Template for Feedback on HSE Open Disclosure Policy Revision DRAFT (1) 27th July 2021

Feedback returned on behalf of: Individual ☐ Organisation ☒ (please specify) ____Irish Medical Organisation_____

Please return completed template to OpenDisclosure.Office@hse.ie by 31st August 2021.

Page	Section	Wording	Comment/Feedback/Recommendations
Example 9	*Example 1.1*	*Example* *"Open disclosure is a core professional requirement which is anchored in professional ethics. Communicating effectively with persons affected in a compassionate, empathic and thoughtful manner, especially when providing information about a patient safety incident, is a crucial part of the therapeutic relationship and if done well can mitigate anxiety and enhance trust in the staff, the organisation and the health care system".*	
9	1.1	…When things go wrong it may be due to a combination of factors including the vulnerability of those receiving care, the fallibility of those providing care and the dynamic and complex nature of the health care environment… …Open disclosure is a core professional requirement which is anchored in professional ethics. Communicating effectively with persons affected in a compassionate, empathic and thoughtful manner, especially when providing information about a patient safety	The IMO supports Open Disclosure whereby patients have the right to an apology and explanation when things go wrong. Doctors and other healthcare professionals have a duty to be open, honest and transparent with patients, to reflect on adverse events and to take steps to ensure that such incidents are not repeated. Open Disclosure is not about apportioning blame but rather about keeping patients informed about investigations and preventing future patient safety incidents. Open Disclosure recognises that healthcare professionals are often the second victims of patient safety incidents and successful policies ensure that both patients and healthcare staff alike are supported throughout the disclosure process and the patient safety investigation.

		incident, is a crucial part of the therapeutic relationship and if done well can mitigate anxiety and enhance trust in the staff, the organisation and the health care system.	However, Open disclosure of patient safety incidents is a complex procedure where there are many variables feeding into cause and effect . Distilling the procedure down to clinical judgement on its own whilst ignoring the multiplicity of factors contributing to the overall outcome lacks balance and may leave clinicians out on a legal limb. There appears to be a narrative which is simplistic in so far as the outcome of a situation is purely based on clinical management - ignoring the factors which have contributed to this outcome - ie the delay in accessing the most appropriate investigations and subsequent treatments contributing to poor outcome. The lack of resources at General Practice level to access appropriate investigations ; the lack of provision for adequate clinics , theatre time , bed capacity - all of which contrive to delay timely treatment and increase risk of poor outcome which can be construed as an adverse event, subject of open disclosure, and for which clinicians may be held accountable. Overall there needs to be greater balance in accountability. Senior decision makers - whether they be senior managers overseeing local budgets or higher authorities who determine overall budgets – must be held to the same standard of accountability.
9-10	Section 1.2	**What is a Patient Safety Incident?** **….** Patient safety incidents may be caused because (i) something goes wrong during the care and treatment of the patient e.g. an error or failure occurs in the delivery of care and treatment which leads to an unexpected or unplanned outcome for the patient, (ii) a recognised risk,	The IMO has grave concerns about the definition of a patient safety incident. Patient care is increasingly complex and there are certain risks attached. Not all events that cause harm are the result of preventable patient safety incidents. In addition there are many health settings risks that create an avoidable risk such as outlined in 1.1 above and may contribute to delayed diagnosis and deterioration in the patient's condition.

		complication or side effect associated with the investigation or treatment of a patient materialises e.g. medication side effect, (iii) the patient was not provided with expected or planned care/treatment e.g. a routine investigation was not performed which lead to delay in diagnosis and further deterioration in the patient's condition and (iv) the outcome of the care and treatment provided was not as expected or hoped for by the patient/health services provider i.e. the patient's condition fails to improve or continues to deteriorate despite the best care and treatment e.g. cancer spreads to another organ.	The definition of a patient safety incident must ensure the following events are excluded: • events which can cause harm to the patient which are either unpredictable (for example, an allergic reaction to a medication that the patient had never taken before); • known side effects of treatment which were fully discussed with the patient in advance but can occur for an unknown reason (for example, a side effect of a medication which occurs in x% of the population but there is currently no way of determining who would suffer that side effect); • adverse events which occurred as a result of an unidentified or unidentifiable risk at the time of occurrence and that is subsequently identified (for example if a patient contracted a disease from a virus which was unknown at the time of the event). Similarly in clinical practice doctors are trained to monitor patient responses and react to clinical feedback. The definition of c), which describes near harm events, must ensure that the following events are excluded: ○ clinical events or reactions that are known and where all necessary action was taken to prevent any harm; ○ other adverse events that were avoided because risk assessment procedures ensured that the necessary actions were taken to reduce the risk of these events occurring. There must be some distinction between patient safety incidents where the implication is that the incident was unnecessary and preventable and other events which may arise despite the best efforts of all involved.

