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ARTICLES

Editor's Note

*Jennifer Anderson**

This issue of the *McGill Journal of Law and Health* brings together the diverse research projects of eight scholars. Yet despite this diversity, one particular theme emerges: the rights of patients and their families across Canada. Toutes les contributions de ce numéro de la *Revue de droit et santé de McGill* en appellent aux gouvernements ainsi qu'aux tribunaux pour sauvegarder les intérêts de l'individu touché par des problèmes de santé.

In the first article, Dave Snow, Françoise Baylis, and Jocelyn Downie examine the Canadian federal government's persistent failure to regulate the payment of surrogate mothers and gamete donors participating in assisted reproduction, as the *Assisted Human Reproduction Act* explicitly provides. The authors hypothesize various reasons why this gap in the regulations has remained and determine that each of the reasons is untenable. Their concluding call for the government to enact the required legislation will surely be welcome among patients involved in assisted reproduction – both donors and recipients.

The second article in the issue, by Ghislaine Mathieu and Bryn Williams-Jones, takes a detailed look at the issue of high-risk medical devices. Their comparative examination of the regulations and practices adopted in Australia, Canada, the European Union, Japan, and the United States raises questions as to whether ethical considerations are sufficiently well addressed at both the premarket and post-market stages. They argue that there is at present a lack of premarket evidence, post-market disclosure, and long-term tracking of device performance, all of which create a situation in which patients and clinicians may be ill-informed of the risks and benefits associated with using these devices. Acknowledging that high-risk devices are frequently used in particularly vulnerable patients who face few remaining options for treatment, the authors recommend greater harmonization across jurisdictions and improvements to the regulatory framework.

In the third article, Louise Bélanger-Hardy and Caroline Quesnel explore the tension at the heart of "patient safety incidents," also known as "adverse events." While the reporting and sharing of information around such incidents is regarded as critical for continuous quality improvement, health care institutions are reticent to disclose information that may expose them to liability; across Canada, the provinces and territories have responded by enacting qualified privilege laws to shield institutions from this sort of disclosure. Through an examination of the

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* Editor-in-Chief, *McGill Journal of Law and Health*, Vol. 9.

legislation and case law, the authors conclude that the courts' strict reading of the relevant statutes creates a "balancing of interests" approach that is appropriate in the current context.

Finalement, dans le quatrième article de ce numéro, Catherine Paschali se confronte aux grandes questions scientifiques, juridiques et éthiques qui entourent le patient en état végétatif qui ne demeure vivant que grâce aux interventions médicales. Elle examine l'état du droit canadien pour le médecin voulant refuser ou cesser le traitement, ainsi que pour les proches du patient qui exigent des soins continus. Après une analyse détaillée, l'auteure conclut en préconisant les initiatives visées à l'encouragement des directives anticipées et à la transparence et la communication ouverte entre les hôpitaux, les médecins et les familles de ces patients.

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The *McGill Journal of Law and Health* is grateful for the collaboration of all of the authors who appear in this issue. Likewise, we cannot overstate our appreciation for the work of the countless peer reviewers from Canada and around the world who commented on all of our submissions this year. As Editor-in-Chief of Volume 9, I also wish to express my sincere thanks to every member of the Editorial Board and the Executive French and English Editors at the helm of the Board for their work on the articles that appear in this issue and those in the previous volume. The articles in Issue 9:1 were brought to completion by the Volume 10 Executive English and French Editors, Editor-in-Chief, and Editorial Board members, who are greatly deserving of thanks as well.

Widening our lens from the journal-as-publication to the journal-as-institution, I would like to express my personal appreciation for the members of all the Boards for the many projects they brought to fruition during my year as Editor-in-Chief. Most importantly, I am enormously grateful to every member of the Executive Committee in Volume 9: Samantha Allen, Benny Chan, Nicolas Charest, Katarina Daniels, David Hamel, and Hersi Hujaleh. It was my privilege to work with all of you. Last but not least, my considerable thanks are also owed to the journal's Faculty Advisor, Professor Alana Klein, for her support and encouragement.

Bonne lecture!

Jennifer Anderson

Why the Government of Canada Won't Regulate Assisted Human Reproduction: A Modern Mystery

*Dave Snow, Françoise Baylis & Jocelyn Downie**

The Canadian *Assisted Human Reproduction Act* (*AHR Act*), passed in 2004, prohibits both paying consideration to a surrogate mother and purchasing sperm and ova from a donor (sections 6–7). Both prohibitions are subject to section 12, which was intended to permit reimbursement of expenditures incurred by surrogate mothers and gamete donors and reimbursement for loss

La *Loi sur la procréation assistée* canadienne, adoptée en 2004, interdit à la fois la rétribution d'une mère porteuse et l'achat de spermatozoïdes et ovules d'une donneuse (articles 6–7). Les deux interdictions sont soumises à l'article 12 qui visait à permettre le remboursement des frais encourus par les mères porteuses et les donneurs de gamètes ainsi que le remboursement des

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Citation: Dave Snow, Françoise Baylis & Jocelyn Downie, "Why the Government of Canada Won't Regulate Assisted Human Reproduction: A Modern Mystery" (2015) 9:1 McGill JL & Health 1.

Référence : Dave Snow, Françoise Baylis et Jocelyn Downie, « Why the Government of Canada Won't Regulate Assisted Human Reproduction: A Modern Mystery » (2015) 9 : 1 RD & santé McGill 1.

of work-related income for surrogate mothers. Remarkably, more than ten years after the *AHR Act* received Royal Assent, and in spite of repeated calls for greater legal clarity, Health Canada has not drafted regulations pursuant to section 12 of the *AHR Act*, which is not yet in force. In this paper, we speculate as to possible reasons why the Conservative government (2006–2015) did not draft regulations, and we explain in turn why each of the possible reasons for inaction is flawed. In light of our rejection of all of the reasons we could imagine, we argue that Health Canada should both explain and justify its failure to draft the regulations that would set the stage for Parliament to bring section 12 into force. It must do so if the federal government is to meet the *AHR Act*'s goal of protecting children, women, and men engaged in, or affected by, surrogacy and third-party egg production.

pertes de revenus d'emploi pour les mères porteuses. Chose étonnante, plus de dix ans après que la *Loi sur la procréation assistée* a reçu la sanction royale, et en dépit des appels répétés pour une plus grande clarté juridique, Santé Canada n'a établi aucun règlement conformément à l'article 12 de la *Loi*, qui n'est toujours pas en vigueur. Dans cet article, nous nous interrogeons quant aux raisons possibles pour lesquelles le gouvernement conservateur (2006–2015) n'a établi aucun règlement et nous expliquons tour à tour pourquoi chacune des raisons possibles de cette inaction est peu convaincante. Compte tenu de notre rejet de toutes les raisons que nous puissions imaginer, nous demandons à Santé Canada d'expliquer et de justifier son refus d'établir les règlements nécessaires pour faire en sorte que l'article 12 entre en vigueur. Il doit ce faire, pour que le gouvernement fédéral puisse atteindre l'objectif de la *Loi sur la procréation assistée*, qui vise à protéger les enfants, les femmes et les hommes engagés dans, ou affectés par, la maternité de substitution et la production d'ovocytes pour autrui.

Introduction

Policy options regarding payment for contract pregnancy and for human eggs vary around the globe. For example, in some countries, such as India and much of the United States, there are largely unregulated free markets in assisted human reproduction.[1] In other countries, such as the United Kingdom, there are legal limits on payments to gestating women and there is a flat fee for egg providers.[2] In still other countries, such as France, there is an outright ban on contract pregnancy, but reimbursement of expenses is permitted for egg donation.[3] In Canada, the issue of legal reimbursement for contract pregnancy (designated "surrogacy" in the legislation) and human eggs is both complex and contested – unnecessarily so, we would argue.

While many believe that Canada prohibits payments but permits reimbursements for surrogacy and human eggs, what happens in practice is not quite so simple. There is a clear legal prohibition on payments, but next to no enforcement of this prohibition.[4] To be specific on this point, there is considerable evidence of commercial transactions in Canada[5] for both surro-

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1 Aaron D Levine, "Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors" (2010) 2:1 Asian Bioethics Rev 36; GKD Crozier & Dominique Martin, "How to Address the Ethics of Reproductive Travel to Developing Countries: A Comparison of National Self-Sufficiency and Regulated Market Approaches" (2012) 12:1 Dev World Bioeth 45.

2 Françoise Shenfield et al, "Cross Border Reproductive Care in Six European Countries" (2010) 25:6 Hum Reprod 1361 at 1367; Guido Pennings et al, "Socio-Demographic and Fertility-Related Characteristics and Motivations of Oocyte Donors in Eleven European Countries" (2014) 29:5 Hum Reprod 1076 at 1085.

3 Pennings et al, *supra* note 2 at 1081, 1087–88.

4 Françoise Baylis & Jocelyn Downie, "Wishing Doesn't Make It So" (17 December 2013), *Impact Ethics* (blog), online: <impactethics.ca/2013/12/17/wishing-doesnt-make-it-so>.

5 Alison Motluk, "The Human Egg Trade", *The Walrus* (April 2010), online: <thewalrus.ca/the-human-egg-trade>; Tom Blackwell, "Canadian Fertility Consultant Received $31K for Unwittingly Referring Parents to U.S. 'Baby-Selling' Ring", *National Post* (15 December 2013), online: <news.nationalpost.com/2013/12/15/canadian-fertility-consultant-received-about-30000-for-unwittingly-referring-parents-to-u-s-baby-selling-ring>. The evidence here consists in media reports and not peer-reviewed literature. On this we offer two comments. First, there are no peer-reviewed articles reporting on empirical

gacy and human eggs,[6] and yet our research reveals that there has only been one conviction in the last ten years.[7] Moreover, while Parliament intended to permit reimbursement of receipted expenditures and, for surrogate mothers, reimbursement for loss of work-related income incurred during pregnancy, the regulations required to give effect to this intent have never been drafted.[8]

The Canadian *Assisted Human Reproduction Act* (*AHR Act*),[9] passed in 2004, prohibits paying consideration to a surrogate mother or someone acting on her behalf, as well as purchasing sperm or ova from a donor or someone acting on behalf of a donor.[10] Both of these prohibitions are subject

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research in this area, not least because such research would require research participants to admit to legally questionable activities. Second, Motluk is a highly regarded investigative journalist. Her article on the human egg trade in Canada (which includes evidence of cancelled cheques) won a silver 2011 National Magazine Award for investigative journalism.

6 There is also evidence of Canadians' involvement in transnational surrogacy and egg selling. While a discussion of the extraterritorial application of the *Assisted Human Reproduction Act* is beyond the scope of this article, two of the authors have addressed this issue in previous work. See Jocelyn Downie & Françoise Baylis, "Transnational Trade in Human Eggs: Law, Policy, and (In)Action in Canada" (2013) 41:1 JL Med & Ethics 224. For an alternative perspective, see Susan G Drummond & Sara R Cohen, "Eloquent (In)Action: Enforcement and Prosecutorial Restraint in the Transnational Trade in Human Eggs as Deep Ambivalence about the Law" (2014) 26:2 CJWL 206.

7 In December 2013, in an unreported decision, Leia Picard, the director of Canadian Fertility Consulting Ltd., received a fine of $60,000 after admitting to violating sections 6 and 7 of the *Assisted Human Reproduction Act*, SC 2004, c 2 [*AHR Act*]. See Public Prosecution Service of Canada, *Annual Report 2013–2014* (Ottawa: Office of the Director of Public Prosecutions, 2014) at 15, online: <www.ppsc-sppc.gc.ca/eng/pub/ar-ra/2013_2014/ar14-ra14.pdf>; see also *R v Picard and Canadian Fertility Consulting Ltd* (2013), Agreed Statement of Facts, online: Novel Tech Ethics <www.dal.ca/content/dam/dalhousie/pdf/sites/noveltechethics/AHRA_Facts.pdf> [*R v Picard*, Agreed Statement of Facts].

8 Downie & Baylis, *supra* note 6 at 229; Françoise Baylis, Jocelyn Downie & Dave Snow, "Fake It Till You Make It: Policymaking and Assisted Human Reproduction in Canada" (2014) 36:6 J Obstet Gynaecol Can 510.

9 *AHR Act*, *supra* note 7.

10 *Ibid*, ss 6–7. Because of existing regulations for the processing and distribution of sperm, there is an established pattern for sperm in contrast to the uncer-

to section 12 of the *AHR Act*, which, once in force, is expected to permit reimbursement of expenditures incurred by surrogate mothers and gamete donors and, for surrogate mothers, reimbursement for loss of work-related income incurred during pregnancy. Until 2012, when the *AHR Act* was amended by Parliament,[11] such reimbursement was to be permitted provided (i) there were receipts for the expenditures or a certificate from a qualified medical practitioner and (ii) the reimbursement was made "in accordance with the regulations and a licence."[12] In 2012, the requirement for a licence was eliminated.[13]

As such, in Canada, once section 12 comes into force, reimbursement for women who provide gestational services or eggs for third-party reproduction should be permissible, provided they have receipts for the expenditures or, in the case of surrogate mothers, a properly executed certificate from a qualified medical practitioner, and also provided the reimbursement is made in accordance with the regulations. But herein lies the rub: section 12 cannot be brought into force in any meaningful way[14] because there are

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tainty for eggs and surrogacy. See *Processing and Distribution of Semen for Assisted Conception Regulations*, SOR/96-254. While we recognize that the introduction of regulations under section 12 of the *AHR Act* could confirm or change existing practices regarding the distribution of sperm, a discussion of this matter is beyond the scope of this paper.

11 *Jobs, Growth and Long-Term Prosperity Act*, SC 2012, c 19, ss 713–53 [*Prosperity Act*].

12 Sections 12(1) and 12(3)(b) of the original *Assisted Human Reproduction Act*, SC 2004, c 2 [*AHR Act* (2004)], prior to amendment by the *Prosperity Act*, *supra* note 11. For the text of the *Act* as it appeared from 1 December 2007 to 15 March 2012, see online: <laws-lois.justice.gc.ca/eng/acts/A-13.4/20071201/P1TT3xt3.html> (amendments prior to 2012 did not concern section 12).

13 *AHR Act*, *supra* note 7, s 12. Prior to 2012, section 12 was under the "Controlled Activities" category of the *AHR Act*, which listed activities that would be permitted only in accordance with regulations and a licence. In 2012, the legislature removed the "Controlled Activities" category and moved section 12 into the "Prohibited Activities" category. In addition, the legislature eliminated the requirement for a licence, but maintained the requirement for regulations. As well as setting out rules for reimbursement of expenditures for sperm, ova, and surrogacy, this section prohibits (except in accordance with regulations) reimbursement for the maintenance or transport of an *in vitro* embryo. *AHR Act*, *supra* note 7, s 12(1)(b).

14 Technically, section 12 prohibits the reimbursement of expenditures for sperm,

no regulations and because Health Canada, the federal agency responsible for creating them,[15] has yet to draft such regulations.

Remarkably, more than ten years after the *AHR Act* received Royal Assent, and in spite of repeated calls for greater legal clarity,[16] Health Canada has not drafted regulations pursuant to section 12 of the *Act*. This is surprising for at least two reasons. First, there is evidence of an established intent to draft such regulations. In a 2005 report on a workshop with stakeholders regarding reimbursement of expenditures for egg and sperm donors, Health Canada indicated that its "next steps" would include the development of

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ova, and surrogacy, as well as the maintenance and transport of embryos unless made "in accordance with the regulations." However, the clear intent of this section was to permit reimbursement for expenditures through the drafting of subsequent regulations. While Parliament could conceivably bring this section into force *without* any corresponding regulations, the effect of doing so would be largely to duplicate sections 6 and 7, which already prohibit "consideration" for these activities. See *AHR Act*, *supra* note 7, ss 6–7, 12; Health Canada, "Prohibitions Related to Purchasing Reproductive Material and Purchasing or Selling *In Vitro* Embryos" (18 July 2013), online: <www.hc-sc.gc.ca/dhp-mps/brgtherap/legislation/reprod/purchasing-achat-eng.php> [Health Canada, "*In Vitro* Embryos"]; Health Canada, "Prohibitions Related to Surrogacy" (18 July 2013), online: <www.hc-sc.gc.ca/dhp-mps/brgtherap/legislation/reprod/surrogacy-substitution-eng.php> [Health Canada, "Surrogacy"]. In practice, regulations are frequently drafted by the relevant administrative agency or department before the coming into force of a provision, so that the adoption of regulations and the coming into force of the provision occur on the same day. As Bédard notes, the federal *Interpretation Act*, RSC 1985, c I-21, "authorizes that actions be taken or regulations be made pursuant to an Act that is not yet in force in order to make the Act in question effective on its commencement." This happened with the appointment of the first Conflict of Interest and Ethics Commissioner, "an example of preliminary actions accomplished pursuant to, but before the commencement of, an Act." Library of Parliament, Legal and Legislative Affairs Division, "Coming into Force of Legislation", by Michael Bédard, Publication No. 2009-03-E (revised version 30 May 2012) at 1, online: <www.parl.gc.ca/Content/LOP/ResearchPublications/2009-03-e.pdf>.

15 Section 65 of the *AHR Act*, *supra* note 7, grants authority to the Governor in Council to create regulations, and section 20(1) of the *Act* grants the Minister of Health responsibility "for the policy of the Government of Canada respecting assisted human reproduction and any other matter that, in the opinion of the Minister, relates to the subject-matter of this Act"; collectively, these two provisions give Health Canada the power to draft regulations.

16 Downie & Baylis, *supra* note 6; Baylis, Downie & Snow, *supra* note 8.

"policy options for the regulations," and that "the normal regulatory process will unfold … with the aim of having the entire regulatory framework in place by 2007 or 2008."[17] In 2007, Health Canada also issued a public consultation document in which it stated that "when section 12 comes into force, it will provide for the reimbursement of receipted expenditures in accordance with the regulations and a licence."[18] A letter to stakeholders accompanying the document noted that regulations for section 12 were "currently being developed, and consultation with Canadians is a key element of this process."[19]

Second, Health Canada is clearly capable of drafting regulations under the *AHR Act*. In 2007, it created the *Assisted Human Reproduction (Section 8 Consent) Regulations*.[20] Given that Health Canada signalled its intent to draft regulations on reimbursement back in 2005 and in 2007, and given that it knows how to go about the business of creating regulations pursuant to the *AHR Act*, it is not obvious why there are still no regulations on reimbursement in 2015.

In this paper, we speculate[21] as to possible reasons why Health Canada has not drafted regulations, and we explain in turn why each of the possible reasons for inaction is flawed. Given our rejection of all of the reasons

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17 Health Canada, Workshop on the Reimbursement of Expenditures for Egg and Sperm Donors – Meeting Report, November 5–6, 2004, prepared by the Intersol Group for Health Canada (final report: 30 March 2005) at 11, online: Government of Canada <publications.gc.ca/collections/Collection/H21-239-2005E.pdf>.

18 Health Canada, "Reimbursement of Expenditures under the Assisted Human Reproduction Act: Public Consultation Document" (n.d. [August 2007]) at 4 [on file with authors].

19 Letter from Health Canada's Assisted Human Reproduction Implementation Office (9 August 2007), accompanying the Public Consultation Document, *ibid*.

20 *Assisted Human Reproduction (Section 8 Consent) Regulations*, SOR/2007-137.

21 Our speculation is based on an analysis of all available evidence and scholarship on this subject, including direct inquiries to Health Canada and Health Canada's public statements on the issue. Our goal is not to impute intent; rather, it is to explore possible reasons for not drafting regulations, precisely because Health Canada has not made its motivations clear. If Health Canada were to offer an explanation, such speculation might not be necessary.

we could imagine,[22] we argue that Health Canada should both explain and justify its failure to introduce the regulations that would set the stage for Parliament to bring section 12 into force. Health Canada must do so if the federal government is to meet the *AHR Act*'s goal of protecting children, women, and men engaged in, or affected by, surrogacy and third-party egg production.

Why Is Health Canada Not Regulating Legally Permissible Reimbursements?

A. Perhaps Health Canada believes the regulations would be superfluous

Perhaps Health Canada has not drafted the regulations for section 12 because it believes that these regulations would be superfluous insofar as the only effect of bringing section 12 into force would be to restrict reimbursements to those for receipted expenditures and properly certified loss of work-related income during pregnancy. Perhaps Health Canada believes it can achieve this goal by fiat, simply by stipulating that such reimbursement is Health Canada's "policy."[23] On this view, the will of Parliament can be respected without undertaking the onerous task of developing and implementing regulations.

However, this reasoning would be seriously flawed.

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22 Other than two recent articles (Downie & Baylis, *supra* note 6; Baylis, Downie, and Snow, *supra* note 8), the scholarly community has been surprisingly absent from discussions on the failure to create regulations for section 12 of the *AHR Act*. Letters to Health Canada from two of us (Françoise Baylis and Jocelyn Downie) seeking clarity on section 12 have similarly failed to elicit an adequate explanation. See "Reproductive Tissues", *NTE Impact Ethics*, online: <www.dal.ca/sites/noveltechethics/projects/selling-the-body/reproductive-tissues.html> ["Reproductive Tissues", *NTE Impact Ethics*] (including sources therein).

23 See *R v Picard*, Agreed Statement of Facts, *supra* note 7 ("Health Canada policy permits reimbursement to donors and surrogates of expenses and disbursements related to donation or surrogacy. This cannot involve paying consideration to donors or surrogates for their services or accepting payment for arranging surrogate services or similar financial gain" at para 3); see also Baylis, Downie & Snow, *supra* note 8.

First, the source of the requirement for receipts comes directly from subsections (1) and (2) of section 12. If section 12(1)–(2) did not exist, there would be no legislated requirement for receipts in order for expenditures to be reimbursable. Without section 12(1)–(2), Health Canada would have no legal basis for its stated "policy" limiting reimbursements to expenses or expenditures for which there are receipts. Because regulations are necessary for section 12 to have any meaning that would differentiate that section from the prohibitions on "consideration" contained in sections 6 and 7,[24] the regulations are necessary for Health Canada's "policy" to have any foundation in law.

Second, section 12(1)–(2) was deliberately created to limit the scope of permissible payments so as not to include any and all possible expenses, but only receipted "expenditures."[25] During the legislative committee hearings leading up to the creation of the *AHR Act*, in testimony regarding an earlier draft of the bill that did not yet include section 12(3), Glenn Rivard on behalf of the Department of Justice noted that an expenditure is "a narrower concept than an expense" (such as forgoing a high salary) insofar as "money must actually have been paid out by the individual."[26] Notably, Health Canada itself has used both the language of "expenses"[27] and "expenditures"[28] when offering its interpretation of the *AHR Act* on its websites.

Third, the rule of statutory interpretation known as the "rule against surplusage" or "presumption against tautology" militates against such reasoning. This rule is the principle that every word in a piece of legislation has been included for a reason. As noted by Ruth Sullivan in her leading

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24 See *supra* note 14 and sources cited therein.

25 *AHR Act*, *supra* note 7, s 12.

26 Rivard's comment was in response to a question from MP Yolande Thibeault, who was concerned that section 12 as then conceived could permit reimbursement for loss of work-related income for someone whose "usual salary is $75,000 a year"; Rivard confirmed that work-related income would not qualify as an expenditure. House of Commons, Standing Committee on Health, *Committee Evidence*, 37th Parl, 1st Sess, No 85 (30 May 2002) at 1155, online: <www.parl.gc.ca/HousePublications/Publication.aspx?DocId=606622&Language=E&Mode=1&Parl=37&Ses=1>.

27 Health Canada, "*In Vitro* Embryos", *supra* note 14; Health Canada, "Surrogacy", *supra* note 14.

28 Health Canada, "*In Vitro* Embryos", *supra* note 14.

text on statutory interpretation, "[e]very word in a statute is presumed to make sense and to have a specific role to play in advancing the legislative purpose."[29] The Supreme Court has cited Sullivan approvingly in this regard.[30] Clearly, the drafters of the *AHR Act* believed that section 12 – and subsequent regulations that would add specificity to section 12 – was necessary to the proper functioning of the *Act*. Thus, the rule against surplusage further counters any potential claim that section 12 is superfluous.

B. Perhaps Health Canada wants to avoid responsibility for the enforcement of limits on the exchange of money in connection with assisted human reproduction

Perhaps Health Canada does not want to write the regulations for section 12 and thereby provide clarity regarding the rules for reimbursement of expenditures and reimbursement for loss of work-related income for surrogate mothers because it hopes that, without the regulations, Canadians who want the services of a surrogate or an egg provider will pursue their reproductive objectives outside of Canada. This would effectively reduce Health Canada's responsibilities for enforcement of the prohibitions on payment. Indeed, the recent report *Avis détaillé sur les activités de procréation assistée au Québec* specifically identifies the prohibition on remuneration as one of the reasons for increased reproductive travel, particularly for eggs.[31]

By not writing the section 12 regulations, Health Canada creates an incentive for Canadians who want to reimburse women for out-of-pocket expenditures (and, in the case of surrogacy, loss of work-related income) to access reproductive goods and services outside Canada in a jurisdiction where the law with respect to reimbursement is clear. Health Canada has specifically said that it "interprets the prohibitions under the *AHR Act* as

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29 Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed (Markham, Ont: LexisNexis, 2008) at 210.

30 See e.g. *British Columbia (Forests) v Teal Cedar Products Ltd*, 2013 SCC 51 at para 28, [2013] 3 SCR 301, 363 DLR (4th) 1.

31 Québec, Commissaire à la santé et au bien-être, *Avis détaillé sur les activités de procréation assistée au Québec* (Québec: Gouvernement du Québec, 2014) at 248, online: <www.csbe.gouv.qc.ca/fileadmin/www/2014/Procreation_assistee/CSBE_PA_detaille_2014.pdf>.

applying to activities that take place *in Canada*."[32] Therefore, any exporting of commercialized reproduction reduces Health Canada's self-perceived enforcement obligations.

If this is the reason for not drafting the regulations, it would of course fly in the face of the commitments implied by the *Act*'s own declaration of its principles, which include protecting "the health and well-being of children born through the application of assisted human reproductive technologies,"[33] protecting "the health and well-being of women" affected by these technologies,[34] and preventing the "trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends."[35] It is indefensible for the government to incentivize Canadians to take conduct that has been deemed harmful out of the country – thus arguably encouraging the exploitation of citizens of destination countries for commercial ends[36] – simply so as to avoid having to enforce the law designed to prevent the harmful conduct in the first place.

C. Perhaps Health Canada wants the legal regime to be more permissive than it would be with section 12 in force

Perhaps Health Canada under the Conservative government (2006–2015) preferred a more permissive regime than was initially intended by both those in Health Canada responsible for drafting the legislation between 1996 and 2004 and the parliamentarians who passed the *AHR Act* in 2004.[37]

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32 Letter from Lynn Mainland, Director, Assisted Human Reproduction, Health Canada to Drs. [Jocelyn] Downie & [Françoise] Baylis (24 September 2013), online: Novel Tech Ethics <www.dal.ca/content/dam/dalhousie/pdf/sites/noveltechethics/HCResponse2013_09.pdf> [emphasis added].

33 *AHR Act*, *supra* note 7, s 2(a).

34 *Ibid*, s 2(c).

35 *Ibid*, s 2(f).

36 Jennifer A Parks, "Care Ethics and the Global Practice of Commercial Surrogacy" (2010) 24:7 Bioethics 333 at 336; GKD Crozier & Françoise Baylis, "The Ethical Physician Encounters International Medical Travel" (2012) 36:5 J Med Ethics 297 at 300; Vida Panitch, "Surrogate Tourism and Reproductive Rights" (2013) 28:2 Hypatia 274.

37 Françoise Baylis & Matthew Herder, "Policy Design for Human Embryo Re-

This could explain why Health Canada currently appears to interpret section 12(1)–(2) of the *AHR Act* as permitting reimbursement of "expenses" as long as they are receipted.[38] In contrast, on their face, these provisions of the *AHR Act* limit reimbursement to the narrower category of receipted "expenditures" and require that such reimbursements be "made in accordance with the regulations,"[39] not in accordance with a Health Canada policy stipulated on a website.[40]

To say the least, it would be deeply problematic if the above hypothesis were Health Canada's reason for not drafting regulations for section 12. It is for elected members of Parliament, not civil servants, to make law establishing the nature and size of expenditures eligible for reimbursement. Indeed, under the *AHR Act,* draft regulations must be put before Parliament.[41] Health Canada's role, consistent with established democratic processes, is not to undermine but rather to advance the will of Parliament – in this case, by drafting the required regulations. Regulations under section 12(1)–(2) would, at the very least, likely need to limit reimbursement to "expenditures" as opposed to the broader category of "expenses" (to be consistent with the enabling legislation). Also, given the principles declared in the *AHR Act*, these regulations would likely need to spell out some limits as to the nature and size of expenditures that would be reimbursable.[42]

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search in Canada: An Analysis (Part 2 of 2)" (2009) 6:3 J Bioeth Inq 351 at 357–59.

38 Health Canada, "*In Vitro* Embryos", *supra* note 14; Health Canada, "Surrogacy", *supra* note 14.

39 *AHR Act*, *supra* note 7, ss 12(1)–(2). Although section 12(3) permits reimbursement of a surrogate for the loss of work-related income incurred during her pregnancy in instances where a "qualified medical practitioner certifies, in writing, that continuing to work may pose a risk to her health or that of the embryo or foetus," that section does not include the word "expenditure"; consequently, our comment on the distinction between expenses and expenditures pertains only to subsections (1) and (2) of section 12.

40 Health Canada, "*In Vitro* Embryos", *supra* note 14; Health Canada, "Surrogacy", *supra* note 14.

41 *Ibid*, s 66(1).

42 Health Canada, "*In Vitro* Embryos", *supra* note 14; Health Canada, "Surrogacy", *supra* note 14.

D. Perhaps Health Canada wants to set the parameters for permissible reimbursement of expenditures without oversight by Parliament

Perhaps Health Canada wants to set the parameters for permissible reimbursements of expenditures without oversight by Parliament. As noted above, draft regulations must be put before Parliament under the *AHR Act*. In contrast, statements made by Health Canada do not require parliamentary review and approval. By publishing an online interpretation of the *AHR Act* and directing fertility clinics, patients, and others to its website for direction on reimbursement,[43] Health Canada is at least trying *de facto* to set the parameters for permissible reimbursement in the absence of parliamentary oversight.

Of course, this too would be deeply problematic as a reason for Health Canada's inaction. To reiterate, section 66 of the *AHR Act* specifically stipulates that regulations pursuant to the *Act* must be placed before the House of Commons and the Senate. Of note, this legislated requirement goes above and beyond the common regulatory requirements for ordinary legislation,[44] suggesting that parliamentary oversight was clearly and forcefully desired by Parliament. Seeking to avoid such oversight would be a remarkable violation of our system of government.

E. Perhaps Health Canada was and continues to be acting on instructions from the previous federal government to keep the issue of human reproduction out of Parliament

It is possible that the previous government wanted to keep the issue of human reproduction out of Parliament and instructed Health Canada not to advance the file. Most of the *AHR Act* came into force in 2004 (when the Liberal Party was in power). In 2006, the Conservative Party came to power and thereafter consistently showed little interest in assisted human

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43 "Reproductive Tissues", *NTE Impact Ethics*, *supra* note 22; Health Canada, "*In Vitro* Embryos", *supra* note 14; Health Canada, "Surrogacy", *supra* note 14.

44 Canada, Privy Council Office, "Guide to Making Federal Acts and Regulations: Part 3 – Making Regulations" (2 December 2009), online: <www.pco-bcp.gc.ca/index.asp?lang=eng&page=information&sub=publications&doc=legislation/part3-eng.htm>.

reproduction policy. Below are a few examples of inaction by the federal Conservative government on matters concerning human reproduction.

According to section 70 of the *AHR Act*, a parliamentary committee was to undertake a comprehensive review of the legislation by 2009, and to submit a report on its review a year thereafter.[45] The Conservative federal government ignored the review requirement.

When Assisted Human Reproduction Canada (the oversight agency created by the *AHR Act*) faced questions about its budget after three of its board members resigned, the federal Conservative government did not respond.[46] When the federal government closed down Assisted Human Reproduction Canada, it did so through provisions in a 425-page omnibus budget-implementation bill, legislation that affected 69 pieces of federal legislation with severely constrained time for debate.[47] Through that same bill, the federal government unceremoniously repealed section 70 of the *AHR Act*, which mandated parliamentary review.[48]

Beyond assisted human reproduction, the Conservative government also sought to keep debates regarding access to abortion and the status of the fetus out of Parliament.[49] Indeed, the government under the Conservatives sought to avoid any debate on policy issues that touched on human

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45 Although the legislation was passed in 2004, the three-year review provision was contingent on the coming into force of section 21, which occurred on 12 January 2006. *AHR Act* (2004), *supra* note 12, s 70.

46 Gloria Galloway, "Human Reproduction Agency Has Little to Show for $30-million", *Globe and Mail* (31 May 2012), online: <www.theglobeandmail.com/news/politics/human-reproduction-agency-has-little-to-show-for-30-million/article4224870/>.

47 *Prosperity Act*, *supra* note 11; see also Gloria Galloway & Daniel Leblanc, "The Tale of 2012's Omnibus Budget Bill", *Globe and Mail* (12 June 2012), online: <www.theglobeandmail.com/news/politics/the-tale-of-2012s-omnibus-budget-bill/article4249856/>.

48 *Prosperity Act*, *supra* note 11, s 738; see also *AHR Act*, *supra* note 7, s 70 (indicating that the section has been repealed pursuant to the *Prosperity Act*).

49 "Harper Says He Won't Reopen Abortion Debate", *CBC News* (21 April 2011), online: <www.cbc.ca/news/politics/harper-says-he-won-t-reopen-abortion-debate-1.1010714>; see also Paul Saurette & Kelly Gordon, "Arguing Abortion: The New Anti-Abortion Discourse in Canada" (2013) 46:1 Can J Political Science 157 at 167.

reproduction, assisted or otherwise. As noted above, under the *AHR Act*, any regulations under section 12 would need to be brought before Parliament. Instructions from that government not to produce regulations would have served the goal of keeping reproduction issues out of Parliament. Perhaps Health Canada's inaction is reflective of compliance with instructions from the government, whether given explicitly or implicitly.

The political desire of the former Conservative government to avoid the issue of human reproduction being raised in Parliament was understandable. However, a desire on the part of the federal government to avoid political consequences at the ballot box is neither an excuse for Health Canada to depart from the will of Parliament (as expressed through the *AHR Act* introduced under a previous Liberal government), nor to avoid its own democratic responsibility for its decision (by being transparent and accountable for choosing not to advance the regulations). Health Canada should not allow itself to be used by any federal government as a cloak for political decision making nor as a shield from accountability for its political decisions. It remains to be seen whether the 2015 federal election of the Liberal Party will lead to any change in this regard.

Conclusion

The *AHR Act* creates a legal regime that clearly prohibits paying consideration to a surrogate mother or someone acting on her behalf, as well as purchasing sperm or ova from a donor or someone acting on behalf of a donor. However, the legal status of reimbursements for expenditures is complicated and confusing, as is the legal status of reimbursement for loss of work-related income for surrogate mothers. This is because the federal government that passed the *AHR Act* intended to allow reimbursement for out-of-pocket receipted expenditures and loss of work-related income during pregnancy, and such reimbursements were to be governed by regulations. However, these regulations have yet to see the light of day. We have been unable to find or fathom defensible reasons for Health Canada not having drafted the regulations. We therefore argue Health Canada should either persuasively defend its failure to draft regulations or get on with the task of drafting. A decade and counting is too long to wait.

Examining the National Regulatory Environment of Medical Devices: Major Issues in the Risk–Benefit Assessment of High-Risk Devices

*Ghislaine Mathieu & Bryn Williams-Jones**

High-risk medical devices (MDs) are mostly used as last-resort treatment or in surgical procedures. Their approval by national regulatory bodies depends essentially on their quality, safety, and efficacy for a particular clinical indication. In our study, we examine the national regulatory processes of the five founding members of the former Global Harmonization Task Force (replaced by the International Medical Device Regulators Forum in 2012) – Australia, Canada, the European Union, Japan, and the United States – with a view to identifying which uncertainties associated with high-risk devices raise sufficiently serious ethical concerns to warrant more robust regulatory oversight and governance. The assessment of the safety and effectiveness of high-risk medical

L'utilisation d'un dispositif médical (DM) à risque élevé nécessite souvent une procédure chirurgicale pour traiter un problème de santé majeur. La décision d'autoriser la mise en marché de ce type de DM relève des organismes nationaux de réglementation et s'appuie sur l'examen des données qui démontrent leur innocuité et leur efficacité pour un usage défini. Les nombreux rappels observés au cours des dernières années semblent témoigner des faiblesses dans cet examen, particulièrement pour les DM à risque élevé, avant et après leur mise en marché, en raison des difficultés pour obtenir des données robustes et fiables quant à leur innocuité et leurs bénéfices réels. Nous avons examiné les processus réglementaires des cinq ju-

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devices is a challenging issue, during both the premarket and post-market phases of evaluation, because there may be a lack of robust and reliable evidence to demonstrate long-term safety and effectiveness, as seen in the many product recalls in recent years (e.g., hip replacement prostheses). Faulty devices can have a significant negative impact on patients and the broader public. The deployment of unsafe or ineffective medical devices raises questions about the extent to which manufacturers, regulators, and clinicians attend to fundamental ethical principles of medicine, such as informed consent, beneficence, and non-maleficence. Respect for these principles is essential to facilitating optimal decision making by patients and clinicians who are considering recourse to a procedure involving the use of a high-risk device; failure to respect these principles can undermine public confidence in clinicians, manufacturers, and regulators. We therefore suggest some avenues to improve the current regulatory requirements and practices for high-risk devices, specifically with regard to how evidence is assessed at both the premarket and postmarket levels.

risdictions membres du *Global Harmonization Task Force*, mis sur pied au cours des années 1990 en vue d'harmoniser les pratiques nationales en matière de réglementation des dispositifs médicaux : l'Australie, le Canada, l'Union européenne, le Japon, les États-Unis. Nous voulions identifier les faiblesses des processus de réglementation actuels et positionner les enjeux éthiques autour des pratiques associées à ces processus, afin d'expliquer la nécessité de renforcer ces pratiques. Des DM défectueux ou inadéquats, non sécuritaires ou encore inefficaces peuvent avoir un impact important pour la santé des patients et affaiblir la confiance du public en général à l'égard des manufacturiers, des organismes réglementaires et des professionnels de la santé. En outre, les pratiques actuelles concernant l'examen des données cliniques interpellent les principes éthiques fondamentaux associés à la pratique médicale et une prise de décision éclairée, à savoir le consentement éclairé, la bienfaisance et la non-malfaisance. Nous proposons des avenues pour renforcer les pratiques entourant les processus réglementaires actuels, en particulier pour ce qui concerne les DM à risque élevé, tant au cours de leur évaluation avant mise en marché que lors de leur suivi après mise en marché.

Introduction

In a context of globalized heath technology innovation and an increasing demand for and use of an ever expanding number of medical devices (MDs) – including a growing number of high-risk, innovative, and implantable MDs (e.g., deep brain stimulation (DBS) or cardiac pacemakers) – it is important to examine how current national regulatory requirements ensure the safety, effectiveness, and reliability of MD. Unlike pharmaceutical drugs, MDs do not typically achieve their intended purpose through chemical action or immunological or metabolic means.[1] MDs are mechanical in nature and have no metabolic effect on the human body. Further, unlike pharmaceutical drugs – which have an extensive product life cycle involving decades of research and development and marketing applications – MDs have a relatively short product life cycle.[2] Some devices are extremely sophisticated and very expensive, and may involve the use of complex procedures by experienced health care providers (e.g., DBS). The MD sector involves hundreds of thousands of products, ranging from simple thermometers to more sophisticated items such as surgical instruments, pacemakers, and imaging equipment. But even some commonplace objects can be considered MDs if they are labelled or otherwise promoted for health-related purposes. For example, the US Food and Drug Administration (FDA) could regulate an iPod as a MD if it were labelled for treating stress or hypertension.[3] Some topical creams may also be regulated as devices – instead of as pharmaceutical products – because they do not contain any active ingredient and involve no chemical or metabolic action in the body (e.g., hyaluronic acid (Restylane) that is injected into the skin to fill moderate to severe wrinkles).[4]

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1 World Health Organization, *Health Technology Assessment of Medical Devices*, WHO Medical Device Technical Series (Geneva: WHO Press, 2011) at 5, online: <apps.who.int/medicinedocs/documents/s21560en/s21560en.pdf>.

2 Industry Canada, "Life Science Industries: Medical Devices – Industry Profile" (27 February 2013), online: <www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html>.

3 Deborah E Tolomeo & Laurie A Clarke, "Medical Devices: The Obvious, the Readily-Accepted, and the Surprising" (2008) 1:4 J Health Life Sci Law 117 at 142.

4 Burgunda V Sweet, Ann K Schwemm & Dawn M Parsons, "Review of the Processes for FDA Oversight of Drugs, Medical Devices, and Combination Products" (2011) 17:1 J Manag Care Pharm 40 at 46–47.

Interestingly, while concerns about ethical issues – e.g., ensuring informed consent in clinical trials, the beneficence/non-maleficence of certain experimental products, justice in access to health services – and the appropriate regulation of pharmaceutical drugs have received significant attention in the bioethics and health policy literatures, there has been relatively little work addressing the concerns that are particular to new MDs and their integration into health care systems.[5] For example, advances in the neurosciences, bioengineering, and nanotechnologies have led to major innovations that raise challenging social, ethical, and policy questions (e.g., brain-machine interfaces extending the use of brain stimulation to the treatment of chronic diseases or enhancement of normal brain function), and these have received much attention in the academic and policy communities.[6] Yet there has been surprisingly limited attention paid to these issues on the part of health technology assessment (HTA) agencies that are responsible for conducting reviews and producing recommendations that can inform decision makers about the appropriateness of integrating certain new MDs into health care systems.[7]

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5 Sue Ross et al, "Ethics, Economics and the Regulation and Adoption of New Medical Devices: Case Studies in Pelvic Floor Surgery", online: (2010) 11 BMC Med Ethics 14 at 3 <www.biomedcentral.com/content/pdf/1472-6939-11-14.pdf>.

6 See e.g. Karim Jebari, "Brain Machine Interface and Human Enhancement: An Ethical Review" (2013) 6:3 Neuroethics 617; Thomas Fuchs, "Ethical Issues in Neuroscience" (2006) 19:6 Curr Opin Psychiatry 600; Sheri Alpert, "Brain–Computer Interface Devices: Risks and Canadian Regulations" (2008) 15:2 Account Res 63; Martha J Farah et al, "Neurocognitive Enhancement: What Can We Do and What Should We Do?" (2004) 5:5 Nat Rev Neurosci 421; Rutger J Vlek et al, "Ethical Issues in Brain–Computer Interface Research, Development, and Dissemination" (2012) 36:2 J Neuro Phys Ther 94.

7 See Devidas Menon & Leigh-Ann Topfer, "Health Technology Assessment in Canada: A Decade in Review" (2000) 16:3 Int J Technol Assess Health Care 896 at 896–902; Sigrid Droste & Ansgar Gerhardus, "Ethical Aspects of Short Health Technology Assessments: A Systematic Review" (2003) 97:10 Zeitschrift für ärztliche Fortbildung und Qualitätssicherung 711; Pascale Lehoux et al, "Redefining Health Technology Assessment in Canada: Diversification of Products and Contextualization of Findings" (2004) 20:3 Int J Technol Assess Health Care 325 at 325–36; Deirdre DeJean & Mita Giacomini, "Ethics in Canadian Health Technology Assessment: A Descriptive Review" (Presentation delivered at the Canadian Agency for Drugs and Technologies in Health 18th Symposium, 23–24 April 2007).

Our paper addresses issues that are specific to *in vivo* high-risk MDs first because in recent years some of these have proven particularly problematic for regulators in terms of both the incidence and potential magnitude of harm for patients, but also because of their cost implications for health care systems and third-party payers (e.g., public or private insurers). While the cost implications of new MDs are clearly a major concern for patients, public policy makers, and third-party payers, we restrict our analysis in this paper to those issues that are within the remit of national regulators, i.e., the current practices for assessing the safety and effectiveness of high-risk MDs where there is a reasonable possibility that their use may cause serious adverse health consequences.[8]

In our study, we examine the regulatory processes governing MDs in the five founding members of the former Global Harmonization Task Force (GHTF) – Australia, Canada, the European Union (EU), Japan, and the United States (US) – the creation of which was initiated by Canada. The GHTF became the International Medical Device Regulators Forum in 2012.[9] The aim of our study was to develop an understanding of international regulatory processes, with particular attention paid to premarket assessment rules and post-market follow-up mechanisms for high-risk MDs and "active implantable" MDs, in order to identify potential differences between the practices of national regulators, including gaps in current processes (e.g., risk classification, premarket evaluation activities, and post-market enforcement practices). High-risk MDs are often very complex technologies and frequently used as last-resort procedures for patients seeking relief

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[8] We have excluded *in vitro* diagnostic MDs from our study. Some of those may be the object of another study as they also raise socio-ethical and legal issues associated with their specific intended use (e.g., genetic-screening MDs).

[9] The Global Harmonization Task Force held its first meeting in January 1993 and was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The five founding members were grouped into three geographical areas (Europe, Asia-Pacific, and North America). Over the years, regulatory agencies and medical device trade associations that were not part of the founding members, as well as public health organizations and international standard-setting bodies, were permitted to nominate observers to participate in GHTF study groups and other expert working groups. See International Medical Device Regulators Forum, "GHTF History", online: <www.imdrf.org/ghtf/ghtf-history.asp>; International Medical Device Regulators Forum, "GHTF Roles and Responsibilities", online: <www.imdrf.org/docs/ghtf/final/steering-committee/procedural-docs/ghtf-sc-n2r12-100421-ghtf-roles-and-responsibilities.doc>.

from sometimes debilitating conditions. Many cannot be removed without significant risks of serious morbidity. It is thus pertinent to examine whether existing MD regulations, requirements, and practices are adequately protecting patients from ineffective or potentially hazardous products. As such, we have focused our review on ethical concerns specific to how evidence is collected regarding device safety and performance in research and clinical practice contexts and in premarket and post-market reviews for high-risk MDs.

