

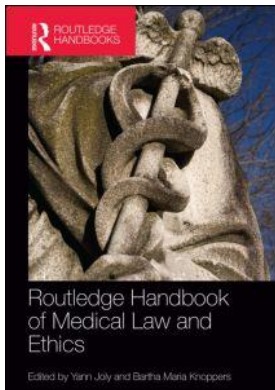
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Healthcare-associated infections

Lara Khoury

11.1 Introduction

Healthcare-associated infections (HAIs) – also called ‘nosocomial infections’ – are recognized as a serious public health problem affecting both patients and healthcare workers (Lange *et al.* 2012: 79–80). The term ‘nosocomial’ is derived from the Greek words *nosos* (sickness) and *komien* (treat), or *nosokomeion* (one who tends to the disease), and the Latin *nosocomium*, meaning hospital (Ellenberg 2004; Duneton *et al.* 1995). Because these narrow meanings do not acknowledge the variety of ways, settings, and environments in which modern healthcare is delivered (Lange *et al.* 2012: 77–9), the expression now preferred is ‘healthcare-associated (or related) infections’.¹

Increased HAI rates near the end of the twentieth century² make these infections a growing concern for health organizations, public health authorities, the medical profession, and the broader community. Modern factors explaining the increased prevalence of HAIs include the overpopulation of hospitals, antibiotic prescription patterns, and an aging population. In addition, medical progress has introduced more invasive procedures that give access to infection, and has increased the survival rates of patients susceptible to a higher risk of infection, such as patients with major burns, organ or bone marrow transplant recipients, premature babies, and the elderly. Finally, new sources of HAIs include the effect of building construction on immunodepressed patients – a factor in the development of Legionnaires’ disease or *aspergillosis* – and the emergence of new bacteria with multiple antimicrobial resistance, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE) (Comité sur les infections nosocomiales du Québec (CINQ) 2004: 7).

At any given time, there are 1.4 million people worldwide suffering from HAIs (World Health Organization (WHO) 2006: para. 2). Between 5 and 10 per cent of patients admitted to modern hospitals around the world contract one or several infections (WHO 2005). The European Centre for Disease Prevention and Control (ECDC) estimates that HAIs occur in an average of one in 20 hospitalized patients in the European Union, causing 4.1 million patients

¹ In French, the expression *infection associée aux soins* (IAS) is also preferred (e.g. Ministère de la santé, de la jeunesse et des sports, direction générale de la santé, direction de l’hospitalisation et de l’organisation des soins & Comité technique des infections nosocomiales et des infections liées aux soins [CTINILS] 2007: 3).

² Some refer to an epidemic (Charney 2012).

to suffer from HAIs and 37,000 deaths each year (Council recommendation 2009, recital (3); Commission of the European Communities 2008: 4).

On any given day, one in twelve adults and one in ten children admitted to a Canadian hospital acquires an HAI (AMMI/CHICA 2012). In 2003, Zoutman *et al.* reported that 220,000 infections are acquired every year in Canadian healthcare institutions, resulting in over 8,000 annual deaths (Zoutman *et al.* 2003: 271). In contrast, Gingin and Hurley calculated that by 2002, HAIs had affected over 320,000 patients, had resulted in costs of close to \$1.5 billion CAD, and had killed between 12,000 and 18,000 people annually (Gingin and Hurley 2012: 107). These infections are the second most frequent adverse event affecting hospitalized patients after medication errors (Zoutman *et al.* 2003: 266). Some consider them the fourth leading cause of death in Canada (Charney 2012: 6), while others believe they are third, behind only heart disease and cancer (Gingin and Hurley 2012: 107).

The Centers for Disease Control and Prevention (CDC) estimates that one in 20 hospitalized patients in the United States contracts an HAI (CDC website; CDC and Association of State and Territorial Health Officials (ASTHO) 2011: 3) and that in 2002 there were approximately 1.7 million patients with HAIs in American hospitals (Klevens *et al.* 2007: 160). Approximately 50 per cent of major hospital health complications are associated with these infections (Lange *et al.* 2012: 82). HAIs are one of the ten leading causes of death in the United States, resulting in approximately 99,000 deaths annually (Klevens *et al.* 2007: 160; Charney 2012: 1–2). In 2009, the CDC estimated that the overall annual direct medical costs of HAIs in US hospitals ranges from \$28.4 to \$33.8 billion or \$35.7 to \$45 billion USD, depending on the adjustment method used (Scott *et al.* 2009: 7).

In 2012, the French Ministry of Health's nationwide *Enquête nationale de prévalence des infections nosocomiales* showed that on any given day, 5 per cent of patients in participating healthcare establishments – representing 90.6 per cent of hospital beds in France – developed an HAI (Ministère des Affaires sociales et de la santé 2012: 1). In 2012, Decoster *et al.* estimated that 3,500 deaths occur annually in France as a result of HAIs, 800 of which they considered preventable (2012: 310).³

Finally, 6.4 per cent of patients in England contracted an HAI in 2011 (Health Protection Agency 2012: 4). It was estimated in 2007 that over 300,000 patients contract an HAI every year and that 9,000 deaths were caused by healthcare-related MRSA or *C. difficile* that year alone (House of Commons 2009: 3). HAIs cost England £1 billion every year (House of Commons 2009: 3).

Several organizations and entities have formally defined nosocomial infections and HAIs. Generally, the patient must contract the infection after being admitted for treatment. In other words, the infection must have been absent at admission. For instance, the European Union Council defines HAIs as 'diseases or pathologies related to the presence of an infectious agent or its products in association with exposure to healthcare facilities or healthcare procedures or treatments' (EU Recommendation 2009).

Other organizations prefer to leave HAIs undefined. During parliamentary debates in February 2002, just weeks before the *Loi du 4 mars 2002* changed the way HAI victims would be compensated in France, Senator Jean-Louis Lorrain proposed to define a nosocomial infection as 'any infection that occurs during or after hospitalization but was absent at admission' (Sargos 2002: para. 276 (our translation)). Then Minister of Health Bernard Kouchner objected

³ Based on a prospective study carried out in 2007 and 2008 in 14 French hospitals.

to this definition, raising potential difficulties in interpretation, and consequently no definition was adopted in the *Loi du 4 mars 2002* (Sargos 2002: para. 276).

Some definitions use timeline indicators to help demonstrate the link between the provision of healthcare and the development of the infection. Most notably, the World Health Organization (WHO) wrote in 2002 that '(n)osocomial infections ... are infections acquired during hospital care which are not present or incubating at admission. Infections occurring more than 48 hours after admission are usually considered nosocomial' (WHO 2002b: 4). The EU Commission Decision of 8 August 2012 similarly states that the onset of infection symptoms must be on day three or later of the current hospital stay (admission being day one) (European Commission 2012/506/EC, page 40).⁴ Such timelines are meant to facilitate identifying the exact moment of onset as many infections are asymptomatic for some time after they are contracted. However, some authors believe that with the increased spread of HAIs and the rise in antimicrobial resistance, the use of time periods may no longer be applicable (Lange *et al.* 2012: 79).

HAIs can be of endogenous or exogenous origin. Endogenous HAIs are caused by a patient's own flora and may develop at the occasion of an invasive act, for instance. Exogenous infections may be acquired from another person (patient or staff member) or from microorganisms contained in the medical environment or on instruments (WHO 2002b: 2). Invasive treatments are more likely to transmit infections (Groutel 1999). Indeed, the most common types acquired in healthcare settings are surgical wound infections, urinary tract infections, and respiratory tract infections. These can arise from the most common agents of infection, namely bacteria (e.g. *Staphylococcus aureus* and *Clostridium difficile*), viruses (e.g. HIV and hepatitis C), parasites, and fungi (e.g. *Aspergillus*) (WHO 2002b: 6–7).

One of the main challenges both medical and legal professions face is the assessment of the causal origin of an HAI. Often, HAIs are the result of a complex interaction between multiple possible causes (Santé et Services sociaux Québec 2005: 8) that may or may not relate to the healthcare provided by healthcare institutions and actors. Factors related to healthcare may include lack of asepsis of the premises, medical devices and instruments; substandard hygiene of the staff; increased invasiveness of medical procedures; physical proximity of hospitalized patients; use of antibiotics that kill the patient's protective flora or drugs that weaken the patient's immune system; and lack of compliance with prevention and control practices. Factors external to healthcare and, as such, outside the control of healthcare institutions and their staff may also complicate the causal analysis. For instance, infection may result from a hospital visitor's infectiousness, a patient's compromised immunity due to his or her state of health, or the microorganism's intrinsic virulence or resistance to antimicrobial agents.

Added challenges exist when wider systemic factors play a role in the occurrence of HAIs. These may include the absence or inefficiency of hospitals' control and prevention teams, overcrowding of hospitals, or acquired antibiotic resistance. They can also pertain to the scarcity of available resources and the decisions regarding their allocation; deficient management and priority setting at the institutional, local, regional, and national levels; the lack of authority held by prevention and control teams, and confusion in the respective responsibilities of relevant actors; aging buildings and infrastructure; lack of specialised human resources; and deficient or non-existent surveillance (e.g. in Santé et Services sociaux Québec 2005; Cinq 2004).

The next section examines the role of legal normativity in the prevention, control and elimination of HAIs, as well as in providing support to their victims. Through examples, it studies

⁴ In the case of surgery or the placing of an invasive device, the onset must be before day three if the surgery or the placing of the device occurred on day one or two of the current hospital admission.

how legislation, public inquiries, class action lawsuits, amicable resolution of conflicts, and state compensation funds reinforce this role in numerous jurisdictions.

11.2 Legal theory

It is widely acknowledged that a large proportion of HAIs are preventable (CDC and ASTHO 2011: 6; Harbarth *et al.* 2003: 260 and 264; Hughes 1988) and the cost of adopting adequate precautions is lower than the cost brought on by the infections they could avoid (Hughes 1988; CINQ 2004: 2).⁵ Consequently, many jurisdictions center their efforts on ensuring adequate prevention measures are implemented. Such initiatives often take place at the level of public policy. Nevertheless, this section focuses on the role formal legal norms – legislative or regulatory texts – play in the prevention and control of infectious risks in the healthcare sector, as well as in responding to injuries that occur when these risks materialize.

