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Rapid Review

Never Events in Acute Care: Policy Lessons from International Comparisons

Prepared for the Canadian Patient Safety Institute

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About NAO

The North American Observatory on Health Systems and Policies (NAO) is a collaborative partnership of interested researchers, research organizations, governments, and health organizations promoting evidence-informed health system policy decision making.

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List of Acronyms and Abbreviations

ACC	Accident Compensation Corporation
CCG	Clinical Commissioning Group
CPSI	Canadian Patient Safety Institute
CQC	Care Quality Commission
DHB	District Health Board
GMC	General Medical Council
HDC	Health and Disability Commissioner
HIQA	Health Information and Quality Authority
HPDT	Health Professional Disciplinary Tribunal
HQSC	Health Quality and Safety Commission
HSE	Health Services Executive
HSIB	Health Services Investigation Branch
ICD	International Classification of Diseases
IT	Information Technology
LocSSIPs	Local Safety Standards for Invasive Procedures
MC	Medical Council (Ireland)
MCNZ	Medical Council of New Zealand
NatSSIPs	National Safety Standards for Invasive Procedures
NPSA	National Patient Safety Agency
NHS	National Health Service
OECD	Organization for Economic Co-operation and Development
PHSO	Parliamentary and Health Service Ombudsman
RFO	Retained Foreign Object
SAC	Safety Assessment Code
SRE	Serious Reportable Event
UK	United Kingdom
U.S.	United States
WHO	World Health Organization

Introduction and Background

Patient safety incidents are estimated to comprise the third-leading cause of death in Canada, behind cancer and cardiovascular disease (1). The concept of *never events*—defined as serious patient safety incidents that are preventable through systemic efforts and that therefore "should never occur"—was first introduced in 2001 by the National Quality Forum in the United States (U.S.) (2,3). In 2004, an international expert panel convened by the Organization for Economic Co-operation and Development (OECD) developed six never event indicators with the aim of standardizing measurement and enabling international comparisons (4). *Retained foreign object* (RFO)[1] is one such indicator, defined as a "failure to remove surgical instruments at the end of a procedure" (4). In 2017, the rate of RFOs in Canada was 9.8 per 100,000 discharges—more than twice the OECD average of 3.8 per 100,000 (5,6). The rates in other high-income jurisdictions were consistently lower, with 0.8 per 100,000 in Ireland, 1.9 per 100,000 in New Zealand, and 7.6 per 100,000 in the United Kingdom (UK) (7).

The publication of the U.S. Institute of Medicine's seminal report "To Err is Human" in 2000 recognized that patient safety incidents stem from poorly performing systems rather than individuals, and set out the national agenda to reduce the occurrence of safety incidents in the US (8). The development of the surgical safety checklist in 2008 as part of the World Health Organization (WHO) Safe Surgery Saves Lives program was another important advancement in patient safety efforts across healthcare organizations globally (9). It has been since widely recognized that higher-level policy interventions may be necessary to strengthen the effectiveness of such clinical and organizational efforts (10–12). Indeed, according to recent OECD evidence reviews, system-level interventions, such as a national agency responsible for patient safety, no-fault medical negligence legislation, patient and public engagement strategies, safety standards linked to provider regulation and accreditation, and national interventions based on safety themes (such as surgery), are prioritized by decision makers as the most impactful and cost-effective (13,14).

In this rapid review, we describe the policy interventions aimed at reducing the occurrence of RFOs and other never events in England, Ireland, and New Zealand in order to identify policy lessons that would be of interest to Canadian decision makers.

[1] Terminology for RFOs varies across jurisdictions, as they are also often referred to as "foreign body left in during a procedure" or "retained surgical item." The abbreviation RFO is used consistently throughout this report, regardless of inter-jurisdictional differences in terminology.

Methods

We conducted a rapid, multiple case study of England, Ireland, and New Zealand. These high-income jurisdictions were selected because they have sustained low RFO rates in the recent OECD data (5,7,15). Although OECD reports on patient safety tend to provide cumulative performance measures for the UK, we chose to focus on England, UK's largest jurisdiction, given the decentralized nature of the UK health system. Case study design is well suited to address "how" and "why" type research questions because it allows for a detailed exploration of the mechanisms underlying the identified phenomena (16). Multiple case studies are more robust than single case studies, because they elucidate best practices through replicability (16). To improve comparability across jurisdictions, we chose to focus on never events (a subcategory of patient safety incidents) as there is a greater precision in the never event definition (2,4,5). We refer to the RFO indicator as a reliable "signal" of overall never event policy efforts (4–6).

Environmental Scan

We performed targeted and iterative searches of academic and grey literature in bibliographic databases and search engines (e.g., MEDLINE, Google Scholar) and websites of key organizations (e.g., each jurisdiction's health ministry and/or designated patient safety data custodian). We carried out separate searches for each selected jurisdiction and used both broad and specific terms related to RFOs, surgical or perioperative harm, and never events.

Local Expert Consultations

The literature scan was supplemented by parallel consultations with 22 local experts whose work related to never events and patient/surgical safety (11 from England, 4 from Ireland, and 7 from New Zealand). Local experts included mid-career and senior clinicians, academic researchers, and quality improvement advisors. Recruitment was done by emailing corresponding authors of key academic publications and scientific reports, members of jurisdiction-specific never event or surgical safety advisory groups whose contact information was publicly available, and professional contacts of the research team. The purpose of these consultations was to contextualize and ensure comprehensiveness of the environmental scan findings. The general list of questions is reproduced in **Appendix A**. Questions were tailored to each jurisdiction and local expert. The consultations took place between June and July 2020 using videoconferencing technologies (i.e., Zoom, Microsoft Teams), and lasted from 30 minutes to 1 hour. The consultations were not video or audio recorded and were not transcribed; rather, the researchers involved with the consultations (DB, ML, MM) took detailed notes of the conversations. As the goal of the consultations was to confirm literature findings, these notes were not treated as a separate data source and did not undergo a formal content analysis. Local experts were assured that they would not be named in the rapid review without their consent and that direct quotations would not be captured.

Limitations

Due to the expedited nature of this report, convenience sampling methods were used. The local expert sample may thus not be comprehensive, particularly as recruitment may have been hindered by the ongoing COVID-19 pandemic. While the selection of cases was guided by the OECD data, the present report does not seek to interpret each country's performance on patient safety indicators; rather, this report aims to provide an in-depth review of certain never event policy interventions.

We selected cases based on the OECD data on the RFO indicator; however, we recognize that RFO events are only one indicator of never events and may not represent the overall status of patient safety in each jurisdiction. Further, RFOs specifically refer to patient safety in the acute care setting, but are not indicative of other healthcare settings, such as primary or long-term care. The observed trends in RFO rates across countries in the OECD data may also represent natural changes over time (maturation bias) or changes attributed to other policy events (historical bias), including better incident reporting systems.

It is important to note that the RFO data submitted to the OECD are measured somewhat differently across jurisdictions. The UK uses the *surgical admission method* to capture RFO rates, while New Zealand, Ireland, and Canada use the *all-admission method* (5,7). The surgical admission method uses unlinked data to calculate the number of discharges with International Classification of Diseases (ICD) codes for RFO complications in any secondary diagnosis field, divided by the total number of discharges for patients aged 15 and older. The all-admission method uses linked data to extend beyond the surgical admission to include all subsequent related re-admissions to any hospital within 30 days (5). The data submitted to the OECD tend to capture reporting from public hospitals only and may undercount RFOs occurring in private facilities. Nonetheless, routinely collected health administrative data are preferred by the OECD, since the completeness and comparability of incident reporting systems depends on reportable incident definitions and cultures of transparency across jurisdictions.

The OECD expert panel defined RFO events as surgical admissions bearing ICD-9 CM diagnostic codes (4). However, a validation study of these codes against electronic medical record data in the Veterans Affairs system in the US revealed a positive predictive value of 45% (17). The most common reasons for misclassification included foreign objects being present on admission or coding errors, such as intentional objects and medical devices being left after surgery (17). The ICD-10 codes for RFOs do not appear to have been validated (18). Overall, there may be substantial risk of information bias in the reported performance among countries on the RFO indicator.

