomes relevant to their care

through decisions that patients make under legal and ethical principles of informed consent (*Reibl*, 1980) satisfy the first stage of the *Anns* test, on grounds of proximity and foreseeability of risk of harm to patients' health interests. In *Cooper*, the Court gave emphasis to the issue of proximity in assessing the first stage of the *Anns* test. If that first stage is satisfied, and a *prima facie* duty of care therefore arose, courts would then have to consider residual policy considerations that may negate that duty.

In addition to possible liability in negligence, issues of possible breach of fiduciary duty or of Charter rights may have to be addressed. Section 25 of the provincial Regional Health Authorities Act 2006 provides that:

> An action for damages does not lie against a trustee, an officer or an employee of an authority personally for anything done or omitted in good faith in the performance or intended performance of a duty or the exercise or intended exercise of a power under this Act, or for a neglect or default in the performance or intended performance of a duty, or the exercise or intended exercise of a power, in good faith, under the Act.

The 2006 Act was enacted to replace the provincial Hospitals Act, and section 25 may influence judicial assessments of whether there are policy reasons that negate a private law duty of care. However, the section leaves open liability to action other than for damages, such as for a mandatory injunction to compel conduct, or for Charter violation. This latter appears improbable, since the Charter binds only governments and their agencies (*Stoffman*, 1990). The Act's immunity covers only "a trustee, an officer or an employee of an authority personally," however, indicating that no immunity is intended for a Regional Health Authority itself against a claim for damages. That too may weigh in the balance of determining whether an Authority can bind government to a private law duty of care.

The challenge in resolving whether a governmental agency owes individuals a private law duty of care is that attention to the interests of particular individuals may distract the agency from the duty and power vested in it by the legislature to serve the interests of a community as a

whole. Individual and communal interests do not necessarily coincide, and may conflict. Applying scarce health care resources in the interests of a community of actual and prospective patients may require decisions from which individual patients suffer, such as by denial or delay of services on which their health and even very survival depends. These decisions have their impact in clinical settings and in relationships between physicians and patients. Courts have to decide whether they are to be viewed, as a matter of policy, as decisions concerning public sector or private sector interests. Regulatory agencies' acts that promote benefit to the community may impose costs and harms on individuals, while protecting individuals' interests may sacrifice coherent pursuit of a public advantage.

Modern Challenges

The challenge of new medical technologies appears manageable under the framework of the policy/operational dichotomy. Decisions about whether to fund newly emerging technologies and to hire or re-train personnel to apply them are the sorts of economic decisions that the policy characterization protects from negligence and comparable claims. A facility's lack of cutting - edge equipment raises private law questions within the doctor - patient relationship of whether practitioners must know and inform patients of where superior equipment for diagnosis, therapy, or, for instance, post-operative monitoring may be accessible. However, the decision to postpone acquisition of state-of-the-art technologies does not attract the liability of governments or, for instance, chief executive officers of institutions, once decisions are made not to fund their availability, or not to make them available to certain classes of patients. The latter may raise Charter questions, however, if the basis of allocation and denial appears to discriminate on a prohibited ground, such as disability, sex, or ethnicity (*Eldridge*, 1997).

If unqualified personnel are required or allowed to apply new or prevailing technologies in the use of which they are unskilled, an operational failure may be found. This may in principle attract liability in negligence, unless policy reasons are established under the *Anns* test for government protection. For instance, if skilled operatives are not available, and on-the-job training of otherwise experienced personnel is

acceptable to adequately informed patients, errors of judgment including those that amount to negligence (Merry 2001), but falling short of recklessness, may be found worthy of judicial protection on policy grounds. Physicians do not have to disclose to patients the first time they are undertaking procedures without supervision (*Mulloy*, 1935), although patients so informed may decline and seek more experienced care, on the policy ground that supply of experienced practitioners requires that each undertake an unsupervised procedure for the first time. A comparable policy may protect a governmental agency that allows an under-skilled practitioner to apply a new technology in care of a human patient.

Innovations in legal process may prove more challenging. The Charter has opened the way to new claims against government (Syrett 2005, 12-17). Section 24(2) allows plaintiffs to have courts determine appropriate remedies when claims succeed, without having to identify in advance the remedies they want, which risks loss of claims successfully presented on grounds of legal liability and evidence, for choice of legally unavailable remedies. This scope for judicial initiative over remedies was shown in 1988 in the case of *Morgentaler*, when the Supreme Court of Canada found breach of security of the person in violation of the Charter, because women suffered anxiety waiting to know if they would be granted procedures for which they were eligible that the government had undertaken to make accessible (*Morgentaler*, 1988). The defendants were making a claim for relief from criminal liability, but in upholding a jury's verdict of acquittal, the Supreme Court declared void the Criminal Code provision under which the conspiracy charge against them arose.

Courts are also more open to claims of misfeasance in public office, which may discard the historical common law distinction between misfeasance and nonfeasance. Under this distinction, a person could not be held liable for not intervening to prevent another's injury, if the person owed no legal duty to protect that other, such as the duty that parents owe their dependent children to protect them. Courts are becoming more willing to find that nonfeasance, meaning failure or refusal to act, can result in legal liability when a public duty to act exists, which may include exercise in good faith of a duty to decide whether or not to take action. In 2003, in the Supreme Court of Canada, Iacobucci J. explained that this tort is aimed at "a public officer who *could* have

discharged his or her public obligations yet willfully chose to do otherwise" (*Odhavji Estate*, 2003 para. 26). The judge described the elements of the tort as follows:

> First, the public officer must have engaged in deliberate and unlawful conduct in his or her capacity as a public officer. Second, the public officer must have been aware both that his or her conduct was unlawful and that it was likely to harm the plaintiff. (*Odhavji Estate*, 2003, para. 23)

However, he added that:

> A public officer may in good faith make a decision that she or he knows to be adverse to interests of certain members of the public. In order for the conduct to fall within the scope of the tort, the officer must deliberately engage in conduct that he or she knows to be inconsistent with the obligations of the officer. (*Odhavji Estate*, 2003, para 28)

Courts may be more willing to require public officers to consider whether becoming responsible for consequences of their conduct and decisions that harm the interests of certain members of the public would violate the obligations of their office.

Certification of class actions against governments has also raised new challenges. Private sector liability results from breach of duties owed to particular individuals or groups, such as duties of due care, while public sector liability, such as to judicial review of decision-making procedures, is based on public duties, such as the duty of public decision-makers to exercise their statutory authority in a fair and reasonable manner. However, it has been observed that "[c]lass actions typically are brought on private law grounds [such as negligence] alleging discrete duties but in contexts where the decision-makers were exercising broad statutory authority in the public interest. Class actions against the Crown often compel courts to draw artificial distinctions between private and public law paradigms" (Sossin 2007, 9).

The advantage for plaintiffs in class actions alleging private law wrongs, such as negligence, is that they can result in multi-million dollar awards against public bodies equipped, through the power for instance of taxation, to acquire the means to pay. The public law right to have

judicial review of decisions harmful to applicants' interests that they claim were made incorrectly, is that when claims succeed, judges may only require the decisions to be made again, correctly. However, the decisions so made may prove to be the same harmful decisions as were made incorrectly before.

Countering advantages to plaintiffs of class action suits against governments is the modern movement towards privatization, or out-sourcing. When governments contract with private entities for delivery of services, such as laboratory testing of patients' tissue samples, and the services are delivered to consumers who suffer injuries when they are performed negligently, consumers who sue successfully may find the private entities, such as private persons or diagnostic laboratories, incapable of paying the sum of damages awarded. The entities may become insolvent due to judgment debts, and as corporations be wound up, but plaintiffs may remain uncompensated. The legal question then arises of whether the contracting governments can be sued directly, such as for breach of non-delegable duties, or on the basis of their vicarious liability (Adjin-Tettey 2007).

It has been noted that "[c]ourts…have been reluctant to recognize statutory non-delegable duty absent specific legislative provisions to that effect" (Adjin-Tettey 2007, 48). Further, vicarious liability depends on master-servant relationships, making the former legally liable for negligence and perhaps other wrongs of the latter committed in the course of employment, on policy ground that the servant acts for the benefit of the master, and the master is likely to have greater means to compensate the victim, from capital assets or commercial insurance. However, when a service is outsourced to an independent contractor, that contractor selects the means to discharge the contracted obligation, and the party engaging the independent contractor is not vicariously liable for torts committed in the choice or use of such means. The employer may be directly liable, however, for negligence in the selection, instruction or facilitation of the independent contractor, such as by selecting a person or laboratory unequipped to perform the contracted service. Where no such direct liability is recognized, the only means by which an employer can be liable for the torts of an independent

contractor is for a court to find that the employer bears a non-delegable duty to ensure that the contracted service is performed according to legal standards.

A case may be made for the employer's non-delegable duty where the recipient of the service reasonably sees its performance as a function of the employer, cannot be expected to know the independent status of the person or agency that directly performs it, and may suffer devastating loss that only the employer can redress or compensate if the service is performed negligently. For instance, when a Regional Health Authority engages independent contractors, such as physicians not on its payroll, to undertake diagnostic tests on patients or their tissue samples, the patients may reasonably regard the Authority as responsible for their care, and legally liable for any negligence in its delivery. They may regard the Authority as underwriting the quality of care they receive, particularly when the Authority or a Department or Ministry of Health has given public assurances of accepting responsibility for the quality of such care.

Physicians are not usually held to guarantee the effectiveness or safety of procedures they undertake, but remain liable for their negligence. Courts may be willing to hold those who engage them as independent contractors as held to the same standard. However, the prevailing jurisprudence appears to the contrary (*Yepremian*, 1980), and academic analysis, while deploring this result as leaving victims of negligence without effective compensation, offers little prospect of its reform by the courts (Adjin-Tettey 2007). Political pressure may need to be mounted to persuade a provincial legislative assembly to impose a non-delegable statutory duty on government to underwrite compensation for improperly performed acts of independent health service contractors that cause injury.

Ethical Obligations

Ethical principles according to which physicians and other health care providers treat patients are now described as bioethics. This has become an established area of knowledge, although many of its applications are contentious and evolving.

Despite writing, as recently as January 2008, that "bioethics continues to be a cultural flashpoint where disagreements run deep, the stakes continue to be high, and the voices and sources of authority diverse," Arthur Caplan, a leading U.S. bioethicist, acknowledged that "bioethics has rapidly evolved to become a discipline" (Caplan 2008). In contrast, ethical principles of public health practice are relatively newly emerging (Nuffield 2007), and pedagogically underdeveloped. Indeed, the Public Health Agency of Canada sponsored the First Canadian Roundtable on Public Health Ethics only in November 2007. Further, it is not clear whether governmentally-funded Regional Health Authority practice is governed by what may be described as conventional or standard bioethics, by public health ethics, or by some ethical combination. The development of bioethics to address relationships between patients and health care providers has been through microethics, concerned with person-to-person interactions. Bioethics also has the dimension of macroethics, however, concerned with administrative or bureaucratic issues in health care, including operation of health service facilities and resource allocation to protect and advance the health interests of communities or populations. Regional Health Authorities may be expected to apply macroethical considerations in discharge of their duties, rather than public health ethics.

However, the academic interest in categorization may be of little relevance, since many issues in resource allocation concern the operation of health systems in the public interest, and involve considerations that may be approached through both bioethics and public health ethics. For instance, when a new infection affects a population, the public health agency of the area will be engaged, applying the ethics of the public health service, including, for instance, compulsory isolation of affected persons and quarantine of persons who may have been exposed to infection, but affected patients will be hospitalized and treated by health care providers whose conduct is usually assessed by principles of routine microethics, and whose availability for that purpose involves the macroethics of health facility administration.

Although bioethics and public health ethics may overlap or coincide, their orientations can be quite different, even at opposing ends

of a spectrum. Microethics is patient-oriented, preoccupied with patient autonomy, disclosure of material facts for decision-making and, for instance, confidentiality. Public health ethics is population-oriented, and can be directive and intrusive, including mandatory reporting to governmental health officials of patients' medical conditions and names, and requirements that patients disclose with whom they have been in contact, and the nature of that contact. Leading commentators have observed that "the difference between the individualistic orientation of bioethics and the population and societal focus of public health…[causes] the deep divide between the central commitments of bioethics and the values that animate the practice of public health" (Callahan and Jennings 2002). They add that "while mandatory measures and recourse to coercion may be necessary [in public health practice], efforts designed to elicit the voluntary co-operation of those at risk…are preferable and indeed may be more effective" (Bayer 2004, 491).

This indicates the spirit in which Regional Health Authorities best apply principles at the macroethical level. The origins of modern bioethics are the subject of dispute (Jonsen 1998, Reich 1999), but it is widely agreed that the principles were most authoritatively expressed in 1979 in the seminal report of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects," often described simply as the Belmont Report. The principles are considered applicable far beyond the areas of medical and behavioural research, and are relevant to clinical care, at the microethical level, and, for instance, to resource allocation, at the macroethical level. They are now expressed in different formulations, but usually number no more than four.

The principles are usually presented in the same sequence, in what is sometimes described humorously as "the Georgetown mantra" because of the affiliation of leading Belmont participants, but the Belmont Report emphasizes that they are not set out in order of priority. A central challenge in bioethical analysis and decision-making is to determine which should prevail over the others in a given case. The principle described first is Respect for Persons, which has two elements, namely

autonomy of persons capable of exercising autonomy, and protection of those incapable. The first element is so dominant in the U.S. that some American texts describe the first principle simply as Autonomy.

The contrast between capacity to exercise autonomous choice and incapacity or dependency may be clearly applicable to biomedical and behavioural research, in which independent individuals can freely decline to participate and from which dependent persons such as children should be appropriately protected. The contrast is often less clear, however, when complex medical choices are available to patients affected by serious diseases. Disclosure of material information to achieve patients' informed decisions regarding their care is designed to serve their autonomy, but patients often remain dependent on their clinicians' judgment and recommendations directed in good faith to their best interests. However independent patients may be in their personal, family, social, and occupational lives, they are often dependent as patients. Paternalistic approaches to patients that infantilize them are properly condemned, and health care providers aim to achieve equal partnerships with their patients, but it may be unrealistic to believe that otherwise competent patients can be in full control of diagnostic or treatment decisions that affect them. There remains an element of trust underlying their relationships with their health care providers which providers, and health facility administrators, should be cautious not to abuse or betray.

The second Belmont principle is Beneficence, meaning the duty to do good and to maximize beneficial potential. This principle may include the classical principle of medicine, Do No Harm, but this is often presented in its own right as a third principle, Non-Maleficence. The final ethical principle is the one to which the law devotes itself, the principle of Justice. The Belmont Report allows expansion of this in the way that philosophers and lawyers often elaborate, to include not only the duty to treat like cases alike, the basis of legal precedent, and to treat different cases in ways that acknowledge the difference, but also duties of distributive justice, meaning striking a fair allocation or balance of burdens and benefits among populations. The former duty serves individual justice, while the latter duties serve social justice.

An expanding bioethical literature has addressed these principles, sometimes supplemented by others, such as the principle to care for and about others (Sherwin 1992, 49-57), but almost exclusively by discussion of clinical and individual cases, many of which are unrepresentative of generally prevailing realities. In the U.S., for instance, intense attention has been given to cases well known by individuals' names, frequently women's, dating from Karen Ann Quinlan in 1976, through the surrogate mother Mary Beth Whitehead in 1987, to the permanently vegetative Nancy Cruzan in the late 1980s and early 1990s, and the more recent Terri Schiavo. However, U.S. bioethicists have paid little regard to whether an estimate of about 47 million citizens who lack health care insurance, and many others who are seriously under-insured, warrant their attention (Lane et al. 2000). The application of bioethical principles at the macroethical level is, at best, work in the earlier stages of progress.

In Canada, preservation of the system of publicly funded universal health care, providing reasonable access to medically necessary services, has come under scrutiny in light of the Supreme Court of Canada's somewhat inconclusive decision in the 2005 *Chaoulli* case (Dickens 2005). Within a system of public funding, however, it must be recognized that not every theoretically possible service can be provided, and that some compromises in the ideal quality of care may be required, although not falling below a legally-determined minimum standard. Sometimes explicitly but often implicitly, rationing of scarce health care resources is required.

A sophisticated literature exists that addresses the principles and justifications of health resource rationing, from various perspectives including the initial law-and-economics approach (Calabresi 1978) and the more recent comparative law approach, represented in Keith Syrett's 2007 book *Law, Legitimacy and the Rationing of Health Care: A Contextual and Comparative Approach*. A more rudimentary approach is also relevant, however, applying the Belmont principles and explaining their interaction and prioritizing.

A relatively low priority is given, for instance, to individual autonomy. Individuals remain free to decline the resources offered for their care, but cannot command resources that administrators find inappropriate for them. That is, the resources are considered better applied elsewhere, in service of the greater public or communal good. In some systems, indeed, such as in Canadian provinces to which the *Chaoulli* decision of the Supreme Court of Canada is inapplicable, individuals may lawfully be denied the legal means freely to purchase, from their own pockets, health services or insurance for services covered by their provincial health plan, unless they do so outside their province of residence.

Protection of persons incapable of autonomy, such as children and intellectually disabled persons of all ages, poses a challenge to which provincial governments in general and provincial health ministries and agencies in particular, are at times hard pressed to respond. The Supreme Court of Canada, for instance, reversing the British Columbia High Court and Court of Appeal, has upheld limits on provincial funding of services for pre-school age children affected by autism (*Auton*, 2004). However, provincial authorities are urged to do more for such children than they are legally required to do, on the claim that ethics requires more than a legal minimum. Similarly, the Canadian Senate's Kirby/Keon Committee report on mental health care provides evidence of serious provincial under-funding of services for those who are mentally impaired (Kirby 2006).

The principle of beneficence, the duty to do, and to maximize, good, underpins the entire enterprise of public health, as does its corollary, non-maleficence, to avoid or at least minimize harm. The challenge, however, is to determine how general health benefits can be determined. A utilitarian pursuit of achieving the greatest good for the greatest number is attractive, but its implication of creating or tolerating disadvantage for minorities risks violation of the protective duty towards the vulnerable in the previous principle and violation of non-maleficence. For instance, resources given to raising levels of preventive health care, such as by population-wide vaccination, and education and incentives for lifestyle variation, may be taken from budgets to fund, for instance,

palliative care programmes, geriatric services, or organ recovery and transplantation programmes. That is, scarce resources allocated to the needs of one segment of the dependent community will be unavailable to serve the needs of another.

This implicates the ethical principle of justice, especially distributive justice, which requires a fair social allocation of benefits and burdens. Strong ethical justification is required deliberately to deprive one segment of society in order to benefit another. A justification has been proposed, however, to allocate resources to the young, to promote their health and survival, at the cost of reducing expenditures on geriatric services and end-of-life care. In his 1990 book, *Setting Limits*, Daniel Callahan introduced the ethical concept of intergenerational justice. By this concept, resources would be given to provide only comfort care to patients who had reached a particular advanced age, but not to provide major surgery, transplantation or, for instance, intensive life-prolonging (meaning death-postponing) services. Instead, resources would be given to newborn, pediatric, child and adolescent services, including preventive health care and encouragement of healthy lifestyle practices, in order to equip younger people to survive into their more advanced years. The injustice of denying costly forms of care in their old age to people who had cared for their health at their own expense while young was considered transitory and tolerable. A socio-political challenge would be, of course, to set the age beyond which taxpayers would no longer have claims to more than comfort measures on a health care programme their taxes, paid over a working lifetime, had funded.

Accountability for Reasonableness

The conflict implicit in subordinating the interests of one segment of a population to the interests of another can be reconciled through recognition of a community. Community members may accept the need for rationing of scarce resources and restrictions on their own access to care, if they are satisfied that resource allocation is based on fair and reasonable principles and processes. It has been noted that allocating limited resources to meet unlimited needs or demands is described as "rationing" because it is, or should be, based on rationality, or reason (from the Latin *ratio*) (Klein 1996, 7). A leading analyst of the ethics of

allocating health care resources, Norman Daniels, has developed a model for measurement of decision-making processes, which he describes as the "Accountability for Reasonableness" model (2000a, 2000b).

Elaborating on this model, Daniels advances proposals for fair decision-making processes that resonate in the area of public law (2002). As Keith Syrett observes, "there are strong parallels between the conditions which constitute the 'accountability for reasonableness' model, and principles which are central to public law (and which, in consequence, find frequent articulation in public law jurisprudence)" (2007, 142). In the 1999 *Stein* case, for instance, the Superior Court of Quebec stated that courts would review health resource allocations "with caution and deference and will intervene only when the evidence, viewed reasonably is incapable of supporting the findings of fact or when the tribunal's interpretation of the legislation is patently unreasonable" (*Stein*, 1999, para.18). Accordingly, this approach enjoys both ethical and legal legitimacy.

However, the special challenge in the ethical allocation of health care resources is to blend the objective, dispassionate rationality of rationing with compassion for sick, dependent individuals. Pioneers of the law-and-economics movement, or analysis, recognized this concerning "tragic," meaning life or death, choices (Calabresi 1978), but this analytical perspective applies more broadly. They make the observation regarding life-or-death choices, but which is equally applicable across a spectrum of health care resource distribution decisions, that:

> when attention is riveted on such distributions they arouse emotions of compassion, outrage and terror. It is then that conflicts are laid bare between on the one hand, those values by which society determined the beneficiaries of the distributions, and (with nature) the perimeters of scarcity, and on the other hand, those humanistic moral values which prize life and well-being. (Calabresi 1978, 18).