I. Background

While the MD market is only half the size of the global pharmaceutical market, this sector is growing faster than its drug counterpart.[10] Unlike the drug sector, the device industry is highly fragmented and diversified, mainly composed of small industries (fewer than 50 employees) and a few major manufacturers (e.g., Medtronic, Johnson & Johnson). Most typically specialize in developing niche technologies.[11] In 2012, the global market for devices was valued at US$327.7 billion (CA$334.0 billion), excluding *in vitro* diagnostic devices (e.g., those based on next-generation-sequencing platforms). For example, from 2007 to 2012, Canadian device exports increased from CA$1.7 billion to $1.8 billion,[12] while in the US, exports were valued at more than US$44 billion in 2012, an increase of more than 7% from the previous year.[13] It is anticipated that the global compound annual growth rate could be more than 4.4% between 2011 and 2018, compared to that of the pharmaceutical sector, which is predicted to grow at an annual rate of only 2.5% during the same period.[14] The MD sector is thus an important actor in many national economies. The MD industry continues to be very dynamic and competitive, producing basic supplies as well as

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10 Michael Rosen, "Global Medical Device Market Outperforms Drug Market Growth", *WTN News* (2 June 2008), online: <wtnnews.com/articles/4790/>.

11 Industry Canada, *supra* note 2; SelectUSA, "The Medical Device Industry in the United States", online: <selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states>.

12 Industry Canada, *supra* note 2.

13 SelectUSA, *supra* note 11.

14 EvaluateMedTech Service, "World Preview 2013, Outlook to 2018: The Future of Medtech", online: <info.evaluategroup.com/rs/evaluatepharmaltd/images/EvaluateMedTech_World_Preview_2013_Outlook_to_2018.pdf>.

highly innovative products that play a vital role in improving patient health through technologically advanced care.

As new MDs prove helpful in treating diseases and disabilities, they may become standard treatments and part of the health care environment, changing medical practice and ideally improving the quality of life of patients, especially those who may be in desperate conditions. Notable examples include stents, defibrillators, orthopaedic prostheses, and functional magnetic resonance imaging (fMRI).[15] Attention to these important benefits must, however, be tempered by the recognition that the integration of innovative and expensive MDs into health care systems also contributes to the problematic growth of overall national health expenditures. For example, it has been estimated that for the US, national spending on MDs in 2009 totalled US$145.6 billion.[16] It is worth noting, though, that in Canada in 2011, per capita medical device expenditure was only half of that in the US (i.e., US$183 in Canada versus US$369 in the US).[17]

II. Regulatory Environment

The main purpose of current regulatory processes for MDs is to ensure access to safe and effective products that can benefit patients, and to ensure that patients have a clear understanding of the potential risks and real benefits that some MDs may pose.[18] The approval of MDs depends

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15 Auditor General of Canada, *2011 Status Report of the Auditor General of Canada to the House of Commons* (Ottawa: Office of the Auditor General of Canada, 2011), ch 6: "Regulating Medical Devices – Health Canada" at 1–2, 5.

16 Gerald Donahoe & Guy King, Advanced Medical Tech Association, "Estimates of Medical Device Spending in the United States" (October 2012) at 14, online: AdvaMed <www.lifechanginginnovation.org/sites/default/files/files/Oct%202012%20King%20Report%20FINAL.pdf>

17 Brett J Skinner, "Medical Devices and Healthcare Costs in Canada and 65 Other Countries, 2006 to 2011", *Canadian Health Policy* (9 May 2013) at 7, online: FDA News <www.fdanews.com/ext/resources/files/archives/0/06/06-13-CanadianSpending.pdf>.

18 Ipsos MORI, *Risks and Benefits of Medicines and Medical Devices – Perceptions, Communication & Regulation: General Public Quantitative Survey* (15 May 2009) at 2, online: UK, Medicines & Healthcare Products Regulatory Agency <www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con052027.pdf>.

essentially on an evaluation of their quality, safety, and effectiveness for a particular application and the risks associated with their use. For example, although they have some side effects, contact lenses do not pose the same risks as hip prostheses or active implantable MDs like deep brain stimulators (DBS). Most devices currently on the market pose minimal or moderate risks. High-risk MDs require particular risk-management procedures in the event of malfunction or serious side effects. As such, there have been calls for more rigorous post-market follow-up due to potentially severe and even irreversible side effects, notwithstanding the fact that many MDs are used as last-resort treatments[19] (e.g., cardioverter defibrillators). Understandably, the approval of MDs is subject to risk-classification regulatory requirements that are modulated according to the particular risks associated with the devices' intended use.

In Canada and the US, drug licensing has existed for almost a century. The Canadian *Food and Drugs Act* was introduced in 1920,[20] thirteen years after the 1906 *US Pure Food and Drug Act*,[21] which was itself then replaced in 1938 by the *Federal Food, Drug, and Cosmetic Act*.[22] But the regulations associated with these laws were specifically focused on addressing drug-related issues. National regulatory requirements specific to MDs would not be addressed until the 1970s. It had by then become obvious that the use of certain devices posed problems for patients (e.g., failures, significant adverse outcomes), making the regulation of MDs a necessity. The US *Federal Food*, *Drug, and Cosmetic Act* was consequently modified by the *Medical Device Amendments of 1976*, which for the first time defined a "medical device," introduced a risk-classification system, and gave the FDA the authority to control the marketing (e.g., bans, recalls, and orders for repair, replacement, or refund) of MDs.[23] In Canada, some of the recommendations in the Lalonde Report, *A New Perspective on the Health*

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19 Kevin L Kilgore, "Introduction and Fundamental Requirements of Neuroprostheses" in Kevin L Kilgore, ed, *Implantable Neuroprostheses for Restoring Function* (Waltham, Mass: Woodhead Publishing, 2015) 3 at 8.

20 SC 1920, c 27.

21 Pub L 59-384, 34 Stat 768 (1906).

22 Pub L 75-717, 52 Stat 2040 (1938) (codified as amended at 21 USC).

23 US, Institute of Medicine of the National Academies, Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process & Board on Population Health and Public Health Practice, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (Washington, DC:

Table 1. Comparison of standard regulatory assessments for medical devices and pharmaceutical drugs

	Manufacturer	
	Device	**Pharmaceutical**
Filing and review	• Device classification (risk-based) • Device description (design input) • Full technical documentation (device specification, production and process, patent description) • Intended use (label) • Clinical evidence of safety and efficacy (clinical data from *in-vitro*, *in vivo* animal data) ↓ • Protocol clinical review ("first-in-human clinical trials with patients") ↓	• Drug description (medical class – e.g., antidepressant – and active pharmaceutical ingredients) • Drug name and structure (physical and chemical characteristics), and controls manufacturing, information about the drug substance and product. • Intended use (label) • Non-clinical pharmacokinetics, bioavailability, microbiology • Pilot background studies (animals *in vivo*) • General investigation plan (Phase I for safety and dosage, Phase II for effectiveness and side effects, Phase III for safety and efficacy) ↓
Trials	• New trials (randomized/placebo) ↓	• Phases I, II, III trials (randomized/placebo trials) ↓
Approval	• For market launch (or re-examination filing) timeline: ≤ 2 years ↓	• For market launch (or amended application) timeline: ≤ 5-10 years ↓
Post-market	• Studies (real-world practice)	• Phase IV studies (real-world practice)

Regulator	
Device	**Pharmaceutical**
• Device classification validation • Design validation (production, manufacturing) • Audit/inspection • Studies/statistical findings to prove or not prove efficacy for intended use ↓ • Process review and validation (device achieves performance for intended use), or • Request for new trials (±100 patient volunteers) ↓	• Drug validation ↓ • Design (production, manufacturing) • Audit/inspection • Study hypotheses/statistical findings prove (or do not prove) efficacy for intended use ↓
• First-in-human clinical trials authorization (± 20 patient volunteers) ↓ • Request for new trials (±100 patient volunteers) ↓	• Phase I clinical trials authorization (>100 healthy volunteer subjects) ↓ • Process review and validation (drug achieves performance for intended use) ↓ • Phase II clinical trials authorization (100–500 patient volunteer subjects) ↓ • Process review and validation (drug achieves performance for intended use) ↓ • Phase III clinical trials authorization (1000–5000 patient volunteers) ↓
• For intended use (or denied) ↓	• For intended use (or denied) ↓
• Manufacturers' reporting ↓ • Recalls, advertisements, bans	• Manufacturers' reporting ↓ • Warnings, recalls, bans

of Canadians: A Working Document,[24] called for increasing controls over MDs because many could be considered "hazardous products" for health. In 1975, amendments to the Canadian *Food and Drugs Act* introduced strict requirements and guidelines to regulate the licensing of MDs.[25] Yet, unlike in the US, in Canada a risk-classification system would only be introduced in 1998. Similarly, in Australia, Japan, and the EU, formal MD regulations were introduced in the 1990s. Table 1 shows key similarities and differences between the device and drug sectors with regard to the premarket evaluation process and the follow-up by regulators and manufacturers after a drug or MD has been approved for marketing.

In 1992, the regulatory authorities of five national systems (Australia, Canada, the EU, Japan, and the US) established the Global Harmonization Task Force (GHTF) to stimulate convergence and ideally the harmonization of standards and regulatory practices concerning the safety, performance, and quality of MDs. To this end, the GHTF developed numerous guidance documents that could be of benefit to any country seeking to improve its MD regulations (providing, for example, a definition of "medical device," guidance about premarket evaluation and post-market surveillance, and procedures for auditing of quality management).[26] In April 2012, the GHTF was dissolved and replaced by the International Medical Device Regulators Forum, whose Management Committee is composed exclusively of regulatory officials from Australia, Brazil, Canada, China, Europe, Japan, Russia, and the US. Through working groups, this Committee will profit from the expertise of the industry, academia, health care professionals, and consumer and patient groups.[27]

National Academies Press, 2011) at 1–2; *Medical Device Amendments of 1976*, Pub L No 94-295, 90 Stat 539.

24 Marc Lalonde, Minister of National Health and Welfare, *A New Perspective on the Health of Canadians: A Working Document* (1974) (reissued: Ottawa: Minister of Supply and Services Canada, 1981) at 47, 69.

25 *Regulations respecting Medical Devices*, SOR/75-526; US, Congress, Office of Technology Assessment, *Federal Policies and the Medical Devices Industry* (Washington: US Government Printing Office, 1984).

26 Major guidance documents generated by the GHTF, especially about classification and premarket and post-market evaluation principles, can be found on the International Medical Device Regulators Forum website. See "GHTF Archived Documents" (nd), *International Medical Device Regulators Forum*, online: <www.imdrf.org/ghtf/ghtf-archived-docs.asp>.

27 The current organization of the International Medical Device Regulators

We have based our review on the current national regulatory processes of the five former GHTF founding members, because under the GHTF's initiative, significant progress has been made towards international harmonization in the regulation of MDs, especially with regard to registration and approval requirements. Table 2 presents a summary of the requirements for MD assessment and approval as set forth by government authorities. The regulatory environment of MDs is evolving rapidly and other changes are likely to be introduced in the coming months. For example, an amendment to the Canadian *Food and Drugs Act* – Bill C-17, *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*[28] – was adopted in 2014; this law introduced innovative measures to reinforce post-market regulatory activities for both drugs and MDs.[29]

Despite the success of the GHTF in harmonizing national regulatory requirements, there has been a notable increase in alerts and recalls of high-risk MDs in recent years, particularly in the US and in Europe. For example, Heneghan and colleagues reported that between 2006 and 2010, there was a 1220% increase in the number of safety notices issued in the United Kingdom (62 in 2006 versus 757 in 2010), nearly half of which concerned high-risk MDs with a probability of causing serious adverse health consequences.[30] There are thus still serious problems with national regulatory review of MDs, both in premarket assessment and evaluation and in post-market surveillance.

Forum can be found online. See "About IMDRF", *International Medical Device Regulators Forum*, online: <www.imdrf.org/about/about.asp>.

28 Bill C-17, *An Act to amend the Food and Drugs Act*, 2nd Sess, 41st Parl, 2014 (assented to 6 November 2014), SC 2014, c 24 [Bill C-17]. See also Health Canada, "Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)/ Amendments to the *Food and Drugs Act* (Bill C-17)" (last updated 31 July 2015), online: <www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-drogues-dangereuses-eng.php>. *Vanessa's Law* is named after the daughter of Terence Young, a Member of Parliament, who died of a heart attack while she was on a prescription drug that was later removed from the market.

29 A previous attempt to amend the *Food and Drugs Act* made it to second reading in the House of Commons in 2008. See Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, 2nd Sess, 39th Parl, 2008 [Bill C-51].

30 Carl Heneghan et al, "Medical-Device Recalls in the UK and the Device-Regulation Process: Retrospective Review of Safety Notices and Alerts", online: (2011) 1:1 Brit Med J Open e000155.

Table 2. Regulatory systems of GHTF founding members†

	Australia	Canada
Legislation	• *Therapeutic Goods Act* (1989) • *Therapeutic Goods Regulations* (1990) • *Therapeutic Goods (Medical Devices) Regulations* (2002)	• *Food and Drugs Act* (RSC 1985) • *Medical Devices Regulations* (1998) • *Protecting Canadians from Unsafe Drugs Act* (2014)
Governance	• Department of Health and Ageing • Therapeutic Goods Administration	• Health Canada • Therapeutic Products Directorate
Device classification	• Class I • Class IIa • Class IIb • Class III • Special Class III (AIMD)	• Class I • Class II • Class III • Class IV
Medical device regulations	• Introduced 1990 • Revised 2002 • 2013 (under review)	• Introduced 1975 • Revised 1998
Pre-approval clinical regulatory requirements	• Quality, safety, and efficacy assessment • Compilation of quality management system design for Class III and AIMD	• Risk assessment for Class IV • Investigational testing authorization (new device) • Emergency use program (unapproved device) • FDA guidance may be used by Health Canada
Post-market structure requirements	• Comprehensive vigilance system • Post-market surveillance reports • Unique device identifier (implantable devices)	• MedEffect • *Protecting Canadians from Unsafe Drugs Act*

† Table sources are provided in the Appendix.

EU	Japan	United States
• Council directives 90-385 EEC, 93/42 EEC, 98/79 EEC, 2007/47/EEC	• *Pharmaceutical Affairs Law* (2005) • *Pharmaceutical Affairs Law* (2013) (name changed to *Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetic* (2014))	• *Medical Device Amendments* (1976) • *Safe Medical Devices Act of 1990* • *Food and Drug Administration Modernization Act of 1997* • *Food and Drug Administration Safety and Innovation Act* (2012)
• European Commission • Laws of the Member States • Notified Bodies	• Ministry of Health, Labour and Welfare • Pharmaceuticals and Medical Devices Agency	• Food and Drug Administration • Center for Devices and Radiological Health
• Class I • Class IIa • Class IIb • Class III • Special Class III (AIMD)	• Class I • Class II (specified control) • Class II (controlled) • Class III • Class IV (specially controlled MD)	• Class I • Class II • Class III
• Introduced 1993 • Revised 2007, 2010, 2012 • 2014 (under review)	• Introduced 1995 • Revised 1997, 2004, 2013, 2014	• Introduced 1976 • Revised in 1997, 2013
• Safety assessment • Clinical trials: mandatory for Class III, AIMD, and long-term-use invasive devices • Most trials: non-randomized and single arm (aim at providing safety)	• Japanese GCP regulations • Clinical risk assessment • Foreign clinical data accepted • Premarket certification (Class IIa) • Premarket approval (classes IIb, III, and IV)	• Mandatory clinical trials for Class III • Premarket approval (PMA) • Premarket notification (510k) • Humanitarian device exemption • *De novo* process • Investigational device exemption (new device and use) • Clinical data are treated as trade secrets
• Vigilance system • Unique device identifier • CE conformity approval • EUDAMED (non-public database) • Unique device identifier (implantable devices)	• Follow-up evaluations • Medical Information for Risk Assessment Initiative Project for implantable devices (MIHARI) • Japanese registry for mechanically assisted circulatory support (J-MACS)	• Post-market Transformation Initiative • Sentinel Initiative • MAUDE • MedWatch • Unique device identifier (implantable devices)

III. Premarket Risk Assessment

To evaluate devices before they enter the market, the GHTF founding members' national MD processes have adopted a risk-classification approach based on the intended purpose and use of each MD, its potential hazards, and the appropriate controls that need to be implemented to ensure its safety and effectiveness.[31] It is understandable that low-risk devices such as bandages and examination gloves would easily obtain clearance before being approved for market, and, in order to speed patient access to such low-risk MDs, some may even be exempted from premarket review. But these low-risk devices are still subject to post-market oversight (i.e., good manufacturing requirements, factory inspections) because they are not free from potential malfunctions or adverse events. On the other hand, high-risk MDs such as orthopaedic implants, pacemakers, and brain stimulators clearly require much closer scrutiny, and their manufacturers must provide "reasonable" evidence of their products' safety and effectiveness.

When filing an application for a licence to market medium- and high-risk devices, manufacturers are normally required to demonstrate that they meet internationally accepted standards in the design and manufacturing of their MDs, i.e., ISO international standards.[32] To be approved, a MD should satisfy specific requirements with regard to potential risks defined according to their severity, ranging from negligible (hence acceptable) and marginal to critical or catastrophic (and thus intolerable) for a patient's health or life. This classification system is based on a series of factors, including how long the device is intended to be in continuous use, the duration of contact in or on the affected body part, whether or not the device is invasive or requires surgical intervention, and whether the device is active or non-active im-

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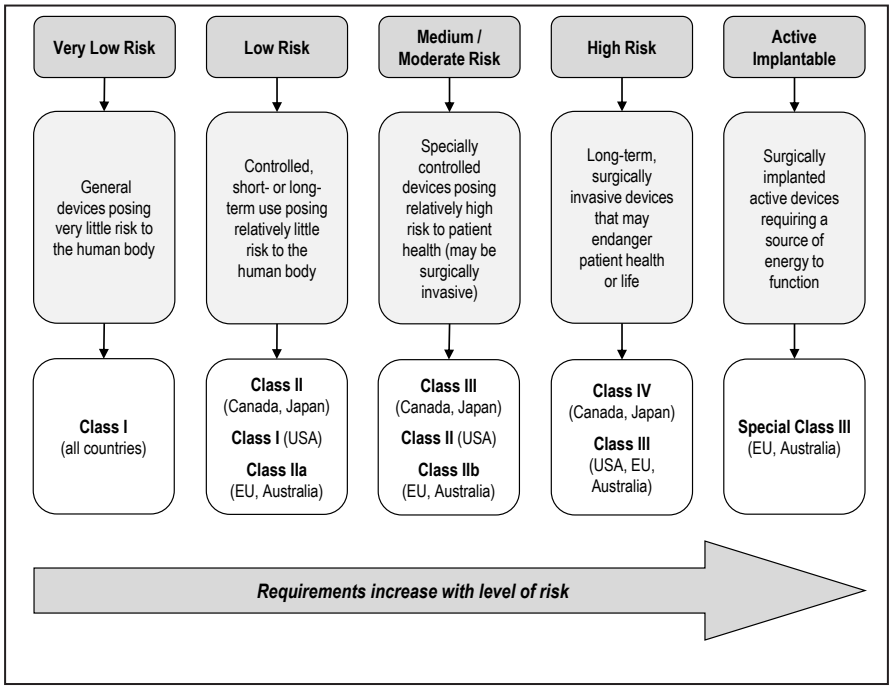
31 See Table 2, above.

32 Most countries recognize the ISO standards. The US FDA does not, and instead follows its own system, although it has many overlapping elements with the ISO standards. See Judith A Johnson, "FDA Regulation of Medical Devices", Congressional Research Service [CRS] Report for Congress (25 June 2012), online: Federation of American Scientists <www.fas.org/sgp/crs/misc/R42130.pdf>; "ISO 13485, 60601 and Other Standards that Apply to the Medical Device Industry" (nd), *Emergo Group*, online: <www.emergogroup.com/resources/articles/use-of-standards>; World Health Organization, *Medical Device Regulations: Global Overview and Guiding Principles* by Michael Cheng (Geneva: WHO, 2003) at 13, online: <www.who.int/medical_devices/publications/en/MD_Regulations.pdf> [World Health Organization, *Medical Device Regulations*].

FIGURE 1. MEDICAL DEVICE CLASSIFICATION



plantable. Figure 1 summarizes the main MD specifications used in national classification systems.

In principle, harmonization should facilitate the development of international best practices that ensure the safety and effectiveness of MDs before and after entering the market, namely through standards regarding how clinical evidence is reported and examined, including clinical-trial registration and the public release of results.[33] Such initiatives should not be limited to classification or be simply a matter of assisting manufacturers in filing documents across regulatory authorities, nor should they be a means to eliminate trade barriers for the device industry or to reduce the time to

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[33] Joel Lexchin, "Who's Calling the Tune: Harmonization of Drug Regulation in Canada", Canadian Centre for Policy Alternatives (January 2011) at 5, 11–14, online: <www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2011/01/Whos%20Calling%20the%20Tune.pdf> [Lexchin, "Harmonization of Drug Regulation"].

market for a device.[34] As is the case for pharmaceutical drugs, regulatory harmonization is a means of protecting public health.[35]

Unfortunately, current national systems are still not fully harmonized across the GHTF founding members, and many weaknesses remain in their control of medium- to high-risk MDs. In premarket review in the US, for example, clinical assessment of MDs is based on "reasonable assurance of safety and effectiveness,"[36] meaning that the assessment is less demanding than for drugs, provided the anticipated benefits outweigh the risks associated with their use. By comparison, pharmaceutical drugs are required to show "substantial evidence" of effectiveness to obtain approval.[37] The same situation is observed in Europe, where the premarket clinical assessment for high-risk MDs is not comparable to that for pharmaceutical drugs because clinical efficacy is usually not part of premarket assessment for MDs.[38]

It is estimated that high-risk MDs account for less than 5% of the many thousands of medical devices on the market internationally. In the US, out of the 8,000 new MDs marketed each year, only 50 to 80 are Class III, the US class designating high-risk MDs.[39] Similarly, in its last regulatory review of performance for pharmaceuticals, biologics, and MDs, Health Canada reported that out of the 4,896 MD applications, only 112 involved Class IV

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34 Susan Lamph, "Regulation of Medical Devices outside the European Union" (2012) 105:1 (supp) J Roy Soc Med S12 at S13; A Kaushik et al, "Harmonized Medical Device Regulation: Need, Challenges, and Risks of Not Harmonizing the Regulation in Asia" (2010) 2:1 J Young Pharm 101 at 104.

35 Lexchin, "Harmonization of Drug Regulation", *supra* note 33 at 14.

36 *Food, Drug, and Cosmetics Act*, 21 USC § 360c.

37 Sweet, Schwemm & Parsons, *supra* note 4 at 43; Jonas Zajac Hines et al, "Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review", online: (2010) 7:7 PLoS Med e1000280 at 6 <www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.1000280&representation=PDF>.

38 Frank Hulstaert et al, "Premarket Clinical Evaluations of Innovative High-Risk Medical Devices in Europe" (2012) 28:3 Int J Technol Assess Health Care 278 at 280.

39 Sanket S Dhruva, Lisa A Bero & Rita F Redberg, "Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices" (2009) 302:24 JAMA 2679 at 2679 [Dhruva, Bero & Redberg, "Strength of Study Evidence"].

(i.e., Canadian high-risk) devices.[40] Nonetheless, while they may represent a small percentage of all the MDs on the market, high-risk MDs are very often used in treatments of last resort, and therefore any failure on the part of regulatory evaluation and oversight can have a significant impact on patients (and on health expenditures) and potentially undermine the public's confidence in regulatory authorities.

A. Challenging issues in US regulation: The 510(k) expedited review process

One aspect of MD regulation that is unique to the US and that merits particular attention is the so-called "510(k) expedited premarket review process" (named after a federal law passed in 1976 and amended in 1990 and 1997).[41] Many in the medical and scientific communities have criticized this "fast-track approval" of MDs because of the numerous problems (i.e., failures and recalls) encountered over the past several years related to devices approved under this process.

Manufacturers filing through the 510(k) process do not have to provide proof of safety and effectiveness data for human use if they claim that a device is "substantially equivalent" to an already approved device, which is called the "predicate." This process was originally intended for medium-risk MDs; but over the years, many high-risk devices have also been approved under this process, when in fact they should have gone through the more stringent Premarket Approval (PMA) Application (see Table 3). A 510(k) clearance requires manufacturers to notify the FDA 90 days in advance of an intention to market a new product that is substantially equivalent to an already approved predicate device.[42] Not only does the 510(k) process make

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40 Health Canada, *Regulatory Review of Pharmaceuticals, Biologics and Medical Devices: 2005 Annual Summary of Performance* (2006) at 8, online: <www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/performance_rendement_2005-eng.pdf>.

41 See Sweet, Schwemm & Parsons, *supra* note 4 at 41–42; "A Brief History of US Medical Device Regulation" (nd), *Emergo Group*, online: <www.emergogroup.com/resources/history-us-medical-device-regulation>.

42 See Kathleen Blake, "Postmarket Surveillance of Medical Devices: Current Capabilities and Future Opportunities" (2012) 36:2 J Interv Card Electrophysiol 119 at 120.

Table 3. Premarket FDA ruling concerning approval process

Premarket Notification under 510(k)	Premarket Approval (PMA) Application
• Submitted to the FDA by the device sponsor/manufacturer 90 days before marketing commences for any Class I or Class II device intended for human use for which a PMA is not required • Most Class I devices are exempt from the 510(k) requirement • May be filed by sponsor/manufacturer for a Class III device, provided that the device is claimed to be at least as safe and effective as a substantially equivalent device that is legally marketed (the "predicate") – that is, if it has the same intended use and the same technological characteristics or different characteristics that do not raise new questions about safety and effectiveness, and if the sponsor demonstrates that the device is at least as safe and effective as the legally marketed device • Substantial equivalence does not mean the new and predicate devices must be identical; this is established according to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, and labelling • Review timeframe: 3–5 months	• The most stringent type of device marketing application required by the FDA; for Class III devices (high-risk) involving any new concept or innovative technology for which there is no predicate, i.e., for which there is no substantially equivalent legally marketed device, or no substantially equivalent Class I or Class II device • Applicants are usually the persons (entities) who own the rights, or otherwise have authorized access, to the data and other information to be submitted in support of FDA approval • A complete set of design control documents are expected as part of the PMA submission, e.g., summary of safety and effectiveness, non-clinical and clinical data, risk assessment, quality plan, device-specific detailed information, manufacturing methods, labelling information, quality system requirements • Device is evaluated according to sufficient valid scientific evidence to assure safety and effectiveness for its intended use, i.e., involving well-controlled investigations for the targeted population • Manufacturers should perform quality control audits • Review timeframe: 12–24 months

Sources: US, Food and Drug Administration, "Premarket Notification 510(k)" (last updated 16 September 2015), online: <www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k>; US, Food and Drug Administration, "PMA Review Process" (26 March 2015), online: <www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm>.

it easier for manufacturers to obtain approval for a new device, but it is also less expensive. As of 30 September 2015, premarket notification fees under 510(k) were US$5,228 (standard fee) or US$2,614 (for small businesses), while for the more rigorous PMA Application, fees were US$261,388 (standard fee) or US$65,347 (for small businesses).[43]

Numerous high-risk MDs have been approved through the 510(k) clearance process.[44] Between 2003 and 2007, up to 228 high-risk MDs obtained FDA approval without a close scientific review, i.e., without providing any appropriate clinical data or any data at all.[45] A study by Zuckerman and colleagues found that 71% of the high-risk devices recalled in the US between 2005 and 2009 were given market approval through the 510(k) process. Recalled devices included cardiovascular, intravenous infusion, anaesthesiological, and neurological devices.[46] In one striking example, Medtronic's Sprint Fidelis Leads – cardiac electrodes for implantable defibrillators – were approved by the FDA in 2004 without any premarket clinical testing and were then recalled in 2011 because the leads could fracture, resulting in serious injuries and even some deaths.[47] Another example is the Birmingham hip, an all-metal hip replacement that Johnson & Johnson's DePuy Orthopaedics claimed was substantially equivalent to other models and so received clearance in the US for marketing without conducting formal clinical trials

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43 US, Food and Drug Administration, *FY 2016 Medical Device User Fee – Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments* (3 August 2015), online: <www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf>.

44 See Carlos Campillo-Artero, "A Full-Fledged Overhaul Is Needed for a Risk and Value-Based Regulation of Medical Devices in Europe" (2013) 113:1–2 Health Policy 38 at 40.

45 See US, Government Accountability Office, *Medical Devices: FDA Should Take Steps to Ensure that High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process* (GAO-09-190) (January 2009) at 16, online: <www.gao.gov/new.items/d09190.pdf>.

46 Diane M Zuckerman, Paul Brown & Steven E Nissen, "Medical Device Recalls and the FDA Approval Process" (2011) 171:11 Arch Intern Med 1006 at 1008.

47 See Rita F Redberg & Sanket S Dhruva, "Medical Device Recalls: Get It Right the First Time" (2011) 171:11 Arch Intern Med 1011 at 1011.

to demonstrate safety and efficacy.[48] After thousands of complaints and lawsuits due to device failures, and after having been implanted in almost 100,000 people worldwide, the device was recalled in 2010 in the UK.[49]

Cardiovascular devices were among those MDs most often recalled, with one study showing that between 2000 and 2007, 65% of such devices were approved after only a single clinical trial.[50] Another study showed that most high-risk cardiovascular devices were approved in the US without presentation of comparative effectiveness data.[51] Among the 123 studies used to support FDA approval of cardiovascular devices in the US between 2000 and 2007, fewer than a third were randomized controlled trials.[52] Further, a study by Boudard and colleagues revealed that more than half of 215 studies seeking to quantify the level of evidence available for innovative MDs included fewer than 30 patients.[53]

In the face of the numerous recalls of high-risk MDs, the US Institute of Medicine advocated for the elimination of the 510(k) process, while Zuckerman and colleagues called on the FDA to strengthen its authority to use the same special controls for 510(k) devices as they use for PMA

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48 See Carl Heneghan, David Langton & Matthew Thompson, "Ongoing Problems with Metal-on-Metal Hip Implants" (2012) 344 Br Med J e1349 at 2.

49 See Matthias Wienroth et al, "Precaution, Governance and the Failure of Medical Implants: The ASR™ hip in the UK" (2014) 10:19 Life Sci Soc Policy 1 at 1. Also, a study published in 2012 reported that 31,172 hip replacements (out of 402,051) undertaken between 2003 and 2011 were stemmed metal-on-metal; see Alison J Smith et al, "Failure Rates of Stemmed Metal-On-Metal Hip Replacements: Analysis of Data from the National Joint Registry of England and Wales" (2012) 379:9822 Lancet 1199 at 1199.

50 See Dhruva, Bero & Redberg, "Strength of Study Evidence", *supra* note 39 at 2680.

51 See Connie E Chen, Sanket S Dhruva & Rita F Redberg, "Research Letter: Inclusion of Comparative Effectiveness Data in High-Risk Cardiovascular Device Studies at the Time of Premarket Approval" (2012) 308:17 JAMA 1740 at 1742.

52 See Dhruva, Bero & Redberg, "Strength of Study Evidence", *supra* note 39 at 2680.

53 Aurélie Boudard et al, "Clinical Studies of Innovative Medical Devices: What Level of Evidence for Hospital-Based Health Technology Assessment?" (2013) 19:4 J Eval Clin Prac 697 at 701.

devices.[54] In response to these and other critiques,[55] the FDA launched a review of the 510(k) process to make it more effective and to ensure the enforcement of the review standards, particularly for high-risk MDs. In August 2012, the FDA released a draft 510(k) guidance document, the *Refuse to Accept Policy for 510(k)s* (followed by a formal release in December that year),[56] to clarify current premarket notification practices. The goal was to assist device manufacturers to better understand (through checklists) which types of information the FDA needs to conduct a thorough review of a new device or a new intended use of a device, prior to its being considered for a more substantive review, especially when the new device is claimed to be "substantially equivalent" to a predicate. Later, the FDA published guidance to improve device review practices[57] to fulfill commitments announced in 2011 in the Center for Devices and Radiological Health (CDRH)'s *Plan of Action*;[58] some of these commitments address the quality and consistency of review standards of 510(k) applications. Initiatives were announced to improve guidance and training for reviewers and industry on the standards and to clarify the clinical/technical data requirements for approval and clearance under 510(k) in order to address misunderstandings of the standards for clearance (e.g., definition of a "substantially equivalent device," "intended use" versus "indications for use," and the types of clinical and technical data to be provided).

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54 US, Institute of Medicine of the National Academies, *supra* note 23 at 3; Zuckerman, Brown & Nissen, *supra* note 46 at 1010.

55 Redberg & Dhruva, *supra* note 47.

56 The latest version is US, Food and Drug Administration, Center for Devices and Radiological Health & Center for Biologics Evaluation and Research, *Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff* (4 August 2015), online: <www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf>.

57 *Proposed Rule: Unique Device Identification System*, 77 Fed Reg 40736 (2012). For the final rule as adopted, see 78 Fed Reg 58786 (2013) (codified at 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830) [FDA, *Final UDI Rule*].

58 The latest update on the implementation of the *Plan of Action* is US, Food and Drug Administration, Center for Devices and Radiological Health, *CDRH Plan of Action for 510(k) and Science* (May 2014) at 4, online: <www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM297583.pdf>. The original 2011 version is available at <www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM239450.pdf>.

B. Adaptive licensing: A better approach for high-risk MDs?

The particularities of the 510(k) process are specific to the US device regulation regime. None of the other GHTF member countries have anything equivalent. Nor is the implementation of such a process on their agenda, even in the long-term. Nonetheless, there are other approaches that could potentially speed up the approval process of high-risk devices while still guaranteeing safety and effectiveness. Specifically, some form of "conditional approval" could be a promising approach to facilitate early access within current regulatory frameworks but without compromising patient safety.

Health Canada started along the path to implementing just such an initiative in 2007, when it announced that it had developed a framework to improve the regulation of drugs (the "Progressive Licensing Model") by providing guidance regarding regulatory requirements for premarket pharmacovigilance and therapeutic effectiveness management.[59] Although no mention was made at the time about expanding this to MDs, existing problems with the approval of high-risk MDs certainly provide grounds for justifying such an extension. To improve post-market surveillance practices for the sale or use of any "therapeutic product," in 2008 the Canadian government introduced Bill C-51, an amendment to the *Food and Drugs Act*, which had a particular focus on regulating natural health products and promoted a "life cycle" regulatory approach for all health products (including drugs).[60] Because of controversy about this proposed legislation, the bill was never adopted. Health Canada chose instead to move on to enforcing measures at the post-market surveillance level for all therapeutic products, including MDs, through Bill C-17, *Vanessa's Law*, which received Royal Assent on 6 November 2014.[61] The many amendments that this law brings to the

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59 Neil Yeates, David K Lee & Maurica Maher, "Health Canada's Progressive Licensing Framework" (2007) 176:13 CMAJ 1845; Health Canada, "Progressive Licensing Model" (last updated 19 September 2007), online: <www.hc-sc.gc.ca/dhp-mps/homologation-licensing/model/index-eng.php>.

60 Bill C-51, *supra* note 29; Marlisa Tiedemann, Law and Government Division, Parliamentary Information and Research Service, "Bill C-51: An Act to Amend the Food and Drugs Act and to Make Consequential Amendments to Other Acts", Legislative Summary LS602E (revised 24 July 2008) at 2, Library of Parliament, online: <www.parl.gc.ca/Content/LOP/LegislativeSummaries/39/2/c51-e.pdf>.

61 *Supra* note 28.

Canadian *Food and Drugs Act* will enable Canada to implement what we consider an optimal post-market surveillance strategy, instead of the current "wait and see" approach that relies on adverse-event reporting (discussed in more detail in Part VI below).

Representatives of the FDA and the European Medicines Agency (EMA) have discussed the opportunity to adopt an approach based on a provisional approval concept (or conditional marketing authorization), referred to as "adaptive licensing."[62] The intent of such a process is to enable better-informed decisions based on iterative phases of data gathering and marketing authorizations throughout the drug development process. A corresponding approach could be extended to MDs, but however promising this might be, it will still meet numerous challenges. Prime among these challenges is the need for the key stakeholders (i.e., regulators, industry, payers, and health care providers) to openly share information regarding safety and efficacy data along with the potential economic impact of MD reimbursement rates. This information is essential for effective HTA and decision making by third-party payers in order to avoid the perception that adaptive licensing means lower standards of efficacy, safety, and/or quality of a device.[63] Further, the very specific development path of MDs – i.e., the iterative process based on constant R&D in close relation with clinical practice, the reactivity to other scientific advances (e.g., new materials, advanced engineering), and the short product life cycles – can raise additional challenges with regard to both off-label use (when and under what conditions is this ethically permissible?) and the term and duration of patents and exclusivity periods.[64] As such, adaptive licensing may constitute a promising and flexible approach to integrating potentially beneficial but still risky MDs into health care provision, while also addressing the pricing and conditions for reimbursements – important issues for third-party payers, clinicians, and patients.

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62 See H-G Eichler et al, "Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval" (2012) 91:3 Clin Phamacol Ther 426; Kenneth Oye et al, "Legal Foundations of Adaptive Licensing" (2013) 94:4 Clin Phamacol Ther 309 [Eichler et al, "Adaptive Licensing"].

63 Jasmina Savic, "Adaptive Licensing: A Solution to the Market Access vs Evidence Dilemma?" (14 August 2013), *Pharmaceutical Compliance Monitor*, online: <www.pharmacompliancemonitor.com/adaptive-licensing-a-solution-to-the-market-access-vs-evidence-dilemma/5390/>; Eichler et al, "Adaptive Licensing", *supra* note 62 at 434.

64 Eichler et al, "Adaptive Licensing", *supra* note 62 at 435.

But attention must also be given to implementing measures to educate health care providers and the public so that they understand the inherent uncertainties that will remain with regard to any MDs approved through adaptive licensing. For example, there might be uncertainties about health benefits or unforeseen risks, or even regarding which MDs are eligible for reimbursement (although many patients with serious life-threatening conditions may be less risk-averse than regulators).[65] Further, the ongoing collection of evidence by regulators and HTA agencies could be challenging. Interestingly, the EMA recently announced that it had selected six drugs to move forward in the Adaptive Pathways Pilot Program, launched in March 2014. This program involves collaboration among a wide range of stakeholders: regulators, the pharmaceutical industry, HTA agencies, organizations issuing clinical treatment guidelines, patient and consumer organizations, health care professionals, researchers, and academics.[66]

The challenge, then, is striking a realistic balance between, on the one hand, patient hopes and interests in benefiting from a new or still conditionally approved "experimental" MD and, on the other hand, a fair evaluation of the risks that remain to be documented and are associated with its use in the health care system. A further problem is preventing undue influence on patients (e.g., by clinicians or manufacturers) and therapeutic misconception.[67] Attention paid by clinician-researchers to core ethical principles, such as beneficence/non-maleficence and respect for patient autonomy, can help ground a healthy therapeutic alliance between themselves and their patients so that patient goals, experiences, and preferences are weighed appropriately against the potential risks and benefits associated with the intervention and its follow-up, especially when clinical safety and efficacy have not yet been demonstrated.[68]

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65 *Ibid* at 428–29.

66 European Medicines Agency, "Adaptive Pathways" (nd), online: <www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp>.

67 See e.g. Gail E Henderson et al, "Clinical Trials and Medical Care: Defining the Therapeutic Misconception", online: (2007) 4:11 PLoS Med 1735 <www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0040324&representation=PDF>; Charles W Lidz & Paul S Appelbaum, "The Therapeutic Misconception: Problems and Solutions" (2002) 40:9 (supp) Med Care V-55.

68 Courtenay R Bruce, "A Review of Ethical Considerations for Ventricular As-

C. *Other national regulatory improvements*

1. The European Union

In September 2012, following harsh criticisms of its existing process, the European Commission (EC) adopted a proposal for significant amendments to the regulatory framework concerning the approval of MDs, particularly with regard to traceability, safety, clinical performance, and active implantable devices.[69] The proposed EC regulations (as opposed to directives) would shift European practice to a "premarket authorization" approach in order to better examine uncertainties and ensure transparency (e.g., through a central registry for clinical studies) and traceability (e.g., through unique device identification). The regulations would apply to certain, mostly high-risk MDs, including implants and other invasive products used for cosmetic purposes, and products that do not serve a medical purpose, such as non-corrective contact lenses. The new rules still remain to be endorsed by the European Union's 28 member states before they can become law.[70] Although the law was originally expected to be adopted in 2014 and implemented between 2015 and 2018, it was only in June 2015 that the Council of Ministers of the European Union decided on a "general approach" for the new regulations. Yet the Council of Ministers confirmed that a mandate has been given for its Luxembourg presidency to open "trilogue" talks with the European Parliament and European Commission on the planned new regulations.[71]

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sist Device Placement in Older Adults" (2013) 4:2 Aging Dis 100 at 104; Hulstaert et al, *supra* note 38.

69 EC, *Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009*, COM(2012) final 542, 2012/0266 (COD) (26 September 2012).

70 For the legislative history of the proposal, see EUR-Lex, "Procedure 2012/0266/COD" (last updated 5 October 2015), online: <eur-lex.europa.eu/procedure/EN/201998>.

71 Ronald Boumans, "Negotiating New Regulations for Medical Devices and IVDs in Europe" (June 2015), *Emergo Group*, online: <www.emergogroup.com/blog/2015/08/negotiating-new-regulations-medical-devices-and-ivds-europe>; "Final Negotiations Set to Begin on New EU Medical Device regulations" (25 September 2015), online: <www.out-law.com/en/articles/2015/september/final-negotiations-set-to-begin-on-new-eu-medical-device-regulations/>.

Eucomed,[72] an industry association representing the European medical technology industry in Europe, fought this reform, claiming that it would kill innovation, and so asked for substantial modifications.[73] The European Commission has nonetheless kept its focus on toughening current requirements (especially for the high-risk class) to ensure that MDs undergo more stringent safety and efficacy assessment by Special Notified Bodies.[74] In September 2013, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) voted in favour of a new and more stringent regulatory framework that would require some devices to go through a premarket assessment process with the EMA. Based on what is currently the norm in drug development, one measure being promoted in the EU at the level of premarket safety and effectiveness assessment is the "adaptive design" of early-phase clinical studies. Under this approach, and based on accumulated data, pre-specified modifications (e.g., to the number of subjects, endpoints, trial duration, and/or patient population) are allowed during the course of a trial. According to Mahajan and Gupta, this path would not compromise the validity and integrity of the trials.[75] The purpose of such an approach is to allow researchers to modify or redesign a trial while it is still ongoing.[76]

Despite the many benefits of adaptive design, some argue that significant ethical concerns need to be considered, including the loss of clinical

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[72] The Eucomed website has recently been incorporated into the MedTechEurope platform, an alliance of European medical technology industry associations founded by EDMA, which represents the European *in vitro* diagnostic industry.

[73] Eucomed, *Towards a Regulation that Guarantees Patient Safety, Ensures Patient Access and Keeps Innovation in Europe: Eucomed's Response to the Commission's Proposal for the Revision of the EU Medical Devices Directives*, Position Paper (30 January 2013), online: <www.medtecheurope.org/node/487>.

[74] Special Notified Bodies (SNBs) are Notified Bodies (NBs) with specific expertise that will be designated to evaluate high-risk (Class III and active implantable) MDs and any novel technologies. Only those will be entitled to conduct conformity assessments. See "New Medical Device Regulation: Introducing Special Notified Bodies" (3 March 014), *Medical Device Plus*, online: <www.ceplus.eu/index.php?id=6137&setlang=EN>.

[75] Rajiv Mahajan & Kapil Gupta, "Adaptive Design Clinical Trials: Methodology, Challenges and Prospect" (2010) 42:4 Indian J Pharmacol 201 at 201.

[76] Shein-Chung Chow, "Adaptive Clinical Trial Design" (2014) 65 Annu Rev Med 405 at 406.

equipoise, the lack of processes for adequate informed consent, and conflict between research and clinical care goals.[77] Current practices for high-risk devices, at both the premarket and post-market levels, raise major ethical issues, primary among which are the guidelines associated with patient selection and informed consent. For instance, in premarket clinical trials, the patients to be selected must meet very specific criteria of acceptability to be considered eligible. The aim is to reduce risks, mitigate adverse events, and also to optimize the risk–benefit assessment according to the intended use of the high-risk device in question. Unfortunately, women, children, ethnic minorities, and aging populations are too often under-represented in clinical trials, thus introducing uncertainties about safety and effectiveness in these populations, which may compromise generalizability once the device is approved and introduced as standard clinical practice.[78]

2. Australia

Australia is also moving rapidly to improve its regulatory process due to recognized problems with the existing system. Between 2000 and 2011,

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[77] See e.g. Scott Brian Saxman, "Ethical Considerations for Outcome-Adaptive Trial Designs: A Clinical Researcher's Perspective" (2015) 29:2 Bioethics 59.