Analytic Overview

In the following section, we describe the key policy levers that have been implemented in England, Ireland, and New Zealand to improve patient safety. *Policy levers* are defined as "mechanisms available to decision-makers to influence system changes" (10,19). The OECD has previously developed a framework [2] outlining a typology of patient safety interventions that can be implemented at the system (macro) level to influence structures, at the organizational (meso) level to influence processes, and at the clinical (micro) level to influence outcomes (13). We referred to this framework to classify the identified interventions and specifically focused on the system (macro) level.

National Authority Responsible for Patient Safety

Establishing a national independent authority statutorily responsible for leading the patient safety agenda is an important component of a whole-system approach to patient safety. As described in detail below, in each of the selected jurisdictions, such an authority was created following the emergence of a national strategy committing to addressing patient safety at the system level (**Table 1**). These national strategies arose from recommendations resulting from public inquiries into high-profile patient safety incidents (21–27). Additional precipitating factors included: (i) trends in population data, such as significant disparities in health indicators between Ireland and the rest of Europe (28) and suboptimal performance on safety indicators in New Zealand compared to the OECD average (5,6,29); as well as (ii) major increases in healthcare funding in England and Ireland (28,30). Indeed, Ireland's strategy was described as the blueprint for the largest-ever expansion of Irish health services at the time (28).

England's National Patient Safety Agency (NPSA) was established within the English National Health Service (NHS) [3] as part of the Department of Health (England) 2001 patient safety strategy (12,32,33). Following several reforms in the English NHS, in 2012, the functions of the NPSA were transferred to the newly created NHS Commissioning Board (later named NHS England), overseeing the allocation of funds to the Clinical Commissioning Groups (CCGs), which purchase health services (31,34,35). In April 2016, the statutory patient safety responsibilities of NHS England were transferred to the newly formed NHS Improvement, an arm's-length non-departmental body overseeing the 223 NHS Trusts, which deliver health services within administrative regions (31,36). More recently, NHS Improvement and NHS England began integrating their activities as part of the NHS Long-Term Plan (2019) (37,38).

In Ireland, the plan for an independent authority focused on patient safety was first outlined in the National Health Strategy (2001) (28), which identified a number of weaknesses in the Irish quality and safety system, including the lack of an overriding national structure responsible for patient safety protocols and standards (39). The Health Information and Quality Authority (HIQA) was established in 2007 in response to the recommendations of the National Health Strategy to set health service quality and safety standards (39–

[2] The OECD framework was developed based on the Donabedian "structure-process-outcome" model for quality of care, in which "structures" include the settings, institutions, and administrative systems governing care; "processes" include the components of the care delivered; and "outcomes" include patient recovery, restoration of function, quality of life, survival, and any harms incurred due to care (13,20).

[3] The NHS is England's universal publicly funded healthcare system. All English residents are automatically entitled to healthcare coverage through the NHS. The NHS covers hospital, physician, and mental health care (31).

41). Shortly prior to this, the Health Service Executive (HSE),[4] responsible for funding and delivering public health services in Ireland, was established by the *Health Act* (2004) (39,41). While the HSE is not a specialized patient safety agency, promoting the general safety and quality of public health services does lie within its mandate (41).

In New Zealand, the *Public Health and Disability Act* (2000), which established the country's current healthcare governance structure,[5] required the Minister of Health to determine a strategy for quality assurance of health services (43). In response to this requirement, the Minister of Health released a quality improvement strategy in 2003 that communicated the country's commitment to a systemic approach to patient safety (44). The Health Quality and Safety Commission (HQSC) was then created in 2010 to advise the Minister of Health on the quality and safety of health and disability services (45,46). The activities of the HQSC are guided by the New Zealand Triple Aim (47).[6]

Table 1. Overview of national patient safety authorities in the selected jurisdictions

	England	Ireland	New Zealand
National patient safety authority	NHS Improvement	Health Information and Quality Authority	Health Quality and Safety Commission
Status	Special Health Authority	Independent Authority	Crown Agent
Main legislation	National Patient Safety Agency (Establishment and Constitution) Order (2001); *Health and Social Care Act* (2012)	Health Act (2007)	*Public Health and Disability Amendment Act* (2010)
Strategy	Building a Safer NHS for Patients (2001)	Quality and Fairness: A Health System for You (2001)	Improving Quality (IQ): A systems approach for the New Zealand health and disability sector (2003)
Reporting to	Secretary of State for Health and Social Care	Minister of Health and Children	Minister of Health

[4] Ireland has a two-tier healthcare system of private and public sectors. HSE was established in 2005 to fund and deliver the country's public health services (39). Over 50% of Ireland's residents are also covered by a private health insurance scheme (39). Prior to the establishment of HSE, healthcare services in Ireland were governed by disparate agencies that were independently answerable to the Department of Health and Children (41).

[5] New Zealand has a universal, mostly publicly funded, regionally administered healthcare system. Approximately a third of the population is covered by a complementary private insurance scheme to cover surgery in private hospitals and private outpatient specialty consults (42).

[6] The New Zealand Triple Aim outlines intended healthcare impacts at the individual (patient), population, and system levels. HQSC activities aligned with individual-level impact include engaging patients using co-design methodologies and administering patient experience surveys; those aligned with population-level impact include measuring healthcare quality processes and impacts using standard performance indicators and reviewing mortality across demographic subgroups; and those aligned with system-level impact include promoting effective interventions to alleviate the burden of ill-health (47).

The functions of the national authorities responsible for patient safety are similar across the three countries and include leading and nationalizing clinical initiatives focused on specific safety themes, liaising and aligning priorities across relevant health system actors, monitoring performance indicators, and disseminating lessons from patient safety incidents nation-wide to inform practice, as depicted in **Table 2**. Notably, in Ireland, HIQA oversees accreditation of healthcare centres, health technology assessment, and investigation of patient safety incidents—this contrasts with England and New Zealand, which have separate regulatory authorities to perform each of these functions (28).[7] In addition, as described in more detail later in the report, the policy framework guiding disclosure of patient safety incidents in the Irish public sector was developed by HSE, while NHS Improvement and HQSC developed such policies in England and New Zealand, respectively. New Zealand's HQSC also oversees five mortality review committees on deaths in children and youth, deaths in the perinatal setting, deaths in the perioperative setting, deaths related to family violence, and deaths related to suicide (45,48).

Table 2. Functions of the national patient safety authorities in the selected jurisdictions

Functions	England	Ireland	New Zealand
Collection and reporting patient safety data	✓	✓	✓
Evaluation of clinical safety interventions	✓	✓	✓
Patient and stakeholder engagement	✓	✓	✓
Policy setting	✓	x	✓
Mortality review	x	x	✓
Health technology assessment	x	✓	x
Accreditation	x	✓	x
Setting safety standards	x	✓	x
Inspection to assess standards of care	x	✓	x
Investigation of patient safety incidents	x	✓	x

National clinical initiatives focused on surgical safety

NHS Improvement in England and HQSC in New Zealand regularly provide recommendations for implementing evidence-based interventions focused on specific safety themes to standardize practice across NHS Trusts and DHBs. The Surgical Never Events Taskforce was commissioned in 2013 by NHS England (currently overseen by NHS Improvement) to examine the factors associated with persistent surgical never events (49). Taskforce recommendations led to the development of the National Safety Standards for Invasive Procedures (NatSSIPs) in 2015. These recommendations were largely based on the WHO surgical safety checklist and the NPSA "Five Steps to Safer Surgery" checklist (49). NatSSIPs are organized around two groups: organizational standards (standards that underpin the safe delivery of procedural care) and sequential standards (logical sequence of steps to be performed for every procedure

[7] These bodies are described later in the report. Briefly, in England, regulation, accreditation, and investigation is performed by the Care Quality Commission, while health technology assessment is performed by the National Institute for Health and Care Excellence. Certain investigations are also performed by the Health Services Investigation Branch. In New Zealand, auditing and accreditation are performed by the Ministry of Health, while the Pharmaceutical Management Agency is responsible for health technology assessment. Investigations occur at the local level only.

and patient) (49). To allow for variation in local practice, NHS Trusts are expected to use NatSSIPs as guidelines to develop their own Local Safety Standards for Invasive Procedures (LocSSIPs) (49). As of September 2018, over 84% of NHS Trusts have implemented LocSSIPs (50).