A utilitarian approach to achieving ethical or equitable health services by allocation of limited resources, combining cost-effectiveness with consumers' quality of life (rather than with their bare survival) is by

calculation of Quality-Adjusted Life Years (QALYs). This involves an estimation of the additional years of life an intervention of health care services will achieve in a given population, multiplied by measurement of quality of life. Measurement is on a scale in which zero denotes death, one denotes a complete absence of disability, distress and discomfort, and intermediate states of disability and illness receive a value between zero and one (Nord 1999). The cost-effectiveness QALYs approach raises ethical concerns, however, such as that it gives priority to routine treatment of generally healthy patients over intensive treatment of critically ill or injured patients, and directs care away from the few patients most in peril and in need, and towards those only mildly or temporarily impaired. The approach runs counter to the influential rule in medicine, embodied in medical triage, to give priority to potentially life-preserving "rescue" interventions, even though this use of resources may not deliver the greatest overall, or indeed individual, benefits (Nord 1993).

Rather than pursuing the goal of achieving a quantified greatest healthiness of the greatest number, a calculus of healthiness analogous to the "calculus of felicity" utilitarians have long been derided for seeking in order to measure the greatest happiness of the greatest number, Norman Daniels seeks ethical allocation of health care resources through reasonable and transparent decision-making processes. This confirms the compatibility of macroethics and law, in that a legitimate resolution of conflict is reached in each through due process of decision-making. Indeed, in their 2002 book *Setting Limits Fairly*, Daniels and Sabin urge the creation in the literature of a body of "case law," meaning recorded instances of decision-making that would provide precedent or guidance for sound practice of ethical rationing. The focus is not so much on making ethical decisions as on making decisions ethically.

Daniels and Sabin require that, to be ethically justified, choices on health care resource distribution be made by "appeals to reasons, including values and principles, that are accepted as relevant by people who are disposed to finding ways of co-operating with each other on mutually acceptable terms" (2002, 5). Reasons supporting choices can include relevant facts, and policies. Facts can be derived from empirical

and epidemiological studies, such as health system evaluations of clinical outcomes, and measurements of conformity and non-conformity with accepted standards, for instance of effectiveness of health care interventions. Facts can at times be elusive, however, since data agreed to be reliably derived may nevertheless be open to different interpretations, and one interpretation may be favoured over another as a basis of decision-making. Policies may also be translated into resource allocation decisions, reflecting "values and principles." For instance, funding a needle-exchange programme for injection drug users can be opposed, in order not to support risk-laden addictions and unlawful behaviour, or be accepted as a pragmatic harm-reduction strategy including a counselling and rehabilitation component.

Many areas of health care are open to policy preferences, particularly on sensitive topics such as birth control, abortion and assisted reproduction. In Canada, for instance, no provincial health insurance plan covers *in vitro* fertilization, which is to be regulated under the Assisted Human Reproduction Act but remains as self-funded or "luxury" medicine. In contrast, all provinces fund forms of cancer care, some including mandatory reporting systems and long-term follow-up monitoring of treatment outcomes. Funding treatment for pre-school age autistic children is varied, some provinces supporting more intensive interventions than others. These different policy responses can all be explained and defended by ethical criteria of reasonableness, and are not easily subject to judicial challenge or review, for instance on administrative law or Charter grounds, because they usually are found on the policy side of the policy/operational dichotomy in decision-making.

Accountability for decision-making on resource distribution is discharged through publicity and transparency, meaning appropriate disclosure of the reasons claimed to shape or condition decisions. Under democratic principles of ministerial responsibility, ministers in political charge of health care services are publicly accountable for decisions within their portfolios, and, by practices of delegation, heads of subordinate units, such as regional health authorities, may bear comparable accountability for decisions within their scope of authority.

Reasons for decisions should be provided in several directions, including upwards to higher levels of government, downwards to staff responsible for implementation, and laterally to the public at large, for instance through public news media and, for instance, publicly accessible explanations such as by pamphlets and electronic means. Where time, resources and circumstances allow, prior consultation with community stakeholders is to be encouraged, but the leadership role and responsibility of publicly accountable decision-makers can be neither delegated nor evaded.

An ethical challenge may concern disclosures to individual patients. Information material to individual patients' clinical care should be provided to them, since their capacity for choice and right to autonomy depend on their adequate comprehension of facts material to their care and well-being (*Reibl*, 1980). When information pertains to a group or class of patients, however, who may or may not be individually affected, general public disclosure may be appropriate, such as by public notification that reliability of diagnoses is under question and that biological samples are being re-tested, but notification of individual patients may be premature. Where notification would cause alarm, anxiety and demoralization to patients who may prove not to be affected, the principle of non-maleficence (Do No Harm) may be at risk by early notification of individual patients. Respect for patients' "right to know" depends on availability of knowledge, but not all data produces knowledge. Data may remain uninterpretable or inconclusive, supporting a spectrum of speculations but not generating knowledge that affords a reliable basis for advice or choice. Policies may have to be based on factual uncertainties, and be contingent. They should include the flexible capacity for revision in light of new evidence and understanding, recognizing that liability to error does not necessarily demonstrate earlier fault or negligence (Merry 2001).

When re-testing requires patients to provide additional samples, they should be told why the re-testing or rediagnosis is indicated. When surplus materials provided for initial testing have been preserved and are suitable for re-testing, non-disclosure may be justified until the re-test results are available. Then, patients found to have been misdiagnosed

would be informed in the context of recommending new treatment based on the new diagnosis. It is now accepted in both ethics and the law of fiduciary duty that patients be informed of medical errors that affect them. Patients should also be given any new information that becomes available that may affect their future care and decisions, such as newly obtained or understood genetic information.

Errors should be communicated to the public in general terms, and to institutional administrative, professional and governmental agencies in more detail, for such enquiries as they consider appropriate. Further, when errors may have been relevant to patients' deaths, coroners and the patients' family members should be informed. Notification policies overcome public suspicion of self-defensive concealment, and serve family members' interests in rights to justice, such as through pursuit of any legal claims on behalf of deceased relatives' estates and by their surviving dependents.

How public news media communicate the policies of health care agencies of government and institutions is an ethical challenge they are required, but often fail, to address. If an issue is considered newsworthy because it involves conflicting opinions and preferences, resource allocation decisions based on unavoidably uncertain facts may feed the appetite for conflict. There may even be scope for an appearance of scandal, such as by governmental or administrative suppression of information, based on the implication that data necessarily produces information, and by a change of policy indicating that the prior policy was misguided and incompetent. In the context of health care, there is often additional capacity to attract consumers' attention by a scare element, perhaps by reference to a story involving a patient or family willing to be publicized as having suffered avoidable harm.

Governmental agencies cannot direct discharge of the ethical responsibilities of news media to which they have to disclose their resource allocation decisions. Further, they should not be distracted from discharge of their own ethical duties of public disclosure by apprehension that their disclosures may be distorted or misrepresented. The care, caveats and nuances they bring to their news media releases

may be stripped away in crude oversimplifications, or be discarded when a sub-editor writes the headline of a story, or decides how a news item can gain attention. Accountability for reasonableness is a responsibility of governmental agencies that distribute public resources to meet health care needs. Such agencies must face but cannot guarantee the reasonableness with which recipients transmit the accounts that governmental agencies should provide.

Conclusion

This overview of legal and ethical obligations of governmental health authorities shows that patients' safety is a responsibility of governmental authorities in general, through policies for which they are politically accountable, but not necessarily in the case of individuals. However, there may be legal responsibility to put policies into operation in ways that safeguard individuals' welfare. Ethical obligations may coincide with legal obligations, but ethics often requires more than law. The law at times determines what must and must not be done, but frequently the law defines only what may but need not be done. For instance, whether legal powers or discretions should be applied in the circumstances of a particular case is an ethical, not a legal, issue. Ethics lacks the procedures for definition, enforcement and reform that are available to the law. Determinations of whether conduct is ethical are therefore left not only to the assessments of philosophers and ethicists, which are liable to differ among themselves, but also to the more democratic influences of popular opinion and sentiment, and a communal sense of what is fair and just.

JUDGMENTS

1. *Anns v. Merton London Borough Council*, [1978] A.C. 728 (House of Lords).
2. *Auton (Guardian ad litem of) v. British Columbia (Attorney General)* (2004), 245 D.L.R. (4th) 1 (Sup. Ct. Canada).
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4. *Chaoulli v. Quebec (Attorney General)* (2005), 254 D.L.R. (4th) 577 (Sup. Ct. Canada).
5. *Cooper v. Hobart* (2001), 206 D.L.R. (4th) 193 (Sup. Ct. Canada).
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Duty of Care and Standard of Care

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Introduction

This paper has been commissioned by the Inquiry on Hormone Receptor Testing in Newfoundland and Labrador (the "Inquiry"). It examines the legal concepts of duty of care and standard of care, and how they apply to health professionals and organizations. The paper begins with an introduction to the principles that govern the law of negligence.

Negligence Law: The Analytical Framework

Negligence in the provision of health care services refers to practices that fail to meet the standard of care legally required, and result in patient injury. Liability for negligence can arise from (i) substandard care or treatment, and from (ii) failure to obtain the patient's informed consent to treatment or adequately warn about risks, even if the treatment is properly performed. In order to succeed in a lawsuit alleging negligence, the person suing (the plaintiff) must prove:

1. The defendant (the person or organization being sued) owed the plaintiff a legal **duty of care**;
2. The defendant breached the standard of care required by law;
3. The defendant's breach caused the plaintiff injury or loss (damages);
4. The plaintiff's damages (injuries) are not too remote as a matter of law to be recoverable.

The burden of proof is on the plaintiff to establish on a balance of probabilities (i.e., that it is more probable than not) that the defendant owed her a duty of care, was negligent, and caused her harm. The

defendant bears the burden of proving any defences, such as compliance with approved practice, or the plaintiff's contributory negligence. A brief description of each of the elements of a negligence action follows.

Elements of a Negligence Claim

Duty of Care: Establishing that the defendant owed the plaintiff a duty of care is essential to a finding of liability for negligence. This is a question of law that requires the plaintiff to show that the defendant was under a legal obligation to take reasonable care for the benefit of the plaintiff (Klar 2003, 153). A defendant owes a plaintiff a duty of care when (i) it is reasonably foreseeable that harm may befall the class of persons to which the plaintiff belongs if the defendant fails to take reasonable care for their interests, (ii) the parties are in a sufficiently proximate relationship, and (iii) the existence or scope of the duty of care is not negated or limited by other policy considerations (*Cooper*, 2001*; Childs*, 2002).

Standard of Care: Someone who owes another person a duty of care is not required to meet a standard of perfection or guarantee her safety; the standard required is that the defendant take the care that is reasonable in the circumstances in order to avoid a risk of foreseeable injury to the plaintiff (Klar 2003, 297). The standard of care is that of a reasonable person (*Arland*, 1955), or in the case of physicians or other professionals, a reasonable professional (*ter Neuzen*, 1995*; Crits,* 1956; *Penney*, 2000). It is an objective standard, and so is not dependent on a particular defendant's motivation or awareness of the risk. What will constitute an unreasonable risk cannot be exhaustively defined, but important factors in making that determination include the foreseeability of the risk, likelihood of damage, gravity of the threatened harm, and the cost of preventive measures (Osborne 2003, 29–32).

Causation: Health care may be deficient because the treatment provided falls below the standard of care, and/or because the health care provider failed to obtain the patient's informed consent or adequately warn about risks. The plaintiff must prove that the defendant's wrongdoing (breach of the standard of care) caused her harm.

(a) Substandard Care: The primary, but not exclusive test for causation is the "but for" test, which requires the plaintiff to show that the injury would not have occurred but for the negligence of the defendant (*Resurfice*, 2007). In *Nicolls v. B.C. Cancer Agency* (1999), for instance, in which the defendants admitted that the interpretations of a patient's Pap smears were inaccurate and fell below the standard of care, the court concluded on the basis of expert evidence that, had the slides been interpreted **accurately**, the disease would have been diagnosed earlier and could have been managed using relatively simple, non-invasive procedures, rather than the much more extensive and invasive treatment caused by the late diagnosis. The defendants were held liable for negligence.

Causation can be difficult for a plaintiff to establish in a medical malpractice case, especially given the risks often inherent in treatment, however skilfully performed, and the background presence of the plaintiff's illness. Medical experts "ordinarily determine causation in terms of certainties," and when they cannot, are often reluctant to provide a firm opinion supporting the plaintiff's theory, making proof difficult (*Snell*, 1990). Recognizing this, in limited circumstances the stringency with which the plaintiff's evidence of causation is assessed may be relaxed (*Snell*, 1990). Additionally, where it is impossible to satisfy the "but for" test, it may be sufficient for the plaintiff to prove that the defendant's wrongdoing materially contributed to the injury she suffered (*Athey,* 1996*; Walker Estate*, 2001). While the applicability of the material contribution test was recently expanded (*Resurfice*, 2007), its availability and limits are still unclear (Gilmour 2007, 141-144). Even with these developments, the barrier presented by the need to prove causation in medical malpractice cases often remains formidable.

However, once that hurdle has been passed, it is not essential that the defendant was the sole cause of harm. Courts recognize that "There will frequently be a myriad of other background events which were necessary preconditions to the injury occurring… As long as the defendant is part of the cause of an injury, the defendant is liable, even though his act alone was not enough to create the injury…most events are the result of a

complex set of causes" (*Athey*, 1996, paras. 17, 20; see also *Walker Estate*, 2001). Once the causal connection has been established, the defendant will be held liable for any injuries caused *or contributed to* by his or her negligence.

(b) Informed Consent: The duty of care that health professionals owe patients includes an obligation to disclose material information about treatment proposed, including any material, special or unusual risks, so that the patient can make an informed decision about whether to consent or not. Courts have steadily broadened the information that must be given to the patient, making this obligation increasingly onerous. In order to establish liability for breach of the duty to obtain informed consent, the plaintiff has to show that if properly informed, she would not have proceeded with the treatment – in other words, that the information would have made a difference to her decision, and therefore, the failure to inform was a cause of her injuries. When determining health professionals' liability, what the plaintiff would have done is determined on a modified objective standard–i.e., what a reasonable person in the plaintiff's position would have done if properly informed (*Reibl*, 1980).

Damages: The defendant's breach of the standard of care must have caused the plaintiff injury or loss. Damages awards in negligence cases are meant to compensate the plaintiff for all losses incurred–i.e., to return her to the position she would have been in if the injury had not occurred, insofar as money can do so (*Andrews*, 1978).

Remoteness of Damages: Even if the defendant owed the plaintiff a duty of care and his or her breach of that duty was the factual cause of the plaintiff's injuries, the plaintiff's recovery may still be limited if the damages suffered are considered to be too remote in law. For instance, if a plaintiff's loss is entirely different from or completely disproportionate to what might have been expected, a court may conclude that there is not sufficient proximity (i.e., a close enough connection) between the defendant's wrongdoing and the consequences to the plaintiff to impose legal liability, and not award damages for those losses (Osborne 2003, 86; Klar 2003, 418).

A plaintiff suing for negligence must prove each of the elements described above to establish liability. I have been asked to concentrate on two of these in this paper, duty of care and standard of care, and consequently, issues that may arise with respect to the remainder will not be addressed further. The discussion of duty of care and standard of care is divided into two parts: first, a more complete explanation of these legal principles in the context of health care, and second, analysis of how they are applied.

Health Services: The Duty of Care

A duty of care is owed when (i) it is reasonably foreseeable that the defendant's failure to take reasonable care may result in harm to the plaintiff, and (ii) the relationship between the two is sufficiently proximate, considering factors such as expectations, representations, reliance, property and other interests, and finally, (iii) there are no residual policy considerations that would negate or limit such a duty (*Cooper*, 2001*; Hill*, 2007, para. 22-24). The doctor-patient relationship is a long established, well recognized category in law in which a duty of care is owed, and in most cases, the question of whether a duty of care existed is not usually an issue (*Hill*, 2007, para. 25; see also *Wilson*, 1956; *Crits*, 1956). This is true of other health professionals caring for patients as well–the relationship between the health care provider and the patient is sufficiently proximate to found a duty of care, and it is reasonably foreseeable that if health care personnel fail to take reasonable care to protect patients, the latter may well be harmed as a result (*Aristorenas*, 2004). In the health care context, the existence of a duty of care is far less likely to be contentious than its scope–i.e., what is required of the health care provider to discharge that duty in the circumstances.

The duty of care extends beyond a duty to avoid acting in ways that harm patients to include a requirement that health care providers take affirmative steps to protect their patients. While courts are generally more cautious about imposing a legal duty requiring positive action to avert risk or danger to others, they will certainly do so where there is a special relationship of proximity between the parties, and harm is reasonably foreseeable (*Childs*, 2002, para. 23-40). Health professionals

are in just such a relationship, and so, owe their patients a duty to take affirmative action to protect them from harm.

Health Services: The Standard of Care

Health care professionals must take reasonable care to avoid a risk of foreseeable injury to patients. In determining the standard of care to be met, they are held to the standard of a reasonably competent member of their profession:

> Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing, and if he holds himself out as a specialist, a higher degree of skill is required of him than of one who does not profess to be so qualified by special training and ability. (*Crits*, 1956, 508)

Other types of health professionals, such as laboratory technicians, will similarly be held to the standard of a reasonably competent member of their profession (*Penney*, 2000, para. 22).

When assessing professionals' conduct, expert evidence that the practitioner complied with generally approved practice in questions of treatment and care is in most cases conclusive evidence of absence of negligence (*ter Neuzen*, 1995). If the common practice is divided, a practice is acceptable if it is followed by a responsible and competent body of practitioners in that field, even if they are in a minority (*Lapointe*, 1992). Thus, professional judgment prevails in determining the standard of care, except in very limited circumstances. Specifically, if the standard practice is "fraught with obvious risks" such that "anyone is capable of finding it negligent without the need for clinical or diagnostic expertise," then a court can find an approved practice, and the defendant who followed it, negligent (*ter Neuzen*, 1995). *Braun Estate v. Vaughan* provides an example of this in the context of laboratory testing. A physician and hospital were held liable when they failed to ensure proper systems were in place to examine and follow up on abnormal test results, decreasing the patient's chances of survival through early diagnosis. The Manitoba Court of Appeal approved the trial judge's finding that in failing to

provide for a reasonably effective "follow-up" system with respect to test results, the physician had failed to adopt "obvious and reasonable precautions which are readily apparent to the ordinary finder of fact" (1999, para. 33-34, citing *ter Neuzen*, 1995, para 51). Thus, in the court's view, this was an instance in which the need for such a system was apparent and could be determined without professional expertise.

An error in judgment does not necessarily equate with negligence, or give rise to liability (*Lapointe*, 1992). In *Wilson v. Swanson* (1956), for instance, the surgeon operating on a patient and the pathologist who tested a tissue sample while the surgery was ongoing mistakenly concluded the patient had cancer. As a result, the surgeon removed larger portions of several organs than would have been necessary if the growth was not malignant. Neither was found to be negligent, since their mistakes were considered errors in judgment that were understandable in light of the patient's history, symptoms, the physical appearance of the tissue, and the results of the test performed during surgery. Negligence and error in judgment can be difficult to distinguish. However, as Picard and Robertson note (2007, 365), "if the error is one that a reasonable doctor would not have made in similar circumstances, liability will be imposed."

Because of advances in medical knowledge and practice, what is required of health care providers to meet the standard of care has become more expansive over time. For the same reason, in a negligence claim, the applicable standard of care is judged using the state of knowledge that existed at the time of the allegedly negligent act, and not on the basis of later advances in treatment or knowledge (*ter Neuzen*, 1995).

It is sometimes suggested that the standard of care should vary on the basis of locality, to take into account differences in facilities, equipment, expertise and staff available. Picard and Robertson (2007, 249-250) comment that, while this idea had fallen into disfavour in Canada, it has made an occasional reappearance in Canadian jurisprudence on standard of care since the 1980s, although with little noticeable effect on the outcome in cases. Caulfield confirms that "Canadian courts have been very hesitant to allow external

circumstances, such as a lack of resources, to result in an actual decrease in the standard of care," and have largely rejected the concept of a locality rule (Caulfield 2002, 6). That said, courts will take actual scarcity into account. In *Bateman* (1991), for instance, the hospital was held not to have been negligent in staffing the emergency department with family physicians who worked there part-time, rather than full-time emergency physicians. While recognizing that the latter might be ideal, the court acknowledged that the unavailability of these specialists, as well as the associated resource implications that would have been involved, made such a standard unrealistic (*Bateman,* 1991, 291).

Applying the Legal Principles

Clearly, physicians and other health care providers involved in patients' diagnoses, testing, treatment planning and care owe them a duty of care. This is true not just of those who have direct and personal relationships with the patients, but also those with a more indirect relationship, such as pathologists and other personnel involved in the laboratory testing of patients. The reasonable expectations and reliance patients place on the laboratory services and the practitioners providing them, and the representations implicit in offering these services to the public, mean they are in a relationship of sufficient proximity with the affected patients to found a duty of care, and harm is certainly reasonably foreseeable if testing is deficient. This is evident in cases such as *Bertin v. Kristoffersen* (2000), in which a family physician and a pathology laboratory were both held to be negligent and equally liable for the patient's loss of expectation of life when the laboratory failed to send the physician its report on an excised mole showing a diagnosis of malignant melanoma, and the physician failed to follow up with the lab.

What does the duty of care include? Picard and Robertson (2007, 296) note that "The most common components of the doctor's duty of care to a patient are the duty to attend, diagnose, refer, treat and instruct." These general headings do not constitute an exhaustive list, and depending on the factual circumstances, the duty owed may encompass other obligations as well, such as a duty to disclose errors in diagnosis or treatment.

Oncologists and Other Treating Physicians

After a patient has been diagnosed with cancer, the treating physicians are responsible for managing his or her care. This includes an obligation to advise the patient about his or her condition, arrange for effective testing to determine the best course of treatment (Freckleton 2003, 192), follow up on test results (*Braun Estate,* 2000*)*, formulate a treatment plan, recommend treatment, and, with consent, undertake the treatment or refer him or her to others qualified to do so. A mistake in the diagnosis, testing or treatment recommended or provided does not necessarily constitute negligence, although it may do so.

