IRISH MEDICAL ORGANISATION
Ceardchumann Dochtúirí na hÉireann

IMO Submission to the Minister for Health on the

General Scheme of the Patient Safety Bill 2018

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The General Scheme of the Patient Safety Bill, published in July 2018 provides for the mandatory open disclosure and notification of serious reportable patient safety incidents, as well as the development of guidance in relation to clinical audit and publishing of outcomes. The Bill also extends the remit of HIQA to private health services and to undertake investigations where there is a serious risk to the health or welfare of service users.

The Irish Medical Organisation (IMO) is firmly committed to improving patient safety, however the IMO has some concerns in relation to the draft legislation as it currently stands, the resources provided to support open disclosure, imbalances in accountability and authority within the health system and the current mechanism of recourse to the courts to resolve clinical negligence claims. The IMO would therefore like to make the following recommendations under the headings of (1) Comments on the General Scheme of the Patient Safety Bill 2018, (2) Organisational Supports and Resources Required for Open Disclosure (3) Accountability and (4) Tort Reform.

1. Comments on the General Scheme of the Patient Safety Bill 2018

The IMO supports Open Disclosure not only as a measure to prevent litigation but more importantly because patients have the right to an apology and explanation, as well as the appropriate supports 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 incidents and investigations and preventing future patient safety issues.

In addition, Open Disclosure recognises that healthcare professionals are often the second victims of a patient safety incident. The practice of medicine is increasingly complex and though healthcare professionals aim to provide the best care for their patients, adverse incidents do occur. Most often harm is due to systems failure or unintentional human error - it is only in exceptional cases that harm is due to wilful misconduct. Successful Open Disclosure policies ensure that both patients and healthcare staff alike are supported throughout the disclosure process and the patient safety investigation.

Fear of litigation, fitness to practise procedures and damage to reputation have been identified as major barriers to open disclosure and the reporting of patient safety incidents. The IMO has been calling for a number of years for legislation to support Open Disclosure and has made a number of representations to the Oireachtas Health Committee on the Civil Liability (Amendment) Act 2017 which provides certain protections to healthcare professionals when making a voluntary open disclosure in accordance with the Act. Information and apology given in accordance with the requirements of the Act cannot constitute admission of liability or fault and cannot be admissible in civil proceedings, fitness to practice proceedings or disciplinary proceedings and cannot be used to invalidate insurance. Part 4 of the Civil Liability (Amendment) Act 2017 was commenced in September 2018 and the IMO has some concerns that the legislation regarding Open Disclosure is already to be amended without allowing any time to evaluate the existing provisions. In particular

the IMO is concerned that the forms and procedures for voluntary open disclosure under the 2017 Act are not fit for purpose under the proposed mandatory system.

The IMO recommends that legislative proposals to introduce mandatory open disclosure and reporting of serious patient safety incidents, as well as the publication of clinical audit, must ensure that medical practitioners are afforded the same protections as under the Civil Liability (Amendment) Act 2017.

Doctors should also be protected from inappropriate criminal proceedings when acting in good faith and disclosing and reporting patient safety incidents and participating in clinical audit in line with the legislation.

The IMO would like to make the following comments with regards to specific aspects of the draft Heads of Bill:

Definition of a Serious 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 issues. If an overly broad interpretation is taken for a "patient safety incident" in a mandatory reporting environment, the system will become clogged with minor reports and the benefit of an appropriate open disclosure system will be lost.

The definition of a patient safety incident under Head 5 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).**

Mandatory Open Disclosure

Head 6 Information disclosed and/or an apology provided in accordance with the procedures provided for under the Civil Liability Amendment Act 2017 will not constitute admission of liability or fault, will not be admissible in proceedings and cannot invalidate insurance.

