Canadian Journal of Law and Technology

Volume 9 Number 1 1 & 2

Article 11

6-1-2011

Institutional Liability in the E-Health Era

James Williams

Craig Kuziemsky

Follow this and additional works at: https://digitalcommons.schulichlaw.dal.ca/cjlt

Part of the Computer Law Commons, Intellectual Property Law Commons, Internet Law Commons, Privacy Law Commons, and the Science and Technology Law Commons

Recommended Citation

James Williams and Craig Kuziemsky, "Institutional Liability in the E-Health Era" (2011) 9:1 CJLT.

This Article is brought to you for free and open access by the Journals at Schulich Law Scholars. It has been accepted for inclusion in Canadian Journal of Law and Technology by an authorized editor of Schulich Law Scholars. For more information, please contact hannah.steeves@dal.ca.

Institutional Liability in the E-Health Era

James Williams* and Craig Kuziemsky**

INTRODUCTION

Despite the fact that health care has changed markedly from the traditional "single patient, single physician" model, certain areas of medical malpractice have remained remarkably static. One commentator has gone so far as to claim that "there have been few (if any) changes of any real significance in health care liability over the last 50 years." In fact, the jurisprudence concerning institutional liability for medical error seems to show few signs of having evolved beyond its traditional formulation in the early 20th century. Given the relatively primitive nature of health care delivery at this point in history, it is worth asking whether the jurisprudence from this era has been deprecated by joint advances in technology and health care delivery methods.

This paper examines the jurisprudence on institutional liability for medical error. We argue that the existing jurisprudence relies on assumptions that have been made obsolete by technological advances. In particular, we concentrate on the use of *information and communication technologies* (ICTs) in the health care domain. As we demonstrate, the use of these tools does not merely increase efficiency and support new health care functions; among other effects, ICT can have a profound influence on how health care practitioners make observations, exercise judgment and perform tasks. These tools influence human capabilities (at both the individual and systems level) in ways that are not recognized in the jurisprudence or scholarly literature on health law.

As the development, deployment and operation of health care ICT is the prerogative of health care organizations (e.g., hospitals) and governments or their agencies (i.e., health authorities), health care practitioners have little control over these tools. Since ICT can be the cause of medical errors at the systems level, it seems appropriate for jurists and lawmakers to take a fresh look at the liability of systems-level actors like institutions, standards bodies and governments.

In fact, we believe that the existing jurisprudence on institutional liability must be reconsidered, as some of its underlying assumptions have been outpaced by developments in technology, clinical practice and systems engineering. This is not

^{*} James Williams, B.A., B.Sc., J.D., M.Sc., Ph.D. (cand.) is a privacy and security consultant with the Community Care Information Management program in Toronto, and a graduate student at the University of Victoria's Faculty of Engineering.

^{**} Craig Kuziemsky, B.Sc., B.Com., Ph.D. is an Associate Professor and Director of the M.Sc. program in Health Systems at the Telfer School of Management, University of Ottawa.

G.B. Robertson, "A View of the Future" (2008) Health Law J. 1. Robertson notes that there is little reason to suspect that there will be any doctrinal changes of "real significance" in the next 50 years either.

merely an academic exercise. We believe that systems level errors will become more common, and failing to hold the actors who design, implement and maintain ICT will lead to serious consequences.

In this paper, we do not set out a positive program for changes to the law of institutional liability. Our goal is merely to point out that the status quo is inadequate from an intellectual, practical and moral standpoint. The first section of this paper discusses the traditional approaches to institutional liability in health care — namely, direct duties and vicarious liability. After summarizing the jurisprudence, we shift our attention to the use of ICT in the health care domain. We outline key themes, and identify some of the major efforts underway in Canada to provide new technologies. In the next section, we argue that the jurisprudence concerning institutional liability is based on dated assumptions; in particular, we show that ICT can have subtle yet profound effects on health care practitioners. Arguing that the system-level errors that arise in these contexts cannot be treated adequately by the current legal framework, we briefly explore the potential of the law of fiduciary duties as a tool to rectify the situation. Our ultimate conclusion is that none of the current legal tools are adequate for dealing with the issue.

I. INSTITUTIONAL LIABILITY

In this section, we examine the jurisprudence concerning the liability of health care institutions for medical error. As we mentioned in the introduction, there appear to have been few fundamental changes in the jurisprudence concerning institutional liability for medical errors. As various commentators have noted, this situation is somewhat surprising, given the increasing role in health care delivery played by health care institutions. As stated by Hardcastle:

Hospitals and other institutions have responded to the complexity of modern medicine by taking on a greater role in organizing and managing the delivery of services, and coordinating the diverse staff and programs. Organization and management has extended to activities related to quality of care, such as forming quality-control committees and creating policies relating to patient outcomes . . . ²

In addition, governments are also taking on additional responsibilities in the health care space. According to Hardcastle,

... as publically funded health care become entrenched in the Canadian identity, government increased its involvement in the governance, management and administration of the system. Motivated by its enormous public investment in health care and growing public concern and expectations, the state has developed an interested in issues such as quality of care and patient outcomes. Governments now take on an active role in setting the overarching policies that guide the way the system operates and evolves.³

Examples of government activity in the operation and management of the health care system include: (1) the development of policies relating to quality of care; (2) the management of surgical scheduling (with concomitant wait time strate-

L. Hardcastle, "Government and Institutional Tort Liability for Quality of Care in Canada" (2007) 15 Health Law J. 401 at 402.

³ Ibid.

gies), and (3) the enactment of legislation pertaining to quality of care.⁴

Despite these developments, the common law jurisprudence has been faithful to a framework in which physicians bear the burden of liability for many cases of medical error, while institutions are characterized primarily as mere locations in which physicians operate. As various commentators have noted, placing the primary responsibility for medical error on individual practitioners is a poor strategy, given that many patient injuries are the result of systematic issues.⁵

In the following sections, we consider the case law on the liability of health care institutions for medical errors. We first deal with direct duties, and then with vicarious liability.⁶

(a) Direct Duties

As a thorough overview of the direct duties of institutions is beyond the scope of this work, we restrict our attention to key themes. As noted by Hardcastle, ⁷ Canadian law recognizes direct duties owed by hospitals to patients. The earliest duties recognized in the law were to select competent staff and to provide proper equipment and facilities. The courts gradually expanded these duties, as we shall discuss below.

(i) Duty to Select Competent Staff

As mentioned above, this duty has long been recognized in Canadian law. The recent case of *Bateman v. Doiron*⁸ appears in contemporary judgments as a concise formulation of the duty. In that case, the court stated that:

A hospital has an obligation to meet standards reasonably expected by the community it serves in the provision of competent personnel and adequate facilities and equipment and also with respect to the competence of physicians to whom it grants privileges to provide medical treatment. It is not responsible for negligence of physicians who practise in the hospital, but it is responsible to ensure that doctors or staff are reasonably qualified to do the work they might be expected to perform.

⁴ *Ibid* at 418. We do not discuss government liability in this work, leaving the reader to explore the presentation in Hardcastle's paper.

As Hardcastle notes, "[t]he failure of the common law to evolve to reflect systemic changes is particularly surprising, given the proliferation of literature demonstrating that many patient injuries are attributable to systemic causes, and that institutions are in a better position to recognize and rectify these problems" (*ibid* at 403). For a penetrating examination of medical error and tort law, see A. Merry & A. McCall, *Errors, Medicine and the Law* (New York: Cambridge University Press, 2001). Also see our recent work, J. Williams & C. Kuziemsky, "Negligence and the Challenge of Collaborative Care" (2011) Health Law J. (forthcoming).

⁶ Later in this work we deal with the issue of fiduciary obligations.

⁷ Supra note 2 at 421.

^{8 (1991), 8} C.C.L.T. (2d) 284 (N.B. Q.B.).

Ibid at 290. This decision was affirmed at appeal, in *Bateman v. Doiron* (1993), 141 N.B.R. (2d) 321, 18 C.C.L.T. (2d) 1 (C.A.).

(ii) Duty to Establish Systems Pertaining to Safety or Quality of Care

A number of cases have held that a hospital has a duty to establish systems that positively impact patient safety and quality of care. Considering safety, the case of *Granger (Litigation Guardian of) v. Ottawa General Hospital*¹⁰ involved an infant who experienced oxygen deprivation during delivery, incurring brain damage as a result. Due to inexperience, the nurse in charge failed to report that the fetal heart monitor showed deceleration of the infant's heart rate. The plaintiffs launched an action against the nurse, the nurse's supervisor, all of the physicians involved, and the hospital itself, (as a result of the fact that it was responsible for hiring and overseeing the nurses). The court found the hospital liable, establishing a precedent that a hospital may be responsible for the care given by its staff. In particular, the court founded liability upon the hospital's responsibility to ensure "safe systems", adequate facilities and competent personnel.

Two years later, another case involving liability of hospitals considered the duty to establish systems that relate to quality of care. In *Wild v. Salvation Army Maternity Hospital*, ¹¹ one of the plaintiff's claims was that the defendant hospital failed to maintain "safe systems" in its provision of medical services. In setting out their decision, the courts reaffirmed *Bateman*, and noted that the duty of care owed by a hospital includes a duty to "establish systems necessary for the safe operation of the hospital." ¹² (In particular, the court noted that this duty to establish and follow safe systems in providing medical services was accepted as a well-established principle by the court in *Granger*).

The issue facing the court in *Wild* was to determine whether the Salvation Army Maternity Hospital had in place (and followed) a system that could deal with the contingencies that might foreseeably arise in an obstetrical unit. The plaintiff had argued that the hospital: (a) failed to have in place adequate systems "to get the right people to the right place at the right time", and; (b) "showed an utter lack of proper policymaking and a lack of implementation and/or enforcement of its existing policies." The court was ultimately not persuaded that these claims had substance, noting that the plaintiffs had not presented significant evidence that the hospital policies or their enforcement contributed to the error. The court gave weight to an expert witness, who found that the hospital's policies were comprehensive, in conformity with national guidelines, and designed to support optimum client care.

