Commission of Inquiry on Hormone Receptor Testing

DUTY OF CARE AND STANDARD OF CARE

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1. 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.

2. 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 v. Hobart,* 2001*; Childs v. Desormeaux*, 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 v. Taylor*, 1955), or in the case of physicians or other professionals, a reasonable professional (*ter Neuzen v. Korn*, 1995*; Crits v. Sylvester,* 1956; *Penney v. East*

Kent Health Authority, 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 v. Hanke*, 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 skillfully 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 v. Farrell*, 1990). Recognizing this, in limited circumstances the stringency with which the plaintiff's evidence of causation is assessed may be relaxed (*Snell v. Farrell*, 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 v. Leonati,* 1996*; Walker v. York Finch General Hospital*, 2001). While the applicability of the material contribution test was recently expanded (*Resurfice v. Hanke*, 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 v. Leonati*, 1996, paras. 17, 20*;* see also *Walker v. York Finch*

General Hospital, 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 v. Hughes*, 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 v. Grand & Toy*, 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.

3. 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 v. Hobart*, 2001; *Hill v. Hamilton-Wentworth Regional Police*

Services Board, 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 v. Hamilton-Wentworth Regional Police Services Board*, 2007, para. 25; see also *Wilson v. Swanson*, 1956; *Crits v. Sylvester*, 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 v. Comcare Health Services*, 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 v Desormeaux*, 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.

4. 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 v. Sylvester*, 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 v. East Kent Health Authority*, 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 v. Korn*, 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 v. Hôpital Le Gardeur*, 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 v. Korn*, 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 v. Korn*, 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 v Hôpital Le Gardeur*, 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, "if the error is one that a reasonable doctor would not have made in similar circumstances, liability will be imposed." (2007, 365).

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 v. Korn*, 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 1980's, 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 v. Doiron* (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 entailed, made such a standard unrealistic (*Bateman v. Doiron,* 1991, 291).

5. 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 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 would be 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 v. Vaughan,* 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 v. Mohan*, 1993), and a duty to refer, either by consulting with colleagues or 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 v. Penney*, 2004; Picard & Robertson, 2007, 313-14). It is difficult to reach definitive conclusions about whether the standard of care was breached in the abstract, 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 v. Lawson*, 1991).

Physicians and other health care providers can rely on each other to discharge their responsibilities in a professional, non-negligent manner (*Granger (Litigation Guardian of) v. Ottawa General Hospital* (1996); *Keilley v. General Hospital*, 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 v. Calgary Regional Health Authority,* 2006), as may a failure to realize that re-testing is needed (*Dann (Litigation Guardian of) v. Chivaro,* 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 surrounding 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 v. Sehmi*, 1993; *Gerula v. Flores*, 1995; *Shobridge v. Thomas*, 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 wellbeing.

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 c. Danais*, 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 v. East Kent Health Authority*, 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 v. East Kent Health Authority*, 2000; New Zealand, Gisborne Inquiry Report, 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 (New Zealand, Gisborne Inquiry Report, 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 that 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 (Freckleton, 2003, 192).

Although not unique to laboratory testing and analysis, formulating the standard of care in areas where interpretation is affected by limited reliability and definitiveness 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 determining 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, but to pass on a smear detected or suspected to be abnormal to a supervisory checker, who either confirmed the first screener's opinion, or if it was still considered abnormal, passed it on to a pathologist for examination and report. 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. Having 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 labeled 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 its scope 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 eg., *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 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 (Litigation Guardian of) v. Ottawa General Hospital*, 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 v. Doiron*, 1991, 290).

The hospital / health authority also has a duty to establish "safe systems" for the protection of patients (*Yepremian v. Scarborough General Hospital*, 1980), and to ensure proper co-ordination among the disparate elements of a patient's treatment program (*Lachambre v. Nair*, 1989). The obligation to provide "safe systems" is both extensive and expansive, and 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 v. Scarborough General Hospital*, 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 v. Vaughan*, 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 c. Solomon*, 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 v. Bain*, 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 v. Hughes*, 1980; *McInerney v. MacDonald*, 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 v. Zajac,* 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 v. Schachter,* 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 v. Curry*, 1933). While consent can cover necessarily incidental procedures 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, eg. *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- 1980's gave implied consent to samples of their blood being stored and tested for HIV ten years later. The court concluded that, except during the time 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 v. Ontario*, 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 v. Ontario*, 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 v. Ontario*, 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 mis-reading and/or mis-reporting 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 (New Zealand, 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 to ensure 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 would not give rise to a well-founded claim in negligence

by members of the public, without more (*Cooper v Hobart*, 2001; *Mitchell Estate v. Ontario*, 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 v. Curry*, 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 v.*

Scarborough General Hospital , 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 v. Curry*,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 v. B.C.*, 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 v. Scarborough General Hospital*, 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 (R. Baker, P. 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; New Zealand, Gisborne Inquiry, 2001). Systemic analysis is considered key to both 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 v. Leonati*, 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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