

International Overview of Legislation Concerning Patient Safety

Country	Legislation	What is being done?
PATIENT SAFETY		
Denmark	Y	<ul style="list-style-type: none"> • Danish Patient Safety Act 2004 • Reporting of adverse events to the National Registry gives absolute protection for disciplinary and legal use of the reports. Spans primary and secondary care, patients and relatives. • Full transparency (therefore no legal restrictions) apart from legislation surrounding personal data protection. • Patients right to full access to all information in their medical records. • No-fault compensation for patients harmed in the health care system.
Norway	Y	<ul style="list-style-type: none"> • Reporting. • Transparency. • No-fault compensation. • Issue raised – hurdle to anonymize all information contained in medical records before providing to external institutes.
Italy	Y	<ul style="list-style-type: none"> • Reporting system in each hospital, a local and regional clinical risk management function, national repository of safe practices. Mandatory reporting of sentinel events and claims. • Patients right to full access to all information in their medical records. • Fair compensation in case of harm. • Publications of aggregate data on adverse events every 6 months. • New legislation (2017) prohibits access to any document produced within RLS for legal actions against the clinician/hospital. http://www.bmj.com/content/357/bmj.i2277 • Issue – minor forms of protection from disciplinary sanction, as a result of the report of an adverse event and principle of confidentiality (RLS and publications of data on service performance).
Spain	Y	<ul style="list-style-type: none"> • Reporting to National or Regional RLS. Anonymized data. • Patients right to full access to all information in their medical records. • Compensation system based on the regions. • Within the Constitution – patients can always proceed to court even if an arbitration or mediation

		<p>has occurred.</p> <ul style="list-style-type: none"> • Limitation – no legal protection for health care professionals that report or participate in root cause analysis of an adverse event at their health care institution. → Discourages reporting
HEALTH CARE PROFESSIONALS		
Austria	Y	<ul style="list-style-type: none"> • Austrian Health Care Quality Act 2005 https://www.bmgf.gv.at/cms/home/attachments/2/8/0/CH1063/CMS1396521704766/health_care_quality_act.pdf • Patients Charter and Rights
United Kingdom	Y	<ul style="list-style-type: none"> • Care Quality Commission (independent agency set by the State) • Health and Social Care Act 2008, Regulation 20: Duty of Candor (2014) http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf Ensures that providers are transparent with patients and other relevant persons. Sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong. • Healthcare Safety Investigation Branch https://www.hsib.org.uk/news/publication-draft-health-service-safety-investigations-bill/ <ul style="list-style-type: none"> - Safe Space in healthcare safety investigations 2016 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/610034/Safe_space_consultation_govt_response.pdf • Issues raised – rising costs of clinical negligence. Government lacks cross-governmental strategy, requires engaging multiple stakeholders across the policy spectrum. <ul style="list-style-type: none"> - National Audit Office Report: Managing the costs of clinical negligence (2017) https://www.nao.org.uk/wp-content/uploads/2017/09/Managing-the-costs-of-clinical-negligence-in-trusts.pdf - Introducing caps on complainant costs.
Canada	Y	<ul style="list-style-type: none"> • Canadian Incident Analysis Framework http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF • Protection for disclosure and incident analysis

New Zealand	Y	<ul style="list-style-type: none"> Health Practitioner Competence Assurance Act 2003 http://www.legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html?search=ts_act%40bill%40regulation%40deemedreg_health+practitioner_resel_25_a&p=1 Quality assurance, confidentiality of information and protection from liability. No-fault compensation for patients harmed in the health care system. Covers all personal injuries and bars suing for compensatory damages. <ul style="list-style-type: none"> Wallis K, Dovey S. No-fault compensation for treatment injury in New Zealand: identifying threats to patient safety in primary care. <i>BMJ Qual Saf.</i> 2011;20(7):587-91. Wallis KA. New Zealand's 2005 'no-fault' compensation reforms and medical professional accountability for harm. <i>NZ Med J.</i> 2013;126(1371). Wallis KA. Learning from no-fault treatment injury claims to improve the safety of older patients. <i>Ann Fam Med.</i> 2015;13(5):472-4. Wallis KA. No-fault, no difference: no-fault compensation for medical injury and health care ethics and practice. <i>Br J Gen Pract.</i> 2017;67(654):38-9.
Singapore	Y	<ul style="list-style-type: none"> Private Hospitals and Medical Clinics Act https://elis.moh.gov.sg/elis/info.do?task=legislation&file=Act_PHMC_Act.pdf Quality assurance, confidentiality of information and protection against defamation. Sentinel event reporting and root cause analysis.
HEALTH INSURANCE		
United States	Y	<ul style="list-style-type: none"> Health Insurance Portability and Accountability Act 1996 Establishes policies and procedures for maintaining privacy and security of individually identifiable health information, offences relating to health care and civil/criminal penalties for violation.
OTHER		
Nigeria	N	<ul style="list-style-type: none"> Tribunal may investigate cases of malpractice/negligence by a health worker if reported by regulatory bodies. Issue raised – punishment perceived too weak.
Malaysia	N	
Chile	N	