New Zealand's HQSC ran its first national campaign, Open for Better Care, between 2013-2016 (51). The campaign was coordinated nationally and implemented locally, tailored to DHB needs. The campaign targeted four areas of interest, one of which was safe surgery. A safe surgery proof-of-concept project was undertaken at three DHBs, which tested the effectiveness of pre- and post-operative team briefings and the paperless WHO surgical safety checklist (51). Evaluative evidence indicated that the proof-of-concept project was successful, with operative theater team members perceiving a more inclusive culture, better teamwork, and better ability to prepare for surgeries (52). These interventions were subsequently nationalized through the Safe Surgery NZ National Program (2015), which is currently in operation (53). NetworkZ is another key intervention currently being implemented nationally across DHBs (54), as recent pilot studies of this program demonstrated that it was feasible and could improve team communication and collaboration (55,56). The intervention involves multidisciplinary simulation-based training using high-fidelity patient models for surgical theater teams (54).

Healthcare Provider Regulation

Regulatory bodies are defined as those with a mandate to develop quality standards, offer accreditation services, and support professionals through education and training (57). The purpose of establishing healthcare regulatory bodies is to make health services more accountable for their performance to the authorities and to the public (58). The role of regulators appears to be somewhat distinct from the national patient safety authorities in England and New Zealand, with national authorities primarily leading the safety and quality improvement policy agenda. However, Ireland's HIQA appears to partially fulfill both roles. Regulators with a statutory mandate to promote and protect patient safety can be categorized as health ombudsmen, service regulators, and professional self-regulators (**Table 3**).

In the Anglo-American countries, regulation of health professionals has historically been the responsibility of autonomous professional bodies ("self-regulation") given their disciplinary expertise in standards of care and medical ethics (30). However, the highly publicized instances of medical malpractice in the 1980s and 1990s and the lack of transparency around clinical care diminished the trust of patients and the general public in the medical profession (30). This led to the belief that self-regulation may be insufficient to ensure high-quality care and resulted in the emergence of external regulatory bodies, tasked with making healthcare providers more transparent and accountable to patients, the general public, and funders (30,58). Offices of the health ombudsmen (also termed "health complaints commissioners")[8] and independent health service regulatory agencies are two such bodies (58).

[8] While health ombudsmen may not self-identify as regulators (59), they nonetheless have regulatory powers over healthcare providers in their jurisdictions and are thus discussed as such.

Table 3. Overview of the statutory healthcare regulators in the selected jurisdictions

	England	Ireland	New Zealand
Health ombudsmen	PHSO	None	HDC
Main legislation (ombudsman)	*Health Service Commissioners Act (1993)*	Not applicable	*Health and Disability Commissioner Act (1994)*
Independent service regulators	CQC	HIQA	None
Main legislation (service regulators)	*Health and Social Care Act (2008)*	*Health Act (2007)*	Not applicable
Professional regulators	GMC	MC	MCNZ, HPDT
Main legislation (professional regulators)	*Medical Act (1983)*	*Medical Practitioners Act (2007)*	*Health Practitioners Competence Assurance Act (2003)*

Abbreviations: Care Quality Commission, CQC; General Medical Council, GMC; Health and Disability Commissioner, HDC; Health Information and Quality Authority, HIQA; Health Professional Disciplinary Tribunal, HPDT; Medical Council (Ireland), MC; Medical Council of New Zealand, MCNZ; Parliamentary and Health Service Ombudsman, PHSO

Health ombudsman office

England and New Zealand have national health ombudsmen (58), while Ireland has an ombudsman office covering all public services (60). An analysis by Healy and Walton (2016) suggested that health ombudsmen fulfill two main roles: (i) an independent officer that aims to mediate and resolve patient grievances, and (ii) a "public watchdog" that aims to make institutions more accountable "by calling for systemic reforms of poor services and procedures and by identifying breaches of people's rights" (58). Although both England and New Zealand also have a public service ombudsman, these were regarded as having insufficient expertise to manage healthcare-related complaints (58). Researchers also argue that internal grievance mechanisms within healthcare organizations, such as hospitals, are not comparable to these national statutory bodies, as they "may lack impartiality and independence" (58).

In New Zealand, the *Health and Disability Commissioner Act* (1994) created the Office of the Health and Disability Commissioner (HDC), which acts as an independent health ombudsman tasked with protecting and advocating for the rights of patients according to the Code of Health and Disability Services Consumers' Rights (61). The HDC was established as part of the recommendations from a 1988 public inquiry into a research trial at a major hospital that enrolled women with cervical carcinoma in situ without their knowledge or consent (62). The HDC is legally mandated to investigate patient complaints that appear to breach the Code and has the authority to initiate prosecutions before tribunals and courts (58,63,64). Concerns about the competence of individual physicians may result in a referral to the Medical Council of New Zealand (MCNZ), whose functions are described in greater detail below (63,64).

England's Parliamentary and Health Service Ombudsman (PHSO) was first created following the *Parliamentary Commissioner Act* (1967) and the *Health Service Act* (1977), which covered England, Scotland, and Wales and was stated to have been implemented to improve accountability in the NHS (58,65). Since devolution, England's PHSO draws its authority from the *Health Service Commissioners Act* (1993) (58,65,66). The primary responsibility of the PHSO is to independently resolve patient complaints that have not been otherwise resolved by the NHS (59). Both England's and New Zealand's health ombudsmen are

also able to: provide recommendations to healthcare organizations to prevent further safety incidents; require a response from healthcare organizations; and impose sanctions (58) (**Table 4**).

Independent service regulators

England and Ireland have independent statutory regulators for health services and healthcare organizations. New Zealand does not appear to have an external regulator, with the accreditation and certification standards set out by the Minister of Health under the *Health and Disability Services (Safety) Act* (2001) (67). The Care Quality Commission (CQC) is the primary statutory healthcare service and organization regulator in England (57). Established as an independent body following the *Health and Social Care Act* (2008), CQC registers, inspects, and monitors healthcare organizations and ensures their compliance with never event disclosure requirements (57,68). Moreover, CQC seeks assurance that lessons learned from never events have been implemented within healthcare organizations to prevent recurrence (69). CQC has the authority to suspend or cancel provider registrations for failure to maintain the required level of safety and quality (70).

As noted earlier, Ireland's HIQA serves both as the lead on patient safety efforts and as the independent regulator of healthcare services and organizations (with the exception of mental health services, which are overseen by the Mental Health Council) (39). HIQA has the authority to register healthcare providers, set safety standards and perform accreditation in accordance with those standards, inspect compliance with the standards, and carry out investigations related to patient safety concerns (71). Similar to CQC, HIQA also has the authority to refuse or cancel registrations of healthcare providers for non-compliance with the standards (71). While HIQA does not directly prosecute healthcare providers, evidence from HIQA inspections is admissible in court in the case of prosecution (71).

Professional self-regulators

The national self-regulatory bodies for physicians in each of the selected jurisdictions are the General Medical Council (GMC) in the UK (72), the Medical Council (MC) in Ireland, and the Medical Council of New Zealand (MCNZ) (63). Each of these bodies are tasked with registering and licensing physicians, regulating clinical practice through standards and annual appraisals, performing investigations and fitness-to-practice assessments, and providing recommendations when physician competence is of concern. Notably, while the GMC and the MC may receive and investigate any complaints from patients, the MCNZ is legally required to refer these to the HDC (63,64). However, if a patient's complaint raises suspicions about a physician's competence, the MCNZ may conduct its own investigation following the completion of the HDC investigation (63). Each of these regulatory bodies also has the authority to decline, cancel, or impose conditions on physician registration. In New Zealand, certain proceedings may be escalated to the Health Practitioners Disciplinary Tribunal (HPDT), which determines any further disciplinary action, if required (63,64,73).