When circumstances warrant, the duty of care can also include both a duty to reconsider the diagnosis (*Crick*, 1993), and a duty to refer, either by consulting with colleagues or by transferring responsibility for the patient's care to another doctor. A duty to reconsider may arise *inter alia* where test results are inconsistent with the diagnosis, raising questions about the accuracy of one or the other, or alerting the practitioner to a need for additional testing. A duty to refer may be triggered by a physician's lack of sufficient expertise or access to facilities or equipment needed to provide appropriate care (*Crawford*, 2004; Picard and Robertson 2007, 313-14). It is difficult to reach definitive conclusions in the abstract about whether the standard of care was breached, because much depends on medical judgment. Except in limited circumstances, neither judges nor jury members have the expertise to determine these issues. Professional judgment plays a key role in determining the conduct expected. To reiterate, in order to meet the required standard of care, a doctor must exercise the care, skill and judgment of a reasonably competent member of the profession (*Laferriere*, 1991).

Physicians and other health care providers can rely on each other to discharge their responsibilities in a professional, non-negligent manner (*Granger,* 1996; *Keilley*, 1997). Otherwise, the health care system would quickly bog down. However, if a physician should have realized that others' services were problematic and exposed patients to risk, then a failure to recognize this may be negligent (*Gemoto,* 2006), as may a failure to realize that re-testing is needed (*Dann,* 1996). Whether inconsistencies between test results not usually associated with a particular diagnosis

should spur physicians to consider the possibility of error, and at what point in time, are questions requiring professional expertise.

Disclosure obligations are the subject of another paper in this series, and so will not be analyzed extensively here. However, since issues of disclosure are significant in this Inquiry, and disclosure obligations are an important part of the duty of care, I review the relevant considerations at common law.

A physician who makes an error in treating a patient and causes him or her harm does have a legal duty to disclose what has occurred to the patient, if it is something that a reasonable person in the plaintiff's position would want to know (Picard and Robertson 2007, 204; Gilmour 2006, 67). There are several bases for this conclusion. It can be considered to be an aspect of the duty to obtain informed consent. As Picard and Robertson (2007, 204) note in their explanation of the decision in *Stamos v. Davies* (1985, para. 25, 26), in which a surgeon was found to have breached the duty he owed the patient to disclose he had punctured his spleen in the course of performing a lung biopsy, "if a patient has the right to be told what may go wrong, surely the patient also has a right to be told what has in fact gone wrong." Damages were not awarded for that breach, however, because there was no causal connection between the failure to inform and the plaintiff's injury, the loss of his spleen; they were awarded instead for negligence in the performance of the biopsy.

The fiduciary nature of the doctor-patient relationship, with its attendant duty of loyalty to the patient, also supports the existence of an obligation to disclose error that has harmed the patient—in effect, a duty of candour (*Vasdani*, 1993; *Gerula*, 1995; *Shobridge*, 1999). The requirement to disclose error is especially important when it can affect the patient's treatment or diagnosis. For instance, in *Kiley-Nikkel c. Danais* (1992), a surgeon performed a mastectomy, based on a pathologist's mistaken report that the patient's biopsy indicated cancer. When the mistake was discovered later, the surgeon was informed, but he did not tell the patient. She only learned the truth six years later. The court held that the surgeon had a duty to advise the patient about the error, and that his failure to do so, leaving her believing and worrying that she had cancer,

was negligent. The pathologist was not held liable, even though he had made the error initially, because the surgeon assured him he would tell the patient, and the pathologist's reliance on this assurance was held to be reasonable. It is also evident from this decision that the timing of disclosure is significant, especially when correct information will have a direct effect on the patient and her well-being.

Another way to understand the physician's duty of disclosure is to relate it to the well-recognized duty to disclose risks and provide adequate warnings to patients about the treatment. Patients undergoing treatment and monitoring for breast cancer were doing so on the basis that their physicians had provided them with a correct understanding of their disease and the treatment that was and was not likely to be effective. It was on that basis that they consented to the treatment plan. If their understanding turned out to be mistaken, they had a right to be told, and their physicians had an obligation to disclose this information. It is difficult to conceive of their consent to the treatment plan remaining valid otherwise, once the physician knew it to be based on a false premise. In a similar vein, Picard and Robertson suggest that, as their counterparts in the United States have done, Canadian courts are likely to recognize a continuing duty of disclosure on doctors to disclose risks to patients and former patients (a "duty to recall") (Picard and Robertson 2007, 178).

Pathologists and Laboratory Personnel

In providing services, pathologists must meet the same general standard of care as other professionals—i.e., the standard of care of an ordinary skilled person exercising and professing to have the relevant skills. Where an error has been made to a patient's detriment, the pathologist must either disclose the mistake to the patient, or take reasonable care to see to it that the error is disclosed (*Kiley-Nikkel*, 1992). The standard of care expected of technicians and others working in the laboratories would be assessed on a similar standard – the reasonably competent technician exercising reasonable care at the time the testing took place (*Penney*, 2000, para 22; Freckleton 2003, 192). This would include having sufficient skill, expertise and practice to competently conduct the testing and interpret results to the extent expected of this

type of practitioner. Thus, except in those limited instances that do not require specialized and technical expertise to evaluate what occurred, professional judgment will again be key in determining whether the standard of care was breached in any particular case.

Assessing the standard of care and whether it is met will also require an awareness of the nature of the testing and any limits on its reliability. Some types of laboratory testing involve an inherent element of subjectivity, and staff interpreting the test results may differ in their conclusions. This may mean there is a "legitimate error rate" in testing, that does not entail negligence at all (Freckleton 2003, 192; *Penney*, 2000; Duffy, Barrett, and Duggan 2001; Miller 1997). However, where the error rate in a particular laboratory is considerably in excess of what might be anticipated in the normal course with proper procedures in place, this could be indicative of substandard practices (Duffy, Barrett, and Duggan 2001). As Ian Freckleton notes in writing about Pap smears and gynaecological cytopathology generally, the fact that errors can occur without negligence

> does not necessarily mean as a matter of common law that all error in smear assessment falls outside the boundaries of negligence. If a want of professional attention by a cytotechnician or a cytopathologist can be established, or if it can be shown that proper protocols are not in place, or that laboratory personnel are being required to undertake an unacceptable level of assessments, then civil liability may well exist. (2003, 192)

However, formulating the standard of care in areas where interpretation is affected by limited reliability and definitiveness, as in some areas of laboratory testing and analysis, is particularly challenging (Freckleton 2003, 186). Indeed, in light of this reality, it would be prudent for those responsible for the testing to ensure adjustments that take this into consideration, adequate systems for review in questionable cases (which will certainly occur), and appropriate systems to ensure quality controls are in place.

A decision of the English Court of Appeal is useful to illustrate the issues that arise when one determines the standard of care in the context of laboratory testing. In *Penney v. East Kent Health Authority* (2000), three

patients sued the Health Authority because cervical smears they had taken as part of a national screening program were mistakenly reported by the Authority's primary cytoscreeners as negative. Without the needed timely follow-up or diagnostic and therapeutic intervention, each developed invasive cervical cancer requiring surgery, including hysterectomy. Despite the surgery, some of the women were gravely ill, with very poor prognoses. The issue for determination was the standard of care expected of the screeners; the parties had agreed not to require a determination of causation (para.1). It was accepted by all parties that the cervical screening in question did not provide a fault-proof test, even when the testing and interpretation were "exemplary" (para. 10, 15). The system in place required the cytology screeners to report negative (i.e., normal) smears or ones of such poor quality as to require re-testing. However, screeners would have to pass on a smear detected or suspected to be abnormal to a supervisory checker, "who either confirms the opinion of the primary screener or if it is still considered abnormal, passes it on to a pathologist for examination and report (para 11)." Such a report would usually call for a repeat test or further gynaecological investigation. Where a patient who had tested negative nonetheless developed cervical cancer, there was a retrospective review to determine whether there were abnormalities that should have been detected initially (paras. 11, 16).

Lord Woolf identified three questions the court had to answer to determine the standard of care and whether it was breached:

(1) What did the slides show?
(2) At the relevant time, could a screener exercising reasonable care fail to see what was on the slides?
(3) Could a reasonably competent screener, aware of what a screener exercising reasonable care would observe on the slide, treat the slide as negative? (para. 27)

In this case, the experts who gave evidence were in substantial but not total agreement about what all but one of the slides showed. It was then up to the judge to make his own finding on the balance of probabilities on this issue of fact. Once he had done so, deciding whether

a screener was in breach of duty would depend on (i) the training and amount of knowledge a screener should have had to properly perform his or her task at that time, and (ii) how easy it was to discern what the judge had found was on the slide (para. 28). As the court noted, "These issues involved both questions of fact and questions of opinion as to the standard of care which the screeners should have exercised" (para. 28). The Court of Appeal confirmed the trial judge's conclusion that the screener should have reported the slides as at least "borderline," given the abnormalities evident, particularly having regard to the potentially disastrous consequences of a mistaken classification (para. 36).

The court distinguished this case from one where there is a responsible body of medical or professional opinion with a different view about whether the cytoscreeners' conduct, though wrong, was excusable. There was no such contradiction here, because one of the two opposing standards of professional conduct supported by expert opinion could not prevail in the face of logical analysis and internal contradictions in the expert's own testimony (para. 34, 38). The court also recognized that, while the state of knowledge may be objectively discernable, and, therefore, a matter of fact, in some instances there is room for differences of opinion about the extent to which screeners at the relevant time should have been aware of the latest information on a subject, and that "respectable opinion" could legitimately differ on this point. Additionally, there could be a legitimate difference of opinion about how much judgment a screener should exercise once a potential abnormality had been spotted (para. 31). However, since there was no indication of such disagreements on the evidence, the court did not address these points further. It affirmed the trial judgment that a reasonably competent screener at the time would not have passed these slides as negative, given the abnormalities they showed. For the same reason, it also concluded it was not necessary to analyze the state of screeners' knowledge at the time in detail; it was enough to establish that slides with these abnormalities should not have been passed. It found the defendant liable, but went out of its way to emphasize that not every slide labelled negative where the person concerned goes on to develop cancer is an indication that the screener was negligent (para. 67).

Regional Health Authorities and Hospitals

Hospitals and health authorities can also be held liable for negligence. The duty of care comes into being on the formation of the hospital-patient or health authority/ laboratory-patient relationship. Which entity owes a duty of care to patients and the scope of that duty will depend on the corporate structure, the division of responsibilities and liabilities among themselves, the statutory framework under which health care services are organized and delivered, and their actual relationships with and obligations assumed to patients (see, e.g., *Regional Health Authorities Act* 2006; *Hospitals Act* 1990). As noted previously with respect to health care providers, the most contentious issue is likely to be the scope of the duty of care, rather than its existence.

Patients suing a hospital, laboratory or health authority for negligence must prove all the elements of a negligence action. This paper focuses on two of these, duty of care and standard of care. However, liability may also be imposed even if the defendant's conduct was not substandard itself. In some circumstances, defendants can be liable for the negligence of others. Because the liability of a health care organization and that of individual health care providers can be highly interdependent, this paper also considers two bases on which a health care institution may be held liable for others' negligence: vicarious liability and non-delegable duties of care. Since the liability of public authorities is the subject of another paper in this series, my review of these last two areas will be brief.

Direct Liability: A hospital or health authority can be held directly liable for its own negligence, and the ordinary principles of negligence law apply in proving such a claim. The most common duties a hospital or health authority owes patients are:

1. To select competent staff and monitor their competence.
2. To provide proper instructions and supervision.
3. To provide proper facilities and equipment.
4. To establish systems necessary for the safe operation of the hospital" (Picard and Robertson 2007, 460).

The hospital / health authority, depending on its responsibilities to patients, owes a duty to review and monitor qualifications and competence of staff, even if they are not employees. In general, it has to ensure that personnel are working within their competence and receive appropriate training and supervision (*Granger*, 1996). Picard and Robertson (2007, 461) note that "the earliest and still most basic and non-delegable duty of the hospital is to ensure that those who treat patients are qualified and competent." That does not necessarily translate to hospital or health authority responsibility for non-employed physician negligence just because it occurs on site; rather (at least to date), the hospital "is responsible to ensure that doctors or staff are reasonably qualified to do the work they might be expected to perform" (*Bateman*, 1991, 290).

The hospital / health authority also has a duty to establish "safe systems" for the protection of patients (*Yepremian*, 1980), and to ensure proper coordination among the disparate elements of a patient's treatment program (*Lachambre*, 1989). The obligation to provide "safe systems" is both extensive and expansive, and it encompasses widely varying responsibilities, ranging from ensuring proper maintenance of equipment to providing sufficient personnel to permit rotation of nurses without danger to patients (for example, to allow for coffee breaks) (*Yepremian*, 1980, 540-541, and cases cited therein).

Braun Estate v. Vaughan (1999) considers some of the ramifications of this responsibility in the context of laboratory testing. Following a patient's death from cervical cancer, her estate sued a physician and the hospital where he worked, alleging negligence for their failure to appropriately follow up when a screening test showed evidence of abnormalities. The physician had taken a Pap smear as a routine screening test during tubal ligation surgery, but failed to examine the cytology report that showed evidence of abnormalities, and did not have any procedures in place to see to it that there was a reasonably effective "follow-up" system to confirm that he reviewed tests he had ordered. The hospital in which he worked had no system or procedures to check that test results were received by and made available to physicians either.

The patient died of cervical cancer one year after the surgery. As the court noted:

> there is a responsibility on hospitals to see to it in a general way that adequate procedures are in place to 'ensure' (but not guarantee) patient safety. The provision of a 'safe system' of health care delivery is an important core duty of a hospital…I have no difficulty in concluding that the hospital…had an independent obligation to provide a reasonable and practical 'safe system' including the coordination of services between physician, patient and the institution…there was a direct obligation to see to it that suitable procedures were put in place to verify that vital test results were received, and made available to the treating physician. It was simply not enough for the hospital to rely on the physician as the ultimate caregiver to shoulder the entire responsibility. It, too, had a direct duty to the patient which could not be 'delegated' to the physician. (*Braun Estate*, 2000, paras. 45, 49)

The court held both the physician and the hospital liable for negligence, assessing their respective degrees of fault at 80 per cent and 20 per cent (para. 56).

Depending on the facts, a health authority could also be seen to owe a duty of care to affected patients in the conduct of a review panel, re-testing program, and communication with patients. While there is little Canadian jurisprudence on point, a hospital has been held liable for the death of a patient based in part on the negligence of its research committee in failing to ensure that the consent form participants in a research project were to sign sufficiently disclosed the risks of participating (*Weiss*, 1989). A health authority that learns that some of its test results were incorrect, and knew or ought to have known that those errors had the potential to harm patients because they precluded their access to potentially helpful therapy, arguably has a duty to develop a system that would accurately identify the cases in which an error had been made, and ensure patients and their treating physicians are notified, all in a timely manner (*Pittman Estate*, 1994). If the patients affected and their physicians are given information that the potentially helpful therapy could assist in their cases, or even that the original tests could have been incorrect, one can expect they may well have made different decisions about treatment. Non-disclosure to preserve patients' peace of mind sounds very like the arguments that used to be made to justify

physicians' "therapeutic privilege" to withhold distressing information from patients about their illnesses or treatment. Therapeutic privilege has been roundly rejected for decades now, except in very limited circumstances (*Reibl*, 1980; *McInerney*, 1992). As Madam Justice Lang noted in *Pittman Estate v. Bain* (1994, 394), commenting on a physician's failure to tell a patient he had become HIV+ as a result of a tainted blood transfusion, "In the normal course, patients have the right to information about their health. Unless a patient conveys a contrary expectation to the doctor, the doctor is obliged to give the patient the information. It is not the doctor's information to withhold." Non-disclosure may be justifiable if re-test results are uncertain, and that is likely a determination requiring professional expertise (*Symaniw,* 1996). However, if that is the case, one would expect whatever reviews are required to confirm the re-test results to be carried out promptly, especially if a conversion on re-testing means the patient is a candidate for therapy that could diminish the likelihood of harm.

One question that has arisen is whether the consent of the women whose tissue samples were being re-tested was required. The tissue samples were retained by hospitals for a number of years, so there was no need to obtain new samples. Women did consent to the initial testing, but there was no specific, new consent for the re-testing. Re-testing may also raise concerns about breaches of patients' right to confidentiality and privacy interests.

Health care providers must obtain consent prior to treating or testing patients, and the patients' consent must be informed. Failure to do so breaches patients' rights to autonomy and bodily integrity. If treatment is halted and then resumed, the need to obtain renewed consent is considered from the patient's point of view, meaning that physicians are obliged to seek renewed consent to continue a procedure, if there was any significant change in the risks involved in continuing the procedure, or in the need for it, or any material change in circumstances that could alter the patient's assessment of the costs and benefits of continuing the procedure (*Ciarlariello,* 1993). This highlights the importance of evaluating the issue from the patient's perspective, or that of a reasonable person in the patient's position.

Consent can be express or implied (*Marshall*, 1933). While consent can cover incidental procedures that are necessary, or minor variations or adjustments in treatment, it would not extend to different treatment or testing than the patient understood was being provided (in some provinces, the scope of consent is specified by statute—see, e.g., *Health Care Consent Act*, Ontario, 1996, s.12). It is also reasonable that consultation with professional colleagues that is needed to better care for the patient would be encompassed in the patient's consent as well, and would not constitute a breach of confidentiality.

The scope of the consent given in connection with initial testing would have to be assessed, to determine whether it expressly or impliedly included later re-testing to determine the accuracy of the initial results. As Picard and Robertson (2007, 52) note, it is not clear whether a subjective or objective standard should be applied to determine what the consent covered. In *Canadian AIDS Society v. Ontario* (1995), the court relied on a "reasonable blood donor test" in determining whether blood donors who gave blood in the mid-1980s gave implied consent to samples of their blood being stored and tested for HIV ten years later. The court concluded that, except during the period when a brochure informed donors about the testing consequences of their donation, blood donors at that time had either no or insufficient information about this prospect, and could not be taken to have impliedly consented to "the right to test blood ten years later, with public reporting repercussions" (*Canadian AIDS Society*, 1995, para. 183). However, in that case, "It is agreed by all that the Red Cross [which retained the samples] is entitled to test the Samples without the donors' consent for the purposes of tracing and warning recipients of the tainted blood, or blood product" (*Canadian AIDS Society*, 1995, para.181). The issue was whether it could comply with statutory reporting obligations to public health authorities, identifying the donors whose blood tested HIV+, without their consent. The court concluded that it could, a decision affirmed on appeal (*Canadian AIDS Society*, 1996).

The decision in *Canadian AIDS Society* (1995, paras. 133, 159) also confirms that rights to confidentiality are not absolute. Even taking into

account the donors' rights under the *Canadian Charter of Rights and Freedoms*, which applied because the reporting obligations were imposed by statute (i.e., government action), there was no breach of the donors' s.7 rights (to life, liberty and security of the person), or s. 8 rights (to be free from unreasonable search and seizure), in complying with the statutory procedures for reporting to public health authorities.

Issues involving disclosure of laboratory test results also arose in New Zealand, where a Committee of Inquiry was appointed to determine whether there had been an unacceptable level of under-reporting as a consequence of misreading and/or misreporting of abnormalities in cervical smears in the Gisborne region, how this occurred, and what changes were needed for the future. Sixteen women in the region whose smear tests had been read as normal by the Gisborne Laboratory during the period 1990-1996 developed cervical cancer. When the same smear tests were re-read in Sydney, Australia, all were reported as cervical cancer or high-grade abnormalities (Duffy, Barrett, and Duggan 2001). The Committee concluded that there was unacceptable under-reporting, and that the reasons for this were both particular to the individual laboratory (including inadequate or absent quality assurance procedures, lack of external oversight, inadequate systems and procedures, and other factors), and also systemic, in the ways in which cytology services were delivered in the country (including inadequate monitoring or evaluation of performance, lack of performance standards, lack of attention to screening failures in other countries—in sum, a failure to design and deliver a soundly based cervical screening program) (2001, 8-9). Health authorities had been unable to conduct an audit of the screening history and management of women with cervical cancer as part of the evaluation of the screening program, in order to assess results (195). Doing so required access to information about identifiable women; the Cancer Registry and the ethics committee consulted refused permission because they interpreted the Health Information Privacy Code at the time to require consent before external evaluation could be permitted (internal audits were specifically allowed) (199). Health authorities could not obtain consent, because they did not know who the women were (197), and in any event, in some instances contacting them would have been impractical.

The Committee considered the denial of access to be based on a misguided understanding of the law, since in its view, this type of evaluation should be seen as an integral part of a woman's treatment under the cervical screening program (200). It considered that checking to see if they were appropriately treated "could be viewed as a necessary part of the treatment the women have received, rather than separate from it" (234). Otherwise, it suggested, women "should be told they are participating in a Programme which cannot carry out the most effective means of monitoring the Programme's success. Only then will they be in a position to exercise informed consent" (236, para. 9.14). The Committee concluded that the Programme had an obligation to the women tested to ensure they knew whether their treatment was irregular, but that the Programme had "no effective quality assurance for its performance since the gold standard for determining its effectiveness [the audit] cannot be carried out for legal reasons" (236, para. 9.13).

This was not the only view of the matter. Women's groups were concerned that if access included primary health records, women might remove themselves from the screening program because of concerns about release of sensitive information about their health and personal lives beyond the doctor-patient relationship. On the other hand, those involved in the screening program were concerned with ensuring the safety and effectiveness of the program, and with the practical impediments to obtaining consent. In the result, the *Health (National Cervical Screening Programme) Amendment Act 2004* amended the *Health Act* 1956 (Part 4A, ss. 112A–112ZP), dispensing with the need for consent (personal communication, Professor Joanna Manning, Faculty of Law, University of Auckland 2008).

