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DISCLOSING PATIENT SAFETY INCIDENTS

Early in its mandate, the CPSI identified the disclosure of adverse events (harmful incidents) and open communication and sharing of information between health-care providers and patients as key to building a culture of safety. However, it has only been in recent years that the disclosure of patient safety incidents to patients and families has been encouraged and adopted as an expected standard of practice in the Canadian health-care system.

At the inception of CPSI in 2003, there were isolated initiatives in Canada to improve the quality of communication around patient safety incidents, driven by professional regulators. There was however little or no consistent practice or guidance of practice across geographic regions, health professions or health-care organizations. Most significantly, the culture of communicating with patients and families about patient safety incidents was characterized by considerable fear and uncertainty, and resulted in great caution and reserve in approaching such communication. This was the impetus to the development of policies that would require a more open and transparent communication with patients when health care "goes wrong."

The Canadian Disclosure Guidelines Working Group was established by CPSI in 2005 to develop these policies. The key issues that had to be addressed were:

- identifying circumstances that should trigger disclosure;
- emphasizing that disclosure is a process not an event; encouraging disclosure as soon as practicable after a patient-safety incident, even if a full investigation is still to come;
- providing guidance on the essential disclosure elements of explanation and apology;
- viewing explanation and apology through the eyes of the patient as well as the health-care provider, but not forgetting the collateral risk to provider morale;
- promoting the integration of disclosure with other key elements of a healthcare culture of patient safety; and
- identifying particularly challenging factors affecting disclosure, such as language, culture, patient age and capacity.

Concerns about civil liability and professional discipline were prevalent themes of consultation and discussion. These concerns were addressed in part by the demonstrated absence of case law precedent directly connecting early disclosure and

liability, and in part by a willingness to balance the risk of increased liability and/or litigation against the benefits of early and open disclosure.

The Canadian Disclosure Guidelines were published in 2008 and this represented a significant achievement in health care in Canada, influencing professional and regulatory policies and health-provider education.

Following the release of the Canadian Disclosure Guidelines in 2008, a focus on patient engagement and the introduction of disclosure and apology legislation in several provinces across Canada incited a critical assessment of the recommended elements of disclosure process, resulting in the need to revise and update the Guidelines. Since then, a culture shift in communication around patient safety incidents has percolated throughout the health system and professional practice across Canada.

Between 2008 and 2011, a smaller Working Group undertook the task of refining the Guidelines and a review process was commenced which considered key learnings from Canadian and international disclosure processes for both individual incidents and large scale events managed over the previous three years. The Working Group focused on several key themes identified through the consultation and emerging literature:

- enhancing patient-centredness by explaining disclosure predominantly through the lens of reasonable patient needs and expectations;
- making apology more direct ("we are sorry") and putting it at the front and centre of disclosure;
- rebalancing system and individual accountability for patient safety incidents (which, in the pre-2008 period, was heavily biased towards framing all patient safety incidents as system failures) while emphasizing that individual accountability must be assessed in a just and fair way; and
- providing more concrete guidance for health-care professionals and organizations on how to disclose to many patients affected by a single-patient safety incident, expense reimbursement related to the disclosure process, and on how to adapt disclosure best practices where language, culture and capacity issues are present.

Canadian Disclosure Guidelines: Being Open with Patients and Families was released in November 2011.

While there had previously been legal cases dealing with disclosure of adverse events or the potential for adverse events as an aspect of informed consent, the 1985 decision of

Mr. Justice Krever of the Ontario High Court in *Stamos v. Davie*,[1985] O.J. No. 2625 (H.C.) appears to be the first legal case to deal, squarely, with the duty to disclose patient safety incidents.