In closing, the court in *Wild* made the following observations on medical malpractice:

It is not reasonable as a society to expect certainty and perfection from medical treatment. While the medical profession is moving gradually toward that objective, its achievement is only a distant possibility. Those in the profession know too well the limitation of their science. We can only demand of them a high standard of training and performance, and when they meet those standards, accept that they cannot guarantee results and that unfortunate, and sometimes inexplicable, outcomes will occur.

¹⁰ [1996] O.J. No. 2129 (Gen. Div.) [Granger].

¹¹ (1998), 171 N.S.R. (2d) 201 (S.C.).

Here, the court cited E.I. Picard & G. Robertson, Legal Liability of Doctors and Hospitals in Canada (Toronto: Carswell, 1996) at 367.

Additional cases on this topic include *Braun Estate v. Vaughan*, ¹³ where the court found that a hospital had an affirmative duty to have policies for review test results, and *Vuchar v. Toronto General Hospital*, ¹⁴ which has established that hospitals are liable for injury caused by inadequate or improperly maintained equipment. As Hardcastle notes, "[the] affirmative duty to take proactive measures relating to patient safety is the closest Canadian courts have come to a duty to furnish a patient with non-negligent medical care." ¹⁵

(iii) Duty to Ensure Proper Coordination

Although one could construe this as a special case of the duty to provide systems pertaining to safety or quality of care, the courts have also explicitly recognized that hospitals have a duty to ensure that proper coordination occurs. For example, in *Lachambre v. Nair*, ¹⁶ the court stated that "[a] hospital which provides the beds, the nurses, the equipment and the technicians cannot escape its responsibilities to the patient by delegating the treatment or control of the procedures to specialists who are independent contractors. The hospital may delegate the treatment, but not the responsibility." On the topic of coordination, Blair J stated that "[w]here a patient in a hospital is treated by more than one specialty, the hospital owes a duty to ensure that proper coordination occurs and that the treatment program operates as a unified and cohesive whole."

(iv) Duty to Ensure Provision of Competent Treatment

One of the most widely cited cases in this area is that of *Yepremian v. Scarborough General Hospital*, ¹⁷ which involved an internist who failed to diagnose and treat diabetes (resulting in severe harm to a patient). Noting that patients expect to receive competent medical care at a hospital, the court posed a key question — namely, does the hospital undertake to provide that medical care, or does it merely undertake to select competent physicians who will provide it? Considering a patient's perspective, the court noted that patients expect that a hospital can provide everything required to "make sure make sure, so far as is possible, that the patient's ailments are diagnosed and that proper treatment is carried out, whether this is done by an employed doctor, a general practitioner or a specialist."

The trial judge found the hospital liable, based on a breach of its duty to the

^[2000] M.J. No. 63 (C.A.). At paragraph 48, the court made the following observation: "It would have been a simple enough matter, for example, for the hospital to set its own policy and procedures to see to it that a "safe system" was in place. Alternatively, the hospital could simply have ascertained from physicians in the hospital clinic what kind of follow-up protocols were required, and coordinate the procedures. There is ample authority in a non-hospital, negligence context, to support the proposition that the absence of a reasonable policy to avoid or reduce a foreseeable risk can result in a finding of negligence."

¹⁴ [1937] O.R. 71, [1937] 1 D.L.R. 298 (C.A.) [Vuchar].

Supra note 2 at 421. See also footnote 90 on the same page for additional cases of this type.

¹⁶ [1989] 2 W.W.R. 749 (Sask. Q.B.).

^{17 (1980), 28} O.R. (2d) 494 (C.A.) [Yepremian].

patient. In particular, the trial judge stated that this duty is breached if there is a failure by a specialist on the hospital's staff to use reasonable skill and competence in the treatment of a patient under his care. While the trial judge found the hospital had an obligation to provide health care services to the public (based on the *Public Hospitals Act* and common sense), the source of the duty mentioned above was grounded on the hospital's having the opportunity of controlling the quality of medical service.

In considering these arguments, the Court of Appeal stated that unless there exists in law a "non-delegable duty of care" owed by the hospital to the patient, the hospital could not be liable for the medical error. In the words of Arnup J.A.:

"No Court in Canada has ever found before that such a duty exists, and with great respect to the trial Judge, I am not persuaded by his reasons that there is such a duty. I am not dismissing those reasons perfunctorily, nor intending to denigrate them, when I say that he seems to me to be saying, in substance, "In all the circumstances, the hospital ought to be liable." In my view, if the criterion is to be what is fair and reasonable, it would be fair and reasonable that the highly — skilled doctor whose negligence caused the damage should be called upon to pay for it.

. . .

I agree with the trial Judge . . . that the Yepremians had every right to expect that a large public hospital like Scarborough General would provide whatever was required to treat seriously ill or injured people, but I do not think it follows that the public is entitled to add the further expectation: "and if any doctor on the medical staff makes a negligent mistake, the hospital will pay for it."

Of the trial judge's claim that the duty of care is grounded in the hospital's having the opportunity to control the quality of medical service, Arnup stated the following:

I do not know upon what evidence he bases this view, if it is intended to reflect some ongoing supervision by the hospital of the quality of medical service after a doctor is appointed to the medical staff. There is some evidence that if a member of the medical staff appears to be neglecting his patient, in the sense of not seeing the patient as often as expected, or at all, a nurse may report this to the superintendent. . . . But a nurse, or a superintendent for that matter, who suggested that some different medical treatment from that being followed by a staff specialist might be preferable would be going beyond any hospital practice established by the evidence . . .

The Government exercises a substantial degree of control over public hospitals, through Regulations and especially through the hospitals' finances. If liability is to be imposed upon hospitals for the negligence of its medical staff, including specialists, not employed by the hospitals, whether directly or by imposing a statutory duty to provide such services, it should be the function of the Legislature, as a policy question, to decide whether and under what conditions such liability is to attach.

Speaking in dissent, Houlden J.A. enunciated an argument for holding the hospital liable:

The provision of a wide range of medical services is thus an integral and essential part of the operation of a modern, general hospital. This is so regardless of the way in which the hospital has structured its relationship with

the professional personnel who provide those services. While the negligent act may be committed by a particular individual, that act is part of the overall medical care provided by the hospital. It is medical care that is sought by the patient; and it is proper medical care that should be provided. The primary responsibility for the provision of this medical care is, in my opinion, that of the hospital, and the hospital cannot delegate that responsibility to others so as to relieve itself of liability.

As explained by Hardcastle, ¹⁸ most courts have followed the majority decision in *Yepremian*. As a result, it is safe to say that the common law does not unreservedly embrace a non-delegable duty of care from the hospital to its patients.

(b) Vicarious Liability

The other avenue by which courts may impose liability on health care institutions in tort concerns *vicarious liability* — the doctrine by which an employer is liable for the tortious conduct of its employees. In order for a claim of vicarious liability to succeed, the conduct must have been undertaken within the scope of the employment relation. If the actions incurring the loss were performed by contractors or volunteers, the employer cannot be held vicariously liable. ¹⁹ In addition, the courts have imposed limits on an employer's liability, by requiring that an employer be in a position to exercise control over the manner in which the employee performs her work. ²⁰

Commenting on vicarious liability in the health care space, Picard and Robertson note that:

Whether a hospital will be vicariously liable for the negligence of a doctor depends upon the relationship among the hospital, the doctor and the patient. In the great majority of cases, patients engage and pay their doctor (usually through medicare plans) and have the power to dismiss them. The hospital does not employ the physicians nor are they carrying out any of the hospital's duties to the patient. They are granted the privilege of using personnel, facilities and equipment provided by the hospital but this alone does not make them employees. They are independent contractors who are directly liable to their patients, and the hospital is not vicariously liable for their negligence. ²¹

According to Hardcastle, institutions are vicariously liable for the majority of health care professionals, including nurses, residents, and medical imaging techni-

Supra note 2 at 423. On page 438, the same author notes that there is one pending case that could lead to reconsideration of hospital liability; due to the lack of activity on the case, she suspects that the parties may have settled.

For a classical formulation of this rule (in terms of masters and servants), see for instance, *Battistoni v. Thomas*, [1932] S.C.R. 144.

See, for instance, Lake v. Callison Outfitters Ltd. (1991), 7 C.C.L.T. (2d) 274 (B.C. S.C.). For a more extensive set of references on vicarious liability, see A.M. Linden & L.N. Klar, Canadian Tort Law: Cases, Notes and Materials, 11th ed. (Toronto: Butterworths, 1999) at 519.

²¹ Supra note 12 at 381.

cians.²² In her words, Canadian courts considering institutional liability tend to focus on factors of remuneration and control, providing little analysis for their categorization of doctors as independent contractors.²³ As a matter of fact, health care institutions exercise more control over physicians than in the past, as they typically constrain the conduct of doctors by means of policies and procedures.²⁴

(c) Summary

This section has briefly outlined the main sources of liability for medical error, as it pertains to health care institutions (rather than individual practitioners). In the next section, we introduce some of the fundamentals of healthcare ICT. We will ultimately argue that these technologies have invalidated some of the assumptions made in the case law outlined above. In particular, these technologies have subtle (yet profound) impacts on health care practitioners; since these systems are designed, implemented and maintained at the organizational level, health care institutions: (a) are causally responsible for corresponding systems-level errors, and; (b) have the ability to alter the way in which health care professionals fulfill their responsibilities.

II. INFORMATION AND COMMUNICATIONS TECHNOLOGY IN HEALTH

(a) Overview

Our healthcare system is evolving from care that is provided by a single provider and setting to care that is provided across multiple providers and settings. Reports such as the 2001 Institute of Medicine Study have stated that *information and communication technologies* (ICT) will be a key driver of this new healthcare system. ²⁵ In response to the call for the re-shaping of healthcare systems, many countries have been investing massive amounts of funding and resources to develop ICT infrastructures to support interoperable healthcare delivery. For instance, the government of Canada formed a new public agency (Canada Health Infoway) that has been tasked with the development of a national, integrated electronic health record (EHR) system. ²⁶ Australia has a national e-Health strategy for electronically collecting and exchanging health information, ²⁷ while the United Kingdom has the Connecting for Health strategy to deliver delivering a national program for health-

²² Supra note 2 at 423.

²³ *Ibid* at 424.