			If an overly broad interpretation is taken for a "patient safety incident" the system will become clogged with minor reports and the benefit of an appropriate open disclosure system will be lost. For example, all known medication side effects that result in negligible or minor harm to a patient (as per the HSE's Risk Impact Table) will initiate a low level response (Paragraph 1.13) and both the incident and the open disclosure meeting must be reported/documented on the National Incident Management System (NIMS). (paragraph 3.8.11) Points (ii) and (iv) should be excluded from the definition as they relate to known potential risks and treatment failure and should be included in the consent procedure. To include these in the definition of a patient safety incident blurs the distinction between avoidable and unavoidable adverse outcomes. While a glossary has been provided in the appendices, a clear glossary of terms is needed at the beginning of the document and the use of each term must be consistent throughout the document.
12	1.6	**Open Disclosure: The Staff Perspective:** .. There needs to be increased awareness at organisation level of the need for staff support and to have effective staff support systems in place which staff are aware of and which are easily accessible. Services should acknowledge the	Emphasis is placed on the psychological impact of patient safety incidents on healthcare staff, however, little acknowledgement is given to fear of litigation and reputational damage, which have been identified as the main barriers to open disclosure among medical professionals. Nor is there any acknowledgement of the potential impact on an individual's career or career decisions or the potential impact on physical health caused by stress.

		potential need for formal psychological intervention for particularly profound reactions e.g. Critical Incident Stress Management.	Clinicians have to and want to provide high quality health services, but in a clinical environment that abounds with systemic and resource related risks that are outside of their control, but that they may be considered accountable for, can already have a detrimental psychological effect contributing to stress and anxiety.
16	1.11	**Just Culture** … Whilst a just culture recognises that individual practitioners should not be held accountable for system failings over which they have no control staff also recognise that it does not absolve them of the need to behave responsibly and with professionalism. In contrast to a culture that touts no blame as its governing principle, a just culture does not tolerate conscious disregard of clear risks to service users or professional misconduct..	The IMO is concerned that there are significant imbalances in accountability and authority within our health system that impede quality and honest Open Disclosure with medical professionals often held accountable for incidents without the requisite authority while those with authority are rarely held accountable. Too often an adverse event occurs on a background of decisions made by senior managers in relation to the deployment or non-deployment of staff or resources. Often there are deficiencies in a system that are well known and documented, but not acted upon and only addressed when an adverse incident occurs. For example, health service managers are not held accountable in the same manner as medical professionals for non-compliance with the EWTD (European Working-Time Directive), gaps in consultant rotas, unsafe staffing levels, hospital overcrowding, long-waiting lists which can contribute to or compound patient care errors. The IMO would support the establishment of a process whereby the senior management and budget/fund holders in hospitals and other designated services are subject to accountability in the same manner as the medical profession. A just culture demands those responsible are accountable.
16	1.12	**Managing Open Disclosure** …	While the Civil Liability (Amendment) Act 2017 provides protections to healthcare professionals from liability and from fitness to practice

		In addition to the principles and process set out in this document, the Civil Liability (Amendment) Act, 2017, sets out some additional steps which provide certain statutory protections to such Open Disclosure.	hearings provided the disclosure takes place in accordance with the Act. However, the IMO has raised concerns that the prescribed statements as laid out in the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018, are onerous, require legal support and are not conducive to an open and honest conversation with a patient or their family. The IMO has called for a review of the current procedures and prescribed statements for Open Disclosure as laid out in the Civil Liability (Open Disclosure) (Prescribed Statements) Regulations 2018,to ensure that they are fit for purpose and do not negatively impact on the doctor-patient relationship, as this may harm the patient.
17	1.13	**Levels of Open Disclosure** … The duration of the open disclosure process will depend on the incident that has occurred, the number of patients involved, the progress of the incident review and the immediate and on-going needs of the patient.	There must be recognition that the Open Disclosure process along with incident management, investigation and clinical risk management processes reduces time spent on other clinical duties. Appropriate resources and protected time must be provided to allow doctors to be released from clinical duties to engage in training, open disclosure meetings, investigations and risk management. The open disclosure process needs to be appropriately resourced.
17-18	1.14	**Communicating Risks to Patients** It is important that complications, risks and side effects associated with medical conditions, care and treatment are communicated to patients in a timely manner that is open and which they can fully understand. Such communication must also explore benefits, the views of the patient and their options and be consistent with HSE values and the HSE Consent Policy.	Doctors communicate potential complications, risks and side-effects associated with care and treatment to their patients in line with professional guidance and legislation allowing patients to make choices about their care and treatment on the basis of informed consent. There are systemic and resource related risks that increase the chance of patient safety incidents, such as insufficient staffing and high workload (which can contribute to stress and errors) and lack of resilience rostering (so that sick staff can't stay home and instead