Legislative approaches to regulating risks associated with HAIs have taken place predominantly at the national level, although the European Union has been active at the regional level. In this section, we first consider the legislative and regulatory oversight international and regional communities provide for the prevention and control of HAIs (section 11.2.1). Next, we examine the role certain legislatures – in Canada, the United States, England and France – play in imposing, or proposing, norms for the prevention and control of HAIs (section 11.2.2). We then turn our attention to two typical reactions to the occurrence of infectious outbreaks in healthcare establishments: the holding of public inquiries and the undertaking of class action law suits (section 11.2.3). This section closes with the review of a modern technique for compensating victims of HAIs, namely the management of litigation through conciliation, and the establishment of compensation funds for victims (section 11.2.4).

11.2.1 The oversight of the international and regional communities

The WHO has taken on a leadership role in raising awareness of HAIs. It has educated professionals and the public about the nature of HAIs, their causes, and means of prevention, and taken regulatory initiatives to curtail their spread. Most notably, in May 2002, the 55th World Health Assembly (WHA) – the decision-making body of the WHO – adopted a resolution urging member states to pay ‘the closest possible attention’ to the issue of patient safety and to establish and strengthen science-based systems necessary for improving patient safety and the quality of healthcare (WHA Resolution 55.18 2002, section 1; see also WHO 2002c). This Resolution expresses concern over the incidence of adverse events that challenges quality of care and causes human suffering as well as financial loss and opportunity costs to health services (WHA Resolution 55.18 2002, recital). In response to this concern, the WHO launched in October 2004 the WHO Patient Safety program, and chose HAIs as the first ‘Global Patient Safety Challenge’ for 2005–2006 (WHO 2006: para. 5). This challenge, called ‘Clean Care is Safer Care,’ produced guidelines on hand hygiene in healthcare settings⁶ (WHO 2009: 12–23), with the goal of ensuring that ‘infection control is acknowledged universally as a solid and essential

⁵ The American SENIC study (see Hughes 1988), which assessed surveillance and control activities in American hospitals in 1970 and 1976, estimates that 32 per cent of HAIs are avoidable if certain conditions are respected. More recently, Harbarth *et al.* noted, based on their 2003 review of published reports, that between 10 and 70 per cent of HAIs are preventable depending on the setting, study design, baseline infection rates, and type of infection.

⁶ Revised in 2009.

basis towards patient safety' (WHO, n.d.). Since its launch, 129 member states have taken up the challenge, and approximately 15,000 hospitals now implement its guidelines (WHO 2012).

The WHO additionally launched a 'WHO Infection Prevention and Control in Health Care' initiative to help member states reduce HAIs 'by assisting with the assessment, planning, implementation, and evaluation of national infection control policies' (WHO 2002a). In 2002, it published a detailed practical guide to HAI control in healthcare facilities (WHO 2002b). The guide makes recommendations regarding control programs, surveillance, outbreaks, prevention methods, the design of the healthcare environment, antimicrobial use and resistance, and the prevention of infections among healthcare workers (WHO 2002b).

The *Treaty on the Functioning of the European Union* (Consolidated version 2012) serves as the legal basis for many initiatives undertaken in Europe to tackle HAIs. Article 168 of the Treaty states that '[a] high level of human health protection shall be ensured in the definition and implementation of all Community policies and objectives,' adding that Community action shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to health. It also requires that member states coordinate among themselves their policies and programs in this respect and allows the Commission to promote this coordination (*European Community Treaty*, article 168(2)).

In 1994, the Council of Europe decided to prioritize the issue of communicable diseases (Decision 2119/98/EC of the European Parliament and of the Council 1998, recital (3)). Thereafter, European legislative approaches centered on the creation of a regional program of surveillance and control, recognizing the need for coordinated efforts among the member states.⁷ By decisions of the European Parliament and of the Council, programs of Community action in the field of public health have also been created. The objectives of the latest program, covering the 2008–2013 period,⁸ include actions to 'improve patient safety through high-quality and safe healthcare, including in relation to antibiotic resistance and nosocomial infections,' which it describes as threats to health in Europe (Decision 1350/2007/EC of the European Parliament and Council 2007, recital (8), article 2(2) and action 1.2.3). The program also aims to strengthen cooperation between the member states in improving citizens' health security (Decision 1350/2007/EC of the European Parliament and Council 2007, recital (5)). One of the actions provided for by this program seeks to '[e]ncourage action aimed at increasing awareness of the problems and including comparable and reliable data on nosocomial infections,' as well as 'promoting knowledge and exchanges of experience on the way in which surveillance results concerning infections caused by germs resistant to normal treatment (antibiotics) are analysed, processed, and used by the actors in the field' (Decision 647/96/EC of the European Parliament and Council 1996, Annex I, action 5).

In 2006, the Council of Europe also adopted a recommendation on the management of patient safety and prevention of adverse events in healthcare. It followed with the decision to make patient safety, including the prevention and control of HAIs, a strategic item under the Commission's legislative and work program in 2008 (Commission of the European Communities 2008: 2). This led to the 2009 Council Recommendations on patient safety, which address HAI prevention and control through, *inter alia*, reporting and learning systems, as well as education and training (Council Recommendation 2009, recital (10); European Parliament Resolution 2009). Stating the importance of HAI prevention and control as a long-term strategy for healthcare

⁷ See section 11.4.1 of this chapter.

⁸ This program, which came into force in January 2008, was preceded by a program covering the 2003–8 period. The period 1996–2002 was covered by a program of Community action on the prevention of AIDS and certain other communicable diseases (Decision 647/96/EC of the European Parliament and Council 1996).

institutions, it recommended the adoption and implementation of such strategy and detailed its objectives (Council Recommendation 2009, recommendation 8 and recital (14)). By June 2011, 18 member states had a national and/or regional strategy in place to implement the recommendations (European Commission 2012: 7).

Most of the above initiatives are non-binding. Formal legal norms are mostly produced at the national level.

11.2.2 Legislative and regulatory approaches: prevention and control obligations for healthcare institutions

Statutory intervention with regard to HAIs may take many forms, ranging from general legislation pertaining to patient safety to legislation specifically tackling HAIs. Moreover, the absence of specific legislation dealing with HAIs does not mean there are no prevention and control programs in place; they may be provided for through policy. This section nevertheless centres on examples of formal legislative initiatives imposing obligations on healthcare institutions and actors for the prevention and control of HAIs. It goes beyond the scope of this chapter to address broader normative documents pertaining to patient safety, adverse events in healthcare, medical accidents, and reportable communicable diseases, which are nevertheless relevant to fully understanding the law's treatment of HAIs.

After a brief overview of Canadian, French and American laws on the prevention and control of HAIs, we examine indirect legal incentives used to address this issue.

11.2.2.1 Legislation as a vector for organizational change – Canada, France, and the United States

The establishment of infection control committees and procedures may be the result of voluntary action on the part of institutions or encouraged through policy. In some jurisdictions, however, HAI prevention and control is mandated formally through legislation. This has been the case in Canada, although not uniformly across all provinces. Some Canadian hospitals have a legal obligation to establish infection control committees (Ontario), risk management committees (Quebec) or Health Services Committees (Northwest Territories) in charge of such prevention and control, as well as procedures to handle infections in hospitals (*Hospital Management Regulations* 1990 (Ontario), subsection 4(b)(vi); *Hospital Standards (Yukon Hospital Corporation) Regulation* 1994 (Yukon), subsection 6(1)(b)(vi); *Act Respecting Health Services and Social Services* (Quebec), sections 183.1 and 182.2; *Hospital and Health Care Facility Standards Regulations* 2005 (Northwest Territories), sections 14(6)(b), 59 and 61(5); *Operation of Approved Hospitals Regulation* 1990 (Alberta), section 16(i)). In Manitoba, legislation gives the relevant medical officers specific authority to make orders to hospitals in relation to infected patients and infection control procedures if they find them lacking (*Public Health Act* (Manitoba), section 45). Canadian legislation also imposes obligations on other types of healthcare institutions, such as personal and long-term care homes (*Personal Care Homes Standards Regulations* (Manitoba), section 36; *Long-Term Care Homes Act* 2007 (Ontario), section 86; *Ontario Regulation 79/10* 2010, section 229) and land and air emergency medical response services (*Land Emergency Medical Response System Regulation* 2006 (Manitoba), section 18; *Air Emergency Medical Response System Regulation* 2006 (Manitoba), section 10; *Stretcher Transportation Services Regulation* 2006 (Manitoba), section 13) to implement infection control programs and, in the case of care and nursing homes, to provide staff with education programs in the prevention and control of infections (*Personal Care Homes Standards Regulations* 2005 (Manitoba), section 36; *Long-Term Care Homes Act* 2007 (Ontario), section

76(1); *Ontario Regulation 79/10 2010*, section 219(4); *Nursing Homes Operation Regulations 1985* (Alberta), subsection 17(1)(d)).