In both *Canadian AIDS Society* and New Zealand's Gisborne Inquiry, the concern was not the testing or re-testing to determine the accuracy of the results, but rather, the extent of disclosure that would be made outside the physician-patient relationship—to whom, and of what information. Indeed, in *Canadian AIDS Society*, the court noted that all were agreed that the blood samples could be tested without consent for the purpose of tracing and warning recipients of the tainted blood

(*Canadian AIDS Society*, 1995, para. 181; see also paras. 135, 150)—donors had a right to know the truth (*ibid*., para. 172). Thus, while consent may be limited to certain uses, in both these examples, testing to determine the presence of disease for the purpose of alerting the persons concerned was acceptable.

As for the more theoretical question of disclosure obligations to the public, it would be difficult to establish there was a legal duty of care owed to the public generally by health authorities, or by physicians or health care personnel, requiring them to disclose information about what occurred, and resulting in legal liability for negligence if they did not. The law does not impose a duty of care owed to the world at large, enforceable by means of a private lawsuit. The requisite foreseeability of harm and proximity of relationship are absent, and residual policy considerations, including concerns about the prospect of indeterminate liability, tell against extending a duty of care so broadly. This is not a comment on ethical or policy considerations, but simply an assessment that lack of public disclosure alone would not give rise to a well-founded claim in negligence by members of the public (*Cooper*, 2001*; Mitchell Estate*, 2004).

As noted above, hospitals may be held liable even if not negligent themselves. An explanation of vicarious liability and non-delegable duties follows.

Vicarious Liability: Vicarious liability is imposed when one person or entity is legally responsible for the torts of another because of the relationship between them. It does not require any wrongdoing by the party who is held vicariously liable. It is most common in the context of employment relationships: an employer is vicariously liable for the negligent acts or omissions of its employees committed within the scope of their employment. Thus, hospitals, regional health authorities and other health care organizations are vicariously liable for the negligence of their employees, such as nurses, laboratory technicians, and employed physicians. Although less common, vicarious liability can also arise from the relationship between principal and agent (Osborne 2003, 335), and for the acts and omissions of volunteers (*Bazley*, 1999).

Vicarious liability is generally not imposed when the relationship between the parties is that of principal and independent contractor. Most often, doctors are considered to be independent contractors to whom the hospital has granted privileges enabling them to admit and treat patients. They are not hospital employees, and the hospital is not liable for their negligence (*Yepremian*, 1980). The characterization of this relationship will depend on all the circumstances – interns and residents, for instance, are generally employed by the hospital as house staff. Recent developments in judicial analysis of vicarious liability in other contexts may support an expansion of hospital and other health care organizations' liability to include responsibility for the negligence of non-employed physicians and others (*Bazley*, 1999; Gilmour 2006, 59-61). However, to date, hospitals have not been held vicariously liable for non-employed physicians' negligence.

Non-Delegable Duty of Care: In some instances, defendants have been held liable on the basis that the nature of the defendant's relationship with the plaintiff (for example, a special undertaking of care and responsibility imposed by statute), was such that it was under a non-delegable duty of care. This means the duty of care could not be discharged by delegating performance to another, no matter how or by whom it arranged to have the work done (*Lewis*, 1997). The defendant is liable for a third party's negligence that injures the plaintiff, regardless of the character of its relationship with the negligent party. The defence of due diligence, i.e., that it took all reasonable steps to select competent people to carry out the tasks and monitor them, is not available, at least if the obligation was to ensure the work was done carefully. However, determining which duties are non-delegable, and articulating the scope of such duties, is a difficult undertaking. Criteria and limits are still being developed (Gilmour 2006, 59-60; Klar 2003, 595; Murphy 2007). Policy considerations and the court's assessment of what is fair in the circumstances will be significant considerations (Klar 2003, 594).

Hospitals/health authorities would be vicariously liable for any negligence by employee physicians and other employees directly or indirectly involved in the care of a patient in carrying out their duties.

However, the question of health authority or hospital liability for non-employed physicians' negligence (such as physicians who are independent contractors and paid on a fee for service basis by the public health insurance plan) is more difficult. As explained previously, Canadian cases have usually held that hospitals are not vicariously liable for physicians' negligence, nor do they owe a non-delegable duty of care to ensure non-negligent treatment (*Yepremian*, 1980). Some commentators have argued that the logic underlying the Supreme Court of Canada's expansion of vicarious liability and non-delegable duties should be extended to hospitals as well, based on their special relationship with a vulnerable population, the public's reliance on hospitals to ensure quality care is delivered, their control over workplace organization, and their statutory duties (Osborne 2003, 324; Fridman 2003, 336; Picard and Robertson 2007, 487). Whether courts will maintain their stand on hospital liability in the face of jurisprudence expanding the applicability of vicarious liability and non-delegable duties of care in other areas remains to be seen.

Broadening hospital liability in this way would reflect changes in the organization and delivery of care more accurately. In many instances, physicians' services cannot be evaluated properly in isolation from treatment provided by other personnel, and the institutional environment in which they are provided (Sinclair, 2000). It would also respond to advances in our understanding of how errors and adverse events in health care occur. Errors are frequent in health care, some as the result of negligence, but most not (Gilmour, 2006). Some of those errors seriously harm patients (Baker and Norton 2004). Patient safety advocates maintain that it is important to move away from the traditional focus on the personal responsibility of health care providers, because it is likely to be the institutional systems within which health care providers operate that cause harm, more than individual practitioners. They contend that reconfiguring the system and the way error is treated within it will result in safer care. Since underlying systemic factors play a significant causal role in most adverse events and near misses in health care, they argue that it is most often inappropriate to blame individual health care providers when patients are injured. Analysis cannot be limited to occurrences at the "sharp end," where practitioners interact

with patients and each other in the process of delivering care, but must also include consideration of the role played by the "blunt" or remote end of the system, i.e., regulators, administrators, funders, policy makers and technology suppliers, who shape the environment in which practitioners work (see generally Gilmour 2006; Duffy, Barrett, and Duggan 2001). Systemic analysis is considered key, both to accurately identify the cause of a patient's injury, and to best determine how to prevent harm in the future.

While this approach contrasts sharply with negligence law, in which recovery of damages is largely premised on a finding of fault, the disparate understandings of how patients are injured are not necessarily irreconcilable. Indeed, courts deciding negligence cases typically acknowledge that events have multiple causes (*Athey*, 1996, paras. 17, 25). That awareness could allow for the systemic analysis of the causes of injury that the patient safety movement advocates. Most often, however, negligence actions are tightly focused on the individuals directly concerned in the events giving rise to the lawsuit. The courts' task is to assess what occurred among the parties; they do not generally engage in at-large analysis of the role that more diffuse, systemic factors played in the plaintiff's injuries. Although institutional decisions about resources and constraints shape the environment in which health professionals treat patients and may significantly contribute to a plaintiff's injuries, that causal connection may go unrecognized without a sophisticated understanding of organizational responsibility. Absent greater openness to theories of enterprise liability, whether by an expansion of direct or vicarious liability or increasing recognition of non-delegable duties of care, the utility of the tort system as a means to identify and deter systemic causes of injury is likely to remain limited.

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The Legal Duty of Physicians to Disclose Medical Errors

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Introduction

As a result of a series of legal decisions beginning in the mid 1980s, it is now well established in Canadian law that if in the course of medical treatment a doctor makes an error which harms (or which has the potential to harm) the patient, the doctor has a legal obligation to disclose this fact to the patient (Gilmour 2006, 67; Hébert, Levin and Robertson 2001; Picard and Robertson 2007, 204-208; Robertson 2002; Waite 2005).

However, although this legal obligation is now well established, many issues relating to its precise scope remain unclear. This paper begins with a discussion of the legal cases that establish the physician's duty to disclose medical error, including a discussion of the underlying legal basis for the duty. It also examines the legal consequences that flow from a breach of the duty of disclosure. The paper then explores in more detail a number of specific aspects of the duty, including the content and timing of disclosure and whether the duty extends beyond physicians to other health professionals such as nurses.

The Case Law

The first Canadian case to impose a legal duty on physicians to disclose medical errors to their patient was *Stamos v. Davies* (1985), a decision of Mr. Justice Krever of the Ontario High Court. The case involved an internist who pierced the patient's spleen while performing a trephine needle lung biopsy, causing a serious haemorrhage. On receiving the pathologist's report two days later, and discovering that he

had biopsied the spleen rather than the lung, the doctor told the patient that he had received no results from the biopsy because he had not obtained what he had wanted. When asked by the patient what in fact had been obtained, the doctor replied "something else," but provided no other details. The patient was discharged from hospital but returned to the emergency department three days later, at which time his spleen was surgically removed. Mr. Justice Krever held that the doctor had been negligent in puncturing the spleen during the biopsy. Relying upon an earlier decision of the English Court of Appeal (*Lee*, 1985), Justice Krever also held that the doctor had a legal duty to inform the patient of what had happened, and that he had breached that duty in failing to be candid with the patient.

The physician's duty to disclose medical errors was affirmed in two later Ontario cases, both of which involved surgeons who operated on the wrong disc during back surgery (*Vasdani*, 1993; *Gerula*, 1995). In *Vasdani* the surgeon mistakenly operated at the L3-4 level instead of L4-5. He was unaware of his error until one year later, when advised of it by doctors at the Workers' Compensation Board (WCB). The surgeon decided not to inform the patient of this, because by then the care of the patient had passed to another surgeon. Seven years later a law student who was examining the patient's WCB file for the purposes of an appeal discovered the truth and informed the patient, who then commenced an action for damages against the surgeon. The Court held that the doctor had a legal duty to inform the patient of his error, and was not relieved of this responsibility merely because care of the patient had passed to another doctor. In the words of the Court:

> Dr. Sehmi, while not denying that there was a duty of disclosure, takes the position that the duty was no longer his when care and treatment of Vasdani was assumed by another doctor. I do not think that position is tenable. The duty of disclosure may have become complicated by the interposition of another doctor in that it may have required consultation to determine when, how and by whom, the disclosure should be made; but the duty was first, last and always, that of Dr. Sehmi, and was not fulfilled. (para. 34)

In *Gerula v. Flores* (1995) the surgeon mistakenly performed a laminectomy on the L4-5 level instead of L3-4, and discovered the error a

few months later. Not only did the surgeon fail to inform the patient of the mistake, he also altered the hospital records in an attempt to cover it up. The Ontario Court of Appeal held that the surgeon's conduct was in flagrant disregard of the patient's right to be informed, and it awarded punitive damages of $40,000 against the surgeon.

Punitive damages were also awarded in a British Columbia case in which a six-foot long gauze roll was left inside the patient's abdomen during gynaecological surgery (*Shobridge*, 1999). The surgeon later performed a second operation, to investigate the cause of the patient's continuing abdominal infection and pain, at which point the retained gauze roll was discovered. The surgeon instructed the nursing staff not to include this discovery in the patient's chart, and not to prepare an incident report as required by hospital policy. He also made no mention of the abdominal roll in his operative report, nor in a subsequent consultation report, and he waited two months before finally disclosing the facts to the patient, and only then after he was told to do so by the vice-president of the hospital. The Court held that the surgeon was in breach of his legal duty to inform the patient of the discovery of the retained abdominal roll "as soon as reasonably practical" (para. 89). In addition, the Court concluded that he had engaged in "covering up his own failures to avoid legal responsibility" (para. 94), which was deserving of an award of punitive damages.

The physician's duty to disclose medical error to the patient has also been recognized in cases from other provinces, including Alberta (*V.A.H.*, 1998, para. 134; *Fehr*, 1999, para. 34), New Brunswick (*Kueper*, 1986), and Quebec (*Kiley-Nikkel*, 1993).

Another Ontario case—*Pittman Estate v. Bain* (1994)—is important for its discussion of whether there may be exceptional circumstances that justify a doctor withholding information from the patient. This is referred to as the defence of "therapeutic privilege," and it has arisen from time to time in the context of informed consent (Picard and Robertson 2007, 173-175). Mr. Pittman received a blood transfusion in 1984 while undergoing cardiac surgery. Five years later the hospital notified Mr. Pittman's family doctor that the blood may have been contaminated with HIV. The

doctor decided not to inform Mr. Pittman, partly because he was concerned about the effect this news might have on Mr. Pittman's physical and emotional health. Mr. Pittman died the following year of AIDS-related pneumonia, and his wife also became infected with HIV as a result of sexual relations with her husband. The Court held that the family doctor was negligent in failing to inform Mr. Pittman of the possibility that he had received contaminated blood, and the doctor was not justified in withholding the information because of his concerns about the possible effect it would have on his patient. The Court recognized that in exceptional circumstances a doctor may be justified in withholding information, but it stressed that those situations are very limited. In the words of the Court:

> With regard to therapeutic privilege, there will be cases where a patient is unable or unwilling to accept bad news from his or her physician. In those circumstances, a physician is obliged to take reasonable precautions to ensure that the patient has communicated their desire not to be told, or that the patient's health is so precarious that such news will undoubtedly trigger an adverse reaction that will cause further unnecessary harm to the patient. (399)

The Underlying Legal Basis For The Duty To Disclose

Two theories have been relied upon in the case law to ground the physician's duty of disclosure (Picard and Robertson 2007, 204; Robertson 2002, 357-358; Waite 2005, 15-16). The earlier cases based it on the doctrine of informed consent. Patients have a fundamental (and indeed, constitutionally protected) right to make their own medical decisions, and to be free from unwanted medical treatment (*Starson*, 2003; *Rodriguez*, 1993; *Ciarlariello Estate*, 1993; *Fleming*, 1991; *Reibl*, 1980; *Hopp*, 1980). In order to make this a meaningful right, Canadian law has recognized that patients also have a right to information concerning proposed treatment, to enable them to make an informed decision whether or not to undergo the treatment. Accordingly, it is well established in Canadian law that doctors have a duty to inform their patient of the material risks of proposed treatment, "material risks" being those which a reasonable person in the patient's circumstances would want to know (*Reibl*, 1980; Picard and Robertson 2007, ch. 3).

Although at first sight it may seem odd to base the duty to disclose medical errors (which arises *after* the treatment is performed) on the doctrine of informed consent (which applies *prior* to treatment), in principle the two are linked. As is stated in Picard and Robertson (2007, 204), "if a patient has the right to be told what may go wrong, surely the patient also has a right to be told what has in fact gone wrong." This is also consistent with the well established principle that the duty of disclosure arising from the doctrine of informed consent does not end after the treatment is finished, but extends to include any material information which is obtained after the treatment is performed (Robertson 2002, 357).

The more recent cases have grounded the duty to disclose medical error on the concept of fiduciary obligation. The relationship between doctor and patient is a fiduciary one, that is, a relationship of utmost trust which imposes on the doctor additional responsibilities and obligations towards the patient (*McInerney*, 1992; Picard and Robertson 2007, 4-7). Cases such as *Vasdani v. Sehmi* (1993), *Gerula v. Flores* (1995), and *Shobridge v. Thomas* (1999) have held that the fiduciary nature of the doctor-patient relationship imposes a duty on the doctor to disclose medical errors to the patient.

It is interesting to note that all of the cases which are discussed above, which impose a duty on physicians to disclose medical error, were decided at a time when the ethical code of the profession did not explicitly recognize such a duty (Robertson 2002). That has now changed. The Canadian Medical Association's Code of Ethics states: "Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient" (Canadian Medical Association 2004, para. 14). In addition, the College of Physicians and Surgeons in all provinces has either expressly adopted the CMA's duty of disclosure or developed its own disclosure policies (Canadian Patient Safety Institute 2006; Vandergrift 2007).

This express recognition of a professional and ethical obligation of disclosure strengthens the legal duty and adds an underlying basis to it.

The overall duty of care owed to the patient requires the physician to exercise reasonable skill and judgment—to act as a reasonable physician would do in similar circumstances (Picard and Robertson 2007, ch. 4). Therefore, it is open to the court to conclude that in addition to the concepts of informed consent and fiduciary duty, the physician's ordinary duty of care imposes a duty of disclosure to patients, because that is what is expected by the profession itself as evidenced by its ethical codes and disclosure policies. Thus, for example, although the *Canadian Disclosure Guidelines* recently published by the Canadian Patient Safety Institute state that they are "not intended to define or serve as a legal or professional standard of care" (Canadian Patient Safety Institute 2008, 10), it is possible that a court might choose to adopt them as reflecting the appropriate standard of disclosure, in the same way as it may adopt other professional guidelines as being indicative of the standard of care (Picard and Robertson 2007, 360).

Legislation

The doctor's legal duty of disclosure is (at least for the time being) entirely a product of the common law; there is no statutory duty of disclosure. Although Manitoba and Quebec have recently introduced legislation requiring disclosure of adverse events to patients, the duty is placed on the health authority or health care institution rather than on individual health care professionals (*Regional Health Authorities Amendment and Manitoba Evidence Amendment Act* 2005; *An Act Respecting Health Services and Social Services* 2002). The legislation in Quebec does impose a duty on individuals to report adverse events to the executive director of the institution (but not to the patient), whereas in Manitoba the legislation provides that health professionals *may* report adverse events to the institution, but are not required to do so (Canadian Patient Safety Institute 2006; Vandergrift 2007).

Another important legislative development is the recent enactment in British Columbia, Manitoba, and Saskatchewan of "apology" laws (*Apology Act*, S.B.C. 2006; *Apology Act*, S.M. 2007; *Evidence Act*, S.S. 2006). Modelled on similar legislation in the United States, these laws have as their purpose to encourage health professionals

to apologize to patients when an adverse event has occurred, without the risk of that apology later being used against them in legal proceedings as an admission of liability. The legislation provides that an apology does not constitute an express or implied admission of fault or liability, and is not admissible in court as evidence of fault or liability (Bailey, Robertson, and Hegedus 2007; Waite 2005).

It should be noted that although the legislation prevents an apology from being used as evidence *of fault or liability*, the apology can still be relevant (and admissible as evidence) with respect to other matters. For example, in a recent B.C. case, evidence that the physician apologized to the patient for having performed the wrong operation was one of the factors the Court took into account in deciding not to award punitive damages against the physician (*Cochran*, 2004).

There is a significance to the apology legislation which goes well beyond the legal protection it confers. It highlights that if physicians are reluctant to discharge their duty to disclose errors to their patients—and there is substantial empirical evidence that they are (Levinson and Gallagher 2007)—one reason is that perception often trumps reality. There appears to be no reported case in Canada in which a physician's apology to a patient has been used as evidence of an admission of liability (Waite 2005), and yet the perception that it could be has led to the enactment of the apology laws. Likewise, physicians often report being reluctant to disclose medical errors to their patients because of a fear of being sued, whereas the empirical evidence suggests that open and candid disclosure actually reduces the risk of being sued (Levinson and Gallagher 2007; Picard and Robertson 2007, 208; Robertson 2002; Waite 2005).

The Legal Consequences Of Non-Disclosure

Sometimes the breach of a physician's duty to disclose medical error will cause no additional harm to the patient, and therefore no legal consequences will flow from it. *Stamos v. Davies* (1985) is an example of this; the surgeon's failure to tell the patient that he had punctured the spleen during the course of the lung biopsy caused no additional harm to

the patient, and hence no damages were awarded for the breach of disclosure.

However, in many instances the breach of the duty of disclosure will have legal consequences. For example, as is discussed above, if the court finds that failure to disclose the error (particularly if it is coupled with active steps at covering up) constitutes egregious and reprehensible conduct deserving of sanction, it may award punitive damages against the doctor (*Gerula*, 1995; *Shobridge*, 1999).

Other legal consequences which may flow from the breach of the duty to disclose error include an award of damages for the patient's emotional suffering in not being told the truth. For example, in a Quebec case a patient underwent a mastectomy following a biopsy which indicated breast cancer. When the surgeon subsequently discovered that the pathologist's report of the biopsy was incorrect, he waited six years before informing the patient. In the subsequent legal action against the surgeon, the patient was awarded damages for the anxiety and stress she suffered during those six years, worrying that her cancer might recur (*Kiley-Nikkel*, 1993). Likewise, in the *Shobridge* case, the patient was awarded substantial aggravated damages for the emotional distress she suffered upon discovering that her doctor had deliberately concealed the truth from her concerning the abdominal roll which had been left inside her during surgery (*Shobridge*, 1999).

Another important legal consequence of non-disclosure relates to limitation periods. Legislation imposes a "limitation period" for civil actions, that is, a time within which the action must be commenced, otherwise it is time-barred. In most provinces that time period is two years from the date when the plaintiff discovered (or ought reasonably to have discovered) the material facts, subject to an overriding limitation of 10 years (in some provinces, 15 years) from the date of the negligent act (Picard and Robertson 2007, 375-385). This overriding limitation period means that even if the plaintiff is unaware of the injury, or of the material facts surrounding it, the action will be time-barred after 10 (or 15) years. However, this is subject to an exception for fraudulent concealment; if the defendant fraudulently conceals the existence of the cause of action, the

limitation period does not start to run until the plaintiff discovers (or ought reasonably to have discovered) the fraud. It has been held that a doctor's failure to disclose medical error constitutes fraudulent concealment, thereby postponing the running of the limitation period for an action against the doctor (Picard and Robertson 2007, 384-385; Robertson 1987).

When Does The Duty Of Disclosure Arise?

As noted above, although the existence of the physician's duty of disclosure is well established, some issues concerning its precise scope remain uncertain. One of the most important of these relates to the point at which the duty arises. What event or types of event will trigger the legal duty to disclose? Specifically, does the duty arise only if the patient has suffered harm? What about *possible* actual harm? What if there is the potential for future harm? What about incidents where an error occurs which almost causes harm to the patient (the "near miss" cases)?