			may pose a threat if infecting patients), breaches of EWTD (tiredness is a known risk factor for poorer quality decision making), patient overcrowding (infectious diseases risk), inadequate bed capacity (infectious diseases risk as well as cause of delayed treatment), inadequate environmental hygiene (e.g. some hospitals were not designed to be easy to clean; some hospitals have an inadequate cleaning regime),excessive levels of noise (many health risks associated), inadequate patient information systems (e.g. unlinked or incomplete health records) etc. However, currently there is no requirement for senior and local managers within the HSE to inform patients of the known systemic and resource related risks before they consent to treatment. The IMO recommend that there should be a pre-admission disclosure to all patients accessing a service as to the already identified risks pertaining to that service.
20	3.4	**Events That Trigger Open Disclosure**	It is important to balance the harms that information can do to the patients wellbeing where it may be of no consequence in the long run, or there is no answer, in these cases, we may be psychologically burdening patients with information that in itself may cause harm, and which the lack of the information would have made no material difference to them. Formalising a process gives weight to the information shared, which may not be appropriate for relatively irrelevant or unimportant information. Part of the duty of care and skill of the clinician is to focus on what is important, taking into account the patient's needs, wants and preferences.
23	3.8.3	**Preparing for a Formal Open Disclosure Meeting** ...	Factors such as hospital overcrowding, insufficient allocation of resources, understaffing, all contribute to patient safety incidents. Non-medical contributing factors such as resource issues,

		Health services providers must adequately prepare for an open disclosure meeting by giving due consideration to: … • the need to consult with relevant stakeholders prior to the open disclosure meeting and to establish the facts available to the health services provider at the time of the open disclosure meeting i.e. a preliminary discussion with the relevant members of the multidisciplinary team to establish the clinical facts at the time of the incident should take place prior to the open disclosure meeting.	understaffing, systems failures must be ascertained and included in the disclosure process. It should also be ascertained if the incident relates to an item that has previously been flagged on a HSE risk register, along with the length of time that item has been on the risk register.
23	3.8.3	**Preparing for a Formal Open Disclosure Meeting** … Health services providers must adequately prepare for an open disclosure meeting by giving due consideration to: … • who should make the open disclosure i.e. establishing the open disclosure team. **Note:** The planning discussions should include all members of the healthcare team who will be involved in the	Where the patient safety incident is a direct result of resource deficits and decisions made by, senior managers and budget holders, then they should be responsible for leading the Open Disclosure Meeting.

		disclosure process. Consider the preferences/expectations of the patient as to who should attend/lead the open disclosure discussion. The team will generally include a lead discloser, a deputy discloser, a note taker and the designated person (See Table in Appendix C for Open Disclosure Team example). The senior clinician/principal healthcare provider who is responsible for the care of the patient should ideally lead the open disclosure discussion.	
26	3.8.6	**Information to be provided at an Open Disclosure Meeting** • Explain the facts available at the time of the open disclosure meeting in relation to how/why the patient safety incident occurred and any known event or factor which lead or contributed to it. Acknowledge what is not known at the time.	As per 3.8.3 above, Non-medical contributing factors such as resource issues, understaffing, systems failures must be included in the disclosure process. Where an incident relates to an item that has previously been flagged on a HSE Risk Register, that fact must also be disclosed to the patient along with the length of time that item has been on the risk register.
27	3.8.7	**Managing the Apology** … When a failure or error in the delivery of care/treatment has been established the patient and/or relevant person must be provided with a sincere and meaningful apology in a timely manner – this	Where deficits in resources and staffing or systems failures have been established there should also be an apology and acknowledgement or responsibility from the Senior Accountable Officer and Budget Holder.

		apology must be personal to the patient and to the given situation and must include an acknowledgement of responsibility.	
28	3.8.11	**Record Keeping**	Non-medical contributing factors such as resource issues, understaffing, systems failures must also be documented in the National Incident Management System (NIMS). Where an incident relates to an item that has previously been flagged on a HSE risk register, that fact must also be documented in the NIMS. As above, the IMO has called for a review the Civil Liability (Open Disclosure) Prescribed Statement Regulations 2018 which have been found to be unfit for purpose.
33	3.14	**Providing a Safe, Supportive Environment for Staff** The HSE will provide a safe, supportive and caring environment for staff involved in or affected by patient safety incidents: The HSE will ensure an environment where staff are safe and supported in the identification and reporting of patient safety incidents and also during the open	Resources and supports must be provided to the National Patient Safety Office to implement the HSE's open disclosure policy across the health services - not only in hospital services but across the health system including General Practice and community health services. • National Open disclosure leads must be appropriately resourced and staffed (administrative and training staff) to ensure the full implementation of the National Open Disclosure Policy across the health services. • Provide specific training in open disclosure to senior HSE Managers and Clinical Directors to ensure the benefits of