In the *Stamos* case, a patient's spleen was pierced while he was undergoing a needle biopsy of his lung. This caused the patient to bleed. The patient was subsequently discharged and had to be returned to hospital in order to undergo surgical removal of his damaged spleen. The physician failed to notify the patient of the injury to his spleen. Justice Krever found that the physician was negligent for injuring the spleen and also found that the physician had a legal duty to inform the patient of events which occurred during the biopsy. Justice Krever made a finding that the failure to advise the patient of the injury to his spleen did not have a causative link to the damage suffered by the patient, and accordingly no damages were ordered in relation to the failure to disclose. Justice Krever further found that while some the actions of the physician in relation to the injury to the patient's spleen could have been classified as errors in judgment the cumulative effect was negligence. It is interesting to speculate as to whether the failure to disclose played any role in tipping Justice Krever's decision toward negligence versus an error in judgment.

The assertion that physicians and possibly other health-care providers and organizations have a duty to disclose is supported by the decision in *Vasdani v. Shemi,* [1993] O.J. No. 2625. In addition, the Courts' willingness to award punitive damages in situations where the involved health-care professional's behaviour is judged to be egregious in the circumstances is shown in the *Gerules v. Flores*, [1995] O.J. No. 2300 (C.A.) and *Shobridge (supra)* decisions.

Courts in other provinces have also rendered decisions that support the duty to disclose adverse events, for example *Kueper v. McMullin* (1986), 73 N.B.R. (2d) 288 (C.A.) and *Kiley-Nikkel v. Danais*, [1992] 16 C.C.L.T. (2d) 290 (Que. S.C.).

More recently, in the Newfoundland and Labrador case of *Rideout v. Labrador Corp* ([2007] N.J. No. 292 (NLTD), Russell, J. explicitly recognized that compensation was not the only goal of the class action litigants. In *Rideout*, a large number of people were affected by the hospital's failure to properly sterilize gynaecological equipment. The Hospital discovered the problem in March of 2003, corrected it, and advised the patients in November of 2003. The 333 plaintiffs in *Rideout*, made up of patients and their spouses who did not contract any infection, brought a class action against the hospital corporation. The representative Plaintiff indicated that she heard about the issue from the press release before she received the letter directed to her, that the

news left her "distraught, horrified and in a state of nervous shock" and that she "feared for her health and the health of her family".

Ultimately, the Court in *Rideout* found that the compensation proposed in the settlement was within range and that the non-monetary relief "which the Representative Plaintiff stated was her first priority (and which many of the 10 objectors to the settlement noted as being important) is something which could only be achieved by settlement and not something the Court would have jurisdiction to grant if the matter proceeded to trial".

The Court in *Rideout* clearly identified the broad goals of litigation, beyond compensation for damage suffered, and the fact that Courts may lack the jurisdiction to provide the remedies which may best address those goals.

Some provinces have a legislative obligation to disclose patient safety events. For example, both Manitoba and Quebec have statutes (respectively the *Regional Health Authorities Act*, C.C.S.M., c. R34, s. 53.2(2) (hereinafter the Act) and *An Act Respecting Health Services and Social Services* (R.S.Q., c. S-4.2) which require health authorities or health institutions to disclose adverse events (in the case of Manitoba "critical incidents" as defined in section 53. 1 of the Act) to those affected by the adverse event, however, as indicated by Gerald Robertson[9] these statutes fall short of requiring health professionals themselves to disclose such incidents. The Manitoba statute goes further and also requires disclosure centrally to the relevant regional health authority (section 53.3(4) of the Act) and to the Manitoba Minister of Health (section 53.3(5) of the Act).

While most provinces lack legislated requirements to disclose patient safety incidents, there are ample policy and guidelines supporting this requirement at the federal and provincial levels across Canada.

There is strong evidence that the disclosure of patient safety incidents to affected patients is legally required now and may always have been required in Canada, except in rare instances. Specifically, the disclosure of adverse events may not be required or appropriate in those rare instances where the detriment or risk of detriment to the patient outweighs the benefit to the patient. This exception cannot be taken lightly and should not be considered outside the context of an established and comprehensive process to reach such a decision.

Disclosure is but one important component of responding to and managing patient safety incidents. The analysis of these incidents can yield important information to

reduce or prevent harm recurrence. Many tools are available to support healthcare providers and organizations in responding to, analyzing and learning from patient safety incidents. The next article in this series from CPSI will focus on the Canadian Incident Analysis Framework.