As noted above, the CMA's Code of Ethics speaks of disclosure of *harm*—if the physician causes harm to the patient, this must be disclosed (Canadian Medical Association 2004, para. 14)—perhaps implying that there is no ethical obligation of disclosure in the absence of harm. Likewise, in keeping with many disclosure policies across the country, the *Canadian Disclosure Guidelines* developed by the Canadian Patient Safety Institute require disclosure of an "adverse event," which is defined as "An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition" (Canadian Patient Safety Institute 2008, 30). As with the CMA's Code of Ethics, the *Canadian Disclosure Guidelines* focus on "harm" to the patient as the triggering event for disclosure. However, it should be noted that they also contemplate a duty of disclosure in cases of potential future harm. They provide that:

> The need to disclose when there is no immediate harm but the potential for harm exists is influenced by the future likelihood of severe consequences, the severity of possible consequences and the potential to prevent, identify or mitigate future harm through clinical testing or

> treatment. When uncertain about whether harm has occurred, it is recommended that disclosure take place; however, further consultation may be required before proceeding. Consider consulting with an ethics committee or another similar body of experts for advice about the clinical risk of future harm and the need to disclose. (Canadian Patient Safety Institute 2008, 18)

With respect to the *legal* duty of disclosure, it cannot be assumed that it applies only in cases where the patient has suffered harm. Indeed, some of the cases suggest otherwise. For example, in the *Vasdani* and *Gerula* cases, discussed above, in which the surgeon mistakenly operated on the wrong part of the patient's back, there was no real "harm" to the patient (other than the fact that the operation did not cure the underlying problem and had to be repeated), and yet the surgeon was held to have a duty to inform the patient of what had happened (*Vasdani*, 1993; *Gerula*, 1995).

In addition, the case law makes it clear that if the physician knows that an error *may* have caused harm to the patient, there is a duty to inform the patient. The *Pittman* case establishes this: on being notified that Mr. Pittman *may* have been transfused with HIV-contaminated blood, his family physician had a legal duty to inform him of this (*Pittman Estate*, 1994).

It seems, therefore, that the physician's legal duty of disclosure may be broader than that envisaged in documents such as the CMA's Code of Ethics, in that it is not confined to cases where the patient has suffered actual harm. This is consistent with one of the underlying theories upon which the legal duty of disclosure is based, namely, the doctrine of informed consent. As is discussed above, the guiding principle which is applied in informed consent cases to determine what information must be disclosed to patients is whether a reasonable person in the patient's circumstances would have wanted the information (*Reibl*, 1980; Picard and Robertson 2007, ch. 3). Applying that principle in the context of medical error, the duty to inform the patient of what has happened would arise if it is something which a reasonable person in the patient's circumstances would want to know. Indeed, that principle is recognized in the *Canadian Disclosure Guidelines* (Canadian Patient Safety

Institute 2008, 18). Certainly in the case of *possible* harm, and potential *future* harm, and perhaps even in cases of serious "near misses," one could argue that a reasonable patient would want to be informed of this.

Another issue with respect to when the duty of disclosure arises relates to timing: how soon must disclosure be made? In this respect the policy guidelines and the law are consistent. As noted above, the *Shobridge* case held that disclosure must take place "as soon as reasonably practical" (*Shobridge*, 1999, para. 89). Likewise, the *Canadian Disclosure Guidelines* provide that disclosure should take place "as soon as reasonably possible after the event," and "at the earliest practical opportunity and preferably within one to two days after discovery of the adverse event" (Canadian Patient Safety Institute 2008, 16 and 20).

What Must Be Disclosed?

Policy guidelines, such as the CPSI's *Canadian Disclosure Guidelines*, emphasize that disclosure should be limited to facts, and in particular, should avoid "speculation, opinion or attribution of blame" (Canadian Patient Safety Institute 2008, p. 21). This is consistent with the duty imposed by law. In particular, it has been held that the doctor's duty of disclosure is limited to facts and does not extend to disclosure of evidence or opinions (*V.A.H.*, 1998, para. 134; *Fehr*, 1999, paras. 34 and 39).

Whose Duty?

Two issues arise under this heading. The first is whether the physician's legal duty of disclosure is non-delegable or can be discharged by someone else on the physician's behalf. The second is whether the legal duty of disclosure extends to other health professionals, including nurses.

Many of the recent policies and protocols with respect to disclosure, including the CPSI's *Canadian Disclosure Guidelines*, adopt a "team approach" to disclosure. They do not place sole responsibility on the physician. Even the policy guidelines (such as the ones in Alberta and

Newfoundland) which provide that the most responsible physician should take a lead role in disclosure conversations do not indicate that the physician must necessarily be the one who personally discloses the information to the patient (Canadian Patient Safety Institute 2006; Vandergrift 2007).

This is consistent with the case law which establishes the physician's legal duty of disclosure. There is no indication in those cases that the physician must *personally* inform the patient, so long as he or she takes reasonable steps to ensure that the patient is informed, including delegating the task to someone else. For example, in the Quebec case in which the patient was incorrectly diagnosed with breast cancer (and underwent unnecessary surgery), the error was that of the pathologist in examining the biopsy. On discovering his error, the pathologist informed the surgeon, who advised him that he would tell the patient (which he did not). The Court held that the pathologist was not liable for failing to inform the patient, because it was reasonable for him to rely on the surgeon's assurance that he would tell the patient (*Kiley-Nikkel*, 1993).

Support for the position that the duty of disclosure can be delegated is also found in the *Pittman* case, discussed above (*Pittman Estate*, 1994). In that case the Court held that, upon learning that the patient may have received a transfusion of HIV- contaminated blood, the hospital acted reasonably in deciding to notify the patient's family physician and leave it to him to inform the patient, so long as appropriate support and advice were made available to the family physician to enable him to carry out this responsibility.

In summary, although the cases impose a duty of disclosure on the physician personally, the legal position is probably consistent with that reflected in the policy guidelines, namely, that so long as the physician takes reasonable steps to ensure that the patient is informed, the actual disclosure does not necessarily have to be made by the physician, and can be delegated to others (in particular, other medical staff or hospital administration).

The other issue that arises in this context is whether other health professionals (in particular, nurses) have a legal duty to disclose errors to the patient. This was discussed in the *Shobridge* case, which involved a patient who had a retained gauze roll in her abdomen following surgery (*Shobridge*, 1999). The Court held that the nurses who were present when the abdominal roll was discovered had no legal duty to inform the patient, even when it became apparent to them that the surgeon was not going to tell the patient; the nurses' only obligation was to prepare an incident report for hospital administration.

As Michael Waite (2005) points out, this aspect of the *Shobridge* decision is problematic, particularly since the nursing staff was negligent (along with the surgeon) in failing to do a proper sponge count in the initial operation, which led to the abdominal roll being left inside the patient. In other words, it was partly the nurses' error which led to the adverse event, and yet the Court held that they had no legal duty to inform the patient; sole responsibility for disclosure lay with the surgeon.

Admittedly it may be more difficult to construct a legal basis for imposing a duty of disclosure on nurses. The principles which have been used to ground the doctor's duty of disclosure—informed consent and fiduciary duty—do not easily apply to nurses. Nurses do not have a legal duty to obtain a patient's informed consent to treatment performed by (or under the direction of) a physician (Picard and Robertson 2007, 172), nor have Canadian courts characterized the relationship between nurse and patient as a fiduciary one (Waite 2005, 19-20). Nevertheless, given that the ethical code of the nursing profession recognizes a duty to "admit mistakes" (Canadian Patient Safety Institute 2006; Vandergrift 2007), it is certainly possible that a Canadian court could impose such a duty (Waite 2005, 20). Indeed, Picard and Robertson (2007) suggest that:

> In view of the modern "team approach" to health care delivery, with nurses playing an important role in patient care in a hospital setting, the correctness of the *Shobridge* decision on this issue is questionable. Both with respect to their own errors, and those of other members of the team, nurses should be regarded as having a duty to take reasonable steps to ensure that the patient is advised of the error. (207, footnotes omitted)

Conclusion

The physicians' legal duty of disclosure of medical error is well established. Whether it is grounded upon the doctrine of informed consent, or upon principles of fiduciary law, or upon the general duty of care imposed by the law of tort (and contract), the duty of disclosure is clear. Yet many of its parameters have still to be determined by the courts. In particular, is it a duty confined to doctors, or is it shared by other health professionals (and indeed, health care institutions)? Is it triggered only in cases of actual harm, or does it arise in cases of possible or future harm, and in cases of "near misses"? Although the case law sheds some light on these issues, the precise scope of the duty to disclose medical error is not yet clear, and awaits further judicial clarification. However, it is noteworthy that Canadian courts have taken a very broad and expansive interpretation of physicians' fiduciary obligations to their patients, as well as their duties with respect to informed consent (Picard and Robertson 2007), both of which underlie the duty to disclose medical error. This may well suggest that in the future Canadian courts will also take an equally expansive interpretation of the duty to disclose medical error to patients.

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2. *Cochran v. Hunter*, [2004] B.C.J. No. 1982, 133 A.C.W.S. (3d) 795 (S.C.).
3. *Fehr v. Immaculata Hospital*, [1999] A.J. No. 1317, 253 A.R. 188 (Q.B.).
4. *Fleming v. Reid* (1991), 4 O.R. (3d) 74, 82 D.L.R. (4th) 298 (C.A.).
5. *Gerula v. Flores*, [1995] O.J. No. 2300, 126 D.L.R. (4th) 506 (C.A.).
6. *Hopp v. Lepp*, [1980] 2 S.C.R. 192, 112 D.L.R. (3d) 67.
7. *Kiley-Nikkel v. Danais*, [1992] A.Q. No. 1836, 16 C.C.L.T. (2d) 290 (Que. Super. Ct.).
8. *Kueper v. McMullin* (1986), 73 N.B.R. (2d) 288, 30 D.L.R. (4th) 408 (C.A.).
9. *Lee v. South West Thames R.H.A.*, [1985] 2 All E.R. 385 (C.A.).
10. *McInerney v. MacDonald*, [1992] 2 S.C.R. 138, 93 D.L.R. (4th) 415.
11. *Pittman Estate v. Bain* (1994), 112 D.L.R. (4th) 257, 19 C.C.L.T. (2) 1 (Ont. Gen. Div.).
12. *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1.

13. *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519, 107 D.L.R. (4th) 342.
14. *Shobridge v. Thomas*, [1999] B.C.J. No. 1747, 47 C.C.L.T. (2d) 73 (S.C.).
15. *Stamos v. Davies* (1985), 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 (H.C.).
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17. *V.A.H. v. Lynch*, [1998] A.J. No. 819, 224 A.R. 359 (Q.B.), reversed in part (2000), 255 A.R. 359, 184 D.L.R. (4th) 658 (C.A.), leave to reargue the appeal and to extend the time for seeking leave to appeal to the S.C.C. dismissed (2000), 277 A.R. 104, 190 D.L.R. (4th) 119 (C.A.).
18. *Vasdani v. Sehmi*, [1993] O.J. No. 44, 37 A.C.W.S. (3d) 856 (Gen Div.).

LEGISLATION

1. *An Act Respecting Health Services and Social Services*, R.S.Q. c. S-4.2 [am. 2002, c. 71].
2. *Apology Act, S.B.C. 2006, c. 19.*
3. *Apology Act, S.M. 2007, c. 25 [in force February 6, 2008].*
4. *Evidence Act, S.S. 2006, c. E-11.2, s. 23.1 [en. 2007, c. 24, s. 2].*
5. *Regional Health Authorities Amendment and Manitoba Evidence Amendment Act, S.M. 2005, c. 24 [in force November 1, 2006].*

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Disclosing Unanticipated Outcomes to Patients: International Trends and Norms

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Introduction

In countries around the world there is a growing expectation that patients will be fully informed about unanticipated outcomes in their care, especially those unanticipated outcomes that were due to medical errors (Gallagher, Studdert, and Levinson 2007). However, it is also increasingly apparent that, at present, the practice of disclosure falls far short of meeting this expectation. Multiple studies in several countries suggest that as few as one-third of patients are told about harmful errors in their care (Blendon et al. 2002; T. H. Gallagher, Waterman, Ebers, et al. 2003; Schoen et al. 2005; Kaiser Family Foundation/Agency for Healthcare Research & Quality/Harvard School of Public Health). These failed disclosures represent a fundamental breach in the provision of patient-centered care, impairing patients' decision making, their trust, and satisfaction (Mazor et al. 2006). Defective disclosures may also make it more likely that patients will file a medical malpractice claim (Kachalia, Shojania, et al. 2003). Finally, breakdowns in transparency generally are considered important impediments to improving the quality of health care and reducing harmful errors (Gallagher, Denham, et al. 2007).

Surveying recent disclosure developments around the world reveals a wide range of activities and programs being undertaken to promote more effective disclosure of unanticipated outcomes to patients. Such programs are being implemented in a variety of health care environments, ranging from the United States, where the medical malpractice system is thought to be "in crisis" and health care is delivered in a fragmented system where many lack health insurance, to the United Kingdom and Canada, where medical malpractice concerns

are somewhat less problematic and health care is available to all citizens, to New Zealand, where a nearly no-fault medical malpractice system exists. Yet despite these different health care delivery and malpractice environments, the disclosure programs emerging in these countries are much more similar than different. Furthermore, almost no systematic data exists regarding the outcomes of these disclosure programs. Nonetheless, reviewing how disclosure practices are evolving in these different countries can help identify important emerging trends and suggest directions for future developments.

United States

The United States is a useful starting point when one considers international norms and developments in disclosure, as the factors that encourage and inhibit disclosure in the United States are also present to a greater or lesser degree in other countries. The absence of a powerful centralized governmental health authority in the U.S. allows considerable innovation in disclosure efforts, particularly at the level of individual institutions. However, the malpractice climate in the United States, a frequently cited barrier to disclosure, is as challenging as it is in any industrialized country around the world (Studdert, Mello, and Brennan 2004). Thus, there is good reason to believe that disclosure programs that have taken root in the United States could serve as successful models for other countries to consider.

The need to disclose unanticipated outcomes to patients has long been recognized by professional organizations and ethicists as an ethical imperative. In 2001, the United States Joint Commission, the body responsible for accrediting hospitals and health care organizations, added disclosure to its list of hospital accreditation requirements (Joint Commission 2007). The requirement itself was deceptively simple: it states that patients must "be informed about all outcomes of care, including unanticipated outcomes." U.S. hospitals took up this Joint Commission standard in a variety of ways, some adopting policies that merely mirrored the Joint Commission statement, and others adopting very detailed disclosure policies and procedures (Gallagher et al., 2006; Lamb et al. 2003).

The evolution of disclosure practices in the United States continued to occur at mostly the institutional level until 2006, when the Harvard Full Disclosure Working Group issued its report, "When Things Go Wrong" (Full Disclosure Working Group, 2006). This report provided a considerably more detailed set of guidelines regarding when and how to disclosure unanticipated outcomes to patients. Particularly significant was the policy's emphasis on accepting responsibility for unanticipated outcomes, as well as the importance of offering a full apology.

Shortly thereafter, the National Quality Forum (NQF), a U.S. organization that articulates consensus standards for high quality health care, added disclosure of unanticipated outcomes to its list of thirty "safe practices" (Gallagher, Denham, et al. 2007; National Quality Forum 2007). This safe practice helped advance disclosure in a number of ways. The Joint Commission standard made no mention of whether patients needed to be informed if an unanticipated outcome was preventable, i.e., whether it was due to a medical error. The NQF safe practice, however, emphasized the importance of informing patients of "the facts" regarding the outcome *including its preventability*. Also innovative was the safe practice's recognition of the challenges of disclosure and its call for hospitals and health care organizations to develop "disclosure support systems," including disclosure education for health care workers, the availability of around-the-clock disclosure coaches, and emotional support for affected patients, their families, and health care professionals. The safe practice also recognized the importance of informing patients about plans to prevent recurrences "in sufficient detail to support informed decision-making." Finally, the safe practice called on institutions to begin studying the outcomes of the disclosure process and to use performance-improvement tools as a means of tracking and improving disclosure outcomes.

The NQF safe practices are important not only because they represent consensus standards, but also because they are used in public reporting and pay-for-performance programs. Thus, consumers can currently visit the Leapfrog group's web site and see hospital-specific scores on each of the thirty safe practices for the over 1,300 hospitals that voluntarily report this data (Leapfrog Group 2007). This public reporting

of institution-specific disclosure practices is a unique strategy for encouraging institutions to improve their disclosure performance.

In addition to these national policies and consensus statements, important disclosure programs have been developing at the local level in the U.S. In 1999, the Veterans Affairs (VA) Hospital in Lexington, Kentucky, published a paper describing their new policy of full disclosure of harmful errors to patients and its impact on their malpractice claims experience (Kraman and Hamm 1999). The Lexington VA program was notable not only for its endorsement of full disclosure, but also for explicitly assisting patients in seeking compensation for their injuries. The Lexington VA's claims experience did not appear dramatically different from that of similar VA hospitals, despite the implementation of this open disclosure policy. More recently, the University of Michigan reported that its program of open disclosure and early offers of compensation had significantly reduced its malpractice expenses and shortened the time to resolution of malpractice claims (Clinton and Obama 2006).

Another well-known U.S. disclosure effort is the "3Rs" program that was developed at COPIC, a large Colorado malpractice insurance company (COPIC Insurance Company 2005). The 3Rs program, like the University of Michigan program, integrates disclosure with early offers of compensation (Gallagher, Studdert, and Levinson 2007). However, there are important differences between the Michigan and COPIC programs. While the University of Michigan program handles all events regardless of their severity or whether negligence was involved, the COPIC 3Rs program excludes events if they involve patient death, if the patient has retained an attorney, if the patient has made a written demand for payment, if the patient has filed a formal complaint with the Board of Medical Examiners, or if the events were due to gross negligence. The 3Rs program is a no-fault program, meaning that no effort is undertaken to determine whether the unanticipated outcome was due to a medical error. COPIC encourages physicians to disclose all unanticipated outcomes to patients. In addition, for those events that meet the 3Rs criteria, patients can receive payments for out-of-pocket expenses and lost time up to $30,000.

To date, the program has handled over 3,000 events in the 3Rs program. Two-thirds of these events have been closed with no payment to the patient. Of those events where payment was made, the average payment was only $5,000. No 3Rs event has proceeded to a formal jury trial. For this selected group of events, COPIC's approach of open disclosure and early offers of compensation appears to be a way to resolve these events less adversarially and more effectively than could be accomplished through the traditional torts system.

Important developments have also been taking place at the level of U.S. state legislatures (Cohen 2000; Sparkman 2005; Wei 2007). Physicians' and health care institutions' fear that disclosure might precipitate litigation is often cited as an important barrier to disclosure. In response, 36 U.S. states have adopted "apology" laws that provide varying degrees of legal protection for these statements. At a minimum, all of these laws protect "an expression of regret" from being used in court as an admission of liability. Six U.S. states also protect "an explanation" of the event. Four states provide protection for the entire disclosure and apology, including an admission of liability. Because many of these laws provide only limited legal protection, it is unclear whether they will have a significant impact on physicians' or health care institutions' fear of disclosure triggering a lawsuit.

In addition to these apology laws, eight U.S. states have adopted legislation requiring disclosure. The disclosure burden is generally placed on the health care institution rather than on the individual health care workers. Of these states, Pennsylvania and Oregon require that the disclosure be made in writing. The content of what needs to be disclosed is not specified in any of these laws, and it is unclear whether and how states intend to enforce these disclosure mandates.

There is very little systematic evidence regarding the impact of these disclosure programs in the U.S., other than the anecdotal evidence cited above. In particular, there is no prospective evidence regarding the effectiveness of any specific disclosure strategy (Gallagher and Lucas 2005). This has hampered efforts to issue disclosure guidelines that are

truly evidence-based. Furthermore, while many U.S. physicians continue to cite the malpractice environment as a major impediment to disclosure, recent research suggests that the external malpractice environment may have less influence on physicians' disclosure decisions than previously thought. For example, one study compared the disclosure attitudes and experiences of physicians in the U.S. and in Canada, a country where physicians are significantly less likely to be sued and pay much lower malpractice insurance premiums than in the U.S. (Baker et al. 2004; Coyte, Dewees, and Trebilcock 1991; Picard and Robertson 1996). The U.S. and Canadian physicians' disclosure attitudes and experiences were much more similar than different in this study, suggesting that these attitudes may be more firmly rooted in the culture of medicine than in the external environment itself (Gallagher et al. 2006). This suggests that making substantive changes in disclosure practices will involve large-scale culture change within the health care profession, a process which will occur over a long period and require considerable energy and resources.

Australia

Australia has also taken a leadership role internationally in the development and dissemination of disclosure standards. In 2003, the Open Disclosure Standard was published and endorsed by the Australian Health Minister's conference (Australian Council for Safety and Quality in Health Care 2003; Grace and Queau 2002). The goal of the standard was to encourage more open and effective communication with patients following adverse events. The standard calls for patients to be informed of the known facts about the event, consequences of the event, and steps being taken to manage the event and prevent recurrences. Patients are also to receive an expression of regret. Parts of this information are typically conveyed in an initial conversation with the patient, while the remainder is discussed with the patient in a follow-up discussion after an analysis has been completed. The standard suggests that the initial conversation be led by the most senior health care professional responsible for the clinical care of the patient, though it also allows for a "substitute person" who is well trained in disclosure to conduct the conversation.

This standard divides events into "low level" and "high level" events based on their severity, and calls for more robust disclosure processes for the higher level events. Low level events are adverse events where there is no permanent injury or increased level of care required, whereas high level events involve death or major permanent loss of function, the need for surgical intervention, a transfer to a higher level of care, or a major change in clinical management. This standard was accompanied by an impressive package of educational material and workshops throughout the country.

The Open Disclosure Standard seeks to strike a balance between promoting transparency and recognizing the potential medico-legal impact of this policy. The Open Disclosure Standard emphasizes the importance of not admitting liability to the patient. While the Open Disclosure Standard encourages "an expression of regret," it does not sanction a full apology; in fact, the word "apology" does not appear anywhere in the standard.