[78] See Daniel B Kramer et al, "Premarket Clinical Evaluation of Novel Cardiovascular Devices: Quality Analysis of Premarket Studies Submitted to the Food and Drug Administration 2000–2007" (2010) 17:1 Am J Ther 2 at 4; Brian L Egleston, Roland L Dunbrack, Jr & Michael J Hall, "Clinical Trials that Explicitly Exclude Gay and Lesbian Patients", Letter to the Editor, (2010) 36:11 New Eng J Med 1054; Mita Giacomini & Françoise Baylis, "Excluding Women from Medical Research: Reasons and Rejoinders" (2003) 3:10 Clinical Researcher 12, online: Yumpu.com <www.yumpu.com/en/document/view/33024653/view-article-novel-tech-ethics>; Sanket S Dhruva, Lisa A Bero & Rita Redberg, "Gender Bias in Studies for Food and Drug Administration Premarket Approval of Cardiovascular Devices" (2011) 4:2 Circ Cardiovasc Qual Outcomes 165; Medhna Ranganathan & Raj Bhopal, "Exclusion and Inclusion of Nonwhite Ethnic Minority Groups in 72 North American and European Cardiovascular Cohort Studies", online: (2006) 3:3 PLoS Med 0329 <www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0030044&representation=PDF>; Maria CS Inacio et al, "Sex and Risk of Hip Implant Failure: Assessing Total Hip Arthroplasty Outcomes in the United States" (2013) 173:6 JAMA Intern Med 435; Anita Holdcroft, "Gender Bias in Research: How Does It Affect Evidence Based Medicine", Editorial, (2007) 100:1 J R Soc Med 2.

6,812 incidents involving MDs were reported to the Australian Therapeutic Goods Administration (TGA), including 295 deaths and 2,357 serious injuries.[79] Although McGee and colleagues' study does not describe which types of device were most often involved, these findings can lead one to conclude that there are important flaws in Australian premarket approval practices, particularly with regard to the way evidence is reviewed to ensure MD safety, quality, and efficacy. The TGA recently announced its intention to develop a series of reforms for MD regulation with the aim of increasing premarket assessment requirements concerning high-risk and especially implantable devices.[80] The TGA has also proposed reclassifying some types of MDs from medium- to high-risk (e.g., hip, knee, and shoulder joint replacement implants).

3. Japan

In Japan, before the introduction of new legislation in 2014, the last modifications to regulatory requirements for drugs and devices date back to 2005, one year after the 2002 amendments to the *Pharmaceutical Affairs Law* (*PAL*)[81] brought into creation the Pharmaceuticals and Medical Devices Agency (PMDA), the purpose of which was to harmonize Japan's requirements with international standard practices.[82] In 2011, the Japan Federation of Medical Devices Associations asked for more specific regulations to take into account the characteristics of MDs. In November 2013, the Japanese Parliament (the Diet) passed legislation revising the *PAL* – called the *Law for Partial Amendment of Pharmaceutical and Medical Device Law (Law no. 84)* – to officially separate marketing authorization holders for pharmaceuticals and devices, and also to put a greater focus on safety and qual-

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79 Richard G McGee et al, "Medical Device Regulation in Australia: Safe and Effective?" (2012) 196:4 Med J Aust 256 at 257.

80 Australia, Department of Health, Therapeutic Goods Administration, "Changes to Premarket Assessment Requirements for Medical Devices: Regulation Impact Statement" (26 June 2013), online: <www.tga.gov.au/regulation-impact-statement-changes-premarket-assessment-requirements-medical-devices>.

81 *Yakujihō* [*Pharmaceutical Affairs Law*], Law No. 96 of 31 July 2002.

82 See Y Furukawa, "Presentation on the New Japanese Pharmaceutical Affairs Law: Overview", PowerPoint presentation on behalf of Omnex Management and Engineering Consultants, LLC (January 2005) at 2, online: <www.omnex.com/training/iso13485/japan/Japan_regulatory_reqs-Jan_05.pdf>.

ity management systems, including greater involvement by the country's Ninsho review system with regard to some classes of MDs.[83] Interestingly, this new law introduces a definition of medical products that contain stem cells, which would thus be defined as regenerative and cellular medicine products.[84] It is also worth mentioning that, in 2014, the Japanese *PAL* was renamed *Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics*.

4. Canada

While the US, the EU, Australia, and Japan were working on tightening their controls over approval and diffusion of high-risk devices during the past three to four years, it was not clear that the existing regulatory framework in Canada would be revisited and assessed in light of new, emerging, and often complex technologies.[85] Striking examples of innovative but potentially problematic high-risk technologies include those at the brain–computer interface (e.g., a wireless, implantable neural prosthesis to translate neural signals from the brain),[86] active systems for improving the memory of Alzheimer's patients,[87] and implantable microchips such as radio-frequency

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83 For an English description of the law, see Japan, Ministry of Health, Labour and Welfare, *Outline of the Law for Partial Revision of the Pharmaceutical Affairs Law (Act No. 84 of 2013)*, online: <www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/dl/150407-01.pdf>.

84 Naoki Watanabe & Ayuko Nemoto, "Japan Enacts Regenerative Medicine Law and Revisions to Pharmaceutical Affairs Law" (18 December 2013), *K&L Gates LLP*, online: <www.klgates.com/japan-enacts-regenerative-medicine-law-and-revisions-to-pharmaceutical-affairs-law-12-17-2013/>.

85 Bruce Pastner, "FDA's Handling of High-Risk Medical Devices under the Microscope", Health Law Perspectives Working Paper [unnumbered] (2009), online: University of Houston Health Law & Policy Institute <www.law.uh.edu/healthlaw/perspectives/2009/%28BP%29%20Medical%20Devices.pdf>; Sheri Alpert, "Canadian Medical Device Regulations: Ready for Prime Time?" (2007) 6:2 CJLT 109 at 116.

86 Y-K Song et al, "Active Microelectronic Neurosensor Arrays for Implantable Brain Communication Interfaces" (2009) 17:4 IEEE Trans Neural Syst Rehabil Eng 339.

87 "Systems and methods for improving memory in Alzheimer's patients", US Patent No 8577470 (5 November 2013).

identification (RFID) that could be used for tracking people[88] or unlocking the door to one's car.[89] Other than developing an electronic submission pilot program for medium- and high-risk device licence and licence amendment applications in 2011, it seems that since 1998, Health Canada has not considered revisiting premarket or post-market review practices for MDs, especially to answer questions posed by the Auditor General of Canada about, for example, how often manufacturer establishments should be inspected; as a result, Health Canada did not know whether it was doing too many or too few inspections in a given year.[90] Post-approval/post-market inspections should normally be conducted during the first year following approval, with the goal of ensuring manufacturer compliance with regulations regarding manufacturing practices and labelling requirements. But as we will explain below, in 2014 the federal government decided to sponsor amendments to the *Food and Drugs Act*, through the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*,[91] an innovative strategy related to enforcing adverse-event reporting and post-market follow-up practices. Upon Royal Assent in November 2014, many of the key provisions of *Vanessa's Law* came into force.[92] In July 2015, final guidance was issued by Health Canada setting out a set of principles, policies, and standards to follow in situations where it may be appropriate for Health Canada to require a person to provide information, to disclose confidential information in certain circumstances, to order a label change or package modification, or to order a recall.[93]

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88 Paweł Rotter, Barbara Daskala & Ramón Compañó, "RFID Implants: Opportunities and Challenges for Identifying People" (2008) 27:2 IEEE Technology & Society Magazine 24.

89 Amal Graafstra, "Hands On: How Radio-Frequency Identification and I Got Personal" (28 February 2007), *IEEE Spectrum* (blog), online: <spectrum.ieee.org/computing/hardware/hands-on>.

90 Auditor General of Canada, *supra* note 15 at 13.

91 See Bill C-17, *supra* note 28.

92 SC 2013, c 24, amending *Food and Drugs Act*, RSC 1985, c F-27.

93 Health Canada, "Amendments to the *Food and Drugs Act*: Guide to New Authorities (Power to Require and Disclose Information, Power to Order a Label Change and Power to Order a Recall)" (last updated 31 July 2015), online: <www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php>.

IV. Premarket Effectiveness Assessment

Even the most robust regulatory process and risk-classification system will be incomplete if it relies solely on premarket review, because this process cannot identify or predict all potential adverse outcomes, such as unanticipated reactions to biomaterials or drugs or unexpected device performance issues.[94] Medical devices are engineered to perform certain functions, according to specific performance and safety requirements, in order to provide the desired therapeutic effects for a specific intended use. But unlike the control point for approving drugs based on four phases of clinical trials – i.e., phases I to III (premarket) and phase IV (post-market), which alone often involves thousands of research participants – many MDs may not be subject to clinical trials, nor tested on large patient populations. As already mentioned, MD manufacturers have to demonstrate that the risks associated with the use of their device have been investigated and found acceptable when weighed against the benefits for the intended patient population, that their study meets international quality standards for the clinical investigation of MDs for human participants,[95] and that they have complied with all appropriate requirements when conducting clinical investigations to assess the safety or performance of the MD for regulatory purposes.[96]

Randomized controlled trials (RCTs) remain the gold standard for regulators and are the norm for pharmaceutical drugs. But for many MDs, this approach has serious limitations. RCTs may be inappropriate when the device addresses a small patient population or when the assessment of performance requires long-term follow-up (as is the case, for example, for orthopaedic implants). Just as for drugs, when a target patient population is relatively small and vulnerable, there may be no appropriate standard treatment for use as a control, something that often arises when the device or drug under investigation is a treatment of last resort. Furthermore, in the case of im-

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94 See Sunil V Rao et al, "Postmarket Evaluation of Breakthrough Technologies" (2008) 156:2 Am Heart J 201 at 204.

95 See International Organization for Standardization (ISO), "ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice", online: <www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=45557>.

96 See Maria Donawa, "US and European Postmarket Clinical Data Requirements" (2005) 16:2 Med Device Technol 36, online: Donawa Lifescience Consulting <www.donawa.com/medical-device/donawa/files/2%20Postmarket%20Clinical%20Data%20Mar2005%20MDT%20issue.pdf>.

plantable devices, using a placebo arm in a clinical trial would necessitate the use of sham surgery, which poses major ethical issues.[97] The choice of comparator or control arm raises significant ethical and practical considerations: how could one justify implanting a placebo vagus nerve system, for example? What other medical treatment or technology could be compared with a cochlear implant or DBS? Further, the clinical success (and thus the validity of the assessment) of implantable MDs such as hip or knee replacement prostheses, pacemakers, and even DBS systems may have a great deal to do with the skills of the surgeon involved and the patient selection criteria. Thus, findings from clinical trials may not be accurately indicative of the balance of harm and benefit for the broader patient population that will encounter these devices in standard clinical practice.[98]

There may also be situations in which trial findings introduce bias into the assessment process due to problems with recruitment. For example, patients who are the "best candidates" (i.e., most likely to respond positively) or individuals from relatively homogeneous study populations may be preferentially recruited into active or control groups, thereby favouring findings of positive device performance.[99] Conversely, an inability to recruit participants from certain groups (e.g., women or persons aged 65 years and older) may produce inaccurate safety and effectiveness findings when the results of studies are generalized across a treatment group. For instance, a study by Inacio and colleagues found dramatic safety concerns for women who received hip implants, with risks of failure 29% higher for women than for men, because men were overrepresented in the premarket clinical studies. This disparity in failure rate may be due to the fact that women generally have smaller joints and bones than men.[100] This situation could introduce

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97 See Heng Li & Lilly Q Yue, "Statistical and Regulatory Issues in Nonrandomized Medical Device Clinical Studies" (2008) 18:3 J Biopharm Stat 20 at 20; Wendy Rogers et al "Strengthening the Ethical Assessment of Placebo-Controlled Surgical Trials: Three Proposals", online: (2014) 15 BMC Med Ethics 78 at 2 <www.biomedcentral.com/content/pdf/1472-6939-15-78.pdf>; Alex J London & Joseph B Kadane, "Placebos that Harm: Sham Surgery Controls in Clinical Trials" (2002) 11 Stat Methods in Med Res 413 at 416.

98 Lawrence M Friedman, Curt D Furberg & David L DeMets, *Fundamentals of Clinical Trials*, 4th ed (New York: Springer, 2010) at 8.

99 Dhruva, Bero & Redberg, "Strength of Study Evidence", *supra* note 39 at 2683; Blake, *supra* note 42 at 120.

100 Inacio et al, *supra* note 78 at 440.

gaps in the data because of very low enrolment of some patient populations in early pivotal studies.[101]

Regardless of the particular design of a trial, a clinician-researcher has a legal and ethical obligation to explain to patients all the relevant medical information concerning the risks and benefits of a procedure so that the patient, as potential research participant, can decide whether or not to consent to the experimental procedure and take part in the study. Ensuring free and informed consent is fundamental to respecting the autonomy and self-determination of patients and research participants.[102] But informed consent can prove problematic because those people who need to use or to have implanted a high-risk device are most often accessing these technologies as last-resort procedures following the failure of other treatments or medications. While these patients may be severely ill or even incapacitated, with many experiencing a very poor quality of life, they may still be capable of understanding that they are undergoing surgery and participating in a research trial.[103] Their vulnerability does not mean that they are incapable of making an informed decision. Nonetheless, this vulnerability could affect their judgment and understanding of the actual and potential risks of a procedure, and they may also overestimate the anticipated benefits. Because these patients are seeking to improve their quality of life and capacities, to improve their family and social life, or even to get back to work, they may misunderstand the impact of the post-surgical long-term monitoring that is required with experimental devices, as well as the possible complications or discomfort of implanted MDs such as DBS or cardiovascular devices.[104]

In practice, many device trials – even those for high-risk devices such as cardiac pacemakers, stents, or DBS – move almost directly from feasibility studies to pivotal research, sometimes because randomization is considered

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101 Sanket S Dhruva & Rita F Redberg, "FDA Regulation of Cardiovascular Devices and Opportunities for Improvement" (2013) 36:2 J Interv Card Electrophysiol 99 at 103; Siobhán Cusack & Paul O'Toole, "Challenges and Implications for Biomedical Research and Intervention Studies in Older Populations: Insights from the ELDERMET Study" (2013) 59:2 Gerontology 114.

102 Bruce, *supra* note 68 at 104. See also Rogers et al, *supra* note 97.

103 See Ryan A Grant et al, "Ethical Considerations of Deep Brain Stimulation for Psychiatric Illness" (2014) 21:1 J Clin Neurosci 1 at 2; Emily Bell, Ghislaine Mathieu & Eric Racine, "Preparing the Ethical Future of Deep Brain Stimulation" (2009) 72:6 Surg Neurol 577 at 580; Rogers et al, *supra* note 97 at 5.

104 See Grant et al, *supra* note 103; Bruce, *supra* note 68 at 105.

unethical (e.g., the use of placebos or sham surgery), or because evidence can come from sources other than well-controlled clinical studies. The approval of MDs is thus often based on evidence from short-term, non-blinded or non-randomized studies involving small cohorts of patients that are rarely large enough to detect low-incidence effects.[105] Often, rare adverse events can be observed only after long-term, real-world use of a MD. For example, there was little data regarding the long-term overall risks and benefits of drug-eluting stents until the device had been approved in clinical practice, especially for higher-risk populations. The pivotal clinical trials were not prospectively designed to detect long-term or less frequent adverse effects, so it was only many years after approval that appropriate actions were taken to identify and respond to these adverse events.[106] Findings from a study that examined the evidence used by France's Haute Autorité de santé for implantable MDs prior to marketing showed that the level of evidence was in fact low and often based on insufficiently robust studies.[107] As such, it is often not possible to identify from premarket clinical studies all performance defects or low-frequency failures,[108] nor to obtain accurate evidence concerning the safety and effectiveness of long-term use of a device.[109]

V. Accessing Findings for All Trials

The difficulty in accessing all findings produced by clinical trials, at both the premarket and post-market levels, poses important challenges for ensuring the clinical obligation of beneficence/non-maleficence. As much for devices as for drugs, the fact that many industry-funded clinical trials

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105 Jeanne J Lenzer & Shannon Brownlee, "Why the FDA Can't Protect the Public" (2010) 341 Brit Med J c4753.

106 David F Kong, Eric L Eisenstein & Robert A Harrington, "Late Adverse Events after Drug-Eluting Stent Implantation" (2008) 10:4 Curr Cardiol Rep 253.

107 Laure Huot et al, "Medical Device Assessment: Scientific Evidence Examined by the French National Agency for Health – a Descriptive Study", online: (2012) 12 BMC Public Health 585 at 6 <www.biomedcentral.com/content/pdf/1471-2458-12-585.pdf>.

108 Robert G Hauser, "Here We Go Again: Another Failure of Postmarketing Device Surveillance" (2012) 366:10 New Eng J Med 873 at 874; Blake, *supra* note 42 at 119.

109 Jacqui Wise, "Medical Devices Regulation Needs to Be Overhauled, Says Cardiologist" (2011) 343 Brit Med J d6671.

still go unpublished can introduce significant biases that influence the strength of the research findings, thereby affecting the conclusions that can be drawn from them for clinical practice and public policy. This can pose a threat to human health and even hamper scientific progress,[110] because physicians as well as patients are then denied access to the full body of current scientific evidence, which is of utmost importance for informed consent and good clinical judgment.[111] Failing to publish clinical findings compromises the ability of clinicians, patients, and policy makers to make informed decisions about health care,[112] and it may constitute a breach of the obligation to inform people who have agreed to participate in a trial and who expose themselves to the risks of experimental interventions.[113] Some scholars have even gone so far as to argue that the under-reporting of research findings is in itself unethical and should be regarded as a form of scientific misconduct.[114]

Current regulatory requirements do not, however, ensure public access to all data coming from studies performed by manufacturers, even when posted to public registries such as ClinicalTrials.gov, a site maintained by the US National Institutes of Health. Findings from a study that examined 137,612 records from this database against 19,158 PubMed records showed that fewer than 15% of the completed studies registered on ClinicalTrials.gov had published results.[115] Further, Gordon and colleagues

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110 Daniele Fanelli & John PA Ioannidis, "US Studies May Overestimate Effect Sizes in Softer Research" (2013) 110:37 Proc Natl Acad Sci USA 15031 at 15031.

111 See Susan Portalupi et al, "Protocol for a Systematic Review on the Extent of Non-Publication of Research Studies and Associated Study Characteristics", online: (2013) 2 Syst Rev 2 at 2 <www.systematicreviewsjournal.com/content/pdf/2046-4053-2-2.pdf>.

112 RMD Smyth et al, "Frequency and Reasons for Outcome Reporting Bias in Clinical Trials: Interviews with Trialists" (2010) 342 Brit Med J c7153.

113 Nicholas J Gross, "Can You Believe It? Evidence of Publication Bias in Clinical Trial Reports", *Medscape* (15 September 2010), online: <www.medscape.com/viewarticle/728214> [subscription required]; Christopher W Jones et al, "Non-Publication of Large Randomized Clinical Trials: Cross Sectional Analysis" (2013) 347 Brit Med J f6104.

114 See e.g. Iain Chalmers, Paul Glasziou & Fiona Godlee, "All Trials Must Be Registered and the Results Published", Editorial, (2013) 346 Brit Med J f105.

115 Tatyana A Shamliyan & Robert L Kane, "Availability of Results from Clinical

showed that when trials were sponsored by government or non-profit organizations, results were more likely to be published within 24 months of study completion.[116] But it remains the case that studies with significant or positive results (as compared to negative results) are more likely to be published and to be accessible to the scientific and clinical communities, thereby creating a risk of positive bias.[117] The usefulness of the ClinicalTrials.gov database is further undermined when many registered trial findings remain unpublished,[118] which may be the case when trials are sponsored by industry, as companies have a vested interest in only publishing positive findings associated with their products.[119] Like the pharmaceutical industry, the MD industry may also be biasing clinical research through, for example, the choice of comparator agents and the publication of positive trial findings to the exclusion of negative results.[120]

In response to this systemic problem, the AllTrials Campaign (www.alltrials.net), launched in January 2013 as an initiative of the *Bad Science* blog, the *British Medical Journal*, Oxford University's Centre for Evidence-Based Medicine, the Cochrane Collaboration, the James Lind Initiative, PLOS, and the UK-based Sense About Science, is calling for the mandatory registration of all clinical trials performed throughout the US and in the EU

Research: Failing Policy Efforts" (2014) 4:1 J Epidemiol Glob Health 1 at 4.

116 Florence T Bourgeois, Srinivas Murthy & Kenneth D Mandl, "Outcome Reporting among Drug Trials Registered in ClinicalTrials.gov" (2010) 153:3 Ann Intern Med 158 at 164.

117 F Song et al, "Dissemination and Publication of Research Findings: An Updated Review of Related Bias" (2010) 14:8 Health Technol Assess 21 at 32; Sally Hopewell et al, "Publication Bias in Clinical Trials Due to Statistical Significance or Direction of Trial Results (Review)" [2009] 1 Cochrane Database Syst Rev.

118 A recent study published in the *New England Journal of Medicine* confirms that in over 13,000 trials registered on ClinicalTrials.gov, only 13.4% of those trials reported results within the first year. See Monique L Anderson et al, "Compliance with Results Reporting at ClinicalTrials.gov" (2015) 372:11 New Eng J Med 1031 at 1034.

119 Bourgeois, Murthy & Mandl, *supra* note 116 at 165; Jones et al, *supra* note 113 at 3.

120 Joel Lexchin, "Those Who Have the Gold Make the Evidence: How the Pharmaceutical Industry Biases the Outcomes of Clinical Trials of Medications" (2012) 18:2 Sci Eng Ethics 247 at 251–52.

member states, as well as for the public disclosure of full study findings to the medical community and to patients. Such a process could help ensure that clinicians and patients are not misled about the benefits and risks of a drug or device, enable regulatory bodies to detect potentially important problems with a new technology, contribute to research planning, and promote more rational use of drugs and MDs.[121] The purpose of this database is to make mandatory the registration of all trials carried out in the EU, with a summary of results to be submitted one year after the end of each registered trial. Under the proposal, clinical study reports should in general no longer be considered confidential commercial information, and fines would be imposed by member states for non-compliance with the transparency requirements. In December 2013, the EU's Committee of Permanent Representatives endorsed a provisional agreement aimed at the development of a public EU database to be set up and run by the EMA. And in April 2014, the European Parliament passed a law that will require all clinical trials to be registered and to report results in Europe starting in 2016.[122]

In Canada, *Vanessa's Law* constitutes a major step towards ensuring the transparency of data collected at premarket and post-market levels, given the amendments that are to be introduced into the *Food and Drugs Act* to make public all information about clinical trials.[123] Unfortunately, the law states that such publication requirements may be set at the discretion of the Minister of Health, thus making transparency measures conditional.[124] This would not guarantee that both positive and negative data would become available for independent and timely scrutiny.[125] In March 2015, Health Canada launched a large, 60-day consultation with different stakeholders

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121 Peter C Gøtzsche, "Deficiencies in Proposed New EU Regulation of Clinical Trials" (2012) 345 Brit Med J e8522.

122 EC, European Parliament, Committee on the Environment, Public Health and Food Safety, Press Release, "Clinical Trials: Clearer Rules, Better Protection for Patients" (2 April 2014), online: <www.europarl.europa.eu/pdfs/news/expert/infopress/20140331IPR41186/20140331IPR41186_en.pdf>.

123 Bill C-17, *supra* note 28, s 21.7.

124 *Ibid*, s 21.1

125 Matthew Herder, "The Opacity of Bill C-17's Transparency Amendments" (23 June 2014), *Impact Ethics* (blog), online: <impactethics.ca/2014/06/23/the-opacity-of-bill-c-17s-transparency-amendments/>; Mathew Herder et al, "Regulating Prescription Drugs for Patient Safety: Does Bill C-17 Go Far Enough?" (2014) 186:8 CMAJ E287 at E290–91.

to seek comments to determine what information should be made public and when. Unfortunately, the final report concerning the *consultation document* has not yet been publicly released. In June 2015, the Honourable Rona Ambrose, then Minister of Health, launched Health Canada's Regulatory Transparency and Openness Framework and Action Plan 2015–2018 to outline concrete steps and measures to improve open access to timely, useful, and relevant health and safety information related to medical and food products.[126]

VI. Post-market Regulatory Practices

Demonstration of device performance at the level of premarket assessment does not necessarily mean that there is proof of clinical safety and efficacy at the post-market level.[127] The result of such limited premarket clinical evidence is that once a MD is approved, there may still be substantial uncertainties regarding the safety and effectiveness of the device in clinical practice.[128] Clinicians employing such devices must then rely on their individual clinical experience and adverse-event notifications from regulatory authorities to judge which MD is appropriate for their patient. High-risk MDs, and more particularly implantable and surgically invasive MDs intended for long-term use, require more comprehensive and robust evidence at the premarket level. To enable this, manufacturers must be required to produce better and more accurate clinical data.

The evidence required for regulatory approval must show that a MD will perform as intended in a defined population when used for a very specific intervention. But, unlike drugs, and for the reasons discussed earlier, MDs are often much less likely to have demonstrated clinical safety prior to being marketed. We may think that once on the market, MDs would then be subject to various (and rigorous) forms of post-marketing surveillance practices, specifically with regard to adverse-event reporting, to ensure adequate performance in the clinical practice environment (see Table 2). Unfortunately, it seems that post-market surveillance mechanisms are deficient in capturing

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126 Health Canada, Regulatory Transparency and Openness Framework and Action Plan 2015–2018, online: <www.hc-sc.gc.ca/home-accueil/alt_formats/pdf/rto-tor/2015-18-fap-cpa-eng.pdf>.

127 Hulstaert et al, *supra* note 38.

128 Deborah Cohen & Matthew Billingsley, "Europeans Are Left to Their Own Devices" (2011) 342 Brit Med J d2748.

unexpected adverse outcomes and measuring performance outcomes.[129] In the EU, for instance, the clinical performance of high-risk MD is still not subject to any premarket authorization by a regulatory authority, as these devices only require a conformity assessment; that is, to enter the European market, they must simply comply with the relevant legislation, i.e., Directive 93/42/EEC (applicable to MDs) or Directive 90/385/EEC (applicable to active implantable devices).[130] The weaknesses with such a system were highlighted by an international scandal in 2012 involving the French company Poly Implant Prothèse (PIP), a manufacturer of silicone breast implants. For several years, PIP had used an industrial silicone gel commonly used as a mattress filler, instead of the medical grade silicone approved by EU regulators.[131] The result was that in spite of existing MD regulations and oversight, hundreds of thousands of women around the world were implanted with a dangerous device that then had to be removed. The time has come, we argue, to move towards more stringent regulatory requirements for risk and evidence assessment of high-risk MDs.

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129 Arjun Sharma et al, "Health Care Policy and Regulatory Implications on Medical Device Innovations: A Cardiac Rhythm Medical Device Industry Perspective" (2013) 36:2 J Interv Card Electrophysiol 107 at 110.

130 EC, *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)*, [1990] OJ, L 189/17; EC, *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, [1993] OJ, L 169/1; both as amended by EC, *Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market*, [2007] OJ, L 247/21. See also Campillo-Artero, *supra* note 44 at 41.

131 Eleanor Beardsley, "Fears Grow over Faulty French-Made Breast Implants", *National Public Radio* (5 January 2012), online: <www.npr.org/2012/01/05/144748209/fears-grow-over-faulty-french-made-breast-implants>; Rebecca Smith, "Pips Breast Implant Scandal: Regulator Warned Years Earlier", *Telegraph* (15 May 2012), online: <www.telegraph.co.uk/health/healthnews/9264541/Pips-breast-implant-scandal-Regulator-warned-years-earlier.html>; Daniel Piotrowski, "Dramatic Rise in PIP Breast Implant Ruptures in Australia", *News.com.au* (11 October 2012), online: <www.news.com.au/lifestyle/health-fitness/bursting-staggering-amount-of-breast-implants-explode/story-fneuz9ev-1226492298726>.

Post-market surveillance mechanisms have thus become increasingly important. Regardless of the rigour of the premarket review process, it would be unrealistic to expect that all possible device failures or incidents arising from device use can be predicted. It is through real-world use that unforeseen problems related to safety and effectiveness can be detected.[132] It is important, then, that regulators monitor how a device actually performs once it is used in large patient populations, i.e., once it is approved for marketing. National regulatory authorities and manufacturers keep track of the manufacturing and the use of devices, for example, through inspections of manufacturing establishments, collecting and reporting device failures, and monitoring adverse-event reports communicated by manufacturers, health care professionals, health care facilities, and even patients. Regulatory authorities should also monitor and assess scientific and medical information about the consequences of incidents and potential risks a device may pose in order to issue warnings in a timely manner or remove a device from the market.[133]

Another challenge with regard to post-market practices concerns the reporting of incidents or adverse events associated with the use of MDs, especially high-risk MDs. Incident reporting is a major source of data for post-market risk assessment and is essential to understanding the long-term benefits and risks in real-world practice. In the case of high risk MDs – some of which are implanted for long-term use, if not permanently – problems with safety and effectiveness that are not captured at the premarket level due to short-term and small-cohort clinical studies may only appear after a substantial period of time, by which point the patients may be receiving devices that differ from those selected in the pre-approval studies.[134]

Yet, while it is compulsory for manufacturers to report any incident to national regulatory authorities, manufacturers have the freedom to decide when a negative outcome is unrelated to a device.[135] Further, reporting adverse outcomes remains voluntary for health care facilities, health care professionals, and patients, which should raise concerns about the accur-

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132 World Health Organization, *Medical Device Regulations*, *supra* note 32 at 13.

133 Auditor General of Canada, *supra* note 15 at 8; Elisabethann Wright & Steven Datlof, "Adverse Event Reporting in the EU and the USA: Similarities and Differences" (2010) 7:3 J Medical Device Regulation 14 at 18.

134 Dhruva & Redberg, *supra* note 101 at 100, 102.

135 *Ibid* at 102.

acy and completeness of adverse incidence data. For example, patients may not even know that they can report device problems to the manufacturer and/or government health authorities.[136] Reporting by health care providers is also significantly lacking. The Office of the Inspector General of the US Department of Health and Human Services (DHHS) reported that between 2003 and 2007, only 6% of adverse-event reports came from health care providers, users, and distributors.[137] This figure is similar to findings in other countries: 10% of adverse outcomes in Canada and 12% of adverse outcomes in Australia (in 2009) were submitted by health care providers or patients/users.[138] Moreover, there is no routine or systematic review of reported adverse events, so it may take time before regulatory agencies publicly disclose them; for example, Dhruva and Redberg report the case of the Bard inferior vena cava (IVC) filter, which accumulated 921 adverse-event reports before the FDA made them public.[139]

Nonetheless, as already mentioned, a significant increase in adverse-event reporting has been observed in recent years. In the US, adverse-event reports rose from 57,000 in 2001 to more than 207,000 in 2009; in 2003, 27% of adverse-event reports were associated with Class III devices, but by 2009 this figure had grown to 40%.[140] In Australia, 47.5% of the 6,812 incidents involving MDs that were reported between 2000 and 2009 were not investigated.[141] Health Canada does not perform any better, according to a 2011 report from the Auditor General of Canada, because it fails to assess whether incident reports on specific devices have been reviewed according to the risks identified or whether the reports are reviewed in a timely man-

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136 Blake, *supra* note 42 at 122.

137 US, Department of Health and Human Services, Office of Inspector General, *Adverse Event Reporting for Medical Devices* (October 2009) at 9, online: <oig.hhs.gov/oei/reports/oei-01-08-00110.pdf>.

138 Health Canada, *Underutilization of the Adverse Reaction Reporting System* (20 June 2007), online: <epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2007/385-06/report.pdf>; McGee et al, *supra* note 79 at 258.

139 Dhruva & Redberg, *supra* note 101 at 101.

140 US, Food and Drug Administration, *Understanding Barriers to Medical Device Quality* (31 October 2011), online: <www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM277323.pdf>.

141 McGee et al, *supra* note 79 at 259.

ner.[142] Under-reporting as much as under-assessment of adverse events has important consequences for the patients affected by these device failures, for their clinicians who must find alternative therapies, and for regulators who may lack up-to-date data to identify the causal factors and thereby determine an appropriate response.[143] Finally, the early detection of device failures or negative outcomes may save hundreds if not thousands of patients from being exposed to unnecessary risks and painful complications.

Adverse-event reporting does not, however, always allow for a quantification or understanding of the nature of the risks involved with a particular MD. The ability to make causal associations between the use of a specific technology or drug and the frequency of known or new reactions may be extremely difficult.[144] Post-market studies may thus be a particularly important tool for post-market surveillance practices because they can assess device performance and safety, detect problems, and monitor conditions of use once a device enters the market. For example, patient-reported outcome studies may provide information about patient perspectives and experiences.[145] Information about performance of approved devices generated from post-market study data could be an important means of identifying trends and use in clinical settings, and could thus provide a better understanding of appropriate follow-up that may be needed in certain circumstances,[146] such as when the findings were not sufficiently supported by premarket clinical data[147] or because patients enrolled in post-market studies may have

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142 Auditor General of Canada, *supra* note 15 at 27.

143 See e.g. McGee et al, *supra* note 79; Aleksandar Videnovic & Leo Verhagen Metman, "Deep Brain Stimulation for Parkinson's Disease: Prevalence of Adverse Events and Need for Standardized Reporting" (2008) 23:3 Mov Disord 343.

144 Kerri Mackay, "Showing the Blue Card: Reporting Adverse Reactions" (2005) 28:6 Aust Prescr 140; JR Nebeker, P Barach & MH Samore, "Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting" (2004) 140:10 Ann Intern Med 795; Lian Duan et al, "Adverse Drug Effection Detection" (2013) 17:2 IEEE J Biomed Health Inform 305.

145 RC Macefield, KNL Avery & JM Blazeby, "Integration of Clinical and Patient-Reported Outcomes in Surgical Oncology" (2013) 100:1 Br J Surg 28 at 28.

146 See e.g. Robert W Yeh et al, "Do Postmarketing Surveillance Studies Represent Real-World Populations? A Comparison of Patient Characteristics and Outcomes after Carotid Artery Stenting" (2011) 123:13 Circulation 1384.

147 Stephen Rothenberg & Matt Levy, "Proactive Postmarket Safety Surveillance

different characteristics and outcomes from those who participated in the pre-approval clinical trials.[148] Longer clinical experience may help identify unforeseen concerns or low-frequency failures or outcomes[149] and identify new safety concerns.[150] Finally, findings from post-market studies may become useful for HTA agencies when they have to review new or on-the-market devices and issue recommendations about their coverage (i.e., use and reimbursement) within the health care system.

VII. RECOMMENDATIONS

A. Premarket

Although the many regulatory changes announced in recent years by the EU, Australia, and the US provide hope that there will be important improvements in premarket review, the current differences between jurisdictions remain substantial. Harmonizing national classification systems could offer significant benefits to manufacturers, users, patients, and regulatory authorities, and even support global convergence of regulatory systems.[151] Many high-risk devices are designed to assist very sick patients suffering from medical conditions or disabilities which cannot or can no longer be treated through drugs; currently, thousands of patients rely on lifesaving

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in Scrutinized World" (22 February 2012), *Medical Device and Diagnostic Industry*, online: <www.mddionline.com/article/risk-management-postmarket-surveillance>.

148 Dhruva & Redberg, *supra* note 101 at 102.

149 Daniel B Kramer et al, "Postmarket Surveillance of Medical Devices: A Comparison of Strategies in the US, EU, Japan, and China", online: (2013) 10:9 PLoS Med at 5 <www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.1001519&representation=PDF>; Hauser, *supra* note 103 at 874.

150 Joseph S Ross et al, "Post-Market Clinical Research Conducted by Medical Device Manufacturers: A Cross-Sectional Survey" (2015) 8 Med Devices (Auckl) 241 at 245.

151 Global Harmonization Task Force, *Principles of Medical Devices Classification* (final document, 2 November 2012), online: International Medical Device Regulators Forum <www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.docx>.

MDs.[152] Faced with a proliferation of MDs internationally and the rapid pace of innovation in the field, ensuring device safety and performance is of utmost importance for patients. For example, many new emerging technologies will incorporate nanomaterials, medicinal products, or biological materials or may be connected to an energy source; these developments necessitate timely public access to the best evidence drawn from findings from all clinical studies conducted around the world. Failure to submit negative data is in itself a major ethical issue. Not only can it create bias, but when regulatory authorities, decision makers, and users have to rely on incomplete evidence, they may overestimate the safety and performance of a MD.[153] As much as regulatory authorities should not be denied access to unpublished findings, high-risk MDs should not be cleared for use without clinical testing, even when long-term trials may not always be possible.[154] Regulatory agencies have a dual mandate of ensuring patient safety and providing timely access to new medical treatments.[155]

We thus support Kaplan and Williams,[156] who suggest a two-step approval process: an *initial* approval and a subsequent *final* approval once a device has entered into clinical use, contingent on accumulated clinical experience at specific end-points. Admittedly, granting only conditional approval for a specified period may impose a financial burden on manufacturers, and health care providers or health care facilities may have reservations about offering their patients a conditionally approved device. Further, both public and private health care payers may refuse to cover the costs of such MDs because of insufficient evidence of effectiveness or lack of substantial evidence of safety, and regulatory agencies may be reluctant to issue final approval even when no alternative exists, so as to protect vulnerable

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152 Hauser, *supra* note 108 at 874.

153 Kay Dickersin & Iain Chalmers, "Recognizing, Investigating and Dealing with Incomplete and Biased Reporting of Clinical Research: From Francis Bacon to the WHO" (2011) 104:12 J R Soc Med 532 at 532.

154 Wise, *supra* note 109.

155 Nicholas S Downing et al, "Regulatory Review of Novel Therapeutics – Comparison of Three Regulatory Agencies" (2012) 366:24 New Eng J Med 2284 at 2291.

156 Aaron V Kaplan & David O Williams, "Medical Device Regulatory Landscape: The Imperative of Finding Balance" (2012) 5:1 Circ Cardiovas Interv 2 at 4.

patients.[157] Yet this approach could allow earlier access to new medical technologies if there are no safety issues already known prior to their marketing. Nonetheless, this approach calls for negotiation between all concerned stakeholders, including those with HTA expertise, to develop explicit criteria for accumulating the necessary scientific evidence and conditions to inform decisions about access and coverage by health care systems.

B. Post-market surveillance

In 2011, following a recommendation of the US Government Accountability Office, Senators Grassley, Blumenthal, and Kohl (unsuccessfully) introduced the *Medical Device Patient Safety Act* in the House of Representatives, which would have required a conditional approval approach to MD regulation in order to protect patients from unsafe medical devices, especially those cleared through the 510(k) approval pathway. This new process sought to improve post-market practices by empowering the FDA to impose conditions on the sale and distribution of a device (namely data collection, labelling information, and post-market studies) while it is undergoing further evaluation for potential testing of its safety, effectiveness, and reliability.[158]

We argue for some form of *conditional* approval based on more data obtained through post-market studies in the case of high-risk MDs, and especially for active implantable devices. As much as for pharmaceutical drugs, post-market studies of MDs can provide all concerned stakeholders (regulators, health care providers, patients, and HTA agencies) with useful risk–benefit performance evidence concerning new products in real-world clinical practice.[159] User-friendly mechanisms need to be implemented to facilitate more frequent and even mandatory reporting of adverse events by users who are directly involved, i.e., patients and health care providers.

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157 Darroy et al, "Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs" (2015) 372:3 New Eng J Med 279.

158 US, Bill S 1995, *Medical Device Patient Safety Act*, 112th Cong, 2011; see also "Medical Device Patient Safety Act" (bill summary), *Hyman, Phelps & McNamara, PC*, online: <www.hpm.com/pdf/blog/Medical%20Device%20Patient%20Safety%20Act%20Summary%20PDF.pdf>.

159 Hans-Georg Eichler et al, "Balancing Early Market Access to New Drugs with the Need for Benefit/Risk Data: A Mounting Dilemma" (2008) 7:10 Nat Rev Drug Discov 818 at 824.

When gaining access to a high-risk device, patients should receive all appropriate and convincing evidence about the nature of the device, details regarding its manufacturing company, and information about its potential outcomes, and they should be invited to report any adverse outcomes not only to their physicians but also to the appropriate regulatory authorities. For now, most patients are still confident that their physicians or hospital facilities will take charge of such reporting, a confidence that is likely misplaced. Proactive post-market surveillance practices should not be limited to corrective or preventive actions, such as inspections and adverse events reporting; they should instead serve to review the effectiveness and performance of a device in routine clinical practice, in order to provide objective information for decision making in health care delivery and health policy.[160]

Reliable clinical registries should also be encouraged. Australia recently evaluated the benefits of developing national quality registries for high-risk implantable devices to provide clinical data from identified individuals who have received those devices and to facilitate disclosure of potential and unforeseen problems with any specific type of device.[161] With the increasing complexity of high-risk devices, such registries may facilitate access to real-world use of data on performance, safety, clinical effectiveness, and reliability and provide critical information on the frequency of device malfunctions or complications.[162] All national jurisdictions should align their practices to those of the FDA, which is promoting the development of national device registries that are independent of manufacturers' registries and the sharing of information with other national registries (where they exist) to generate new data.[163]

More importantly, device traceability practices should become a key post-market surveillance practice to improve safety and performance capabilities. In July 2012, the FDA proposed a rule for establishing a unique

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160 Markus Siebert et al, "Health Technology Assessment for Medical Devices in Europe" (2002) 18:3 Int J Technol Assess Health Care 733 at 736.

161 Australia, Department of Health and Ageing, *Regulation Impact Statement: Clinical Registers for High Risk Implantable Medical Devices* (18 February 2013), online: Australia, Department of the Prime Minister and Cabinet, Office of Best Practice Regulation <ris.dpmc.gov.au/files/2013/06/RIS_Clinical_Registers.pdf>.

162 Sharon-Lise T Normand et al, "Postmarket Surveillance for Medical Devices: America's New Strategy" (2012) 345 Brit Med J e6848.

163 *Ibid* at 1.

device identification (UDI) system in order to improve patient safety and make post-market follow-up more efficient throughout the whole life cycle of a device. This measure could help identify product problems more quickly and enable better and more targeted recalls, thereby enhancing patient safety. A UDI could take the form of a unique permanent marking (e.g., a unique numeric or alphanumeric code) specific to any device, and would allow more accurate reporting, reviewing, and analyzing of adverse-event reports. This would then allow problem devices to be identified and corrected more quickly, improve incident reporting, reduce medical errors, and even help fight the use of counterfeit devices.[164] All UDIs should be designed to be readable by humans and machines and should be used in the supply chain software of health systems, in electronic health records, and in registries; needless to say, such a system could greatly facilitate device tracking, safety surveillance, and research.[165]

Conclusion

Innovations in the field of MDs aim at improving patient care and responding to unmet health care needs. Yet high-risk MDs pose particular ethical and policy challenges that can undermine the responsibilities of clinicians and regulators to work in the best interests of patients, ensure public safety, and protect public health. Current regulatory practices contribute to an ongoing lack of high quality evidence associated with premarket clinical studies, the non-public disclosure of new evidence, and inadequate data on the overall use and long-term outcomes of high-risk MDs.[166] The time has come to improve harmonization among national regulatory systems, especially for high-risk MDs, in both the premarket assessment of evidence (e.g., classification and premarket safety and performance requirements for clinical assessment) and in post-market surveillance. In the face of the rapid development of complex and sophisticated medical technologies, current regulatory processes appear inadequate to ensure not only patient safety but also informed decision making by patients, health care providers, and third-party payers. We argue that the device development process should be seen as a continuum, beginning with first clinical use and extending initially to

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164 *Cf* FDA, *Final UDI Rule*, *supra* note 57 at 58786.

165 Normand et al, *supra* note 162 at 1.

166 Hulstaert et al, *supra* note 38; Normand et al, *supra* note 162.

market launch and then to eventual use in routine clinical practice.[167] Regulation may be an imperfect tool, but it is nonetheless essential to ensuring that patients receive the right treatment for the right condition and benefit from safe and effective MDs. It is a matter of both personal and public health.

The creation of the Globalization Harmonization Task Force was a Canadian initiative, so it is disappointing to see that Canada is lagging behind the other founding member nations in updating its regulatory system. Given the many measures adopted by the US, Australia, Japan, and the EU with regard to high-risk MDs, it is time that Canada moves forward on adapting its current system and working with its partners in the new International Medical Device Regulators Forum[168] to harmonize practices across national jurisdictions. Such a development would help eliminate differences between jurisdictions, decrease the costs of regulatory compliance, and address major ethical and policy concerns associated with the accurate risk–benefit assessment of high-risk MDs, both before and after they enter the marketplace and become part of clinical practice and health service provision.

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[167] Roxana Mehran, "Post-Market Approval Surveillance: A Call for a More Integrated and Comprehensive Approach" (2004) 109:25 Circulation 3073 at 3077.

[168] See *supra* note 9 and accompanying text.

APPENDIX. SOURCES FOR TABLE 2

Australia: *Therapeutic Goods Act 1989* (Cth); *Therapeutic Goods Regulations* 1990 (Cth); *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).

Canada: *Food and Drugs Act*, RSC 1985, c F-27; *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, SC 2014, c 24; *Medical Devices Regulations*, SOR/98-282.

EU: EC, Commission, "Medical Devices: Guidance" (last updated 12 November 2015), online: <ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm>; EC, *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)*, [1990] OJ, L 189/17; EC, *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, [1993] OJ, L 169/1; EC, *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, [1998] OJ, L 331/1; EC, *Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market*, [2007] OJ, L 247/21.

Japan: Pharmaceuticals and Medical Devices Agency, "Regulatory Information" (nd), online: <www.pmda.go.jp/english/review-services/regulatory-info/0002.html>; Y Furukawa, "Presentation on the New Japanese Pharmaceutical Affairs Law: Overview", PowerPoint presentation on behalf of Omnex Management and Engineering Consultants, LLC (January 2005), online: <www.omnex.com/training/iso13485/japan/Japan_regulatory_reqs-Jan_05.pdf>.

US: Food and Drug Administration, "Premarket Notification [510(k)] Review Fees" (last updated 29 October 2015), online: <www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm>; Food and Drug Administration, "PMA Review Fees" (last updated 29 September 2015), online: <www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm>; Food and Drug Administration, "Overview of Device Regulation" (last updated 14 August 2015), online: <www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>; *Food and Drug Administration Safety and Innovation Act*, Pub L No 112–144, 126 Stat 993 (2012); *Safe Medical Devices Act of 1990*, Pub L No 101-29, 104 Stat 4511; *Food and Drug Administration Modernization Act of 1997*, Pub L No 105-115, 111 Stat 2296.

