The National Patient Safety Office

Introduction

Patient safety is now a fundamental component of quality healthcare. The reality of harm that may be done to patients receiving care has only been recognised over the past 20 years or so, with the landmark study "*To Err is Human - Building a Safer Health System*" (1999) estimating that up to 98,000 people in the United States suffered fatalities as a result of medical error.

It is clear now therefore that delivery of healthcare is an inherently risky activity and it is inevitable that things will go wrong. Studies of adverse events worldwide demonstrate that between 4% and 16% of patients admitted to hospital experience one or more adverse events, of which up to half are preventable. Ireland is not out of sync with these statistics. Such incidents directly affect patients and families, while the associated costs are also of concern. The Irish National Adverse Events Study (INAES), based on 2009 records from Irish hospitals, found a prevalence of adverse events of 12.2%. In addition, patients who suffered an adverse event had a longer hospital stay and their care was a higher cost.

The OECD in 2017 estimated that more than 15% of hospital expenditure goes towards correcting preventable medical mistakes or infections that people catch in hospitals across its member countries. Expenditure in excess of €350 million is attributed by the State Claims Agency to healthcare patient safety claims for the years 2012-2016 for 2,809 claims. This figure is likely to continue to increase year on year unless actions are taken to prevent patient safety incidents through a set of patient safety and risk management initiatives.

Strategic Actions for Patient Safety as National Level

It is recognised that much can be done to prevent harm and error, to identify it when it occurs, to take actions to mitigate its effects and to learn lessons from the resulting investigations. In November 2015, the then Government approved a major programme of patient safety reforms focused on patient safety policy and legislation, extending the clinical effectiveness agenda and the establishment of a National Patient Safety Office (NPSO) in the Department of Health. The NPSO was officially launched by the Minister for Health in December 2016 and is now leading a programme of patient safety policy developments.

The work of the NPSO builds on significant developments in patient safety in recent years, including the publication of the Report of the Commission on Patient Safety and Quality Assurance

(2008), chaired by Professor Deirdre Madden, the establishment of HIQA in 2007, the publication of HIQA's *National Standards for Safer Better Healthcare* in 2012, the commencement by the HSE of national reporting of Serious Reportable Events in 2015, the establishment of the Quality Assurance and Verification Division in the HSE 2015 and the setting up of the National Incident Management System (NIMS) which has been rolled out across the health service.

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- The programme of patient safety centres on initiatives such as the establishment of a national patient advocacy service, the introduction of a patient safety surveillance system, the measurement of patient experience, extending the clinical effectiveness agenda and setting up an Independent Patient Safety Council.
- The NPSO is also progressing a programme of legislation.
- The NPSO works with a range of stakeholders in patient safety and seeks to include patient representation on committees and projects. It also organises and holds an annual National Patient Safety Office Conference. This attracts 400 delegates from across the country. The programme includes international speakers, national experts, workshops and posters. The most recent conference took place on 17th & 18th October 2018 in Dublin Castle.

A number of key patient safety initiatives are planned and being delivered under the auspices of the NPSO, as outlined below:

Legislation

- The **Patient Safety Licensing Bill**, which will for the first time introduce a licensing requirement for all hospitals, public and private, and certain designated high risk activities in the community was approved by Government in December 2017 and has been referred to the Oireachtas in order for drafting to commence. The Bill underwent Pre-Legislative Scrutiny at the Oireachtas Health Committee on 13 June last.
- In advance of a formal licensing regime for public and private hospitals it is proposed to bring the private/independent healthcare sector within the remit of the Health Act 2007. The relevant Heads, extending HIQA's powers to set and monitor standards, and

undertake investigations, where necessary, in the private healthcare sector are included in the Patient Safety Bill.

Open Disclosure

- In November 2015 the Government gave its approval to the drafting of provisions to support open disclosure of patient safety incidents. These provisions were included in the Department of Justice and Equality's Civil Liability (Amendment) Act which was signed into law in November 2017. The Act is part of a broader package of reforms aimed at improving the experience of those who are affected by adverse events.
- Part 4 of the Civil Liability (Amendment) Act 2017, which provides the legal framework to support open disclosure came into effect on 22nd September, 2018. The Civil Liability (Amendment) Act 2017 (Prescribed Statements) Regulations 2018 came into effect on the 23 September 2018.
- The general scheme of the Patient Safety Bill, which contains provisions for mandatory open disclosure of serious patient safety incidents, external reporting of serious patient safety incidents to HIQA, the Mental Health Commission and the State Claims Agency, clinical audit and extension of HIQA's powers to the private sector was approved by government on 8th May, 2018. The Bill underwent pre-legislative scrutiny at the Oireachtas Health Committee in September 2018.

Patient Safety Surveillance

- A National Patient Safety Surveillance System is being developed. This will involve interrogation of data and information from multiple datasets through a health analytic function in order to produce national patient safety profiles. This will then provide indications of where both challenges and good practice are emerging within the health system in order to direct and inform quality improvement.
- Continued publication of the Annual Report of the National Healthcare Quality Reporting System (NHQRS). The 4th Annual Report was published by the NPSO on 4th July 2018. The NHQRS aims to provide a mechanism through which data or information about the quality of Ireland's healthcare structures, processes and outcomes can be made publicly available and compared against acceptable standards

or best practice. It includes both intra and international comparison. In 2018 there are were total of 35 indicators of performance reported upon with a further 3 indicators to be added in the 2019 report.