Table 4. Functions of the statutory healthcare regulators in the selected jurisdictions

Functions	England			Ireland			New Zealand	
	PHSO	CQC	GMC	HIQA	MC	HDC	MCNZ	HPDT
Register	x	✓	✓	✓	✓	x	✓	x
Accredit	x	✓	✓	✓	✓	x	✓	x
Inspect	x	✓	✓	✓	✓	x	✓	x
Investigate	✓	✓	✓	✓	✓	✓	✓	x
Prosecute	✓	✓	x	x	x	✓	x	✓
Sanction	✓	✓	✓	✓	✓	✓	✓	✓
Recommend	✓	✓	✓	✓	✓	✓	✓	✓
Require response	✓	✓	✓	✓	✓	✓	✓	✓
Directly support patients	✓	x	x	x	x	✓	x	x
Directly support providers	x	x	✓	x	✓	x	✓	x

Note. Adapted from Oikonomou et al. (2019) (57); Healy and Walton (2016) (58)

Abbreviations: Care Quality Commission, CQC; General Medical Council, GMC; Health and Disability Commissioner, HDC; Health Information and Quality Authority, HIQA; Health Professional Disciplinary Tribunal, HPDT; Medical Council (Ireland), MC; Medical Council of New Zealand, MCNZ; Parliamentary and Health Service Ombudsman, PHSO

Disclosure of Never Events

Three types of never event disclosures were identified in the selected jurisdictions: (i) disclosure to a health authority (typically, the national patient safety authority), (ii) disclosure to the public, and (iii) disclosure to patients who experienced a safety incident. As discussed in detail below, disclosure to health authorities is not legally mandated; however, compliance to the reporting policy is enforced through contracts between healthcare funders and healthcare organizations (as in England and New Zealand) and through the medical asset and liability processes (as in Ireland). Public reports on never events are produced by these health authorities. Disclosure to patients is mandated by legislation in England and New Zealand. While disclosure to patients is currently voluntary in Ireland, the process of disclosure and apology is protected from litigation by legislation.

Disclosure to the national patient safety authority

The reporting requirements to a designated health authority are outlined in each jurisdiction's national policy (**Table 5**). The purpose of this reporting is to formally document the incident, initiate an appropriate investigation, and learn from it to prevent future harm. In England and New Zealand, these policies were developed by the national patient safety authorities (NHS Improvement in England and HQSC in New Zealand), while in Ireland, this policy was developed by the national public health services funder and provider (HSE) (74–77).

Definitions of reportable never events and RFOs

In all three jurisdictions, never events (termed "never events" in England, "serious reportable events" in Ireland, and "always report and review" events in New Zealand) must be reported to the national patient safety authority and investigated, regardless of whether they resulted in patient harm, because they may signal systemic failures (74,75,78). RFOs are included on the list of reportable never events in the three jurisdictions (75,77,78), though RFO definitions somewhat differ. England and New Zealand employ the same definition, where RFOs include any instruments subject to a formal check at the beginning and end of a surgical or invasive procedure that have been left unintentionally, including procedures related to radiology, cardiology, vaginal birth, and those conducted outside the surgical environment (79,80). However, in Ireland, reportable RFOs only include items that have been unintentionally left in an enclosed body cavity, which excludes items related to vaginal birth (77,81,82). This may result in undercounting of RFOs in Ireland, as many RFO cases occur during obstetrical procedures. For instance, in New Zealand, approximately a quarter of RFO cases in the most recent fiscal year occurred in the maternity setting (83). In England and New Zealand, reporting to the national patient safety authority is also mandatory for severe patient safety incidents that do not meet the definition of a never event (74,76,78).

Reporting policy compliance mechanisms

While there are no legal frameworks directly mandating the reporting of never events to the national patient safety authorities, policy enforcement mechanisms exist to ensure compliance. In Ireland, compliance to the reporting policy is required through the Clinical Indemnity Scheme (CIS), established in 2002 and managed by the State Claims Agency, which provides asset and liability management services to the Irish Government (41,84). Under the CIS, the state assumes responsibility for the indemnification of medical malpractice and clinical negligence claims (41,84). The CIS covers all public health service providers in Ireland, including clinical staff and hospitals (41,84). Although, similar to the Irish CIS, clinical negligence claims against NHS healthcare providers in England are handled by the Clinical Negligence Scheme for Trusts (CNST), which is managed by NHS Resolution, CNST membership is voluntary and never event reporting in England is not linked to CNST (85).

The seminal report of the Commission on Patient Safety and Quality Assurance (2008), which reviewed highly publicized incidents to provide a framework for patient safety and quality in Ireland, suggested that the national incident reporting system needs to be strengthened to improve incident reporting (86). Drawing heavily from the Commission recommendations and the recent HSE Patient Safety Strategy (2019-2020) (87), the *Patient Safety (Notifiable Patient Safety Incidents) Bill* (2019) aims to provide the legislative framework to strengthen the reporting of "notifiable patient safety incidents" (88). Under the new bill, a set of 12 notifiable incidents, including RFOs resulting in unanticipated death, must be reported to HIQA and failure to report will be liable to a fine (88). The bill also extends these reporting requirements to private hospitals. As of late July 2020, the bill was being examined by the Irish legislature (89).

According to England's first national reporting framework for never events, developed by the NPSA in 2010, failure to comply with reporting requirements resulted in financial sanctions (74,90). However, the most recent Never Events Policy and Framework (2018) was updated to remove the financial sanctions associated with never events, as many healthcare providers reported that such penalties reinforced a "blame culture" (75). Instead, compliance with the never events and serious incident reporting policies in England is a condition of the NHS Standard Contract, which is used by CCGs to contract health services (91,92). Failure to report may be further referred for sanctions to CQC, an independent health service regulator described earlier (75). Similarly, in New Zealand, the requirement to comply with the National Adverse Events

Reporting Policy (2017) is part of the Ministry of Health Operational Policy Framework, which establishes the business rules, policies, and requirements for the 20 District Health Boards (DHBs) (93), responsible for purchasing and providing health services within their catchment areas (43).

Table 5. Mechanisms for never event disclosure to authorities in the selected jurisdictions

	England	Ireland	New Zealand
Current policy governing reporting to national authority	• Never Event Policy and Framework (2018) • Serious Incident Framework (2015)	• Incident Management Framework (2018)	• National Adverse Events Reporting Policy (2017)
Current definition of reportable patient safety incident	• Never events: incidents arising from systemic failures that should be reported regardless of whether harm was incurred • Serious incidents: acts or omissions that resulted in unexpected or avoidable death, injury, serious harm, or abuse	• Serious reportable events: a subset of incidents that are serious or are considered to be largely preventable if appropriate measures have been implemented by the healthcare providers	• Always report and review: incidents that are preventable with strong organizational systems; should be reported irrespective of harm incurred • SAC 1 and SAC 2: severe and major adverse events that led to death, or temporary or permanent loss of function [9]
Current definition of reportable RFO	• Items subject to pre- and post-operative counting • Include interventions related to radiology, cardiology, vaginal birth, and interventions outside the surgical environment. • Exclude objects left intentionally	• Unintended retention of a foreign object in an enclosed body cavity after surgery or other procedure performed by healthcare provider • Excludes objects in unenclosed body cavities (e.g., vaginal birth)	• Items subject to pre- and post-operative counting, • Include interventions related to radiology, cardiology, vaginal birth, and interventions outside the surgical environment • Exclude objects left intentionally
RFO classification	Never event	Serious reportable event	Always report and review
Safety incidents reported by	NHS Trusts	Hospitals	DHBs
Safety incidents reported to	NHS Improvement and NHS England	HSE	HQSC
National IT safety incident reporting system	• National Reporting and Learning System • Strategic Executive Information System • Patient Safety Incident Management System (unified system replacing the above, in development)	National Incident Management System	None (DHB-level/local only)
Policy compliance mechanism	NHS Standard Contract with CCGs	Clinical Indemnity Scheme of the State Claims Agency	Ministry of Health Operational Policy Framework for DHBs
Incident review and investigation	• NHS Trusts where the never event occurred perform investigations	• Hospitals where the never event occurred perform investigations	• DHBs where the never event occurred perform investigations

[9] SAC3 and SAC4 capture adverse events that had moderate, minor, or minimal impacts, including near misses. To enable national-level learning, DHBs are encouraged, but not required, to report the occurrence and review findings for near misses and SAC3 or SAC4 adverse events to HQSC as well (78).