		disclosure and review process following a patient safety incident.	open disclosure are fully understood and embedded at senior management level. • Doctors and all health and social care professionals should be provided with comprehensive training in open disclosure and on induction. Training should be tailored for different clinical specialities and for different health and social care professionals. • Adequate supports must be provided for patients and their families and for staff following an adverse event including appropriate emotional and psychological supports and liaison staff. • A formal debriefing should be provided after a traumatic patient safety incident to all staff involved along with access to appropriate employee assistance programmes as required. • Appropriate resourcing of serious incident management and risk management teams. • There must be recognition that Open Disclosure, incident management, investigations and clinical risk management reduces time spent on other clinical duties. Appropriate resources must be provided to allow doctors to be released from clinical duties to engage in training, open disclosure meetings, investigations and risk management.
		3.14.2: The HSE will ensure that staff are aware of the clinical indemnity provided by the State Claims Agency on the basis of enterprise liability	Doctors should be informed of the limitations of the State Clinical Indemnity scheme which does not cover doctors for allegations in relation to poor professional performance.

		3.14.3: In addition, the HSE will ensure that staff are informed of the legal protections available to them under the provisions of Part 4 of the Civil Liability (Amendment) Act 2017 and of the procedure that must be followed for staff to avail of these protections. Part 4 of this Act provides certain protections regarding the information and apology provided during CLA Open Disclosure. To avail of the protections available within Part 4 of the Act the open disclosure process must be undertaken in strict compliance with (i) the procedure as set out in Part Four of the Act and (ii) the Civil Liability (Open Disclosure) Prescribed Statement Regulations 2018 accompanying Part 4 of the Act. • The Act is available **here** • This procedure is available **here** • The prescribed statements (forms) are available **here**	As above, the IMO has called for a review the Civil Liability (Open Disclosure) Prescribed Statement Regulations 2018 which have been found to be unfit for purpose.
	3.15.4	**Managing Open Disclosure of a Patient Safety Incidents occurring in another team or service**	

45	Section 5	**Scope** This policy is intended to cover all publicly funded health and social care services provided in Ireland including but not limited to: - Hospital Groups - Community Healthcare Organisations - National Ambulance Services - National Services e.g. National Screening Services, National Transport Medicine Programme, Irish Blood Transfusion Service - HSE Funded Agencies e.g. Section 38/39 agencies. Note: Following planned organisational restructuring these entities will transition to Regional Health Areas	General Practice is excluded from the Scope of this document. The IMO recommend that Specific Guidance and supports are developed for General Practice. Public Health Medicine is not really considered either and requires specific guidance.
48	8.4	**The Department of Health Supporting a Culture of Safety Quality and kindness: A Code of Conduct for Health and Social Service Providers (May 2018)** "Openness and transparency, honest communication, learning and accountability – we will communicate honestly and ensure learning when a service user has suffered harm as a	While the Code of Conduct applies to the Board and Management of Health and Social care providers, they are not held accountable in the same way as medical professionals. A just culture requires fairness and honesty in this. All decision makers need to be accountable for their decisions.

		result of care and accept full responsibility for our actions.”	
48	Section 9	**Performance and Accountability**	As per 1.1 above, the IMO would support the establishment of a process whereby the senior management and budget holders in hospitals and other designated services are subject to accountability in the same manner as the medical profession.
58	Section 14	**Appendix A: Glossary of Terms**	A clear and concise, Glossary of Terms is required at the beginning of the document. In Appendix A many of the definitions are confusing. For example the definition of a patient Safety Incident refers to the Civil liability (Amendment) Act 2017, while the definition of an Incident, a no harm incident and a near miss event are taken from a range of other documents. The definition of a Health Service Provider as per the Glossary of Terms defines Providers as external to the HSE.

General Comments / Further Suggestions:

Greater focus must be made on the prevention of patient safety incidents. IMO doctors have repeatedly expressed their concerns about inadequate staffing levels, insufficient hospital capacity, overcrowding and growing waiting lists for outpatient and elective care. The largest barrier to patient safety in the country is the low number of medical specialists per head of population and the inadequate distribution of resources based on medical or social need. Our health services are significantly over-stretched and clinicians are dealing with a constant stream of emergency patients without time or resources to adequately engage in audit and patient safety and quality improvement initiatives. It is imperative that all clinical services operate with sufficient minimum financial and manpower resources necessary to provide safe, quality