CLINICAL RISK INSIGHTS

Welcome to the first edition of Clinical Risk Insights, which is brought to you by the State Claims Agency (SCA). In this edition, we bring you an update on Open Disclosure, as well as articles on communication, medication safety and a clinical vignette relating to a claim where documentation came under the spotlight.

Editorial

Clinical Risk Unit - Our strategic priorities

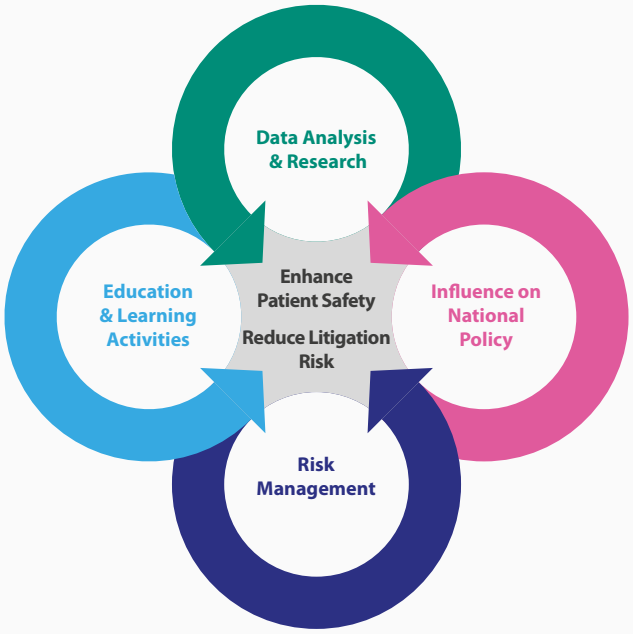


Figure 1: Clinical Risk Unit strategic priorities

The SCA indemnifies the HSE and other publicly funded health and social care organisations. The SCA also has a risk management mandate and indemnified organisations have a statutory obligation under the National Treasury Management Agency (Amendment) Act 2000 to report incidents and claims to the SCA.

The Clinical Risk Unit is one of the business units of the SCA and our mission is to innovate, promote, sponsor and support patient safety initiatives, drawing on data analysis and evidence. We also aim to inform policy, regulations, standards and clinical risk management strategies at local and national level in collaboration with key stakeholders.

What we do

We aim to deliver our strategic objectives by:

+ Reviewing, analysing and extracting learning from patient/service user safety incident and claims data.
+ Sharing that learning with health and social care enterprises and national stakeholders to inform risk mitigation strategies at local and national level.
+ Supporting health and social care enterprises and clinical risk management.
+ Providing advice on risk management and clinical indemnity.
+ Providing advice on the development of risk policies, regulations and standards at national level.
+ Developing, sponsoring and supporting safety initiatives.
+ Delivering education and training programmes.

Clinical Risk Insights will be published on a regular basis and through it we aim to provide our stakeholders with news on current issues relating to clinical risk and safety and quality as well as providing advice and guidance derived from our analysis of National Incident Management System (NIMS) data and claims analysis.

We hope you find Clinical Risk Insights will help you in your day-to-day work and we would love to hear your feedback.

Dr Cathal O'Keeffe
Head of Clinical Risk

Open Disclosure - An evolving landscape

Ann Duffy, Senior Clinical Risk Manager, discusses how Open Disclosure is changing in Ireland and what this means for health and social care professionals.

Patients/service users reasonably expect transparency and place their trust firmly in the hands of the professionals caring for them during their interaction with the healthcare system. Trust can be fragile and tested to the point of collapse when things go wrong and an incident or an outcome is not communicated or expressed clearly, and in a timely manner, by the health or social care professional.

What is Open Disclosure?

Open Disclosure is **"an open, consistent approach to communicating with patients 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".**

(Australian Commission on Safety & Quality in Healthcare. 2008)

Open Disclosure is not solely about error management. It is also relevant to patient/service user outcomes which may not have been expected but are not necessarily an error. When undertaken in an informed, clear and sensitive manner, Open Disclosure assists patients/service users and health and social care professionals to engage proactively about the incident or outcome.

How has Open Disclosure evolved in Ireland?

In 2008, the Commission on Patient Safety and Quality Assurance made a number of recommendations specific to Open Disclosure. Figure 2 outlines key milestones in the development of Open Disclosure in Ireland since then.

Figure 2: Key milestones in Open Disclosure in Ireland

Key recent developments

Civil Liability (Amendment) Act, Part 4, 2017:

The Act provides protection for Open Disclosure when undertaken by health and social care professionals. If disclosure is undertaken in accordance with the Act it does not invalidate indemnity or insurance, constitute an admission of liability nor is it admissible in legal proceedings.