France has tackled the issue of HAIs through legislative action since as early as 1988. Obligations were imposed to organize surveillance of HAIs, as well as to create a ‘CLIN’ (*Comité de lutte contre les infections nosocomiales*) in all public healthcare establishments and private clinics participating in public healthcare delivery (Décret 88-657 du 6 mai 1988; Stingre and Verdeil 2004: 111 and 112–21). CLINs are committees in charge of organizing and coordinating surveillance, prevention, and continuing education for the fight against HAIs (Ministère des Affaires sociales et de la santé (MASS) 2009; Stingre and Verdeil 2004: 126–8). This initiative was extended to private healthcare establishments in 1998, the year a national program was implemented with the objective of reducing the frequency of infections in French healthcare establishments (Loi 98-535 du 1 juillet 1998, article 4, now *Code de la santé publique* (CSP), article L. 6111-1; Stingre and Verdeil 2004: 111). Since 1992, an additional five coordination centres called CCLIN (*Centre de coordination de lutte contre les infections nosocomiales*) have been entrusted to provide support to health establishments (Arrêté du 3 août 1992, articles 6–7; Stingre and Verdeil 2004: 111). A national structure, the CTINILS (*Comité technique des infections nosocomiales et des infections liées aux soins*)⁹ proposes orientations for national policies, provides expertise in the assessment and management of infectious risks, and examines all scientific and technical questions in this area (Arrêté du 23 septembre 2004, articles 1–2; Arrêté du 3 août 1992; Stingre and Verdeil 2004: 111, 124–6). Numerous other French legal texts impose obligations regarding asepsis and HAI prevention measures, and create bodies to address HAIs (see Sargos 2002: 1117; Khoury 2004: 650 and note 136; Stingre and Verdeil 2004).¹⁰

The United States also shows ‘a significant trend of increasing state action to address the burden of HAIs on the U.S. healthcare system’ (Reagan and Hacker 2012: 77). Numerous laws promote HAI prevention. As it is impossible to paint a complete picture of American normativity related to HAIs in only a few lines only brief highlights are mentioned. In 2009, the United States Department of Health and Human Services developed the ‘National Action Plan to Prevent Healthcare-Associated Infections,’ in order to assess national progress in reducing HAI rates and to provide a road map for preventing HAIs in healthcare facilities (US Department of Health and Human Services). The priorities outlined in the action plan formed the basis of prevention efforts at the federal, state and local levels thereafter (CDC and ASTHO 2011: 7–8). In 2011, the CDC called upon all states, especially on state health agencies, to initiate or enhance their HAI programs in light of several federal initiatives underway (CDC and ASTHO 2011: 3 and 6).

Acute care hospitals that participate in Medicare or Medicaid, or those that are accredited through the Joint Commission, must have an infection control program (US Government Accountability Office 2008). In addition, many state laws require the establishment of infection control and prevention measures or programs (e.g. *California Health and Safety Code* 2013, § 1288.8; *Georgia Rules and Regulations for Hospitals* 2012, r. 290-9-7-.13 and 290-9-7.16; *Indiana Administrative Code* 2013 Title 410, regulation 5-1.5-2, regulation 16.2-3.1-18, regulation 1.5-3-5; *General Laws of Massachusetts* 2013 Chapter 111, § 511; *Nebraska Administrative Code* 2013, § 9-006-08; *Nevada Administrative Code* 2012, § 449.3152; *New Jersey Administrative Code* 2013, § 8:43G-14.1; *Illinois Compiled Statutes* 1997 20 ILCS 1705, § 10.5; *Illinois Compiled Statutes* 1996 210 ILCS 85, § 6.23; *Illinois Compiled Statutes* 2007 210 ILCS 83, § 5). Many state laws also require the use of hospital infection control committees or other types of institutional bodies

⁹ Called the CTIN (*Comité technique des infections nosocomiales*) prior to 2004.

¹⁰ They are too numerous to be described fully here: see Khoury (2004: note 136).

entrusted with the prevention and control of infections (e.g. *Georgia Rules and Regulations for Hospitals*, r. 290-9-7.16; *Indiana Administrative Code* 2013 Title 410, regulation 15-1.5-2; *Nevada Administrative Code* 2012, § 449.3152; *New Jersey Administrative Code* 2013, § 8:43G-14.1; *New Mexico Annotated Statutes* 2009, § 24-29-3), sometimes referring specifically to the necessity to follow CDC guidelines (*New Jersey Administrative Code* 2013, § 8:43G-14.1; *California Health and Safety Code* 2013, § 1288.8; *Prevention and Control of Multi-Drug Resistant Organisms* 2007, § 20 (Illinois)). Some provisions deal precisely with hygiene and asepsis requirements (e.g. *California Health and Safety Code* 2013, § 1279.7; *Georgia Rules and Regulations for Hospitals*, r. 290-9-7.16). In many states, such as New York, South Carolina, and New Hampshire, the hospital prevention program is statutorily required to provide education on HAI prevention to hospital staff (CDC and ASTHO 2011: 25). Some state laws provide for healthcare establishments to evaluate the judicious use of antibiotics (*California Health and Safety Code* 2013, § 1288.8 for acute care). In addition, the *Patient Protection and Affordable Care Act* of 2010 (PPACA) (US) mandates the Secretary of State to establish a national strategy for quality improvement in healthcare. One of the priorities of this strategy is to 'improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections' (PPACA, § 3011). The *Act* also establishes a Center for Quality Improvement and Patient Safety as part of the Agency for Healthcare Research and Quality, whose responsibilities include researching practical methods to address HAIs, including MRSA, VRE, and other emerging infections (PPACA, § 3501).

11.2.2.2 Indirect legal normativity: codes of practice, registration requirements and financial incentives

In addition to directly requiring infection prevention and control, legal normativity is also expressed more flexibly through mechanisms aimed at encouraging or indirectly compelling such measures. England provides an interesting example as it addresses the prevention and control of HAIs through binding regulation, its registration process, and a non-binding code of practice. Financial incentives, such as those used in Canada and the United States, demonstrate other techniques for placing indirect pressure on healthcare institutions.

Following an earlier reform in 2006,¹¹ the *Health and Social Care Act* 2008 (*H&SC Act*) (England) created the Care Quality Commission (CQC).¹² Established in 2009, the CQC is a single inspection agency responsible for the registration, review, and inspection of England's health and social care services. The 2008 *Health and Social Care Act* also grants the Secretary of State the power to adopt regulations for safeguarding individuals from the risk or increased risk of exposure to HAIs¹³ or of rendering patients susceptible or more susceptible to them (section 20(5)). It also allows the Secretary of State to issue a Code of Practice with any requirements related to the prevention or control of HAIs (*H&SC Act*, section 21). In accordance with the *Act*, the *Health and Social Care Act 2008 (Regulated Activities) Regulations* (England) (the *Regulations*) came into force in April 2010. These regulations prescribe the kinds of activities that are

¹¹ Originally, the *Health Act* 2006 added a series of new provisions to the *Health and Social Care Act* 2003 dealing with, among other matters, the possibility for the Secretary of State to issue a code of practice for the prevention and control of HAIs (*Health Act* 2006 (England), section 47A).

¹² Replacing the Commission for Healthcare Audit and Inspection created under the 2003 *Health and Social Care Act* (England), as well as the Mental Health Act Commission and the Commission for Social Care Inspection. A further reform took place under the *Health and Social Care Act* 2012 (England).

¹³ Defined at section 20(6) of the *H&SC Act*.

regulated, outline the requirements for carrying out these activities, and provide for the registration of persons performing them.¹⁴ In December 2010, the Department of Health also adopted the *Health and Social Care Act 2008 Code of Practice on the Prevention and Control of Infections and Related Guidance (Code of Practice)*, applicable to registered providers of all healthcare and adult social care in England.

The *Regulations* state¹⁵ that a registered person *must, so far as reasonably practicable*, ensure that service users – persons employed to perform a regulated activity and others who may be at risk of exposure to an HAI arising from a regulated activity – are protected against *identifiable risks* of acquiring an HAI (section 12). To do so, it must rely on the means specified in detail in the *Regulations*, as well as in the *Code of Practice (Regulations, section 12; Code of Practice, part 2)*. These include the effective operation of systems designed to assess the risk of an HAI and to prevent, detect, and control its spread; the provision of appropriate treatment; and the maintenance of appropriate standards of cleanliness and hygiene in relation to premises, equipment, reusable medical devices, and materials at risk of being contaminated with an HAI (*Code of Practice, p. 13*). Nuances are inserted in the text to acknowledge that such prevention can never be perfectly achieved: obligations are imposed ‘so far as reasonably practicable’ and apply only against ‘identifiable risks’ of acquiring an HAI. The *Code* also sets out ten criteria against which the Care Quality Commission judges whether a provider complies with the cleanliness and infection control requirement imposed by the *Regulations*. Despite its textured language, the *Regulations* do provide for sanctions. Failure to comply with sections 9 to 24, which include obligations regarding cleanliness and infection control, is an offence that may lead, on summary conviction, to a fine not exceeding £50,000. However, a registered person may present a defence based on the fact that they took all reasonable steps or exercised all due diligence to ensure that the provision in question was complied with (*Regulations, section 27*).

The English legal approach also uses the registration process to ensure compliance with the *Code of Practice*. The Care Quality Commission must take the *Code* into account when it makes decisions about providers’ registration¹⁶ (*Regulations, section 26*), an evaluation which must be proportionate to the risk of infection (*Code of Practice, pp. 10–11 and part 3*). Providers must therefore take the *Code* into consideration when deciding how they will comply with registration requirements: ‘by following the *Code*, registered providers will be able to show that they meet the requirement set out in the regulations’ (*Code of Practice*). Where a provider does not comply with its legal obligations as set out in the *Regulations* and the *Code of Practice*, the Commission may use its enforcement powers or take any other action. However, it may do so only after verifying whether the breach occurred because the *Code’s* norms were not appropriate to the type of service provided. As the *Code* is not mandatory¹⁷ (*H&SC Act, section 25*), registered providers may demonstrate that they meet ‘the regulations in a different way (equivalent or better) from that described’ in the *Code* (*Code of Practice, pp. 6 and 10–11*).

Another indirect means of improving prevention and control of infection in healthcare establishments is through financial penalties or advantages. In Canada, the *Excellent Care for All Act 2012 (ECFAA)* of Ontario has mandated since 2012 that compensation given to healthcare executives be linked to achieving quality improvement targets (sections 1, 8 and 9). In 2008,

14 A first set of regulations was adopted in 2009 but was replaced very shortly after by the 2010 Regulations.

15 Reproducing in great part section 5 of the 2009 Regulations, with some modifications.

16 Regulations made under the *H&SC Act* describe the care activities that may only be carried out by providers registered with the Commission (*Code of Practice, p. 9*).