	• CCGs perform quality assurance • Selected investigations are performed independently by HSIB	• External independent reviews may be commissioned for complex incidents	• Findings of the investigation are reported to HQSC

Abbreviations: Clinical Commissioning Group, CCG; Care Quality Commission, CQC; District Health Board, DHB; Health Quality and Safety Commission, HQSC; Healthcare Safety Investigation Branch, HSIB; Information Technology, IT; National Health Service, NHS; Retained Foreign Object, RFO; Severity Assessment Code, SAC

Never events review and investigation

According to England's Serious Incident Framework, Ireland's Incident Management Framework, and New Zealand's National Adverse Events Reporting Policy, healthcare organizations (NHS Trusts in England, hospitals in Ireland, and DHBs in New Zealand), are expected to have local policies for never event review, in compliance with national guidelines (74,77,78). All three jurisdictions have targets for turnaround times of investigations to provide clear expectations to patients and to collect accounts from individuals involved in the incident while the information is recent (74,77,78). Findings of never event investigations are submitted to the national patient safety authority to enable system-wide learning.

The Chief Medical Officer Report on Perinatal Deaths in HSE Midland and Regional Hospital Portlaoise (2014) in Ireland revealed there was confusion regarding incident classification and the method of review required, inconsistencies in the time taken to conduct and complete reviews, the quality of reviews, and insufficient anonymization of the disseminated review findings (94). As a result of this report, HIQA published a set of national standards in 2017 to ensure that the reviews of patient safety incidents are standardized, transparent, timely, and person-centered (94). External independent reviews by HSE or HIQA may be commissioned in complex incidents where multiple service providers are involved (94).

In England, quality assurance of investigative reports is performed by CCGs (74). Nonetheless, there has been significant variation in the quality and depth of investigations, with the methods outlined in the Serious Incident Framework being applied inconsistently (95). The Healthcare Safety Investigation Branch (HSIB) was thus created in 2016 to improve the process of investigations and learning from patient safety incidents (96,97). HSIB is funded by the Department of Health and Social Care and is hosted by NHS England and NHS Improvement (96). HSIB conducts up to 30 investigations per year, focusing on incidents where learning can be maximized nationally and all incidents related to birth trauma (in the latter case, HSIB replaces the local NHS Trust investigation) (96). HSIB is guided by a "no blame" approach by providing a "safe space" for patients, families, and staff involved in the incident to share information (96). The *Health Service Safety Investigations Bill (HSSIB)* (2017) is currently undergoing legislative proceedings to establish HSIB as an independent investigative body—the first of its kind in the world (98).

Disclosure to the public

In England, Ireland, and New Zealand, never events reported to the national patient safety authorities are published (in aggregate and anonymized form) by the authorities each fiscal year (11,81). Publication of these data aims to make healthcare organizations more compliant with never event reporting policies and to demonstrate a commitment to transparency and open communication to patients and the general public

(81,99,100). An example of the type of data [10] reported publicly by each jurisdiction is shown in **Table 6**. Such observational data should be interpreted with caution, as they were not subject to statistical analysis and provide only cross-sectional snapshots of never events reported at specific time points. Nonetheless, in addition to a possible general increase in reporting over time, increased reporting appears to also be related to the expansion in never event definitions.

Specifically, the revised Never Event Policy and Framework (2015) in England clarified that the definition of a never event requires "the potential to cause serious harm/death rather than actual harm to have occurred" (101). Similarly, the National Adverse Events Reporting Policy (2017) in New Zealand introduced the "always report and review" list, which includes safety incidents that should be reported regardless of the degree of harm (78). [11] Ireland began public reporting of patient safety incidents after HSE developed the serious reportable event definition and guidance, following the 2014 iteration of the Incident Management Framework (81); as such, a similar comparison is not possible.

Table 6. Public never events data before and after changes in reporting policies

Change in reporting policy	England		Ireland		New Zealand	
	RFO	Never Events	RFO	Never Events	RFO	Never Events
Before never event definition[a]	102	306	-	-	17	25
After never event definition[a]	114	445	-	-	31	114
Baseline public reporting year[b]	130	290	14	233	13	22
Most recent public reporting year[b]	90	435	-	123	31	114

Abbreviations: Retained Foreign Object, RFO

[a] England: before: 2014/15, after: 2016/17 (2015/16 policy change: "The definition of what constitutes a Never Event was amended as it now requires the potential to cause serious harm/death rather than actual harm to have occurred") (101–103); New Zealand: before: 2016/17, after: 2018/19 (2017/18 policy change: "Introduction of an Always Report and Review list – a subset of events that should be reported and reviewed irrespective of whether there was harm to the consumer") (78,83,104).

[b] Considering the most comprehensive baseline year, following the release of the NHS England Never Event Policy and Framework 2012 in England, the first Serious Reportable Event guidance in 2015 from HSE in Ireland, and the first National Adverse Events Policy 2012 from HQSC in New Zealand. Voluntary data from certain health units may have been reported prior to these dates. England: baseline: 2012/13, most recent: 2019/20 (100,105); Ireland: baseline: 2014/15, most recent: 2018/19 (81,106–109); New Zealand: baseline: 2012/13, most recent: 2018/19 (83,99,110). Following the baseline year, Irish SRE data were not disaggregated by type of event.

[10] Sources of publicly reported never event data in each of the selected jurisdictions:

- England: https://www.england.nhs.uk/patient-safety/never-events-data/
- Ireland: https://www.hse.ie/eng/services/publications/performancereports/
- New Zealand: https://www.hqsc.govt.nz/our-programmes/adverse-events/projects/adverse-events-reports/

[11] Prior to the introduction of the always report and review list in New Zealand, only "serious and sentinel events" were reported, which correspond to SAC1 and SAC2 events in **Table 5**.

Quality accounts

In addition to aggregate reports by national patient safety authorities in England and New Zealand, healthcare organizations may publish *quality accounts*. Quality accounts are reports by healthcare organizations (NHS Trusts in England and DHBs in New Zealand) about the quality and safety of their services and include never event data (111,112). England's NHS and New Zealand's HQSC view quality accounts as the means of demonstrating the role the public and local communities play in "making health services better and more responsive" (111,112). Quality accounts also aim to enable comparability and to stimulate competition between healthcare organizations (42).

In England, the reporting of quality accounts is mandated through the *Health Act* (2009) (113), with the contents of these accounts regulated through the *National Health Service (Quality Accounts) Regulations* (2010) (114). These regulations require quality accounts to include a statement from the chief executive of the healthcare organization; priorities for quality improvement (including why they have been chosen and who has been involved in determining them); and a review of the quality of the services offered, based on selected indicators chosen by the healthcare organization (115). Participation in quality accounts is also a requirement of the NHS Standard Contract with CCGs, which gives CCGs the authority to charge financial penalties (92,116). CCGs do not have the authority to permit NHS Trusts to "opt out" of their obligation to participate in the reporting requirement (116). The public inquiry into the Mid Staffordshire NHS Foundation Trust further recommended that CQC audit quality accounts for accuracy, fairness, and balance (117). New Zealand began implementing quality accounts in 2012 and their reporting is not currently mandated, though it is encouraged by HQSC (112). Early evaluations of quality accounts found inconsistent reporting and limited comparability across healthcare organizations (115,118). As such, both England and New Zealand provide guidance materials to support NHS Trusts and DHBs in quality account reporting (111,112).

Disclosure to patients

Disclosure to patients (referred to as *open disclosure*) has been described as an ethical duty of healthcare providers. The goal of open disclosure policies is to facilitate a formal apology to patients and their caregivers, ensure appropriate follow-up in the care of the patient, and demonstrate that action has been taken to prevent future harm. As shown in **Table 7**, Ireland is the only jurisdiction of those examined with a voluntary open disclosure process, though efforts are underway to make it mandatory. While the mechanisms for implementing open disclosure differ between the three jurisdictions, the features and requirements of open disclosure are similar (**Table 8**), emphasizing the need to provide a factual account of the incident, an opportunity for patients to share their story, and a sincere apology. New Zealand's policy also includes the principle of culturally appropriate practice in the incident communication, reporting, review, and learning processes (78). Asking patients about their needs and employing culturally appropriate means of reconciliation have been shown to confer more impactful apologies in the New Zealand setting, particularly for Indigenous patients (119).