- Patient Safety Statements – Maternity Patient Safety Statements have been published online monthly from each of the 19 maternity units from December 2015. Hospital Patient Safety Indicator Reports are also now published online by each hospital on a monthly basis.
- A Partnership of HIQA, the HSE and the Department of Health is leading work on Ireland's National Patient Experience Survey. The survey takes place each May, when all patients who were admitted to hospital during the month are invited to participate. The survey has been undertaken in 2017 and 2018, with almost 14,000 hospital patients responding to the survey on each occasion, a response rate above 50%. A national report has been published following each survey, with reports on the six participating hospital groups and each individual hospital also being released. The HSE are using the results of the survey to help improve the quality of care provided to hospital patients. In response to the results, each participating hospital has developed and published a quality improvement plan, while the Department of Health is also using the findings to inform national policy development, and HIQA is applying the results of the survey to guide its ongoing inspection work.

Policy Measures

- The development of a Patient Safety Complaints and Advocacy Policy saw a public consultation exercise which resulted in over 170 submissions undertaken during the summer of 2017, and the final report of that exercise has now been published. A competency framework for a patient safety complaints advocacy and training programme has also been developed. A new National Patient Advocacy Service will become operational in the second half of this year; it will provide independent support and advocacy for those who need it when something has gone wrong with their healthcare or when they have a complaint to make.
- Antimicrobial Resistance and Healthcare Associated Infections (AMR) Ireland's National Action Plan on Antimicrobial Resistance 2017 – 2020, (known as iNAP) was

jointly launched with the Department of Agriculture, Food and Marine in October 2017. This is in line with WHO and EU commitments to tackle this key patient safety issue in a cross sectoral approach. The impact of AMR/HCAIs has been seen recently in Ireland with the increasing numbers of cases of the superbug, CPE. In response to this and a National Public Health Emergency Team was established in October 2017. Work continues on both implementation of the iNAP and the actions on foot of the public health emergency.

- Patient safety is becoming embedded across major policies – both the Maternity and Cancer Strategies have dedicated sections on patient safety to drive improvements for both these services.
- HIQA and the Mental Health Commission have developed National Standards on the Conduct of Reviews of Patient Safety Incidents which expand on the National Standards for Safer Better Healthcare. This set of standards along with the mandatory reporting of serious reportable events provided for in the Health Information and Patient Safety Bill and the provisions intended for open disclosure will provide a comprehensive patient-centred approach to preventing, managing and learning from incidents. These informed the HSE Incident Management Framework published in January 2018.
- The establishment of an Independent Patient Safety Council is also being progressed.
- A review, in association with the Health Service Executive, the Office of the Ombudsman and the Department of Public Expenditure and Reform, of Statutory Instrument No. 652/2006 - Health Act 2004 (Complaints) Regulations 2006, with a view to enhancement of the statutory provisions for management of complaints within the health services, is ongoing.

Clinical Effectiveness

- Clinical effectiveness aims to ensure that healthcare practice is based on the best available data and evidence of effectiveness. It is a key component for improving patient safety and quality health service delivery.
- The National Clinical Effectiveness Committee (NCEC) was established in 2010 as a partnership between key stakeholders in patient safety and clinical effectiveness.

The NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service-user care. The NCEC members are appointed by the Minister for Health, and the committee is supported by the Clinical Effectiveness Unit of the Department of Health. Membership includes a wide range of stakeholders, including two patient representatives.

- To date, 18 NCEC National Clinical Guidelines have undergone prioritisation, quality assurance, endorsement and publication, including standardised approaches to the management of clinical deterioration, clinical handover, sepsis, diabetes, cancer and palliative care. A number are in development, for example in Maternity Care, Chronic Obstructive Airways Disease (COPD) and Prescribing in Dementia. The last guideline to be launched was the Emergency Department Early Warning System (EMEWS) in October 2018.
- The first NCEC National Clinical Audit (National Office for Clinical Audit's Major Trauma Audit) was prioritised, quality assured, endorsed and published in December 2016. A second clinical audit has been prioritised and is going through quality assurance. The audit function of the NCEC will be formally launched this year.
- The "Framework for Public Involvement in Clinical Effectiveness Process" was launched in March 2018. This framework contains information and practical tools for guideline and audit groups to assist them with meaningful public engagement. The aim is to strengthen public participation in healthcare decision-making by bringing public knowledge and experience to guideline and audit development.
- The "Implementation Guideline and Toolkit for National Clinical Guidelines" was published in September 2018 and provides support and guidance to help implement guidelines in the healthcare services. It is based on evidence from implementation science.
- The "National Standards for Clinical Practice Guidance" was published in November 2015. They aim to ensure consistency of approach and utilisation of appropriate methodology to develop clinical practice guidance nationally. Work is currently underway to update the Standards.

Patient Safety Incident Management

- An enhanced Communications Protocol for major Patient Safety Incidents between the Department and the HSE was finalised and agreed by HSE Leadership and Department's Management Board in October 2016. Further liaison between the NPSO and all relevant parties has continued. The Protocol continues to be used for major patient safety incident management and its fitness for purpose is kept under review.
- A new National Incident Management System (NIMS), hosted by the State Claims Agency, was introduced in 2014. Since June 2015 all incidents in the healthcare sector are now being reported directly on to NIMS, which facilitates more detailed and consistent reporting of these events. This is a key data resource for inclusion in the Patient Safety Surveillance System under development.

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