The Heads of the Patient Safety Bill refer to the UK Duty of Candour Legislation which places the onus on the service provider rather than the individual practitioner to make the disclosure to the patient, however, under Part 4 of the Civil Liability (Amendment) Act 2017, the onus is clearly on the principal health practitioner to make the disclosure to the patient. **The Patient Safety Bill must ensure that it is the service provider that is responsible for disclosing serious patient safety incidents, and not individual practitioners who are already subject to sanctions by their statutory regulator.**

The IMO also has serious 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. **Prior to moving to a system of mandatory open disclosure, the IMO is calling for a review of the current procedures and prescribed statements for open disclosure under Part 4 of the Civil Liability (Amendment) Act 2017 to ensure that they are fit for purpose and do not negatively impact on the doctor-patient relationship.**

Factors such as hospital overcrowding, insufficient allocation of resources, understaffing, all contribute to patient safety incidents. **Non-medical factors such as resource issues, understaffing, systems failures must be included in the disclosure process.**

Following a recent high-profile case in the UK, doctors In Ireland are concerned that a case could arise in Ireland whereby an individual doctor could be subject to a criminal investigation for gross negligence manslaughter where death was caused by an unintentional clinical error and / or system's failure. The IMO are calling on the Government and the Medical Council to ensure that doctors are protected from criminal proceedings when acting in good faith and disclosing and reporting serious patient safety incidents. Cases of gross negligence manslaughter are rare in the UK and even rarer in Ireland, however, the threshold for gross negligence manslaughter in lower in Ireland than in the UK. **A review of gross negligence manslaughter in the healthcare sector is required to ensure that such criminal proceeding are not taken inappropriately against medical practitioners in Ireland. This review must take place before moving to a system of mandatory open disclosure and reporting of serious patient safety incidents.**

Patient safety incident notifications not admissible in certain civil proceedings

Under Head 8 and Head 9 - Serious patient safety incidents shall be reportable incidents. Within 7 days of becoming aware of a serious patient safety incident, a relevant health service provider must report a serious patient safety incident to the relevant authority - the State Claims Agency, HIQA, the Chief Inspector of Social Services or the Mental Health Commission. Under Head 11 provides for the voluntary reporting of near misses and no harm incidents.

Under Head 15, Patient Safety Incident notifications, made in accordance with the standards set by HIQA and the MHC will not be admissible in civil proceedings as evidence of liability of a health and social care provider (including any employee or agent of the provider acting in capacity of employee or agent). In order to support a culture of blame-free reporting and learning following adverse events, the same protections should apply to patient safety incident notifications as to open disclosure. **It should therefore be explicit that that the information contained in patient safety incident notifications (mandatory and voluntary) cannot be admissible either in civil proceedings, disciplinary or fitness to practice procedures against individual healthcare professionals and cannot invalidate insurance.**

In their Report on Pre-Legislative Scrutiny of the General Scheme of the Patient Safety Bill, the Oireachtas Joint Committee on Health recommends that a single database be used by the authorised bodies to record all reportable incidents and that a standard operating procedure be established to set out clear guidelines as to which agency is required to act upon notifications when necessary. The

IMO recommend also that a standard national incident reporting form is used, which ideally should be electronic and feed into the database in real time. The standard national incident reporting form must be designed with the end user in mind and should be piloted to ensure that it is fit for purpose and practical in a busy clinical environment. Again the non-medical factors that contribute to a patient safety incident must be identified in the reporting form.

Clinical Audit

Under Head 18 – the Minister will issue Guidance in relation to clinical audit and may issue guidance in relation to different categories of health service providers. The Guidance will cover the governance framework, the methodology, and identification of the relevant clinical standard.

The Minister for Health must ensure appropriate resources are available to implement the relevant clinical standard.

Under Head 21 a record created solely for the purposes of clinical audit will not be admissible in evidence where the audit has been carried out and published in accordance with Guidance issued by the Minister. Again in order to support a culture of blame-free reporting and learning, the same protections should apply to clinical audit as to open disclosure. **Records created for the purpose of clinical audit cannot be admissible in civil proceedings against healthcare professionals, disciplinary or fitness to practice procedures and cannot invalidate insurance.**

Under the draft Bill, Freedom of Information (FOI) exemptions will only apply to clinical audit that has been carried out in accordance with Ministerial Guidance., However under the Medical Council requirements to maintain professional competence, medical practitioners are required to carry out one clinical audit per year. **Records created for the purpose of all clinical audit should be exempt from FOI legislation.**

Part 4 Amendment of the Health Act 2007

The IMO welcomes the provisions under Part 9 which extends HIQA's remit to cover private health services in particular private facilities providing aesthetic surgery and non-surgery services.