Open disclosure requirements

While not legislated or enforced, open disclosure has been the expectation of public health service providers in Ireland since 2008, embedded in the HSE Incident Management Framework (2008), HIQA Standards for Safer Better Healthcare (2012), and the HSE National Open Disclosure Policy (first published in 2013 (120) and updated most recently in 2019 (121)). A 2018 public inquiry into the national cervical cancer screening program determined that the open disclosure policy was "deeply contradictory and

unsatisfactory" due to the lack of an audit and evaluation process and the lack of scrutiny when providers choose to not disclose an incident (120,122). An Independent Patient Safety Council was established in early 2020 to advise the Minister of Health on implementing the recommendations (123), which included the development of a national governance framework for open disclosure with a formalized audit and evaluation process, subject to external review from patient advocates (122). The Council began a consultation process aimed at informing the National Open Disclosure Policy Framework in October 2020 (124). In addition, the *Patient Safety (Notifiable Patient Safety Incidents) Bill* (2019), currently under review in the Irish legislature, seeks to make open disclosure of notifiable patient safety incidents (which include RFOs) mandatory (88). Although patients may refuse an open disclosure meeting, failure to make an attempt at notifying the patient of a safety incident would be an offence, resulting in referral to a regulatory body (HIQA) and liable to a fine (88).

Prior to 2014, open disclosure (termed *duty of candour* in the UK) was an expectation of healthcare providers in England, enforced through the NHS Standard Contract (125). However, the public inquiry into the Mid Staffordshire NHS Foundation Trust revealed several systemic failures that led to patient harm, including a lack of response to patient complaints and an assumption that monitoring and performance management were not the responsibilities of the Trust (117). The recommendations of the inquiry were published in 2013 and included a need to make the duty of candour a statutory mandate, where healthcare organizations and those working in them are honest, open, and truthful with patients and the public (117). Regulation 20 of the *Health and Social Care Act* (2008) *(Regulated Activities) (Amendment) Regulations* (2014) defines the notifiable safety incidents and the harm thresholds that trigger the duty of candour (126). The definition of notifiable incidents aligns with the definition of never events, as it includes unintended or unexpected incidents that could result have resulted in the death of a service user or moderate or severe harm (126). The Royal College of Surgeons of England publishes a guidance document on the duty of candour in the surgical context (127). Compliance with the duty of candour is currently enforced by CQC at the point of registration and as part of inspections of healthcare organizations (125). Failure to disclose a safety incident in accordance with the duty of candour requirements is a criminal offense that is subject to regulatory action by CQC or prosecution (126,128,129).

Table 7. Mechanisms for never event disclosure to patients in the selected jurisdictions

	England	Ireland	New Zealand
Open disclosure type	Mandatory	Voluntary	Mandatory
Disclosure by	Healthcare providers	Health service providers	Health and disability service providers
Disclosure to	A patient and/or a relevant person (acting lawfully on the behalf of the patient)	A patient and/or a relevant person	A patient and their whānau, family, or key support people
Apology protection	Yes	Yes	Not applicable
Current policy governing open disclosure	• *Compensation Act* (2006) • *Health and Social Care Act* 2008 (Regulated Activities) (Amendment) Regulations (2014)	• Civil Liability (Amendment) Act (2017) • National Open Disclosure Policy (2019)	• Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (1996), under the *Health and Disability Commissioner Act* (1994) • National Adverse Events Reporting Policy (2017)

Failure to disclose	• Lack of open disclosure tools (e.g., staff training, incident reporting forms, oversight structures) in an organization seeking registration with CQC may result in refusal of registration or conditional registration • Lack of disclosure is a criminal offense and is subject to CQC regulatory action or prosecution	Not applicable	• Investigation by HDC as breach of the Code and follow-up action as recommended by HDC • Referral to professional regulatory body (only if there is concern regarding individual healthcare providers' competence)

Abbreviations: Care Quality Commission, CQC; Health and Disability Commissioner, HDC

In New Zealand, patients have a statutory right to be fully informed regarding the results of medical procedures, including any harm incurred (130). This is expressed in Right 6 of the *Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations* (1996), which establishes the rights of patients and the obligations and duties of healthcare providers (130). The regulations fall under the *Health and Disability Commissioner Act* (1994), which created the HDC (61), following the recommendations of a public inquiry (62). The HDC has a guidance document outlining the expectations of the open disclosure process (131). The National Adverse Events Reporting Policy, first released in 2012 (110) and updated in 2017 (78), states that each DHB is expected to have a local open disclosure policy that follows the HDC guidance (110). However, recent research found substantial heterogeneity across DHB open disclosure policies, suggesting the need for a nationwide open disclosure policy (132). Failure to disclose a safety incident is a breach of the Code of Health and Disability Services Consumers' Rights and may be investigated by HDC; if there are concerns regarding professional competence, the case may be referred to a professional regulatory body (63,64).

Table 8. Features of open disclosure policies in the selected jurisdictions

Features	England	Ireland	New Zealand
Timeliness	✓	✓	✓
In-person meeting	✓	✓	x
Acknowledgment of incident and impact	✓	✓	✓
Factual account of events	✓	✓	✓
Apology	✓	✓	✓
Demonstrate cultural safety	x	x	✓
Provide opportunity for patient to share their story	✓	✓	✓
Shared decision making for ongoing care/treatment	✓	✓	x
Provide complaint and advocacy support	✓	x	✓
Provide details regarding the incident review process	✓	x	✓
Provide details regarding incident review outcome	✓	✓	✓
Explain actions taken to prevent future occurrences	✓	✓	✓
Provide and retain copy of written disclosure record	✓	✓	x

Apology protection

The goal of apology protection laws is to enable healthcare providers to openly disclose safety incidents and express an apology, without fear of litigation. Malpractice litigation is not practiced in New Zealand due to the availability of a public no-fault compensation scheme for medical injury, described below. Patient complaints and healthcare provider disciplinary mechanisms are handled by the HDC and professional regulatory bodies. In Ireland and England, apologies are protected through legislation.

In Ireland, the *Civil Liability (Amendment) Act* (2017) provides the legal framework to support voluntary open disclosure of all patient safety incidents (133,134). This legislation is described as a mechanism aimed at strengthening open disclosure, following the release of the first HSE National Open Disclosure Policy (2013) (120). Specifically, the Act provides legal protection to healthcare providers in relation to the disclosed incident and the apology made to a patient, where the information provided does not constitute an admission of fault, liability, professional misconduct, poor professional performance, unfitness to practice, or negligence, and is not admissible as evidence of such (133,134). The disclosure and apology will also not invalidate or otherwise affect clinical indemnity coverage (133,134). HSE publishes a document for healthcare providers to guide them through the voluntary open disclosure process, noting that the National Open Disclosure Policy must be closely adhered to in order for the protections afforded by the *Civil Liability (Amendment) Act* (2017) to apply (135). These conditions are also expressed in the current *Patient Safety (Notifiable Patient Safety Incidents) Bill* (2019), which is seeking to make open disclosure mandatory (88).

In England, apologies are protected by the *Compensation Act* (2006), which contains a provision aimed at preventing apologies from being an admission of negligence or breach of statutory duty that would be admissible in court (136). The Act does not provide a definition of apology and instead defers to "existing law" (136); according to Regulation 20 (duty of candour) of the *Health and Social Care Act* (2008) *(Regulated Activities) (Amendment) Regulations* (2014), an apology is defined as an "expression of sorrow or regret in respect of a notifiable incident" (128).

Some researchers have noted that England's definition of an apology is narrow and may result in legal consequences (129,137). Notably, England's Medical Protection Society advises physicians to present apologies as "I am sorry this happened to you," rather than "I am sorry I caused this to happen to you" (137). While NHS Resolution acknowledges that an apology and an explanation do not constitute an admission of liability (127), this is not embedded in legislation. Some researchers have thus raised questions regarding whether apologies could void professional indemnity coverage (137). Although the literature suggests that sincere apologies are valued by patients and may deter litigation (119), incomplete apologies may cause further harm to patients and damage the patient-provider relationship (137). For this reason, researchers have advised that more comprehensive apology protection legislation is necessary in England to be conducive to a greater culture of transparency and safety (129,137).

No-fault Compensation Scheme for Medical Injury

No-fault compensation schemes can be distinguished from tort-based litigation. In the latter, patients or their families may receive compensation once medical malpractice is proven through litigation and financial payouts are made through the courts or out-of-court settlements (138). In no-fault schemes, patients receive compensation for medical injuries by filing a claim to an insurance board.