After the standard was endorsed in 2003, individual states within Australia were responsible for drafting local policies that were consistent with the standard and the specific state laws (State government of Victoria 2007). Over time, areas of tension between state laws and elements of the open disclosure process have become apparent. For example, in New South Wales the results of root cause analysis information are considered legally protected, complicating disclosure to the patient after the root cause analysis process has started. In addition, around the same time that the Open Disclosure Standard was being disseminated, a highly publicized scholarly paper suggested that the disclosure process might generate more malpractice claims, not fewer (Studdert, Mello, Gawande, et al. 2007). Using malpractice claims data and computer modelling, the authors concluded that open disclosure was more likely to prompt a patient to sue than it was to prevent a patient from suing. The paper heightened concern amongst some Australian hospitals about unanticipated consequences of the open disclosure process (Koh and Alcock 2007; Madden and Cockburn 2007; Wakefield, Jorm, and Ryan 2007).

Across Australia, an extensive pilot project has been underway to evaluate the initial implementation of the Open Disclosure Standard. Formal reports from this pilot are not yet available but will be published soon. Informal conversations with the authors of these reports suggest that the initial implementation of this standard has been a qualified success. As was found in research amongst U.S. physicians, support among health care workers in Australia for the open disclosure process was widespread but many unanswered questions about implementation remain. For example, while the standard calls for disclosure conversations to be led primarily by the patient's clinician, in practice many of the initial and follow-up disclosure conversations are led by health care workers and administrators trained in the Open Disclosure process but who have not cared for the patient. Relying on disclosure "experts" to conduct these delicate conversations makes sense in many respects. Few clinicians have had disclosure training, and even for those who have, disclosure conversations are relatively infrequent events for any individual clinician. Nonetheless, patients may prefer to have the event disclosed directly by their clinician (Gallagher, Waterman, Ebers, Fraser, and Levinson 2003; Mazor et al. 2004). In addition, balancing the time needed to conduct a thorough investigation of the event with the patient's desire to receive information promptly proved a challenge in many cases.

The United Kingdom

Australia's publication of its Open Disclosure Standard was influential in the United Kingdom's development of its disclosure policy. In 2003 the Department of Health published the document *Making Amends*, which reported results from interviews with 400 people who had been harmed as a result of their health care treatment (National Patient Safety Agency 2003). A prominent finding from this report was that patients valued an apology, as well as an investigation and emotional support, after a harmful health care event.

In 2006 the National Patient Safety Agency published its safer practice notice introducing their Being Open policy (National Patient Safety Agency (UK) 2005). The Being Open policy emphasizes the importance of being open when patients are harmed by their health care.

In contrast to Australia's Open Disclosure project, the Being Open policy puts an apology at the centre of the disclosure process. The policy notes "patients and/or their carers should receive an apology after the patient safety incident has occurred and staff should feel able to apologize on the spot. Saying sorry is not an admission of liability and it is the right thing to do. The patients have a right to expect openness in their healthcare."

The safer practice notice requires that all National Health Service organizations providing patient care in England and Wales should:

1) Develop a local policy, based on the NPSA's Being Open policy but adapted to suit local requirements, by June 2006.
2) Raise awareness of local policy among health care staff and provide them with the appropriate information and support.

As in Australia, a wide-ranging set of educational materials has been developed to accompany the Being Open policy. Being Open training workshops are available for interested organizations, the most extensive of which includes opportunities to practice disclosure skills with actors. No published information is yet available about the local implementation of the Being Open policy.

Canada

Canada issued major guidelines on disclosure more recently than did the United States, Australia and the United Kingdom, with the Canadian Patient Safety Institute releasing its in 2008 (Canadian Patient Safety Institute). The guidelines incorporate many of the key features from other countries. Most notable, however, is the guidelines' reflection of the ongoing tension between open disclosure and acknowledgement of error. The guidelines emphasize the importance of open and transparent communication with patients following adverse events. However, the guidelines are explicit about the recommendation to avoid the use of the term "error" in the context of disclosure.

> These guidelines purposely avoid the use of the term error. Adverse events are known to most often result from a complex interplay of factors… A single failure rarely leads to harm. Most often a series of failures cascade to result in harm. While healthcare provider error may appear to be the most obvious

> contributing factor, latent conditions…usually contribute to the cause of the harm. Providers must still be responsible for the quality of their work and will be held professionally and legally accountable when warranted. Furthermore, the use of the term error in disclosure discussions might be misunderstood or confused to mean that the care provided was substandard or was negligent in law, however, this is often not the case. (p. 11)

However, the guidelines note, "if applicable, and when all the facts are established, a further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate" can be included in the disclosure statement (p. 21). The guidelines acknowledge the complexity of walking this fine line between expression of regret and full apology.

> In principle, apology as part of disclosure of an adverse event... is consistent with patient-centered care, honesty and transparency, and intuitively is the right thing to do. In practice, apology as part of disclosure is complex because of the ambiguity of commonly used apology language. There is a belief that apology implies blame from providers, which is often inconsistent with a just patient safety culture. (p. 23)

Clearly, considerable work remains in Canada and countries around the world regarding how to balance these competing requirements for open and honest disclosure with the medical legal realities in these countries.

New Zealand

New Zealand is of interest in the international disclosure landscape primarily because it highlights the disconnect between the malpractice climate and the development of disclosure programs. New Zealand has moved away from negligence-based strategies for compensating patients who have been harmed by their medical care (Kachalia, Mello, Brennan, and Studdert 2008). The Accident Compensation Corporation (ACC) was established in 1974 to administer a new program for compensating individuals who were injured as a result of their employment. Though the ACC was not intended initially to address injuries due to medical care, in 1992 legislation was passed to clarify that the ACC did apply to two types of medical injuries: "medical errors" and "medical mishaps." In 2005, the eligibility criteria were

relaxed, such that any injury that is causally related to the process of health care is eligible for compensation, with the exception of injuries that are a "necessary part of treatment" or an "ordinary consequence of treatment." However, this nearly no-fault approach to compensation is coupled with an active system whereby patients can file complaints about their health care providers, as well as a vigorous disciplinary system for health care providers (Bismark, Dauer, Paterson, and Studdert 2006; Bismark and Dauer 2006; Bismark and Paterson 2006; Bismark 2006; Bismark, Brennan, Davis, and Studdert 2006).

Despite what in many ways would be considered a favourable litigation climate for providers, and despite the country's geographic proximity to Australia, New Zealand's disclosure programs are less far along than those of other countries. There is clearly a strong expectation that New Zealand health care workers will communicate openly with patients about unanticipated outcomes. For example, the New Zealand Code of Health and Disability Services Consumers' Rights includes the patients' right to open disclosure (Health & Disability Commissioner 1994). In March of 2007 the Health and Disability Commissioner issued guidance on Open Disclosure, and articulated basic guidelines for the open disclosure process (Health & Disability Commissioner 1994). Educational materials are being developed but have not yet been released. The Health and Disability Commissioner's Strategic Plan includes the target that all District Health Boards will have open disclosure policies in place by 2010.

Looking Forward

The experiences with developing and implementing disclosure programs across these different countries share important common threads and highlight areas for future growth:

1) **Support for the concept of open disclosure is high, but implementation is uneven.** Developing thoughtful disclosure policies and educational programs is an important first step towards closing the gap between expectations that unanticipated outcomes will be disclosed to patients and current practice. Yet the challenges with implementing these ideals highlight how

difficult it will be to change the entrenched culture of health care related to disclosure. The key barrier does not appear to be health care workers' commitment to disclosure, but rather, important unanswered questions about the most effective disclosure strategies (Gallagher, Waterman, Ebers et al. 2003; Gallagher et al. 2006). For example, who should disclose the event—the patients' caregivers or a team of disclosure experts? What is the appropriate balance between timely disclosure and allowing for a full investigation of an event? What is the relative importance of a full apology vs. an expression of regret in the disclosure process?

2) **Little is known about how the disclosure process is currently taking place.** Even in those countries that have made major investments in developing and disseminating disclosure training programs, little quantitative information is available about how disclosures are currently taking place, or about patients' or health care workers' assessment of the quality of actual disclosures. Developing and implementing systematic strategies for measuring the effectiveness of disclosures in real time will be essential for applying performance improvement tools to the disclosure process (Gallagher, Denham, et al. 2007). Even less is known about the relative contribution of disclosure vs. compensation to the overall resolution of these events.

3) **The malpractice environment is an obstacle to open disclosure, but not the most important obstacle.** Fear of litigation is clearly a barrier to disclosure. However, there is no clear relationship between the malpractice environment in a given country and its progress towards implementing open disclosure. Many of the most advanced disclosure programs have taken place at individual U.S. institutions committed to transparency, some of which are located in states that provide little to no legal protection for apologies or disclosures.

4) **Some of the legal barriers to disclosure are erected from within health care itself, rather than imposed by the external malpractice climate.** Patients clearly want to know why an

unanticipated outcome happened and how recurrences will be prevented (Gallagher, Waterman, Ebers, et al. 2003; Hobgood et al. 2002; Mazor et al. 2004, 2005). Yet in some countries, laws meant to protect event analyses from legal discovery conflict with the ability to provide patients with this information.

Important progress has been made towards creating a health care culture where patients can expect to be informed openly, promptly, and compassionately when they are injured by their health care. Yet the journey towards transparency is still in its early stages. Developing tools to measure how the disclosure process is currently taking place, using this information to identify effective disclosure strategies, and then training health care workers to implement these evidence-based disclosure techniques consistently are critical next steps towards meeting patients' justifiable expectations for open disclosure.

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Examining Disclosure Options: Procedures for Disclosing Adverse Events: A Literature Review

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Executive Summary

Introduction

This report reviews existing literature on the disclosure of adverse events within the Canadian health care system. Concerns about the disclosure of adverse events were raised by the public disclosure that faulty hormone receptor testing was conducted in Newfoundland and Labrador between 1997 and 2005. A Commission of Inquiry into the

faulty testing was established July 3, 2007. The appointed Commissioner of the Inquiry, Justice Margaret A. Cameron, requested the preparation of this report. The ultimate purpose of the report is to assist the Commission in situating its inquiry within the larger patient safety field.

Methods

A targeted literature review on the disclosure of adverse events within the Canadian health care system was undertaken. Key data sources included policy documents and reports, peer-reviewed research literature (accessed through scholarly health care databases), and media sources obtained from several relevant websites. This review of literature focused on current and developing policies and guidelines; key terms and concepts associated with patient safety; and the assumptions and frameworks that underlie current disclosure procedures and practices.

Findings

Over twenty major reports on patient safety and the disclosure of adverse events were included in this review. A number of themes emerged across these reports: the growing attention to patient safety; the high incidence of preventable adverse events within Canada; the responsibility of health care providers to fully disclose medical errors to their patients; methods of how to disclose, including the approach of public disclosure; key stages of the disclosure process (preparation to disclose, initial disclosure, and documentation); the central importance of culture change to patient safety. The literature also suggests that many improvements must be made within the Canadian health care system in terms of patient safety and the policies associated with disclosure. Some of the key recommendations include addressing the need for culture change to promote patient safety; providing more education on the processes and practices of disclosure within health care facilities; and embracing the advantages of the disclosure process for patients and health care professionals.

Conclusions

Disclosure procedures and practices within Canada continue to develop as many facilities are "adopting increasingly comprehensive

polices [policies] supporting the open and transparent disclosure of adverse events to patients and families" (Sidorchuk 2007, 2). With this in mind, health care facilities must continue to build a foundation for disclosure and to create a culture of patient safety that balances the system and individual in order to prevent the recurrence of adverse events. The ultimate goals of disclosure are to "provide information to the patient, assist with the disclosure process, provide support, and facilitate ongoing patient care" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 16).

Disclosure Examples

A number of widely publicized adverse events have occurred within Canada's health care system. These examples will set the frame for this report by illustrating the importance and consequences of disclosure practices.

The case of faulty hormone receptor testing in Newfoundland and Labrador provides the example that prompted this report. This case sparked media attention around the problems of medical error, the culture of patient safety, and the procedures for disclosure within Canadian hospitals, and is the focus of this inquiry. The case of the Newfoundland and Labrador hormone receptor testing is just one of the public cases of adverse events to occur within Canada recently. In 2003, Oshawa's Lakeridge Health Corporation reported that 150 patients had to be screened for Hepatitis A, B, and HIV because of "improperly sterilized equipment" used during scoping procedures (Goveia 2003, 7). Sunnybrook and Women's Health Sciences Centre in Toronto also reported the use of "improperly sterilized equipment" during prostate biopsies (Goveia 2003, 7). In 2007, a public apology was issued by the Alberta Health officials when "a 44-year-old Edmonton mother of three died from an accidental overdose of a chemotherapy drug" (Talaga and Cribb 2007).

In all of these examples, the adverse events have been disclosed to the individuals who were directly affected and, subsequently, through the popular media, to the public. One benefit of such public disclosure is that it often leads to improvements in patient safety practices both within

the local institution where the event(s) occurred and across other institutions and health care systems. For example, according to the *Toronto Star* investigation *Coming Clean on Medical Mistakes* (2007), serious action took place within the walls of Princess Margaret Hospital in Toronto after the Alberta health officials made the disclosure of the overdose of the chemotherapy drug public. Princess Margaret "reviewed their procedures on dispensing chemo[...] to prevent the same mistake from happening" (Talaga and Cribb 2007). Following their public apology, Lakeridge Health announced "that the hospital had implemented a new 'double-check' process, verifying proper disinfection procedures" (Goveia 2003, 7).

Media attention and academic research both emphasize the value of transparency when it comes to adverse events in health care. According to the *Toronto Star's* 2007 report, Dr. Steve Kraman, Professor of Medicine at the University of Kentucky and author of a study titled "Extreme Honesty May Be The Best Policy," explains that studies have shown that people are legitimately satisfied with learning the truth about what went wrong during their hospital stay, and therefore are less likely to sue, when disclosure occurs. People are ultimately receptive to being told the truth and to receiving the information being disclosed to them. The "deserved" truth becomes more valuable than money (Talaga and Cribb 2007). Therefore, Dr. Kraman believes that disclosure benefits all in years to come, whether it is made public or limited to the individuals directly involved. Interestingly, the *Toronto Star* investigation concludes that "the consensus from most in the health field is to make it *all* public" (Talaga and Cribb 2007). Physicians and patient safety researchers Wendy Levinson and Thomas Gallagher similarly conclude that the "healthcare environment is clearly changing toward supporting physicians in effective and full disclosure" (Levinson and Gallagher 2007, para. 10). They envision a future in which disclosure is routine, communication is transparent, and negative events are used to facilitate quality improvement.

Literature Review

How is Disclosure Defined?

With the growing attention to patient safety within Canada, The Royal College of Physicians and Surgeons of Canada, along with its partners, thought it was necessary to create a dictionary dedicated to patient safety. The *Canadian Patient Safety Dictionary* was published in 2003. It is a useful resource that collects key terms and information associated with patient safety, and also highlights potential problems and common misunderstandings about the terms.

Within the dictionary, "patient safety" itself is defined as "the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes" (2003, 12). The following recommendations are presented for using the term "disclosure":

> Disclosure should "be understood as the imparting, by health-care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an adverse outcome. (RCPSC 2003, 19)

The *Canadian Disclosure Guidelines* (2008) is another report that will be a particular focus in this review. These guidelines provide a shorter list of definitions that are especially relevant to disclosure. They define disclosure more simply as "The process by which an adverse event is communicated to the patient by health care providers" (2008, 30). This definition is significant because it emphasizes that disclosure is an ongoing *process* of communication rather than a singular event. The components of this process will be discussed later in this report. Table 1 presents a selection of terms from the guidelines that will be helpful for this discussion.

Table 1. Terms Related to Patient Safety

Term	Definition
Adverse event	An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.
Informing	Providing information about adverse events and the performance of the healthcare system to the public, mainly through the media.
Close call	The event did not reach the patient because of timely intervention or good fortune. (The term is often equated to a near miss or near hit.)
Reporting	The communication of information about an adverse event or close call by health care providers, through appropriate channels inside or outside of health care organizations, for the purpose of reducing the risk of reoccurrence of adverse events in the future.

(Canadian Patient Safety Institute 30)

One term that is not included as a key concept in either of these resources is "error." This is because both reports emphasize that an important distinction must be made between harm itself (the effect or potential effect on a patient) and the causes of the harm. The process of identifying the underlying causes of harm is often challenging and complex. For example, the harm could result from inherent risks of a patient's treatment, from features of the health care system, from the actions of individuals, or from a combination of all of these factors. The term "error" tends to muddy the distinction by implying that the actions of individuals are the primary cause of harm. The preferred term in many research and policy documents is "preventable adverse event." The term "error" is nonetheless important to the practice of disclosure. Research has shown that health care professionals and patients have different understandings of the term "error" that may affect their attitudes toward

disclosure (Espin et al. 2006). "Error" is also frequently used in commentaries, both in the medical literature and the popular media.

What are the Current Standards for Disclosure in Canada?

According to Levinson and Gallagher, many organizations in Canada are rapidly developing policies and procedures to support and facilitate disclosure practices (2007, 3). As new patient safety policies are being created, it is important to understand the multiple levels at which they take effect. Disclosure practices are established at various levels within the Canadian health care system. These levels include the "macro level" (government systems such as the provincial legislation on disclosure), "meso level" (health care organizations), and "micro level" (teams and individuals).

At the Macro Level: Provincial Disclosure and Legislation

A review of the Canadian provincial policies, guidelines, and legislation related to the disclosure of adverse events is provided in the Canadian Patient Safety Institute's Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events (2006). The existing, province-specific guidelines for "what must be disclosed" are summarized in Table 2.

Table 2. Provincial Guidelines

Province	What must be disclosed?
Alberta	At all disclosure meetings, information shared should be factual and agreed upon through a process of consensus by the health care team prior to initiating the disclosure process. Information to be disclosed should only be related to the event, and not about any health care providers involved. Only facts related to the patient's diagnostic, treatment and care information (as defined by the Health Information Act (HIA) Section 1 (1)(k)) should be shared. This information includes: • a description of what happened;

Province	What must be disclosed?
	• the sequence of events; • diagnostic test results; • consequences of the harm and resulting changes to the treatment plan; and • any other relevant factual information. [...].. Other specific elements to be included in the initial conversation are corrective actions that were and will be taken; an expression of remorse and empathy to the patient and family; an appropriate apology based upon whether the expected standard of care was met (benevolent apology) or not met (full apology); and a brief overview of the investigative process that will follow and what the patient and family can expect to learn, with timelines. (Health Quality Council of Alberta: Disclosure of Harm to Patients and Families Provincial Framework 2006)
British Columbia	FACTS: Stick to the facts during an explanation of the events. The nature of the event, the level of severity and outcomes if known. Do not speculate on any details surrounding the event or begin to attribute blame to any individual. APOLOGIZE: Empathize with the patient/family, "we are so sorry this has happened to you." However, the discussion should not involve a legal admission of liability. TAKE RESPONSIBILITY: The team should communicate ownership of the event to the patient and family. This is separate and distinct from an assumption of liability. The patient and family must feel confident that the team takes responsibility for determining the causes of the event, ensuring the patient's care is managed and any future complications are expressed to the patient and family. CLARIFY: If the adverse event was clearly not due to

Province	What must be disclosed?
	an error, or the cause is unclear, make sure the patient understands that the injury is not the result of a failure of care, but an inherent risk. (Provincial Health Services Authority: Disclosure of Adverse Events 2006)
Newfound-land and Labrador	The nature, severity and cause (if known) of the adverse event(s)/occurrence(s) (AE/O) should be presented in a straightforward and non-judgmental fashion. An expression of sympathy is often appropriate and not an admission of guilt. Speculation should be avoided and focus should be placed on what is known at the time. Answer questions and provide assurance that unanswered questions will be investigated further. Describe what, if anything can be done to correct the consequences of the AE/O. Offer a second opinion, the involvement of outside assistance, or transfer of care to another practitioner if applicable. (Association of Healthcare Risk Management: Policy on Adverse Events/Occurrence 2005)
Nova Scotia	The initial disclosure should include: • the facts of the event and its outcome, known at the time • the next steps to be taken in the care of the client • any changes to the overall plan of care • the offer of opportunities for further discussion • a designated contact person for further discussion and support • the support of other resources such as spiritual services, counselling, social work, etc. as relevant • what the organization is doing to find out how the event occurred The policy recognizes that the disclosure obligation is a continuing one, as more information becomes available. (Nova Scotia Health: Disclosure of Adverse

Province	What must be disclosed?
	Events Policy 2005)

Saskatch-ewan	Discussions should focus on currently known information about the facts surrounding the event. Blame should not be assigned, and speculation as to cause should not occur. Disclosure should occur as soon as possible following a triggering event, ideally within 24–48 hours. Follow-up discussions may be necessary for information discovered at a later time. (Saskatchewan Health: Disclosure of Harm Guideline 2005)

(Canadian Patient Safety Institute 2006, Appendices D and E, 38–41)

At the Meso Level: Disclosure Policies of Health Organizations

Health organizations often develop policies and procedures specific to their local context. Table 3 highlights the adopted disclosure policies of some health organizations as reported by the Canadian Patient Safety Institute's Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events (2006).

Table 3. Adopted Disclosure Policies of Health Care Organizations

Health Care Organization	Content of Disclosure
• McGill University Health Centre • Montreal, Quebec	Disclosure should be made at the earliest possible moment, as appropriate. It should include the facts of the accident; the measures taken to correct the consequences suffered and an explanation of plans to prevent such an accident from recurring. Personal opinions as to fault or responsibility are to be avoided.