The Bill amendment intends to include particular high risk services where the use of general anaesthetic is required to be administered to the patient, however the IMO is concerned that there are a range of private healthcare services that may not fall into this category including privately provided telemedicine services, slimming clinics, dermatology clinics, private ultrasound services, screening services etc, each with their own potential for risk of adverse outcomes. **HIQA's remit should be extended to cover all private healthcare facilities.**

2. Organisational Supports and Resources Required for Open Disclosure

Open Disclosure is a medical professional duty and has also been the policy of the HSE since 2013. In addition to legislation, additional resources and supports are required to support open disclosure including clear guidelines, comprehensive training and appropriate governance measures.

Open disclosure policies can fail without an organisational culture that supports open disclosure. Open disclosure can be both stressful and time consuming. Serious patient safety incidents are often

a result of system-wide failures and rarely attributable to the actions of a single individual. Often it can take some time to establish the facts, there may be differences in opinion between colleagues or a breakdown in communication.

Doctors as well as patients must have confidence in the open disclosure process and it is essential therefore that in addition to the proposed legislation, the Department of Health, and the HSE must ensure that all the supportive structures and resources are in place to support Open Disclosure not only in hospitals but also in general practice and community settings including education and training programmes, support from colleagues and line managers, guidance material, counselling services, risk management teams.

The evaluation of the HSE's National Open Disclosure pilot 2016, identified a number of challenges and barriers to implementing open disclosure as well as critical success factors. In particular, the evaluation found that:

> *"Reduced staffing levels and resources, resulting in a lack of time to implement open disclosure, carry out investigations and release staff for training, was seen to impact on an increased risk environment and the potential for errors to occur"*

Other challenges included the need for improved lines of accountability and support when an incident occurs, clear guidance on how and when to make a formal disclosure. Also the increasingly hostile environment from adverse media reporting was seen to impact on staff morale.

Critical success factors identified in the evaluation include a supportive hospital environment and organisational culture, leadership from hospital management and buy-in from clinical directors and clinicians, sufficient resources within the hospital including a risk management department with expertise to support and engage clinical and non-clinical staff in Open Disclosure, good quality training and clear guidance on reporting, including targeted training and guidance in clinical specialties, as well as multi-disciplinary approaches to reporting and learning.

The evaluation made a number of detailed recommendations to support the implementation of open disclosure across all health and social care settings, however the recent Inquiry into the CervicalCheck screening programme by Dr Gabriel Scally has revealed that Open Disclosure in relation to cervical screening has been significantly flawed with contradictory messages in the HSE/SCA guidelines, limited resources to support its implementation, difficulties engaging medical staff in the process and no systematic evaluation of the implementation of the policy or audit of its operation. In addition concerns were expressed from clinicians over responsibility for disclosure.

Within community settings there are little supports for General Practitioners, whilst there is advice and templates provided by the IMO, ICGP and the medical defence organisations, there are no HSE officers dedicated to support GPs in the disclosure process.

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 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.**
- **Open disclosure should be integrated into all medical and surgical undergraduate, postgraduate and CPD programmes.**
- **Clear guidance on open disclosure must be provided detailing when to disclose, how, as well as who is responsible for disclosure. Guidance should be tailored for different clinical specialties 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. Accountability

The IMO are concerned that there are significant imbalances in accountability and authority within our health system that impede quality 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 supports the recommendation by the Oireachtas Joint Committee on Health that a process be established to ensure that management in hospitals and other designated services are subject to accountability in the same manner as the medical profession.

4. Tort Reform

The current system of litigation following an adverse event is not in the interests of patients, healthcare professionals or the State.

Patients can often experience significant trauma or injury as a result of an adverse event. For many patients lengthy and expensive court proceedings are often the only recourse available to them in order to receive an explanation and compensation for what happened and to ensure appropriate long-term care and support. Further, this process can subject the patient to a considerable amount of emotional stress and serve to aggravate the patient's condition.

Doctors are often the second victims of an adverse event. In addition to the trauma of inadvertently causing injury to a patient, the majority of doctors undergo a significant amount of emotional stress as a result of litigation and fitness to practice procedures that may accompany litigation. Fear of damage to their reputation and loss of livelihood can impact on a doctor's psychological and physical health resulting in anxiety, depression and exacerbations of existing health problems.