17 Failure to observe the *Code of Practice* does not make a person liable to any criminal or civil proceedings, although the *Code* is admissible as evidence in such proceedings.

the United States' Centers for Medicare and Medicaid Services (CMS) ceased giving additional payments for hospitalizations resulting in complications deemed preventable, including some HAIs (see also *Public Health* 2013, [Chapter 11](#), section 51H (Massachusetts)). This policy drew increased attention to the targeted HAIs, although its effect on health outcomes remains unclear (Lee *et al.* 2012: 314–15). Moreover, the PPACA penalizes hospitals if they do not perform well with regard to hospital-acquired conditions (section 3008).

In addition to statutory governance, HAIs are also subject to public inquiries and class action lawsuits when they lead to outbreaks.

11.2.3 Public inquiries, audits and class action lawsuits

The spread of HAIs and the occurrence of outbreaks have led to public inquiries and audits to identify their causes and future solutions for prevention. Public inquiries and audits are therefore also a source of normativity in this sector.

11.2.3.1 Public inquiries and audits: Canada

Canada provides an example of how public inquiries can serve as non-legislative vectors of change. For instance, a 2004 Ontario Ministry of Health and Long-Term Care Report (MHLTCR) enumerated 103 recommendations after an audit of all hospital infection-control practices in the province ordered by the government following the spread of SARS in this province. One of the Report's recommendations was for the creation of a Health Protection and Promotion Agency (HPPA) whose core functions would include the establishment of standards and guidelines for infection control.¹⁸ This Agency has existed since 2007 and now operates as Public Health Ontario. The Report also proposed the establishment of a standing Provincial Infection Control Committee responsible for supervising existing audits of hospital infection control policies, programs, and resources and undertaking additional ones. Informed by these audits, the Committee would also be entrusted with developing provincial infection control standards for all healthcare facilities in Ontario, as well as mechanisms to ensure compliance with existing and new infection control standards (MHLTCR, pp. 20–1 and 29). This Committee, known as the Provincial Infectious Diseases Advisory Committee (PIDAC), was created in 2004.

Additionally, the Alberta Minister of Health and Wellness requested in 2007 that the Health Quality Council of Alberta conduct a review of the underlying causes and contributing factors that led Alberta's Medical Health Officer to close St Joseph Hospital to new admissions and to shut its Central Sterilization Room in March 2007 after several patients contracted MRSA. (This event also led to a class action lawsuit.¹⁹) The Minister also asked for an assessment of other sites in the health region with respect to infection prevention and control policies and procedures, as well as risk management and sterilization practices. Interestingly, the investigating team concluded that one of the root causes of the problem was found in the legislation governing the health region and the healthcare establishment (Health Quality Council of Alberta 2007: 1).

A final example, from the province of Quebec, is Coroner Rudel-Tessier's 2007 report inquiring into the origin of *Clostridium difficile* (*C. difficile*) infections that killed 16 patients at Hôpital Honoré-Mercier in St-Hyacinthe. Coroner Rudel-Tessier blamed the hospital

¹⁸ The recommendations also deal with training, the availability of specialized staff, the funding of control programs, emergency preparedness, the communication infrastructure, and surveillance.

¹⁹ See [section 11.2.3.2](#) of this chapter.

management for giving insufficient authority to the infection prevention and control team. Among other factors, she found that patients' state of health, their physical proximity to each other, poor hygiene, the absence of surveillance, and the excessive workload of the staff had contributed to the outbreak (Rapport Rudel-Tessier 2007). The initiation of a class action lawsuit followed the publication of her report in 2008 and was settled for \$1 million CAD in 2011 (*Dorion v. C.S.S.S. Richelieu-Yamaska* 2012 QCCS 727).²⁰ Indeed, infectious outbreaks in healthcare facilities in Canada and the United States have sparked numerous class actions over the past ten years.

11.2.3.2 Class action lawsuits in Canada and the United States

In Canada, the spread of SARS in Toronto-area hospitals in 2003 led to several class action lawsuits (*Williams v. Canada (Attorney General)* (2005) 76 OR (3d) 763; *Williams v. Canada (Attorney General)* (2009) 95 OR (3d) 401; *Abarquez v. Ontario* (2005), 257 DLR (4th) 745; *Larozza v. Ontario* (2005) 257 DLR (4th) 761). Other lawsuits were launched by patients who were exposed to or contracted tuberculosis through contact with an infected patient (*Healey v. Lakeridge Health Corp* (2006) CarswellOnt 6574; *Healey v. Lakeridge Health Corp* (2010) CarswellOnt 556), and by persons affected in an outbreak of Legionnaire's Disease and Pontiac Fever at a home for the elderly in Ontario which infected 135 persons and killed 23 (*Glover v. Toronto (City of)* (2009) 70 CPC (6th) 303; *Glover v. Toronto (City of)* (2010) 95 CPC (6th) 206). In 2008, an outbreak of the multidrug-resistant bacteria *Pseudomonas aeruginosa* at the Toronto General Hospital led to a class action after the death of 17 patients (*Sherman v. University Health Network* (2011) CarswellOnt 13165). A last notable Canadian example is the class action against an Alberta hospital and regional authority on the ground that failure to implement infection control practices led to patients contracting MRSA (*Bruce Estate v. Toderovich* (2010) AJ No. 1324²¹).

Most Canadian class action cases have not made it to final judgment, and several have been settled out of court. In addition to the aforementioned settlement by Hôpital Honoré-Mercier, a class action against the Scarborough Hospital by dialysis patients who contracted or were at risk of contracting hepatitis B or C was settled in 2010 (*Notice of the Settlement of the Dialysis Class Action against the Scarborough Hospital* 2010). A 2008 class action against the Joseph Brant Memorial Hospital, alleging negligence in cleaning, maintenance, and disinfection during a one-year *C. difficile* outbreak that killed 91 patients was also settled for \$9 million CAD (*Elliot Estate v. Joseph Brant Memorial Hospital* 2013 ONSC 124; see also *Rose v. Pettle* (2004) 23 CCLT (3d) 21 Ontario). Two claims grounded on the improper sterilization of ultrasound equipment and gynecological instruments (*Farkas v. Sunnybrook and Women's College Health Sciences Centre* (2004) OJ No. 5134 (SCJ); *Farkas v. Sunnybrook and Women's College Health Sciences Centre* (2009) 179 ACWS (3d) 764 (SCJ)) were settled for \$1.2 million CAD and \$179,850 CAD respectively (in the second, no patients had been infected). Interestingly, this last settlement required the defendant to publish a notice outlining the changes in policy and procedure implemented in response to the sterilization breach, and to have its Chief Executive Officer apologize and offer a public statement discussing these changes. It also provided for the defendant's insurer to conduct an education seminar on the topic of infection control (*Rideout v. Health Labrador Corp* (2007) NLTD 150).

²⁰ For an English example, see Mid Staffordshire NHS Foundation Trust Public Inquiry (2013, recommendations 106 and 107).

²¹ See below.

However, claims against the province of Ontario by patients and nurses – and their families – who contracted SARS during the 2003 outbreak were struck out for, *inter alia*, absence of a duty of care on the part of the province. Plaintiffs argued that the province was negligent in managing the risks associated with SARS and the protection of their safety.²² The Court of Appeal of Ontario ultimately dismissed the actions. It believed, among other conclusions, that imposing a duty of care in this respect would create a conflict with the overarching duties the province owes to the public at large in protecting their health (*Larosa v. Ontario*; *Williams v. Canada (Attorney General)*; *Abarquez v. Ontario*). The demonstration of a duty of care is also jeopardized where claimants only invoke exposure to the risk of contracting an infection, rather than actual infection (e.g. *Bruce Estate v. Toderovich*).

The United States has also had its share of HAI-related class action lawsuits. Patients exposed to infection risk have waged class actions for the re-use of single-use material (e.g. *Kinney v. Siouxland Urology Associates* (2011) WL 796237 (DSD) where certification was denied; *Calvillo v. Siouxland Urology Associates* (2011) WL 5196542 South Dakota);²³ or improper sterilization of equipment (e.g. *Creech v. Foote Memorial Hospital* (2004) WL 1258011 (Mich. App.); *Creech v. Foote Memorial Hospital* (2006) WL 2380825 (Mich. App.), certified in part; *Doctors Hospital Surgery Centre, LP v. Webb* (2010) 704 SE 2d 185 Georgia, certification reversed on appeal). Other examples include a case alleging the omission to disclose the infectious tuberculosis status of a physician and to take precautions to protect patients from exposure (*Hannis v. Sacred Heart Hospital* (2000) 49 Pa. D. and C.4th 13 (Pa.Com.Pl.), certified). Certification of such class actions is not necessarily obtained straightforwardly. For instance, in a claim against a surgical centre for non-compliance with sterilization protocols of endoscopes, the certification obtained in the first instance was reversed partly because individual factual questions pertaining to causation predominated over common questions within negligence claims for damages related to anxiety, emotional distress, and loss of consortium (*Doctors Hospital Surgery Centre, LP v. Webb*; *Kinney v. Siouxland Urology Associates*; *Rader v. Têva Parenteral Medicines Inc.* (2011) 276 FRD 524).

Finally, legislation also plays a role in the response to injuries suffered by victims of HAIs, sometimes through innovative techniques, as is the case in France.

11.2.4 Conciliation and state compensation – the French model²⁴

In addition to the possibility of litigation by victims of HAIs under civil and administrative liability rules, France has had a mechanism for amicably resolving litigation and a state compensation fund for HAI victims since 2002 (*Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé* 2002; *Loi n° 2002-1577 du 30 décembre 2002 relative à la responsabilité civile médicale* 2002). The *Loi du 4 mars 2002*, modifying the *Code de la santé publique*, is a major legislative initiative dealing in part with HAIs, transfusional HIV,²⁵ and medical accidents in general. Specific provisions pertaining to HAIs create a special regime dealing with the liability of physicians and hospitals and create a compensation fund to benefit the most injured victims of these infections.

²² Precise allegations are found at paragraph 7 of the 2009 decision.

