Submission to Judge Meenan Expert Group on the Management of Clinical Negligence Claims.

1. Introduction

The commitment in the Programme for Partnership Government (PfPG) states that "*the rising cost of claims will be tackled by establishing an expert group to report within 6 months on options for reforming the law of torts and the current claims process, particularly when it comes to birth injuries and catastrophic injuries, and injuries that can result from vaccination".* This current review was agreed by Government in June this year, partly to address that brief, but equally importantly to consider whether there might be an alternative mechanism to the court process for resolving clinical negligence claims, or particular categories of claims, particularly from the perspective of the person who has made the claim.

2. Role/Actions of the Department of Health

The Department of Health has undertaken the following actions relating to clinical negligence claims:

- Collaboration with the Department of Justice and Equality in formulating tort reform legislation
- Improving patient safety and minimising risk through in health and social care services through a broad range of actions
- Formulating patient safety legislation

2.1 *Collaboration with the Department of Justice and Equality in formulating its legislation*

The Department of Justice and Equality has passed a number of important Acts which will impact on how clinical negligence cases are managed. The full impact of the provisions in this legislation will not be obvious for a number of years.

2.1.1 The Legal Services Regulation Act 2015, No 65/2015

This Act inserts a number of provisions into the Civil Liability and Courts Act 2004 to provide for the use of pre-action protocols in clinical negligence actions. Work is underway on draft regulations for pre-action protocols for the management of clinical negligence actions. These regulations should help reduce the time that it takes for cases to move through the courts.

2.1.2. The Mediation Act 2017

This legislation promotes mediation as a viable, effective and efficient alternative to court proceedings, thereby reducing legal costs, speeding up the resolution of disputes and reducing the stress and acrimony which often accompany court proceedings.

2.1.3 The Civil Liability (Amendment) Act 2017

This Act gave the court the option to make Periodic Payment Orders (PPO) for catastrophically injured plaintiffs who require life-long care and attention. It also made provisions for Open Disclosure and during the passage of this Bill it was agreed that Open Disclosure would be placed on a mandatory footing for certain serious reportable patient safety incidents. See section 2.3.1 below for more details.

2.2. *Patient Safety Initiatives*

Any adverse clinical incident is one too many. While legislation has a role in reducing costs it cannot be seen as the only solution. Prevention through the role of education and training, clinical guidelines and best practice, learning from past experiences etc. are essential tools in delivering best care for patients and minimising risk in working conditions for the medical professions.

2.2.1 National Patient Safety Office (NPSO)

A National Patient Safety Office (NPSO) was established in the Department of Health in 2016. The NPSO is providing the required leadership with regard to patient safety policy, legislation and oversight. The NPSO is guided by a National Advisory Council for Patient Safety and has 3 streams (i) clinical effectiveness, (ii) patient safety surveillance and (iii) patient safety and advocacy policy.

(i) Clinical Effectiveness

Clinical effectiveness is a collection of activities and tools, based on research and measurement that are used to improve the quality of healthcare. The activities include, but are not limited to, guidelines, audit, research and evaluation.
The aim of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost effectiveness of healthcare in Ireland. To date 16 standards have been developed, which aim to improve the delivery of healthcare.

(ii) National Patient Safety Surveillance

A national patient safety surveillance system was established in 2017 which will provide evidence to inform patient safety policy and leadership decisions, bring data from many

sources together to inform prioritisation and monitoring of implementation. This creates the opportunity to address the 'precursors to harm, and not just the harm itself' and help to develop a 'problem sensing' culture that actively seeks patient safety alerts.

A surveillance system is likely to include, but is not limited to, elements on clinical activity, clinical outcomes, complaints trends, notifications to the Health Products Regulatory Authority, information from the Coroner and the State Claims Agency. The collection of data is not an endpoint and it is important that the surveillance of patient safety profiles for patients, service and clinical cohorts is part of the quality improvement cyclical process. It will also assist in identifying and developing processes to address data gaps of importance.

(iii) Patient Safety and Advocacy Policy

The Department of Health is developing a Patient Safety Complaints and Advocacy Policy. It aims to provide policy to improve how the health service responds to complaints and advance on the Programme for Partnership Government (2016) commitment to establish a national patient advocacy service. A national consultation is currently underway with stakeholders, staff and the public to inform the development of the policy.
The impact of the National Patient Safety Office and associated patient safety initiatives will be to ensure safe health services are informed by good data and supported by legislation. Surveillance of patient safety information will inform and direct patient safety improvements for hospital and community care. The national clinical effectiveness framework will promote evidence based healthcare and the focus on patient advocacy will ensure that service users have a say in the development and provision of safe effective services.

2.3 *Patient Safety Legislation*

The Department of Health is in the process of developing a range of patient safety legislation to strengthen healthcare systems and reduce the adverse incidents.