Regulations for the Act were introduced in September 2018. To gain the protective provisions of the Act, prescribed forms must be used during the Open Disclosure process. A 'statement of information' must be provided at the initial Open Disclosure meeting. If for any reason the patient/service user cannot attend a meeting, requires additional information, refuses to accept the statement, or requests a clarity meeting, then a separate and specific prescribed form must be completed for each of these particular scenarios.

Training for doctors:

The HSE has commissioned the development of a Communications and Open Disclosure training programme for doctors, including current and future legislative requirements for Open Disclosure. The SCA will support the work of the HSE, professional bodies and other stakeholders to develop this programme.

HSE National Open Disclosure Steering Committee & National Open Disclosure Office:

To strengthen corporate oversight, strategic leadership and accountability in the practice of Open Disclosure, the HSE has established a National Open Disclosure Steering Committee. The committee will provide strategic guidance to the newly established HSE National Open Disclosure Office on the implementation of Open Disclosure taking account of current and upcoming legislation, and the recommendations of the Scally report.

Patient Safety Bill:

The Patient Safety Bill was published in 2018. When enacted, this will introduce mandatory reporting and disclosure of a prescribed list of serious patient safety incidents. The legislation will contain sanctions for failure to disclose such incidents.

So what does it mean for front-line staff?

+ Health and social care professionals need to be aware of the requirements to engage in Open Disclosure when things go wrong or unexpected outcomes occur in the care of their patients or service users.
+ To avail of legal protections, Open Disclosure must be undertaken using the forms set out in the regulations as prescribed by the Civil Liability (Amendment) Act 2017.
+ Mandatory Open Disclosure of certain serious patient safety events is likely to be a legal requirement in the near future.

Challenging times

The evolution of Open Disclosure in Ireland in recent years presents challenges for all those providing health and social care services. Practical support and education are required to assist health and social care professionals, and in particular the medical profession, to comply with the legislation. Transparency and disclosure are now expected more than ever before by patients and service users.

All health and social care professionals need to respond to the challenge by engaging with Open Disclosure as part of an on-going process of open, clear and honest communication between health and social care providers and patients/service users.

Medication incidents reported by Irish hospitals in 2018

Mark McCullagh, Clinical Risk Adviser, presents a selection of National Incident Management System (NIMS) data on medication incidents reported by Irish hospitals in 2018.

What is a medication incident?

A medication incident is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer.[1] The terms 'medication incident' and 'medication error' are similar.

What is the medication use process?

The medication use process describes the sequence of stages of medication utilisation from prescribing, transcribing, dispensing, administration through to monitoring.[2]

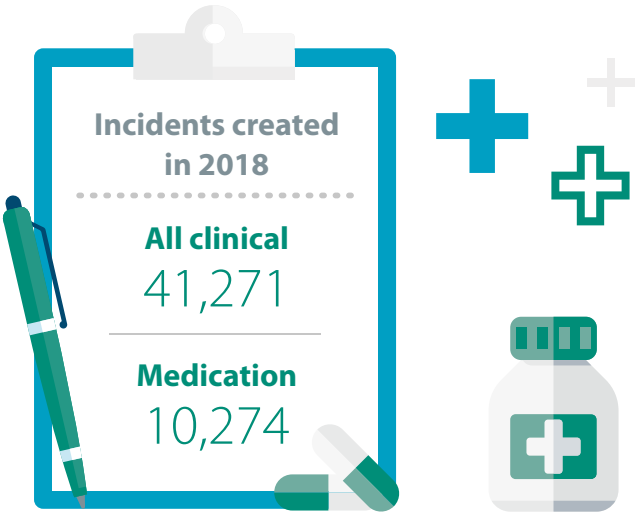
What is medication reconciliation?

Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route — and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points.[3]

Did you know?