In addition to the growing cost of claims experienced by the State Claims Agency, the consequences of an adversarial litigious system is that doctors will often practice defensively ordering more diagnostics or treatment than necessary or doctors may avoid treating certain high-risk patients. For some it may lead to early retirement or they may discourage others from entering the profession. In addition with increasing cost of medical indemnity, it may become impossible for certain specialties such as Obstetrics, Orthopaedics or spinal surgery to practice privately in Ireland, placing greater pressure on the public system.

A number of changes to Tort Law and the litigation process have been introduced to speed up the process and reduce the cost of litigation including the introduction of pre action protocols and case management rules as recommended by the Working Group on Medical Negligence (Legal Services Regulation Act 2015), measures to encourage greater use of mediation (Mediation Act 2017) and the introduction of periodic payment orders (Civil Liability (Amendment) Act 2017). However, the IMO is of the view that urgent consideration should be given to the introduction of a no-faults claims system for certain cases where there is no dispute about liability.

No faults claims mechanisms can provide timely and efficient access to compensation for injured parties without recourse to the courts. In addition no faults claims mechanisms can encourage reporting of patient safety incidents by separating the reporting system from the compensation mechanism. Under no faults claims systems it is no longer necessary to prove clinical negligence but patients do have to prove that the treatment or medical process caused them harm. No-Fault Claims mechanisms are criticised for increasing the number of claims. However, there is generally some guidance on compensation payments and awards and the legal bill is greatly reduced.

There is great variation in how no-fault claims mechanisms are implemented in different countries. For example in New Zealand the no-fault mechanism applies to all injury claims, while in France the system applies to certain injuries in the public system only. In certain US states of Florida and Virginia a no-fault claims system applies to birth injuries only. A balance can be struck between the potential increase in claims against the savings that can be made.

The Personal Injuries Assessment Board (PIAB), a statutory body set up in 2004, provides independent assessment of personal injury compensation for victims of workplace, motor and public liability accidents, without the need for many associated litigation costs. While some reform of the PIAB processes and awards may be needed, **consideration should be given to establishing a Medical Injuries Assessment Board (similar to the PIAB) to assess certain clinical negligence cases.**

Summary of Recommendations

Comments on the General Scheme of the Patient Safety Bill 2018

Definition of a Serious Patient Safety Incident

- **The definition of a patient safety incident under Head 5 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);**
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Mandatory Open Disclosure

- **The Patient Safety Bill must ensure that it is the service provider that is responsible for disclosing serious patient safety incidents, and not individual practitioners who are already subject to sanctions by their statutory regulator.**
- **Prior to moving to a system of mandatory open disclosure, the IMO is calling for a review of the current procedures and prescribed statements for open disclosure under Part 4 of the Civil Liability (Amendment) Act 2017 to ensure that they are fit for purpose and do not negatively impact on the doctor-patient relationship.**
- **Non-medical factors such as resource issues, understaffing, systems failures must be included in the disclosure process.**
- **A review of gross negligence manslaughter in the healthcare sector is required to ensure that such criminal proceeding are not taken inappropriately against medical practitioners in Ireland. This review must take place before moving to a system of mandatory open disclosure and reporting of serious patient safety incidents.**

Patient safety incident notifications not admissible in certain civil proceedings

- **It should therefore be explicit that that the information contained in patient safety incident notifications (mandatory and voluntary) cannot be admissible either in civil proceedings, disciplinary or fitness to practice procedures against individual healthcare professionals and cannot invalidate insurance.**

- **The IMO recommend also that a standard national incident reporting form is used, which ideally should be electronic and feed into the database in real time. The standard national incident reporting form must be designed with the end user in mind and should be piloted to ensure that it is fit for purpose and practical in a busy clinical environment. Again the non-medical factors that contribute to a patient safety incident must be identified in the reporting form.**

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- **Records created for the purpose of all clinical audit should be exempt from FOI legislation.**

Part 4 Amendment of the Health Act 2007

- **HIQA's remit should be extended to cover all private healthcare facilities.**

Organisational Supports and Resources Required for Open Disclosure

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- **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.**

Accountability

- **The IMO supports the recommendation by the Oireachtas Joint Committee on Health that a process be established to ensure that management in hospitals and other designated services are subject to accountability in the same manner as the medical profession.**

Tort Reform

- **Consideration should be given to establishing a Medical Injuries Assessment Board (similar to the PIAB) to assess certain clinical negligence cases.**