Furthermore, the courts have recognized that physicians are bound to follow these policies. Hardcastle cites the case of *MacPhail v. Desrosiers*, [1998] N.S.J. No. 353 (C.A.).

Institute of Medicine, "Crossing the Quality Chasm: a New Health System for the Twenty-first Century" (Washington, D.C.: National Academies Press, 2001).

²⁶ See the Canada Health Infoway website, online: http://www.infoway-inforoute.ca/lang-en/>.

E.J.S. Hovenga, "The Importance of Achieving Semantic Interoperability for National Health Information Systems" (2008) 17:1 Texto Contexto Enferm 158.

care IT.²⁸ In 2009 the United States Congress allocated more than \$20 billion for health information technology.

Many of these projects involve "top down" approaches to ICT deployment, where national or regional bodies develop standards, reference architectures and other artefacts that impose constraints of the ICT solutions deployed in their jurisdiction. Critics have questioned the utility of "top down" models; for instance, the Canadian approach has been characterized as a "Soviet" style approach that is unlikely to yield benefits. ²⁹ In contrast, the United States has taken a different direction, in that they are starting at the individual provider level where they are connecting multiple provider systems into a health information exchange. ³⁰ The panoply of information exchanges will then be scaled up to form a national health information system. ³¹

Despite the increased use of ICT in healthcare the evaluation of these technologies on remains mixed. In September 2011 the United Kingdom announced it was dismantling their healthcare IT program after a cost of 12.7 Billion pounds. High failure rates in Healthcare ICT projects are common.³² Even more significant is that the implementation of ICT in healthcare are frequently met with user, organizational and clinical issues.³³ One major concern is that these systems often change how healthcare providers and administrators do their jobs. As will be discussed below, these changes can have adverse effects on care delivery.

(b) Types of ICT

Before we engage in a discussion about the effects of ICT on health care delivery, we pause briefly to review some of most important types of systems in use today.

(i) Patient Management Software

One of the most common types of ICT in the health care domain consists of patient management software.³⁴ *Scheduling and billing applications* (SBAs) provide a core set of functionality supporting the financial and logistical workflows of

²⁸ Connecting for Health, online: http://www.connectingforhealth.nhs.uk/.

Paul Christopher Webster & Wayne Kondro, "Medical data debates: Big is better? Small is beautiful?" (2011) 109:1 CMAJ 3799.

W.A. Yasnoff et al, "A consensus action agenda for achieving the National Health Information infrastructure" (2004) 11:4 J. Am. Med. Inform. Assoc. 332.

³¹ E. Coiera, "Building a national health IT system from the middle out" (2009) 16:3 J. Am. Med. Inform. Assoc. 271.

R. Heeks, "Health information systems: Failure, success and improvisation" (2006) 75 Int. J. Med. Inform. 125.

B. Kaplan & K.D. Harris-Salamone, "Health IT Success and Failure: Recommendations from Literature and an AMIA Workshop" (2009) 16:4 J. Am. Med. Inform. Assoc. 291.

For a more comprehensive overview of patient management software, see J. Williams & J. Weber, "Regulation of Patient Management Software" (2010) 17:8 Health Law J. 73.

a health care delivery location, including: (a) tracking patient contact information, and; (b) scheduling appointments. *Electronic medical records* (EMR) systems extend the functionality of SBAs by allowing health care providers to manage health information for use in clinical care. EMRs are designed to store a wide variety of *personal health information* (PHI), including care plans and test results; it is also common for them to provide support for automated alerts, diagnostic aids, and case-specific best practice guidelines. Lastly, an *electronic health record* (EHR) system is a "multi-tenant" EMR that focuses on providing *shared* access to multiple health care providers. EMRs typically have more depth and are often single site, but they feed into the broader EHR to enable cross site data sharing. Records in an EHR are intended to be comprehensive, life-long and accessible across a variety of care settings.³⁵

(ii) Decision Support Systems

Decision support systems (DSS) have been (broadly) defined as "any program designed to help health-care professionals make clinical decisions." Specific categories of DSS include: (1) systems for information management; (2) systems for focusing attention, and; (3) systems for providing patient-specific suggestions. We describe some of the tasks to which DSS can be applied in the paragraphs below: 37

Alerts and reminders:

DSS can be used to send reminders to caregivers concerning a patient's need for medication or diagnostic tests. For critical care, DSS can be used to monitor sensors (e.g., pulse oximeters), issuing alerts when thresholds are reached.³⁸

Diagnostic assistance:

DSS can aid clinicians in drawing inferences about the patient's condition. Where a human expert may miss rare conditions, a DSS can present a comprehensive range of hypotheses.³⁹

N.P. Terry & L.P. Francis, "Ensuring the Privacy and Confidentiality of Electronic Health Records" (2007) U. Ill. L. Rev. 681.

M. Musen, Y. Shahar & E. Shortliffe, "Clinical decision support systems" in: E. Shortliffe et al, eds., *Medical Informatics. Computer Applications in Health Care and Biomedicine*, 2d (New York: Springer-Verlag, 2001) at 573.

For an introduction to decision support, see E. Coiera, *Guide to Health Informatics*, 2d (London: Arnold, 2003) at 330.

As we discuss below, studies have shown that alerts or reminders ate frequently disabled or overridden by providers. H. Van der Sijs et al, "Overriding of drug safety alerts in computerized physician order entry" (2006) 13:2 J. Am. Med. Inform. Assoc. 138.

Of particular interest for our purposes are *knowledge-based systems* (also known as *expert systems*). These DSS provide representation and reasoning functionality; their databases contain formalized rules that represent clinical knowledge, typically focusing on one clinical task (e.g., diagnosing skin ailments). Clinicians can enter data about individual patients, and query the system for advice.

Therapy critiquing and planning:

DSS are often used to examine treatment plans for inconsistencies, errors and omissions. More advanced artefacts (planning systems) can even use a database of treatment protocols to construct a care plan for a patient.

Prescribing medications:

DSS are often used to provide advice for clinicians who are prescribing medications, supplying them with information on interactions, dosage errors and contraindications.

Image recognition and interpretation:

DSS are frequently used for interpreting images (e.g., MRI scans); computers can process hundreds of images in batch mode, flagging worrisome cases for human inspection.

(iii) Protocol Systems

ICT-based protocol systems augment the capabilities of clinicians by providing support for the use of *clinical practice guidelines* (CPGs), or *care maps*. These systems are intended to facilitate evidence based medicine by guiding the user through a set of primitives that represent steps in a clinical encounter. An encounter of the protocol systems are sources of information that clinicians can access during care. In contrast, active protocol systems constrain the actions of clinicians, as opposed to merely providing information. To take but a single example, they might force a clinician to enter information into an EMR in a particular sequence; alternatively, they might provide partial automation of this data entry.

(iv) Medical Devices

Although some medical devices (e.g., cardiac stents, surgical tubing) are unpowered, many modern offerings contain sophisticated electronics, including computer processors and software. In addition, many medical devices are now being designed with interfaces that allow them to exchange data with: (a) other medical devices, and; (b) software systems, such as EMRs. This data can be used for care planning (e.g., glucose monitors that send data to a centralized repository for review by a nurse), decision support and other clinical/administrative functions.

(v) Other Systems

There are at least two additional categories of ICT that are associated with

These primitives can include: (1) action steps, clinical tasks to be performed or avoided; (2) decision steps, selections from a set of alternatives, and; (3) patient states, descriptions of the clinical status of a patient. See D. Wang et al, "Representation primitives, process models and patient data in computer-interpretable clinical practice guidelines: a literature review of guideline representation models" (2002) 68 Int. J. Med. Inform. 59.

Drug pumps and glucose monitors are but two examples of medical devices that are now designed with either onboard computing power or downloadable memories. For a review of electronic medical devices, see J.B. Weitzman, "Electronic Medical Devices: A Primer for Pathologists" (2003) 127 Arch. Pathol. Lab. Med. 814.

medical error. First, *collaborative/communication systems* are intended to facilitate team work between health care practitioners. Second, *computerized physician order entry* (CPOE) systems are meant to automate a particular task (i.e. patient medication order) in order to improve efficiency.

III. IMPACTS OF HEALTHCARE ICT

In this section, we examine the impacts of ICT on health care practitioners. We begin by reviewing some of the basic concepts on systems-level medical errors. After that, we discuss the various impacts associated with the use of ICT in the health care domain.

(a) Medical Errors

A recent study in Canada found that adverse events occurred frequently, with an observed rate of 7.5% of hospital admissions.⁴² Merry and McCall's work⁴³ on medical error and the law highlights the ease with which society is ready to blame individuals (e.g., physicians) for errors that may be systematic in nature. In fact, Rosenthal and Sutcliffe⁴⁴ have argued that 85% of errors are the result of systemsissues. In their work, they grouped systemic causes for errors into two high level categories: (1) organizational factors, and; (2) institutional factors. The various types of *organizational factors* include team factors, work environment, organizational design, culture and leadership. *Institutional factors* include regulatory contexts, health care standards and the complexity of care delivery. Rosenthal and Sutcliffe point out that errors that result from systems concerns are more likely to be serious than those that arise from the actions of individual care providers. In their words, "the higher an error is when it occurs, the more likely it is to be disseminated through amplifying power of the organization."

(b) The Impact of ICT on Care Delivery

While the introduction of ICT into health care can result in tremendous improvements, it can also introduce new risks. In particular, information technology clearly has the potential for causing medical errors. Ash et al report that despite the potential of healthcare ICT to reduce errors (through the use of alerts, drug interaction checking and other means), many applications seemed to foster errors rather than reduce their likelihood. In the words of the authors, "[i]n health care

⁴² G.R. Baker et al, "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada" (2004) 170 CMAJ 1678 (cited in Hardcastle, *supra* note 2).

⁴³ A. Merry & A. McCall, *supra* note 5.

M. Rosenthal & K. Sutcliffe, *Medical Error: What Do We Know? What Do We Do?* (San Francisco: John Wiley and Sons, 2002) (cited in Hardcastle, *supra* note 2).

⁴⁵ See, for instance, R. Anderson, "Do Summary Care Records Have the Potential to do More Harm than Good? Yes" (2010) 340 Brit. Med. J. 1390.