Health Care Organization	Content of Disclosure
• Vancouver Coastal Health and • Richmond Health Services • Vancouver and Richmond, British Columbia	Facts of an incident (i.e. not suppositions, conjecture, or conclusions). The patient should also be advised that an investigation will be undertaken, and appropriate follow up implemented
• The Ottawa Hospital Ottawa, Ontario	Disclosure discussions concerning preventable adverse events should include: • The facts of the adverse event or adverse outcome, no speculation and blame • The cause of the event, if known • Regret that the adverse event or adverse outcome occurred. • Plans for a review to identify causative factors and prevent its recurrence • Impact and consequences of the occurrence to the patient and proposed treatment plan • Offers of assistance, including support of Social Work, Spiritual Care, Patient Relations Disclosure should be made as soon as reasonably possible after the adverse event occurs.

(Canadian Patient Safety Institute 2006, Appendix F, 42–45).

At the Micro Level: Disclosure at the Microsystem

Disclosure at the micro level is focused on the practices of health care professionals and health care teams. Disclosure cannot work at the provincial or the organizational level without support from these individuals and teams. At this level, the general recommendations for disclosure (provided at the macro and meso levels) must be adapted to the specific situation. The physician and/or the best qualified individual within the health care management team should disclose to the patient. A closer look into disclosure at the micro level is provided in the section "Disclosure Approaches and Procedures."

What Do We Know About Disclosure Practices?

Canadians are paying particular attention to patient safety, as reported by a Canadian adverse events study in 2004, because of the number of legal cases and media stories resulting from adverse events within Canadian hospitals (Baker et al. 2004). Therefore, the Canadian government has created the Canadian Patient Safety Institute, "at the cost of $50 million dollars for its creation as a start in battling preventable adverse events" (Baker et al. 2004). The sudden attention to patient safety is not surprising, as the statistics on medical errors illustrate a need for help. In 2004, a major study published in the Canadian Medical Association Journal found that between 9,000 and 24,000 deaths in Canadian hospitals every year are due to preventable adverse events (Baker et al. 2004, 1684). Interestingly, in 2007, The Canadian Institute for Health Information (CIHI) reported a decrease in the number of adverse events within hospitals between 2002 and 2005. Although improvements have been reported, Canadians still feel insecure about the quality of patient safety within hospitals. The Health Care in Canada Survey revealed that over 50% of adults believe that a hospital stay could potentially cause them harm, as a "serious medical error" could occur (POLLARA Research 2006). Canadians are becoming increasingly conscious of the alarming numbers of adverse events within their own health care system. The CIHI analysis found that:

> some adverse events are relatively rare, such as those related to blood transfusions... Others, however, occur more frequently. Of those examined, the most common adverse events are related to medications, infections and obstetric trauma during childbirth. Less common are adverse or fatal events due to blood transfusions and having a foreign object, such as a sponge or an instrument, left in after a procedure. (2007, 4)

With the number of preventable adverse events occurring within Canadian hospitals, the act of disclosing errors to patients and families has been widely encouraged—yet the actual practice of disclosure has been criticized by patients, health care workers, and the media. Interestingly, a status report in 2007 reveals that within the last ten years, disclosing errors has gradually become more acceptable and frequent between doctors and their patients (Levinson and Gallagher). However, studies have shown that patients and health care providers have not always seen eye to eye when it comes to disclosure: "A 2002 survey found that disclosure of errors occurred in less than one-third of cases, falling short of patient expectations" (Blendon et al. 2002).

Past studies have indicated that patients want full disclosure (Espin et al. 2006; Gallagher et al. 2003). According to one of these studies conducted in 2003, physicians believe in disclosure but are very cautious and selective when explaining medical errors to their patients (Gallagher et al. 2003, 1001). Similarly, a study suggested physicians and nurses advocated for partial disclosure ("to disclose only what happened") more often than full disclosure (Espin et al. 2006, 1). Thus, patients fear they are not being told the truth (Levinson and Gallagher 2007, para. 3). However, a study conducted in 1997 argues that patients receiving full disclosure of a medical error might cause unwanted resentment towards the physician, medical team and/or health care system, as well as cause unnecessary "anxiety" (Wu et al. 1997, 771). The motivation and responsibility for full, open, and honest disclosure of adverse events is supported by "ethical, professional and legal considerations; national and international leading practices; and current literature" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 9). The Canadian Medical Association's Code of Ethics provides the following advice to physicians: "provide patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of your ability; consider first the well-being of the patient, [and] make

every reasonable effort to communicate with patients in such a way that information exchanged is understood" (2004).

How and Where Does Disclosure Occur?

The literature behind the processes and approaches to disclosure suggests that disclosure of adverse events involves a couple of key stages. The Canadian Patient Safety Institute's *Canadian Disclosure Guidelines* (2008) outlines two stages that are necessary to ensure that a full and accurate disclosure takes place. The two main stages include:

1. Initial Disclosure:	2. Post-Analysis Disclosure
Who should disclose? When should disclosure take place? Where should disclosure take place? What should be disclosed? How should disclosure take place?	Documentation

Table 4 illustrates a literature review, based on the Canadian Patient Safety Institute's (2008) criteria of the disclosure process that should be used when planning and disclosing an adverse event to a patient.

Table 4. Recommended Components of the Disclosure Process

1. Initial Disclosure
Who should disclose?
• "Assistance by those trained in the disclosure process, with strong interpersonal skills may be helpful. The participation of others over time may be appropriate to help the patient understand his or her current and anticipated health status and needs" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 16).

- The patient and the family should hear from the physician immediately involved with the patient's care (ASHRM 2004, 6).
- "The medical practitioner who was the most responsible physician for the health care treatment during the course of which the adverse outcome occurred, should disclose the adverse outcome to the patient" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 10).

"A medical student or resident should disclose an adverse outcome to his or her clinical teacher or supervisor. If the clinical teacher or supervisor is not the most responsible physician for the affected patient, then the clinical teacher or supervisor should ensure that the most responsible physician is informed of the adverse outcome. Upon becoming aware of the adverse outcome, the most responsible physician should disclose the adverse outcome to the patient" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 13).

When should disclosure take place?

- "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. Subsequent disclosure discussions should also occur in a timely fashion. When harm has occurred, the immediate and ongoing welfare of the patient is of the highest priority. However, a delay in disclosure may precipitate anxiety and feelings of abandonment in patients who suspect an adverse event has occurred" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 17).
- "Where harm or deterioration of condition may result unless there is immediate disclosure of the adverse outcome, the medical practitioner should disclose the adverse outcome with the according urgency, to either the patient or an authorized substitute decision maker" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 17).

Where should disclosure take place?

- "The choice of setting and location for disclosure discussions is important. The discussions should be, to the extent possible: in person; at a location and time of the patient's preference; in a private area to maintain confidentiality; and free from interruptions" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 17).
- "Disclosure to the patient directly should first be considered. The setting for the disclosure should afford the patient privacy. The patient should be offered the opportunity to be accompanied by a support person. The medical practitioner himself or herself may want to have a support person present" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 20).

What should be disclosed?

- "The initial disclosure discussion should include:
  - the facts of the adverse event and its outcome known at the time;
  - the steps taken and the recommended options and decisions in the care of the patient (changes to care plan as applicable);
  - an expression of sympathy or regret, a statement saying sorry as appropriate;
  - a brief overview of the investigative process that will follow, and what the patient can expect to learn from the investigation, including appropriate timelines;
  - an offer of future meetings, including key contact information;
  - an allowance of time for questions;
  - an offer or offers of practical and emotional support, such as spiritual care services, counselling, social work, and patient safety advocates, as needed; and
  - facilitate further investigation and treatment if required" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, p. 17).
- "The adverse outcome should be factually described, with care taken to explain medical terminology so that it is understandable by the patient. Speculation or conjecture should be avoided, and

the practitioner may respectfully decline to respond to questions or comments from the patient which invite speculation or conjecture" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 21).

- "Options for treatment to address the adverse outcome should be raised. The patient should be told when such treatment or a second opinion may be able to be provided, or should be provided, by another practitioner" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 22).

How should disclosure take place?

- "If upon commencing disclosure, it becomes evident that the patient is unable or unwilling to continue the discussion, the medical practitioner should offer to continue or resume the discussion at another time. In some circumstances, the patient may want to have the disclosure made to an authorized substitute decision maker or in writing, and the practitioner should give due consideration to such requests" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 23).
- "Some programs already exist which provide advice about how to disclose an adverse event. Effective communication strategies are essential for the disclosure process and various factors influence the content and direction of the communication. Some considerations and communication strategies for the initial and subsequent disclosure discussions include:
  - terminology and words that are likely to be understood by the patient;
  - active listening skills such as empathizing to help understand the patient's experiences and needs;
  - open and forthright approach, conveying sincerity with body language;
  - adequate time for questions;

– clarification of whether the information is understood; and
sensitivity to cultural and language needs" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 18).

2. Post-Analysis Disclosure

Documentation

- "Documentation of the disclosure process should be consistent with the requirements of the provider's policies and practices of the organization for documentation of patient care and communication. Documentation should include:
  – time, place and date of disclosure discussion;
  – identities of all attendees;
  – facts presented in the discussions;
  – offers of assistance and the responses;
  – questions raised and the answers given; and
  – plans for follow-up, including key contact information for the dedicated contact person" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 18).
- "Details of the adverse outcome and of its disclosure to the patient should be documented in the patient's record. Where necessary for the observation or treatment of the patient, the patient's family doctor or other treating physicians should also be informed of an adverse outcome" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome 2006, para. 24).
- "Describe the event. Documentation should be factual – not an emotional catharsis for the caregiver. Only known facts of the event should be included. Opinions that a particular event caused a specific result do not belong in this record" (ASHRM 2004, 9).

What are the Advantages and Disadvantages of Disclosure?

A 2007 study reported that there are many potential advantages and disadvantages associated with disclosure (Levinson and Gallagher, 1). Health care providers and health care facilities should use full disclosure to patients when faced with an adverse event because it is

especially helpful to the patient and because it is the patient's right to know. The advantages of disclosure could include the physician being "relieved to admit the mistake" as the "patient or family member may be the only person to forgive the physician" for it. This could perhaps serve as a cathartic experience for the physician and/or medical team, and encourage the practice of full disclosure in the future (Wu et al. 1997, 771–772). Table 6 summarizes some of the key advantages of disclosure from the perspective of patients, health care professionals, and health care organizations.

Table 5. Disclosure Advantages

Patient	• Full disclosure could positively benefit the patient as he/she would be able to receive "timely and appropriate treatment" (Wu et al. 1997, 771). • "Disclosure of a medical mistake may also prevent the patient from worrying needlessly about the etiology of the medical problem" (Wu et al. 1997, 771). • It improves the quality of treatment patients receive as "it allows patients to be more active participants in their health care and encourages organizations to practise more safety" (Stewart 2002, 188). • "Acknowledgement of fallibility brings uncertainties into the open, reduces the possibility for misunderstandings and encourages the patient to take greater responsibility for his or her own care" (Wu et al. 1997, 771).
Physician	• "The physician may be relieved to admit the mistake. In the case of a serious mistake, the patient or family member may be the only person able to forgive the physician for making the mistake" (Wu et al. 1997, 771–772). • Physicians can view their colleagues' disclosures of adverse events as learning experiences, as well as their own (Wu et al. 1997, 772).

	• The physician can "strengthen the doctor-patient relationship" (Wu et al. 1997, 772).

Risk Management	• Historically, healthcare organizations have been reluctant to admit mistakes because of potential legal liability. Admitting mistakes and taking corrective and compensatory action may reduce the likelihood of a lawsuit and, if a lawsuit is lost, may reduce the punitive damage award. Financial consequences involve admitting mistakes and incurring the associated compensatory costs or not admitting mistakes and incurring associated compensatory and punitive damages for the mistakes that are discovered later… "Managers in healthcare organizations frequently are reluctant to admit mistakes, especially in patient care, because they perceive that they have a duty to protect the organization from legal liability. Such action, however, has not only legal consequences but also financial and ethical consequences that, in the long run, may not serve the best interests of the organization" (Nowicki 1998, paras. 1 and 3).

In terms of the process of disclosure, there is another approach to revealing the mistakes of an adverse outcome, which includes not only the immediate parties involved but the public as well. Usually, when a health care facility decides to reveal an adverse event to the public, a massive error has taken place. During the public disclosure, the adverse event is explained, along with the steps the facility took, and will take, in order to make improvements for the future. Although health care institutions have been both criticized and praised for publicly reporting their adverse events, it is still ultimately up to the health care facility to publicly disclose or not. Therefore, a "balance" needs to be established between the privacy of patients and the public's right to know, which asks if health care professionals can "honour their duty to patients and the organization when public disclosure of medical errors is involved" (Stewart 2002, 187). To answer this question, a further look into the

advantages and disadvantages of public disclosure is needed, as there is little research into this concept. Table 6 outlines both sides:

Table 6. Advantages and Disadvantages of Public Disclosure

Advantages	• "The safety of the public outweighs individual confidentiality. If managers take the position of greater public good, they are no longer forced to choose between duty to patients and their organizations" (Stewart 2002, 189). • "It permits individuals to protect their organizations appropriately while protecting patients from harm. Ultimately, patients would benefit from this proposal because of improved safety and quality" (Stewart 2002, 189). • "Public disclosure of medical mistakes is in the best interest of the health care system and the public and ... it does not compromise the fiduciary duties to patients or organizations" (Stewart 2002, 188).
Disadvantages	• Public disclosure of risk management documents could place physicians and health care organizations at risk for litigation (Stewart 2002, 188). • Changes may not occur immediately following public disclosure of adverse events; therefore, patient safety is not ensured, leading both organization and patient to be compromised (Stewart 2002, 188). • There are concerns about how to manage relations with the press. It can be politically embarrassing if a family member learns for the first time of a serious reportable event involving a family member when it appears in the media" (Weissman et al. 2005, 1360).

Both sides present powerful arguments. However, we all learn from mistakes, and without taking an interest in them, we would never have the opportunity to teach others not to do the same (Stewart 2002, 189). Publicly disclosing an adverse event can serve as a global learning experience and reminder to us all that we need to continually improve

our health care policies and educate medical professionals. Therefore, the health care system needs to stay vocal.

What is Required for Disclosure to Take Place?

One point emphasized in all of the reviewed documents is that successful disclosure requires a strong patient safety culture. Patient safety culture is defined as "the collective values, knowledge, skill and commitment to safer patient care that is demonstrated by every member of the organization" (National Disclosure Working Group and the Canadian Patient Safety Institute 2007, 10). More specifically, positive safety culture within organizations is broken down into 10 dimensions as delivered in a presentation by the Agency for Healthcare Research and Quality (AHRQ 2004). The 10 dimensions are listed in Table 7.

Table 7. 10 Dimensions of Patient Safety

1. Supervisor/manager expectations and actions promoting patient safety.
2. Organizational learning—continuous improvement.
3. Teamwork within units.
4. Communication openness.
5. Feedback and communication about error.
6. Non-punitive response to error.
7. Staffing.
8. Hospital management support for patient safety.
9. Teamwork across hospital units.
10. Hospital handoffs and transitions.

(AHRQ 2004, slide 35)

In a strong patient safety culture, failures are not automatically blamed on individuals; instead, they prompt a critical review of the whole system in which the failure occurred. According to the National

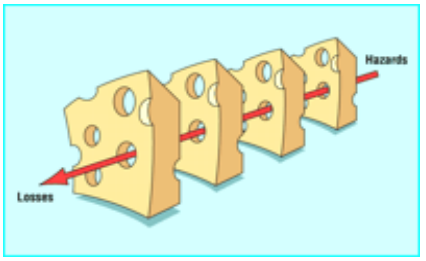
Disclosure Working Group together with the Canadian Patient Safety Institute in *Creating a Culture of Patient Safety* (2007):

> Many adverse events in healthcare are now recognized as system failures, where safeguards to protect patient safety were not in existence, or a series of safeguards that were in place failed in sequence, resulting in harm to the patient. Adverse events often occur after recurrent patterns of failures, regardless of the dedication or experience of the health professionals involved.
>
> Systems theory emphasizes that focusing on the system rather than on the individual will prevent more adverse events. (2007, 10)

For this reason, Powell writes that there must be a "paradigm shift" away from the errors associated with patient safety. However, this shift is not easy when you face "fear, shame, and blame" (2004, 212). Therefore, Reason created "The Swiss Cheese Model of System Accidents" as an analogy for understanding the "system" versus the "individual" during adverse events. Reason's model illustrates how some parts of a system rely on "people (surgeons, anaesthetists... etc.)", and "others depend on procedures and administrative controls." Reason further explains that:

> [A system's] function is to protect potential victims and assets from local hazards [and] they do this very effectively, but there are always weaknesses. In an ideal world each defensive layer would be intact. In reality, however, they are more like slices of Swiss cheese, having many holes—though unlike in the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one "slice" does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity--bringing hazards into damaging contact with victims [Figure 2]. The holes in the defences arise for two reasons: active failures and latent conditions. Nearly all adverse events involve a combination of these two sets of factors. (Reason 2000, 768)

Figure 2. The Swiss Cheese Model of how defences, barriers, and safeguards may be penetrated by an accident trajectory.



(Reason, 2000, 768)

As regards the "individual" versus the "system," Reason says that "blaming individuals is emotionally more satisfying than targeting institutions" (769–770). Therefore, the National Disclosure Working Group together with the Canadian Patient Safety Institute concludes:

> Healthcare providers in a just culture are held professionally accountable for the quality of their work in a fair way. Blaming an individual for an adverse event is discouraged except for those rare situations in which system factors play a limited role and the individual's behaviour or judgment is shown to be unprofessional. All other occurrences are viewed in the context of identifying *system* contributors in order to improve safety. The adverse event is analyzed for such system contributors, and the lessons learned are used to strengthen the system, and if appropriate to support and educate the healthcare providers to help prevent like events. (2007, 11)

According to a study conducted in 2006, there is a call "for a culture change in health care to improve patient safety. However, effective change cannot proceed without a clear understanding of perceptions and beliefs about error" (Espin et al. 2006, 12). As with Reason's theories, "the dominant refrain by the ensuing patient safety movement has been the call for a culture change: to move health care from a blame-and-shame response to error toward a high reliability response that confronts, reports, and learns from error. To meet the

demand for change we must understand both professional and patient perceptions and beliefs about errors" (Espin et al. 2006, 13).

Discussion

The existing literature on the approaches to and procedures for disclosure indicates that great strides have taken place within the Canadian health care system, but further education and action are still needed to create and improve a consistent and mandatory disclosure system for the treatment of adverse events across Canada. The literature reviewed suggests that there are many advantages to the disclosure process, such as allowing the patient to receive necessary and "timely treatment," allowing the patient to be more vocal in his or her treatment, and allowing for health care institutions to recognize their mistakes and make quality improvements for the future (Wu et al. 1997, 771). These advantages outweigh the disadvantages. Health care officials and workers should not fear the processes of disclosure, as the culture of blame is shifting away from attacking the individual. Instead, people are recognizing that the health care system is not perfect; patients' safety and their right to information need safeguarding. The *Canadian Disclosure Guidelines* (2008) address many important points to ensure that facts are learned and that "further discussions occur to ensure full and complete disclosure" (Sidorchuk 2007, 2). The literature based on the disclosure process further reveals that 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 an organization. (Sidorchuk 2007, 2)

However, according to the Canadian Institute for Health Information, there are still unanswered questions regarding "the state of

patient safety and how to translate these findings into improvement initiatives" (2007, 20). Some of the most important questions CIHI has included in their report on patient safety in Canada are:

- How is patient safety changing over time? What is driving these trends?
- What does patient safety look like across the health care continuum? What are the rates and types of adverse events occurring outside of the acute inpatient hospital environment?
- What are some of the risk factors contributing to different types of adverse events? How can these be addressed? Do hospital types and hospital volumes play a factor in the rate of adverse events?
- How can we translate adverse events into learning opportunities? How is reporting and communication of adverse events changing? How can it be increased or encouraged?
- Which policies, strategies and practices are most effective in improving patient safety, and how can this knowledge be applied more broadly?

(2007, 19-20)

Addressing more of these questions is critical, as is institutional support. In order to promote disclosure, "it is essential that senior leaders in hospitals, including chief executive officers and board members, take responsibility for regularly reviewing medical errors and for creating policies related to disclosure" (Levinson and Gallagher 2007, para. 9).

Conclusion

The disclosure of adverse events is an increasingly important process in the Canadian health care system. Education is key to developing and improving disclosure policies and procedures. Adverse events within Canada's health care system are continuous reminders that human errors occur, and therefore health care providers need constant support and education so that they may participate in the improvement

of the system. As the *National Guidelines for the Disclosure of Adverse Events* concludes, "Disclosure is always the right thing to do" (Sidorchuk 2007, 2).

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Disclosure: Ethical and Policy Considerations

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Abstract

Failing to tell the truth to patients and the public was common practice in medicine in times past. However, over the past 50 years, in North America at least, the standard has turned in the direction of openness with patients. I will examine ethical considerations for and against truth-telling in medicine, reflect on how these apply to the disclosure of adverse events in health care, and, finally, discuss the core aspects of policies regarding disclosing adverse events.

Medicine's Past

Historically, medicine has been known for its rather stingy approach to truth-telling. Consider the origin of the phrase 'doctoring the truth' : "to treat so as to alter the appearance, flavour, or character of, to disguise, falsify, tamper with, adulterate, sophisticate, cook" (Oxford English Dictionary 2002). Hippocrates advised against disclosure to patients, encouraging physicians to hide their methods from the ill. Oliver Wendell Holmes (Medical Essays, 1842-1882), writing in 1871, captured this Hippocratic attitude: "Your patient has no more right to all the truth than he has to all the medicine in your saddle-bags, if you carry that kind of cartridge-box for the ammunition that slays disease. He should get only just so much as is good for him" (p.528).