Patient Safety Incidents and Protection of Quality Assurance Activities: Legislative and Jurisprudential Responses in Canada

*Louise Bélanger-Hardy & Caroline Quesnel**

Patient safety incidents (PSIs), also called adverse events, are an ongoing challenge for Canadian health institutions such as hospitals. Sharing information and gathering data about these incidents is an important element in a strategy to reduce their occurrence. In order to encourage the sharing of information and open discussions within health institutions, Canadian provinces and territories have developed a statutory evidentiary framework protecting quality of care information from use in legal proceedings. These qualified privilege laws operate in a context in which underlying policies reveal a tension between, on the one hand, the benefit of full disclosure to patients and, on the other, the need to encourage health care providers and institutions to discuss PSIs fully and to make positive systemic changes to improve patient safety. This article reviews Canadian qualified privilege laws pertaining to quality of care information and the judicial treatment they have been given

Les incidents touchant la sécurité des patients, aussi appelés événements indésirables, représentent un défi constant pour les établissements de santé canadiens, y compris les hôpitaux. Le partage d'information et la collecte de données concernant ces incidents sont des éléments importants dans le cadre d'une stratégie visant à en réduire la fréquence. Afin d'encourager le partage de l'information et des discussions ouvertes au sein des établissements de santé, les provinces et territoires canadiens ont développé un cadre législatif protégeant les renseignements sur la qualité des soins d'une utilisation lors de procédures judiciaires. Ces lois qui accordent une immunité relative s'inscrivent dans un contexte qui révèle une tension entre deux considérations de politique générale, soit le bénéfice de la divulgation complète au patient d'une part et, d'autre part, la nécessité d'encourager les professionnels de la santé et les établissements de la santé à discuter en profondeur des in-

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in order to assess whether the legislation and its judicial interpretation favour one policy objective over the other, or whether a more nuanced approach has been adopted. The article argues that the "balancing of interests" approach adopted by legislators and courts is appropriate and should be encouraged, as it is the best way, at least at this time, to support efforts to improve patient safety while recognizing patients' informational needs following a patient safety incident.

cidents touchant la sécurité des patients et à apporter des changements systémiques et bénéfiques pour améliorer leur sécurité. Cet article examine les lois canadiennes régissant l'immunité relative concernant les renseignements sur la qualité des soins ainsi que leur traitement judiciaire afin de déterminer si cette législation et son interprétation judiciaire favorisent davantage un des deux objectifs de politique générale, ou si une approche nuancée a été adoptée. Cet article soutient que la mise en équilibre des intérêts, approche adoptée par les législateurs et les tribunaux, est appropriée et devrait être encouragée, puisqu'il s'agit du meilleur moyen – du moins à l'heure actuelle – pour soutenir les efforts visant à améliorer la sécurité des patients tout en reconnaissant le besoin de ces derniers d'obtenir l'information rattachée à un incident suite à sa survenue.

Introduction

The importance of patient safety within hospitals and other health care settings was highlighted in the well-known *To Err Is Human* report published by the American Institute of Medicine in late 1999.[1] In Canada, the 2004 Canadian Adverse Events Study (CAES)[2] and the more recent Canadian Paediatric Adverse Events Study (CPAES)[3] have both confirmed that patient safety incidents (PSIs)[4] are an ongoing challenge for Canadian health institutions.[5] Indeed, the CAES concluded that an estimated 7.5% of

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1 Committee on Quality of Health Care in America, Institute of Medicine, *To Err Is Human: Building a Safer Health System*, ed by Linda T Kohn, Janet M Corrigan & Molla S Donaldson (Washington: National Academy Press, 1999) [*To Err Is Human*].

2 G Ross Baker et al, "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada" (2004) 170:11 CMAJ 1678 [Baker et al, "CAES"].

3 Anne G Matlow et al, "Adverse Events among Children in Canadian Hospitals: The Canadian Paediatric Adverse Events Study" (2012) 184:13 CMAJ E709.

4 This is the term that will be retained here and, at times, the term "adverse event" will be used as a synonym. The literature on patient safety relies on a variety of terms to which different definitions are given. The World Health Organization (WHO) has also suggested definitions. A patient safety incident is defined by the WHO as "an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient." Distinctions are then made between "harmful incidents," which result in harm to the patient; "no harm incidents," which affect patients but without causing discernible harm; and "near misses," which describe PSIs that never reach the patient. See World Health Organization, *More Than Words: Conceptual Framework for the International Classification for Patient Safety, Version 1.1*, Technical Report (Geneva: WHO, 2009) at 15–16, online: <www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf>. The latest *Canadian Incident Analysis Framework* has adopted the WHO terminology and, for reasons of consistency, so will the present paper. See Canadian Patient Safety Institute, *Canadian Incident Analysis Framework* (Edmonton: CPSI, 2012) at 8–9, online: <www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF> [*Canadian Incident Analysis Framework*].

5 Not to mention a huge economic burden. See Canadian Patient Safety Institute, *The Economics of Patient Safety in Acute Care*, Technical Report, by Edward Etchells et al (Edmonton: CPSI, 2012) at 21, online: <www.patientsafetyinstitute.ca/English/research/commissionedResearch/EconomicsofPatientSafety/Docu

patients admitted to acute care hospitals in Canada suffered a PSI and that 36.9% of these incidents were judged preventable,[6] while the CPAES revealed that the weighted rate of adverse events in Canadian academic paediatric centres and community hospitals was 9.2%.[7]

One of the key conclusions of the *To Err Is Human* report is that most safety incidents in health care settings are caused by a combination of human error and underlying factors,[8] including organizational structures, policies, levels of funding, and institutional culture. Thus, according to the report, PSI reduction can be achieved, at least in part, through a system-wide approach rather than through a culture of "blame and shame" that places emphasis on individual responsibility.[9] The notion of systemic errors has been widely embraced and, for the past decade, there has been increased emphasis on capturing, monitoring, and measuring PSIs through incident reporting systems, patient safety indicators, and, more recently, trigger tools.[10]

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ments/Economics%20of%20Patient%20Safety%20-%20Acute%20Care%20-%20Final%20Report.pdf> (estimating the economic burden of adverse events in Canada in 2009–2010 as $1.1 billion).

6 Baker et al, "CEAS", *supra* note 2 at 1683.

7 Matlow et al, *supra* note 3 at E712.

8 *To Err Is Human*, *supra* note 1 at 55–56. The "Swiss cheese model" is often used to describe this phenomenon. Specific occurrences at the "sharp end" of a system, i.e., the locus of interaction between a health professional and a patient, are not the only cause of adverse events; rather, latent or "blunt end" factors such as policy, technology, and administrative decisions are the root causes of an undesirable outcome. As explained by Robert M Wachter, *Understanding Patient Safety*, 2nd ed (New York: McGraw Hill Medical, 2012) at 21–22, online: <accessmedicine.mhmedical.com/content.aspx?bookid=396&Sectionid=40414534>, the model "highlights the need to focus less on the (futile) goal of trying to perfect human behavior and more on aiming to shrink the holes in the Swiss cheese … and create multiple overlapping layers of protection to decrease the probability that the holes will ever align and let an error slip through." The Swiss cheese model was first proposed by JT Reason, *Human Error* (New York: Cambridge University Press, 1990).

9 *To Err Is Human*, *supra* note 1 at 56. Of course, the recognition of the need for a system-wide approach does not eliminate entirely the need for other mechanisms such as internal sanctions or professional oversight, which, in some cases, can be more appropriate responses to errors by health care providers.

10 For a description of these processes, see Wachter, *supra* note 8, especially chapters 1, 3, 14. See also Kaveh G Shojania, "The Frustrating Case of In-

Indeed, once PSIs are detected, methods such as root cause analysis, administrative data analysis, and morbidity and mortality conferences can be used to provide vital information to help understand and hopefully prevent future undesirable outcomes. Quality of care initiatives become opportunities to learn from PSIs, with the ultimate goal of improving patient care.

Most measures to detect adverse events require the participation of health professionals, administrators, and other staff, who are called upon not only to report and input data but also to investigate, analyze, and interpret the information gathered in order to eventually develop strategies to reduce PSIs. Even if quality of care initiatives increasingly rely on electronic systems and e-triggers, human intervention remains essential. For instance, in many reporting systems, data entries about a patient safety event are followed by a clinical review where staff must determine whether a true PSI has in fact occurred.[11]

In order to encourage health care providers to share information and participate in data gathering processes, many jurisdictions, in Canada and elsewhere,[12] have felt the need to strengthen the statutory evidentiary frame-

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cident-Reporting Systems" (2008) 17:6 BMJ Qual Saf 400 at 401; Richard Thomson & Alison Pryce, "Patient Safety: Epidemiological Considerations" in Brian Hurwitz & Aziz Sheikh, eds, *Health Care Errors and Patient Safety* (Chichester, UK: Wiley-Blackwell, 2009) 207 at 210, online: <onlinelibrary.wiley.com/book/10.1002/9781444308150> (where error measurement methods are summarized in a useful table).

11 DO Farley et al, "Adverse-Event-Reporting Practices by US Hospitals: Results of a National Survey" (2008) 17:6 BMJ Qual Saf 416 at 416 (describing the essential components of an effective system including staff participation).

12 See Joan Gilmour, *Patient Safety, Medical Error and Tort Law: An International Comparison*, Final Report [to Health Canada] (Ottawa: Health Policy Research Program, 2006) at 63–66, 99–101, 168–69, 194–95, online: Osgoode Hall Law School <apps.osgoode.yorku.ca/osgmedia.nsf/0/094676DE3FAD06A5852572330059253C/$FILE/FinalRepFin_Full.pdf> (examining statutory interventions in Canada, the United States, Australia, and New Zealand). See also Jocelyn Downie et al, *Patient Safety Law: From Silos to Systems*, Final Report [to Health Canada] (Ottawa: Health Policy Research Program, 2006), online: Queensland University of Technology <eprints.qut.edu.au/62121/1/HLI_Patient_Safety-Main_Report_(final).pdf> (discussing the situation in Denmark, New Zealand, Australia, United Kingdom, and the United States). In the United States, *The Patient Safety and Quality Improvement Act of 2005*, Pub L No 109-41, 119 Stat 424, creates an evidentiary privilege to protect

work protecting quality of care information from use in legal proceedings. The focus of the statutes is not on PSIs as such, but rather on quality of care activities generally, of which PSIs are of course a part. In Canada, "qualified privilege" laws can be found in each province and territory.[13]

Although qualified privilege laws have existed for some time in Canada – usually as part of legislation on evidence – the *To Err Is Human Report* led to a renewed interest in patient safety initiatives, and many provinces were thus encouraged to review existing legislative measures. Important modifications were brought in the laws of evidence of many jurisdictions – for example, Alberta in 2000, Saskatchewan in 2006, Manitoba in 2008, and Prince Edward Island in 2011. In Nova Scotia and Ontario, legislation has been adopted to deal specifically with the protection of quality of care information.[14]

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information submitted voluntarily to designated organizations that compile information on medical errors. See Charles M Key, "The Role of PSQIA Privilege in Medical Error Reduction" (2008) 21:1 The Health Lawyer 24.

[13] See full list, *infra* note 20. The relevant legislation is discussed briefly in *Canadian Incident Analysis Framework*, *supra* note 4 at 120–24. See also Gilmour, *supra* note 12; Canadian Patient Safety Institute, "Appendix B: Review of Provincial, Territorial and Federal Legislation and Policy Related to the Reporting and Review of Adverse Events in Healthcare in Canada", by G Ross Baker et al (Edmonton: CPSI, 2007) at B6–B7, B34–B43, online: Fasken Martineau <www.fasken.com/files/Publication/b64114ad-8b04-4fe3-9888-0e5531939f3d/Presentation/PublicationAttachment/73222cfe-7cef-4d60-9fd7-165b52760585/CAERLS%20Consultation%20Paper%20AppendixB.pdf> [Baker et al, Canadian Patient Safety Institute, "Review"]; Deborah Gregory, "Adverse Health Event Management: International and Canadian Practices" in Newfoundland and Labrador, Task Force on Adverse Health Events, *Background Documents*, *Volume II: Additional Reports* (St John's: Office of the Queen's Printer, 2008) 187 at 205, 224. Finally, there is an excellent review of the legislation applicable to Ontario in Halyna Perun, Michael Orr & Fannie Dimitriadis, *Guide to the Ontario Personal Health Information Protection Act* (Toronto: Irwin Law, 2005) at 607–45.

[14] Nova Scotia has very recently adopted the *Quality-improvement Information Protection Act*, SNS 2015, c 8 [*QIPA – NS*]; this act repeals and replaces sections 60 and 61 of the *Evidence Act*, RSNS 1980, c 154 [*Evidence Act – NS*], which previously addressed the qualified privilege. On 16 September 2015, the Ontario government introduced Bill 119, *An Act to amend the Personal Health Information Protection Act, 2004*, 1st Sess, 41st Parl, Ontario, 2015, to make certain related amendments and to repeal and replace the *Quality of Care Information Protection Act*, *2004*, SO 2004, c 3, Schedule B [*QCIPA 2004 – ON*].

At this juncture, it is useful to recall the key policy choices related to the protection of quality of care information. As noted at the time of the enactment of Ontario's *Quality of Care Information Protection Act, 2004*, the objective of such protection is to "encourage health professionals to share information and hold open discussions that can lead to improved patient care and safety."[15] Thus, the policy rationale is "to encourage candidness and the free flow of information in circumstances in which that is regarded as socially beneficial."[16] The policy is based on the public interest in optimal quality of care, which is achieved, at least in part, through detailed analysis of PSIs and their aftermath.

However, there are arguments against such a choice. The main counterpoint to the policies favouring protecting quality of care activities from disclosure is the ethical/legal obligation to disclose PSIs and system failures to patients.[17] This is based on the notion that patients who are injured should

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It should be noted that although Bill 119 will repeal the current legislation, the basic framework and most of the current provisions of the *Quality of Care Information Protection Act*, *2004* will be incorporated unchanged into the new legislation. According to the Bill, the new Act will be known as the *Quality of Care Information Protection Act, 2015*. When discussing Ontario's *Quality of Care Information Protection Act*, *2004*, this article will refer to the current (i.e. 2004) legislation (i.e., the 2004 *Act* as amended through 2015) and it will highlight the provisions of Bill 119 only insofar as they will bring about significant changes if adopted.

15 Ontario, Legislative Assembly, Standing Committee on General Government, "Bill 31, Health Information Protection Act, 2003", *Official Report of Debates (Hansard)*, 38th Parl, 1st Sess, No G-2 (26 January 2004) at G-7 (Hon George Smitherman) [Ontario Bill 31 Standing Committee Deliberations]. The importance of patient safety is also noted in the "object" of the Québec legislation, *An Act respecting health services and social services (HSSS – QC)*, *infra* note 20, s 2(8.1), which refers "to ensur[ing] users the safe provision of health services and social services."

16 David M Studdert & Mark W Richardson, "Legal Aspects of Open Disclosure: A Review of Australian Law" (2010) 193:5 Med J Aust 273 at 273.

17 For discussion on the issue of disclosure, see Canadian Patient Safety Institute, Disclosure Working Group, "Canadian Disclosure Guidelines: Being Open and Honest with Patients and Families" (Edmonton: CPSI, 2011), online: <www.patientsafetyinstitute.ca/English/toolsResources/disclosure/Documents/CPSI Canadian Disclosure Guidelines.pdf>; Elaine O'Connor et al, "Disclosure of Patient Safety Incidents: A Comprehensive Review" (2010) 22:5 Int J Qual Heath Care 371; Tracey M Bailey & Nola M Ries, "Legal Issues in Patient

benefit from a wide access to information related to the incident at the root of the harm caused. Indeed, the ability to build a strong legal case is linked to accessing as much relevant information as possible. Another key policy consideration is compensation. In the absence of a "no-fault" system for medical injuries, civil liability provides a means to be indemnified. Lastly, there is also the notion that full disclosure helps to maintain trust in the health care system and health care providers.[18] From a public interest perspective, disclosure contributes to the integrity of both the judicial and health systems: access to justice for litigants and safety when receiving care. Thus, qualified privilege laws operate in a context where underlying policies reveal a tension between, on the one hand, the benefit of full disclosure to patients and, on the other, the need to encourage health care providers and institutions to discuss PSIs fully and to make positive systemic changes to improve patient safety.

In this context, this article reviews Canadian qualified privilege laws pertaining to quality of care information and the judicial treatment they have been given in order to assess whether the legislation and its interpretation favour one policy objective over the other, or whether a more nuanced approach is being adopted. Thus, Part I describes and compares provincial and territorial qualified privilege laws and examines the cases which have discussed them over the last fifteen years.[19] This material is considered in some detail, not only in order to provide a good overview of the Canadian legisla-

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Safety: The Example of Nosocomial Infection" (2005) 8 Healthc Q (Special Issue) 140; Michael Waite, "To Tell the Truth: The Ethical and Legal Implications of Disclosure in Medical Error" (2005) 13 Heath LJ 1; Gilmour, *supra* note 12 at 62–68; Gerald B Robertson, "When Things Go Wrong: The Duty to Disclose Medical Error" (2002) 28:1 Queen's LJ 353. See also *Hospital Management*, RRO 1990, Reg 965, s 2(4)–(5), which provides for mandatory disclosure of critical incidents to a number of entities and individuals, including patients.

18 Gilmour, *supra* note 12 at 63.

19 The decisions analyzed below were identified through legal databases and cover the period from January 2000 to September 2014, with a few pre-2000 cases discussed when appropriate. Most are judicial decisions but a few come from administrative tribunals – typically information and privacy commissions. Most of the decisions flow from PSIs. Those that do not nevertheless provide valuable insight into the way courts interpret qualified privilege laws. The search was conducted by mapping decisions related to the laws in each province and territory. Judicial activity has been more intense in some areas of the country than in others; for instance, courts have yet to consider Ontario's *Quality of Care Information Protection Act*, *2004* in any reported decision.

tive landscape, but also to contextualize the various fact situations where health professionals and institutions may have to rely on qualified privilege laws. In Part II, the article assesses and analyzes legislative and judicial responses to the quality of care information protection schemes in light of the policy objectives outlined above. The article argues that the "balancing of interests" approach adopted by legislators and courts is appropriate and should be encouraged as it is the best way, at least at this time, to support efforts to improve patient safety while recognizing patients' informational needs following a PSI.

I. Qualified Privilege in Canadian Provinces and Territories

All Canadian provinces and territories have comparable qualified privilege laws. In most instances, the relevant legislative provisions can be found in the laws on evidence.[20] So far, Ontario and Nova Scotia are the only provinces that have enacted stand-alone legislation dealing with the protection of quality of care information.[21]

In general terms, the legislative schemes provide that witnesses involved in legal proceedings are protected from the obligation to answer questions or disclose information related to the work of quality of care committees.[22]

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[20] *Alberta Evidence Act*, RSA 2000, c A-18 [*Evidence Act – AB*]; *Evidence Act*, RSBC 1996, c 124 [*Evidence Act – BC*]; *Manitoba Evidence Act*, CCSM c E150 [*Evidence Act – MB*]; *Evidence Act*, RSNB 1973, c E-11 [*Evidence Act – NB*]; *Evidence Act*, RSNL 1990, c E-16 [*Evidence Act* – NL]; *Evidence Act*, RSNWT 1988, c E-8 [*Evidence Act – NWT*]; *Evidence Act*, RSNWT (Nu) 1988, c E-8 as duplicated for Nunavut by s 29 of the *Nunavut Act*, SC 1993, c 128 [*Evidence Act – NU*]; *Evidence Act*, SS 2006, c E-11.2 [*Evidence Act – SK*]; *Evidence Act*, RSY 2002, c 78 [*Evidence Act – YK*]. Prince Edward Island and Québec deal with the qualified privilege in other legislation: *Health Services Act*, RSPEI 1988, c H-1.6 [*HSA – PEI*]; *An Act respecting health services and social services*, CQLR c S-4.2, ss 183.3–183.4 [*HSSS – QC*].

[21] See *QCIPA 2004 – ON*, *supra* note 14; *QIPA – NS*, *supra* note 14. Ontario's context is particularly interesting because the *Quality of Care Information Protection Act*, *2004* was enacted along with the *Personal Health Information Protection Act*, SO 2004, c 3, Schedule A, as part of the same bill – Bill 31, *An Act to enact and amend various Acts with respect to the protection of health information*, 1st Sess, 38th Parl, Ontario, 2004 – but as separate legislation.

[22] For typical wording of the privilege, see *Evidence Act – NL*, *supra* note 20, s 8.1(4):

The privilege applies in a variety of settings depending on the jurisdiction. For instance, in the Newfoundland & Labrador *Evidence Act*, the privilege can be relied on in a "legal proceeding," which is very broadly defined as an "action, inquiry, arbitration, judicial inquiry or civil proceeding in which evidence may be given and also includes a proceeding before a board, commission or tribunal."[23] Similarly broad wording is found in the legislation of most other Canadian provinces and territories.[24] However, in New Brunswick, the qualified privilege is limited to legal proceedings "in any court," which means that administrative tribunals, inquiries, and professional colleges probably do not fall under the protection of the legislation.[25] Moreover, a significant number of jurisdictions specify that the privilege cannot be relied on in disciplinary matters.[26] Nevertheless, generally speaking, in Canada, health professionals and staff can rely on qualified privilege laws to

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> Where a person appears as a witness in a legal proceeding, that person shall not be asked and shall not (a) answer a question in connection with proceedings of a committee set out in subsection (2); or (b) produce a report, evaluation, statement, memorandum, recommendation, document of information of, or made by, for or to, a committee to which this section applies.

The *Evidence Act – AB*, *supra* note 20, s 1(a)(i) does not refer to proceedings but to an "action," which is defined as including "an issue, matter, arbitration, reference, investigation or inquiry."

23 *Evidence Act – NL*, *supra* note 20, s 8.1(1)(a).

24 *Evidence Act – AB*, *supra* note 20, s 1(a); *Evidence Act – BC*, *supra* note 20, s 51(1); *Evidence Act – MB*, *supra* note 20, s 1; *QIPA – NS*, *supra* note 14, s 2(d); *Evidence Act – NU*, *supra* note 20, s 13; *Evidence Act – NWT*, *supra* note 20, s 13; *QCIPA 2004 – ON*, *supra* note 14, s 1; *HSA – PEI*, *supra* note 20, s 26(c). In Saskatchewan, the qualified privilege arises in civil proceedings or inquiries but not in "legal proceedings founded on defamation, breach of contract or civil conspiracy": *Evidence Act – SK*, *supra* note 20, s 10(4)(b). Yukon has a similar provision: *Evidence Act – YK*, *supra* note 20, s 13(3)(c).

25 *Evidence Act – NB*, *supra* note 20, s 43.3(1) (definition of "legal proceeding").

26 British Columbia, the Northwest Territories, and Nunavut specifically exclude such bodies: *Evidence Act – BC*, *supra* note 20, s 51(1) (definition of "legal proceedings", subsection (b)); *Evidence Act – NWT*, *supra* note 20, s 13 (definition of "legal proceedings", subsection (b)); *Evidence Act – NU*, *supra* note 20, s 13 (definition of "legal proceedings", subsection (b)). Saskatchewan provides that the privilege does not apply in "disciplinary proceedings where the impugned conduct is a disclosure or submission to a committee": *Evidence Act – SK*, *supra* note 20, s 10(4)(c). In Ontario, the legislation specifically *includes*

protect them in a fairly wide number of settings in which they may be called upon to testify or to produce records and other information.[27]

In most Canadian provinces, the privilege cannot be waived. This was stated quite clearly by the Alberta Court of Queen's Bench in *Bruce Estate v Toderovich*: "As a statutory rule of evidence, the prohibition on production is absolute. It is not a privilege or a confidence that a party or witness can elect to waive or that can be waived impliedly by public disclosure."[28] However, in New Brunswick, because witnesses are "excused" from answering questions, producing documents, and disclosing opinions, it appears that a waiver may be possible in that jurisdiction.[29]

The best way to examine the legislative schemes and their judicial interpretation is to focus on two key elements, namely the constitution of quality of care committees and the scope of the qualified privilege. These are addressed in the next two sections, respectively.

A. Constitution of quality of care committees

A key element of all qualified privilege legislative schemes is the quality of care committee (the name of which varies),[30] a pre-established ad-

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the "committee of a College" within the purview of the privilege: *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "proceeding").

27 The question of the forum to which the qualified privilege applies has not been the subject of many court decisions. But see *Freedom of Information and Protection of Privacy Act (NS) (Re)* (1996), 137 DLR (4th) 410, 64 ACWS (3d) 1255 (NSSC).

28 2010 ABQB 21 at para 43, 483 AR 322 [*Bruce Estate*]. See also *Dawe v Evans*, 2009 ABQB 724 at paras 27–28, 483 AR 72 [*Dawe*]; in British Columbia, see *Sinclair v March*, 2000 BCCA 459 at para 26, 78 BCLR (3d) 218 [*Sinclair*].

29 See *Evidence Act – NB*, *supra* note 20, s 43.3(2). This was the court's interpretation in *McCormack v Nova Scotia (AG)* (1993), 123 NSR (2d) 271 at 282, 41 ACWS (3d) 1088 (SC), and *MacKenzie v Kutcher*, 2004 NSCA 4 at para 43, 220 NSR (2d) 285 [*MacKenzie*], two Nova Scotia cases dealing with section 60 of the province's *Evidence Act* (*supra* note 14), which has now been repealed. The wording in Nova Scotia's new *Quality-improvement Information Protection Act* (*supra* note 14) has eliminated the problem in that province, but it appears the matter warrants further clarification in New Brunswick.

30 Four provinces and territories use the term "quality assurance committee" (see *Evidence Act – AB*, *supra* note 20, s 9(1)(b); *Evidence Act – NL*, *supra* note 20,

ministrative committee within which privileged discussions can be held and documents exchanged without concern for subsequent disclosure in a legal proceeding. It is crucial to note that these committees are at the heart of the legislative schemes[31] and that information flowing from other bodies will not benefit from the qualified privilege.[32] This being said, the description of the committees whose information is protected varies throughout the coun-

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s 8.1(b); *Evidence Act – NWT*, *supra* note 20, s 13; *Evidence Act – YK*, *supra* note 20, s 13(1)); three refer to "committees" established for the purpose of evaluating and improving hospital care (see *Evidence Act – NU supra* note 20, s 13; *Evidence Act – BC*, *supra* note 20, s 51(1); *Evidence Act – NB*, *supra* note 20, s 43.3(2)); three use "quality improvement committee" (*QIPA – NS*, *supra* note 14, s 2(h); *HSA – PEI*, *supra* note 20, s 26(f); *Evidence Act – SK*, *supra* note 20, s 10(1)); and the remaining provinces use "critical incident review committee" (*Evidence Act – MB*, *supra* note 20, s 9(1)), "quality of care committee" (*QCIPA 2004 – ON*, *supra* note 14), or "risk management committee" (*HSSS – QC*, *supra* note 20, ss 183.1–183.2). However, this diverse nomenclature invariably refers to committees created to assure or improve the quality of health care. The authors will be faithful to the terminology chosen by a given province when discussing specific examples. Otherwise, the term "quality of care committee" will be used.

31 As explained by Ms. Carol Appathurai, Acting Director, Health Information Privacy and Sciences Branch, to the Ontario legislature's Standing Committee on General Government during its deliberations on the then-proposed *Quality of Care Information Protection Act, 2004*, "[t]he 'quality of care committee' is a body that's established, and we wanted to be sure that quality-of-care committees wouldn't just spring up self-appointed, so there had to be some conditions around them. … It has to be 'established, appointed or approved by a health facility' or 'by an entity that is prescribed by the regulations,' and it has to carry on activities for the purpose of quality care improvement" (Ontario Bill 31 Standing Committee Deliberations, *supra* note 15 at G-21).

32 For information about the type of health care body that is entitled to establish a quality of care committee, see *Canadian Incident Analysis Framework*, *supra* note 4 at 121–22. There are important variations. For example, under Ontario's *Quality of Care Information Protection Act*, *2004*, hospitals and other health facilities have the authority to create such committees (see *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "quality of care committee", subsection (a)); Bill 119, *supra* note 14, Schedule 2, s 2(1) (definition of "quality of care committee", subsection (a)) (adding "quality oversight entity" to the list of bodies entitled to create committees). Conversely, in Alberta and British Columbia, the provincial health minister may also create such committees by order or regulation (*Evidence Act – AB*, *supra* note 20, s 9(1)(b)(iii)); *Evidence Act – BC*, *supra* note 20, s 51(1) (definition of "committee", subsection (d)).

try. For instance, in New Brunswick, the privilege attaches to information flowing from "a committee established … to conduct any study, research or program for the purpose of medical education or improvement in medical or hospital care or practice."[33] Some provinces and territories extend the protection beyond the hospital setting but rely on a dominant purpose test. For example, Alberta's *Evidence Act* defines a "quality assurance committee" as a "committee, commission, council or other body that has as its *primary* purpose the carrying out of quality assurance activities."[34] The latter expression is defined as "planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of (i) the quality of health care or health services, or (ii) the level of skill, knowledge and competence of health service providers."[35]

In the past several years, courts have examined the issue of committee constitution. For instance, in *Forsberg v Naidoo*, the Alberta Court of Queen's Bench concluded that a committee set up immediately following a patient safety incident and comprised of only one member was properly constituted.[36] The court held that "[i]t would seem at odds with the legislative purpose of improving health care that the statutory privilege could be overcome on the basis that it was triggered by a particular incident."[37]

Another flexible interpretation of the legislative requirements related to committee constitution is found in *Sinclair v March*,[38] the leading case on section 51 of British Columbia's *Evidence Act*. The Court of Appeal noted

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33 See *Evidence Act – NB*, *supra* note 20, s 43.3(2)(a).

34 *Evidence Act – AB*, *supra* note 20, s 9(1)(b) [emphasis added].

35 *Ibid*, s 9(1)(a).

36 2009 ABQB 369 at para 15, 484 AR 234. The plaintiff, who had undergone several amputations because of a meningococcal disease contracted while at the defendant Leduc Community Hospital, sought the production of letters and memos listed as privileged in the Affidavit of Records of the defendant.

37 *Ibid* at para 16.

38 *Sinclair*, *supra* note 28. The plaintiff, who had suffered complications following bariatric surgery, sued her doctor and the hospital where the procedure took place. She sought the production of various correspondence, memoranda, minutes of meetings, and reports dating from 1962 to 1994. The hospital argued that the materials were protected by the qualified privilege. The chambers judge had ordered the production of some of the documents and greater description of

that "[w]hile it must be shown that the witness participated in committee work as described in s. 51, I do not think that the terms of s. 51 should be narrowly construed to balance the loss of access by the litigant."[39] The court added that section 51 "must be given its full effect even in circumstances where there is more than one aspect to the committee's function."[40]

The Nova Scotia Court of Appeal adopted a similar approach in *MacKenzie v Kutcher*.[41] The plaintiff had argued that the hospital committee was not properly constituted as it included "external" experts who did not prac-

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others. The Court of Appeal affirmed the order for the hospital to provide fuller descriptions but set aside the order to produce the documents at issue.

39 *Ibid* at para 22.

40 *Ibid* at para 30. Another interesting case is *Parmar (Litigation guardian of) v Fraser Health Authority*, 2012 BCSC 1596, 225 ACWS (3d) 448, where an infant plaintiff argued that there was no evidence that the committee tasked with reviewing a PSI connected with the plaintiff's birth had been approved by the hospital's board of management. The British Columbia Supreme Court disagreed. It appeared that when the infant plaintiff was born, a Local Quality Review Committee (LQRC) already in existence was seized of the matter. The committee was accountable to the defendant health authority, which also approved the committee's membership. The court was satisfied on the basis of the evidence before it that the defendant hospital had taken the necessary steps to set up the LQRC in accordance with the requirements of the province's *Evidence Act*.

41 *MacKenzie*, *supra* note 29. This case did not involve a PSI but is of interest nevertheless. Mr. MacKenzie, an administrative director for a mental health unit in a Yarmouth hospital, was dismissed from his job following a review by the defendants, two doctors (experts from another region) who were retained to conduct an operational review of all programs delivered by the mental health unit. The review was prompted by concerns related not only to management but also to patient safety. The plaintiff subsequently sued the two doctors on the basis of various torts including negligence and defamation. For a recent case involving another non-PSI setting, see *Hamburger v Fung*, 2014 BCSC 1625 at para 31, 244 ACWS (3d) 54 [*Hamburger*], where, in dismissing an application to strike out civil claims related to a dispute about access privileges to a lab by cardiologists, the court expressed sympathy for the defendants' submissions that section 51 of British Columbia's *Evidence Act*, *supra* note 20, provided a complete defence to the claims. The plaintiff had submitted, *inter alia*, that before a court could determine the scope of section 51's protection, evidence had to "be adduced to determine whether a 'committee' as defined exist[ed] and whether the required activities were been carried on by that committee" (*ibid* at para 23). The matter was left for the trial judge to resolve.

tice within the region. However, the court adopted a broad interpretation of the phrase "hospital committee"[42] and noted that the restriction to internal staff could not be read into the legislative provision given its purpose "to support the activities of hospitals improving medical or hospital care or practice by ensuring confidentiality for the documents and proceedings of committees that are given the task of studying or evaluating medical or hospital care or practice."[43]

The cases discussed so far reveal the courts' inclination to reinforce legislated initiatives to protect quality of care information from disclosure, at least in relation to committee constitution or structure. Caution should be exercised, however, because courts can insist on strict adherence to the legislative dispositions. The decision in *Eastern Regional Integrated Health Authority v Newfoundland and Labrador (Commission of Inquiry on Hormone Receptor Testing)*[44] is instructive in this regard. The defendant Commission conducted a public inquiry following serious problems with laboratory tests conducted at the Health Sciences Centre in St. John's. The plaintiff relied on section 8.1 of Newfoundland and Labrador's *Evidence Act*, arguing that reports from outside experts should not be made public as they were "made by, for or to" a "quality assurance committee" or a "peer review committee," as specified in sections 8.1(4)(b) and 8.1(2)(b)–(c) of the *Act*, respectively, and were thus protected.[45] The application was denied. Discussing the "peer review committee" issue first, the court noted that the process of retaining the two experts did not comply with the hospital's own

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42 *MacKenzie*, *supra* note 29 at paras 20, 25. The case dealt with the now repealed section 60 of Nova Scotia's *Evidence Act* (*supra* note 14), but is nevertheless instructive as it illustrates the court's willingness to adopt a broad view of committee constitution. That provision's replacement, the *Quality-improvement Information Protection Act* (*supra* note 14), brings about significant changes. Indeed, section 3(1) provides that "[a] quality-improvement committee may be established or designated by (a) a health authority; (b) the Minister; or (c) an entity prescribed by regulations, with terms of reference and membership … to carry out quality-improvement activities." Section 2(h) defines "quality-improvement activity" as "an activity of a quality-improvement committee … implemented for the purpose of assessing, investigating, evaluating or making recommendations respecting the provision of health services."

43 *MacKenzie*, *supra* note 29 at para 24.

44 2008 NLTD 27, 274 Nfld & PEIR 172 [*Eastern Regional Integrated Health Authority*].

45 *Ibid* at paras 30–33.

peer review policies.[46] There was no "sentinel event" (i.e., PSI) report given to the experts or to the physicians under review to comment upon as required by the policy.[47]

The plaintiff's submission that the external reports were prepared for a quality assurance committee did not fare better. The evidence before the court revealed that the hospital did not have a quality assurance committee in place at the time, nor were there policies in place relating to such a committee.[48] The selection of the two experts had occurred quite informally[49] and no terms of reference had been provided to them until well after they had agreed to provide their expertise.[50] In addition, as the term "quality assurance committee" is not defined by the legislation, the court considered similar legislative dispositions in Alberta and Saskatchewan,[51] among other definitions, and concluded that the external reports were "not part of a continuous Quality Review process involving research on long-standing Policies set out in a particular department."[52]

The conclusion to be drawn from *Eastern Regional Integrated Health Authority* is that a properly constituted quality of care committee is the first step to ensuring the protection of the law for all those involved in quality of care investigations. The scope of the qualified privilege – to whom and to what it applies – is also an important element of the protection envisaged by legislation, and it will now be examined.

B. The scope of the qualified privilege

1. Witnesses

Who can claim the qualified privilege? In the majority of provinces and territories, the qualified privilege can be invoked only by a "witness" in

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46 *Ibid* at para 44.

47 *Ibid* at para 41.

48 *Ibid* at para 82.

49 *Ibid* at para 99.

50 *Ibid* at para 75.

51 *Ibid* at paras 82–83.

52 *Ibid* at para 99.

a proceeding.[53] As already noted, New Brunswick is the only province to "excuse" the witness from answering questions and producing documents.[54] All other provinces and territories have formulated a prohibitive provision.[55]

The term "witness" is usually defined broadly and has not been the subject of legal debate very often. An example of a case where the issue was considered is *KD v British Columbia's Women's Hospital*.[56] The court had to determine whether information seen by the plaintiff herself was subject to the qualified privilege. Counsel tried to lead evidence from the plaintiff

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53 A typical example is found in section 9(1) of the *Manitoba Evidence Act* (*supra* note 20), where the term "witness" is defined as follows:

> [I]n addition to its ordinary meaning, [it] includes a person who, in the course of a legal proceeding,
>
> (a) is examined for discovery;
>
> (b) is cross-examined on an affidavit made by him or her;
>
> (c) answers interrogatories;
>
> (d) makes an affidavit as to documents; or
>
> (e) is called upon to answer any question or produce any record, whether under oath or not.

Some provinces and territories, such as Alberta, Nunavut, and Ontario, specify that the term "witness" includes persons who are not parties to the proceedings: *Evidence Act – AB*, *supra* note 20, s 9(2); *Evidence Act – NU*, *supra* note 20, s 14(1); *QCIPA 2004 – ON*, *supra* note 14, s 1. Prince Edward Island's and Québec's statutes employ the more general term "person" instead of "witness": *HSA – PEI*, *supra* note 20, s 29(1); *HSSS – QC*, *supra* note 20, ss 183.3–183.4. Yukon is the only jurisdiction where the privilege is not clearly attached to an individual. Rather, section 13(2) of its *Evidence Act*, *supra* note 20, states that "*evidence* is not admissible in a legal proceeding" [emphasis added].

54 *Evidence Act – NB*, *supra* note 20, s 43.3(2).

55 See e.g. *Evidence Act – AB*, *supra* note 20, s 9(2)(a) ("[a] witness in an action, whether a party to it or not, is not liable to be asked, and shall not be permitted to answer, any question"); *Evidence Act – NL*, *supra* note 20, s 8.1(4) ("[w]here a person appears as a witness in a legal proceeding, that person shall not be asked and shall not (a) answer a question in connection with proceedings of a committee").

56 2003 BCSC 2016, [2005] BCWLD 2023. This is a ruling on an objection made during evidence in connection with an action related to the death of one of the plaintiff's twins following an emergency caesarean section.

about a letter she had been shown during a post-incident meeting with one of the defendants who had prepared a written response to the allegations of negligence for the hospital. The court concluded it had no discretion to admit this evidence, as the plaintiff was a witness within the meaning of section 51 of British Columbia's *Evidence Act*.[57] The court noted that to admit the evidence "would likely defeat or impair the purpose of the legislation."[58] The court upheld the privilege but stated that the plaintiff was "entitled to give evidence about her state of mind following her review of the letter."[59]

2. Records

The qualified privilege extends not only to witness testimony but also to the production of records and other documents. Four provinces simply state that reports and other types of information are not admissible as evidence in legal proceedings,[60] while others, such as Alberta, provide that a witness "is not liable to be asked to produce and shall not be permitted to produce any quality assurance record."[61]

A crucial point must be noted: the privilege does not apply to information contained in medical, patient, or hospital records concerning a patient.[62]

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57 *Ibid* at para 29.

58 *Ibid*.

59 *Ibid* at para 30. Another example of a decision on the issue of witnesses is *Boissonnault c Fortin*, 2010 QCCA 1620, EYB 2010-179103, where, in a terse judgment, the Québec Court of Appeal confirmed that the risk manager of Ste Justine Hospital in Montréal was protected by sections 183.3 and 183.4 of Québec's *Act respecting health services and social services* (*HSSS – QC*, *supra* note 20), and thus did not have to provide information to the court.

60 See *QCIPA 2004 – ON*, *supra* note 14, s 5(2) (providing that "quality of care information is not admissible in evidence in a proceeding"); see also *Evidence Act – MB*, *supra* note 20, s 9(3); *HSA – PEI*, *supra* note 20, s 29(2); *Evidence Act – SK*, *supra* note 20, s 10(3).

61 *Evidence Act – AB*, *supra* note 20, s 9(2)(b).

62 For instance, information in a hospital chart or record of care. See e.g. *Evidence Act – BC*, *supra* note 20, s 51(3); *Evidence Act – NL*, *supra* note 20, s 8.1(5). There is a similar provision in almost all provinces and territories: *Evidence Act – AB*, *supra* note 20, s 9(3); *Evidence Act – MB*, *supra* note 20, s 9(4)(a); *Evidence Act – NB*, *supra* note 20, s 43.3(3)(b); *QIPA – NS*, *supra* note 14,

This is so because this information relates to patient care rather than to quality of care activities. Some jurisdictions specify that the facts which are contained in a record or incident report are not privileged either,[63] unless such facts are also included in a patient or medical record and accessible to the patient.[64] As noted by Perun, Orr, and Dimitriadis, "[t]he underlying

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s 2(j)(i); *Evidence Act – NU supra* note 20, s 14(2); *Evidence Act – NWT*, *supra* note 20, s 14(2); *Evidence Act – SK*, *supra* note 20, s 10(4)(a)(i); *Evidence Act – YK*, *supra* note 20, s 13(3)(b); *HSA – PEI*, *supra* note 20, ss 26(g)–(i), 29(2); *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "quality of care information", subsection (c)). Exceptionally, in Québec, the legislative scheme adopts a broader focus based on confidentiality of the records and minutes of risk management committees, while recognizing the right of patients to access their medical records: *HSSS – QC*, *supra* note 20, ss 17, 183.4.

63 This is mentioned in the laws of Manitoba, Ontario, PEI, and Saskatchewan with variations in wording. See respectively *Evidence Act – MB*, *supra* note 20, s 9(4)(b); *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "quality of care information", subsection (e)); HSA – PEI, *supra* note 20, ss 26(g)(ii), 29(2); *The Regional Health Services Act*, SS 2002, c R-8.2, s 58(7) [*RHSA – SK*].

64 This exception is found in the laws of Manitoba, Saskatchewan, and Ontario. The manner in which the exception is worded varies somewhat from one province to another, and a careful reading of these provisions is essential. See respectively *Evidence Act – MB*, *supra* note 20, s 9(4)(b); *RHSA – SK*, *supra* note 63, s 58(7)(a); *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "quality of care information", subsection (e)). In Bill 119, *supra* note 14, the Ontario government has attempted to clarify the exemption for facts, and has significantly expanded the type of information that will not be protected by the statutory privilege. Section 2(3) of the proposed legislation provides:

> "Quality of care information" does not include any of the following:
>
> …
>
> 3. Information relating to a patient in respect of a critical incident that describes,
>
> i. facts of what occurred with respect to the incident,
>
> ii. what the quality of care committee or health facility has identified, if anything, as the cause or causes of the incident,
>
> iii. the consequences of the critical incident for the patient, as they become known,
>
> iv. the actions taken and recommended to be taken to address the consequences of the critical incident for the patient, including any health care or treatment advisable, or

principle appears to be that facts relating to health care incidents should not be shielded from the patient involved."[65] They suggest, based on the language in Ontario's *Quality of Care Information Protection Act, 2004*, that "where the facts are not included in a record that will be accessible to the patient, they will not be able to be shielded as quality of care information, even if they are recorded in the context of a review by a quality of care committee."[66] According to their interpretation, "unrecorded facts; any information that does not relate to 'an incident involving the provision of health care;' and information that does not consist of 'facts'" (for example, an opinion or evaluation of a PSI) are protected as quality of care information.[67] The issue of the exclusion of facts from the privilege was addressed in *Lancaster v Minnaar*,[68] where the court noted that the onus was on the defendant Health District Board to show that the facts recorded in the minutes of a quality assurance committee and unedited notes related to them "were also contained in medical and hospital records prepared for the care and treatment of the plaintiff."[69]

> v. the systemic steps, if any, that a health facility is taking or has taken in order to avoid or reduce the risk of further similar incidents.

65 Perun, Orr & Dimitriadis, *supra* note 13 at 623–24.

66 *Ibid* at 623.

67 *Ibid* at 623–24. This interpretation may change if the new legislation is adopted. See *supra* note 64.

68 2006 SKQB 380, 288 Sask R 31. The case dealt with an earlier version of the Saskatchewan legislation, but is nevertheless instructive since the requirement therein, whereby facts related to an incident had to be fully recorded in a medical record in order to be protected, was similar to the current provision.

69 *Ibid* at para 21. There are interesting comments on the issue by Saskatchewan's Court of Appeal in two older decisions. In *Soerensen (Litigation guardian of) v Sood* (1994), 115 DLR (4th) 598 at 505–06, 123 Sask R 72 (CA), the court wrote:

> Second, the term "facts related to the incident" in ss. (4)(a)(ii) must be read as referring only to the facts related to the incident which are recorded in the document under consideration, rather than all the facts of the incident. This is the only interpretation which does not make the exception in ss. (4)(a)(ii) so broad as to nullify entirely the privilege which the legislature so painstakingly created in ss. (2) and (3). If the words in the subsection were taken to mean all the facts of the incident in their broadest

To assess the scope of the qualified privilege, it is essential to consider the description of the protected documents. This varies in specificity from one province or territory to the next. Manitoba, for instance, refers to "any information that is written, photographed, recorded or stored in any manner, on any storage medium or by any means, including by graphic, electronic or mechanical means,"[70] while Alberta refers to a "quality assurance record," which includes, among other things, "books, documents, maps, drawings, photographs, letters, vouchers and papers."[71]

There have been a number of judicial decisions on issues related to the protection of documents. In *Bruce Estate*,[72] the plaintiff and others alleged inadequate sterilization and procedures for dealing with a nosocomial infection at the defendant hospital. In her application to certify an action as a class proceeding, the plaintiff swore an affidavit containing a report (in the form of a root cause analysis) and a news release summarizing it. Both the report and the news release were publicly available on the website of the Health Quality Council of Alberta (HQCA). The Council sought intervener status to argue that neither the report nor the news release were admissible in evidence because of section 9 of the *Alberta Evidence Act*.[73] The Alberta Court of Queen's Bench concluded that the report was protected by section

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> sense, a hospital could never prove that such facts were fully recorded in the ss. (4)(a)(i) records; there would always be small details overlooked, or deemed irrelevant, or too insignificant to be recorded by the person making the record.