⁴⁶ J.S. Ash, M. Berg & E. Coiera, "Some Unintended Consequences of Information Technology in Health Care: the Nature of Patient Care Information System-related Errors" (2004) 11:2 J. Am. Med. Inform. Assoc. 104 at 105.

practices in the United States, Europe, and Australia alike, we have seen situations in which the system of people, technologies, organizational routines, and regulations that constitutes any health care practice seemed to be **weakened** rather than **strengthened** by the introduction of the [patient care information system] application. In other words, we frequently observed instances in which the intended strengthening of one link in the chain of care actually leads unwittingly to a deletion or weakening of others."⁴⁷ At a minimum, we should be aware that ICT initiatives can have drastic (and unanticipated) impacts on the provision of care delivery.⁴⁸

One of the unpredictable aspects of deploying ICT systems is the degree to which the technology can actually influence the people who use it. As opposed to being a mere facilitator, ICT influences the way in which health care practitioners understand evidence, exercise judgment, engage in reasoning and execute work processes. As stated by Niazkhania et al,⁴⁹ the implementation of health information technology systems is a "process of mutual transformation in which the organization and the system transform each other." Although perhaps novel to legal professionals, the unpredictable dynamics of large scale ICT systems have been documented for years in the systems engineering, software engineering and health informatics literature. In the sections to follow, we describe some of the major risks pertaining to ICT.

(i) Errors in Software and Hardware Artefacts

As with any artefact, software and hardware can contain latent defects; these can arise through errors in the design process (e.g., logical errors in the design of circuits), or through errors in the manufacturing or fabrication process (e.g., physical flaws in circuit boards). Disruptions of this sort can have system-wide consequences, as in the case of a failure in a communications network that connects multiple care settings. ⁵⁰

(ii) Failures in Implementation and Operation

The introduction of ICT changes the way that health care organizations work with data. There are two types of risks here. First, there are risks associated with switching over from a "legacy" information management system. Second, there are ongoing risks of system failure during day-to-day operation. Both types of risk have caused serious injury, hospital-wide breakdown, and even death.

⁴⁷ *Ibid* at 104.

As stated by Ash et al, *ibid* at 104, "[w]hen such technologies become an integral part of health care work practices, we are confronted with a large sociotechnical system in which many behaviors emerge out of the sociotechnical coupling, and the behavior of the overall system in any new situation can never be fully predicted from the individual social or technical components."

⁴⁹ Niazkhania et al, "Evaluating the medication process in the context of CPOE use: The significance of working around the system" (2011) 80 Int. J. Med. Inform. 490.

Methodologies and practices exist to deal with many of the defects encountered in practice. This type of error is not our concern at present, and we shall have little to say about it in the remainder of the paper.

(iii) Errors in Designing ICT for a Health Care Environment

One of the most important categories of ICT-based error concerns the potential mismatch between the design of a system and the operational demands of the health care environment in which it is deployed. As noted by Ash et al,⁵¹ these errors are not easily found by a technical analysis of the design, or even suspected after the first encounter with the system in use. Instead, they only emerge when the technical system is embedded into a working organization. Although the errors can vary from one organization to another, some common features of health care can (and should) be anticipated by the organizations who put these systems into operation.

(A) Unanticipated Uses

Even the most perfectly engineered software may give rise to error through a mechanism that is often overlooked by designers — namely, the humans who use it. A case in point is the Therac-25 radiation therapy machine, whose software caused patients to receive massive radiation overdoses.⁵² Some fatal accidents involving Therac-25 happened when human operators became faster and more proficient with entering data. Since the software was not designed or tested with operators with this level of skill, the use of the machine was effectively being pushed passed the boundaries envisioned during design and implementation.

(B) Errors in the Process of Entering and Retrieving Information

One of two fundamental categories of ICT error identified by Ash et al,⁵³ this category of error concerns the special demands involved in providing clinicians with information. Health care users face constraints that are not common in other workplaces, such as case management, legal or accounting work. First, health care ICT generally has to offer fast response times and minimal downtime. Second, many health care ICT systems have to be deployed in a form suitable for dynamic environments; for instance, instead of static desktop machines, many computer systems have to be on mobile carts that can be wheeled from ward to ward. Third, the user interfaces must be clean, elegant and readily understandable by users whose primary task is dealing with patients (and often many at once), rather than with computers.

One major problem with ICT is that the user interfaces may be unsuitable in a variety of ways. To take a simple example, many user interfaces assume that the user is engaged in only one task; in health care environments, most clinicians are constantly navigating a complex flow of tasks, with patients and other professionals competing for their time at any given moment. Issues associated with human data entry in healthcare ICT include *juxtaposition hazards*, in which a poorly designed

⁵¹ Supra note 46 at 105.

A detailed analysis of Therac-25 has been published in N.G. Leveson & C.S. Turner, "An Investigation of the Therac-25 Accidents" (1993) 26:7 IEEE Computer 18.

⁵³ Supra note 46 at 106.

interface results in many clinicians selecting the wrong option due to misleading cues.

Another example of user interface errors involve cognitive overload. First, there are issues that arise when ICT imposes too much structure on clinicians. Health care professionals need to communicate information rapidly and accurately, preferring unstructured text (e.g., notes in a paper chart) for communicating information. When ICT forces clinicians to enter data in structured format, it can interfere with the clinician's ability to devote herself fully to the clinical task at hand. This is an example of an interruption hazard, in which errors are caused by interrupting the clinician's workflow or "train of thought." Even worse, some ICT may prevent clinicians from fully thinking through problems in the first place. An important (and perhaps surprising) point is that the act of writing down clinical information is actually a form of thinking; this "writing-as-thinking" phenomenon has been documented in several case studies, which jointly indicate that interrupting this process is actually detrimental to the cognitive processes involved in providing care.⁵⁴ Since some ICT forces users to enter information in highly structured formats, it creates a risk of disruption and cognitive disturbance that may ultimately degrade the quality of care and result in adverse events for patients.

An example of *altered cognition* is the change from a manual to an automated process. One of the authors of this paper is currently conducting a study of a perioperative system that automatically retrieves patient data such as blood pressure and respiratory rate. Whereas in the past the anaesthetist would have had to manually record the patient data, in the new system vital signs will be pulled automatically from patient monitoring devices. One of the anaesthetists in the study worries that clinicians could pay less attention to the numbers because they no longer have the manual recording step. The "check in" assessment of the patient's vital signs is a process that is driven by the current manual system. That is an example of how manual tasks can be altered by technology.⁵⁵

A second issue is that user interfaces may overload a clinician, requiring so much effort to navigate (and presenting such a *fragmented* view of the information) that they lose their ability to gain an *overview* of the case. As stated by Ash et al, "records might overly separate the information flows according to work task or responsibility. In everyday practice, doctors can gather information from nurses' notes, or those of other specialists, that relate to the problem. Information systems could limit this easy access to other people's notes or other parts of the record, and thereby severely hamper the professional's ability to be optimally informed." 56

A third issue is that the *completeness* offered by healthcare ICT (particularly EMR and EHR systems) can cause difficulties for practitioners. The inclusion of standard phrases and comprehensive views of patient histories embedded in reports

See for example M. Berg, "Practices of reading and writing: the constitutive role of the patient record in medical work" (1996) 18 Sociology of Health & Illness 499.

Other domains have described similar issues with *excess computerization*. Specifically the aviation industry has shown that excess computerization may dull a pilot's skills and impact his ability to perform certain procedures manually. See for instance: http://www.cnn.com/2011/TRAVEL/09/01/airlines.autopilot/index.html>.

⁵⁶ Supra note 46 at 107.

forces clinicians to search for meaningful content. For instance, a clinician may not know whether an observation was merely selected from a template, automatically generated by an expert system, or was carefully and thoughtfully recorded by another clinician, who considered it integral to the case. The tendency to "cut and paste" is a problem in any workplace that relies on templates and standardized formats.

(C) Errors in the Communication and Coordination Process

The second major category introduced by Ash et al, these errors concern the way computers can undermine communication about (and coordination of) events and activities. As stated by Ash, "[h]ealth care work can be characterized as the managing of patients' trajectories; under continuous time pressure, and in constant interaction with colleagues and the patient, health care professionals have to try to keep a patient's problem on track. This implies simultaneously acting on a whole range of dimensions, including interpreting physical signs and diagnostic tests, and dealing with organizational policies and the patient's individual needs."⁵⁷

While computers excel at routine, monotonous and standardized work, ICT that is not designed for the complex, non-routine and dynamic nature of health care is likely to interfere with the task of health care delivery. One of the major problems in health informatics is that ICT is typically designed for linear workflows, while health care is inherently non-linear and dynamic. The inflexibility offered by these systems can become a major constraint for clinicians, who are forced to adhere to steps in a linear workflow that may be irrelevant, unnecessary or even completely erroneous in the circumstances of the case at hand. To deal with this, clinicians will often invent *workarounds*, defined by Niazkhania et al as "informal rules or work methods — not formally considered and outlined in the system design — employed in working with a system to handle a workflow problem." Unfortunately, workarounds can be unreliable and unstable; they can also increase the cognitive burden on clinicians to the detriment of care.

Another type of error introduced by ICT arises from potential losses of communication. Simply put, the act of entering data into a computer is not the same as that involved in talking to colleague. Sometimes the synchronous communication involved in picking up the phone and calling a clinician (e.g., to alert them about the availability of diagnostic test results) is highly useful, and assumed by clinical practice. The use of ICT can disrupt traditional patterns of communications by frus-

⁵⁷ Supra note 46 at 105.

⁵⁸ *Supra* note 46 at 107.

⁵⁹ *Supra* note 49 at 491.

M. Kobayashi et al, "Work coordination, work flow, and workarounds in a medical context" in *Human Factors in Computing Systems* (New York: Association for Computing Machinery, 2005) at 1561.