Medical Paternalism

This was the prevailing attitude until 40 or 50 years ago, even in Western democratic societies with some sort of commitment to informed consent. Who else, other than a patient's doctor, would know the ideal amount of information to share with that patient? This is the attitude of medical paternalism, which is based on the premise that medical

professionals, possessing superior knowledge and skills, should know what is best for their patients. This includes understanding better than patients themselves what information patients need and are capable of handling. Of course, this benevolent dictatorship by higher powers was not unique to medicine but was common in all areas of social life.

What was perhaps unique to medicine was that non-disclosure was advocated because of concern for the patient's welfare alone. Doctors were to do no harm first and foremost. If words could wound, then these were to be avoided. If no medical good could come from disclosure of bad news, there was no point in revealing to patients certain facts or truths about their condition. Indeed, just because the truth could cause patients harm – worry, anger, depression – it was felt to be in their best interests to remain uninformed. A happy life over a knowledgeable life. Patients, like children, were to be looked after by kind and wise physicians. Paternalism was not unique to physicians; all of the health care professions – nursing, psychology, physical therapy – drew their ethos from the same inspirational well.

For the Good of Patients

For a long time, society and the courts went along with this attitude. At a time when effective treatments were lacking for many serious illnesses, there was concern that disclosing such diagnoses might cause a patient to lose the will to live, despair, falter and decline. A thin theory of human psychology – that humans were fragile and easily suggestible – loomed behind the profession's reluctance to take patients into its confidence.

This was a forgiving time. For example, in a 1953 case concerning a gynaecologist who accidentally left a large needle in a patient's perineum following an episiotomy but did not inform her because it might cause her "excessive worry," the judge opined that this failure to disclose was acceptable as it was done for her own good.

"I cannot admit any abstract duty to tell patients what is the matter with them…it all depends on circumstances…the patient's character, health, social position…" *(Daniels v. Heskin, 1954)*

Medical Attitudes

Failing to be truthful with patients was common in times past. Oken's well-known 1961 survey of 219 physicians in the United States found that 90% would not disclose a diagnosis of cancer to a patient. Many expressed pessimism and futility about cancer treatment and so saw no point to disclosing. Others feared their patients would become depressed or commit suicide if the truth were told.

Professional attitudes changed in the subsequent two decades – no doubt in part because some cancers became amenable to treatment. A survey of 264 American physicians in 1979 showed that 97% would now disclose a diagnosis of cancer (Novack et al. 1979), an almost complete reversal in the practice of telling patients the truth, at least as far as the diagnosis of cancer goes. More recent studies of professionalism in medicine illustrate the profession's allegiance to honesty and veracity with patients (Campbell et al. 2007).

Nonetheless, old attitudes die hard in areas of medicine where diseases have little effective treatment. For example, suspected diagnoses of dementia and multiple sclerosis were commonly not revealed to patients in the recent past. A court in Ontario in the 1990s failed to find fault with a neurologist and a family physician who, *for more than 7 years,* did not tell a patient that she likely had multiple sclerosis. In fact, the patient discovered her diagnosis only when she attended a different neurologist. The court nevertheless assessed no liability, viewing the diagnosis as "speculative," and concluded that at the time in question (the early 1980s) most physicians would have acted as the first neurologist then did *(Symaniw v. Zajac and Birnbaum, 1996).* Dementia and multiple sclerosis are now more commonly disclosed, in North America at least, in part on account of useful treatments now being available.

Patient Views

The development of effective treatments was not the primary reason for the medical profession's change in view around truthful disclosure, however. A therapeutic rationale was not needed by most

patients – they wanted to know the truth long before clinicians were convinced this was a good idea. Studies as far back as 1950 revealed that the overwhelming majority of patients wanted to be told if the examination revealed a diagnosis of cancer. Typical was one conducted by Samp and Curreri (1957) in which 87% of a group of 560 cancer patients and their families felt a patient should be told the truth about this diagnosis. An American survey in the early 1980s by the President's Commission for the Study of Ethical Problems in Medicine (1982) revealed that 94% of patients wanted 'to know everything' about their condition, 96% wanted to know a diagnosis of cancer, and 85% wanted to know a realistic estimate of their time to live, even if this was less than one year. More recent reports have indicated that over 90% of respondents would want to be told a diagnosis of Alzheimer's disease (Erde, Nadal, and Scholl 1988) and over 80% of patients with amyotrophic lateral sclerosis want as much information as possible (Silverstein et al. 1991). Studies of older patients, sometimes thought to be less interested in the truth, have shown that almost 90% want to be told the diagnosis of cancer (Ajaj, Singh, and Abdulla 2001).

The Rise of Self-Determination

The increasing recognition that patients are persons with the right of self-determination, rather than passive individuals to be taken care of by benevolent health care providers, lies at the root of modern medicine's attitude shift towards more truthful disclosure. Not divulging accurate information prevents patients from autonomously making informed decisions about whether to have or forego medical treatment. On a larger level, failure to provide information that may be of central importance to patients' futures means depriving them of one means by which they can live as they see fit. As Elian and Dean wrote in their 1985 article, rather than asking, "Can the patient stand being told?" one should ask: "Can the patient stand *not* being told?" (28). Imparting accurate information about an illness that will affect how they will lead their lives in the future allows patients to plan for that future.

Respect Due Persons

Thus, patients may have an interest in information that concerns who they are as people – this may be above and beyond what is needed to be known for informed consent to medical treatment (an aspect of disclosure that is of most import to clinicians). Whether patients *do* anything with medical or "personal health" information, as it is now called, is a separate issue from that of treatment choice. For example, a patient's desire to take an active role in making decisions about treatment "may be less strong than [simply] the need for clear and accurate information" (Fallowfield et al. 1994, 448). It is the patient-centred modern emphasis upon autonomy which is not found in the Hippocratic canon.

In this modern view, patients should be told the truth because of the respect due to them as persons. This is the democratic as opposed to therapeutic rationale for truth-telling. *We, as health care providers, share information with patients not to get them to accept our treatment recommendations, not to placate their emotions, but in order that they can live their lives the way they see fit:* the truth can empower them and encourage authenticity and autonomy. Empowering patients has been recognized as one of the central goals of modern medicine, as important as the amelioration of suffering and the prevention of premature death.

Interviews with patients generally support this perspective. For example, in a study done before any treatment for MS existed (Elian and Dean 1985), patients with the disease felt they had a right to know what was wrong with them. Some were angry about being asked why they wished to know. One said: "Do I have to explain why? Just so that I know" (27).

Truth or Consequences?

Utilitarian vs. Deontological Approaches to Disclosure

There is a theme evident in the medical profession's traditional approach to disclosure and truth-telling. Medicine has a largely utilitarian approach to providing information to patients. *Utilitarianism*

judges the merits of an option by its *consequences*: the Truth is to be dispensed according to its benefits and not offered if harmful. In other words, the ends may sometimes justify the means. But according to whose standards of utility are we to judge the harms and benefits of disclosure? The patient's? The doctor's? The patient's family's? Society's?

The contrasting ethical theory of *deontology* judges an action's moral acceptability depending on its adherence to a rule which should always be followed irrespective of the consequences. In other words, there are intrinsically moral rules which persons are duty-bound to follow. But according to whose sense of duty? And what if duties collide?

Duty or consequences? Which theory gives the best account of morality? Neither does – for professional purposes we ought to combine both approaches. We try to maximize good outcomes *and* also adopt rules such as the obligation to respect privacy.

Truth-telling in Modern Medicine Defined

Truth-telling is the modern attitude and practice of being open and forthright with patients. It encompasses disclosure. Information necessary for patients to make sense of their condition or situation is conveyed. It is not necessarily about telling the whole truth and nothing but the truth, usually an impossible task. *Truth-telling is about intending not to mislead or deceive*. There are so many ways to mislead patients, it takes clinicians some work and thought to decide how best to present patients with information in comprehensible and unbiased ways (Bowing and Ebrahim 2001). Cabot wrote in 1903 that the physician's duty is to strive to create a "true impression" in the mind of the patient about his or her condition and thereby foster the covenant of trust between physician and patient.

The Covenant of Trust

Trust is at the heart of the doctor-patient relationship. Trust in the health care professional enables patients to, among other things, reveal private information, expose their vulnerabilities, and accept the professional's recommendations for treatment in the face of uncertainties.

Trust enhances the efficacy of any offered treatment and is a necessary component of a satisfactory clinician-patient relationship (Goold 2002). *Trust must be gained and maintained, not only by individual providers but also by their institutions* (Scott, Aitken, and Mechanic 1995). Patients can experience a betrayal of this trust when their providers and/or their institutions act in self-protective and deceptive ways.

Not to tell patients the truth about events pertinent to their condition requires deception and sometimes collusion by others to cover up the troubling events. One deception often involves a network of lies and cover-up. Bok (1979) notes: *"it is easy to tell one lie but hard to tell only one"* (26). Such deceit undermines the bond of trust between the health care provider and patient and produces "corrosive worry" (247) in patients who are deceived.

Proper disclosure to patients saves providers from entering this labyrinth of lying. It maintains the trust that patients have in their particular health care providers and, more importantly, in the medical system in general.

Modern Professional Codes of Ethics

Truthful disclosure is now an accepted tenet in modern medical professionalism. The British Medical Association (2004) in this regard notes that the "relationship of trust depends upon 'reciprocal honesty' between patient and doctor" (41) and also encourages the sensitive delivery of bad news. The Canadian Medical Association's (2005) Code of Ethics recommends that physicians provide patients with whatever information might, from the patient's perspective, have a bearing on medical decision-making and communicate that information in a comprehensible way.

Arguments over Truth-telling

Truth-telling increases patient compliance with prescribed medications (Greenhalgh, 2005), reduces morbidity such as pain (Egbert et al. 1964), and anxiety (Luck et al. 1999) associated with medical interventions, and improves patient comprehension of medical decision-

making (Woloshin, Schwartz, and Welch 2007). Nonetheless, there is still reluctance to tell the truth to patients for a variety of reasons.

Harm to Patients

It has been argued that disclosure does not always lead to good outcomes: it can result in labeling patients and result in loss of insurability, shunning, discrimination, and exile. (Think of how patients diagnosed with leprosy, AIDS, or schizophrenia were and are treated.) Sometimes, however, it is not the diagnosis but the path to the diagnosis that causes the greatest concern. What can be very difficult for patients is being told of the uncertainty as to when and how badly a condition will affect them. These uncertainties are magnified by the inevitable waiting for testing to be done and the results to be made available. If there are suspicions that all is not right with the accuracy of the testing process - suspicions that are not addressed in an urgent way - this, too, will make the bad outcomes of disclosure even harder to bear.

The traditional concern about causing psychological harm to patients by telling them the truth has not been borne out by research. For example, giving patients very detailed information about the risks of hernia surgery did not increase their anxiety (Kerrigan et al. 1993). Warning patients about the potential side-effects of certain prescribed drugs (anti-hypertensives, antibiotics, and anti-inflammatory pills) did not make it more likely they would experience such side-effects (Lamb, Green, and Heron 1994). Greater information disclosure to advanced cancer patients did not increase poor patient outcomes and only increased their anxiety levels, in this study, if accompanied by encouraged participation in their own care (Gattellari et al. 2002).

Destroying Hope

It used to be (and still is in some places) thought that health care professionals would destroy a patient's hope by disclosure. In one U.S. study, physicians, who reported that they commonly tell cancer patients the truth, said they did so in a way intended to preserve hope and the will to live, both valued notions in U.S. society (Good et al. 1990). For similar reasons, compared to their North American counterparts,

gastroenterologists from southern and eastern Europe are less likely to be candid with patients about serious disease (Thomsen et al. 1993).

But hope can be maintained in many ways. Hope does not require dishonesty (Groopman 2005). Doctors who withhold critical information about a diagnosis and its prognosis from patients are denying them the opportunity to live and die as they see fit – this practice denies patients an opportunity to cope and hope on their own terms. Very ill patients may want someone to look after and guide them, but this does not necessarily mean a preference for ignorance or deception. Allowing others to make decisions for oneself, to be "taken care of" in the full sense of this phrase, can be consistent with wishing to remain informed about one's condition (Ingelfinger 1980). This healing milieu relies upon an atmosphere of trust between patients and providers. Threats to the network of trust should be taken as threats to the enterprise of health care generally.

The Right Not to Know

Studies suggest that 10-20% of all patients do not want to know the details of their condition. This waiver may be a legitimate preference on the part of patients and is, in general, their right not to know. No one should have the truth forced on them. However, this ought to be an informed refusal: persons declining information need to know, in choosing not to know, that they may be denying themselves potentially life-prolonging diagnostic testing and treatment.

Cultural Influences

Not surprisingly, there may be cultural influences upon truth-telling preferences. For example, one study found a greater percentage of Korean-born patients preferred to be given less information than did U.S.-born patients (Blackhall et al. 1995). In Italy, lack of candour about the diagnosis of Alzheimer's disease is common (Pucci et al. 2003). In our multicultural society, it is important to take such cultural attitudes into account when making decisions around medical disclosure.

Nevertheless, while certain cultural traditions seem to militate against truthfulness, there are several caveats:

- cultural attitudes are not fixed,
- recent trends suggest a global interest in obtaining information and a decline in professional discretion to withhold it,
- all members do not necessarily share their culture's totems and taboos. Each person is unique and should be offered the opportunity to know the truth (Freedman 1993).

Information Sharing

Nondisclosure and deceit can harm patients in many ways. For example, if not informed about their medical condition, they may fail to obtain medical attention when they should, or accept unnecessary aggressive treatments. They also may, if not fully informed, make life decisions they may later regret. Most importantly, nondisclosure and deceit in medicine undermine the covenant of trust between patient and health care provider.

Unless patients have indicated a preference not to be informed, the assumption should be that they ***would*** *want to be informed* – especially if there are significant results pertinent to their well-being. Uncertainty is not always problematic (Logan and Scott 1996). Informing patients about the uncertainties and the range of available treatment options allows them to appreciate the complexities of medicine, to ask questions, to make informed and realistic decisions, to assume responsibility for those decisions, and to be better prepared for untoward outcomes of care.

Studies show that the way in which the information is given may be just as important as the information itself (Brown et al. 1999). Poor disclosure practices, even if the information conveyed is accurate, can have devastating consequences for patients (Shattner 2002). Such disclosure is typically done too hurriedly, in the wrong setting, without appreciation of the patient's circumstances, and without addressing the patient's real needs and fears.

Care must be taken that information is given at the right time and in the right place, "a compassionate milieu" (Mann 1981). Even if telling the truth does have some negative consequences, this does not in itself warrant nondisclosure. It is important to break bad news carefully and considerately: in person, sitting down, in a comfortable setting, with a trusted professional, prepared for emotion, ready to answer questions, having all the time needed, and being knowledgeable about the next steps. The news may be brutal for a patient; the telling of it need not be (Jonsen, Siegler, and Winslade 1992, 63).

Adverse Medical Incidents

Deception – or the failure to be fully truthful – about untoward incidents in health care is increasingly an area of particular concern for the medical professions and their institutions. When mishaps occur, the health care professional's reaction can be one of shame, guilt and embarrassment. "Shame is so devastating because it goes right to the core of a person's identity, making them feel exposed, inferior, degraded; it leads to avoidance, silence" (Davidoff 2002, 623). Nonetheless, this cannot override the damage done to patients and their trust in the health care system if they are not told about such adverse events. The ethical underpinnings of truth-telling in medicine are particularly applicable to the disclosure of adverse medical incidents. Patients must be told of adverse events because that information may be crucial to decisions they must subsequently make about their medical health, just because they are due the respect of being told the truth, and so they can maintain their trust in the medical system.

The cases of medical harm that prompt patient and public concern are those seriously adverse events where:

- there is a perception of a cover-up by those involved, and/or,
- no one has taken responsibility/been held accountable, and/or,
- many patients have been harmed (due to a correctible hazard in the medical environment, such as an impaired colleague or defective device), and/or,
- patients and families must pursue legal action to obtain answers, and/or,
- those implicated in the mishap have not taken corrective action.

Honest Communication about Adverse Events

When things don't go well, truthfulness and forthrightness are important protective factors against legal actions initiated by patients (Davies and Bacon 1990). Justice Krever, in a judgment regarding medical negligence, wrote that the court action might have been avoided had the physician taken the patient into his confidence (*Stamos v. Davies*, 1985). The doctor didn't do so and the patient felt he had no choice but to sue in order to obtain a better explanation for his injury.

One study revealed that over 90% of patients want to be informed about even minor errors in health care (Witman, Park, and Hardin 1996). Promptly informing patients and families in a straightforward way as to what is known about harmful incidents fosters a healthier and more realistic understanding of medical care and may prevent mistrust.

While error disclosure may be no guarantee against suits and complaints, such honesty can reduce the punitive 'sting' that sometimes accompanies judgments against clinicians and their institutions. Surveyed individuals were more likely to seek legal action if they discovered that mishaps affecting them were not openly disclosed to them (Mazor et al. 2006).

Disclosure Policies

Health care institutions have been encouraged to adopt robust policies and procedures that address the disclosure of error and adverse incidents. At the core of disclosure policies must be an affirmation of truth-telling. The objective of the institutional and professional response is to give patients/families a true impression of a critical incident or adverse event as thoroughly as possible. The policy must affirm the need and capacity for an urgent, patient-centred response to adverse events. To maintain the public's trust and the confidence of every patient, professionals must see to it that they and their institutions are ready to respond to health care safety meltdowns. *Critical incidents are a form of medical emergency imperilling trust that require prompt professional 'resuscitative' efforts by those involved. Critical incidents that involve more than*

one patient require swift attention from the highest levels of the health care institution.

There are now recognized to be three essential elements to be addressed in all adverse event policies (Canadian Patient Safety Institute 2008).

When to Disclose

When adverse events transpire,

- the default assumption should be that patients/families want to be informed about harmful events that may affect/have affected their welfare;
- the decision about notifying patients rests with the individuals and institutions responsible for the incidents;
- timely disclosure is key. The more serious the incident–that is, the greater the harm or the risk thereof–the shorter the delay in notification should be;
- disclosure should take place as soon as possible after the incident has been identified, where possible, when the patient is stable and able to understand and appreciate the information;
- where death or serious injury occurs, those involved should disclose the incident to families within hours;
- initial disclosure should not await definitive answers about what went wrong.

How Should Error be Disclosed?

When an adverse event has been discovered,

- the most responsible clinician ought to lead the discussion of the incident;
- this individual should be a trusted clinician known to the patient/family;
- disclosure would be best done in person, with adequate time, in a comfortable, private setting;
- less direct means of notification–phone call, fax, or registered mail–are acceptable but should only take place in cases of great

geographic distance or where timely direct communication is not feasible;
- 'cold calls' to affected individuals or their families by persons unknown to the patients are a recipe for disaster and disappointment;
- media notification of affected individuals should only ever happen when all other means of contact have been exhausted.

What Should be Told?

During the discussion of the event with the patient/family, one would expect,

- an admission of regret and apology for the incident. Such admissions need not (and indeed should not) await definitive investigation of an adverse event. They are not admissions of liability but empathic expressions acknowledging outcomes that no one wanted (to even hesitate for a moment to offer an apology to a patient harmed by medical care is akin to considering whether one ought or not to help save a drowning child. It is to have, as the philosopher Bernard Williams wrote, "one thought too many," [1981, 18]);
- a disclosure of the sequence of events leading to the incident as far as these are known;
- a disclosure of the incident's likely consequences, and any corrective treatment;
- a disclosure of the steps taken to prevent the incident's recurrence;
- answers to any questions the patient/family may have;
- an offer to meet again as needed to promote understanding.

Who is Responsible for Telling?

The problem today is what Balint (1988) called the "collusion of anonymity": when different health care professionals are involved in the care of a patient, it is all too easy for the patient's care to fall between the cracks and for no one person to be responsible. In modern health care, where multiple specialties and professions are almost always involved in the care of a patient, this failure to provide coordinated and comprehensive leadership can have serious repercussions for the patient.

The responsibility for patient welfare and communication with the patient does not end if one claims to be only indirectly involved in the care of a patient.

To meet these expectations, the following recommendation for radiologists (Berlin 2005) could apply to any health care professional–*whether or not they provide direct patient care.* He or she:

- must coordinate his or her efforts with those of other health care professionals involved in the care of the patient;
- must have a system in place whereby unusual, hazardous findings can be communicated to the patient and/or the treating team; and
- may have a duty to communicate directly with the patient if he or she is unable to contact the most responsible clinician in a timely way.

What About the Public Interest?

Critical events have a way of becoming public knowledge very quickly these days. Lapses in confidentiality, digital recorders, cell phones and cameras–all make it hard to hide from public scrutiny critical incidents, especially those involving more than one patient. The institutions involved are also responsible for informing the public when significant adverse events occur, in order to help maintain public trust in the health care system. Public notification, done carefully to protect personal health information, should be undertaken after every effort has been made to inform directly affected patients or families. This is important in order to prevent public doubts and worry about the commitment of public officials to the safety and reliability of the health care system. Without the public's confidence and trust in the health care system, the whole enterprise may be grievously wounded and the legitimacy of medicine called into question. Such trust, once lost, is hard to regain.

Bottom-Line Regarding Truth-telling

There are no statute laws requiring health care professionals and administrators to be honest with patients or the public. There are, however, patient and public expectations, moral obligations, and

professional duties that require a commitment to truth-telling and transparency on the part of health care providers and those responsible for the management of the health care system. This openness is especially important for the best management of adverse incidents–events which not only harm patients but also call into question the trustworthiness of health care professionals and their institutions. Disclosure policies for adverse medical events are critical to buttressing the truth-telling practices and attitudes of health care professionals. Properly applied, they can help regain some of the trust in the health care system that adverse events can undermine.

JUDGMENTS

1. *Daniels v. Heskin* [1954] IR 73 at 86-87 (SC).
2. *Stamos v. Davies* [1985] 52 O.R. (2d) 10 (H.C.): 25-26.
3. *Symaniw v. Zajac and Birnbaum* (Ontario Court, General Division), 1996. Court File no. 93-cu-67230 cm).

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