See also *Kerr v Saskatchewan (Minister of Health)* (1994), 115 DLR (4th) 588, 123 Sask R 63 (CA), aff'g (1992), 98 DLR (4th) 66, 106 Sask R 77 (QB).

70 *Evidence Act – MB*, *supra* note 20, s 9(1) (definition of "record").

71 *Evidence Act – AB*, *supra* note 20, s 9(1)(c).

72 *Supra* note 28.

73 See *ibid* at para 28, where an affidavit in support of the HCQA's position is reproduced in part and reads:

> Participants in any quality assurance activity must feel comfortable and confident that their disclosures to a quality assurance committee will not form the foundation for evidence in a court or other legal proceeding. The HQCA is concerned if a report from a quality assurance activity can become evidence in a proceeding, there will be a chill on the willingness of individuals and organizations to participate in and be candid in dealing with the quality assurance committee or its subcommittees.

9(1) of the *Act* as it was created for and received by the quality assurance committee for quality assurance purposes.[74] The plaintiff tried to convince the court to read section 9(2)(b) narrowly, because she was not "asked" to produce the evidence but produced it of her own free will in her affidavit. The court refused to interpret section 9(2)(b) in this way, reading the phrase "is not liable to be asked to be produced and shall not be permitted to produce" as being disjunctive and thus as prohibiting two acts, i.e., both asking to produce and producing voluntarily.[75] The fact that the plaintiff was not "asked" to produce the evidence was therefore irrelevant because she still sought to "produce" it. The plaintiff also argued that because the report had been made public and was available from another source, section 9 should no longer apply. The court rejected this interpretation[76] and stated:

> The Legislature has chosen to place the goal of improving the quality of health care and health services ahead of any litigation advantage that may accrue to a party by the use of such a report. The prohibition is intended to ensure that an investigation can be completed and a report prepared in a comprehensive, efficient, effective and expeditious manner so as to identify and hopefully rectify any problems or potential problems in the delivery of health care services as soon as possible.[77]

The report and news release were therefore expunged from the plaintiff's affidavit.

In *Dawe v Evans*, a letter summarizing the circumstances of a newborn's death and the discussions held by the Neonatal Mortality Review Committee was considered privileged under section 9 of the Alberta *Evidence Act*.[78] The court found that because the opinion expressed in the letter was likely a result of the quality assurance process, the doctor who had written the letter was not allowed to answer questions pertaining to it. He was, however, required to answer questions with regard to any opinion he may have formed before participating in quality assurance activities. The

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74 *Ibid* at para 23.

75 *Ibid* at para 37.

76 *Ibid* at para 41.

77 *Ibid* at para 42.

78 Dawe, *supra* note 28 at para 35; *Evidence Act – AB*, *supra* note 20.

court also held that the prohibition persisted even after the quality assurance activities had ended.[79]

Finally, in *Mackenzie v Kutcher*,[80] the debate was whether certain documents related to an operational review by the defendant doctors were privileged. The documents included data and findings obtained from focus groups, handwritten notes about the operational review, completed ques-

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[79] Other cases confirm that courts tend to uphold the privilege. See e.g. *MM c Centre hospitalier régional de Trois-Rivières (CHRTR)*, 2012 QCCAI 48 at para 45 (available on CanLII), a decision by the Commission d'accès à l'information du Québec, in which a patient who had sustained injury following a fall in a hospital sought production of various documents including nurses' notes, the disclosure report, and an investigation report from the hospital's risk management officer. The hospital agreed to provide the patient with the first two documents but sought the protection of qualified privilege legislation regarding the investigation report. The Commission agreed with this position, noting the "watertight protection" offered by sections 183.3–183.4 of *An Act respecting health services and social services* (*HSSS – QC*, *supra* note 20), which require the absolute confidentiality of the documents and minutes of the hospital's quality of care committee. See also *Descamps c Hébert*, 2011 QCCS 7490 at para 33, EYB 2011-204867, where the Québec Superior Court, ruling on 37 objections to questions posed to two doctors and a nurse being sued for the misdiagnosis of a myocardial infarction, held that questions pertaining to risk management protocol, hospital rules and procedures, and the facts themselves were allowed. However, questions pertaining to the content of risk management records and other confidential information obtained by the risk manager or risk management committee were not allowed, and the objections in respect of these documents were sustained. Finally, see *Hamburger*, *supra* note 41 at para 18, where the court discussed the unreported *voir dire* procedure in *Fouad v Longman*, 2014 BCSC 327 [unpublished]. Following the *voir dire*, the court in *Fouad* upheld the qualified privilege regarding letters and other communications, noting, "I do not agree that the defendant's motives or additional agenda in requesting the review, even if proven to be malicious, is sufficient to prevent the operation of s. 51 of the *Evidence Act*. The policy behind s. 51 is to encourage absolute candour in matters of patient care and professional competency" (*Fouad*, *ibid*, at para 13, cited in *Hamburger*, *supra* note 41 at para 18).

[80] *Mackenzie*, *supra* note 29; see *supra* note 41 for the facts of the case. While, as noted above, section 60 has been repealed by Nova Scotia's *Quality-improvement Information Protection Act*, the analysis in *Mackenzie* is useful in understanding courts' interpretation of legislative requirements. The new legislation relies on the term "quality-improvement information," which is defined very broadly to include "information in any form"; this presumably covers a wide array of documents and records. See *QIPA – NS*, *supra* note 14, s 2(j).

tionnaires by staff, and confidential notes taken during meetings by staff, including peer reviews. Generally, the data and information gathered during the review were seen as confidential in nature by the reviewers and the individuals who provided information to them. Interestingly, Hamilton JA paraphrased one of the defendants' affidavits as stating that "many of the staff members interviewed expressed concern that there would be reprisals if they met the respondents and that some of them would not have participated in the review if the information given by them could be divulged at a later date."[81] The Superior Court judge who first heard the application had determined that the documents were protected by what was then section 60 of Nova Scotia's *Evidence Act*.[82] The Court of Appeal agreed and gave a broad interpretation of the phrase "document … of, or made by … a committee" in the statute,[83] finding that it included documents that were not authored by the committee, such as questionnaires filled out by staff, if these documents were authored at the committee's request and for its purposes only. This conclusion leads to a consideration of the issue of "dominant purpose" found in some of the Canadian qualified privilege laws.

3. Dominant purpose

In some provinces, the privilege is linked to a dominant purpose test. This notion was mentioned briefly above in discussing properly constituted quality of care committees and the requirement, in Alberta for example, that their primary purpose be the carrying out of quality of assurance activities. More commonly, however, the dominant purpose requirement is that the *information* prepared by a committee be primarily for quality of care purposes. The legislative objective is the same: to ensure that the qualified privilege does not extend to information or committees that are vaguely or peripherally linked to quality of care issues. For example, in the Saskatchewan legislation, the protection extends to documents, reports, and information "prepared exclusively for the use of or made by a committee" or to information "used exclusively in the course of, or aris[ing] out of, any investigation, study or program carried on

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81 *Mackenzie*, *supra* note 29 at para 7.

82 See *MacKenzie v Kutcher*, 2003 NSSC 76 at paras 23–24, 213 NSR (2d) 288; *Evidence Act – NS*, *supra* note 14, s 60.

83 *Evidence Act – NS*, *supra* note 14, s 60(2).

by a committee."[84] In Ontario, the privilege is linked to the protection from disclosure of "quality of care information," which is defined as "information that is collected by or prepared for a quality of care committee for the *sole* or *primary* purpose of assisting the committee in carrying out its functions."[85]

Courts have occasionally grappled with the issue. The case of New Brunswick is particularly interesting in this regard, as court decisions eventually prompted the province to modify section 43 of its *Evidence Act* to make it somewhat less restrictive. Indeed, in the 1996 case of *Doyle v Green*,[86] the province's Court of Appeal had to consider an earlier version of section 43.3(2)(b), which stated that a witness was excused from producing a document "prepared exclusively for the purpose of being used in the course of, or arising out of, any study, research or program, the dominant purpose of which is medical education or improvement in medical or hospital care or practice."[87] Noting the importance of the qualifiers "exclusively" and "dominant purpose," the court wrote:

> These words are intended to limit the exclusionary privilege to documents generated by a hospital or committee. A hospital or hospital committee cannot be required to produce a document prepared exclusively for the purpose of being used in the course of, or arising out of, any study, research or program, the dominant purpose of which is medical education or improvement in medical or hospital care or practice.[88]

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84 *Evidence Act – SK*, *supra* note 20, s 10(2)(b).

85 *QCIPA 2004 – ON*, *supra* note 14, s 1 (definition of "quality of care information", subsection (a)) [emphasis added]. No significant changes are envisaged in the proposed *Quality of Care Information Protection Act, 2015* (Schedule 2 of Bill 119, *supra* note 14) on this part of the definition. See also *Evidence Act – MB*, *supra* note 20, s 9(2)(b)(i)–(ii); *Evidence Act – NB*, *supra* note 20, s 43.3(2)(b); *Evidence Act – NU*, *supra* note 20, s 14(1)(b); *Evidence Act – YK*, *supra* note 20, s 13(2)(b).

86 (1996), 182 NBR (2d) 341, 463 APR 341 (CA) [*Doyle*]. The case involved an application to produce 127 documents related to a hospital investigation following the unexpected paraplegia of a patient who had undergone a hernia operation.

87 *Ibid* at 353.

88 *Ibid* at 356. The reasoning in *Doyle* was followed in *Comeau v Saint John Regional Hospital* (1997), 192 NBR (2d) 161 at 176, 74 ACWS (3d) 845 (QB).

In 1999, the wording of the legislative provision was modified to remove the word "exclusively" so that section 43.3(2)(b) now retains only the requirement that the document must apply to activities "the *dominant purpose* of which is medical education or improvement in medical or hospital care or practice."[89]

The New Brunswick legislator's decision to relax the wording of section 43.3 somewhat, and consequently to increase the breadth of the privilege, highlights the inherent dilemma in enacting qualified privilege legislation, namely the need to counterbalance the protection of quality of care information with access to information and transparency. Understanding how to minimize this tension requires a more in-depth examination of the policy choices that must be made and their consequences for health institutions and practitioners on the one hand and for patients and their families on the other.

II. Protecting Quality of Care Assurance Activities: An Assessment

As noted at the beginning of this article, qualified privilege laws are seen as one component of a culture shift aiming to recognize the importance of system-based institutional responses to adverse events in health institutions and the need to encourage health care providers to participate in quality of care assessments. However, relying on qualified privilege laws raises questions of fairness for patients who seek access to as much information as possible about PSIs having a bearing on their health, especially when outcomes are serious.[90] In this part, the article considers the challenges involved in striking the right balance between these two competing interests.

A. Legislative and judicial perspectives

The discussion of Canadian qualified privilege laws in Part I above shows that legislators have attempted to strike a fair balance between the interests of patients/litigants and those of health providers, while ensuring that the public interest is met. For example, in Ontario's *Quality of Care Information Protection Act, 2004*, the legal protection of quality of care

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89 *Evidence Act – NB*, *supra* note 20, s 43.3(2)(b) [emphasis added].

90 For a report outlining patients' expectations, see Ontario, Ministry of Health and Long-Term Care, *QCIPA Review Committee Recommendations* (23 December 2014) at 22, online: <www.health.gov.on.ca/en/common/legislation/qcipa/docs/qcipa_rcr.pdf>.

information is achieved through (a) a general prohibition against disclosing quality of care information;[91] (b) a qualified privilege prohibiting persons, courts, and other bodies from disclosing quality of care information in proceedings;[92] and (c) a wide definition of the proceedings to which the privilege applies.[93] At the same time, the legislation tries to limit the privilege so that patients have access to some information; this is made possible through (a) a fairly narrow definition of quality of care information with a built-in dominant purpose test,[94] (b) the exclusion of health records and of facts contained in a record of an incident from the application of the non-disclosure privilege,[95] and (c) the definition of what constitutes a quality of care committee.[96]

These features help circumscribe, at least to some extent, the ambit of the quality of care information that is protected from disclosure in legal proceedings, and they confirm that the competing policies at play are recognized by legislators.[97] However, it remains the case that the enactment

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91 See *QCIPA 2004 – ON*, *supra* note 14, s 4(1). The *Act* provides exceptions where disclosure is permitted, namely: if it is made to a quality of care committee (s 3), if it is made to the management that established a quality of care committee (s 4(3)), or if it has the purpose of preventing or reducing bodily harm (s 4(4)).

92 See *ibid*, s 5.

93 See *ibid*, s 1 (definition of "proceeding").

94 See *ibid*, s 1 (definition of "quality of care information", subsections (a)–(b)).

95 *Ibid*, s 1 (definition of "quality of care information", subsections (c)–(f)). This will be expanded if Bill 119, *supra* note 14, is adopted.

96 *QCIPA – ON*, s 1 (definition of "quality of care committee").

97 See, for instance, the comments made by Ms. Carol Appathurai, Acting Director, Health Information Privacy and Sciences Branch, to the Ontario legislature's Standing Committee on General Government during its deliberations on the then-proposed *Quality of Care Information Protection Act, 2004*: "In this act, we've attempted to bring a balance between protecting quality-of-care information but ensuring that information that needs to be public for the sake of the patient is not shielded" (Ontario Bill 31 Standing Committee Deliberations, *supra* note 15 at G-21). The balance is also reflected in the "Purposes" of the *Personal Health Information Protection Act*, SO 2004, c 3, Schedule A, s 1(b), which include "to provide individuals with a right of access to personal health information about themselves, subject to limited and specific exceptions set out in this Act"; one of those exceptions is quality of care information, as set

of a qualified privilege law is, in itself, an indication that protecting quality of care activities is prioritized over full access to health information by patients.

As can be gleaned from the survey in Part I, when Canadian courts have been called upon to assess and apply qualified privilege laws, they have been generally supportive of the need to protect quality of care information. This has not always been the case. Indeed, decisions predating the 1999 *To Err Is Human* report showed a fairly clear reluctance to limit litigants' access to information.[98]

However, the more recent trend reveals a different approach, as noted in *Sinclair*:

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out in section 51(1)(a). The same point of view was present in the legislative debate in Manitoba: see Manitoba, Legislative Assembly, *Hansard*, 38th Leg, 3rd Sess, Vol 56, No 33 (20 April 2005) at 1645 (Hon Tim Sale). Interestingly, the preamble of the proposed *Quality of Care Information Protection Act, 2015* (Schedule 2 of Bill 119, *supra* note 14) explicitly recognizes the competing policy choices and the need to attempt to reconcile them:

> The people of Ontario and their Government:
>
> …
>
> Are committed to ensuring that measures to facilitate the sharing of information for quality improvement purposes do not interfere with the right of patients and their authorized representatives to access information about their health care or with the obligations of health facilities to disclose such information to patients and their authorized representatives ….

98 See David G Duff, "Evidentiary Privilege for Hospital Quality Assurance and Risk Management: Assessing Statutory Reform" (1989) 47:2 UT Fac L Rev 526 at 535–36. See e.g. *Finley v University Hospital Board* (1986), 33 DLR (4th) 200 at 211, 53 Sask R 124 (QB), where the court stated:

> I conclude that in cases where an investigation is prompted by circumstances which are or become the subject matter of litigation, the question of balancing the respective interests of the community against those of the litigant weigh[s] in favour of the latter. Unless special circumstances exist that suggest the maintenance of confidentiality is deemed desirable for the purpose of public policy, the weight of authority appears to hold that disclosure should be ordered in cases where the matter of the complaint under review is the subject matter of the litigation for which disclosure is sought.

> [T]he Legislature intended to protect this area of hospital activity by preventing access by litigants. Rather than striking a balance of interests, the Legislature made a clear choice in favour of one interest, hospital confidentiality. In the course of deciding an issue under s. 51 [of British Columbia's *Evidence Act*] a court should give the language of the enactment its full force and effect with the object in mind.[99]

This approach has been maintained even in the face of perceived injustice by patient-plaintiffs. For instance, in *Parragh v Eagle Ridge Hospital and Health Care Centre*,[100] the two plaintiffs sought compensation for the harm they suffered after having contracted a serious bacterial infection shortly after undergoing day surgery at the defendant hospital. The plaintiffs argued, *inter alia*, that it was fundamentally unjust to be denied access to the results of an internal inquiry carried out by the hospital as a result of the infectious outbreak. The court answered in stating: "[I]t is not unjust in the sense the notion is understood in this context. The legislature has made a determination as to how the competing interests at play when a hospital, with a view to improving medical or hospital care, undertakes an investigation into that care, are to be treated."[101]

As matters currently stand, as surveyed in Part I of this study, judicial denial of legislative protection has occurred only in cases of failure by health providers and institutions to abide by the specific requirements of the legislation.[102] Indeed, decisions such as *Eastern Regional Integrated Health Authority* show that some courts will refuse to apply the statutory protection if the details of the legislative scheme are not strictly adhered to.[103] However, none of the decisions take a stance against the fundamental policy position stipulating a need for at least some protection of quality of care information.

This is not to say that courts have been oblivious to the impact of a restrictive interpretation on claimants. Some judges have remarked on the

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99 *Sinclair*, *supra* note 28 at para 26.

100 2008 BCSC 1299, 170 ACWS (3d) 729.

101 *Ibid* at para 34.

102 See e.g. *Eastern Regional Integrated Health Authority*, *supra* note 44.

103 *Ibid*; Davinder Sidhu & Máire A Duggan, "Statutory and Common Law Protection of Laboratory Quality Assurance Data in Canada" (2012) 4:2 Can J Pathology 54 at 57–58.

importance of disclosure and access to information. This is clear from the words of the chambers judge in *Sinclair* while discussing section 51 of British Columbia's *Evidence Act*:

> But the section does not give blanket protection to all of a hospital's documentary workings under the rubric of improving patient care and practice. Such a broad interpretation would not achieve the balance intended by the legislature between the public interest in the search for truth in litigation and freedom to improve patient care. The duty not to disclose should not be lightly extended to other classes of documentation just because they involve personnel who provide or administer patient care in a hospital. The scope of public interest identified in the section does not go so far. At the same time, the section should not be given so restrictive a meaning as to defeat the intention of the statutory provision.[104]

Overall, then, whether one considers the choices made by legislators in the drafting of qualified privilege statutory schemes or those that arise in judicial interpretation, there is a clear endorsement of the basic principle whereby quality of care information – as defined in qualified privilege laws – should be protected. But there is also a recognition that patients' access to information cannot be completely limited. Access is essential not only in the context of a specific PSI, when answers are sought about the event and its aftermath, but also in relation to the public interest in the safety of health institutions and health care generally.

B. Balancing protection of information and disclosure to patients

In order to assess whether the "balancing of interests" approach upon which legislators and courts have relied should be endorsed, it is useful to consider a scenario in which patients would be given full access not only to the information contained in their own medical records but also to reports, discussions, assessments, and other quality of care initiatives flowing from an institutional investigation of an adverse event – in other words, a scenario in which the qualified privilege would be abandoned.[105]

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[104] *Sinclair v March*, 2000 BCSC 349 at para 12, 73 BCLR (3d) 86 (Dillon J), cited in *Sinclair*, *supra* note 28 at para 21.

[105] For an interesting case study, see Kelly G Dunberg, "Just What the Doctor Ordered? How the Patient Safety and Quality Improvement Act May Cure

Presumably, such a measure would increase access to information about adverse events at least within the context of "legal proceedings" as defined in qualified privilege laws.[106] This could be useful during litigation, complaints, or other proceedings against health care providers and institutions, especially if post-PSI reports and statements disclose admissions of fault. Access to this type of information could perhaps enhance the chances of finding civil liability and increase the possibility of compensation.[107]

The consequences for health providers' behaviour if the privilege were removed are not as clear and need more assessment.[108] However, there is research supporting the notion that in the absence of qualified privilege protection, health care practitioners would be more reluctant to disclose PSIs and to participate in the information gathering processes following their occurrence.[109] This would mean that less quality of care information would

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Florida's Patients' Right to Know about Adverse Medical Incidents (Amendment 7)" (2012) 64:2 Fla L Rev 513. The author discusses a 2004 amendment to the Florida Constitution that effectively eliminated privilege protections in that state and allowed access to records and reports of past PSIs involving health practitioners and institutions.

106 See Part I, above, for a discussion of "proceedings" in Canadian legislation.

107 As found in the literature on disclosure of adverse events, access to more complete information may lead to other benefits as well, in terms of patient trust in the health care system and health care providers. See e.g. Fred Rosner et al, "Disclosure and Prevention of Medical Errors" (2000) 160:14 Arch Intern Med 2089 at 2090.

108 Generally speaking, since patient-safety legal initiatives (including qualified privilege laws) are relatively new, there is very little data as to their effectiveness and efficiency; see Downie et al, *supra* note 12 at 5; Gilmour, *supra* note 12 at 65–66.

109 See *To Err Is Human*, *supra* note 1 at 109–12; Bianca Perez et al, "Understanding the Barriers to Physician Error Reporting and Disclosure: A Systemic Approach to a Systemic Problem" (2014) 10:1 J Patient Saf 45 (discussing a number of barriers to transparency about errors); Norna F Waters et al, "Perceptions of Canadian Labour and Delivery Nurses about Incident Reporting: A Qualitative Descriptive Focus Study" (2012) 49:7 Intl J Nurs Stud 811 at 814–15 (addressing specifically the fear-of-litigation issue); Nick O'Connor, Beth Kotze & Murray Wright, "Blame and Accountability 2: On Being Accountable" (2011) 19:2 Australas Psychiatry 119 at 119 (arguing that a "no blame culture" is essential to voluntary reporting); Lauris C Kaldjian et al, "Reporting Medical Errors to Improve Patient Safety: A Survey of Physicians

be generated. Such a consequence would not necessarily benefit injured patients, as the information about the adverse event that produced the injury would not be as complete and explicit.

Given this, and despite the lack of empirical evidence within the health context, it intuitively seems that abandoning the privilege would not necessarily be advantageous in terms of patients' access to information. The experience of other industries – aviation in particular – provides valuable insights into the need for incentives to encourage reporting of adverse events without fear of reprisal.[110]

Moreover, as discussed above, qualified privilege laws protect only some information from access by patients/litigants, namely the work of quality of care committees. Patients remain free to pursue legal action or rely on the complaint process if they so wish and, in that context, substantial information may be gleaned from medical records, professional colleges' records of investigation, and the testimony of expert witnesses appearing on a patient's behalf.[111]

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in Teaching Hospitals" (2008) 168:1 Arch Intern Med 40 at 44 (considering factors affecting error reporting by physicians).

[110] See Paul Barach & Stephen D Small, "Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting Systems" (2000) 320:7237 Brit Med J 759. For other articles comparing the health sector to other industries, see e.g. Lucian L Leape, "Reporting of Adverse Events" (2002) 347:20 New Eng J Med 1633 at 1635 (discussing the experience in aviation); René Amalberti et al, "Five System Barriers to Achieving Ultrasafe Health Care" (2005) 142:9 Ann Intern Med 756 (looking at industries viewed as "ultrasafe" and the barriers encountered by the health sector to achieve this status); Linda SGL Wauben, Johan F Lange & Richard HM Goossens, "Learning from Aviation to Improve Safety in the Operating Room – A Systematic Literature Review" (2012) 3:3 J Healthc Eng 373 (making very interesting comparisons between the aviation and health care sectors – in particular the operating room setting – and arguing for "strong (horizontal) leadership communicating urgency for change and creating a safe culture to speak up and report error" at 386); Sidney Dekker, "The Criminalization of Human Error in Aviation and Healthcare: A Review" (2011) 49:2 Saf Sci 121 (discussing why criminal prosecution is a threat to safety and has an effect on willingness to report and disclose safety-related information).

[111] Duff, *supra* note 98 at 541.

When discussing whether a "balancing of interests" approach in the enactment and application of qualified privilege laws is defensible in the context of PSI reduction strategies, it is important to recognize the complexity of the landscape in which these laws operate. As noted by Flood and Thomas, the Canadian focus so far has been on "improved information gathering and dissemination of best practice standards,"[112] and indeed, qualified privilege laws are linked to these efforts as they aim to encourage active participation of health care providers in collecting information. However, other types of legal interventions may also contribute to the goal of adverse event reduction. Proposed measures include expanding disclosure obligations to patients,[113] enacting "apology legislation,"[114] mandating compensation through no-fault rules,[115] adopting organizational liability rules,[116] and others. Some studies have even suggested that civil litigation can have a positive effect on PSI reduction.[117]

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[112] Colleen M Flood & Bryan Thomas, "Canadian Medical Malpractice Law in 2011: Missing the Mark on Patient Safety" (2011) 86:3 Chicago-Kent L Rev 1053 at 1092.

[113] Richard C Boothman, Sarah J Imhoff & Darrell A Campbell Jr, "Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Directions" (2012) 28:3 Front Health Serv Manage 13. For an assessment of the efforts in the United Kingdom in this regard, see Yvonne Birks et al, "An Exploration of the Implementation of Open Disclosure of Adverse Events in the UK: A Scoping Review and Qualitative Exploration", online: (2014) 2 Health Services and Delivery Research 20 <eprints.whiterose.ac.uk/79933/1/openDis.pdf>. See also *supra* note 17.

[114] Roy Ilan & Yoel Donchin, "Creating Patient Safety Capacity in a Nation's Health System: A Comparison between Israel and Canada" (2012) 1:19 Isr J Health Policy Res 1 at 2; Stuart McLennan, Leigh E Rich & Robert D Truog, "Apologies in Medicine: Legal Protection Is Not Enough" (2015) 187:5 CMAJ E156 (raising doubts about the effectiveness of these laws).

[115] Barry R Furrow, "Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation" (2012) 46:3 New Eng L Rev 437 at 467–70. For interesting studies on patient safety in the context of a no-fault regime, see Katharine Wallis & Susan Dovey, "No-Fault Compensation for Treatment Injury in New Zealand: Identifying Threats to Patient Safety in Primary Care" (2011) 20:7 BMJ Qual Saf 587; Joanna Manning, "New Zealand's Remedial Response to Adverse Events in Healthcare" (2008) 16:2 Torts LJ 120.

[116] See e.g. Tracey Evans Chan, "Organizational Liability in a Health Care System" (2010) 18:3 Torts LJ 228.

[117] There is an interesting debate on this issue. See Joanna C Schwartz, "A Dose

Debating the merits of these options is beyond the scope of this article, and the point being made here is simply that qualified privilege laws are but one element of the "patient safety culture" that all health institutions are encouraged to develop.[118]

Therefore, keeping in mind the complexity of multifaceted interventions to reduce PSIs in institutional settings and the fact that more empirical research is needed to assess how they contribute to safer health care, a "balancing of interests" approach regarding qualified privilege laws seems very reasonable and should be encouraged. This approach is especially important from the patient perspective as the ambit of privilege appears to be expanding, at least in some jurisdictions. This tendency is linked to some provinces' new reporting requirements to ministries of health or regional health authorities and the fact that these requirements are coupled with protection from disclosure through statutory privilege.[119] The perception that adverse

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of Reality for Medical Malpractice Reform" (2013) 88:4 NYUL Rev 1224. The author conducted a national survey of American health care professionals and risk managers in the United States, and came to conclude that "the openness and transparency promoted by the patient safety movement has pried open the historically secretive world of malpractice litigation," as lawsuits are seen as a valuable source of information about safety issues (*ibid* at 1299). See also George J Annas, "The Patient's Right to Safety: Improving the Quality of Care through Litigation against Hospitals" (2006) 354:19 New Eng J Med 2063; Barry R Furrow, "The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool" (2011) 4:1 Drexel L Rev 41. For the opposite point of view, see Bryan A Liang, "A Policy of System Safety: Shifting the Medical and Legal Paradigms to Effectively Address Error in Medicine" (2004) 5:1 Harvard Health Policy Rev 6 at 9.

[118] For an interesting assessment by patient safety leaders in the United States regarding efforts since the *To Err Is Human* report and next steps for the future, see Robert M Crane & Brian Raymond, "Roundtable on Public Policy Affecting Patient Safety" (2011) 7:1 J Patient Saf 5.

[119] See Gilmour, *supra* note 12 at 63–64. The author gives Saskatchewan as an example; see *RHSA – SK*, *supra* note 63, c R-8.2, s 58(5). See also, in Manitoba, the *Regional Health Authorities Act*, SM 2005, c 24, CCSM c R34, s 53.10. See Downie et al, *supra* note 12 at 15–16 (where the authors note a general trend towards expansion of the "legal frameworks," including qualified privilege, that regulate quality of care and patient safety). For a concrete suggestion to expand the qualified privilege, see Carol Brass, "A Proposed Evidentiary Privilege for Medical Checklists" (2010) 2010:3 Colum Bus L Rev 835 at 842 (proposing an evidentiary privilege to bar admissibility of medical checklists in court). As the author notes, "[c]hecklists are the ideal way to look at medical

events are under-reported could also lead to a possible expansion of qualified privilege laws to encourage health professionals to participate fully in reporting initiatives.[120]

In light of this, giving patients access to some information while protecting quality of care information from disclosure in certain contexts is defensible. If the objective of improving quality of care through quality assurance activities and risk management can be achieved without diminishing disclosure rights and thereby limiting patients' access to justice (or to a fair trial, or to compensation), then, as stated by Duff, "the public interest may legitimately sustain a statutory rule of privilege."[121] Hopefully, the approach will assist in the ultimate quest to improve patient safety.

Conclusion

The objective of this article was to examine qualified privilege laws protecting quality of care information in Canada and the treatment of these laws by Canadian courts, in order to better understand how they fit within current strategies to reduce PSIs and thus improve patient safety. The analysis of the relevant laws and their judicial treatment revealed that Canadian courts have generally recognized and endorsed the legislative goal of improving the quality of health care and health services by encouraging health practitioners and administrators to fully discuss undesirable outcomes in patient care, secure in the knowledge that they are protected, at least to some degree, from negative personal and professional repercussions. The courts' insistence on strict adherence to legislative criteria ensures that this statutory privilege is balanced with patients' need to access information about their care.

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error on a broad-based, institutional level, to diagnose systematic problems, and to ensure that individual actors are incorporating the solutions into their everyday actions." For a general encouragement to extend the privilege to "all documentation resulting from the quality assurance process including RCA, recommendations, reports and notices," see Baker et al, Canadian Patient Safety Institute, "Review", *supra* note 13 at B17.

120 Under-reporting is identified as an issue in a number of studies. See e.g. Tim Outerbridge, "Building Systemic Models for Medical Error Reporting" (2004) 12 Health LJ 275 at 276–77; Sarah Burningham, Wayne Renke & Timothy Caulfield, "Is Patient Safety Research Protected from Disclosure?" (2013) 20 Health LJ 47 at 48; Waite, *supra* note 17 at 25.

121 Duff, *supra* note 98 at 543.

As can be seen from the present study, both legislators and judicial actors have a role to play in coming to a fair compromise between the necessity of protecting quality of care information and ensuring access to health information by patients. Adopting a "balancing of interests" approach in this context is sensible. However, even if legislators tweak existing laws and judges are mindful of the interests at play, the optimal formula to reduce PSIs remains elusive for now. There is therefore a pressing need for more research to assess the possible links not only between qualified privilege laws and incentives to report PSIs, but also between other legal interventions – including civil litigation[122] – and improved quality of care.

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[122] See studies cited *supra* note 117.

L'exigence de maintien de traitement chez le patient à l'inconscience irréversible

*Catherine Paschali**

Alors que les progrès technologiques repoussent les frontières de la mort, un nouveau débat éthique et légal émerge. Lorsqu'un patient se retrouve en état végétatif et que tout espoir de réhabilitation s'éteint, la communauté médicale propose de cesser les soins de maintien de la vie et de ne pas tenter la réanimation en cas d'arrêt cardio-respiratoire. Or, certaines familles, la plupart religieuses, s'opposent à toute cessation des traitements, et en exigent le maintien. Avec l'éclairage des données scientifiques actuelles qui permettent d'accéder à l'esprit de patients en apparence inconscients, l'état du droit canadien sera examiné. Dans un premier temps, l'auteure examine en quoi la perte apparemment irréversible de la conscience peut justifier le refus des médecins de poursuivre les soins de maintien de la vie. Dans un deuxième temps, elle aborde les droits fondamentaux pouvant être invoqués par les proches au soutien de l'exigence de la poursuite des traitements. Dans un dernier temps, elle évalue les pistes

As technological progress pushes the boundaries of death, a new ethical and legal debate is emerging. When a patient is in a vegetative state and all hope of rehabilitation is gone, the medical community proposes withdrawing life-sustaining treatment and withholding resuscitation. However, some families, in most cases religious, oppose withdrawing treatment and request that it be maintained. In light of recent scientific advances allowing unprecedented access to the minds of apparently unconscious patients, the Canadian legal landscape will be explored. First, the author examines how irreversible unconsciousness may justify a doctor's refusal to pursue life-sustaining treatment. Secondly, she examines the fundamental rights invoked by the relatives to support their requests for life-sustaining treatment. Lastly, she evaluates proposed solutions aimed at clarifying who has the power to decide or to initiate a dispute resolution process. In the background to this debate, science continues to advance, with

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de solution proposées visant à clarifier à qui appartient le pouvoir décisionnel ou à mettre en place un processus de règlement des différends. En arrière-plan de ce débat, la science continue de progresser, avec l'espoir d'un meilleur respect des droits des patients apparemment inconscients dans le futur.

the hope of improving respect for the rights of apparently unconscious patients in the future.

Introduction

En invalidant, sous certaines conditions bien précises, les dispositions du *Code criminel* qui prohibaient l'aide médicale à mourir, l'arrêt *Carter* de la Cour suprême du Canada a ramené au premier plan les débats concernant les décisions de fin de vie[1]. Dans la même foulée, au Québec, l'adoption de la *Loi concernant les soins de fins de vie*[2], suite à la Commission spéciale sur la question de mourir dans la dignité, encadrait l'aide médicale à mourir à la demande d'une personne en fin de vie.

Or, la mort fait l'objet d'un débat parallèle qui se déroule actuellement devant les tribunaux de plusieurs provinces canadiennes. S'il existe un mouvement prônant le droit de mourir, que ce soit par euthanasie ou par suicide assisté, le droit de vivre est aussi réclamé par les proches de patients chez qui les médecins envisagent la cessation de tout traitement[3] de maintien de la vie. Malgré l'existence de plusieurs recours judiciaires qui visaient à clarifier le cadre légal des exigences de traitement, les interrogations demeurent sans réponse.

L'arrêt *Rasouli*, une cause ontarienne entendue en 2013 devant la plus haute Cour du pays, n'a pas offert l'éclairage souhaité et attendu[4]. M. Rasouli était inconscient et maintenu en vie artificiellement suite à une infection postopératoire ayant causé de graves lésions cérébrales. Les médecins souhaitaient cesser les traitements, estimant qu'il n'y avait plus de possibilité de rétablissement du patient alors que l'épouse de M. Rasouli s'y opposait. Les juges majoritaires, sous la plume de la juge en chef McLachlin, ont considéré que la situation relevait du régime législatif ontarien prévoyant un

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1 *Carter c Canada (PG)*, 2015 CSC 5, [2015] 1 RCS 331 [*Carter*]. Atteinte de maladie dégénérative, Mme Gloria Taylor contestait la constitutionnalité des articles 14 et 241 du *Code criminel*, RSC 1985, c C-46, qui prohibaient respectivement le consentement à l'infliction de sa mort et l'aide ou l'encouragement à se donner la mort ; ensemble, ces deux articles avaient pour effet de prohiber l'aide médicale à mourir. Mme Taylor souhaitait mettre un terme à sa vie lorsqu'elle jugerait qu'elle ne serait plus capable d'en jouir, mais serait alors incapable de mettre fin à ses jours sans assistance. Cet arrêt a renversé la décision rendue vingt ans auparavant dans *Rodriguez c Colombie-Britannique (PG)*, [1993] 3 RCS 519, 107 DLR (4e) 342 [*Rodriguez* avec renvois aux RCS].

2 RLRQ c S-32.0001. Cette loi est actuellement en vigueur.

3 Dans ce texte, les termes « traitement » et « soin » seront utilisés indistinctement.

4 *Cuthbertson c Rasouli*, 2013 CSC 53, [2013] 3 RCS 341 [*Rasouli*].

recours à un tribunal spécialisé en cas de désaccord entre le médecin traitant et le mandataire du patient. Ce faisant, la Cour a évité de se prononcer sur la prise de position ultime quant à la poursuite ou non des traitements. La dissidence, quant à elle, a soutenu que le litige relevait de la common law et non de la loi ontarienne et que, suivant un processus particulier, le consentement du mandataire n'est pas nécessaire pour cesser des traitements[5].

Au quotidien, dans les hôpitaux, les médecins, les patients et leurs proches ont à prendre des décisions qui les confrontent à leur conception de la vie et de la mort. Loin d'être décriés, des traitements intensifs en fin de vie sont parfois réclamés et exigés. Ces luttes nées des progrès technologiques sont l'une des incarnations d'une nouvelle ère où les progrès en médecine devancent les questionnements éthiques. Cet engouement suscité par l'arrivée de nouvelles procédures médicales qui permettent de retarder la mort impose toutefois un temps de réflexion sur les enjeux qui en découlent. Au-delà des aspects positifs évidents, les progrès technologiques peuvent ultimement complexifier la prise de décision.

En considération de ce qui précède, le texte suivant se veut une analyse des exigences de traitements de maintien de la vie qui s'attarde aux points les plus intéressants de la controverse. Nous explorerons plus précisément la notion d'inconscience irréversible, puisqu'elle est au cœur de plusieurs litiges. L'enjeu du rôle de la conscience dans les décisions d'arrêt de traitement est soulevé dans les cas de patients en état végétatif ou en état de conscience minimale. L'état végétatif, caractérisé par une perte apparemment irréversible de la conscience, pose la question du but des traitements médicaux et de leur possible futilité.

Aujourd'hui, un courant de pensée soutient que les patients en état végétatif ont irrémédiablement perdu ce qui constitue l'essence de l'être humain, c'est-à-dire la conscience[6]. Au-delà du corps physique, biologique, le « cerveau, partie somatique du corps, exerce une fonction particulière en tant que siège de ce qu'on appelle l'esprit ou la volonté de l'être hu-

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5 *Ibid*.

6 Sur la notion de personne humaine définie par la conscience, voir Peter Singer, *Practical Ethics*, 3e éd, New York, Cambridge University Press, 2011 ; H Tristam Engelhardt, Jr, *The Foundations of Bioethics*, 2e éd, New York, Oxford University Press, 1996. Sur le rejet des arguments utilitaristes par la Cour suprême du Canada, voir Éric Folot, *Étude comparative France–Québec sur les décisions de fin de vie : le droit sous le regard de l'éthique*, Cowansville (Qc), Yvon Blais, 2012 aux pp 98 n 472, 213 n 854, 252 n 982.

main »[7]. La cessation de traitement chez ces patients a donc des fondements philosophiques particuliers. Bien que l'acceptation d'une telle décision soit généralisée, les causes récentes démontrent qu'elle ne fait pas l'unanimité, certains s'opposant toujours à la cessation des soins de maintien de la vie[8].

En l'espèce, nous aborderons uniquement le cas problématique où la personne ayant le pouvoir de consentir aux soins, le plus souvent un proche du patient, ne consent pas à l'arrêt de traitement suggéré par un médecin et exige au contraire la poursuite des soins. La question de savoir si un patient apte à consentir pourrait exiger la poursuite de soins de maintien de la vie mérite une analyse distincte, d'autant plus que cet aspect n'est pas reflété dans les causes judiciarisées au Canada[9].

Notre analyse porte sur deux formes de traitements qui font l'objet de demandes : les traitements de maintien de la vie et les manœuvres de réanimation. Parce qu'ils peuvent être considérés excessifs, les traitements visés par ce texte sont parfois qualifiés d'« acharnement thérapeutique »[10]. Ces traitements ne visent pas à guérir une pathologie du patient ou à améliorer ses conditions de vie, mais uniquement à le maintenir en vie.

Dans le premier cas, il est question de soins sans lesquels le patient ne peut vraisemblablement pas survivre, soit le ventilateur et les antibiotiques, mais aussi l'alimentation et l'hydratation artificielles, qui sont aujourd'hui acceptés comme des formes de traitement[11]. Ces soins peuvent être initiés

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7 Robert P Kouri et Suzanne Philips-Nootens, *L'intégrité de la personne et le consentement aux soins*, 3e éd, Cowansville (Qc), Yvon Blais, 2012 au para 9.

8 Il importe de noter que la cessation de traitement doit être distinguée de l'euthanasie, dont l'objectif est de donner la mort, alors que la mort n'est que *l'effet* de l'arrêt des soins.

9 Glen Rutland, « Futile or Fruitful: The *Charter* and the Decision to Withhold or Withdraw Life Sustaining Treatment » (2009) 17 Health LJ 81 aux pp 82–83.

10 La Commission spéciale sur la question de mourir dans la dignité définissait l'acharnement thérapeutique comme étant le « recours à des traitements intensifs dans le but de prolonger la vie d'une personne malade au stade terminal, sans espoir réel d'améliorer son état » : Québec, Assemblée nationale, Commission spéciale sur la question de mourir dans la dignité, *Document de consultation* (mai 2010) à la p 10.

11 Joan M Gilmour, « Death, Dying and Decision-Making about End of Life Care » dans Jocelyn Downie, Timothy Caulfield et Colleen M Flood, dir, *Canadian Health Law and Policy*, 4e éd, Markham (Ont), LexisNexis, 2011, 385

suite à un accident pour permettre à l'équipe médicale de constater l'étendue des dommages ou suite à l'aggravation de l'état clinique d'un patient. De tels soins n'ont pas *a priori* de caractère permanent. Nous verrons que la cessation de soins comme l'alimentation et l'hydratation artificielles entraînera inévitablement la mort, contrairement au retrait du ventilateur, qui n'est pas toujours essentiel si le patient peut respirer par lui-même.

Dans le deuxième cas, il sera question des demandes de suspension d'ordonnances de non-réanimation qui peuvent être inscrites au dossier du patient. Les traitements recherchés sont des manœuvres de réanimation sur un patient en état d'arrêt cardiaque ou respiratoire. Ces manœuvres sont à l'évidence des tentatives, c'est-à-dire qu'elles n'offrent pas de garantie de succès, mais sans elles, l'arrêt cardiaque ou respiratoire s'avérerait fatal.

Dans un premier temps, nous examinerons en quoi consistent les bases scientifiques de la perte irréversible de la conscience. L'imagerie par résonnance magnétique fonctionnelle (IRMf) permet aujourd'hui d'évaluer avec beaucoup plus de précision les fonctions cognitives du patient qui, selon toute apparence, est inconscient. Nous verrons que la prémisse du refus de traitement fondé sur la permanence de l'état d'inconscience n'est plus aussi incontestable à la lumière de découvertes scientifiques récentes en neuroimagerie. Or, la détermination avec exactitude du diagnostic et du pronostic revêt une importance fondamentale dans la prise de décisions quant aux traitements.

Une fois les bases scientifiques établies, nous serons alors en mesure d'explorer trois légitimations du refus du médecin d'offrir des soins. Celui-ci peut juger qu'il est dans l'intérêt du patient de cesser tous traitements, dès lors que ces derniers n'apportent aucune amélioration de sa qualité de vie. Il peut par ailleurs qualifier les soins de futiles, entre autres parce qu'ils ne permettront jamais la réhabilitation du patient, mais uniquement sa survie. La justice distributive, par la priorisation de l'allocation des ressources à d'autres patients, est aussi invoquée au soutien du refus. La possibilité de redéfinir les critères de définition de la mort sera également explorée. Finalement, pour clore la perspective médicale,les préoccupations des médecins face à la possibilité d'erreur diagnostique et la crainte de poursuite seront abordées.

à la p 398 ; Suzanne Philips-Nootens, Pauline Lesage-Jarjoura et Robert P Kouri, *Éléments de responsabilité civile médicale : le droit dans le quotidien de la médecine*, 3e éd, Cowansville (Qc), Yvon Blais, 2007 au para 228 ; *Manoir de la Pointe bleue (1978) inc c Corbeil*, [1992] RJQ 712 aux pp 720–22, AZ-92021128 (CS) [*Manoir de la Pointe bleue*].

Dans un deuxième temps, nous établirons quels fondements juridiques pourraient soutenir une exigence de maintien de traitement par les proches. Nous commencerons par un rappel de l'encadrement législatif de l'accès aux soins de santé en passant par les droits fondamentaux protégés par les chartes, notamment les droits à la vie, à la liberté et à la sécurité. L'opposition à la cessation de traitement qui serait dans le meilleur intérêt du patient fait également appel à la notion d'autonomie décisionnelle dans un contexte très particulier de demande plutôt que de refus. Cette demande peut émaner des proches ou du patient lui-même par le biais de directives anticipées.

La liberté de religion est aussi incontournable dans ce débat, puisque des croyances religieuses sont associées aux premiers cas judiciarisés de conflits. Au Canada, cette tendance est confirmée dans les cas litigieux qui se sont retrouvés devant les tribunaux mettant notamment en scène des patients et leurs proches juifs et musulmans. La liberté de religion protégée par les chartes peut alors être invoquée pour justifier la prolongation des traitements de maintien de la vie au nom du respect de ces croyances.