Studies have shown that ICTs such as CPOEs can be a significant cause of medical errors and workarounds. See for example R. Koppel et al, "The role of computerized physician order entry systems in facilitating medication errors" (2005) 293:10 JAMA 1197.

trating these expectations. For example, problems arise when a person sending a message trusts that a technological solution at the other end (e.g., fax machine, printer, EMR system) will take care of notifying the receiver. This creates a distinction between a request or order that has been *communicated*, and one that has been *executed*. In the words of Ash et al:

As a result of miscommunication, orders or appointments are missed, diagnostic tests are delayed, and medication is not given. Communication involves more than transferring information. Communication is about generating effect — the laboratory personnel wanted to make sure that the doctors would act on their data. Similarly, communication is about testing out assumptions regarding the other person's understanding of the situation and willingness to act on your information. In addition, communication is always also about establishing, testing, or maintaining relationships. ⁶²

Errors can also result from decision support systems (DSS), through the phenomenon of *overload*. In practice, DSS systems can bombard clinicians with alerts and warnings, leading to *alert fatigue*, in which errors occur due to the software desensitizing users. Clinicians may disregard warnings deliberately, or sometimes even go to the trouble of turning the warning system off. Although this behaviour may seem negligent, the scarcity of time at the disposal of clinicians means that they are sometimes making a rational decision in decreasing the amount of interruptions caused by DSS systems, albeit at the risk of missing the rare alert that could save a patient from an adverse event.

Lastly, when ICT systems disrupt traditional patterns of communication, they can disrupt the natural checks and balances inherent in traditional processes. For instance, Ash et al use the example of prescriptions, wherein pharmacists often catch mistakes in prescriptions that have been caused by physicians. Although prescription errors are very common, medication errors (i.e., the patient consuming the wrong medication) are much lower. This distributed workflow, while not perfect, has some constraints operating against errors by prescribing physicians. If replaced by a CPOE system, these traditional advantages could be eliminated — (in some cases, for the worse). While there is much room for improvement in health care, it would be hubris to suggest that the various and sundry workflows developed by health care practitioners have no merits in terms of patient safety or effective communication.

(iv) Errors in Standards

In order for information to be communicated from one health care setting to another, a number of conditions must be satisfied. Not only must the health information system at the receiving location be able to receive and understand the data, but the clinicians at that location must be able to understand and use it. To this end, the health informatics community has developed numerous standards for interchange of health information, including messaging standards, and coding standards. To take a recent example, the "Systematized Nomenclature of Medicine — Clinical Terms" (SNOMED-CT) is a collection of medical terms that cover clinical

⁶² Supra note 46 at 109.

⁶³ Supra note 46 at 110.

areas such as diseases, procedures, drugs and pathogens. In the absence of such a standardized terminology, practitioners are left to their own devices to enter descriptions for these and other aspects of clinical care.⁶⁴

While semantic interoperability standards are intended to resolve confusion and ambiguity, they are themselves the result of collaborative efforts by health care organizations, and hence subject to error. Errors in terminologies or data interoperability standards can result in harm to a patient, even though the local health care professionals and organizations involved in providing care conducted themselves in an optimal (even flawless) manner. In general, health care practitioners who rely on standardized terminologies have little chance of detecting such problems.

(v) Integration of Errors

Although the above errors are described individually, in actually practice an individual error can lead to systematic errors. Earlier we described how healthcare delivery is moving towards care provided across multiple providers and settings. Collaboration can make individual errors have a more profound impact as they can ripple to become systematic errors that impact several providers. For example, although errors due to altered cognition or information retrieval take place at the level of an individual clinician, the impact of these errors will resonate when an error laden decision (or error laden information) is communicated to team members. Collaborative care delivery, although beneficial to patients, also has the ability to accentuate the impact of errors by giving them a dissemination channel.

IV. TOWARD GREATER INSTITUTIONAL LIABILITY

In previous sections we have: (1) outlined key principles of institutional liability for medical error; (2) provided an overview of healthcare ICT, and; (3) discussed the types of error that health information systems can cause. Of course, most legal professionals are aware that deploying ICT in the health care domain can induce *system-level errors*, such as malfunctions of communications channels serving disparate care locations. The novel content in our presentation concerns the ability of ICT to affect the behaviour of health care professionals themselves. As we saw, ICT can interfere with users in various ways, such as impairing their ability to comprehend information, multitask, communicate with colleagues, exercise judgment and follow optimal workflows. ICT can also be disruptive on a macro-level, dislodging the safeguards built up in traditional methods of care delivery.

In the following sections, we explore the liability of institutions for certain classes of medical error. As we stated above, the deployment of ICT in health care not only carries risks, but has a profound influence on individual health care practitioners. Since the design and deployment of ICT is an organizational or govern-

For instance, the terms "myocardial infraction" and "heart attack" may be synonymous to physicians, but an expert system may not be programmed to reflect this.

A recent paper identified a high percentage of cases in which SNOWMED-CT terms with a similar word structure had dissimilar logical modeling. See A. Agrawal, G. Elhanan & M. Halper, "Dissimilarities in the Logical Modeling of Apparently Similar Concepts in SNOMED CT" (2010) AMIA Annu. Symp. Proc. 2010 at 212.

mental responsibility, policy considerations (and common sense) dictate that institutions should be held responsible for related errors. The sections below examine this claim in more detail.

(a) Updating the Model of Care Delivery

First, it is clear that the traditional model of care delivery is completely outdated. The traditional framework, (in which a hospital is a mere staging ground for the performances of contractor physicians), is archaic. Currently, health care is delivered by individuals drawn from a dizzying array of professional disciplines, working in dynamic and unstructured care teams, acting across geographical distances, with the help of administrative and technical support offered by multiple health care organizations. In many cases, the technical infrastructure includes complex ICT systems that are implemented and maintained by institutions, and often funded by governments. International standards bodies and public agencies (e.g., Canada Health Infoway) inform the design of these systems by setting architectural and semantic interoperability standards. Not only are clinicians (including doctors) subject to bylaws, codes of conduct, statutes and common law obligations, but ICT systems themselves have a profound and subtle impact on their ability to provide care.

On the whole, this is a dramatic change from the simple "physician occupying a hospital room" model of yesteryear. Not only is the role of the doctor diminished, but the myriad systems, collaborations and activities involved mean that *systems-level concerns* are exceedingly important. This fact has been recognized in the literature at times, as in the Winnipeg Inquiry, which stated that:

While some of the problems that the program faced related to the abilities and conduct of specific individuals, other problems were largely systemic in nature

[It is] unrealistic to believe that human error can be totally eliminated. More importantly, it is impossible to design a system that relies totally on everyone doing the tasks assigned to them properly. Allowances must be made for the possibility that errors will be committed and mechanisms to address that possibility must be put into place.⁶⁶

As a result, any mechanism that attempts to address the errors involved in modern care delivery must have the ability to impact the actors responsible for implementing and maintaining systems. Healthcare is set to become more complex in the years ahead, not less.

(b) Impacts of ICT on Clinicians

Reviewing our discussion of errors and ICT in the previous section, we saw that there are a number of ways in which information technology can drastically alter the way in which clinicians perform their duties. Implementing ICT is a pro-

Associate Chief Justice Murray Sinclair, *The Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994*, (Winnipeg, Provincial Court of Manitoba: 2000) at 465 and 487 (cited in Hardcastle, *supra* note 2 at 409).

cess of "mutual transformation", as opposed to merely handing a tool to clinicians. Among other implications, mutuality means that: (1) a system may be used in ways that its designers did not expect, and; (2) users may be impacted or impaired by its presence. Among the errors we have seen are:

- Unanticipated uses, where users violate the assumptions made during the design of the product.
- *User interface issues*, which yield juxtaposition hazards, cognitive overload, and interruption hazards. This class of problems can also disrupt a clinician's ability to reason and exercise judgment, as well as their ability to come to a comprehensive picture of a case (fragmentation).
- Completeness issues, whereby standard phrases and a wealth of detail make it difficult for clinicians to communicate the key aspects of the case. This entails a search cost on the part of a receiving clinician, in order to find information of value. (In contrast, paper notes are usually written in a manner that affords easy access to this material).
- Workflow issues, where ICT either forces clinicians to follow a linear (and inappropriate) workflow, or to abandon traditional workflows that suit the care setting in which they operate. This leads to workarounds, which can be a major source of error.
- Losses of communication, in which systems are relied upon for communicating task requests. The difference between communication and execution means that senders cannot ensure that receivers have actually processed a request. The human aspects of communication are elided, to the detriment of care.
- *Overload*, in which clinicians are bombarded by messages from decision support systems. This can lead to alert fatigue; in other cases, the clinician will ignore or disable the warnings.
- *Disrupting traditional processes*, where some of the checks and balances inherent in traditional approaches to care are removed.
- Errors in standards, which are difficult (if not impossible) for clinicians to detect. If errors in semantic interoperability standards arise, clinicians can no longer trust that the information that they receive about a patient's status means the same thing to them as it does to the clinician who was responsible for recording the information.

In short, the impact of ICT in a health care setting goes well beyond the predictable hardware and software failures studied in software and hardware engineering. ICT can have a profound impact on the way clinicians observe, communicate, reason, exercise judgment and execute tasks. At a high level, the systems with which a clinician interacts can act in several modalities. First, they act as enablers, allowing clinicians to perform a vast array of functions that are novel and useful. Second, they constrain clinicians in several key respects, including their ability to communicate, cogitate, and follow traditional workflows. Third, ICT can actually change the way clinicians observe and exercise judgment. Decision support systems, for instance, can suggest novel possibilities, while diagnostic aids or medical devices can actually furnish epistemological primitives by which clinicians form a

view of a case. In a sense, a clinician dealing with ICT begins to think in a fashion that mimics the design choices built into the technology (assuming she does not invent workarounds for every function).

In this respect, the impact of ICT on clinicians (and hence care delivery) is more profound than that of *policies and procedures*. The psychological effects of ICT are significant, capable of penetrating into basic cognitive processes such as reasoning and perception. Additionally, policies and procedures are typically drafted by health care practitioners, whereas ICT is often designed in isolation from clinicians, and then transplanted into an environment that could prove to be a mismatch.

(c) Evaluating the Current Approach to Institutional Liability

In this section, we assess the existing jurisprudence in terms of its adequacy for addressing the issue of ICT-related medical error. We begin with direct duties, followed by a consideration of vicarious liability.

(i) Is the Law of Direct Duties Sufficient?