²³ Case stayed until a decision in *Kinney v. Siouxland Urology Associates* was issued.

²⁴ Compensation schemes were also set up by the Government of Ontario following the SARS crisis in this province (Jacobs 2007: 535–6).

²⁵ CSP, article L 3122-1-L 3122-5. These are not discussed here although they qualify as HAIs.

HAI victims can seek liability under the relevant provisions of the *Code de la santé publique*. These affirm the principle of liability based on fault, but create an exception for HAIs, holding public and private healthcare establishments, services, and organizations liable without negligence unless they present evidence of absence of causation (*cause étrangère*) (CSP, article L 1142-1(I)). Physicians escape the application of this rule: victims must demonstrate their fault (CSP, article L 1142-1(I)).

The 2002 provisions also introduced a special conciliation mechanism for claims made under these provisions.²⁶ Conciliation is administered by the CRCIs (*Commissions régionales de conciliation et d'indemnisation*), the CNAM (*Commission nationale des accidents médicaux*), and the ONIAM (*Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales*). A CRCI is a multidisciplinary body,²⁷ presided over by a judge, in charge of facilitating the amicable settlement of litigation concerning HAIs (CSP, articles L 1142-5–L 1142-6). It is charged with inquiring into and formulating an opinion on the circumstances, causes, nature, and extent of the damages, as well as on the applicable compensation regime within six months after a claim is instituted (CSP, article L 1142-8). Its conclusion rests on the opinion of experts chosen from a national list managed by the CNAM (CSP, article L 1142-10, article L 1142-12). If the CRCI believes that a claim falls under 'national solidarity,' the ONIAM must make a compensation offer to the victim within four months of receiving the CRCI's opinion. Compensation must be provided within one month after the claimant accepts the offer (CSP, article L 1142-17, article L 1142-22). If the CRCI believes that the liability of a healthcare actor is involved, the actor's insurer must provide the victim with a compensation offer, and with compensation should the victim accept, within the same time frame (CSP, article L 1142-1, article L 1142-14). In cases where the insurer remains silent, refuses to make an offer, or the person liable for the injury is not insured, the ONIAM takes the place of the insurer, but is subrogated to the victim's rights against the person responsible for the injury or their insurer up to the amount it has paid in compensation (CSP, article L 1142-15). Hence, the process instituted by the *Loi du 4 mars 2002* prioritizes the interest of HAI victims in receiving fast compensation.

The 2002 provisions also establish the principle of 'national solidarity' for HAI victims through a no-fault, no-responsibility compensation fund. Two types of access to the fund exist. The first, referred to as the 'subsidiary regime,' is available for HAI victims who have not been successful in seeking the liability of relevant healthcare actors, either because they could not prove the physician's fault or because the healthcare establishment was able to point to another cause for the injury (CSP, article L 1142-1(II)). However, the patient's injury must have caused partial permanent incapacity of 24 per cent or more (CSP, article D 1142-1) and the infection must be directly imputable to an act of 'prevention, diagnosis or treatment.'

After insurers reacted against the subsidiarity of this regime by withdrawing from the healthcare insurance market, the legislator introduced a second regime (Pansier 2003: 26). Since December 2012, HAI victims who are deceased or who suffer from partial permanent incapacity

²⁶ Judicial claims are still possible (CSP, article L 1142-19). However, if the tribunal believes that the case is admissible to direct or subsidiary compensation by the ONIAM, the latter becomes a defendant in the proceedings (CSP, article L 1142-21). In cases where the tribunal concludes that the ONIAM must compensate the patient through the mechanisms of direct access to the compensation fund by virtue of article L 1142-1-1, the ONIAM has no recourse against the concerned healthcare professional, establishment, service, or body or their insurers unless fault has been committed, such as through 'characterized failure' (*manquement caractérisé*) to comply with the obligations imposed by regulation for the fight against HAIs (CSP, article L 1142-21).

²⁷ Aside from the presiding judge, members include representatives of patients, healthcare professionals, persons responsible for healthcare establishments, and representatives from ONIAM and the insurers (CSP, article L 1142-6).

of over 25 per cent are offered direct access to the fund (CSP, article L 1142-1-1). In cases where compensation has been paid by virtue of the above two regimes, the ONIAM is subrogated to the rights of the victims and can sue the professional, establishment, service, or organizations concerned (CSP, articles L 1142-1 II, 1142-17, and L 1142-17-1). This system has been criticized, particularly on the grounds that the minimum partial incapacity condition is too stringent (Pansier 2003: 5). Authors also contend that members of the medical profession are held less accountable for their actions (Bertella-Geffroy *et al.* 2002).

Individual litigation has also been undertaken by victims of HAIs, despite serious challenges, as the state of Canadian litigation demonstrates.

11.3 Illustration at the national level: individual litigation in Canada

Individual litigation by HAI victims is revealing of the role that private law plays in responding to medical accidents, as well as in regulating the behaviors that may lead to them. This section briefly addresses the Canadian common law and civil law litigation pertaining to liability for HAI occurrences. It then contrasts this body of case law with French litigation prior to the adoption of the *Loi du 4 mars 2002* to demonstrate the ways in which France has become one of the more progressive jurisdictions in securing judicial compensation for victims of HAIs.

Beyond the liability of physicians who carried out the medical act allegedly at the origin of an infection, the liability of healthcare institutions is often sought. In addition to their potential vicarious liability for the negligence of healthcare staff, healthcare institutions could be held personally negligent for failing to adopt reasonable infection prevention and control protocols, or for their negligent implementation (McQuoid-Mason 2012: 353). In practice, however, both Canadian physicians and healthcare institutions have rarely been held negligent for the occurrence of an HAI.²⁸ In individual lawsuits claiming compensation for injury caused by alleged HAIs, plaintiffs face major hurdles when attempting to prove negligence, causation, or failure to provide information regarding the risks of infection (Khoury and Iokheles 2009: 227).

11.3.1 Demonstration of negligence

Most Canadian cases assessing negligence in relation to an HAI tackle the issue from a diagnostic or post-occurrence treatment angle (e.g. *Rietze v. Bruser* (No. 2) (1978) CarswellMan 99); *Hajgato v. London Health Association* (1982) 36 OR (2d) 669; *Hajgato v. London Health Association* (1983) 44 OR (2d) 264; *Thorne v. Murphy* (1985) CanLII 873 (British Columbia); *Andree v. Pierce* (1986) MJ No. 121 (Manitoba); *Smith v. Miller* (1988) OJ No. 2365; *Painchaud-Cleary v. Pap* (2002) JQ no 1026 (Quebec); *Aldcroft v. Cameron* 2004 BCSC 1624; *Mangelana v. McFadzen* (2006) 275 DLR (4th) 178 (Northwest Territories); *Hasmani (Litigation Guardian of) v. Nagai* (2007) CarswellOnt 2198; *Lévesque v. Hudon* 2013 QCCA 920). They more rarely inquire whether negligence may be at the *source* of the infection. It is surely because of difficulties in proving that their infection originated from a negligent act that plaintiffs rather allege negligent diagnosis and treatment of the infection once it is contracted.

Courts in Canada have generally been reluctant to hold physicians and institutions negligent for the occurrence of an infection for two reasons. First, the risk of infection is inherent to many medical acts and therefore may occur regardless of whether reasonable precautions were taken

²⁸ The issue of negligence in the treatment of an HAI is not discussed here as it raises questions that are no different from those that arise in all cases of alleged negligent medical treatment.

or how carefully the act in question was performed (e.g. *White v. Turner* (1981) 120 DLR (3d) 269 (Ontario), para 77; *Andree v. Pierce* (1986) MJ No. 121 (Manitoba); *Normand v. Stranc* (1994) 10 WWR 175 (Manitoba), para 62; not at issue on appeal in *Normand v. Stranc* (1995) 9 WWR 446). This is particularly true if the infection was post-operative, or of endogenous origin (e.g. *Arlinski v. Donis* (1986) BCJ No. 2253; *McArdle Estate v. Cox* (2003) 13 Alta LR (4th) 19, paras 35 and 48; *Best v. Hoskins* (2006) AWLD 1300 (Alberta), paras 88 and 104; *Baert v. Graham* (2011) 371 Sask. R. 1, 518 WAC 1). Because infections are known complications of many medical procedures, relying on inferences to demonstrate negligence is also a challenge (e.g. *Hajgato v. London Health Association* (1982); *Wintle v. Piper* (1994) 93 BCLR (2d) 387; *Parragh v. Eagle Ridge Hospital and Healthcare Centre* (2008) BCJ No. 1836, paras 63–4). When the risk of infection is inherent to the procedure undertaken, some plaintiffs have opted to challenge the appropriateness of the choice of the procedure itself (e.g. *Tremblay v. Maalouf* (2000) RRA 772 (Quebec), pp. 775 and 779; *Lévesque v. Baribeau* (2001) RRA 639 Québec; *Baert v. Graham* (2011) 371 Sask. R. 1).

Second, considering the impossibility of completely eradicating infection risks in healthcare settings, courts believe there is no negligence as long as reasonable precautions were taken to reduce or control the risk of infection before, during, and after the medical act (e.g. *A.G. v. Hôpital Fleury* (2008) RRA 459 (Quebec), paras 94–5; *J.G. v. Taguchi* (2008) RRA 206 (Quebec), paras 32–3, 41 and 43; Khoury 2012: 784). The success of an allegation that physicians and healthcare institutions omitted to take precautions against a known risk of infection often depends on accepted professional standards of practice (e.g. argument rejected: *Garceau v. Lalonde* (1998) RJQ 1279 (Quebec), p. 1288; *Doucet v. Bourque* (1999) NBJ No. 168; *Rossmann v. Sas* (1999) OJ No. 3028; *Marchand v. Jackiewicz* (2010) CarswellOnt 1723 (*obiter dictum*); argument accepted: *Semeniuk v. Cox* 2000 ABQB 18; *Tremblay v. Maalouf* (2000) RRA 772 (Quebec), pp. 776 and 778). Still, Canadian courts rarely assess the reasonableness of general preventive measures adopted by healthcare institutions (e.g. *Jablonski v. Marosi* (1985) EYB 1985-145409 (Quebec); *Tonizzo v. Moysa* (2007) AJ No. 430 (*obiter dictum*)). There is a tendency to deny the occurrence of institutional negligence as long as precautions and control standards existed and were generally respected at the relevant time (Khoury 2012: 788–9; Khoury 2004: 634). Claims against hospitals have also been dismissed by courts invoking the general impossibility of preventing a particular infection from occurring (*Bissell (Next friend of) v. Vancouver General Hospital* (1979) BCJ No. 481) or the fact that the precautions necessary to prevent such an infection would have been unworkable (*Dineen v. Queen Elizabeth Hospital* (1988) RRA 658 (Quebec); Khoury 2004).