Dans un dernier temps, nous aborderons les pistes de solution face aux exigences de traitement. Le pouvoir décisionnel peut être attribué à l'un des acteurs de la relation médecin–patient, en y incluant le représentant du patient inapte. Cependant, la possibilité de confier le pouvoir décisionnel au patient ou à un proche se heurte à la liberté professionnelle du médecin qui refuse de prodiguer les soins et qui devra alors tenter de transférer le patient. À l'inverse, le dernier mot peut être donné au médecin, mais cette option n'est pas à l'abri de nombreuses critiques. Tel que discuté ci-dessous, le Collège des médecins et chirurgiens du Manitoba a choisi cette voie en élaborant une déclaration prévoyant une procédure à suivre en cas de conflit, mais confiant ultimement le pouvoir au médecin.

En l'absence de clarification législative, les tribunaux seront les ultimes décideurs appelés à trancher ces litiges. Les recours judiciaires présentent plusieurs avantages, notamment parce qu'ils permettent l'avancement de débats de société par la médiatisation de causes types. Contrairement aux provinces canadiennes, plusieurs États des États-Unis ont légiféré pour clarifier le cadre légal des exigences de traitement. Parmi ceux-ci, le Texas a créé un régime procédural novateur.

À la lumière des arguments de chaque acteur du débat, de même que de l'analyse critique des diverses initiatives visant à gérer ces conflits, nous nous demanderons comment résoudre cette problématique dans le respect des droits.

I. La perte apparemment irréversible de la conscience

L'arrêt de traitement chez les patients se trouvant en état d'inconscience permanente n'a pas toujours été éthiquement acceptable ou même légal. Autrefois, la possibilité d'accusations en vertu du *Code criminel* était soulevée si le médecin envisageait la cessation de traitement alors que la vie du patient était en jeu[12]. Or, depuis la reconnaissance du droit au refus de traitement et l'acceptation généralisée de la cessation, cette pratique a libre cours dans les hôpitaux[13].

L'un des premiers cas ayant soulevé la question de l'arrêt de traitement est celui de l'affaire américaine *Quinlan*[14]. En 1975, Karen Ann Quinlan, âgée de 22 ans, est retrouvée dans le coma suite à la consommation de drogues et d'alcool qui avait mené à deux arrêts respiratoires. Le diagnostic d'état végétatif ayant été posé, son père désirait cesser les traitements de maintien de la vie qui avaient cours depuis plusieurs mois, mais s'est vu opposer un refus de la part de l'hôpital. Il a dû faire appel aux tribunaux pour qu'il puisse, à titre de *guardian*, refuser les soins, en particulier l'utilisation du ventilateur. Malgré le retrait du ventilateur, Karen Ann Quinlan a survécu plusieurs années avant de mourir d'une pneumonie[15].

Par la suite, toujours aux États-Unis, l'affaire *Cruzan* a étendu le raisonnement au retrait de tous les traitements[16]. En 1983, Nancy Cruzan est réanimée suite à un accident d'automobile, mais elle reçoit le diagnostic d'état végétatif persistant. Trois ans plus tard, ses parents souhaitent cesser la nutrition et l'hydratation artificielles et portent leur demande devant les tri-

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12 Voir par ex *Nancy B c Hôtel-Dieu de Québec*, [1992] RJQ 361, JE 92-132 (CS) [*Nancy B*].

13 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 aux para 219 et s ; Kouri et Philips-Nootens, *supra* note 7 aux para 379 et s ; Pauline Lesage-Jarjoura, *La cessation de traitement : au carrefour du droit et de la médecine*, Cowansville (Qc), Yvon Blais, 1990 aux pp 43 et s.

14 *In re Quinlan*, 355 A (2d) 647 (NJ 1976) [*Quinlan*] ; Kouri et Philips-Nootens, *supra* note 7 au para 146.

15 Bryan Rowland, « Communicating Past the Conflict: Solving the Medical Futility Controversy with Process-Based Approaches » (2006) 14 : 2 U Miami Intl & Comp L Rev 271 à la p 289.

16 *Cruzan v Director, Missouri Department of Health*, 497 US 261 (1990) ; Rowland, *supra* note 15 aux pp 289–91.

bunaux lorsque l'hôpital refuse d'honorer leur souhait. La Cour suprême des États-Unis décidera ultimement que les traitements peuvent être cessés sur la foi de la preuve que Mme Cruzan n'aurait pas voulu vivre en état végétatif.

Ainsi, les causes américaines *Quinlan* et *Cruzan* ont levé le voile sur l'acceptation de l'arrêt de traitement chez les patients en état végétatif. Plus de 30 ans plus tard, à la lumière de certaines découvertes issues de progrès technologiques, il est aujourd'hui pertinent de se pencher à nouveau sur les bases du raisonnement ayant mené à l'acceptation de l'arrêt de traitement chez ces patients inconscients. Ces découvertes remettent en question un des piliers de cette acceptation, soit la certitude du diagnostic et du pronostic quant au niveau de conscience du patient. S'il est maintenant possible de tracer un continuum des degrés de conscience qui se distinguent par leurs caractéristiques, leur diagnostic et leur pronostic, la science se heurte toutefois à ses propres limites quant au degré de certitude.

En bénéficiant de la perspective disciplinaire de la médecine, nous examinerons comment la vision neurophysiologique de la conscience s'inscrit dans la pratique médicale en ce qui concerne l'arrêt de traitement d'un patient inconscient. Dans un premier temps, le caractère irréversible de la perte de conscience sera remis en question. Pour ce faire, nous définirons d'abord la conscience d'un point de vue médical, en détaillant les altérations de la conscience. Nous aborderons ensuite certaines études récentes utilisant l'imagerie par IRMf qui sèment le doute sur certaines présomptions relatives au niveau de conscience des patients en état végétatif. Nous nous attarderons ensuite à l'étape du diagnostic et du pronostic, et à son impact sur l'opinion du médecin quant aux soins appropriés.

A. Les données scientifiques actuelles

1. La science de la conscience

La conscience est définie comme « une connaissance de l'environnement qui permet à l'être vivant d'interagir avec le monde environnant et ainsi de mener diverses actions en réponse à d'éventuels stimuli extérieurs »[17]. Les deux dimensions de la conscience, soit l'état d'éveil et l'état d'interac-

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[17] Franklin Grooten et al, « Étiologie des altérations de la conscience : comas, états végétatifs et mort encéphalique » dans Jean-Michel Guérit, dir, *L'évaluation neurophysiologique des comas, de la mort encéphalique et des états végétatifs*, Marseille, SOLAL, 2001, 71 à la p 72.

tion, permettent de définir le continuum des degrés de conscience[18]. Dans la langue anglaise, ces dimensions sont nommées respectivement *wakefulness* (l'état d'éveil) et *awareness* (l'état d'interaction)[19]. L'état d'éveil est relié au tronc cérébral, au cycle veille–sommeil et à l'ouverture spontanée des yeux[20]. L'état d'interaction est la « capacité d'un êtr[e] conscient à capter une modification du monde qui l'environne et à réaliser une action motrice adaptée »[21].

Parmi les situations cliniques où l'on note une altération de la conscience, on compte notamment les accidents vasculaires cérébraux (AVC), la maladie d'Alzheimer, la démence, le coma et les traumatismes crâniens. Or, celles qui nous intéressent particulièrement dans le cadre du débat portant sur l'arrêt de traitement sont plutôt l'état végétatif et l'état de conscience minimale. Il est utile à cette étape de préciser que le syndrome de verrouillage (communément appelé *locked-in syndrome*) n'est pas un trouble de la conscience[22], puisque la personne atteinte « conserv[e] une parfaite cognition »[23], mais est enfermée dans un corps paralysé où seuls des mouvements et clignements des yeux peuvent être observés[24].

C'est en 1972 que l'état végétatif a été défini. Il est le résultat d'une mort néocorticale combinée à un état d'éveil apparemment préservé. Parce que la conscience et la souffrance sont reliées au néocortex, l'inconscience permanente que l'on associe à l'état végétatif signifie la perte de toute fonction néocorticale[25]. De ce fait, ces patients n'interagissent pas avec leur environnement, mais ont un cycle veille–sommeil et conservent certains réflexes[26].

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18 *Ibid*.

19 Eric Racine et al, « Observations on the Ethical and Social Aspects of Disorders of Consciousness » (2010) 37 : 6 Can J Neurol Sci 758 à la p 759.

20 Grooten et al, *supra* note 17 aux pp 72–73.

21 *Ibid* à la p 73.

22 Racine et al, *supra* note 19 à la p 759.

23 Grooten et al, *supra* note 17 à la p 90.

24 *Ibid*.

25 Ronald E Cranford et David Randolph Smith, « Consciousness: The Most Critical Moral (Constitutional) Standard for Human Personhood » (1987–1988) 13 : 2–3 Am J L & Med 233 à la p 237.

26 Grooten et al, *supra* note 17 aux pp 84–87.

Ainsi, ces patients ont les yeux ouverts et ils peuvent pleurer, sourire et émettre certains bruits[27]. Cette présence de réflexes, pouvant erronément être interprétée comme étant un comportement volontaire, est une situation particulièrement difficile pour les proches de ces patients et leurs soignants[28].

En 1994, le Multi-Society Task Force on PVS, formé de représentants de cinq associations médicales et assisté d'une comité consultatif interdisciplinaire, définissait l'état végétatif et comment établir son diagnostic. Néanmoins, on ne manquait pas d'y soulever la possibilité de faux positifs, c'est-à-dire de patients diagnostiqués en état végétatif alors qu'ils ne sont pas complètement inconscients :

> *By definition, patients in a persistent vegetative state are unaware of themselves or their environment. They are noncognitive, nonsentient, and incapable of conscious experience. There is, however, a biologic limitation to the certainty of this definition, since we can only infer the presence or absence of conscious experience in another person. A false positive diagnosis of a persistent vegetative state could occur if it was concluded that a person lacked awareness when, in fact, he or she was aware* […] *Thus, it is theoretically possible that a patient who appears to be in a persistent vegetative state retains awareness but shows no evidence of it. In the practice of neurology, this possibility is sufficiently rare that it does not interfere with a clinical diagnosis carefully established by experts*[29].

En 1995, l'état de conscience minimale apparaît dans le jargon médical[30]. Il vise « des patients vigilants dont l'état d'interaction est à la limite de la conscience »[31]. Ils ont un certain niveau de conscience que l'on peut

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27 *Ibid* à la p 85.

28 *Ibid* ; Adrian M Owen et Martin R Coleman, « Detecting Awareness in the Vegetative State » (2008) 1129 Ann N Y Acad Sci 130 à la p 130.

29 Multi-Society Task Force on PVS, « Medical Aspects of the Persistent Vegetative State (First of Two Parts) » (1994) 330 : 21 New Eng J Med 1499 à la p 1501 [notes omises]. Les membres du comité étaient les suivants : Stephen Ashwal, Ronald Cranford, James L Bernat, Gastone Celesia, David Coulter, Howard Eisenberg, Edwin Myer, Fred Plum, Marion Walker, Clark Watts et Teresa Rogstad.

30 Grooten et al, *supra* note 17 à la p 89.

31 *Ibid*.

observer par des comportements tels la réponse à des ordres ou des réponses appropriées à des stimuli environnementaux comme des sourires ou des pleurs.

Ainsi, un prérequis de la conscience est la capacité de la communiquer : « mere sensation, mere representation, is not enough for consciousness – some further recursive stage, of reflection, commentary, report, articulation is needed »[32]. Si un arbre tombe dans la forêt, et que personne n'est là pour l'entendre, fait-il tout de même un bruit ? Dans le cas de la conscience, ce proverbe philosophique n'a qu'une réponse : il faut que quelqu'un entende l'arbre tomber pour affirmer qu'il fait un bruit. Ainsi, pour être en présence de conscience, il faut que l'expérience puisse être partagée.

Si le diagnostic repose essentiellement sur une recherche de signes de communication, l'on se doit de noter que « de *l'absence de signes d'une réalité* humaine on ne peut déduire *l'absence totale de cette réalité* »[33]. Cette recherche inlassable de signes chez les patients apparemment inconscients est primordiale et s'améliore au fil du temps à mesure que la technologie permet de préciser le portrait clinique des patients. Malgré tout, « [i]t will always be more difficult to prove a lack of a mental life than to demonstrate its presence »[34].

Avec les avancées technologiques en neuroimagerie, le diagnostic basé sur une observation de signes pourrait être désuet. Des découvertes récentes tirées d'études où l'IRMf a été utilisée ont créé des opportunités innovatrices de déceler la conscience chez des patients chez qui l'inconscience avait été diagnostiquée selon les moyens traditionnels. L'IRMf lie l'activité neurale résiduelle à la présence d'une fonction cognitive[35], en identifiant les changements d'oxygénation du sang[36].

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32 Adam Zeman, « The Problem of Unreportable Awareness » dans Steven Laureys, Nicholas D Schiff et Adrian M Owen, dir, *Coma Science: Clinical and Ethical Implications*, New York, Elsevier, 2009, 1 aux pp 3–4.

33 P Verspieren, « Questions éthiques posées par le soin des patients en état végétatif et leurs enjeux : Le point de vue du groupe de travail du Centre Sèvres » dans Guérit, *supra* note 17, 411 à la p 414 [italiques dans l'original].

34 Allan H Ropper, « *Cogito Ergo Sum* by MRI », Éditorial, (2010) 362 : 7 New Eng J Med 648 à la p 649.

35 Owen et Coleman, *supra* note 28 à la p 130.

36 Par exemple, l'IRMf permettra de voir si la région du cerveau associée au

Pour certains, l'IRMf ne serait pas la meilleure approche pour évaluer un patient, car elle ne permet que d'identifier une activité localisée : « *islands of activation do not mean much unless functional connectivity can be established* »[37]. L'électroencéphalogramme (EEG) serait alors une meilleure technique, car cette évaluation électrophysiologique identifie l'activité neurale rapide et distribuée, ce que l'IRMf ne peut faire[38].

En 2005, la première étude ayant réussi à repousser les frontières de la communication avec les patients a été réalisée par Adrian M Owen, titulaire actuel de la Chaire d'excellence du Canada sur les neurosciences cognitives et l'imagerie. La capacité de communiquer une expérience subjective, intrinsèque à la notion de conscience, était ici au cœur de l'expérience menée : « *In short, our ability to know unequivocally that another being is consciously aware is ultimately determined, not by whether they are aware or not, but by their ability to communicate that fact through a recognized behavioral response* »[39]. Dans la recherche de cet indice de communication, l'expérience a tenté de détecter la conscience chez une patiente se trouvant dans un état végétatif depuis cinq mois. Il est impératif de saisir la différence marquante entre l'expérience d'Owen et son collègue Martin Coleman et les expériences précédentes, soit l'aspect du comportement volontaire du patient. Il a été démontré que le cerveau réagit à des stimuli tels un visage ou le langage même sans que le patient ne soit véritablement conscient de son environnement[40], d'où le risque d'interpréter une activité cérébrale comme étant un signe de conscience alors qu'il s'agit d'une réponse biologique derrière laquelle ne se retrouve aucune volonté.

Pour éviter toute ambiguïté, l'étude par Owen et Coleman consistait à demander à une patiente diagnostiquée en état végétatif suite à un accident de s'imaginer pratiquer des activités sollicitant des régions différentes du cerveau. Par l'IRMf, on pourrait identifier si elle a compris, mémorisé et suivi les directives selon la région activée. En l'occurrence, elle devait s'imaginer jouer au tennis ou visiter des pièces de sa demeure, des activités

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langage est activée lorsque le patient entend des mots ou des phrases, par opposition à des sons.

37 Robert T Knight, « Consciousness Unchained: Ethical Issues and the Vegetative and Minimally Conscious State » (2008) 8 : 9 Am J Bioeth 1 à la p 2.

38 *Ibid*.

39 Owen et Coleman, *supra* note 28 à la p 134.

40 *Ibid*.

qui sollicitent des régions distinctes et bien documentées du cerveau. La patiente devait avoir une réponse à la commande soutenue pendant plusieurs secondes et arrêter sur commande. Étonnamment, les chercheurs ont découvert que l'activité cérébrale chez cette patiente ne pouvait être distinguée de celle d'un patient en santé. L'expérience a « confirmé au-delà de tout doute qu'elle était consciente d'elle-même et de son environnement »[41].

Par la suite, Martin Monti, docteur en psychologie et en neuroscience, a réalisé une étude qui poursuit dans la même lancée que celle d'Owen[42]. Des questions étaient posées à des patients et ils devaient répondre « oui » ou « non » en imaginant les mêmes activités, soit par exemple jouer au tennis pour indiquer « oui » et visiter des pièces pour indiquer « non ». Ils ont découvert que cinq patients pouvaient volontairement moduler leur activité cérébrale[43]. Par la suite, des évaluations cliniques additionnelles ont démontré des signes comportementaux de conscience chez deux des cinq patients[44] : « *Thus, in a minority of cases, patients who meet the behavioral criteria for a vegetative state have residual cognitive function and even conscious awareness* »[45].

Dans les années qui ont suivi, des études supplémentaires ont confirmé que des patients en apparence en état végétatif ou de conscience minimale démontraient une capacité à répondre à des commandes par le biais de l'IRMf[46].

La principale remise en question de l'interprétation des résultats de l'étude initiale d'Owen a trait au niveau de conscience réel de la patiente. Même en période d'inconscience, notamment chez les patients sous anesthésie, plusieurs fonctions cérébrales supérieures sont présentes. Pour cette raison, la possibilité que les réponses soient automatiques et non volon-

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41 *Ibid* à la p 135 [notre traduction].

42 Martin M Monti et al, « Willful Modulation of Brain Activity in Disorders of Consciousness » (2010) 362 : 7 New Eng J Med 579.

43 *Ibid* à la p 583.

44 *Ibid* à la p 588.

45 *Ibid* à la p 585 [notes omises].

46 Voir par ex Lorina Naci et Adrian M Owen, « Making Every Word Count for Nonresponsive Patients » 2013 70 : 10 JAMA Neurol 1235.

taires ne peut être écartée pour certains experts[47]. Même si l'on convient que la patiente était consciente, l'étendue de cette conscience est loin d'être précisée : « *cortical activation does not provide evidence of an internal "stream of thought"* […], *memory, self-awareness, reflection, synthesis of experience, symbolic representations, or – just as important – anxiety, despair or awareness of one's predicament* »[48].

La recherche de communication avec le patient est donc au cœur des études portant sur les patients en état végétatif ou de conscience minimale. Par ces tentatives, on espère que les patients considérés inconscients et inaptes pourront un jour participer au processus décisionnel quant à leurs traitements, dans le respect du principe de l'autonomie. De cette manière, ils pourront avoir un certain contrôle sur leur environnement et augmenter leur qualité de vie[49].

Toutefois, le succès de la communication basée sur la neuroimagerie se fait toujours attendre. Les efforts à ce jour n'ont pas porté fruit, notamment en raison de l'état de conscience variable des patients, qui demande des évaluations répétées, et des dommages potentiels aux fonctions cognitives particulières sollicitées[50]. Même si la communication était établie avec le patient, l'enjeu de la capacité à prendre des décisions demeurerait.

L'impact majeur de ces études a plutôt été de remettre en question la présomption d'inconscience permanente chez les patients en état végétatif. L'enjeu le plus pressant est bien celui de la méthode d'évaluation diagnostique et de la place que prendront ces nouvelles technologies dans les milieux hospitaliers. Devrons-nous utiliser l'IRMf chez tous les patients se trouvant depuis peu de temps en état végétatif ? Les découvertes ont nourri deux grands espoirs : premièrement que les patients puissent regagner un

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47 Dominic J Wilkinson et al, « Functional Neuroimaging and Withdrawal of Life-Sustaining Treatment from Vegetative Patients » (2009) 35 : 8 J Med Ethics 508 à la p 508. Pour d'autres commentaires par divers auteurs, voir Susan Byrne et Orla Hardiman, « Willful Modulation of Brain Activity in Disorders of Consciousness », Lettre à la rédaction, (2010) 362 : 20 New Eng J Med 1936.

48 Ropper, *supra* note 34 à la p 649.

49 Monti et al, *supra* note 42 à la p 589.

50 Jonathan C Bardin et al, « Dissociations between Behavioural and Functional Magnetic Resonance Imaging-Based Evaluations of Cognitive Function after Brain Injury » (2011) 134 : 3 Brain 769 à la p 778.

rôle dans leurs décisions de traitement et deuxièmement, qu'un diagnostic plus précis puisse diriger les efforts pour mener à une réhabilitation chez les patients ayant un meilleur pronostic.

2. La détermination du diagnostic et du pronostic

En 1994, le Multi-Society Task Force on PVS a élaboré des critères de diagnostic de l'état végétatif[51]. Le diagnostic clinique de cet état repose essentiellement sur une observation du patient, une recherche de signes subtils dénotant une interaction, une réponse adaptée ou une compréhension de langage[52]. Cette observation doit être prolongée et répétée afin, entre autres, de contrer la possibilité que le patient soit en période de sommeil pendant l'observation[53]. Ce n'est que si l'on conclut qu'il y a absence totale d'interaction que le patient recevra le diagnostic d'état végétatif.

Parce que le tronc cérébral de ces patients n'est pas endommagé, ils ont une capacité respiratoire et peuvent survivre pendant des années ou des décennies[54]. La possibilité de cesser les traitements de maintien de la vie prend alors tout son sens :

> Les chances de récupération s'amenuisent avec le temps et se rapprochent de 1 % à un an. L'espérance de vie moyenne d'un patient demeurant végétatif est de 5 ans, mais des survies de 40 ans ont déjà été observées. Les patients végétatifs représentent ainsi une charge importante tant sur le plan social que familial[55].

La qualification de chronicité, soit d'« absence d'évolution prévisible de l'état où se trouve le patient, [du] caractère hautement improbable d'un éveil »[56], dépendra de la cause de l'état. On qualifie un état végétatif qui dure

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51 Multi-Society Task Force on PVS, *supra* note 29.

52 Grooten et al, *supra* note 17 aux pp 84–87.

53 François Tasseau, « Définition et caractéristiques cliniques des états végétatifs » dans Guérit, *supra* note 17, 347 à la p 350.

54 Cranford et Smith, *supra* note 25 aux pp 237–38.

55 Grooten et al, *supra* note 17 à la p 87.

56 Verspieren, *supra* note 33 à la p 413 [notes omises].

plus d'un mois de « persistant », mais il ne sera qualifié de « permanent » qu'après un an s'il résulte d'un traumatisme crânien ou après trois mois pour une origine non traumatique comme l'anoxie[57]. Il est aujourd'hui suggéré d'abandonner l'utilisation des termes « persistant » ou « permanent », car ils créent une confusion entre le diagnostic et le pronostic[58]. L'importance du pronostic ne saurait être minimisée : « *The accurate clinical prediction of the long-term outcome in patients with disorders of consciousness remains the main guide for making treatment-limitation decisions, as well as for disentangling the knot between bioethics and human mercy* »[59].

Un an après un traumatisme, le pronostic est significativement plus favorable chez les patients en état de conscience minimale que chez les patients en état végétatif. La moitié des patients en état de conscience minimale atteindront un niveau de handicap modéré alors que seuls 3 % des patients en état végétatif auront une telle récupération[60]. Dès qu'un patient considéré en état végétatif manifeste des signes de conscience, il reçoit plutôt le diagnostic d'état de conscience minimale.

La prévision de l'évolution de l'état est essentielle pour évaluer les chances de récupération[61]. Un patient venant de subir un traumatisme pourrait donc se retrouver dans le coma avant une transition à l'état végétatif puis à l'état de conscience minimale. La cause de l'inconscience de même que sa durée depuis l'événement causal serviront à guider le pronostic. Les difficultés liées à la détermination du diagnostic font en sorte que jusqu'à 41 % des patients diagnostiqués en état végétatif pourraient avoir un état de conscience minimale et ce taux d'erreur diagnostique n'a pas substantiellement changé dans les quinze dernières années[62].

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57 Grooten et al, *supra* note 17 à la p 87 n 12.

58 Racine et al, *supra* note 19 à la p 759.

59 Pasquale Striano, Federico Zara et Carlo Minetti, « Willful Modulation of Brain Activity in Disorders of Consciousness », Lettre à la rédaction, (2010) 362 : 20 New Eng J Med 1937 à la p 1937.

60 Joseph T Giacino et al, « Behavioral Assessment in Patients with Disorders of Consciousness: Gold Standard or Fool's Gold? » dans Laureys, Schiff et Owen, *supra* note 32, 33 aux pp 35–36.

61 Grooten et al, *supra* note 17 aux pp 74–76.

62 Caroline Schnakers et al, « Diagnostic Accuracy of the Vegetative and Minimally Conscious State: Clinical Consensus versus Standardized Neurobeha-

Eric Racine et ses collègues rappellent que l'un des buts de l'imagerie fonctionnelle est d'identifier les candidats les plus aptes à la neuroréhabilitation et ayant les meilleurs pronostics. En l'occurrence, des thérapies comme la stimulation physique ou environnementale, la stimulation électrique du cerveau et la stimulation pharmacologique n'ont pas eu les effets souhaités chez les patients en état végétatif, mais elles ont un potentiel certain chez les patients en état de conscience minimale[63].

Ainsi, la limite entre l'état végétatif et l'état de conscience minimale n'est pas clairement définie, alors que cette distinction a un impact non négligeable sur les décisions de traitement et leurs chances de succès[64]. Une étude récente a démontré que les patients en état végétatif chez qui la transition à l'état de conscience minimale se fait dans les huit semaines suivant le traumatisme crânien ont de bonnes chances de récupération. Plusieurs atteignent même une indépendance partielle ou peuvent retourner au travail ou aux études[65].

Les études d'Owen et de Monti sont récentes, mais la découverte de conscience chez une patiente diagnostiquée en état végétatif est une rare occasion de remettre en question les méthodes diagnostiques et les connaissances quant au fonctionnement du cerveau. Cet événement est surtout un grand pas vers une meilleure sélection des patients qui pourront le plus bénéficier de traitements en vue d'une réhabilitation.

En revanche, on ne peut nier qu'un patient conscient a des intérêts[66]. Parmi ces intérêts, l'arrêt de la souffrance peut s'avérer un puissant argument des tenants de la cessation de traitement. Plus particulièrement, chez les patients en état de conscience minimale, il est possible que la souffrance soit présente sans qu'elle puisse être communiquée pour recevoir des soins

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vioral Assessment », en ligne : (2009) 9 : 35 BMC Neurol aux pp 3–4 <www.biomedcentral.com/1471-2377/9/35>.

63 Racine et al, *supra* note 19 à la p 762.

64 Knight, *supra* note 37 à la p 1.

65 Douglas I Katz et al, « Natural History of Recovery from Brain Injury after Prolonged Disorders of Consciousness: Outcome of Patients Admitted to Inpatient Rehabilitation with 1–4 Year Follow-Up » dans Laureys, Schiff et Owen, *supra* note 32, 73 à la p 84.

66 Wilkinson et al, *supra* note 47 à la p 509.

appropriés[67]. Bien que la présence de conscience remette en question les fondements de l'arrêt de traitement fondé sur l'inconscience, elle peut alors paradoxalement renforcer le retrait des soins de maintien de la vie s'il y a une présence potentielle de souffrance inadéquatement soulagée.

B. Le refus du médecin d'offrir des soins jugés futiles

1. Les légitimations de l'arrêt de traitement et la redéfinition de la mort

Les conditions médicales présentées précédemment sont des produits de la capacité grandissante de la médecine de sauver des vies. Elles sont le résultat de l'utilisation de soins intensifs et de soins de maintien de la vie. Or, il faut reconnaître les limites de la médecine moderne. Pour les patients en réel état d'inconscience permanente, les chances de récupération sont nulles.

Dans la détermination des soins appropriés pour les patients en état végétatif, les médecins considèrent aujourd'hui l'option d'arrêter tous les traitements, y compris l'alimentation et l'hydratation, ce qui entraîne inévitablement le décès du patient. S'il a déjà été suggéré qu'un tel patient est mourant, nous partageons plutôt l'avis que le décès n'est pas imminent et qu'il s'agit d'un état chronique, le processus de mort ayant été interrompu par la médecine[68]. L'argument de l'imminence du décès ne saurait donc être utilisé pour justifier l'arrêt de traitement.

La cessation des traitements de maintien de la vie proposée par le médecin peut être fondée sur trois légitimations principales : le meilleur intérêt du patient, la futilité et la justice distributive. Ces arguments s'appliquent à l'état végétatif, mais peuvent également s'appliquer à l'état de conscience minimale, bien qu'il n'y ait pas une absence totale de conscience[69]. Par ailleurs, nous examinerons la proposition d'établir un nouveau critère définissant la mort, soit la mort néocorticale.

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67 *Ibid*.

68 Voir par ex Verspieren, *supra* note 33 aux pp 416–18.

69 Pour une analyse spécifique des décisions reliées à l'état de conscience minimale, voir Courtenay R Bruce, « The Awful Stranger, Consciousness: A Proposed Analytical Framework for Minimally Conscious State Cases » (2008) 1 Phoenix L Rev 185.

a. Le meilleur intérêt du patient

La première légitimation a trait au meilleur intérêt du patient, qui, dans son état clinique, n'aurait pas intérêt à ce qu'on le maintienne en vie. Dans le cadre de ses décisions, non seulement le médecin doit agir dans le meilleur intérêt du patient, mais son code déontologique lui *impose* de « refuser sa collaboration ou sa participation à tout acte médical qui irait à l'encontre de l'intérêt du patient, eu égard à sa santé »[70]. Cette notion de meilleur intérêt est souvent le nœud des désaccords.

Or, ce sujet épineux soulève un problème additionnel, à savoir sur quelle personne repose la tâche de déterminer ce qui correspond au meilleur intérêt du patient. Si le patient lui-même est le mieux placé pour apprécier les risques et les bienfaits d'un traitement, la situation se complexifie lorsqu'un tiers est amené à déterminer son meilleur intérêt. Ce jugement porté par un tiers devrait tendre vers l'objectivité, tel que le rappellent Suzanne Philips-Nootens, Pauline Lesage-Jarjoura et Robert P Kouri :

> Même s'il est admis que l'incapable a les mêmes droits que la personne capable, l'application pratique pose certains problèmes. Ainsi, malgré toutes les précautions prises pour assurer la meilleure décision possible, cette dernière ne peut être qu'une approximation de ce que la personne aurait voulu réellement, à moins qu'elle n'ait clairement indiqué à l'avance sa volonté, par mandat ou testament biologique. Une protection accrue s'impose donc : il n'y a pas de place ni pour l'arbitraire, ni pour les considérations subjectives dans les décisions la concernant. Les critères de décision doivent refléter l'objectivité et le meilleur intérêt du patient, c'est-à-dire tenir compte du critère de proportionnalité des risques et des bienfaits, de l'aspect bénéfique des soins et de leur opportunité dans les circonstances[71].

Pour certains, il relève de l'évidence que la notion même d'intérêt chez les patients en état végétatif est absurde :

> *Medicine cannot promote the best interests of these patients because these patients have no interests in further treatment or discontinuation of treatment, or in continued existence at all.*

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[70] *Code de déontologie des médecins*, RLRQ c M-9, r 17, art 60.

[71] Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 238. Voir aussi art 12 CcQ ; Rasouli, *supra* note 4 aux para 88, 98.

> […]
>
> *Medicine cannot preserve and maintain health because there is no health for a patient in a persistent vegetative state, only life in terms of the most primitive vegetative functions.* […]
>
> […] *Permanently unconscious patients are not weak, disabled, disadvantaged, handicapped, or helpless any more than someone who is dead*[72].

Ces patients n'ont aucune expérience sensorielle, ils ne ressentent pas de joie ou de souffrance et ils n'ont pas conscience de leur propre existence. Devant cette réalité, comment parler d'intérêts actuels au sens traditionnel pour ces patients[73] ? À travers cette réflexion, on dénote également une remise en question du but de la médecine, qui naît de cette confrontation avec des êtres humains qui paraissent avoir perdu toute essence de leur personne, n'ayant plus que l'existence physique de leur corps. Ainsi, ils sont plus près des « morts » que des « vivants » et cela devrait guider le choix du traitement approprié[74].

Au-delà de ces diverses approches, certaines objections peuvent être relevées quant à l'utilisation du critère du meilleur intérêt. D'abord, le « meilleur intérêt » d'un patient qui ne peut communiquer ses volontés est difficile à distinguer d'un jugement porté sur sa qualité de vie[75]. Le refus du médecin de poursuivre les traitements de maintien de la vie associe l'intérêt d'un patient à sa qualité de vie. On estime que la qualité de vie d'un patient en état végétatif est si négligeable (sinon nulle) que la mort semble une meilleure avenue. Généralement, le concept de qualité de vie englobe la notion de conscience de soi et de capacité d'interaction, de sorte que la perte de ces capacités affecte lourdement la qualité de vie[76].

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72 Cranford et Smith, *supra* note 25 aux pp 241–42 ; voir aussi Lois Shepherd, « In Respect of People Living in a Permanent Vegetative State – and Allowing Them to Die » (2006) 16 : 2 Health Matrix 631.

73 Voir Andrea J Fenwick, « Applying Best Interests to Persistent Vegetative State: A Principled Distortion? » (1998) 24 : 2 J Med Ethics 86.

74 Cranford et Smith, *supra* note 25 à la p 242.

75 Verspieren, *supra* note 33 aux pp 417–18.

76 Edward W Keyserlingk, Commission de réforme du droit du Canada, *Le carac-*

Au demeurant, la vulnérabilité de ces patients inconscients est évidente. Le patient en état végétatif est dépendant dans ses besoins vitaux, mais aussi au plan relationnel, où l'on note une asymétrie dans la relation du fait qu'il ne peut communiquer : « Le patient est dans un véritable *isolement* perceptif par l'atteinte de ses organes sensoriels, en isolement intellectuel par les troubles cognitifs et neuropsychologiques, et en isolement affectif suite à la rupture de ses liens avec ses proches »[77]. Pour certains, une telle dépendance diminuerait la dignité du patient et, dans une culture centrée sur l'autonomie, n'aurait pas sa place[78].

Le débat sur le traitement approprié de ces patients soulève des craintes sur l'impact qu'auront de telles décisions sur l'approche envers d'autres pathologies comme la démence ou la maladie d'Alzheimer[79]. Le risque de réduire l'être humain à sa condition, de déclarer un patient « moins humain », est grand. Cela pose également la question suivante : « [Q]uelles sont les fondements neurobiologiques minimaux pour la conscience ? »[80]. Bien qu'il soit accepté que la mémoire, l'introspection, le langage ou la motivation ne sont pas des éléments essentiels, où tracer la limite ? Il est suggéré qu'un système sensoriel et un niveau d'éveil suffisant seraient des bases essentielles[81].

b. La futilité

La deuxième légitimation de l'arrêt de traitement est la futilité, concept central dans le présent débat. Un traitement futile se définit comme un traitement inutile ou inefficace. Cette définition est donc reliée au but espéré

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tère sacré de la vie ou la qualité de la vie, Ottawa, Ministre des Approvisionnements et Services Canada, 1979 à la p 76.

77 Thierry Willemart, « Techniques d'éveil du patient en état végétatif » dans Guérit, *supra* note 17, 353 à la p 354.

78 Jeffrey B Hammond, « The Minimally Conscious Person: A Case Study in Dignity and Personhood and the Standard of Review for Withdrawal of Treatment » (2009) 55 : 2 Wayne L Rev 821 aux pp 826–27.

79 Verspieren, *supra* note 33 à la p 415.

80 Zeman, *supra* note 32 à la p 5 [notre traduction].

81 *Ibid* aux pp 5–6.

du traitement[82]. La notion de futilité étant particulièrement controversée, les auteurs ne s'entendent pas sur une définition unique. Au lieu de tenter de réconcilier des définitions en compétition, nous retiendrons ici la théorie proposée par Eric Chwang, qui identifie quatre raisons distinctes pour lesquelles un traitement est futile[83].

Le premier argument pour qualifier un traitement de futile est l'inefficacité physiologique, dont l'exemple typique est l'antibiotique pour traiter une infection virale, puisque les antibiotiques ne détruisent que les bactéries et non les virus. Ainsi, le traitement proposé est futile puisqu'il n'a aucun effet bénéfique sur la condition médicale que l'on souhaite modifier. Les traitements avec un très faible pourcentage de réussite sont aussi inclus dans cette catégorie, les probabilités de succès étant si faibles qu'elles justifient la qualification de futile[84]. Un tel constat émanerait d'un consensus de la communauté médicale, des pourcentages découlant d'études cliniques, appliqués en considération des particularités de chaque cas[85]. Thaddeus Mason Pope reprend les propos de Lawrence Schneiderman et Nancy Jecker, qui soulignent que « *treatment should be regarded as medically futile if it has not worked in the last 100 cases* »[86].

Le deuxième argument de futilité est l'imminence du décès, qui doit survenir dans les semaines qui suivent. Le troisième est la condition fatale, où les soins curatifs seraient futiles, alors que les soins palliatifs visant à soulager la souffrance seraient de mise. Le quatrième est lié à la pauvreté de la qualité de vie du patient[87]. Nous nous attarderons au premier et au quatrième arguments, qui sont pertinents à notre analyse puisqu'ils ont trait à l'inefficacité physiologique et à la perte substantielle de qualité de vie.

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82 Eric Chwang, « Futility Clarified » (2009) 37 : 3 JL Med & Ethics 487 à la p 489.

83 *Ibid* à la p 490. D'autres auteurs offrent une classification et qualification différentes de situations de futilité.

84 Rowland, *supra* note 15 aux pp 281–83 (qualifiant cette situation de futilité quantitative plutôt que de futilité physiologique).

85 Thaddeus Mason Pope, « Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment » (2007–2008) 75 : 1 Tenn L Rev 1 aux pp 32 et s [Pope, « Medical Futility Statutes »] (qualifiant également cette situation de futilité quantitative plutôt que de futilité physiologique).

86 *Ibid* à la p 33.

87 Chwang, *supra* note 82 aux pp 487–88.

Quant au premier argument au soutien de la futilité, la réanimation est un exemple intéressant de la difficulté à qualifier des traitements de futiles au plan physiologique. Pour un patient en état végétatif, la réanimation est inutile si le but est d'améliorer la qualité de vie, mais elle est utile si le but est de faire réapparaître une fonction cardiaque[88]. Selon le *Joint Statement on Resuscitative Interventions* produit par l'Association médicale canadienne, la réanimation n'est pas toujours appropriée, car pour certains patients, les chances de succès sont très faibles[89]. Pour certains proches, la tentative de réanimation est un acte médical qui vaudra toujours l'effort, puisqu'en son absence, le décès est inévitable[90]. La réanimation représente donc une ultime opportunité.

Parce que la définition du concept de futilité se détermine par rapport au but espéré du traitement, la difficulté réelle est d'identifier ce but, qui peut justifier le recours à d'autres experts ou à une équipe multidisciplinaire (médecins, éthiciens). Si le but du traitement est clair, alors les désaccords quant au traitement devraient être réglés par d'autres médecins et non par d'autres experts, car cela relève de leur profession et de leurs connaissances scientifiques[91].

Cela soulève la question du rôle du médecin dans de telles situations conflictuelles. Nous estimons que Joel B Zivot soutient avec justesse que « [*a*] *critical care physician cannot be resuscitator and palliator at the same time* »[92]. Par exemple, il serait paradoxal pour un médecin d'être placé dans une situation où il doit à la fois offrir des soins visant à soulager les souffrances d'un patient en phase terminale et tenter de le réanimer en cas d'arrêt cardio-respiratoire. L'objectif du plan de traitement doit donc être bien défini afin que l'ensemble des décisions soit cohérent.

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88 *Ibid* à la p 489.

89 Canadian Medical Association, *Joint Statement on Resuscitative Interventions (Update 1995)*, CMA Policy Summary, (1995) 153 : 11 CMAJ 1652A aux pp 1652A–1652B. Par ailleurs, la réanimation peut augmenter les souffrances de patients conscients si, par exemple, des fractures aux côtes surviennent.

90 Toutefois, l'arrêt cardiorespiratoire peut avoir causé des dommages cérébraux importants si l'oxygénation du cerveau a été déficiente.

91 Chwang, *supra* note 82 à la p 493.

92 Joel B Zivot, « The Case of Samuel Golubchuk » (2010) 10 : 3 Am J Bioeth 56 à la p 57.

Quant à la cessation de traitements de maintien de la vie chez les patients en état végétatif, il est admis que ceux-ci ont généralement pour unique objectif le maintien de la « vie », c'est-à-dire de certaines fonctions biologiques du corps humain. La futilité s'explique alors par l'absence d'espoir de réhabilitation des fonctions cognitives supérieures. Par opposition, si l'on considère que le maintien de la vie est malgré tout un objectif en soi, de tels traitements ne pourraient être qualifiés de futiles.

Finalement, quant à la quatrième raison, Edward W Keyserlingk propose deux critères d'appréciation permettant d'évaluer la qualité de vie : (1) la capacité d'interaction et la conscience de soi et (2) l'intensité de la douleur et de la souffrance du malade ainsi que de sa capacité d'y faire face[93]. Il va de soi que le meilleur juge de la qualité de vie est le patient lui-même. La difficulté se pose donc lorsque le patient ne peut communiquer.

Puisque l'évaluation de la qualité de vie tend vers la subjectivité, il faut se méfier des jugements basés sur un regard extérieur. À cet effet, un sondage récent effectué chez des personnes atteintes du syndrome d'enfermement a révélé une réalité surprenante. La majorité de ces patients (72 %), généralement paralysés et ne communiquant que par clignements des yeux, se sont dits heureux et seuls 7 % désiraient l'euthanasie [94]. Il faut toutefois ajouter que 58 % des patients interrogés ne souhaitaient pas être réanimés[95]. Le danger dans la cessation de soins fondée sur la qualité de vie est la diminution de la valeur de la vie des personnes gravement handicapées, particulièrement celles qui sont plus vulnérables du fait de leur incapacité.

Le constat que l'on peut dresser de ces quelques réflexions sur la futilité est que de telles décisions ne sont pas purement médicales, elles sont à l'évidence teintées de jugements de valeur. Elles ne sont qu'un exemple de choix complexes qu'ont à prendre les médecins tous les jours :

> Le médecin doit trouver un juste équilibre entre, d'une part, ce qu'il estime lui-même être le bien du patient, la conviction dont il peut témoigner, ses tendances thérapeutiques person-

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93 Keyserlingk, *supra* note 76 à la p 76.

94 Marie-Aurélie Bruno et al, « A Survey on Self-Assessed Well-Being in a Cohort of Chronic Locked-In Syndrome Patients: Happy Majority, Miserable Minority », en ligne : (2011) 1 : 1 BMJ Open aux pp 3, 7 <bmjopen.bmj.com/content/1/1/e000039.full>.

95 *Ibid* aux pp 6–7.

> nelles conservatrices ou, au contraire, agressives, une certaine forme de persuasion justifiée, et d'autre part, le respect de l'autonomie de son vis-à-vis[96].

Le degré de conscience, lorsqu'il est abordé dans les discussions entourant la futilité, n'est que la pointe de l'iceberg du débat. Ce n'est pas l'absence de conscience au sens strictement médical qui est invoqué, mais plutôt sa signification dans le cadre du débat. Le patient inconscient souffre-t-il ? A-t-il un intérêt ? Est-il encore une personne ? L'application de la notion de futilité aux patients en état végétatif ne peut se réduire à une analyse de la possibilité d'amélioration de leur état.

c. La justice distributive

Au meilleur intérêt du patient et à la futilité s'ajoute la troisième légitimation, basée sur l'argument de la justice distributive. Celle-ci est souvent invoquée conjointement avec la futilité pour justifier l'arrêt de traitement au motif que les ressources devraient être consacrées aux patients qui peuvent le plus en bénéficier[97]. Certains soutiennent que lorsque les chances de récupération d'un patient en état végétatif sont presque nulles, les efforts devraient être concentrés ailleurs[98]. Les patients en état végétatif requièrent beaucoup de soins et sont un fardeau pour leurs proches et pour les équipes soignantes. Les coûts liés aux soins de maintien de la vie sont aussi élevés et dans un contexte de ressources limitées, il est discutable de consacrer tant de ressources à des patients qui n'en retirent aucun bénéfice[99].

Si plusieurs légitimations justifient l'arrêt de traitements de maintien de la vie chez les patients à l'inconscience irréversible, un autre courant controversé préconise plutôt une redéfinition de la mort en fixant le critère de la mort néocorticale[100]. Au Québec, la mort n'est pas définie par le législateur, les critères relevant plutôt d'un consensus de la communauté

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96 Kouri et Philips-Nootens, *supra* note 7 au para 233.

97 Wilkinson et al, *supra* note 47 à la p 510.

98 *Ibid*.

99 Cranford et Smith, *supra* note 25 à la p 246.

100 Kouri et Philips-Nootens, *supra* note 7 au para 147.

scientifique auquel adhèrent les tribunaux[101]. Le nouveau courant propose que la conscience soit le critère moral et constitutionnel principal qui définit la personne[102]. Au moment où toute trace de l'essence d'une personne a disparue, il ne serait pas immoral de considérer qu'elle est morte, qu'elle n'est plus qu'une « coquille vide ». Autrement dit, « *the person's bodily processes should be stilled to match the stillness within her brain* »[103].

Ainsi, aux deux critères de mort existants, soit l'arrêt cardio-pulmonaire et l'arrêt irréversible de l'ensemble des fonctions cérébrales, on ajouterait l'arrêt des fonctions cérébrales supérieures comme critère suffisant de décès, lorsque cet arrêt induit une perte irréversible de conscience (mort néocorticale)[104]. Ce faisant, on estime que la définition de la mort traditionnellement associée à la vie biologique doit être élargie. La simple existence biologique sans conscience de soi ou de son environnement n'est plus considérée comme une vie humaine, mais bien comme un décès : « C'est en recourant à la notion d'identité personnelle et de continuité de la conscience de soi et du monde comme traits décisifs de l'humain que l'on peut fonder le critère de mort cérébrale »[105].