In terms of *direct duties*, we saw that the courts have recognized several different species, including: (1) a duty to select competent staff, including physicians; (2) a duty to establish systems that positively impact patient safety and quality of care; (3) a duty to utilize adequate equipment, and; (4) a duty to ensure that proper coordination occurs, and that care programs operate as a "unified and cohesive whole." We also saw (via *Yepremian*) that the courts have not embraced a non-delegable general duty of care between a hospital and its patients.

The least promising direct duty concerns the obligation of the hospital to hire competent staff. None of the errors we outlined above depended on failings of individual skill, and some (such as cognitive impairment and overloading) would affect even the best practitioners. If interpreted broadly, the duty to provide adequate equipment could cover errors arising from poor user interface design. However, it could not cover the remainder of the issues; for instance, unanticipated uses are by definition unforeseeable by systems designers and health care administrators. ⁶⁹ The duty to ensure that proper coordination occurs (and that care programs operate as a "unified and cohesive whole") might cover the "losses of communication" issues we described above. The most promising duty consists of the obligation to put in place "safe systems." One could easily find an interpretation of this phrase that encompassed the user interface issues described above. ⁷⁰

⁶⁷ If the reader will recall, in *Granger*, *supra* note 10, the courts recognized a duty to provide "safe systems."

⁶⁸ Vuchar, supra note 14 in which hospitals were held liable for injury caused by inadequate equipment.

⁶⁹ Similarly, issues of completeness or overload are not straightforwardly addressed by the concept of "adequacy." Whether a system is biased towards providing the user with too much information (as in the case of a DSS) is a matter of systems design, with no clear normative standards at play to serve as guides.

For instance, juxtaposition errors are fairly obvious design flaws that can impact patient safety.

Despite this initial appeal, it is not sure the concept of a "safe system" can be extended to deal with the other issues that we identified above.

- First, from the case law, the scope of these duties seems to extend to policies and procedures that impact safety and quality of care. The courts explicitly highlight the need for written documents binding staff members to follow certain work processes. None of the issues that we have identified can be dealt with by policies and procedures alone, as they are inherent in the architecture and design of the ICT systems in question.
- Second, since any system has unanticipated uses (no matter how safely engineered), the concept of safety is not adequate for dealing with risks arising from this category of error.
- Third, extending the concept of "safety" to cover completeness, workflow, loss of communication and overload risks may be stretching the concept too far. Just about any hospital procedure can be interpreted to impact patient safety, including payroll and collective bargaining procedures. Some of the risks that we have outlined have implications for patient safety, but they are not inherently about safety. For instance, overload issues are just as much about cognitive impairment and job performance as they are about safety.
- Fourth, in many of our risks, safety issues lurk on both sides. Taking the issue of overload issues as an example, there are at least two competing arguments: (1) swamping clinicians with alerts creates safety issues by distracting them from other tasks, and; (2) not alerting clinicians creates safety issues by foregoing an opportunity to inform them of critical developments in a patient's trajectory of care.

We conclude, therefore, that the current common law approach to direct duties is not sufficient to deal with the issues arising from the use of ICT in health care. Absent a stronger duty of care, there are significant gaps in the common law's ability to address these issues.

(ii) Is the Law of Vicarious Liability Sufficient?

In our brief review of the jurisprudence, we saw that institutions are liable for actions of the majority of health care professionals, including nurses and residents. The Supreme Court (commenting on vicarious liability in general) has stated that in determining employee status, the courts should examine the total relationship between the parties, including factors such as control, opportunity for profit, and the degree of responsibility for management held by the worker.

Unfortunately, the law of vicarious liability is even less useful than the law of direct duties when it comes to addressing the errors we identified above. The main problem is that these errors are typically not the fault of staff members such as nurses, occupational therapists and imaging technologists. Instead, they are *systemic*, arising from the complex interactions between humans and software. As we have argued elsewhere, it would be difficult (and pointless) to try to attribute these

After all, if staff members go on strike, patients suffer.

systemic errors to the failings of individual practitioners.⁷² If we are to argue that the hospital should be liable for systemic errors arising from ICT, it should be on a different ground than vicarious liability.

(iii) The Tension between Institutions and Individual Practitioners

The jurisprudence pertaining to institutional liability is generally biased towards pinning responsibility for the quality of care onto physicians. In an age where hospitals were mere locations rented out by independent physician contractors, this tendency made perfect sense. However, modern health care has transcended this model in numerous ways. Not only is the complexity of care delivery much greater, but institutions are deploying ICT systems that have profound effects on health care practitioners. Hospitals may not exert full control over physicians and allied health professionals, but their power to adopt policies and procedures (e.g., quality of care, privacy) does grant them some measure of control. One of the novel contributions of this work is to point out that ICT has a more significant effect on health care practitioners than any policy could hope to achieve. ICT can not only influence workflows, but basic cognitive processes. Institutions are in a position to drastically influence the ability of health care professionals to make observations, reason about evidence, formulate plans and execute them. The systems that institutions put into place not only constrain practitioners, but transform their thought processes.

This is an important fact, as it has implications for the liability of health care professionals. In *Wilson v. Swanson*, 73 the Supreme Court of Canada considered several issues, including the standard of care required for surgeons. Justice Rand, speaking for the majority, stated that "[w]hat the surgeon by his ordinary engagement undertakes with the patient is that he possesses the skill knowledge and judgment of the generality or average of the special group or class of technicians to which he belongs and will faithfully exercise them." The jurisprudence has previously assumed that the exercise of skill, knowledge and judgment by a physician is independent of the control of the hospital. ICT invalidates this assumption. For instance, ICT may result in distraction, cognitive impairment, alert fatigue and other psychological impacts. Judgment may be impaired by completeness issues (the inability to source the most important information in time), or by overload from DSS systems.

While it may be the case that courts grappling with particular cases may recognize that an institution shares fault with a physician for errors arising from ICT, this result is by no means assured. Recognizing the impacts of ICT is a first step in developing a robust and considered response to the challenges of liability in this area.

(d) Is it Time for a New Direct Duty of Care?

In this section, we consider some arguments for adopting a new duty of care.

Williams & Kuziemsky, *supra* note 5.

⁷³ [1956] S.C.R. 804, 5 D.L.R. (2d) 113.

⁷⁴ *Ibid* at 811.

As indicated by the Supreme Court of Canada in *Cooper v. Hobart*,⁷⁵ the "*Anns*" test⁷⁶ is a useful framework by which courts may decide whether a new duty of care should be recognized. The *Anns* test has two components: (1) a *proximity branch*, which analyzes whether the harm was the reasonably foreseeable consequence of the defendant's act, and; (2) a *policy branch*, which asks whether there are reasons (notwithstanding the analysis in the proximity analysis) that tort liability should not be recognized.⁷⁷ We discuss both branches below.

(i) The Proximity Branch

This component of the *Anns* test focuses on factors arising from the relationship between the plaintiff and the defendant. The seminal case of McAlister (*Donoghue*) v. *Stevenson*⁷⁸ established that: (1) a person can be held liable only for reasonably foreseeable harm, and; (2) not all reasonably foreseeable harm will result in liability. Indeed, the *Anns* test buttresses reasonable foreseeability of the harm with considerations of *proximity*. If foreseeability and proximity are established at the first stage, a *prima facie* duty of care arises.⁷⁹

With respect to the notion of proximity, the term has been used to describe certain "close and direct" relationships between the plaintiff and defendant. ⁸⁰ According to the Court in *Cooper*, "[d]efining the relationship may involve looking at expectations, representations, reliance, and the property or other interests involved. Essentially, these are factors that allow us to evaluate the closeness of the relationship between the plaintiff and the defendant and to determine whether it is just and fair having regard to that relationship to impose a duty of care in law upon the

⁷⁵ 2001 SCC 79, [2001] 3 S.C.R. 537 [Cooper].

⁷⁶ The Anns test was introduced in Anns v. Merton London Borough Council, [1978] A.C. 728 (H.L.) [Anns].

Cooper, supra note 74 at para. 30. Also useful is the formulation of the Anns test in Hill v. Hamilton-Wentworth (Regional Municipality) Police Services Board, 2007 SCC 41 at para. 20, [2007] 3 S.C.R. 129 [Hill], where the Court stated that "[t]he test for determining whether a person owes a duty of care involves two questions: (1) Does the relationship between the plaintiff and the defendant disclose sufficient foreseeability and proximity to establish a prima facie duty of care; and (2) If so, are there any residual policy considerations which ought to negate or limit that duty of care?"

⁷⁸ [1932] A.C. 562 (H.L.).

⁷⁹ Cooper, supra note 4 at para. 30.

The Court in *Cooper* cited the following statement by Lord Atkin in *Anns*: "Who then, in law is my neighbour? The answer seems to be — persons who are so <u>closely and directly affected</u> by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question . . . I think that this sufficiently states the truth if <u>proximity</u> be not confined to mere physical proximity, but be used, as I think it was intended, to extend to <u>such close and direct relations</u> that the act complained of directly affects a person whom the person alleged to be bound to take care would know would be directly affected by his careless act." (*Anns*, *supra* note 75 at 580) Lord Atkin further claimed that a defendant "must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour" (*Anns* at 580).

defendant."⁸¹ The Court further notes that these factors are diverse, and depend on the circumstances of the case. Of particular utility are the *categories of negligence*, by which novel situations may be compared and classified; indeed, proximity may be established by reference to them.⁸² These categories are not closed.⁸³

Considering ICT-based medical error, there seems to be a prima facie case for *proximity*. First, errors by medical practitioners have been recognized as a category of negligence.⁸⁴ Second, many of the factors outlined in *Cooper* will be significant. To take but a single example, we say that the courts have recognized (e.g., *Yepremian*)⁸⁵ that patients have strong expectations of health care institutions, including trustworthiness, confidentiality, safety and quality of care. There seems to be no shortage of material from which to craft an argument that a close connection exists between institutions and patients.

Unfortunately, the major issue with ICT-based medical error concerns the requirement of *foreseeability*. First, many of these errors are not predictable until a system is brought into operation. Second, a large number of these errors result not from the system itself, but from the way in which individual users adapt their behaviour in response to it. Third, many ICT-related errors are low probability. It is an axiom of process re-engineering that improvements to any business (let alone health care) carry a certain element of risk. Stalling improvements to health care on the basis that they carry some residual risk of unpredictable error might result in worse outcomes in the long term.

