



Commission of Inquiry on Hormone Receptor Testing

**LEGAL and ETHICAL OBLIGATIONS of PUBLIC HEALTH
AUTHORITIES and GOVERNMENT**

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1. Introduction

Individuals who together compose the population of a province expect the provincial governments they elect to employ the taxes they pay, as a principal duty among other duties, to provide them with 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 healthcare 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 legal effect through law, 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).

2. 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 healthcare 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 healthcare 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 by 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.

3. Private Law Duties of Care

The arrival in Canada of new viruses, such as the West Nile virus and 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 negate 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 counselors. Courts may in time have to consider whether regulation of healthcare services are 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 healthcare 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 healthcare 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 Act, which will replace the provincial Hospitals Act, has not yet been proclaimed in force, but the intention of this provision 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 healthcare 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

communicated within 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.

4. Modern Challenges

The challenge of new medical technologies appears manageable under the framework of the policy/operational dichotomy. Decisions 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 undertakes 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), eased by section 24(2), which 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:

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

grater 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.

5. Ethical Obligations

Ethical principles according to which physicians and other healthcare 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 US bioethicist, acknowledged that "bioethics has rapidly evolved to become a discipline" (Caplan, 2008, 108). 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 healthcare 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 healthcare, 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 healthcare 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, and 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" (Bayer, 2004, 475). 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 US 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 humourously 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 US 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, concerning complex medical choices 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 healthcare 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 healthcare 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 US, 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 Terry Schiavo. However, US bioethicists have paid little regard

to whether an estimate of about 47 million citizens who lack healthcare insurance, and many others who are seriously under-insured, warrant their attention (Lane, 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 healthcare, 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 healthcare 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 (Syrett, 2007). 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 healthcare, 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 dependant 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 (Callahan, 1990) 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 healthcare 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 healthcare programme their taxes, paid over a working lifetime, had funded.

6. 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 healthcare resources, Norman Daniels, has developed a

model for measurement of decision-making processes, which he describes as the “Accountability for Reasonableness” model (Daniels, 2000A, 2000B).

Elaborating on this model, Daniels advances proposals for fair decision-making processes that resonate in the area of public law (Daniels, 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).” (Syrett, 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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, 2002), 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 healthcare 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” (Daniels, 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 healthcare 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 healthcare 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 healthcare 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 newsmedia 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 retesting requires patients to provide additional samples, they should be told why the retesting or rediagnosis is indicated. When surplus materials provided for initial testing have been preserved and are suitable for retesting, non-disclosure may be justified until the retest 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 notified 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 newsmedia communicate the policies of healthcare 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 healthcare, 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 newsmedia 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 newsmedia 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 healthcare needs. Such agencies must face but cannot guarantee the reasonableness with which recipients transmit the accounts that governmental agencies should provide.

7. 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.

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