En redéfinissant la mort pour y inclure la mort néocorticale, on évite de justifier l'arrêt de traitement pour les patients en état végétatif par des notions subjectives de qualité de vie ou de hiérarchie de vies humaines[106]. Un tel raisonnement reconnaît que toutes les vies humaines sont égales et que l'arrêt de traitement est justifié par le décès, sans qu'il soit fondé sur le fait que le patient est moins digne ou moins humain. L'avantage de l'ajout de la perte irréversible de conscience comme définition de la mort est qu'il met un frein à la pente glissante vers l'arrêt de traitement chez les autres patients à l'état de conscience altéré. Seule la mort néocorticale justifie cette cessa-

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101 *Ibid* au para 169 ; voir notamment *Leclerc (Succession de) c Turmel*, [2005] RJQ 1165 au para 52, JE 2005-805 (CS).

102 Cranford et Smith, *supra* note 25 à la p 236 (on oppose ici la « personne » à l'« être humain »).

103 Hammond, *supra* note 78 à la p 830. Nous reviendrons sur cet argument dans la partie III.A.

104 Marc Crommelinck, « Bases neurologiques de la conscience » dans Guérit, *supra* note 17, 23 aux pp 25–26.

105 *Ibid* à la p 26.

106 Hammond, *supra* note 78 aux pp 836–38.

tion, donc les patients en état de conscience minimale méritent une protection. Ceci n'empêche pas tout arrêt de traitement pour ces patients, mais il sera fondé sur les limites de la médecine et non sur des considérations de pertes de caractéristiques essentielles à la personne humaine[107].

Or, l'époque où un troisième critère de mort fera l'objet d'un consensus n'est guère arrivée. Il en résulterait un véritable bouleversement de la notion de vie humaine. Une barrière médicale importante s'érige à l'encontre de l'acceptation de l'état d'inconscience permanente comme catégorie distincte de mort[108]. Le problème de la certitude du diagnostic des patients en état végétatif était soulevé il y a 20 ans, mais il est toujours d'actualité :

> Cependant, en l'absence d'une procédure infaillible nous permettant de poser un diagnostic certain, comme c'est le cas de la mort cérébrale, en raison également de la réticence du public, cette redéfinition de la mort attend toujours une confirmation médicale, légale et sociale. Suspendus entre la vie et la mort, ces cas relancent donc le dilemme de la cessation de traitement[109].

Malgré ces discussions, les patients en état végétatif sont bel et bien encore considérés comme vivants. La perte des fonctions néocorticales associées à la conscience justifierait cependant l'arrêt des traitements de maintien de la vie.

2. Les craintes associées à l'incertitude du diagnostic

L'absence de certitude du diagnostic a été illustrée récemment devant les tribunaux canadiens. Dans la cause *Rasouli*[110], le patient avait développé une méningite suite à une opération pour enlever une tumeur bénigne. Il avait des dommages au cerveau, au cervelet et à la moelle épinière, et était dans le coma. Les médecins désiraient cesser les traitements de maintien de la vie de leur patient en état végétatif. La femme de M. Rasouli s'y opposait, croyant fermement que son mari avait un état de conscience plus élevé que

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107 *Ibid*.

108 Cranford et Smith, *supra* note 25 aux pp 236–37.

109 Lesage-Jarjoura, *supra* note 13 à la p 39.

110 *Supra* note 4.

celui diagnostiqué. Effectivement, entre la cause de première instance et le moment où la cause allait être entendue devant la Cour suprême, soit en un peu plus d'un an, le diagnostic de M. Rasouli était passé d'état végétatif permanent à celui d'état de conscience minimale[111]. Ce développement laisse croire que le diagnostic initial était inexact et que la capacité de communiquer de M. Rasouli s'était légèrement améliorée.

Les arguments appuyant le refus de poursuivre les traitements de maintien de la vie chez les patients en état végétatif ont généralement un dénominateur commun : la certitude de l'irréversibilité de la condition. Pour cette raison, la possibilité d'une erreur de diagnostic ou de pronostic est une épée de Damoclès. Les conséquences d'une telle erreur sur laquelle est fondée une décision de cessation de traitement sont graves puisqu'elles sont irréversibles. Or, puisque certains patients diagnostiqués comme étant dans un état végétatif pourraient avoir un niveau de conscience plus élevé qu'on le croit, la neuroimagerie aurait alors un rôle à jouer dans ces litiges portés devant les tribunaux[112]. La crainte principale en l'espèce est de poser un diagnostic erroné chez un patient qui est conscient mais incapable de communiquer[113]. Cette difficulté à diagnostiquer avec précision l'état d'un patient est intimement liée à la difficulté d'interpréter les résultats des tests de neuroimagerie[114].

Cette préoccupation se retrouve dans le cas manitobain de M. Golubchuk, un patient aux soins intensifs qui bénéficiait d'un ventilateur et de nutrition artificielle[115]. Il avait d'abord souffert de dommages cérébraux suite à une chute en 2003. Sa condition était critique, car il souffrait d'une condition cardiaque et ses reins étaient endommagés. La famille soutenait que certains tests médicaux n'avaient pas été effectués afin d'établir avec plus de certitude le niveau de conscience du patient[116]. L'inquiétude de la famille

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111 La Cour suprême a néanmoins choisi d'entendre la cause.

112 Carl E Fisher et Paul S Appelbaum, « Diagnosing Consciousness: Neuroimaging, Law, and the Vegetative State » (2010) 38 : 2 JL Med & Ethics 374 à la p 374.

113 *Ibid* à la p 376.

114 *Ibid* à la p 381.

115 *Golubchuk v Salvation Army Grace General Hospital*, 2008 MBQB 49, 290 DLR (4e) 46 [*Golubchuk*].

116 *Ibid* au para 9.

était facile à comprendre, car il y avait absence de consensus médical quant à l'état du patient. Par exemple, bien que des médecins aient refusé de traiter le patient, en alléguant sa souffrance indue, le docteur Zivot, qui s'est porté volontaire pour traiter M. Golubchuk, estimait que son patient ne souffrait pas[117]. Un tel désaccord dans la communauté médicale affecte sans contredit le lien de confiance entre la famille et l'équipe soignante.

Dans le même ordre d'idées, dans la cause albertaine *Sweiss*, la famille du patient demandait au juge d'accorder une injonction interlocutoire pour suspendre une ordonnance de non-réanimation et interdire aux médecins de retirer le respirateur, invoquant les croyances religieuses de M. Sweiss[118]. Celui-ci souffrait de problèmes de santé importants (hypertension, diabète, maladie pulmonaire obstructive chronique, obésité) et avait déjà été hospitalisé 98 fois. En septembre 2009, 40 minutes de réanimation avaient été nécessaires suite à un arrêt cardiaque et des dommages importants au cerveau en avaient résulté[119]. Les médecins invoquaient l'inconfort du patient pour justifier le retrait du respirateur. Du même souffle, ils affirmaient que le patient était minimalement conscient, et qu'en conséquence il souffrait peu[120]. À la lumière de ces prétentions contradictoires, le juge a déterminé que le maintien du respirateur n'était pas une situation excessive, accordant la requête en injonction interlocutoire de la famille[121].

Enfin, dans la cause albertaine *Jin*, les médecins considéraient que leur patient inconscient depuis un traumatisme crânien serait dans le meilleur des cas dans un état neurovégétatif persistant[122]. Or, la famille s'objectait à une ordonnance de non-réanimation inscrite au dossier et une injonction interlocutoire a été accordée par le juge pour qu'elle soit retirée. Deux mois plus tard, l'état de santé de M. Jin s'était remarquablement amélioré. Il pouvait

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117 Sam Solomon, « End-of-Life War Outlives Golubchuk », *National Review of Medicine* 5 : 7 (juillet 2008), en ligne : <www.nationalreviewofmedicine.com/issue/2008/07/5_patients_practice_07.html> ; Zivot, *supra* note 92 à la p 57.

118 *Sweiss v Alberta Health Services*, 2009 ABQB 691 au para 9, 314 DLR (4e) 474 [*Sweiss*].

119 *Ibid* aux para 2, 4.

120 *Ibid* aux para 6, 12, 67.

121 *Ibid* au para 67.

122 *Jin v Calgary Health Region*, 2007 ABQB 593 au para 19, [2008] 2 WWR 723.

marcher avec de l'aide, écrire et parler[123]. Nous pouvons en conclure que le diagnostic et le pronostic des médecins étaient manifestement erronés.

Ces quelques situations judiciarisées rappellent l'importance de bien diagnostiquer l'état du patient avant de prendre des décisions comme la cessation des soins de maintien de la vie ou la non-réanimation, puisqu'elles sont lourdes de conséquences. Ces cas ne justifient certainement pas la remise en question de toute forme de cessation de traitement, mais une telle rétrospection a l'avantage de légitimer les revendications des proches.

Lorsque l'état de santé de certains patients fait en sorte que le médecin estime que la poursuite des soins est inappropriée, la famille ou la personne apte à consentir en lieu et place du patient inapte peut requérir l'intervention des tribunaux. Une injonction du tribunal obligeant le médecin à fournir de tels soins le met donc dans une position particulièrement inconfortable, d'autant plus que le non-respect d'une injonction est passible d'une condamnation pour outrage à la cour. Dans ce contexte, un des médecins de M. Golubchuk a affirmé que son obligation de ne pas nuire au patient avait préséance sur les conséquences légales possibles de sa décision[124]. En outre, l'injonction interlocutoire émise a mené au refus de trois médecins de traiter M. Golubchuk[125].

La Cour suprême dans l'arrêt *Rasouli* a remis en perspective les préoccupations des médecins : « [L]e médecin peut estimer que son obligation juridique de ne pas retirer le traitement de maintien de la vie entre en conflit avec son éthique professionnelle ou personnelle. De telles tensions sont inhérentes à la pratique de la médecine »[126]. La Cour a même fait le parallèle avec l'inconfort des médecins face au développement du droit en matière de consentement et la possibilité de refus de traitement, comme le refus de transfusions de sang par les Témoins de Jéhovah. Or, il convient de préciser, tel que le souligne Hilary Young, que dans l'exigence de maintien de traitement, l'intérêt du médecin est plus sollicité que dans la possibilité de refus de traitement par un patient[127].

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123 P Beauchamp, « Court Fight Saved Man's Life, Family Says », *The Calgary Herald* (24 novembre 2007), en ligne : <www.canada.com/calgaryherald/story.html?id=92773f2e-550a-49d3-b207-ff9008f590f1&k=42669>.

124 Solomon, *supra* note 117.

125 *Ibid*.

126 *Rasouli*, *supra* note 4 au para 73.

127 Hilary Young, « Why Withdrawing Life-Sustaining Treatment Should Not Re-

Finalement, les exigences de maintien des traitements peuvent entraîner la menace de recours en responsabilité civile contre le médecin. La règle générale est à l'effet que le médecin a une obligation de moyens et qu'il doit agir avec prudence et diligence selon les règles de l'art, « en conformité avec les données actuelles de la science »[128]. Le médecin doit tenter d'établir le diagnostic à l'aide de moyens raisonnables, conformément aux bonnes pratiques[129]. Cependant, il n'a pas à agir « en fonction de la fine pointe de la recherche scientifique. Il n'a pas à recourir d'emblée à tous les examens et traitements, si ceux-ci ne sont pas couramment utilisés »[130].

En l'espèce, les études poussées de Monti et d'Owen, mentionnées plus haut, ont révélé des niveaux de conscience insoupçonnés chez des patients ayant le diagnostic d'état végétatif. En revanche, les examens entrepris au cours de ces études scientifiques ne sont pas aisément transférables dans un contexte de soins hospitaliers quotidiens. Devrait-on alors considérer que de tels examens ne sont pas courants et que les méthodes plus traditionnelles de diagnostic sont néanmoins fiables ? Quand un médecin peut-il véritablement affirmer que l'inconscience est irréversible ?

Une telle erreur de diagnostic ne constituerait pas nécessairement une faute entraînant la responsabilité civile du médecin, si celui-ci a usé des moyens raisonnables[131]. Puisque le médecin n'a pas l'obligation de fournir un diagnostic précis lorsque ce n'est pas possible dans les circonstances[132], il pourrait être opportun de partager avec les proches certains doutes quant au caractère « complet » ou permanent de l'inconscience. Par exemple, le médecin pourrait indiquer que toute amélioration de l'état ou possibilité que le patient ait un certain niveau de conscience est hautement improbable. Tel que vu précédemment, le niveau de certitude varie selon la cause de l'inconscience, l'anoxie ayant des effets potentiellement plus dévastateurs qu'un traumatisme crânien. Il va sans dire que de telles incertitudes de la part du corps médical pourraient avoir pour effet de réduire les possibilités d'obtenir un consentement à la cessation de traitement.

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quire "*Rasouli* Consent" » (2012) 6 : 2 RD & santé McGill 54 à la p 89.

128 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 299.

129 *Ibid* au para 308 ; *Code de déontologie des médecins*, *supra* note 70, art 46.

130 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 300.

131 *Ibid* au para 316.

132 *Ibid* au para 315.

En 2011, une équipe de médecins a comparé le taux de mortalité associé à la cessation de traitements de maintien de la vie chez des patients victimes de traumatismes crâniens importants dans six centres canadiens[133]. Ces patients avaient subi ces traumatismes principalement suite à des accidents d'automobiles, des chutes ou des agressions[134]. La moitié des décès survenaient dans les trois premiers jours de l'admission aux soins intensifs, majoritairement suite à la cessation des soins de maintien de la vie[135]. Les motifs de cessation des soins étaient de faibles chances de survie, un pronostic incompatible avec les souhaits du patient et un pronostic neurologique faible à long terme[136]. Une grande variabilité dans les taux de mortalité a été constatée, ce qui est très significatif puisque ces patients sont souvent jeunes et présentent peu de comorbidité. De plus, les décisions de cesser les traitements sont principalement basées sur le pronostic et sont prises quelques jours après l'admission, ce qui est inquiétant puisqu'il peut être trop tôt pour un pronostic neurologique exact[137]. La difficulté de prévoir les possibilités de réhabilitation du patient milite plutôt en faveur de la prudence et d'une période d'évaluation du patient prolongée.

Quoi qu'il en soit, la crainte de poursuite peut être une préoccupation des professionnels de la santé et des établissements de santé. En 1997, dans la cause ontarienne *London Health Sciences Centre*, un médecin et l'établissement demandaient à la cour de se prononcer sur une immunité de poursuite pour l'équipe soignante advenant la cessation de traitement ou l'absence de tentative de réanimation[138]. La femme du patient en l'espèce, un homme de 83 ans en état végétatif persistant, refusait initialement de consentir à la cessation de traitements de maintien de la vie. Bien qu'elle ait consenti après l'institution des procédures, les demandeurs craignaient un retrait du consentement ou une poursuite. Le juge a confirmé que la cessation de traitement était dans le meilleur intérêt du patient, mais a refusé de

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133 Alexis F Turgeon et al, « Mortality Associated with Withdrawal of Life-Sustaining Therapy for Patients with Severe Traumatic Brain Injury: A Canadian Multicentre Cohort Study » (2011) 183 : 14 CMAJ 1581.

134 *Ibid* à la p 1583.

135 *Ibid* à la p 1584.

136 *Ibid* à la p 1585.

137 *Ibid* aux pp 1585–87.

138 *London Health Sciences Centre v RK (Guardian ad litem of)*, 152 DLR (4e) 724, 74 ACWS (3e) 1071 (ON CS).

se prononcer sur l'état du droit ou sur une immunité de poursuite, rappelant l'inconfort des tribunaux face à de tels débats :

> *If what is being sought is a declaration that a physician has a legal right in these circumstances to withdraw life support from R.K., I am not at all certain that is a declaration a court should make. Questions such as this, involving as they do complex moral, ethical, religious, and legal issues are best dealt with in a multicultural society by Parliament rather than the courts. They lie essentially within the purview of the legislative branch of government, whose function is to decide upon and enumerate policy, and not within that of the judicial branch*[139].

Par ailleurs, le juge a insinué que la crainte de poursuite était non fondée face à l'absence de tels antécédents au Canada[140].

Qu'arrive-t-il lorsqu'un médecin refuse catégoriquement de fournir les soins exigés ? Puisque le droit actuel ne permet pas au médecin de décider unilatéralement de cesser les soins qu'il juge inappropriés[141], il a l'obligation déontologique d'assurer le suivi médical requis par l'état de son patient jusqu'à la prise en charge de celui-ci par un confrère[142]. Si le patient bénéficie d'un droit au refus de traitement, la liberté du professionnel est plus restreinte[143].

Face à un patient à l'inconscience irréversible, un médecin peut donc juger que la poursuite des soins est inappropriée au regard du meilleur intérêt du patient. Il peut aussi juger qu'ils sont futiles parce qu'inefficaces phy-

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139 *Ibid* au para 17.

140 *Ibid* au para 21.

141 Suzanne Philips-Nootens, « La personne en fin de vie : le regard du droit civil du Québec » (2009–2010) 40 : 1–2 RDUS 327 aux pp 355–56 [Philips-Nootens, « La personne en fin de vie »].

142 *Code de déontologie des médecins*, *supra* note 70, art 19, al 1, art 32–33 ; Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 39. Il est à noter que le droit au refus de traitement est limité et permet certains cas d'atteinte à l'intégrité non consentie, notamment par des considérations de santé publique en ce qui a trait aux maladies contagieuses à traitement obligatoire (voir *ibid* aux para 212 et s).

143 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 40.

siologiquement ou parce que la qualité de vie du patient est déjà trop compromise. La famille du patient peut être en désaccord avec les conclusions du médecin et exiger que les traitements se poursuivent, ce qui mène à des conflits éthiques où les fondements des demandes méritent d'être étudiés.

II. L'exigence par les proches de la poursuite des traitements

A. Les fondements juridiques

1. Le droit aux soins de santé et l'applicabilité de la *Charte canadienne*

La perspective médicale ayant été abordée, il convient maintenant de s'attarder à la position de ceux qui désirent que se poursuivent les traitements de maintien de la vie. Au chevet d'un patient inconscient chez qui les médecins n'entrevoient plus d'espoir de réhabilitation, les discussions entourant le niveau de soins à offrir peuvent sembler relever d'un cadre purement privé. Parfois, la difficulté à faire le deuil du patient peut à elle seule expliquer le refus par les proches de cesser les traitements.

Or, pour exiger le respect de leur volonté, certains proches n'hésitent pas à faire appel aux droits fondamentaux protégés par les chartes. Ceci entraîne une judiciarisation de différends et transporte dans la sphère publique des conflits soulevant des questions éthiques.

Avant d'aborder la possibilité d'invoquer certains droits, la question de l'application des chartes canadienne et québécoise doit nécessairement être soulevée[144]. Ces chartes protègent entre autres le droit à la vie, à la liberté et à la sécurité de la personne[145] et le droit à la liberté de religion[146]. Traditionnellement, les chartes protègent contre l'action étatique. Or, une famille qui souhaite la réanimation d'un proche advenant un arrêt cardiorespiratoire

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144 *Charte canadienne des droits et libertés*, partie I de la *Loi constitutionnelle de 1982*, constituant l'annexe B de la *Loi de 1982 sur le Canada* (R-U), 1982, c 11 [*Charte canadienne*] ; *Charte des droits et libertés de la personne*, RLRQ c C-12 [*Charte québécoise*].

145 *Charte canadienne*, *supra* note 144, art 7 ; *Charte québécoise*, *supra* note 144, art 1.

146 *Charte canadienne*, *supra* note 144, art 2(a) ; *Charte québécoise*, *supra* note 144, art 3.

réclame une protection qui se traduit par la prestation d'un service médical. De la même manière, réclamer la poursuite de soins de maintien de la vie exige des gestes médicaux quotidiens par une équipe multidisciplinaire. En l'espèce, nous cherchons à savoir quel impact le respect des droits protégés par les chartes aura sur la décision d'un médecin confronté à une situation qu'il estime être inappropriée. Le médecin, en refusant de fournir les soins de maintien de la vie ou de tenter de réanimer un patient, porte-t-il atteinte au droit à la vie ? Le droit à la vie pourrait-il faire en sorte que le médecin soit tenu de fournir certains soins ?

S'il ne fait aucun doute que la *Charte québécoise* s'applique aux situations problématiques faisant l'objet de cette analyse, puisqu'elle s'applique autant dans les rapports privés que dans les rapports publics, l'application de la *Charte canadienne* demeure quant à elle incertaine[147]. Les droits protégés y étant néanmoins similaires, nous en ferons une analyse commune, sous réserve de cette incertitude quant à son applicabilité. Cette incertitude repose sur la complexité des liens légaux existant entre les acteurs, soit entre l'établissement de santé, le médecin portant un jugement clinique quant au niveau de soin à offrir et le patient.

Au Québec, le droit général d'accès aux soins est consacré dans la *Loi sur les services de santé et les services sociaux* (ci-après *LSSSS*)[148] : « Toute personne a le droit de recevoir des services de santé et des services sociaux adéquats sur les plans à la fois scientifique, humain et social, avec continuité et de façon personnalisée et sécuritaire »[149]. Ce droit est loin d'être un droit absolu, notamment en vertu d'une clause de la *LSSSS* qui en restreint l'exercice :

> 13. Le droit aux services de santé et aux services sociaux et le droit de choisir le professionnel et l'établissement prévus aux articles 5 et 6, s'exercent en tenant compte des dispositions législatives et réglementaires relatives à l'organisation et au fonctionnement de l'établissement ainsi que des ressources humaines, matérielles et financières dont il dispose[150].

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147 Rutland, *supra* note 9 aux pp 96–100.

148 *Loi sur les services de santé et les services sociaux*, RLRQ c S-4.2 [*LSSSS*].

149 *Ibid*, art 5.

150 *Ibid*, art 13.

Pour ces motifs, les balises limitant l'accès aux soins de santé sont multiples. Elles se retrouvent au plan législatif, mais également au sein des établissements[151].

En principe, les hôpitaux sont des entreprises de services publics auxquels la *Charte canadienne* ne s'applique pas. Or, depuis l'arrêt *Eldridge* de la Cour suprême, les hôpitaux sont assujettis à la *Charte canadienne* dans leur application de lois ou de politiques gouvernementales[152]. Dans cette cause, des personnes sourdes contestaient la décision des hôpitaux de ne pas défrayer les coûts d'interprètes pour les personnes atteintes de surdité lors de consultations médicales. Le but de la *Hospital Insurance Act* de la Colombie-Britannique était de fournir gratuitement des services de santé à la population[153]. En fournissant les services de santé nécessaires, l'hôpital remplissait un objectif gouvernemental déterminé, il était le mécanisme choisi par le législateur pour l'exécution de son programme et il devait le faire dans le respect de la *Charte*.

Au sein des établissements, les médecins sont des travailleurs indépendants qui y exercent leur profession, mais sans en être les préposés[154]. Ils exercent de manière autonome leur profession et l'absence d'un lien de subordination avec l'établissement de santé où ils exercent leur profession est importante. Néanmoins, les établissements peuvent être poursuivis pour un manquement à l'obligation de fournir des soins de santé adéquats, et ils peuvent poursuivre les médecins en retour[155].

La *LSSSS*, conjuguée aux codes déontologiques des professionnels de la santé, structure les rapports dans lesquels se déroule la prestation de soins. Or, il faut distinguer l'accès aux services de santé de la prestation de soins spécifiques offerte par un professionnel. Ainsi, la possibilité de consulter un médecin relève de l'accès aux services de santé, mais celui-ci n'a pas d'obligation de fournir des soins spécifiques en vertu de la *LSSSS*.

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151 Voir Catherine Régis et Anne-Marie Savard, « L'accès aux soins et aux médicaments au Québec ; entre l'idéal et la réalité » (2009–2010) 40 : 1–2 RDUS 269.

152 *Eldridge c Colombie-Britannique (PG)*, [1997] 3 RCS 624, 151 DLR (4e) 577.

153 *Ibid* aux pp 663–64.

154 *LSSSS*, *supra* note 148, art 236.

155 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 46. Cependant, la Cour d'appel s'est déjà prononcée à l'effet contraire dans *Hôpital de l'Enfant-Jésus c Camden-Bourgault*, [2001] RJQ 832, JE 2001-835 (CA).

Se pose alors la question de la portée de ce droit aux soins. Une première piste se trouve dans l'arrêt *Chaoulli* de la Cour suprême du Canada, où un usager (George Zeliotis, le deuxième appelant) contestait l'interdiction de souscrire une assurance privée pour des soins de santé offerts par le système public et invoquait une violation du droit à la vie dans le cadre de ses difficultés d'accès[156]. À cet égard, cet arrêt nous offre un aperçu de l'impact qu'une décision judiciaire fondée sur ce droit peut apporter. La Cour suprême a déterminé que les listes d'attente pour certaines chirurgies portaient atteinte au droit à la vie des usagers, car l'attente risquait d'aggraver leur condition et augmentait leur risque de mortalité. Suite à ce jugement, le gouvernement a dû apporter des modifications à ses politiques afin de respecter ce droit fondamental.

Pour prétendre qu'un médecin, à titre individuel, est mandataire du gouvernement, ce qui pourrait impliquer un assujettissement aux chartes, il faut considérer que de par sa prise de décision quant à la prestation des soins, il détient le pouvoir d'en contrôler l'accessibilité[157]. S'il ne fait aucun doute que les questions d'accessibilité aux soins relèvent des chartes depuis l'arrêt *Chaoulli*[158], il demeure prématuré de faire du médecin un agent du gouvernement par sa seule prestation de soins au sein d'un établissement.

C'est donc à juste titre que le qualificatif de « *gatekeepers* » est parfois attribué aux médecins, car ils contrôlent en quelque sorte la véritable accessibilité aux soins. Or, l'application de la *Charte canadienne* à la prestation de soins dans le cadre d'une relation médecin–patient reste à être confirmée.

2. Les droits fondamentaux devant les tribunaux

Peu de causes judiciaires traitant d'une opposition à la cessation de traitements de maintien de la vie ont soulevé des droits protégés par les chartes, mais nous avons le bénéfice des affaires récentes *Golubchuk* et *Rasouli*[159].

Dans l'affaire *Golubchuk*, la famille du patient a demandé à la cour une injonction interlocutoire ordonnant aux médecins et à l'hôpital de ne pas

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156 *Chaoulli c Québec (PG)*, 2005 CSC 35, [2005] 1 RCS 791 [*Chaoulli*].

157 Rutland, *supra* note 9 à la p 98.

158 *Chaoulli*, *supra* note 156 au para 104.

159 *Golubchuk*, *supra* note 115 ; *Rasouli*, *supra* note 4.

cesser les soins de maintien de la vie[160]. La famille invoquait des croyances religieuses, sans mentionner explicitement la *Charte canadienne*, mais les médecins soutenaient qu'elle ne s'appliquait pas. Sur ce point, la cour s'est contentée de mentionner que la question de l'applicabilité n'était pas résolue[161].

Dans la cause *Rasouli*, la femme de M. Rasouli sollicitait une injonction pour empêcher les médecins et l'hôpital de cesser les soins de maintien de la vie[162]. Devant la Cour supérieure de l'Ontario, elle invoquait la liberté de conscience et de religion et les droits à la vie, à la liberté et à la sécurité, mais, encore une fois, les médecins soutenaient que la *Charte* ne s'appliquait pas[163]. Le juge Himel a indiqué qu'il n'était pas convaincu que la *Charte canadienne* s'appliquait à la décision des médecins, puisque ceux-ci sont des travailleurs indépendants :

> *A doctor's status as an independent contractor owing an individual duty of care to a patient is such that the doctor may not be considered a government agent in the same manner as a hospital as determined in* Eldridge. *Furthermore, the fact that hospitals cannot be held vicariously liable for the actions of doctors puts into question the argument that doctors' decisions are subject to the* Charter *because they are being made on behalf of the hospital. The current common law relationship between hospitals and doctors, as well as between doctors and patients, provides a basis for the assertion that the decisions of doctors are not subject to the* Charter *in the same manner as those of hospitals*[164].

Le lien entre l'hôpital et la politique gouvernementale en matière de santé est en ce sens difficilement transférable au médecin lui-même dans sa pratique quotidienne. En Cour d'appel et en Cour suprême, la question de l'applicabilité de la *Charte* n'a pas été abordée[165].

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160 *Golubchuk*, *supra* note 115 au para 1.

161 *Ibid* au para 25.

162 *Rasouli*, *supra* note 4 au para 9.

163 *Rasouli v Sunnybrook Health Sciences Centre*, 2011 ONSC 1500, 105 OR (3e) 761 [*Rasouli* ONSC].

164 *Ibid* au para 90.

165 Voir *Rasouli v Sunnybrook Health Sciences Centre*, 2011 ONCA 482 au para 36, 107 OR (3e) 9 [*Rasouli* ONCA] ; *Rasouli*, *supra* note 4 au para 4.

Tout compte fait, la jurisprudence actuelle indique qu'il est peu probable que le jugement clinique du médecin puisse être assujetti à la *Charte canadienne*[166]. Le raisonnement soutenu par le juge de première instance dans l'affaire *Rasouli* serait alors exact[167]. Le talon d'Achille de l'argumentaire en faveur de l'application de la *Charte* à la décision du médecin réside donc dans son indépendance et dans l'absence de lien de préposition avec l'hôpital.

Bien que quelques causes judiciaires offrent un aperçu des droits invoqués qui sont protégés par les chartes, certaines s'en remettent plutôt à la common law. Les juges y reconnaissent que le droit pour les médecins de décider unilatéralement de la cessation ou de l'abstention de soins est loin d'être avéré[168]. Néanmoins, les droits fondamentaux demeurent une base légale qui devra faire l'objet d'une analyse par les tribunaux. Partant de ce fait, il est pertinent d'étudier les droits fondamentaux les plus susceptibles d'être invoqués.

Pour ce faire, nous analyserons d'abord l'article 7 de la *Charte canadienne*, qui énonce trois droits distincts[169] : le droit à la vie, le droit à la liberté et le droit à la sécurité de la personne[170]. Ces droits ont fait l'objet d'une analyse récente dans l'arrêt *Carter* portant sur l'interdiction de l'aide médicale à mourir :

> [L]e droit à la vie entre en jeu lorsqu'une mesure ou une loi prise par l'État a directement ou indirectement pour effet d'imposer la mort à une personne ou de l'exposer à un risque accru de mort. Par contre, on a traditionnellement considéré que les préoccupations relatives à l'autonomie et à la qualité de vie étaient des droits à la liberté et à la sécurité[171].

De manière similaire, la *Charte québécoise* protège le droit à la vie, à la sûreté et à la liberté de sa personne[172]. L'effet de la cessation de tous les soins

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166 Voir aussi Rutland, *supra* note 9 aux pp 96 et s.

167 *Rasouli* ONSC, *supra* note 163.

168 Rutland, *supra* note 9 à la p 95.

169 *Rodriguez*, *supra* note 1 aux pp 583–89 (juge Sopinka).

170 *Charte canadienne*, *supra* note 144, art 7.

171 *Carter*, *supra* note 1 au para 62.

172 *Charte québécoise*, *supra* note 144, art 1.

de maintien de la vie ou de l'abstention de manœuvres de réanimation étant inévitablement la mort, le droit à la vie est le premier droit invoqué.

Une présomption en faveur de la vie (*in dubio pro vita*) existe en droit canadien[173]. En 1982, la Commission de réforme du droit du Canada avait affirmé :

> La Commission est d'avis que toute réforme portant sur la vie humaine doit au départ fermement admettre une présomption en faveur de celle-ci. Autrement dit, on ne doit jamais présumer qu'un patient en phase terminale entend renoncer à la vie à moins d'une expression claire, libre et informée de volonté contraire. Cette règle nous paraît d'une grande importance. En effet, il est parfois impossible de savoir si une personne désire ne pas continuer à vivre ou souhaite au contraire que l'on utilise à son égard tous les moyens pour prolonger une vie déjà sérieusement compromise. Il en est ainsi de ceux qui sont privés de la faculté d'exercer ce pouvoir décisionnel (par exemple le patient comateux). Dans tous ces cas, la seule politique d'orientation législative valable est de présumer ce que dicte le sens commun c'est-à-dire que chaque être humain préfère la vie à la mort.
>
> Il ne faut pas cependant, et c'est là où le problème devient difficile, que cette présomption en faveur de la vie ne serve de base à toute la pratique médicale. Il serait désastreux, par exemple, que cette présomption ait pour effet d'obliger le médecin à pratiquer l'acharnement thérapeutique dans les cas où le patient est incapable de manifester sa volonté[174].

La Cour suprême concède des nuances au droit à la vie :

> Le caractère sacré de la vie est une des valeurs les plus fondamentales de notre société. L'article 7 émane d'un profond respect pour la valeur de la vie humaine, mais il englobe aussi la vie, la liberté et la sécurité de la personne durant le passage

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173 Commission de réforme du droit du Canada, « Euthanasie, aide au suicide et interruption de traitement » (1982) Ministre des Approvisionnements et Services Canada, Document de travail 28 à la p 41 [Commission de réforme du droit du Canada]; voir aussi art 13 CcQ ; *Charte québécoise*, *supra* note 144, art 2, al 2 ; *Rasouli*, *supra* note 4 au para 21.

174 Commission de réforme du droit du Canada, *supra* note 173 à la p 41.

> à la mort. C'est pourquoi le caractère sacré de la vie « n'exige pas que toute vie humaine soit préservée à tout prix »[175].

L'absolutisme du droit à la vie n'est pas prôné. Dans l'arrêt *Rasouli* de la Cour suprême, la dissidence avait souligné la pertinence de cette approche, en rappelant que la dignité est une exception au principe du caractère sacré et que le fait de prolonger artificiellement la vie d'un patient n'est pas toujours dans son intérêt[176].

S'ajoutant au droit à la vie, le droit à la liberté prévoit que l'État ne s'immisce pas dans la sphère privée de l'individu. Cette liberté fait référence aux « décisions personnelles fondamentales »[177], tel que l'affirme la juge Wilson, comme le choix de mettre fin à une grossesse par exemple[178]. Le droit à la sécurité vise à la fois la sécurité physique et psychologique[179]. Tout comme le droit à la liberté, il implique un contrôle sur certaines décisions, telle la terminaison d'une grossesse[180]. C'est donc un droit qui comprend l'autonomie personnelle[181], notamment lorsqu'il est question de traitements médicaux. À la base de ces droits à la liberté et à la sécurité se trouve « [l]e souci de protéger l'autonomie et la dignité de la personne »[182].

Si tant est que la *Charte canadienne* s'applique, les droits à la vie, à la sécurité et à la liberté sont à l'évidence atteints par le refus de poursuivre les soins de maintien de la vie lorsque le patient ou les proches n'y consentent pas. Cependant, pour qu'il y ait une violation de l'article 7 de la *Charte canadienne*, la Cour doit également conclure en la non-conformité de cette atteinte avec les principes de justice fondamentale, une question bien plus

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175 *Carter*, *supra* note 1 au para 63, citant Rodriguez, *supra* note 1 à la p 595, juge Sopinka.

176 *Rasouli*, *supra* note 4 au para 197 ; voir aussi *Rodriguez*, *supra* note 1 aux pp 595–96.

177 *R c Morgentaler*, [1988] 1 RCS 30 à la p 166, 63 OR (2e) 281 [*Morgentaler*].

178 *Blencoe c Colombie-Britannique (Human Rights Commission)*, 2000 CSC 44 au para 86, [2000] 2 RCS 307.

179 *Carter*, *supra* note 1 au para 64.

180 *Morgentaler*, *supra* note 177.

181 *Rodriguez*, *supra* note 1 aux pp 587–88.

182 *Carter*, *supra* note 1 au para 64.

controversée. Les principes de justice fondamentale ne seront pas respectés si la règle est arbitraire ou si elle a une portée excessive ou un caractère totalement disproportionné[183]. En ce sens, Glen Rutland souligne que la décision du corps médical pourrait être considérée arbitraire puisqu'elle repose sur une décision unilatérale, sans le consentement de la personne dont le droit à la vie est en cause[184]. Par contre, un mécanisme de révision de la décision ou de résolution des différends pourrait suffire pour conclure à un respect des principes de justice fondamentale[185].

Finalement, advenant une violation d'un droit protégé par la *Charte canadienne*, il faudra examiner si la disposition est sauvegardée par l'article premier, c'est-à-dire si les droits peuvent être restreints par des limites raisonnables et dont la justification puisse se démontrer dans le cadre d'une société libre et démocratique[186]. Sous la *Charte québécoise*, l'article 9.1 propose un exercice similaire[187].

Au cœur des revendications de traitements, l'on retrouve également le droit à la dignité. Ce droit est protégé par la *Charte québécoise*[188] et, sans être explicite dans la *Charte canadienne*, la dignité y a néanmoins un statut particulier. L'arrêt *Rodriguez* rappelle que son respect « est l'un des principes fondamentaux de notre société »[189]. Dans l'arrêt *St-Ferdinand*, le syndicat fautif a prétendu que la négligence d'offrir des soins d'hygiène à des bénéficiaires déficients mentaux n'était pas une atteinte à leur dignité, car ils n'avaient pas de sentiment de pudeur[190]. Or, la Cour suprême a précisé que l'article 4 de la *Charte québécoise* « vise les atteintes aux attributs fondamentaux de l'être humain qui contreviennent au respect auquel toute personne a droit du seul fait qu'elle est un être humain et au respect qu'elle

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183 *Ibid* au para 81.

184 Rutland, *supra* note 9 à la p 105.

185 *Ibid* à la p 106. Cet aspect est abordé dans la partie III.B du présent texte.

186 Cette ultime étape de l'analyse n'est pas détaillée dans le présent texte en raison de la réserve que l'auteure doit s'imposer à cet égard.

187 *Ford c Québec (PG)*, [1988] 2 RCS 712 aux pp 768–71, 54 DLR (4e) 577.

188 *Charte québécoise*, *supra* note 144, préambule, art 4.

189 *Rodriguez*, *supra* note 1 à la p 592.

190 *Québec (Curateur public) c Syndicat national des employés de l'hôpital St-Ferdinand*, [1996] 3 RCS 211 à la p 224, 138 DLR (4e) 577.

se doit à elle-même »[191]. Ainsi, tout être humain est digne et doit être traité avec respect, peu importe son niveau de conscience. La dignité « survit à la disparition de la possibilité d'exercer cette liberté, elle survit la disparition de la conscience de soi, de la capacité de relation »[192].

Cette approche de la dignité par la Cour suprême se réfère à la première des deux conceptions de la dignité, telles que décrites par Éric Folot :

> La première [conception] soutient que la dignité humaine est universelle, absolue, collective et objective. La simple appartenance à l'espèce humaine confère à l'être humain sa dignité. Transcendante, elle justifie des limites légitimes à la liberté individuelle (« human dignity as constraint »). Il s'agit d'un appel à notre commune humanité […].
>
> La deuxième conception soutient que la dignité humaine est relative, individuelle et subjective. Elle ne justifie pas l'imposition de limites à la liberté individuelle, car il appartient à l'individu d'en définir lui-même le contenu et de juger de son respect (« human dignity as empowerment »)[193].

Au Québec, le *Code de déontologie des médecins* impose à ces professionnels le devoir « d'exercer [leur] profession dans le respect de la vie, de la dignité et de la liberté de la personne »[194], mais également « d'agir de telle sorte que le décès d'un patient qui [leur] paraît inévitable survienne dans la dignité. Il[s] doi[ven]t assurer à ce patient le soutien et le soulagement appropriés »[195]. Le Québec a aussi intégré le respect de la dignité dans ses lignes directrices visant à guider la prestation des services de santé[196].

Néanmoins, le droit à la dignité peut également militer en faveur de la cessation ou de l'arrêt de soins. Dans la cause *Rasouli*, les médecins soutenaient que la poursuite des soins entraînerait une mort lente suite à des com-

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191 *Ibid* à la p 256.

192 Philips-Nootens, « La personne en fin de vie », *supra* note 141 aux pp 361–62.

193 Folot, *supra* note 6 aux pp 31–33 [notes omises].

194 *Code de déontologie des médecins*, *supra* note 70, art 4.

195 *Ibid*, art 58.

196 *LSSSS*, *supra* note 148, art 3(3).

plications liées à l'alitement du patient, ce à quoi ils s'opposaient[197]. Selon Jocelyn Downie, la cessation ou l'abstention de traitement décidée unilatéralement par le médecin viole le droit de prendre des décisions personnelles d'importance fondamentale. Cette capacité est incluse dans le droit à l'autonomie, mais est également sous-jacente au concept de dignité[198].

Si tous s'entendent sur l'importance de la dignité, l'intégration de cette notion dans la recherche du meilleur intérêt du patient peut être problématique. La réalité des traitements de maintien de la vie fait ainsi ressortir les différentes perceptions du concept de dignité. Tout compte fait, l'utilisation du droit à la dignité de part et d'autre du débat portant sur les exigences de traitements rend le succès d'un tel argument imprévisible.

B. La détermination du meilleur intérêt du patient inconscient

1. L'autonomie exprimée par les directives anticipées

Conjuguée au droit à l'inviolabilité, l'autonomie est à la base du droit de consentir à un traitement ou de le refuser[199]. Également un principe éthique, l'autonomie permet à l'individu de décider pour lui-même. Le droit au refus de traitement est bien reconnu, notamment à la lumière de décisions judiciaires telles que *Nancy B* et *Manoir de la Pointe bleue*[200].

La Cour suprême du Canada, dans l'arrêt *Starson c Swayze*, a aussi reconnu que le droit de refus est fondamental pour la dignité et l'autonomie d'une personne[201]. Philips-Nootens rappelle que l'expression de cette autonomie par le patient doit être respectée, peu importe la décision qui en résulte :

> Un patient possédant la pleine capacité d'exercice de ses droits (c'est-à-dire toute personne majeure ou mineure plei-

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197 *Rasouli* ONSC, *supra* note 163 au para 3.

198 Jocelyn Downie, « Unilateral Withholding and Withdrawing of Potentially Life-Sustaining Treatment: A Violation of Dignity under the Law in Canada » (2004) 20 : 3 J Palliat Care 143.

199 Art 10 CcQ ; *LSSSS*, *supra* note 148, art 9.

200 *Nancy B*, *supra* note 12 ; *Manoir de la Pointe bleue*, *supra* note 11 ; Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 219, n 250.

201 2003 CSC 32 au para 75, [2003] 1 RCS 722.

> nement émancipée) et apte (l'aptitude est présumée) à donner un consentement valide doit voir sa volonté respectée, qu'il accepte ou refuse les soins proposés, et ce, même si sa décision peut sembler déraisonnable aux yeux des tiers. Il est le seul juge des motifs qui l'animent, en fonction des valeurs qui lui sont propres, de la façon dont il voit sa qualité de vie et apprécie les bienfaits et les risques des traitements proposés[202].

Pour que le médecin prenne en considération l'autonomie décisionnelle du patient quant à ses soins, ce dernier doit communiquer ses volontés. Dans un contexte idéal, le patient communique directement avec son médecin, mais advenant son incapacité, comment le médecin peut-il être informé de ses volontés ? Il va de soi qu'un patient inconscient est inapte à consentir, mais celui-ci peut avoir préalablement rédigé ses volontés dans un mandat en prévision de l'inaptitude[203] ou dans des directives anticipées[204]. Outre l'article 12 du *Code civil du Québec*[205] qui édicte le principe du respect des volontés exprimées, la nouvelle *Loi concernant les soins de fin de vie* encadre et formalise les directives médicales anticipées[206]. En cas d'inaptitude, celles-ci auront la même valeur que des volontés exprimées par une personne apte à consentir aux soins[207]. Par ailleurs, ce sont ces directives qui prévaudront en cas de conflit entre ces volontés et celles qui auraient été exprimées dans un mandat donné en prévision de l'inaptitude[208].

Les directives anticipées émanent de la conjoncture du développement des soins de maintien de la vie et de l'autonomie grandissante du patient dans la relation médecin–patient[209]. Une crainte de perte de contrôle sur

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202 Philips-Nootens, « La personne en fin de vie », *supra* note 141 à la p 331.

203 Art 2166 et s CcQ.

204 Kouri et Philips-Nootens, *supra* note 7 aux para 382 et s ; Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 240.

205 Art 12 CcQ : « Celui qui consent à des soins pour autrui ou qui les refuse est tenu d'agir dans le seul intérêt de cette personne en tenant compte, dans la mesure du possible, des volontés que cette dernière a pu manifester […]. »

206 *Supra* note 2, art 51 et s.

207 *Ibid*, art 58 et s.

208 *Ibid*, art 62, al 2.

209 Emily Clough, « A Critique of Advance Directives and Advance Directives

sa fin de vie a conduit au désir d'indiquer ses volontés en prévision de circonstances qui mèneraient à une perte de capacité de le faire. Traditionnellement, cet instrument cherche à limiter les interventions médicales, par exemple en exprimant la volonté de ne pas être réanimé advenant un arrêt cardiorespiratoire. Le refus de soins qui y est inscrit est aujourd'hui largement accepté et respecté dans le cadre juridique.

Dans le cas des demandes de maintien de traitement, on retrouve la situation opposée au refus de traitement, où le patient ou un proche exige certains traitements auxquels le médecin refuse de procéder. Cependant, l'on ne semble guère avoir prévu que de telles directives anticipées puissent exiger des soins. L'autonomie dans ce cas déborde de la sphère personnelle de l'individu et implique la participation active d'une autre personne. Pour cette raison, l'exigence de traitement impose une réserve au respect absolu de l'autonomie du patient et de ses volontés[210].