Given the importance of professional standards of practice when assessing the occurrence of negligence, the detailed and sophisticated prevention and control standards developed over the past few decades are likely to play a central role in HAI-based litigation. While failure to comply with these standards is not evidence of negligence *per se*, at least in Canadian law, they provide good indicators of the prevention and control norms considered to be reasonable by experts in the field (e.g. *Kovacich v. St Joseph's Hospital* (2004) OJ No. 4471).²⁹

11.3.2 Causal analysis

Before Canadian courts, causation is a particularly burdensome requirement to prove for patients who allege that the defendant – healthcare institution, physician or healthcare staff –

²⁹ Data compiled by the Infection Control Committee of the defendant hospital was one of the elements used to evaluate the general situation regarding the occurrence of necrotizing fasciitis resulting from a Group A *Streptococcus* infection, as well as its nosocomial nature and the risk of its occurrence.

is at the source of an infection.³⁰ Patients must of course establish that the infection was contracted in the healthcare setting. The timing of onset of an infection can be extremely difficult to determine, as many infections are asymptomatic for some time after contraction (e.g. *Hajgato v. London Health Association* (1982); *Havens v. Hotel-Dieu of St Joseph Hospital* (1989) OJ No. 1095). However, the typical incubation period may assist experts in this regard. Even if it is possible to link an infection to the provision of healthcare, establishing the exact origin of the infection may be difficult, if not impossible, in light of the many factors that may be at play (Khoury and Iokheles 2009: 206 and cases cited). Claims are typically rejected when there is an alternative explanation for the infection unrelated to any act of negligence. This is often the case for post-operative infections and infections of endogenous origin known to arise in the absence of negligence on the part of healthcare professionals and providers (Khoury and Iokheles 2009: 207 and cases cited). Canadian courts rarely rely on factual inferences to prove causation in this context (Khoury and Iokheles 2009: 214–24 and cases discussed), although they have done so in a few cases (*Aristorenas v. Comcare Health Services* (2004) CarswellOnt 3599, reversed on this point on appeal in *Aristorenas v. Comcare Health Services* (2006) 42 CCLT (3d) 220; *Parragh v. Eagle Ridge Hospital and Healthcare Centre* 2008 BCSC 1299). Finally, some judges dispense with attempting to identify the cause of an infection when they believe that none of the possible causes could result from negligence (Khoury and Iokheles 2009: 224–6 and cases analyzed).

Most of the case law in Canada concerns individual occurrences of infections. Causal inquiries might certainly be easier in outbreak situations where several infections occur in the same environment, at the same time, in patients treated by the same medical team, or in patients receiving similar treatment (Khoury and Iokheles 2009: 219–20). These circumstances, coupled with an identified culpable microorganism, could provide a court with sufficient indicators to infer the link between an infection and the healthcare provided, although this would not necessarily denote negligence (e.g. *Parragh v. Eagle Ridge Hospital and Healthcare Centre*, pp. 37–8 and 63–4; Khoury and Iokheles 2009: 220–1). However, even in outbreaks the evidence can conflict on the issue of causation due to the multiplicity of possible infection sources within the healthcare setting (e.g. Rapport Rudel–Tessier's 2007). Although they have rarely been part of Canadian courts' analyses, the findings of infection prevention and control teams could help determine the sources of outbreaks if admissible in evidence before the court (Khoury and Iokheles 2009: 219–20).

11.3.3 Informed consent

Finally, plaintiffs suffering from HAIs often plead that the risk of infection inherent in their procedure was not disclosed and that if it had been, they (in civil law) or the reasonable patient (in common law) would not have consented to the medical act. As is the case for any medical risk, the obligation to disclose infection risks associated with healthcare depends on the probability they will occur and the seriousness of their consequences (e.g. disclosure not required: *Chouinard v. Landry* (1987) RJQ 1954 (Quebec); *Jablonski v. Marosi*; *Williamson v. Kozak* (2003) ABQB 953; *Hajgato v. London Health Association* (1982), affirmed on appeal in *Hajgato v. London Health Association* (1983) 44 OR (2d) 264; disclosure required: *Cantin-Cloutier v. Gagnon* (2001) RRA 75 (Quebec)). However, Canadian courts have stated that patients are presumed to have basic knowledge of the risks inherent in any operation, including scarring, bleeding, and infection (*Hajgato v. London Health Association*; *Videto v. Kennedy* (1981) 33 OR (2d) 497; *White v. Turner*, para. 54; *Drolet v.*

³⁰ Cases in which the causal analysis focuses on whether negligence in *treating* an infection has caused the plaintiff's injury are not discussed here since the causal assessment they necessitate is typical of that undertaken in any case alleging failure to properly diagnose and treat a medical condition.

Parenteau (1994) RJQ 689 (Quebec); Baudouin and Deslauriers 2007: 2–53; Picard and Robertson 2007: 143–4), although some authors doubt whether one can presume that a reasonable patient knows the risks of infection associated with surgical procedures (Kouri and Nootens 2012, para. 314). A risk of infection that goes beyond the general risks of surgery, and is specific to a surgery or procedure, must be disclosed (e.g. *Thorne v. Murphy*, para. 13; *Wintle v. Piper* (1992) BCJ No. 1414). Disclosure is also required if the patient asks questions, voices particular concerns (*Aldcroft v. Cameron*; *Hopp v. Lepp* (1980) 112 DLR (3d) 67 SCC) or is at a particular risk of developing an infection. Finally, extremely rare infection risks do not need to be disclosed, as determined in two cases involving necrotizing fasciitis (*Kovacich v. St Joseph's Hospital*; *Best v. Hoskins*). On the basis of the above, it is likely that disclosure would be required in the presence of an unusually high or severe infection rate, or in the presence of a potential or confirmed outbreak, as such risks obviously do not constitute general and common infection risks related to all medical procedures.

The difficulties faced by Canadian plaintiffs are in sharp contrast with the activism of French courts.

11.3.4 Some comparisons with France

Prior to France's legislative scheme of 2002,³¹ French courts were particularly concerned with the situation of HAI victims. Both the Cour de cassation (with jurisdiction over private clinics and healthcare actors within such clinics) and the Conseil d'État (public hospitals and their healthcare staff and physicians) imposed an obligation of result on clinics, public hospitals, and physicians.³² This meant that these actors could be liable for the sole occurrence of an HAI, even absent negligence on their part (Daël 1993: 575; *Civ. 1^{re} 29 juin 1999*, *Bull. Civ.* 1999.I.22; Hocquet-Berg 2000: 625). Victims, however, had to prove that the infection resulted from a medical act that had taken place in the doctor's office or healthcare establishment or, in other words, that it was not present or incubating at the moment of admission (Khoury 2004: 640–1). The *Loi du 4 mars 2002* partially reversed this case law, by reinstating the principle of fault-based liability for physicians (CSP, article L 1142-1).

Contemporary legal trends with regard to the prevention of HAIs also center on the reinforcement of surveillance programs and the exchange of information. Moreover, a contentious issue has emerged: the public disclosure of infection rates by individual healthcare establishments.

11.4 Current and emerging legal issues: surveillance, reporting, and disclosure to the public

11.4.1 Surveillance and reporting

The reinforcement of global surveillance and information exchange systems has become a central aspect of international reforms on HAIs. In many jurisdictions, the law participates in this reinforcement.

In the European community, coordinated surveillance has been the focus of several recent initiatives. A 1998 decision of the European Parliament and Council set up a network for epidemiological surveillance and control of a number of communicable diseases, including HAIs (Decision 2119/98/EC of the European Parliament and Council 1998, recital (1) and article 1). It requires that member states provide the community network with information, notably on

³¹ Section 11.1.4 of this chapter.

³² However, between 1996 and 1999 they imposed a presumption of fault on physicians in cases where patients developed an HAI (*Cass civ 1^{re} 21 May 1996*, JCP éd. G. 1996.I.3985; Khoury 2006).

cases of HAIs (Decision 2119/98/EC of the European Parliament and Council 1998, article 4) and on the urgent control measures they adopt in response to communicable diseases. Member states must coordinate among themselves, in liaison with the Commission, the national measures they adopt or intend to adopt (Decision 2119/98/EC of the European Parliament and Council 1998, article 6). Relevant information on HAIs detected in their national surveillance systems must also be disseminated within the network (European Commission Decision 2000/96/EC 2000, article 6, annex I). The 1998 decision was implemented through the HELICS projects (*Hospitals in Europe Link for Infection Control through Surveillance*), which in 2005 became part of the IPSE project (*Improving Patient Safety in Europe*). In 2008, the IPSE was transferred to the ECDC, an independent agency which has assisted the European Union since 2005 by ‘identifying and assessing the risk of current and emerging threats to human health by infectious diseases’ (European Commission, *Public Health*). It gathers surveillance data from European Union members, analyzes and interprets this data, and disseminates information through surveillance reports and standardized tables and charts. One of its main programs addresses antimicrobial resistance and HAIs. Since 2008, the ECDC coordinates a European disease-specific network (HAI-Net) to manage HAI surveillance.³³ In addition, the European *Clostridium difficile* surveillance network (ECDIS-Net), funded by the ECDC, focuses specifically on surveillance of *C. difficile* infections.