2.3.1 The Patient Safety Bill

The General Scheme of the Patient Safety Bill was published on 5 July this year. The Bill provides for mandatory open disclosure of serious reportable patient safety incidents, notification of reportable incidents, clinical audit to improve patient care and outcomes and it also extends the Health Information and Quality Authority's remit to private health services.

The purposes of open disclosure overall are to:

- ensure that patients are informed when adverse events happen as soon as is practicable,

- assist in supporting appropriate patient care,
- increase trust between patients and their clinicians,
- support staff in managing adverse events, and
- improve patient safety and quality of care through organisational learning.

Open Disclosure can be viewed as an integral part of patient safety incident management and it is Government policy that a system of open disclosure is in place and supported across the health system. Open disclosure is an open and consistent approach to communicating with patients and their families when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event. It is important for building patient and public trust in the health system. While the provisions in the Civil Liability (Amendment) Act were for voluntary open disclosure, it will be made mandatory for certain serious reportable incidents in this legislation.

The Minister will prescribe a list of reportable incidents which are required to be notified by public providers to the relevant reporting Authority (e.g. HIQA and the Mental Health Commission) and by private providers to the Mental Health Commission and the Chief Inspector of Social Services.

2.3.2 The Patient Safety Licensing Bill

Last December, the Government approved the draft general scheme of the Patient Safety (Licensing) Bill. The Oireachtas Joint Committee on Health and Children published its report on pre-legislative scrutiny of the draft Heads of the Bill on 17 July last.

When enacted, this Bill will require all hospitals in the State, public and private, to be in possession of a licence in order to operate. It will also apply to certain high risk activities that take place outside a hospital setting, such as those involving general anaesthesia. The licensing authority will be the Health Information and Quality Authority. The licensing regime will have a quality improvement approach, and will place a heavy emphasis on ensuring that appropriate clinical and corporate governance arrangements are in place so that the hospital is in a position to deliver all of the services which it is licensed to provide in as safe a manner as possible.

3. Accountability/Code of Conduct

Accountability, effective organisational alignment and good governance are central to the organisation and functioning of the health system. Staff at all levels within the health service

are accountable for their delivery of relevant aspects of the health service to the population within their responsibility through specific, known performance measures.

The Slaintecare Report placed an emphasis on the need for both clinical and managerial accountability and states that the *'Committee strongly believes there is a requirement for clearer clinical and managerial accountability and governance throughout the system. This includes clarity at all levels, from the Minister for Health, the Department of Health, the HSE and healthcare providers'.*

The Department of Health is finalising a new unified Code of Conduct (the Code) that applies to all service providers and individuals acting on behalf of those service providers that come into contact with a user of health or social services.[1] The primary objective of the Code is to ensure the safety of those that access our services, while striving to ensure that the quality of these services is always improving. The Code is intended to establish a single, shared ethos in health and social services provided publicly or privately, in any setting; hospital, mental health facility, community or home.

The guiding principles are:

- Patient Centredness / Putting people first – we will put the needs and the voices of service users, and those providing the services, at the centre of all of our work, treating both groups with kindness, dignity and respect. We will strive for equity in access and care for all.
- Kindness, Dignity and Respect – we will be kind, respectful and courteous in our dealings with service users, organisations and each other
- Openness and transparency, honest communication, learning and accountability - we will communicate honestly and ensure learning when a service user has suffered harm as a result of care and accept full responsibility for our actions.
- Excellence, Effectiveness and efficiency – we will take personal responsibility for excellence in our work, and seek continuous improvement through self- evaluation and innovation.
- Working together/team work and patient/family involvement – we will commit to collaborative working, and engage with people providing and people using the services in improving and developing all aspects of our work.

The Code sets out the obligations of service providers at Board and executive level to support them in adopting and adhering to the Code and in carrying out their duties. The Code also sets out the individual responsibilities of all health and social services employees, from those in support functions to those in the frontline, in the delivery of quality, safe care.

[1] Health or social services subject to the Health Acts 2004 to 2007 and the Mental Health Act 2001

4. Department of Health Oversight of Regulatory Bodies

An integral part of patient safety is ensuring that the health professionals providing health and social care services have protection of the public as a primary objective. The following professional regulators, the functions of which are set in legislation, regulate the clinical practice of the professions which provide health and social care. They are:
Medical Council of Ireland,
Nursing and Midwifery Board,
Dental Council,
Pharmaceutical Society of Ireland
Health and Social Care Professionals Council, and
Pre Hospital Emergency Care Council.

The Department monitors the governance and activities of these bodies and works with them where amendments are required to legislation to assist the bodies to carry out their roles more effectively.