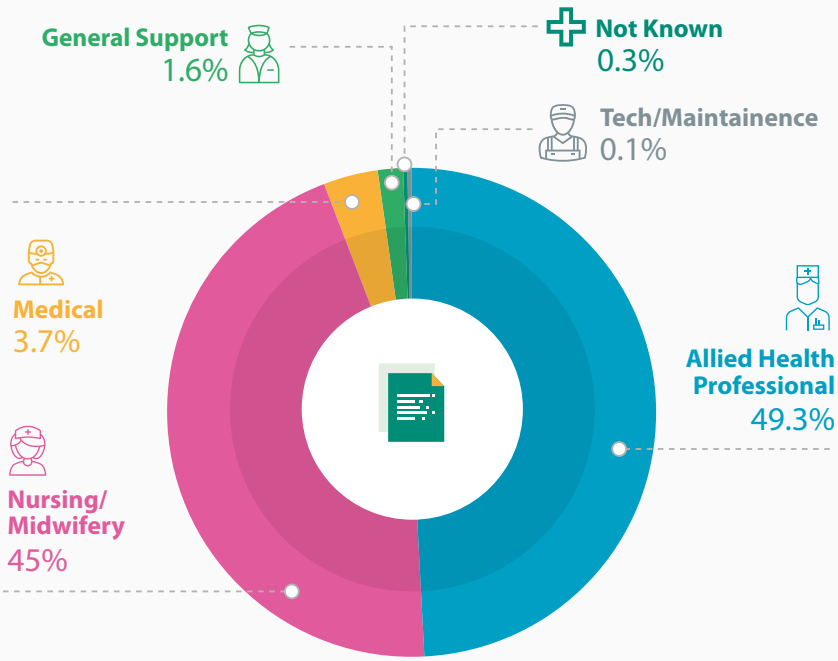
- A recent study across primary and secondary care estimated that **237 million medication errors** occur at the various stages of the medication use process each year in England, of which **25.8% and 2%** have the potential to cause moderate and severe harm respectively.[2]
- This same study estimated the cost to the NHS of definitely avoidable adverse drug reactions (ADRs) to be **£98.5 million (€115.3 million)** annually.
- The World Health Organisation launched its third Global Patient Safety Challenge in 2017. Entitled Medication without Harm, the aim of this challenge is to **reduce severe avoidable harm related to medications by 50% over five years.**[4]

Medication incidents in acute hospitals

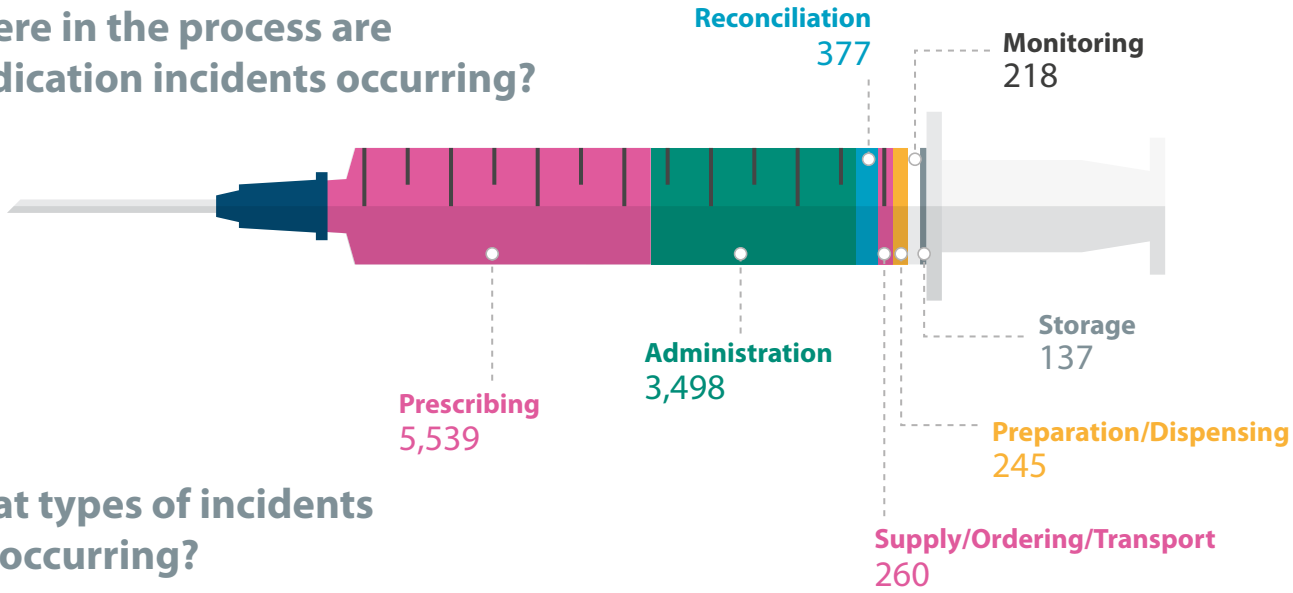


Higher incident reporting rates are considered nationally and internationally to be indicative of a stronger patient safety culture.[5]

Who's reporting medication incidents?



Where in the process are medication incidents occurring?



What types of incidents are occurring?

Incomplete/Inadequate	**2,428**
Wrong Dose/Strength	**2,127**
Omitted/Delayed Dose	**1,427**
Wrong Drug	**729**
Wrong Frequency	**726**
Not Performed when Indicated/Delay	**578**
Contraindicated	**535**
Adverse Drug Reaction	**504**
Wrong Quantity/Duration	**294**
Wrong Formulation/Route	**249**
Failure/Malfunction of Equipment	**195**
Wrong Label/Instructions	**180**
Drug Interaction	**156**
Wrong Patient	**146**

'Incomplete/Inadequate' was the most common incident category reported on NIMS in 2018. This category is frequently selected in conjunction with 'prescribing' to report incidents in which the prescriber has omitted important information on the prescription such as dose, route or frequency.