In 2007, the European Parliament and the Council reiterated the need to monitor the state of public health across the European Union. It advocated for the exchange of information facilitated by a program of community action, while insisting on the need to improve dissemination of information to the public (Decision 1350/2007/EC of the European Parliament and Council 2007, recital (17)). In a 2009 recommendation, the Council also stressed the importance of establishing and strengthening surveillance systems at the regional, national, and healthcare institution levels, and of maintaining and improving comprehensive reporting and learning systems on the causes and extent of adverse events (Council Recommendation 2009, recital (15) and recommendation 8(c)). Furthermore, it emphasized the need to collect comparable and aggregate data at the community level in order to establish efficient and transparent patient safety programs, structures, and policies (Council Recommendation 2009, recitals (10)–(11)).

Legislation strengthens surveillance and reporting at the national and institutional levels in Europe and beyond. The situation in the United States is particularly interesting in this regard, as the growing concern for patient safety motivated several states and territories to adopt legislation pertaining to the reporting – sometimes publicly – of infection rates in healthcare facilities. The wide range of legislative options adopted by the different American states, described as ‘highly variable’ (Reagan and Hacker 2012: 75; Haustein *et al.* 2011: 472), exemplifies the variety of possible reporting approaches. They include obligatory data reporting to the state agency responsible for the oversight of the state’s HAI program, voluntary reporting, and reporting to the public with or without the identity of the facilities revealed (Reagan and Hacker 2012: 75). According to the CDC, 29 states and Washington, DC required HAI reporting to the state health agency or another state-level entity such as a hospital association or a quality improvement organization as of 2011 (CDC and ASTHO 2011: 15). The vast majority of states with mandatory reporting also have a mandate to publicly report data pertaining to HAIs (CDC and ASTHO 2011: 16).³⁴ In 2012, 22 states adopted a comprehensive reporting strategy, namely requiring the submission of data to relevant state agencies as well as public reporting with facility

³³ The HELICS project laid the foundations for a European Network and created a surveillance system (WHO 2010: 9). Two HALT projects (*Healthcare-Associated Infections and Antimicrobial Use in European Long-Term Care Facilities*) funded by the ECDC have also taken place, one from 2009 to 2011 and another starting in 2013.

³⁴ See section 11.4.2 of this chapter.

identifiers (Reagan and Hacker 2012: 77). Only a small number of states required confidential reporting to a state agency or only had voluntary public reporting policies (Reagan and Hacker 2012: 76–7).

Since 1994, the Canadian Nosocomial Infection Surveillance Program (CNISP) has the mandate to provide information on HAI rates and trends at Canadian healthcare facilities (AMMI/CHICA 2012). Its objective is to enable the comparison of rates and 'to provide data that can be used in the development of national guidelines on clinical issues related to healthcare-associated infections' (Public Health Agency of Canada (PHAC) 2013).³⁵

In France, the creation of a coordination body, the RAISIN (*Réseau d'Alerte, d'Investigation et de Surveillance des Infections Nosocomiales*) sought to reinforce surveillance in 2001 (Stingre and Verdeil 2004: 111). An *Observatoire des risques médicaux*, attached to the ONIAM, has existed since 2004. One of its responsibilities is to analyze all data pertaining to HAIs, including information about their compensation and consequences (*Loi du 13 août 2004*, article 15; CSP, article L 1142–29). The *Institut de veille sanitaire* has also participated in infection surveillance since 1998, but its mission is much broader, as it is charged with surveying all sanitary risks. In addition, France's *Code de la santé publique* requires that all healthcare professionals or establishments that observe or suspect the occurrence of an HAI declare it to the director of the *Agence régionale de santé* (CSP, article L 1413–14). Moreover, when a CRCI concludes that a patient's injury is due to an HAI and causes a partial permanent incapacity of more than 25 per cent, it must inform the aforementioned director as well as the ONIAM (CSP, article L 1142–8).

Voluntary surveillance has been in effect for many years in England (Public Health England n.d.). In the 1990s, the Health Protection Agency commissioned and ran a Nosocomial Infection National Surveillance Scheme (NINSS) based on voluntary and confidential reporting (Haustein *et al.* 2011: 472). After MRSA became a major issue in England, the NINSS was not developed further. In 2001, focus shifted to mandatory reporting of *Staphylococcus* bloodstream infections by all acute hospital trusts (Haustein *et al.* 2011: 472). Mandatory surveillance was later extended to glycopeptide-resistant *Enterococcal* bacteraemia in 2003, *C. difficile* in 2004, methicillin-sensitive *Staphylococcus aureus* and *Escherichia coli* (*E. coli*), both in 2011 (Haustein *et al.* 2011: 472; Public Health England n.d.).

HAI-specific reporting can also be required by legislation devoted to public health or communicable diseases. For instance, in Canada, the Manitoban *Public Health Act* requires the reporting of *C. difficile*, MRSA, and VRE infections (*Reporting of Diseases and Conditions Regulation* 2009); *C. difficile* is reportable under the New Brunswick *Public Health Act* (*Reporting and Diseases Regulation* 2009); and MRSA and VRE must be reported under Nova Scotia's *Health Protection Act* (*Reporting of Notifiable Diseases and Conditions Regulations* 2005). Finally, Alberta's *Communicable Disease Regulation* 1985 requires the reporting of HAIs whenever there is an outbreak.

The law frequently mandates surveillance at the institutional level as well. Ontario law requires hospital boards to establish and operate a communicable disease surveillance program (*Hospital Management Regulations*, section 4(1)(e)). It obliges physicians and registered nurses to report suspected infections with an agent of a communicable disease to the medical officer of the health unit in which their services are provided (*Health Protection and Promotion Act* 1990, section 26; *Hospital Management Regulations*, section 14(2)). The same obligation applies to hospital administrators and superintendents of institutions if an entry in the records states that a patient is infected or may be infected with an agent of a communicable disease (*Health Protection and Promotion Act* 1990, section 27). In the Northwest Territories, statutory provisions also oblige medical or professional staff members of healthcare establishments to report to the hospital

³⁵ The CNISP faced significant budget cuts in 2013 (AMMI/CHICA 2012).

management boards and to the Chief Public Health Officer the existence or suspected existence of any condition indicating an HAI (*Hospital Insurance and Health and Social Services Administration Act* 1988, section 61(1)(2)(3)). Finally, risk management committees within Quebec healthcare institutions are in charge of establishing monitoring systems that include local registers of medical incidents and accidents. The purpose of these registers is to analyse the causes of incidents and accidents, including HAIs, and recommend prevention and control measures to the institution's board of directors (*An Act Respecting Health Services and Social Services* (ARHSSS), section 183.2(3)).³⁶ Drawing on these local registers, the Minister of Health must maintain a national register of healthcare-related incidents and accidents (ARHSSS, section 431).

Greater transparency and communication with patients are notable trends in recent patient safety initiatives, including those aimed at preventing HAIs. The demand for transparency has come mainly from the media, patient advocacy groups, legislative bodies and accreditation organizations (Haustein *et al.* 2011: 471). Legal requirements exist in some jurisdictions for the disclosure of adverse events to patients (for instance, ARHSSS, sections 8 and 235.1; CSP, article L 1142-4), but the final section focuses on the more controversial topic of mandatory public reporting of HAI rates in hospitals. The examples below demonstrate the diversity in approaches to reporting, disclosure, and benchmarking around the world.

11.4.2 Public disclosure of hospital infection rates

The United States provides one of the best examples of the use of legal normativity to impose public reporting of information regarding HAIs. A major Consumers Union campaign launched in 2003 encouraged legislative developments in HAI reporting by urging states to adopt laws requiring public disclosure of hospital-specific infection rates (Stricof *et al.* 2013: 294). Indeed, legislative provisions on HAI reporting have been largely driven by consumer demand for transparency and accountability, as well as by public outrage over the spread of HAIs in the United States (CDC and ASTHO 2011: 4, 7 and 14). The majority of states with HAI reporting statutes require that this reporting be public (Reagan and Hacker 2012: 75).³⁷ Moreover, the majority of these laws require that facilities be identified in public reports (Reagan and Hacker 2012: 75 and 77).

Most states with public reporting legislation use the CDC's National Healthcare Safety Network (NHSN), a web-based data collection and surveillance system (CDC and ASTHO 2011: 15–16; e.g. *Health and Safety Code* (California), § 1288.55). From data reported by participating healthcare facilities, the NHSN produces 'Healthcare-associated Infections Summary Data Reports' to provide the public with national and state-specific information on efforts to prevent HAIs (CDC 2013).³⁸ Healthcare facilities use NHSN in all 50 states, as well as Washington, DC and Puerto Rico. As of December 2012, 30 states and Washington, DC required or planned to require the use of NHSN for state-specific reporting (Malpiedi *et al.* 2013: 3).

³⁶ Definitions of incident and accident can be found at sections 8 and 183.2. Healthcare institutions in Quebec must also report to the Minister of Health and Social Services on MRSA and VRE when there are indications that they have infected a serious burn victim (*Regulation respecting the information that institutions must provide to the Minister of Health and Social Services*, schedule V).

³⁷ Thirty-three states have such provisions (Reagan and Hacker 2012: 77). Of the states with HAI legislation, only Utah has not included public reporting provisions in its legislation.