5. Expenditure on Clinical Indemnity and General Insurance Schemes

The State provides indemnity insurance cover for clinical negligence claims and general insurance claims in respect of property, motor, and public liability. The State Claims Agency (SCA) has a statutory responsibility to manage claims to ensure that the State's liability and associated legal and other expenses are contained at the lowest achievable level. Its role also includes the recovery of costs from third parties.

- **2018 allocation:** €274m.
- **2017 Expenditure**: The net cost of both managing on-going active claims and the cost of resolving claims was €283.2m. This figure takes account of contributions from third parties, collected by the SCA.
- **2016 Expenditure**: The net cost of both managing on-going active claims and the cost of resolving claims was €228.9 million. This figure takes account of contributions from third parties, collected by the SCA.

5.1 Costs of clinical indemnity

The State Claims Agency has informed the Department that in actuarial terms the Clinical Indemnity Scheme, which was established in 2003, has yet to reach maturity and is not expected to plateau in terms of volume and cost of clinical claims until 2020 at the earliest.

The increasing costs of the Clinical Indemnity Scheme (CIS) are not due exclusively to the increasing numbers of claims but also to the increasing costs of awards and the very high costs associated with catastrophic injury claims.

- Two other factors can have a significant effect on costs.

- 2016 Court decision to decrease the Real Rate of Return (RROR) from 3% to 1.1%.
- Even though legislation for Periodic Payment Orders (PPOs) is in place, each Judge may still decide, on a case by case basis, whether to award a PPO as opposed to a lump sum award.
  While it is accepted that the use of PPOs may reduce the annual costs it is considered too early to assess the potential impact of PPOs as the relevant legislation was enacted in November 2017.

6. Catastrophic Birth Injuries

Birth related injury, and in particular catastrophic birth injury (mainly cerebral palsy), is the category of adverse clinic incident that incurs the highest costs. The number of cerebral palsy (CP) cases occurring in Irish hospitals is in line with the international norm of 3.50 per 1,000 live births. But not all CP cases are linked with clinical negligence.

CP can be caused by the following risk factors which may not be related to clinical negligence:-

- Low birth weight and premature birth;
- Disruption of blood and oxygen supply to the developing brain whether before or during birth;
- Maternal infection;
- Other factors such as birth defects of the central nervous system.

6.1 No-fault system for certain clinical negligence claims such as catastrophic birth injuries

New Zealand, Sweden, Finland, Norway, Denmark and France, and some American States have no fault systems. For example, in the New Zealand system, patients who sustain an avoidable medical injury can apply, without a lawyer, for compensation, regardless of whether their injuries can be attributed to the negligence or other wrongdoing of a medical professional.

Scotland has undertaken analysis and consultation on the issue. A Consultation Report setting out our proposed way forward was published on April 4, 2014. The report indicated that the Government would proceed with caution to explore the complexities of the scope, shape and development of a no-fault compensation scheme in Scotland.

An assessment was carried out by the Health Research Board in 2011 on the introduction of a no fault scheme in the case of catastrophic birth injuries in Ireland.

6.2 Advisory Group on No Fault Compensation for Brain Damaged Infants

An Advisory Group was established by the Department of Health in 2001 to examine the feasibility of establishing a no fault scheme for infants who suffered cerebral damage at, or close to, the time of their birth. This was chaired by Dr Peter McKenna, who has contacted the Review Group to say he would be happy to discuss this issue with the Group.

The Terms of reference of the Advisory Group were:
1. To examine the equity, effectiveness and appropriateness of existing arrangements for compensating persons who suffer cerebral damage at, or close to, the time of birth.

2. To review the clinical literature and other evidence on the causes of cerebral injury in infants.

3. To review the existing legal framework within which persons seeking compensation must process their claims.

4. To collect appropriate data on the incidence of brain damage caused in infancy.

5. To review existing services for persons who suffer cerebral injury.

6. To examine alternatives to that tort system whereby the care of brain damaged infants can be provided for including systems based on the no fault principle.

7. To examine strategies that might be used to reduce the incidence of cerebral damage at birth.

8. To make such recommendations as the Group sees fit.

The Group met on a number of occasions until around 2008 but failed to provide a report.

6.3 No-fault Scheme for Vaccine Damage

The Programme for a Partnership Government includes a commitment to "*…put in place a scheme, on a no-fault basis, that will respond to the needs of people with disability arising from vaccination*." The policy objectives in putting in place a scheme are to provide fair and just compensation for those who may have been injured by a vaccine administered as part of a State immunisation programme, to reduce the costs to the State by providing an alternative to litigation and to maintaining public confidence in immunisation. The Department is formulating a proposal based on evidence concerning vaccine damage schemes; taking into account inputs from the Department of Employment Affairs & Social Protection, PIAB, SCA, the Departments internal legal advice; and an evidence review of the international experience conducted by the Health Research Board.

August 2018