⁸¹ Cooper, supra note 74 at para. 34.

⁸² *Ibid* at para. 31.

The Court in *Hill, supra* note 76 at para. 25, explains: "From time to time, claims are made that relationships hitherto unconsidered by courts support a duty of care giving rise to legal liability. When such cases arise, the courts must consider whether the claim for sufficient proximity is established. If it is, and the prima facie duty is not negated for policy reasons at the second stage of the *Anns* test, the new category will thereafter be recognized as capable of giving rise to a duty of care and legal liability."

Although we do not have space to investigate this claim, an argument could be made that institutional liability should fall under the category of professional negligence by health care practitioners. See our discussion on fiduciary obligations below for relevant material.

Supra note 17. It is interesting to note that one of the reasons that the court in Yepremian declined to impose liability on the hospital concerned the presence of an independent (non-employee) physician, who likely carried insurance for such eventualities. In the case of ICT-based medical error, the ultimate cause is systemic, and therefore not typically attributable to the failings of individual practitioners. If Yepremian had involved this type of circumstance, the court may have been compelled to delve more deeply into the relevance of a new duty of care.

For instance, introducing a new airline booking system will ultimately improve efficiency, but at the risk of disrupting operations and causing major losses in the short term.

We return to this theme below, when we discuss the deterrence objective.

(ii) The Policy Branch

In this stage of the *Anns* test, the court must consider whether there are "residual policy considerations outside the relationship of the parties that may negative the imposition of a duty of care." Since a thorough answer to this question is beyond the scope of this work, we content ourselves with a discussion of policy concerns that is organized according to the overarching goals of the law of torts.

Goal 1) Compensation:

On the positive side, there are several reasons for thinking that a new duty of care would serve the compensation objective. First, this objective may be frustrated if a new duty is not recognized, since a plaintiff who has suffered loss caused by systemic errors will likely be unable to show that individual health care practitioners (whether consultants or employees) were at fault. Second, courts sympathetic to the loss distribution theory of tort law should consider the possible advantages of transferring losses to the organizations deploying such systems, enticing them to improve their practices through making ICT deployment more expensive.

On the negative side, we note that courts should be wary of imposing additional costs on the health care system. Most health care institutions in Canada are publically funded, receiving most of their operating budgets from various levels of government, and not from user fees. Imposing additional costs on a health care system that is overburdened is a prospect that courts have not embraced wholeheartedly in the past.

In addition, the empirical evidence does not provide strong support for the efficacy of tort-based compensation. As noted by Brine, ⁹¹ very few patients who suffer injuries during stays in hospital receive any form of compensation for their loss. Recent research suggests that less than 10% of viable claims result in compensation. ⁹² Another issue is that the assessment of damages and compensation in the tort law system may be unpredictable, subjective, and predisposed to awarding large sums to patients who fit common patterns of injuries. ⁹³ This is a critical issue for ICT-related medical error, which are typically unpredictable, and capable of

Cooper, supra note 74 at para. 30. At para. 39, the court states that "[t]he second step of Anns generally arises only in cases where the duty of care asserted does not fall within a recognized category of recovery. Where it does, we may be satisfied that there are no overriding policy considerations that would negative the duty of care."

The case of *Frandle v. MacKenzie* (1990), 51 B.C.L.R. (2d) 190, 5 C.C.L.T. (2d) 113 (C.A.) serves as an example of a case in which the courts were willing to apportion fault between a hospital and its contractor physicians. However, this case did not involve systemic errors, so much as errors of judgment in a simple workflow.

⁹⁰ A.M. Linden, Canadian Tort Law, 6th ed. (Toronto: Butterworths, 1997) at 5.

For a discussion of the difficulties of using tort as a means of compensating patients who have incurred loss as a result of medical error, see Andrew Brine, "Medical Malpractice and the Goals of Tort Law" (2003) 11 Health Law J. 241 at 244.

⁹² R.G. Elgie, T.A. Caulfield & M.I. Christie, "Medical Injuries and Malpractice: Is it time for no-fault?" (1993) 1 Health Law J. 97 at 99 (cited in Brine, *supra* note 90).

Robert E. Astroff, "Show me the money!: Making the case for no-fault medical malpractice insurance" (1996) 5:3 Health L. Rev. 9 at 9 (cited in Brine, *supra* note 90).

occurring at low frequencies.⁹⁴ A tort system that is biased against low frequency errors may not be a good mechanism for providing compensation in this context.

Goal 2) Deterrence:

As describe in Linden,⁹⁵ three types of deterrence have been identified by legal scholars: (1) specific deterrence; (2) general deterrence, and; (3) market deterrence.⁹⁶ Specific deterrence focuses on the particular defendant, with the aim of encouraging her to alter her conduct. General deterrence aims at changing the behaviour of all members of society, by providing them with disincentives to engage in tortuous conduct. Lastly, market deterrence focuses on activities, as opposed to individuals; the goal is to make activities that are prone to accidents more expensive, by forcing those connected to them to bear the costs associated with tortuous incidents.

From an initial impression, it looks as though recognition of a new duty of care for ICT-based medical error may be compatible with the deterrence objective. Institutions facing liability for systemic errors may take more care in future; they may also pass costs along to the vendors and systems integrators who are responsible for designing and implementing the system.

Unfortunately, the situation is a bit more nuanced than an initial glance might convey. First, many of the errors associated with health care ICT are: (a) subtle; (b) impossible to predict, and; (c) visible only after the system is in operation. Apart from the fact that there are no best practices or sound methodologies to avoid some of these issues, we noted above that some risk is inherent in attempting any form of improvement in health care delivery. Discouraging institutions from carrying out upgrades and improvements to the health care system on the basis of unknowable residual risk is not a policy objective that many courts or lawmakers will embrace with relish.⁹⁷

Second, specific deterrence will fail if an organization is dealing with a systems-level error resulting from complex interactions. Unless the organization is omniscient, it will have only a dim grasp of how the error came to pass. Even with the information furnished by an investigation, the organization may be hard pressed to avoid errors of this type in future; indeed, they may never occur again, due to the fact that many ICT-based errors are highly dependent on the right confluence of circumstances. Complex, systems-level issues cannot be addressed using piecemeal, reactive mechanisms like tort actions; instead, they must be addressed using

Although some classes of error (e.g., errors in technical infrastructure and communications systems) may affect many patients at the same time, many of the errors that we have discussed will arise less frequently, harming one patient at a time. The variability in the frequency and scope of ICT-based medical error is one of the reasons that it is difficult to address using standard risk management techniques.

⁹⁵ Supra note 89.

⁹⁶ P.H. Osborne, *The Law of Torts* (Toronto: Irwin Law, 2000) at 13.

One could argue that frustrating advances in health care delivery methods could result in greater harm over the long term. Due to space constraints, we do not pursue this line of thought in this work.

broad, collaborative, and comprehensive approaches.⁹⁸

Lastly, public safety scholars have raised concerns about the deterrence value of tort law in the context of medical errors. One of the major issues is the phenomenon of *defensive medicine*, described by Astroff as "the unnecessary use of medical resources to protect against lawsuits and the refusal to provide care or adopt new methods of treatment for fear of increased liability exposure . . . "99 As Brine notes, some defensive medicine can be beneficial for patients, as in the case of a physician who increases her attention to detail, and seeks secondary opinions from colleagues. ¹⁰⁰ It may also stimulate organizations to fund risk management and quality assurance activities. ¹⁰¹ On the other hand, it could also decrease the willingness of organizations to experiment with new care delivery methods. On an empirical level, Elgie et al conclude that "[t]he best estimate is that tort law has only a tangential effect on the quality of health care." ¹⁰²

Goal 3) Psychological Redress:

A new duty of care may fulfill important aims of tort law connected to human psychology. In Linden's words, tort law may counteract the feelings of alienation and despair that are evoked in a society in which large institutions that control many aspects of life (e.g., government agencies) have become "too large and impersonal." ¹⁰³

For a defense of this claim, see Australia, *Tackling Wicked Problems: A Public Policy Perspective* (Sydney, Commonwealth of Australia: Australian Public Service Commission, 2007). Interestingly enough, research shows that complex cases are more likely to lead to malpractice claims. See S.L. Clark et al, "Improved outcomes, fewer caesarean deliveries, and reduced litigation: results of a new paradigm in patient safety" (2008) 105 Am. J. Obstet. Gynecol. 199.

Additionally, various researchers have noted the fact that medical errors are often due to other systematic issues such as poor communication or information flows. They further claim that these systematic issues will still exist, regardless of the state of malpractice suits or tort law developed to prevent errors. See, for instance, Ash et al, *supra* note 46 and R. Koppel et al, *supra* note 60.

⁹⁹ *Supra* note 98 at 12.

A recent article has claimed that physicians may be biased to treat patients in a mechanistic manner, creating an atmosphere conducive to the occurrence of error. The same article cites a breakdown in the patient-physician relationship as a driver of defensive medicine. See W. Kondro, "Medical errors increasing because of complexity of care and breakdown in doctor-patient relationship, physician consultant says" (2010) 182:13 CMAJ e645.

¹⁰¹ Brine, supra note 90 at 252.

¹⁰² *Supra* note 91.

Linden, supra note 89 at 18. Systemic errors that cause injury are by definition impersonal, as there is no single agent who can be blamed for the loss.

Goal 4) Education:

Some scholars have promoted tort law as a means of providing education. ¹⁰⁴ As Klar notes, many losses tend to occur through ignorance, rather than through intentional adoption of more risky forms of behaviour. ¹⁰⁵ Second, tort law may serve to reinforce key cultural or moral values. According to Linden, tort law enshrines some of the traditional moral principles of Anglo-American society, ¹⁰⁶ such as the notion of *individual responsibility*. Third, tort law may reinforce attitudes of respect for human dignity, and of the importance of recognizing individual interests.