³⁸ Prior to 2004, HAI rates were recorded through the National Nosocomial Infection Surveillance System established in 1970. It was combined with other national surveillance systems into the Internet-based NHSN in 2004 (Tokars *et al.* 2004: 1347)

Mandatory public reporting is sometimes limited to specific infections or procedures (CDC and ASTHO 2011: 16). For instance, the HAIs that must be reported to California's department of health are central-line-associated bloodstream infections, MRSA, VRE, *C. difficile*, and surgical site infections (Health and Safety Code, § 1288.55). In Missouri, disclosure concerns incidence rates for certain types of surgical site infections, ventilator-associated pneumonia, central-line-related bloodstream infections and other infections that may be established by the state's department of health (*Missouri Nosocomial Infection Contract Act of 2004* (NICA), § 192.667(12)). In Utah, reporting to the state health agency is mandated for certain HAI outcomes and only reporting process measures, such as compliance with infection control procedures, are the object of a public report (CDC and ASTHO 2011: 16). The format of the reports varies, with some states requiring that the healthcare facility provide summary reports, while others entrust this task to the state itself (CDC and ASTHO 2011: 20). Some reports are provided to the state legislature while others are placed online for direct public access (CDC and ASTHO 2011: 20). Likewise, the frequency of reporting is highly variable (CDC and ASTHO 2011: 20). Finally, some legislation requires that public reporting compare infection rates for each healthcare facility in the state (Reagan and Hacker 2012: 79), while others demand that the HAI rates be risk-adjusted (e.g. NICA, § 192.665(7)).

The legislation of the state of New York is often cited as an example. Its *Public Health Law* 2013 has required mandatory reporting of HAIs since 2005, and specifically demands that each general hospital maintain a program capable of identifying and tracking HAIs for the purpose of public reporting and quality improvement (*Public Health Law*, § 2819). The data must be reported to the New York State Department of Health, which makes this information available on its website (*Public Health Law*, § 2819(3)). After a one-year pilot project in 2007, reports were made available on a yearly basis including HAI rates at each hospital (New York State Department of Health 2013).

After receiving authorization to pay hospitals a higher annual update to their payment rates upon successfully reporting designated quality measures, the Centers for Medicare and Medicaid Services instated the 'Hospital Inpatient Quality Reporting Program.'³⁹ Reported information from over 4,000 Medicare-certified hospitals is collected using NHSN and made publicly available on the Medicare Hospital Compare website, including a specific section concerning HAIs (CDC and ASTHO 2011: 8; Hospital Compare). Financial incentives are in place to encourage hospitals to participate in this reporting program (CMS 2013a, 2013b).

Finally, in addition to state legislation, the *Patient Protection and Affordable Care Act* 2010 requires that the Center for Quality Improvement and Patient Safety make its research findings available to the public (PPACA, section 3501) and that websites be set up to share 'performance information summarizing data on quality measures' (PPACA, section 3015). The PPACA also mandates public reporting of the measures for hospital-acquired conditions that are currently used by the CMS when adjusting the amounts of payment to hospitals based on HAI rates (PPACA, section 10303).

At the European level, recommendations issued by the European Union in 2009 insist on empowering and informing citizens. They recommend the establishment or strengthening of blame-free reporting and learning systems on adverse events in general (Council Recommendation 2009: 2–3). One of its specific recommendations was that institutions should be 'making available objective and understandable information about the risk of healthcare associated infections, the measure implemented by the healthcare institution to prevent them and on how patients can help to prevent those infections' (Council Recommendation 2009, section 8(e)(i)).

³⁹ This program was originally created in 2003 by s. 501(b) of the *Medicare Prescription Drug, Improvement, and Modernization Act* (CMS 2013b).

Canada's Association of Medical Microbiology and Infectious Disease (AMMI) and Community and Hospital Infection Control Association (CHICA) jointly produced a 2006 position paper in which they advised against using individual hospital-generated reporting of infection rates as a way of comparing or ranking hospitals (AMMI/CHICA 2006). Despite this opposition, some Canadian provinces have also moved in the direction of transparency, although not always in response to statutory interventions. When requested by the Ontario Minister of Health, public hospitals are mandated by statute to disclose information concerning indicators of the quality of healthcare they provide. This information includes diagnoses of HAIs, activities to reduce them, and mortality rates. Moreover, this information must be disclosed through the hospital's website and 'through such other means and to such other persons as the Minister may direct' (*Hospital Management Regulations*, section 22.2). In May 2008, the Ministry of Health and Long-Term Care announced the public reporting of patient safety indicators including rates for *C. difficile*, MRSA, VRE, and central-line-associated primary bloodstream infections (Ontario Ministry of Health and Long-Term Care 2013). Since December 2012, Ontario hospitals have provided reports on a number of HAIs through Health Quality Ontario's patient safety public reporting website (Health Quality Ontario 2013).

In British Columbia, health authorities collect and report information on *C. difficile* and MRSA rates using the Provincial Infection Control Network (PICNet) website. In March 2013, media pressure in New Brunswick led its largest health authority to release the number of *C. difficile* and MRSA infections reported in its ten hospitals during the 21 preceding months (McHardie 2013). Since April 2013, monthly reports for *C. difficile* and MRSA infections have been available on the website for the province's Chief Medical Officer (Office of the Chief Medical Officer of Health (Public Health) – New Brunswick 2014).

Lastly, the Quebec Ministère de la Santé et des Services sociaux produces a quarterly bulletin informing the public about the surveillance of *C. difficile* infections, providing provincial, regional, and hospital incidence rates. Healthcare institutions in Canada are also asked to report their rates of either *C. difficile* or *Staphylococcus aureus* when obtaining accreditation by Accreditation Canada,⁴⁰ an 'evaluation process used to assess and improve the quality, efficiency, and effectiveness of health care organizations' (Nicklin 2013: 1) which is mandatory in only a few provinces, such as Quebec and Alberta (Eggertson 2007: 1403; Nicklin 2013: 5). Whether or not these reports are made public is left to the discretion of the participating institutions.

England also has a system for public reporting of HAIs (Haustein *et al.* 2011: 471). Reporting of MRSA bloodstream infection rates has been mandatory since 2001, and publicly available on the Public Health England (formerly the Health Protection Agency) and the Department of Health websites since 2002 (Haustein *et al.* 2011: 472). Public reporting of other types of infections developed thereafter (Haustein *et al.* 2011: 472), and tables for all mandatory reporting infections are available on the Public Health England website.

While the above jurisdictions mostly choose to publicly report rates of infection – and have therefore been preoccupied with the *results* of infectious outbreaks – the French approach has been to focus on process disclosure (Haustein *et al.* 2011: 471 and 473). In 2005, the French Ministry of Health set up the publicly available ICALIN (*Indicateur composite des activités de lutte contre les infections nosocomiales*), with the goal of encouraging healthcare establishments to measure their initiatives and results in the fight against HAIs. This indicator discloses the actions undertaken in the healthcare facility, using a notation system that reveals its performance in preventing HAIs (Ministère des Affaires sociales et de la santé, 2013).

⁴⁰ Formerly the Canadian Council on Health Services Accreditation.

Some argue, especially in jurisdictions with a private healthcare system, that the ability to compare infection rates across institutions allows informed patient choice (Reagan and Hacker 2012: 79) and that payers want performance data in order to become better purchasers of health-care services (Wong *et al.* 2005: 210). However, there are worries that data communicated to the public might be flawed, misleading, misinterpreted, or misunderstood (Wong *et al.* 2005: 210; Haustein *et al.* 2011: 475). Methodological issues are particularly troubling and authors emphasize the need to standardize and risk-adjust the data for differences in population or range and type of medical procedure (Haustein *et al.* 2011: 471). For instance, in 1991 the CDC worried that inter-hospital comparisons might be invalid or misleading because rates were not adjusted for patients' intrinsic risk for infection; surveillance techniques were not uniform among hospitals or were used inconsistently; and inaccurate recording and insufficient sample size might affect the validity of the rates (CDC 1991: 610). Even where there is risk-adjustment, the scientific validity of the adjustment method may be questioned. The need for uniform definitions and surveillance methods has also been raised (Haustein *et al.* 2011: 471), as well as worries about the effect of the complex and contentious nature of some HAI diagnostics (Haustein *et al.* 2011: 471).

Other objections to public reporting include cost, variations in surveillance practices among reporting hospitals, under-reporting, the comparability of data from each reporting hospital, and patients' confidentiality (Stricof *et al.* 2013: 294; Wong *et al.* 2005: 210). Some commentators have also noted the paucity of evidence that reporting improves the quality of patient care or their safety or decreases HAI incidence (AMMI/CHICA 2006; Haustein *et al.* 2011: 471 and 475) or that patient decision-making is improved by public reporting of HAI rates at individual institutions (AMMI/CHICA 2006; Haustein *et al.* 2011: 475; Daneman *et al.* 2012). However, Haustein *et al.* observed an impressive and unexpected decrease in the reported incidence of MRSA bloodstream infections in England after public reporting became compulsory there (2011: 477). Moreover, Daneman *et al.* found that public reporting of *C. difficile* rates in Ontario hospitals, which began in 2008, was associated with a substantial reduction in these infections (2012). Haustein *et al.* remark that reporting acts as an 'external reinforcement' and is indeed associated with changes in organizational culture and increase in prevention activities (Haustein *et al.* 2011: 471 and 476). Similarly, Daneman *et al.* hypothesize that public reporting in Ontario 'elevated *C. difficile* to greater prominence on hospital quality improvement agendas, and motivated hospitals to adhere more closely to best practices in *C. difficile* prevention' (2012).

11.5 Conclusion

The law has been called to play an active role in the fight against HAIs, particularly in the last two decades. It has done so through a multiplicity of statutory interventions that tackle issues such as prevention, control, management, surveillance, and reporting. Publicly mandated inquiries and audits have also played a part in bringing about change. Moreover, class action lawsuits have risen in response to infectious outbreaks and consequent deaths. Yet individual litigation in Canada, the jurisdiction studied in this respect, presents serious challenges to patients due largely to the difficulties in identifying precise sources of infections and connecting them to acts of negligence. Because of the limited success of individual litigation, and the fact that most class action lawsuits do not make it to final judgment, it is doubtful whether the power of judicially created legal normativity can assist in HAI prevention and response. Nevertheless, France offers an interesting example of a jurisdiction where legislators, courts, and administrative agencies have collaborated to achieve these goals, partly through non-traditional means such as legislatively mandated conciliation systems and a state compensation fund. Finally, the public reporting of infection

rates among healthcare institutions is an ongoing contemporary issue which, while growing in importance in the United States and elsewhere, is still controversial in some countries.

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