Néanmoins, la simple existence de directives peut s'avérer insuffisante pour clarifier efficacement la prise de décision à l'égard d'un patient inconscient. En effet, le vocabulaire employé peut être considéré vague, notamment par l'emploi des termes « extraordinaires » ou « agressifs »[211]. À cet effet, la neuroimagerie pourrait être utile pour clarifier les directives de fin de vie en permettant de préciser les traitements à offrir en fonction des différents états, ou même en exigeant certains tests[212].

Dans les demandes de traitements, le médecin prend certainement en considération les volontés du patient et de ses proches dans le cadre de la relation thérapeutique. L'enjeu est plutôt de savoir s'il a une obligation légale de s'y conformer. Pope rappelle que l'autonomie est à la base un droit négatif : « *It has almost never been formally construed to give patients a positive right to demand nonindicated treatmen*t »[213].

Legislation » (2006) 11 Appeal 16 aux pp 18, 20–21.

210 Philips-Nootens, « La personne en fin de vie », *supra* note 141 à la p 342.

211 Lara Khoury, « La responsabilité médicale et hospitalière pour le non-respect des volontés de fin de vie en droit civil québécois » [2007] 85 Médecine & Droit 119 à la p 121.

212 Fisher et Appelbaum, *supra* note 112 aux pp 379–80.

213 Thaddeus Mason Pope, « The Case of Samuel Golubchuk: The Dangers of Judicial Deference and Medical Self-Regulation » (2010) 10 : 3 Am J Bioeth 59 à la p 59 [Pope, « The Case of Samuel Golubchuk »].

Selon Philips-Nootens, Lesage-Jarjoura et Kouri, il est inacceptable qu'un médecin inscrive une ordonnance de non-réanimation sans discussion avec le patient ou ses proches, ou contrairement à des volontés exprimées[214]. En 1998, dans la cause manitobaine *Sawatzky*, une ordonnance de non-réanimation avait été émise sans le consentement du patient atteint de la maladie de Parkinson ou de sa femme[215]. Le juge avait accordé une injonction interlocutoire interdisant d'émettre l'ordonnance de non-réanimation jusqu'au procès, notant qu'il aurait été préférable que le litige soit réglé hors cour[216].

John J Paris est très critique de la tendance vers la primauté de l'autonomie et de la « montée du consumérisme médical » où les patients et leurs proches se croient ultimes décideurs de l'intensité des soins, notamment en fin de vie[217]. En s'éloignant d'un paternalisme médical où le médecin avait le dernier mot, on risque de se retrouver dans la situation inverse, qui n'est guère plus souhaitable.

À cette étape, il est utile de revenir sur un débat qui semblait être caduque, mais qui a été relancé récemment dans le jugement de la Cour d'appel de l'Ontario dans la cause de M. Rasouli[218]. Au plan éthique et légal, il est largement reconnu qu'il n'y a pas de distinction entre la cessation (ou arrêt) et la non-initiation (ou abstention) de traitement[219]. Même si une situation implique une intervention et l'autre l'absence d'intervention, les mêmes règles s'appliquent. Ainsi, l'expression « traitement » ne doit pas seulement référer à des interventions positives, contrairement à ce qui avait été affirmé dans la cause *Lavallee* de la Cour d'appel du Manitoba, en 1997[220]. Dans

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214 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 229.

215 *Sawatzky v Riverview Health Centre Inc* (1998), 167 DLR (4e) 359 aux pp 363–64, [1999] 6 WWR 298 (MBQB) [*Sawatzky*].

216 *Ibid* aux pp 373–75.

217 John J Paris, « Autonomy Does Not Confer Sovereignty on the Patient: A Commentary on the Golubchuk Case » (2010) 10 : 3 Am J Bioeth 54.

218 *Rasouli* ONCA, *supra* note 165.

219 Lesage-Jarjoura, *supra* note 13 aux pp 26–27 ; Commission de réforme du droit du Canada, *supra* note 173 aux pp 65 et s.

220 Gilmour, *supra* note 11 aux pp 410–11 ; *contra Child and Family Services of Central Manitoba v RL (Lavallee)* (1997), 154 DLR (4e) 409 à la p 412, 75 ACWS (3e) 1063 (Man CA) [*Lavallee*].

cette décision, le juge Twaddle avait affirmé que les règles de consentement aux soins, au sens de la loi manitobaine, ne s'appliquaient pas à une décision de non-réanimation contestée par les parents d'un enfant de trois mois en état neurovégétatif, puisque ce n'était pas une intervention positive.

Or, les juges de la Cour d'appel de l'Ontario dans la cause *Rasouli* ont ramené au premier plan ce raisonnement, unique dans la foulée des causes similaires contemporaines. Ils ont ravivé la distinction en évoquant la possibilité que le consentement ne soit pas nécessaire pour la cessation ou l'abstention de traitements médicalement inappropriés, au sens de la *Loi de 1996 sur le consentement aux soins de santé* de l'Ontario[221]. Toutefois, selon la cour, le consentement était nécessaire pour les soins palliatifs dans le cadre d'un plan de traitement qui incluait de manière indissociable la cessation de traitement. Conformément à l'état de la jurisprudence antérieure, cette distinction hypothétique n'a pas été retenue par la majorité de la Cour suprême, qui a jugé que le terme « traitement », au sens de la loi ontarienne, englobait également le retrait de soins de maintien de la vie :

> De plus, le bon sens veut que le législateur n'ait pas souhaité que le retrait d'un traitement de maintien de la vie requière le consentement seulement dans le contexte d'un plan de traitement. La question du consentement serait ainsi à la discrétion exclusive des médecins. Le plan de traitement est simplement un moyen, que peuvent choisir les médecins, de regrouper et de présenter les divers traitements au patient dans le but d'obtenir le consentement. Permettre aux médecins de déterminer unilatéralement si le consentement est nécessaire dans un cas donné va à l'encontre de l'autonomie du patient et de l'objet de la Loi visant à prévoir des règles en matière de consentement qui s'appliquent de façon uniforme dans tous les milieux[222].

De ce fait, la Cour suprême rejette la prétention des médecins à l'effet que le consentement n'est pas nécessaire pour le retrait de traitement de maintien de la vie pour M. Rasouli, notamment parce qu'elle nie la prémisse selon laquelle le retrait de traitement de maintien de la vie serait exclu du terme « traitement »[223].

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221 LO 1996, c 2, annexe A ; *Rasouli* ONCA, *supra* note 165 au para 46.

222 *Rasouli*, *supra* note 4 au para 57.

223 *Ibid* au para 68.

Or, les juges Karakatsanis et Abella, dissidentes, considèrent que le terme « traitement » de la loi n'englobe pas le retrait de traitement et que les règles de common law s'appliquent[224]. Ces règles ne prévoient pas l'obligation pour le médecin d'obtenir le consentement du patient pour le retrait du traitement, puisque le patient n'aurait pas de droit d'exiger son maintien[225]. La dissidence reprend ainsi le raisonnement de la décision *Lavallee*, qui n'avait pas été repris par les tribunaux dans les décisions subséquentes[226].

Sans directives anticipées, le meilleur intérêt du patient inapte est déterminé par consentement substitué, c'est-à-dire par le biais de son représentant légal ou d'un proche[227]. Celui-ci agira en fonction de sa connaissance personnelle du patient, en prenant en considération les valeurs personnelles de ce dernier.

2. Le rôle des valeurs religieuses

Lorsque le patient est incapable d'exprimer ses souhaits face à ses traitements, ce sont ses valeurs personnelles et non celles du proche qui doivent servir de guide dans la détermination de son meilleur intérêt. Face à des décisions de fin de vie, les valeurs religieuses sont au cœur de la plupart des litiges où des traitements sont exigés. Elles sont aussi généralement associées à des soins plus intensifs en fin de vie[228].

Bien que la liberté de religion protégée par les chartes puisse être considérée comme une facette de l'autonomie, nous en traitons séparément afin de faire ressortir les nuances propres aux croyances religieuses. Cette liberté de religion est une liberté fondamentale protégée par la *Charte québécoise* et par la *Charte canadienne*[229] qui

> se définit essentiellement comme le droit de croire ce que l'on veut en matière religieuse, le droit de professer ouvertement

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224 *Ibid* au para 157.

225 *Ibid* au para 168.

226 *Ibid* au para 180.

227 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 aux para 238–49 ; art 12 CcQ.

228 Pope, « The Case of Samuel Golubchuk », *supra* note 213 à la p 60.

229 *Charte québécoise*, *supra* note 144, art 3 ; *Charte canadienne*, *supra* note 144, art 2(a).

> des croyances religieuses sans crainte d'empêchement ou de représailles et le droit de manifester ses croyances religieuses par leur mise en pratique et par le culte ou par leur enseignement et leur propagation[230].

Lorsque des croyances religieuses sont évoquées dans un contexte juridique, le tribunal évaluera la sincérité de la croyance, car « l'État n'est pas en mesure d'agir comme arbitre des dogmes religieux […], les tribunaux ne so[nt] pas qualifiés pour se prononcer sur la validité ou la véracité d'une pratique ou croyance religieuse, ou pour choisir parmi les diverses interprétations d'une croyance »[231]. Dans un arrêt de la Cour suprême, *B(R) c Children's Aid Society of Metropolitan Toronto*, la Cour a précisé que même si la liberté de croyance est vaste, la liberté d'agir selon ses croyances est plus restreinte[232]. Dans le contexte de droits opposés, l'analyse devrait donc se faire sous l'article 1 de la *Charte canadienne*[233].

Le cas récent de M. Golubchuk illustre bien l'impasse résultant de la confrontation entre une opinion médicale et des volontés de fin de vie prescrites par une religion[234]. Dans cette affaire, la famille de M. Golubchuk, un patient juif orthodoxe, s'est opposée avec véhémence à la décision des médecins de cesser les soins de maintien de la vie. Dans l'attente du procès, le juge a cru bon d'accorder l'injonction interlocutoire interdisant aux médecins de cesser les soins.

Une autorité en matière d'éthique dans la religion juive orthodoxe, le rabbin Moshe Feinstein, a établi une distinction entre la non-initiation de traitement, qui serait permise pour un patient en phase terminale, et la cessation de traitement, qui serait à proscrire[235]. Par ailleurs, Alan Jotkowitz

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230 *R c Big M Drug Mart Ltd*, [1985] 1 RCS 295 à la p 336, 18 DLR (4e) 321.

231 *Syndicat Northcrest c Amselem*, 2004 CSC 47 aux para 50–51, [2004] 2 RCS 551.

232 *B(R) c Children's Aid Society of Metropolitan Toronto*, [1995] 1 RCS 315 à la p 435, 122 DLR (4e) 1. L'arrêt portait sur la possibilité de faire une transfusion sanguine chez une enfant, contrairement aux croyances de ses parents Témoins de Jéhovah. La majorité estimait que la loi privait les parents du choix de traitement, violant leur droit à la liberté de religion, mais que la protection de l'enfant justifiait l'intervention de l'État.

233 *Ibid* au para 110.

234 *Golubchuk*, *supra* note 115.

235 Alan B Jotkowitz, Shimon Glick et Ari Z Zivotofsky, « The Case of Samuel

et ses collègues proposent que la conception du caractère sacré de la vie privilégiée par la communauté juive pourrait être reliée au passé de cette communauté et aux abus qui ont eu lieu durant l'Holocauste[236].

Alors que certains auteurs comme Jotkowitz et ses collègues ont critiqué le manque de sensibilité culturelle dont ont fait preuve les médecins de M. Golubchuk[237], d'autres ont plutôt dénoncé l'impact que peut avoir une décision fondée sur la religion :

> Même si la religion et la culture aident à mieux comprendre le contexte de la prise de décision, elles ne doivent pas empiéter sur les droits d'autrui. Il est injuste que la religion joue un rôle dans l'attribution des lits d'hôpital, car cela privilégie les patients religieux par rapport à ceux qui peuvent avoir besoin de soins plus urgents et qui peuvent avoir une meilleure chance de s'en sortir[238].

Dans le même ordre d'idées, le cas de M. Sweiss a l'avantage d'être basé sur les directives anticipées du patient, qui confirme le souhait que la loi islamique soit respectée[239]. Dans cette cause, le patient avait signé des documents indiquant ses volontés quant aux soins de fin de vie. Il y reconnaissait son adhérence à la religion islamique, dont les principes en matière de soins étaient détaillés dans une annexe. Dans son analyse, le juge mentionne le libellé obligatoire de la législation sur les directives anticipées :

> *Given the mandatory wording of s. 19(1) of the Personal Directives Act, it appears that where a personal directive with clear instructions conflicts with recommended medical treatment, the wishes, directions and instructions of the patient will prevail. In my view, this drafting reflects the fact that the Legislature only contemplated that personal directives would state that no extraordinary measures be taken to keep a patient alive. The Legislature does not appear to have antici-*

Golubchuk and the Right to Live » (2010) 10 : 3 Am J Bioeth 50 aux pp 51–52.

236 *Ibid* à la p 52.

237 *Ibid* à la p 51.

238 Amir Attaran, Paul C Hébert et Matthew B Stanbrook, « Finir sa vie dans la grâce et la concorde » (2008) 178 : 9 CMAJ 1117 à la p 1117.

239 *Sweiss*, *supra* note 118 au para 43.

> *pated that some directives would provide for indefinite life support. Thus, as the law currently stands, it appears that if a personal directive directs that all possible measures be taken to keep the patient alive, whether or not he is brain dead or no longer breathing on his own, the direction must be followed despite the fact that life support may be required for an indefinite period of time*[240].

Le juge détermine que le respirateur doit être maintenu, conformément aux directives de M. Sweiss, car il ne lui cause pas de souffrance vu ses dommages cérébraux. Il estime également qu'il n'est pas dans son meilleur intérêt que les médecins tentent de le réanimer. Le juge souligne que l'abstention de réanimation n'est pas contraire aux croyances religieuses du patient[241].

Selon le document produit par le Centre islamique canadien et déposé devant la cour, il est permis de cesser les soins de maintien de la vie dès qu'une personne est cliniquement décédée, soit lorsque l'une des deux situations suivantes survient[242] : d'abord, si le cœur et la respiration du patient ont cessé complètement et que le médecin a décidé qu'ils ne peuvent être remis en fonction; et, autrement, si les fonctions cérébrales sont en arrêt complet, que des médecins et spécialistes expérimentés en affirment l'irréversibilité et que le cerveau a commencé à se désintégrer. Dans ces conditions, l'arrêt de traitement est permis, même si des parties du corps fonctionnent artificiellement à l'aide de machines. Force est de constater que ces deux situations rejoignent les critères reconnus par le droit et qui définissent la mort.

Ainsi, la Charia considère que les humains sont des gardiens de leurs corps et non des propriétaires, et qu'ils ont l'obligation d'en prendre soin. Les musulmans doivent donc déployer tous les efforts pour trouver un remède, la futilité étant un concept étranger à leurs croyances[243]. La Charia interdit la cessation de traitement chez un patient qui respire sans l'aide

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240 *Ibid* au para 48.

241 *Ibid* aux para 66–70.

242 *Ibid* (preuve, interprétation de la loi charia du Centre islamique canadien, reproduite à l'annexe 2 de l'arrêt).

243 Kartina Choong et Mahmood Chandia, « Technology at the End of Life: "Medical Futility" and the Muslim PVS Patient », en ligne : (2013) 9 : 2 Intl Rev L 9 aux pp 9–10 <www.qscience.com/doi/abs/10.5339/irl.2013.9>.

d'un ventilateur. Par contre, si le patient est maintenu en vie artificiellement et que l'irréversibilité de son inconscience est démontrée hors de tout doute raisonnable, la cessation n'est plus interdite[244].

Dans l'affaire *Rasouli*, en première instance, la femme de M. Rasouli avait soulevé qu'il était de religion musulmane et que cette religion prévoyait que la vie devait être préservée jusqu'à ce que tout signe de vie soit disparu[245]. L'hôpital étant un agent de l'État selon ses prétentions, la *Charte canadienne* protégeait le droit à la vie, à la liberté et à la sécurité de même que le droit à la liberté de conscience et de religion de son mari[246]. Malheureusement, cet argument n'a pas été repris en Cour d'appel et en Cour suprême et n'a pu être approfondi.

Les quelques cas judiciarisés abordés illustrent que l'exigence de traitement est souvent ancrée dans des croyances religieuses qui peuvent avoir des dictats très précis pour leurs fidèles[247]. L'acceptation de la cessation de traitement chez les patients en état végétatifs par la communauté médicale est loin d'être partagée par certaines communautés religieuses pour qui la sacralité de la vie est interprétée plus strictement.

Une connaissance de base des principes religieux est certainement utile pour clarifier les fondements des revendications. Les exigences de traitement font appel à des droits fondamentaux protégés par les chartes, mais avant tout aux principes sous-jacents de respect de l'autonomie et de la dignité. Comment alors concilier le désir des proches de poursuivre les soins de maintien de la vie et l'opinion des médecins qui estiment que ceux-ci sont futiles ?

III. Les pistes de solution face aux exigences de traitement

A. Les problèmes associés au pouvoir unilatéral du médecin, du patient ou d'un proche du patient

La relation médecin–patient est « unique et inégale : le médecin détient le monopole des connaissances scientifiques, le malade possède le mono-

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244 *Ibid* aux pp 11–12.

245 *Rasouli* ONSC, *supra* note 163 au para 7.

246 *Ibid* au para 8.

247 Voir aussi en matière de réanimation la cause *Sawatzky*, *supra* note 215 à la p 380, où le patient était Témoin de Jéhovah.

pole des connaissances personnelles ; de l'échange de ces deux connaissances naîtra une entente valable : la décision thérapeutique »[248]. La collaboration est donc de mise, mais lorsque des désaccords surgissent, certains soutiennent que le conflit devrait être résolu en accordant le pouvoir décisionnel à l'un des acteurs de la relation, soit au médecin ou à un proche du patient inconscient.

Parmi les tenants du pouvoir décisionnel unilatéral du médecin, on ne sera pas surpris d'apprendre qu'on retrouve les médecins, qui peuvent considérer qu'une telle décision relève de leurs compétences professionnelles. Cette option ne manque pas de soulever la crainte d'un retour du paternalisme médical :

> *It is also important to recognize that unilateral physician decision-making about questions of futility is a departure from the model of shared decision-making in consent to health care, which assumes that patients and substitute decision-makers are capable of making reasonable choices with good information. That model originated, at least in part, to address the power imbalance that exists between doctors and patients, which remains an ongoing concern*[249].

À l'opposé, on peut estimer que le patient devrait être maître de sa fin de vie et que, par exemple, « *it is not the role of a physician to play God, legislator, or judge. Samuel Golubchuk should have been allowed to live according to his personal values and health care beliefs* »[250]. Or, la possibilité de donner le pouvoir unilatéral au patient ou à un proche de refuser de mettre fin à un traitement heurtera toujours la liberté professionnelle du médecin. Les obligations déontologiques du médecin font en sorte qu'il ne peut être véritablement contraint de prodiguer des soins qu'il considère être contraires à l'intérêt de son patient.

Pour refuser de traiter, les médecins peuvent ultimement invoquer la clause de conscience prévue, au Québec par exemple, au *Code de déontologie des médecins*[251]. Celle-ci prévoit que « [l]e médecin doit informer

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248 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 178.

249 Gilmour, *supra* note 11 aux pp 415–16.

250 Jotkowitz, Glick et Zivotofsky, *supra* note 235 à la p 52.

251 *Code de déontologie des médecins*, *supra* note 70. Voir aussi Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 20.

son patient de ses convictions personnelles qui peuvent l'empêcher de lui recommander ou de lui fournir des services professionnels qui pourraient être appropriés, et l'aviser des conséquences possibles de l'absence de tels services professionnels »[252]. Le médecin a donc un droit de refus, même s'il est dans l'erreur quant à son opinion professionnelle et que les traitements pourraient être appropriés[253]. Cet aspect est important, car on évite alors la nécessité de se prononcer sur la futilité des traitements, le refus devant uniquement être fondé sur une croyance sincère et non arbitraire[254].

Une telle situation pose le problème du transfert de patient, car comme Philips-Nootens, Lesage-Jarjoura et Kouri le soulignent, un médecin qui refuse de fournir ses services parce qu'il juge les soins inappropriés ou en raison de ses convictions personnelles devrait transférer le patient à un collègue[255]. Or, trouver un nouveau médecin n'est pas nécessairement une tâche simple à accomplir et peut se révéler impossible.

Rutland note qu'au Canada, les tribunaux s'en remettent à l'opinion médicale, particulièrement lorsqu'elle est unanimement en faveur de la cessation de soins[256]. Les litiges sont plus susceptibles de porter sur des cas où il y un désaccord entre les opinions médicales[257]. Malgré l'insistance des médecins et des établissements de santé devant les tribunaux, les tribunaux ont à ce jour refusé de leur reconnaître un pouvoir unilatéral décisionnel[258].

Au Manitoba, le Collège des médecins et chirurgiens a offert une solution à cette controverse en élaborant une déclaration qui vise à faciliter la re-

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252 *Code de déontologie des médecins*, *supra* note 70, art 24, al 1. Cette clause de conscience est invoquée pour refuser, notamment, de pratiquer des avortements.

253 John K Davis, « Futility, Conscientious Refusal, and Who Gets to Decide » (2008) 33 : 4 J Med Philos 356 à la p 366.

254 *Ibid*.

255 Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 11 au para 229.

256 Rutland, *supra* note 9 à la p 93.

257 *Ibid* à la p 96.

258 Voir Robert P Kouri, « Le traitement futile et le devoir de soigner en droit québécois : l'impact normatif du désespoir » dans Benoît Moore, dir, *Mélanges Jean-Louis Baudouin*, Cowansville, Yvon Blais, 2012, 59 aux pp 62–64 ; *Rasouli*, *supra* note 4 au para 73.

cherche de consensus lors de conflits impliquant les traitements de maintien de la vie[259]. Cette déclaration est basée sur la prémisse qu'il n'existe pas de droit à demander des soins de maintien de la vie[260]. Le Collège des médecins et chirurgiens définit ainsi le « but minimum de traitement de maintien de la vie » :

> *Minimum Goal of Life-sustaining Treatment*
>
> *This term is clinically defined as the maintenance of or recovery to a level of cerebral function that enables the patient to:*
>
> - *achieve awareness of self; and*
> - *achieve awareness of environment; and*
> - *experience his/her own existence*[261].

En cas d'absence de consensus sur le retrait de traitements de maintien de la vie, si le médecin conclut que le but minimum de traitement de maintien de la vie ne peut réalistement être atteint, il peut retirer les traitements malgré l'absence de consensus, à condition qu'il ait réalisé certaines démarches obligatoires[262]. En l'occurrence, le médecin doit consulter un autre médecin pour obtenir son avis sur la possibilité d'atteindre le but minimum de traitement. Si le médecin consulté estime que le but peut être atteint, le médecin traitant doit offrir le traitement ou faciliter le transfert du patient à un autre médecin. Si le médecin consulté est du même avis, soit que le but minimum ne peut être atteint, le médecin n'a plus l'obligation de tenter d'arriver à un consensus, mais doit aviser la famille de cette consultation et de la date à laquelle il sera mis fin au traitement[263].

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259 College of Physicians and Surgeons of Manitoba, « Withholding and Withdrawing Life-Sustaining Treatment », Statement No 1602, Winnipeg, CPSM, 2007. Depuis le 14 décembre 2015, cette déclaration ainsi que toutes autres déclaration et lignes directrices adoptées par le Collège ont été intégrées dans un nouveau règlement. Voir College of Physicians and Surgeons of Manitoba, Règlement nº 11, *Standards of Practice of Medicine* (14 décembre 2015), annexe D, « Withholding and Withdrawing Life-Sustaining Treatment » à la p 49, en ligne : <cpsm.mb.ca/cjj39alckF30a/wp-content/uploads/ByLaws/By-law%2011.pdf> [College of Physicians and Surgeons of Manitoba, Règlement nº 11].

260 College of Physicians and Surgeons of Manitoba, Règlement nº 11, *supra* note 259 à la p 49.

261 *Ibid* aux pp 49–50.

262 *Ibid* aux pp 55–56.

263 *Ibid*.

Le même processus s'applique aux cas de discussions entourant la possibilité d'une ordonnance de non-réanimation. Cependant, si un arrêt cardiaque survient avant l'émission d'une ordonnance de non-réanimation ou avant que le processus visant un consensus ne soit complété, le médecin n'a pas l'obligation d'initier des manœuvres de réanimation si celles-ci ne permettront pas au patient d'atteindre le but minimum de traitement[264].

Ainsi, le processus mis en place au Manitoba évite le recours aux tribunaux et donne le pouvoir décisionnel au médecin en cas d'impasse, à condition qu'un deuxième médecin soit du même avis professionnel. Malgré les problèmes identifiés[265], l'initiative du Collège des médecins et chirurgiens du Manitoba a l'avantage d'offrir une plus grande transparence en cas de conflit. Elle explicite également les fondements de la cessation de traitement en la rattachant presque exclusivement à un état d'inconscience permanente. De surcroît, elle a l'avantage d'être applicable à tous les médecins, peu importe l'établissement dans lequel ils pratiquent.

Dans l'arrêt *Rasouli*, la Cour suprême invite avec sagesse à la recherche d'une solution pratique comme le transfert du patient plutôt que d'une position éthique absolue :

> Lorsqu'on tente de trancher, les médecins ont forcément à composer avec des conflits éthiques concernant le retrait d'un traitement de maintien de la vie. Aucun principe juridique ne saurait écarter tous les dilemmes éthiques. Il faudrait plutôt trouver une solution pratique permettant aux médecins de se conformer à la loi et de respecter leur éthique professionnelle et personnelle[266].

Par ailleurs, bien que les comités d'éthique clinique puissent jouer un rôle essentiel dans la résolution de conflits, ceux-ci n'ont pas de pouvoir légal contraignant au Canada. Les membres de ces comités multidisciplinaires ont le mandat d'étudier les problématiques éthiques et agissent à titre de conseillers et d'accompagnateurs. Les comités formulent des recomman-

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264 *Ibid* aux pp 58–59.

265 Pour une critique du processus au Manitoba, voir Jocelyn Downie et Karen McEwen, « The Manitoba College of Physicians and Surgeons Position Statement on Withholding and Withdrawal of Life-Sustaining Treatment (2008): Three Problems and a Solution » (2009) 17 Health LJ 115.

266 *Rasouli*, *supra* note 4 au para 75.

dations et peuvent élaborer des lignes directrices[267]. Il ne fait aucun doute que ces comités peuvent constituer un outil important dans la résolution de conflits et ont l'avantage d'utiliser une structure déjà en place dans les établissements[268]. Cependant, nous ne croyons pas que les comités d'éthique devraient avoir un pouvoir décisionnel en soi, en raison de leurs liens trop rapprochés avec les établissements de santé qui créent, à tout le moins, une apparence de partialité.

La possibilité de donner le pouvoir unilatéral au médecin, au patient ou à un proche du patient pose des problèmes éthiques importants. Les solutions proposées de part et d'autres se montrent insatisfaisantes, car elles opposent le respect absolu des valeurs du patient à la liberté professionnelle du médecin. Si le transfert du patient à un autre médecin semble être la meilleure option au plan théorique, la réalité indique plutôt que cette option n'est pas toujours offerte si aucun établissement ne se montre intéressé à prendre en charge la poursuite des traitements de maintien de la vie du patient inconscient.

B. Le rôle des tribunaux en l'absence de clarification législative

Nous avons établi qu'au Canada, le cadre légal ne précise pas que le médecin, le patient ou un proche aurait le pouvoir unilatéral de décider des soins appropriés. Par conséquent, il doit y avoir un accord sur le niveau de soins à offrir. En cas de désaccord, le juge peut être désigné comme ultime décideur. Il sera appelé à trancher les litiges en prenant en considération l'opinion de chaque partie, dans la quête du meilleur intérêt du patient. Il faut se garder de dégager dans les injonctions interlocutoires accordées à ce jour une tendance à appuyer les droits des patients. Au stade de l'injonction interlocutoire, les requérants n'ont qu'à démontrer une apparence de droit. De plus, le critère du risque de préjudice sérieux et irréparable, auquel le jugement final ne pourra remédier, milite évidemment en faveur du statu quo temporaire et de la poursuite des traitements.

Alors que plusieurs espéraient à travers la décision de la Cour suprême dans la cause *Rasouli* une clarification des droits et obligations dans le débat

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267 Bartha Maria Knoppers et Ma'n H Zawati, « De l'éthique et des avocats : les comités d'éthique dans le milieu hospitalier » dans École du Barreau du Québec, dir, *Éthique, profession juridique et société*, *Collection de droit 2011–2012*, vol 13, hors série, Cowansville (Qc), Yvon Blais, 2011, 55 aux pp 57 et s.

268 Voir Rowland, *supra* note 15 aux pp 307–08.

légal et éthique des exigences de traitement, celle-ci ne s'est pas prononcée sur cette question précise. La majorité, sous la plume de la juge en chef McLachlin, a confirmé que le régime en matière de consentement prévu par la loi ontarienne s'appliquait à ce litige[269]. Ce faisant, la Cour suprême a rejeté implicitement l'option d'une décision unilatérale du médecin, tel que proposé par les médecins de M. Rasouli. Le différend aurait donc dû être porté devant la Commission du consentement et de la capacité et non devant les tribunaux de droit commun ontariens.

Les juges de la Cour suprême accueillaient également favorablement le fait que la procédure prévue dans la loi ontarienne faisait reposer le fardeau d'entamer une démarche judiciaire pour obtenir le consentement sur les épaules du médecin, lorsque confronté à un refus de traitement. Vu la vulnérabilité des patients inaptes, la nécessité d'entreprendre des démarches serait problématique si le fardeau était inversé[270]. Cette décision ne fait pas l'unanimité, puisque Hilary Young a soulevé le fait que la Commission du consentement et de la capacité ne serait pas l'organisme approprié pour trancher de tels litiges, en raison de son manque d'expertise[271].

Douglas B White et Thaddeus Mason Pope soutiennent que le recours aux tribunaux, comme ultime étape dans un conflit, doit être préservé en raison de trois avantages potentiels[272]. Le premier a trait à une intensification des négociations qui résulterait du fait qu'aucune partie n'a le pouvoir ultime de décider. Ainsi, face au désir d'éviter la judiciarisation, chacun aurait intérêt à participer activement à la recherche d'une entente. Le deuxième avantage est celui que retire la société par des décisions judiciaires qui redéfinissent les limites de la pratique médicale à travers l'évolution des mœurs. Si certains litiges ne se retrouvaient plus devant les tribunaux, la société serait privée de ces décisions phares qui guident la résolution de problématiques futures. L'avantage final est lié au fait qu'un litige judiciarisé met à l'avant-plan un enjeu social qui mérite un débat public[273].

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269 *Rasouli*, *supra* note 4 aux para 2–3.

270 *Ibid* au para 114.

271 Young, *supra* note 127 aux pp 93–94.

272 Douglas B White et Thaddeus M Pope, « Courts, Futility, and the Ends of Medicine » (2012) 307 : 2 JAMA 151.

273 *Ibid*.

Pour certains, la solution face aux exigences de traitements ne peut reposer sur la décision d'un seul acteur. Une telle décision est lourde de conséquences et peut être un fardeau pour les médecins ou le proche d'un patient incapable de communiquer. Actuellement, les décisions relèvent du cas par cas, ce qui peut être source d'iniquités. Pour ces raisons, un débat de société permet d'assumer une responsabilité collective face à ces situations. La juge Wilson de la Cour suprême exprime avec éloquence qu'« [u]n individu ne constitue pas une entité totalement coupée de la société dans laquelle il vit. Cependant l'individu n'est pas non plus un simple rouage impersonnel d'une machine subordonnant ses valeurs, ses buts et ses aspirations à celles de la collectivité. L'individu est un peu les deux »[274]. L'intérêt collectif est donc aussi un facteur à considérer.

Dans les débats entourant les services de santé, la question de l'allocation des ressources ne peut être ignorée. Il faut alors déterminer comment conjuguer le jugement professionnel du médecin et le meilleur intérêt du patient dans un contexte de ressources limitées. Barney Sneiderman, qui est en faveur de la cessation des soins de maintien de la vie chez les patients en état neurovégétatif, formule la question suivante : « [*D*]*oes it represent a cost-effective application of scarce medical resources to devote so much time and effort with so little result?* »[275]. Au même effet, certains soutiennent que « *some minimal varieties of awareness may not, in practice, be worth the costs of sustaining them* »[276]. La présence ténue de conscience ne sera alors pas considérée suffisante pour valoir l'octroi de ressources hospitalières.

Bien que le médecin soit déontologiquement obligé d'« utiliser judicieusement les ressources consacrées aux soins de santé »[277], les considérations économiques sont susceptibles de miner la relation thérapeutique. Philips-Nootens remet en perspective le rôle de chaque acteur dans la prise de décisions : « [a]ux politiciens et administrateurs de viser le bien du plus grand nombre, au médecin de décider encore et toujours dans le meilleur

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274 *Morgentaler*, *supra* note 177 à la p 164.

275 Barney Sneiderman, « A Do Not Resuscitate Order for an Infant against Parental Wishes: A Comment on the Case of *Child and Family Services of Central Manitoba v. R.L. and S.L.H.* » (1999) 7 Health LJ 205 aux pp 209–10.

276 Zeman, *supra* note 32 à la p 7.

277 *Code de déontologie des médecins*, *supra* note 70, art 12.

intérêt du patient »[278]. Cette position est partagée par Zivot qui soutient que les médecins n'ont à rationner les soins qu'en situations extrêmes comme des catastrophes naturelles ou des pandémies[279].

Sur ce point, nous partageons l'opinion de Robert D Truog quant à la place des questions financières dans les questions de futilité :

> [*D*]*enying futile care to patients and families should have nothing to do with saving money through the fair allocation of scarce resources. If a treatment is futile, it is not worth doing, no matter how much it costs, no matter how little it costs – indeed, futile treatments are not worth doing even if they are free*.
>
> [… *Nonetheless*,] *even if one were to agree that futility judgments should be isolated from financial considerations, in the real world these judgments tend to be applied primarily in situations that are resource-intensive*[280].

La qualification d'un traitement de « futile » serait donc une manière déguisée d'aborder l'enjeu de priorisation et de rationnement des ressources. Cependant, il importe de noter que les coûts reliés aux problématiques réelles de la cessation de traitements de maintien de la vie, bien que potentiellement élevés, ne seraient pas significatifs lorsque considérés par rapport à l'ensemble des dépenses en santé[281].

L'aspect du débat relatif aux ressources se complexifie significativement lorsqu'il est question des coûts associés aux traitements de maintien de la vie. Citons par exemple les assureurs privés qui peuvent avoir leur mot à dire quant aux frais assumés, ajoutant au débat un acteur ayant des intérêts strictement financiers. À ce jour, les législatures des provinces canadiennes ne se sont pas immiscées dans ces conflits. Aux États-Unis, plusieurs États ont des lois confirmant le pouvoir unilatéral du médecin de cesser certains soins si la tentative de transfert vers un autre médecin échoue[282]. Certaines

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278 Suzanne Philips-Nootens, « La relation médecin–patient et les décisions de traitement » (1990) 20 RDUS 377 à la p 392.

279 Zivot, *supra* note 92 à la p 57.

280 Robert D Truog, « Medical Futility – Case: Sun Hudson » (2008–2009) 25 : 4 Ga St U L Rev 985 aux pp 990–91.

281 *Ibid* aux pp 991–94.

282 Pope, « Medical Futility Statutes », *supra* note 85.

de ces lois offrent une définition de ce que constituent des soins « inappropriés » ou clarifient les cas visés, alors que d'autres sont silencieuses à ces égards[283]. Néanmoins, ces lois ont un effet limité, puisque les hôpitaux se montrent réticents à appuyer une décision unilatérale par crainte de poursuite, mais également par difficulté d'application[284]. Pour cette raison, Pope considère que ces lois ne confèrent pas de protection adéquate aux médecins et aux hôpitaux s'ils désirent cesser des traitements sans l'accord du patient ou du proche du patient.

Le *Texas Advance Directives Act* de 1999 fut la première initiative législative américaine à mettre en place un mécanisme de règlement des différends[285]. Advenant un refus d'un médecin d'honorer des directives anticipées du patient ou la demande de soins par un proche du patient, un comité d'éthique clinique doit être consulté. Si l'impasse persiste, une période de 10 jours doit servir à chercher un transfert vers un autre médecin qui acceptera de prodiguer les soins réclamés. La famille du patient peut également demander une prolongation de ce délai à la cour si elle prouve une expectative raisonnable de trouver un médecin ou un établissement qui acceptera le transfert. Si la recherche de transfert échoue, et avec l'accord du comité, le médecin n'est plus obligé de fournir les traitements de maintien de la vie qu'il estime médicalement inappropriés et peut unilatéralement les cesser. Or, suite à des amendements apportés à la loi en 2015, sauf en cas de circonstances particulières prévues dans la loi, le médecin est tenu de maintenir la nutrition et l'hydratation artificielles. Une immunité de poursuite est alors accordée aux professionnels de la santé[286].

L'incertitude entourant le cadre légal des exigences de traitement chez les patients à l'inconscience présumée permanente offre potentiellement un bénéfice insoupçonné : celui du temps. Les délais procéduraux des quelques

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283 *Ibid*.

284 *Ibid* aux pp 66–68, 72 et s.

285 Tex Health & Safety Code tit 2 § 166.046 (2016) [*Texas Advance Directives Act*].

286 *Ibid*. Pour des critiques de cette loi, voir Lisa L Dahm, « Medical Futility and the Texas Medical Futility Statute: A Model to Follow or One to Avoid? » (2007–2008) 20 Health Lawyer 25 ; Nora O'Callaghan, « Dying for Due Process: The Unconstitutional Medical Futility Provision of the Texas Advance Directives Act » (2008) 60 : 2 Baylor L Rev 527 ; Nora O'Callaghan, « When Atlas Shrugs: May the State Wash Its Hands of Those in Need of Life-Sustaining Medical Treatment? » (2008) 18 Health Matrix 291.

litiges au Canada ont permis à la vie de suivre son cours. Si certains patients comme M. Jin ont vu leur état s'améliorer[287], plusieurs ont succombé à leurs maux. Le temps permet aussi à la science de progresser et d'offrir un éclairage toujours plus précis et plus fidèle à la réalité. Il permet avant tout d'établir un diagnostic et un pronostic avec une plus grande précision.

Bien que le débat de société présente plusieurs avantages, il est assujetti à une volonté politique qui fait en sorte qu'un effort législatif n'est pas une solution réaliste à court terme. Qui plus est, la nécessité de légiférer pour clarifier le cadre juridique est loin d'être établie. Les quelques cas qui se sont retrouvés devant les tribunaux canadiens n'incarnent pas un problème d'une ampleur telle qu'une intervention gouvernementale serait absolument requise. Accorder le pouvoir décisionnel à un acteur revient à cristalliser une rupture du dialogue et des négociations qui visent l'atteinte d'un consensus. Si le pouvoir décisionnel est placé entre les mains d'un des acteurs, cela aura inévitablement un impact néfaste sur leur relation et leur collaboration. De plus, cela crée un antagonisme non souhaitable entre les médecins et le proche du patient.

Les efforts devraient plutôt être portés vers une ouverture aux directives anticipées et une amélioration de la communication et de la transparence. Axées sur un processus de résolution de conflits[288], les discussions pourront bénéficier de l'apport des comités d'éthique. Abordant les directives anticipées, Philips-Nootens élabore la réflexion suivante, qui s'applique parfaitement au débat portant sur l'exigence de traitement :

> Il faut, dans un tel domaine, se méfier des solutions de facilité et d'une approche par trop abstraite de la question. L'élément essentiel, la véritable sauvegarde, résidera toujours dans la qualité de la communication entre le médecin et les proches, l'empathie, le profond respect du malade et de toutes les personnes impliquées[289].

L'on ne saurait minimiser l'importance de clarifier les souhaits des patients, notamment avant certaines interventions médicales risquées ou à leur arrivée à l'établissement de santé, avant que leur état ne s'aggrave et qu'ils

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287 Voir le texte correspondant aux notes 122–123.

288 Rowland, *supra* note 15 aux pp 305–10 ; Pope, « Medical Futility Statutes », *supra* note 85 aux pp 79–81.

289 Philips-Nootens, « La personne en fin de vie », *supra* note 141 à la p 352.

ne deviennent inconscients. Ceci simplifie la détermination du meilleur intérêt du patient et assure un meilleur respect de ses volontés. Puisque la cessation des soins de maintien de la vie n'implique pas l'arrêt de tous les soins, la transition vers les soins palliatifs peut alors se faire plus facilement si cette voie est retenue par toutes les parties.

En considérant que dans certaines religions l'abstention de traitement est acceptable alors que la cessation ne l'est pas, tous auraient avantage à discuter des possibilités de traitement le plus tôt possible, alors que toutes les options sont encore envisageables. Une approche préventive pourrait donc éviter des conflits en permettant au proche de prendre des décisions dans le respect des valeurs les plus profondes du patient.

À défaut d'encadrement, le recours ponctuel aux tribunaux en cas de disputes, tel qu'il existe actuellement, semble pleinement justifié par les garanties procédurales qu'il offre. La couverture médiatique de ces litiges est également un outil de sensibilisation de la population aux conflits qui peuvent survenir lorsque confrontée à des décisions de fin de vie et, de ce fait, peut inciter à une communication plus transparente.

Conclusion

À l'échelle du Canada, quelques débats judiciarisés ont révélé des situations médicales dans lesquelles les médecins jugent les traitements de maintien de la vie futiles ou les manœuvres de réanimation inappropriées, alors que les proches de patients inconscients s'opposent ardemment à toute cessation ou abstention de traitement. L'état du droit penche en faveur du fait qu'il n'y aurait pas au Canada de droit à conserver des soins de maintien de la vie, ni d'obligation pour les médecins à offrir ces soins lorsqu'ils les considèrent inappropriés. Comment, alors, concilier ces positions ?

Partant du constat que le caractère irréversible de l'inconscience d'un patient est central au pronostic, mais aussi un facteur crucial dans le consentement ou non par le proche du patient à l'arrêt de traitement, une mise à jour des données scientifiques actuelles s'impose. Or, le diagnostic d'absence de conscience, le pilier des arguments en faveur de l'arrêt de traitement chez les patients en état végétatif, demeure un défi pour la médecine moderne. Les études récentes de neurologie, par le biais de l'imagerie par résonance magnétique fonctionnelle, remettent en question la présomption d'inconscience totale chez certains patients en état végétatif.

Malgré l'engouement créé par ces études, nous nous trouvons devant plus de questions que de réponses. Si l'on considère effectivement que l'expérience du chercheur Owen a démontré qu'un patient en état végétatif peut être conscient et répondre à des questions en modulant ses pensées, comment cette découverte affectera-t-elle les décisions de traitement ? Qu'advient-il de ces patients chez qui on dénote la conscience lors d'une étude, mais qui demeurent confinés à leur mutisme ?

Néanmoins, face à un diagnostic d'inconscience irréversible, l'arrêt de traitement est considéré légitime par la communauté médicale et est éthiquement accepté depuis de nombreuses années. L'incapacité d'interagir est considérée par certains comme une lacune dans les caractéristiques essentielles qui font d'un être humain une personne. La légitimation de la cessation des soins passe alors par la notion de meilleur intérêt du patient, par des considérations de futilité ou de justice distributive. Un autre courant préconise plutôt la redéfinition de la mort pour y inclure les patients en état végétatif.

Le risque d'erreur de diagnostic, en toile de fond, est une épée de Damoclès pour les médecins, qui s'exposent aussi à des recours en responsabilité civile s'ils agissent sans le consentement du proche du patient. La suggestion du médecin de cesser les traitements peut susciter une vive réaction de la part des proches, qui exigeront la poursuite des traitements et auront recours aux tribunaux pour faire respecter leur interprétation du meilleur intérêt du patient inconscient.

Ceux-ci pourront invoquer des droits fondamentaux protégés par les chartes, tels le droit à la vie, à la liberté et à la sécurité. Contrairement à l'application de la *Charte québécoise*, l'application de la *Charte canadienne* à ces situations est loin d'être certaine, voire improbable. Si le droit au refus de soins est reconnu, conformément au principe de l'autonomie décisionnelle, la possibilité d'exiger des soins sous le couvert de l'autonomie a des implications plus vastes et litigieuses.

Dans la détermination du meilleur intérêt du patient, sa religion aura sans contredit un impact important, celle-ci étant associée à des soins plus intensifs en fin de vie. Certaines religions ont aussi des préceptes précis qui varieront si les traitements n'ont pas encore été entamés ou si l'on envisage de les cesser.

Face aux exigences de traitement, plusieurs pistes de solution s'offrent en vue de régler les conflits. Malgré la crainte d'un retour du paternalisme médical, la liberté professionnelle du médecin demeure une barrière érigée

à l'encontre de la possibilité d'accorder au seul patient ou proche le pouvoir décisionnel.

Nous sommes d'avis que l'incertitude qui règne quant au cadre juridique a des avantages indéniables, notamment celui de ne pas rompre les négociations entre médecin et proche. À une plus grande échelle, l'absence de consensus a récemment été débattue devant le plus haut tribunal du pays, sans clarification explicite des droits.

Les études d'Owen et de Monti nous rappellent qu'on ne peut se satisfaire de présomptions lorsque la médecine est confrontée à ses limites. L'inconscience permanente associée à l'état végétatif n'offre plus le même degré de certitude et les craintes exprimées par les proches de ces patients méritent d'être écoutées. Néanmoins, il y a lieu de se demander si une preuve plus fiable d'absence de conscience aurait réellement un impact sur les exigences de maintien de traitement par les proches d'un patient religieux. De la même manière, une preuve de présence ténue de conscience ne modifierait peut-être pas la propension de la communauté médicale à cesser les traitements chez les patients à l'état de conscience fortement altéré. Quoi qu'il en soit, ce sont les doutes qui subsistent concernant l'état végétatif qui poussent à innover et qui mèneront un jour à une forme de communication avec certains patients présumés inconscients et à l'amélioration des soins qui leur sont offerts, s'ils les désirent.

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