While a direct duty of care for ICT-based error may provide some reinforcement of the dignity of the individual, it is clear that there are major deficiencies on the other fronts. First of all, the type of education function alluded to by Klar works where an individual is confronted with a set of options, of which several are unacceptably risky. It is not clear that education works with an institution that is presented with unknown, unanticipated and system level risks associated with deployment of ostensibly useful information technology. Second, the notion of individual responsibility is not particularly useful in dealing with losses arising from systemic errors that by definition are not the result of the failings of an identifiable set of individuals.

(iii) Other Considerations

One of the main challenges with defining a duty of care in support of tort liability for institutions is the difficulty involved in formulating a proper standard of care. In the case of health care ICT, we have seen that many of the major risks that arise are impossible to anticipate, manifesting themselves only after a system has been put into operation and the transformation of user behaviour has begun to occur. In many cases, there may be no way to design a system that lacks risks, and any modification will merely trade off one set of risks for another. This complexity (together with the novelty of the domain) make it difficult to formulate systems engineering practices that would serve as a standard of care for institutions deploying ICT systems. There is simply no body of art or expertise to rely upon in evaluating whether an institution met the standard of care. Of course, some errors may be so glaringly obvious and predictable that courts may feel that liability is warranted, but this would be an exceptional case. As we stated above, in order to improve health care, some risks must be taken, and some lessons learned. The nature of the complex interactions between ICT systems and health care practitioners means that some of these lessons will be learned the hard way.

(e) Alternatives to a New Duty of Care

Lastly, we should mention that there are at least two alternatives open to those

In the healthcare domain, tort is particularly effective in this regard if the results of lawsuits are taken up and disseminated by the media, trade associations or industry groups.

L.N. Klar, Tort Law, 2d ed. (Toronto: Carswell, 1996) at 15.

¹⁰⁶ Linden, supra note 89 at 14.

sympathetic to the plight of patients who have incurred ICT-related losses.

(i) No Fault Compensation

While the literature on this topic is far too expansive for us to provide an overview in this work, we should mention that no-fault compensation schemes might be an attractive alternative to imposing liability on institutions through tort law. Since the public would bear the cost of the liability in either case, this approach would have the advantage of further burdening an overtaxed court system. In addition, since individuals suffering from ICT-related medical error are unlikely to achieve psychological gratification from a court case, the impersonal and faceless nature of no-fault compensation is not a drawback. 107

(ii) Fiduciary Duties

A second alternative involves the law of fiduciary duties. ¹⁰⁸ Although it is difficult to succinctly define the notion of a fiduciary duty precisely, a fiduciary is an actor who is required to look after the interests of others with vigilance, dedication and selflessness. ¹⁰⁹ A fiduciary voluntarily accepts legal constraints upon its ability to act; as a result, self-interested actions that violate the fiduciary duty are not merely ethical transgressions, but breaches of a legal duty.

In considering the utility of the law of fiduciary duties to the problem of ICT-related medical error, we must ascertain: (1) what relevant fiduciary duties exist, and; (2) what obligations follow from them. While Canadian courts have unequivocally recognized a physician's fiduciary duties to her patient, ¹¹⁰ the jurisprudence on institutional duties is less clear. Litman argues that the indicia ¹¹¹ of fiduciary

In cases of systematic error (particularly where multiple institutions are involved), it is unlikely that legal action will identify an individual who is responsible for the loss. The distributed fault inherent in systems-level issues makes it difficult for a claimant to take solace in the knowledge that the right people have been "taught a lesson."

Due to space constraints, we can only make a preliminary investigation into the utility of fiduciary law for addressing ICT-related medical error.

For a detailed discussion of the nature of fiduciary duties, see M.M. Litman, "Fiduciary Law and For-Profit and Not-For Profit Health Care", in Timothy A. Caulfield & Barbara von Tigerstrom, eds., *Health Care Reform and the Law in Canada: Meeting the Challenge* (Edmonton, Alta.: University of Alberta Press, 2002) 85 [Litman, "For-Profit"].

For a recent example, see *McInerney v. MacDonald*, [1992] 2 S.C.R. 138, 93 D.L.R. (4th) 415 in which the Court held at para. 28 that a physician's fiduciary duty can be superseded by concerns that are "connected to the safety of individuals or of the public".

Helpful guidance on recognizing fiduciary relationships was introduced in *Frame v. Smith*, [1987] 2 S.C.R. 99 at para. 60, 42 D.L.R. (4th) 81, in which Justice Wilson set out three characteristics (*indicia*) seemingly possessed by fiduciaries. First, they have the scope for the exercise of some discretion or power. Second, they can affect the legal or practical interests of beneficiaries through the unilateral exercise of their discretion or power. Third, beneficiaries are peculiarly vulnerable to or at the mercy of fiduciaries holding the discretion or power.

duties are not an "impediment" to the claim that health care providers and health authorities are fiduciaries, ¹¹² noting that: (1) patients are almost always at the "mercy" of their health care providers; (2) patients are vulnerable and completely dependent on the institution in which they are receiving care; (3) institutions and their staff have specialized and sophisticated knowledge, and are gatekeepers with respect to important services, procedures and drugs, and; (4) patients have very little scope to personally take precautions to avoid the risks posed by the institution. ¹¹³

However, the presence of these factors is not conclusive of the existence of a fiduciary relationship. As an empirical matter, fiduciary duties are often demarcated by *pledges of loyalty*, and the Supreme Court has developed test to recognize them, namely: (1) an undertaking by a party to selflessly and exclusively dedicate oneself to the interests of another; (2) a reasonable expectation of such dedication, or; (3) a reasonable basis for reliance on such a dedication. Factors determining whether such a *reasonable expectation* exists include: (a) the presence or absence of "trust" and "confidence"; (b) the sophistication of the services being provided, and; (c) the level of fidelity implicated in relevant community and industry standards. Is

Litman claims there is "good reason to believe that fiduciary obligations owed to patients [by physicians] extend beyond physicians to other health care providers . . . as well as to hospitals and health authorities." His arguments are: (1) that the early trends in the case law support this; (2) that the propensity for institutions to enact policies, procedures, protocols and practice guidelines indicates commitments or pledges to dedicated service; (3) that certain legislative trends align with this view; (4) the roles of non-physician health care providers suggest that they have the same fundamental mandate as physicians; 117 (5) the case law is compatible with this claim, with the courts having agreed that the fiduciary status of health care institutions is an issue to be established on the facts of each case. 118

Even if Litman is correct, an attempt to use fiduciary duties to establish institutional liability for ICT-related medical error will founder when one ponders the obligations owed by institutions (as fiduciaries) to patients. One of the dominant themes in the jurisprudence is that a fiduciary must "promote the best interests" of beneficiaries. In short, it is difficult to argue that ICT-related medical errors are

M. Litman, "Fiduciary Law in the Hospital Context" (2007) 15 Health Law J. 295 at 307 [Litman, "Hospital Context"].

These reasons can also be invoked in arguing that hospitals have a duty of care.

Litman, "For-Profit", *supra* note 108 at 89.

Litman, "Hospital Context", supra note 111 at 311, citing Justice La Forest in Hodgkinson v. Simms, [1994] 3 S.C.R. 377, 117 D.L.R. (4th) 161.

¹¹⁶ *Ibid*

In particular, Litman cites the use of health care teams. For more on this issue, see our recent paper, *supra* note 5.

Litman, "Hospital Context", *supra* note 111 at 317.

¹¹⁹ Ibid at 319. This duty to act in the "best interests" of a beneficiary can be overridden by other objectives in compelling circumstances. Examples from the hospital context include prioritization (e.g., scheduling surgeries) and cost containment. As a matter of

a violation of this type of duty. First, these errors arise when institutions deploy new systems in an effort to improve their health care delivery methods; ¹²⁰ this does not fit the model of a failure to respect "best interests." Second, many of the fiduciary issues that arise in medical contexts are analyzed by the courts with the help of concepts like "trust" and "confidence"; while applicable to many situations, it is difficult to see how these apply to ICT-based medical error. Third, Litman notes that the "gravamen of fiduciary misconduct is a failure of loyalty." ¹²¹ The courts may have a difficult time interpreting failures in systems design and implementation as a failure of loyalty. The errors that we outlined in previous sections are difficult to anticipate, arising only when systems are deployed in a health care environment. In doing so, institutions are not deliberately overriding best interests; in fact, they undertake projects precisely to improve either the quality or efficiency of care.

CONCLUSION

This work has concerned itself with errors arising from the introduction of ICT systems into health care settings. We have seen that health care ICT can have profound impacts on the health care practitioners who interact with it. The introduction of ICT into health care institutions can transform workflows, disrupt communication, and result in profound impacts on the cognitive abilities of clinicians. These impacts can be so powerful that they eclipse other control mechanisms used by health care institutions, such as policies and procedures.

The medical errors that can arise from healthcare ICT are numerous. Most of them are difficult to rectify, and almost impossible to anticipate in advance of a system actually being put into an operational environment. Many of the errors that result are system-level issues, not attributable to the failings of individual care providers. Other forms of errors occur when clinicians are affected by the cognitive impacts of healthcare ICT, resulting in losses apparently caused by individual practitioners, but ultimately traceable to systems-level concerns.

In this paper, we argued that holding individual practitioners accountable for systems-level errors is untenable. At some point, systems-level actors must take responsibility. As a result, we investigated mechanisms by which institutions could be held liable for their ICT initiatives. After discovering that the current law of direct duties and vicarious liability was not up to the task, we engaged in a high level discussion of whether a new duty of care is warranted. Examining the rationales of tort law and the difficulties involved in formulating a standard of care, we noted that many problems lie in wait for proponents of this approach. As alternatives, we mentioned the law of fiduciaries, as well as no-fault compensation schemes.

Due to the complexity of the issues involved, we could only make a preliminary effort to address institutional liability for healthcare ICT related error. Al-

general interest, Litman mentions that the best interest test makes sense in the context of health care, as health care decisions involve a "limited number of alternatives." We do not have space to pursue this avenue of thought.

As we noted in the case of tort law, improvements come with a price tag.

Litman, "Hospital Context", *supra* note 111 at 324.

INSTITUTIONAL LIABILITY IN THE E-HEALTH ERA 309

though we are not certain of which direction will be most appealing to the courts, we are entirely certain that this type of error will become more frequent as health care becomes more complex. It is well past time to revisit the liability of health care institutions.