Although New Zealand is the only jurisdiction of those examined that has had a longstanding national no-fault compensation scheme for medical injuries, such a scheme has also been considered in both England and Ireland.[12] In England, a no-fault compensation system for medical harm has been proposed several times since 1978, largely due to the costs of the tort-based system, particularly those owed to obstetric services. However, these efforts were ultimately rejected due to the perceived difficulties in overhauling the tort-based system, difficulties in adjudicating causation of harm, the possibility of further increasing system costs due to an increase in claims, and the possibility of a reduced amount in payouts available to patients "most in need" (138–140). In June 2018, Ireland's Department of Health and Department of Justice and Equality convened an independent expert group to consider an alternative to the court process for resolving clinical negligence claims, particularly in regard to birth injuries (141). The expert group released its interim report in March 2019, stating that the group will consider no-fault liability schemes further, with attention to the appropriate extent of a no-fault scheme, adjudicating causation, ensuring accountability, and determining compensation amount and system costs (142).

In New Zealand, the Accident Compensation Corporation (ACC) arose out of workers' compensation reforms, with a 1967 Royal Commission concluding that "accident victims needed a secure source of financial support when deprived of their capacity to work" (143). The ACC manages the national publicly funded no-fault compensation scheme for personal injury related to accidents (144). The scheme covers all of New Zealand's citizens, residents, and visitors (145) and medical claims must be filed through a physician not involved in the injury (146). A 1992 reform clarified that ACC provided compensation for "medical errors" and "medical mishaps," which, respectively, included negligent injury (failure to observe the standard of care) or rare and severe injury (occurring in <1% of the time) (146). Following a series of additional reforms between 2001 and 2005 (144,145), the definition of compensable injury was expanded to "treatment injury," which included personal injuries suffered while receiving treatment from health professionals (143). A study by Kachalia et al. (2007) suggested that the reform was prompted by clinicians finding the "medical error" standard to be too punitive and stigmatizing, which made them less willing to facilitate the patient claim process (146). The reform also sought to make the claims criteria more uniform across the ACC, as claimants of non-medical injuries do not have to prove that an error has occurred to receive compensation (146).

To receive compensation, a causal link between the personal injury and treatment must be established (143). Although the "treatment injury" criterion was expected to simplify causation adjudication decisions, distinguishing ordinary complications of treatment from avoidable injuries has been identified as challenging (146). RFOs and other events are likely to be compensable according to prior research, and

[12] England and Ireland both have tort-based systems. As noted earlier in the report, both countries also have government-led medical indemnity schemes for public health service providers (Clinical Negligence Scheme for Trusts [CNST] overseen by NHS Resolution in England and Clinical Indemnity Scheme [CIS] overseen by the State Claims Agency in Ireland).

adjudication decisions tend to rely on precedent (146). ACC is statutorily required to make the first decision on a claim within nine months of its filing (143). Entitlements are categorized as: (i) treatment and rehabilitation, (ii) compensation for loss of earnings, (iii) lump-sum payment for permanent impairments, and (iv) support for dependents (143). There are no minimum requirements or caps on total damages and before the 2005 reform, the average payout per patient has been estimated to be $12,500 (U.S.) (146).

Evidence of impact of no-fault compensation schemes

New Zealand's no-fault scheme eliminated medical malpractice litigation, as healthcare providers cannot be sued for damages following a treatment injury, regardless of cause (143,147). The presence of the no-fault compensation scheme was highlighted among some local experts as an important aspect of the patient safety system in New Zealand. Firstly, patient access to compensation for medical injuries was viewed to be more efficient and equitable, as patients do not require legal representation. Secondly, the patient compensation, patient complaints, and health professional disciplinary mechanisms are decoupled and handled by three independent national bodies (Crown Entities) in New Zealand—ACC (no-fault compensation scheme), HDC (national health ombudsman) and MCZN (physician regulator) (46) (**Table 8**). This structure is thought to contribute to a culture of patient safety, as it makes institutions and systems accountable for medical harm, rather than individuals (11,148). In addition, the public no-fault system provides a framework for the collection of comprehensive medical injury data, enabling system learning (11,146,149).

From the empirical evidence, the impacts of the no-fault scheme remain unclear. Costs owed to litigation, both for patients and for the healthcare system, are expected to be lower in no-fault systems, compared to tort-based ones (143,148). Yet, health system costs in New Zealand have increased following the 2005 reform, possibly due to an increased number of claims (150). Considering that this was not accompanied by an increase in health professional disciplinary actions, the increase in claims may be attributable to an increased access to compensation for medical injury and increased willingness of physicians to facilitate them (150). In addition, the time to first decision after a claim has been filed has also decreased between 2001 and 2010 due to fewer claims being contested by physicians (150). However, it is also possible that the no-fault scheme resulted in reduced provider accountability, as the number of patient complaints to the HDC has increased over the same time period (150). Nonetheless, there is no evidence to indicate that the 2005 reforms resulted in poorer patient safety outcomes (150).

Overall, compared to other OECD countries, those with decoupled patient compensation and professional accountability mechanisms (including New Zealand) have been found to have modestly lower healthcare spending (151). Given the ACC's interest in reducing the occurrence of safety incidents, the ACC is a funder for evaluation studies of national clinical patient safety initiatives in New Zealand, with over $30 million (U.S.) committed to treatment injury prevention programs until 2021 (149).

Table 9. Overview of the decoupled patient compensation, patient complaints, and professional accountability mechanisms in New Zealand

	Injury compensation	Patient complaints	Professional accountability
Agency	ACC	HDC	MCZN
Legislation	*Accident Compensation Act* (1972) (latest reform in 2005)	*Health and Disability Commissioner Act* (1994)	*Health Practitioners Competence Assurance Act* (2003)
Functions	• Provides compensation for personal injury suffered while receiving treatment from health professionals. • Focused on injury rehabilitation and restoration of quality of life. • If a claim review yields evidence of "risk of harm to the public," the matter is referred to the MCZN for possible investigation of the involved personnel.	• Provides patients with an opportunity to receive non-monetary resolution to medical harm, such as a formal apology. • Focused on advocating for and protecting the patients' rights according to the Code of Health and Disability Services Consumers' Rights. • Legally mandated to investigate patient complaints that appear to breach of the Code and only refer to MCNZ when there are concerns about physician competence.	• Registers and regulates the standards and expectations for physicians to practice medicine. • Conducts independent investigation upon referral from HDC if physician competence is of concern. • Investigation may result in requirement to complete a "competence program" to demonstrate that physician skill is adequate to practice. • Proceedings may be escalated to the HPDT, which determines disciplinary action.

Abbreviations: Accident Compensation Corporation, ACC; Health and Disability Commissioner, HDC; Health Practitioners Disciplinary Tribunal, HPDT; Medical Council of New Zealand, MCZN

Patient and Public Engagement

Patient and public engagement was similar across the three jurisdictions, where patients and the public were primarily engaged through their inclusion in patient safety initiatives. Public reporting of never event data and safety indicators; public inquiries; and media reports on high-profile safety incidents could also be viewed as means of public engagement.

Inclusion of patients and the public in safety initiatives

Including patients, patient representatives, caregivers and families, and the lay public in quality improvement initiatives serves to recognize patients and their kin as important stakeholders in fostering a culture of patient safety. According to the local experts in New Zealand, patients and members of the lay public must be included in the Expert Advisory Committees of HQSC to participate in committee-related activities. Similarly, in England, patients and members of the public have been involved in the development of the national surgical standards and the Surgical Never Events Taskforce (152). In Ireland, patients and patient representatives organized into advocacy groups, including the Irish chapter of the WHO initiative called Patients for Patients Safety (153). Through sharing of patient stories, such groups aim to promote dialogue and assist in developing patient safety initiatives (153).

Future directions in patient and public engagement

Both the literature and local expert consultations have recognized that the aforementioned efforts may still represent limited patient and public involvement. Since 2016, New Zealand's HQSC has been promoting the use of co-design principles in quality improvement and patient safety interventions, in an effort "to move

away from tokenistic engagement with consumers, to a more meaningful model of engagement and partnership in which consumers and staff together define the challenges to their current experiences of delivering or receiving care, and co-design solutions" (154). In addition, HQSC has begun to routinely administer national patient experience surveys, including a survey focused on inpatient experience, one on primary care experience, and most recently, one on COVID-19 patient experience (155). These surveys are used as an additional quality-performance metric (155). In England, noting the lack of patient and public involvement at local (as compared to national) levels, CQC recommended increasing the support and resources for NHS Trusts to involve patients in meaningful ways (156). Recently, a framework has been developed (draft dated March 2020) to provide guidance for NHS organizations regarding how to involve patients, their caregivers, and lay people in patient safety initiatives (157).

Conclusions

Patient harm is a key policy issue in Canada, as the rate of never events in Canada is higher than most other OECD jurisdictions. The lack of a national never event definition, inconsistencies in reporting policies, and few regulatory mechanisms for accountability and transparency present challenges to learning from never events in Canada (158,159). In this rapid case study of three jurisdictions that have consistently maintained low RFO rates (England, Ireland, and New Zealand), we described several national policy interventions aimed at reducing the occurrence of RFOs and other never events. While these jurisdictions have unitary political systems with a central governance authority, which precludes direct comparability to the Canadian federal system, several considerations and lessons can nonetheless be drawn for Canadian decision makers.

Most high-level patient safety policy efforts first appeared on government agendas in the early 2000s, following a number of high-profile patient safety incidents in the prior decade and the publication of the Institute of Medicine 2000 report, "To Err is Human," which recognized the role of systems in the occurrence of iatrogenic harm (8). Overall, national policy approaches in the selected jurisdictions tended to address never events or patient safety more broadly, rather than specifically focusing on RFOs. No single intervention could be identified as essential, suggesting that multiple policy interventions may be necessary to reduce never events. This aligns with James Reason's seminal "Swiss cheese" model for medical errors, whereby multiple layers of protection are required to reduce the possibility of an error reaching the patient and resulting in harm (160).

Legislating an independent patient safety authority was one of the first policy initiatives implemented in each jurisdiction to demonstrate a commitment to patient safety and systemic improvement. These authorities had some overlapping functions with healthcare regulators, but were largely distinct, as they were mandated to lead the patient safety policy agenda, liaise and coordinate with other partners in the healthcare and government sectors, harmonize data collection and reporting, and enable widespread implementation of evidence-based clinical patient safety initiatives, such as surgical safety checklists and simulation-based training. In New Zealand, local experts noted that the public and other stakeholders viewed the data and the recommendations put forth by such an organization as trustworthy and impartial due to its independent legal status. Cooperation between health quality councils within the Canadian provinces and territories (which are not independent of the provincial and territorial ministries of health) could be leveraged to standardize never event definitions, reporting policies, and data collection systems, as their mandates align with these functions (161).

Policy reform was typically triggered by the recommendations arising out of public inquiries into major patient safety incidents. The focus of these policy efforts has been to increase accountability and transparency of individual healthcare providers and organizations. Attempts at improving accountability resulted in the establishment of external regulators to compensate for the perceived insufficiencies of professional self-regulators, who were seen as not being impartial. Regulators were statutorily mandated to develop, monitor, and enforce standards for safe care in healthcare organizations, including through investigative and prosecutorial actions. Professional self-regulators collaborated with external regulators and were engaged for follow-up and disciplinary actions related to individual healthcare providers. England is also in the process of legislating an independent regulator of the quality of never event investigative processes—currently, the only jurisdiction in the world to implement such a body. While regulators may lead to improved accountability, they may also result in an increasingly more complex and fragmented

system (57). Empirical evidence is necessary to understand the effect of regulation on healthcare provider behaviour and safety outcomes (162).

Attempts at improving transparency resulted in policies for never event disclosure to: (i) independent patient safety authorities, (ii) the public, and (iii) patients. Despite differing terminology, the definitions of reportable never events were similar across the three jurisdictions. Specifically, never events were delineated on a list of patient safety incidents deemed to be particularly serious regardless of whether they caused harm to the patient. Reporting policies noted that the occurrence of such events likely indicated systemic failures, which justified their mandatory reporting to the independent patient safety authority. Reporting triggered the review and investigation processes, aimed at learning from the never event. Notably, Ireland's definition of reportable RFOs differed from that of England and New Zealand, as it excluded surgical items retained in unenclosed body cavities. Since up to a quarter of RFOs may occur in the maternity setting (83), such RFOs could be underreported and undercounted in Ireland. However, reporting to national patient safety authorities was not legally mandated; rather, reporting policies were enforced through contracts between healthcare funders and healthcare providers (as in England and New Zealand) and through the medical asset and liability processes (as in Ireland). Overall, these findings suggest that clear and enforceable reporting policies are necessary to optimize reporting. Our findings align with a prior rapid review in the Canadian setting, which suggested that legislation may not be a prerequisite for improving compliance with patient safety policies (163).

Public reporting of never events was linked to reporting to the independent patient safety authority, who published regular public reports. The main goal of public reporting was to demonstrate a commitment and responsiveness to patient safety to the public. NHS Trusts in England and DHBs in New Zealand also published quality accounts, defined as statements of the health service quality and safety within healthcare organizations, including never event rates. While the reporting of quality accounts in England was made mandatory through legislation following a major public inquiry, quality accounts are currently voluntary and encouraged by the national patient safety authority in New Zealand. As public reporting of never events has been of interest in the Canadian setting (158), quality accounts could present a mechanism through which this practice is implemented and standardized.

Open disclosure to patients is mandated by legislation in England and New Zealand. Although disclosure to patients is voluntary in Ireland, the Irish legislature is currently reviewing a bill that would make this process mandatory for certain never events, including RFOs. Fear of litigation or loss of indemnity coverage were key barriers to open disclosure reported by health professionals. Ensuring comprehensive and unambiguous apology protection in mandatory open disclosure legislation may lead to more impactful apologies for patients. No-fault compensation schemes for medical injury may present an alternative mechanism of facilitating open disclosure. However, the empirical evidence of the impacts of such schemes on open disclosure, safety outcomes, and healthcare costs remains unclear.

Publishing of quality and safety data and the involvement of patients on task forces and committees were the routinely employed patient and public engagement methods. However, novel methods were also developed to engage patients and the public more meaningfully, including: (i) developing patient and public engagement frameworks, which may be tailored locally; (ii) employing co-design approaches to set out, prioritize, and address patient safety efforts; as well as (iii) administering regular patient experience surveys and including them among the monitored patient safety performance measures. Nonetheless, meaningful patient and public engagement remains a recognized evidence and practice gap that should be prioritized to build more proactive learning systems for patient safety.

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Appendix A. Questions for Local Experts

- Who are the policy actors (governments, researchers, professional organizations, NGOs, etc.) involved in RFO reporting in your jurisdiction? Do these policy actors work together in a coordinated system? If so, how?
- What are the mechanisms for consistently measuring and monitoring RFO incidents in your jurisdiction? Can you describe what sorts of efforts are made to prevent, respond, and learn from an RFO incident in your jurisdiction?
- Can you describe the legislation (if any) in your jurisdiction that enables the reporting of RFO events in your jurisdiction?
- Can you talk about the policies in your jurisdiction that are enablers to reducing RFO incidents?
- To what extent do organizations (hospitals) in your jurisdiction set their own standards, practices, and initiatives to reduce never events (especially regarding RFO)? If they do, how are best practices, lessons learned, etc., shared across organizations in your jurisdiction?
- How would you describe the "culture of patient safety" in your jurisdiction? Can you describe the leadership (i.e., board-level, organization CEOs, and other senior leaders) involved in promoting patient safety in your jurisdiction (i.e., allocating time and resources to patient safety, daily management systems, etc.)?
- Do you know of any professional associations and regulatory bodies in your jurisdiction that include patient safety competency standards into their professional standards of practice?
- Are there professional regulators in your jurisdiction that have the legal mandate to set out standards for professional conduct and practice regarding RFO events?
- Are healthcare organizations in your jurisdiction accredited through a national body? Are there national standards that cover RFO events?
- How are patients and the public engaged as partners in setting priorities, policies, systems, and decisions that influence reducing RFO events in your jurisdiction?
- Do you think the observed lower never event rates in your jurisdiction can be attributed to the policy levers of interest (legislation, organizational policies, regulations, standards, public engagement) discussed here vs. other factors (why or why not, which ones)?
- Can you share with us some key lessons learned in terms of design and implementation of RFO reporting in your jurisdiction?
- Is there anyone you recommend we speak with to learn more about RFO events in your jurisdiction?

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