What can hospitals do to improve medication safety?

Provide **medication safety education and training** for health and social care professionals.

Ensure **availability of a recognised reference** source(s) at the point of prescribing.

Develop a **safe prescribing guide/app** to ensure non-consultant hospital doctors have access to evidence-based current prescribing guidelines.

Ensure clinical areas have **access to clinical pharmacy services.**

Ensure **medication reconciliation** at transfers between care settings.

Empower the patient or carer through participation in programmes such as the HSE's 'Know, Check, Ask' safer medicines campaign.

Encourage medication incident reporting and timely uploading to NIMS to allow detection of trends and clusters at both local and national level.

A report on medication incidents reported by Irish hospitals in 2017 & 2018 is due to published later in the year.
References available on request.

Let's talk about communication

Claire O'Regan*, Clinical Risk Adviser, and Ann Duffy, Senior Clinical Risk Manager, examine communication in healthcare and how it can be improved.

Open, clear and honest communication between health and social care providers and patients/service users, as well as effective inter-professional communication, is a critical element of effective, safe and professional health and social care delivery.

Is poor communication a problem?

Communication is a recognised skill which requires improvement. Review of closed claims by the Clinical Risk Unit of the State Claims Agency shows that deficits in written and verbal communication feature frequently as contributory factors to adverse outcomes. Service-delivery issues relate to sub-optimal documentation and handover within and between teams. Patient-related issues include:

+ Inadequate or incomplete consent for interventions.
+ Inadequate or incomplete Open Disclosure after adverse events/incidents.
+ Inadequate or incomplete handling of complaints.

The Medical Protection Society (MPS) reports that 70% of litigation in healthcare is related to poor communication. The society emphasises the importance of continuity of care, adequate transition of care, clear lines of communication with colleagues and clear lines of responsibility.[1] The Medical Council annual report 2018 stated 161 complaints had been received about poor communication with patients. This represents 56.09% of all complaints received.[2]

Breakdown in communication was the leading root cause of sentinel events reported to the Joint Commission in the USA between 1995 and 2006.[3]

According to Vincent and Amalberti (2016), 'poor communication across different settings is frequently implicated in studies of adverse events in hospital and in inquiries into major care failures in the community'.[4]

Communicating effectively and compassionately with patients/service users is an integral aspect of delivering care. Communication is a two way dialogue. Listening to a patient or service user's concerns, queries or feedback allows for a respectful partnership at a time when he/she can feel vulnerable, in an environment which may be alien to them. When explanations are clear, patients/service users have more confidence and trust in their health and social care provider. The avoidance of jargon, abbreviations and acronyms helps with providing clear explanations.

Complaints can arise and escalate when the patient/service user is unclear about their care pathway. This can be compounded if they perceive the style and delivery of communication as abrupt, dismissive, rushed or unprofessional. In the words of Maya Angelou: "I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel."

How can communication be improved?

Document well

Clear, concise, accurate, timely and legible documentation is required and expected when treating a patient. While there are valid reasons to make an entry to a clinical record retrospectively, any such entry should be clearly marked as retrospective and the rationale explained. Clear documentation, as described, can assist the defence of a claim, should one arise.

Use tools such as ISBAR and Huddles

The National Clinical Effectiveness Committee (NCEC) published its first clinical guideline in February 2013[5] – the National Early Warning Score – which incorporated the ISBAR communication tool, to facilitate a structured format for the handover of clinical care (Identification, Situation, Background, Assessment, and Recommendation). This tool was since augmented to R3 to include Risk and Read-back. Huddles provide a multi-disciplinary structured opportunity for handover of care, ensuring attendance of all staff.

Be aware of human factors

The application of human factors and attention to non-technical skills is recognised as essential to effective and safe health and social care delivery. There is increasing evidence that team-based initiatives and training in human factors is associated with significant reductions in adverse events and improvements in patient outcomes.[6] Non-technical skills include: situational awareness, decision making, communication and teamwork, and leadership.

Improve your skills through training

The National Patient Experience Survey (a joint initiative by HIQA, the HSE and the Department of Health) identified the development and improvement of communication and consultation skills as a key priority. A National Healthcare Communication Group reviewed patient comments in the national surveys, which led to the development of a National Healthcare Communication Programme.[7] This programme is a joint collaboration between the HSE and EACH (International Association for Communication in Healthcare). The programme 'is designed to support healthcare staff to learn, develop and maintain their communication skills with patients, their families and with colleagues'.

Attend the SCA's National Quality, Clinical Risk & Patient Safety Conference

This year's conference takes place on Tuesday, 19th November 2019 and will explore the theme of communication in the health and social care sector.

For more information visit: **https://bit.ly/2Yah48G**

References available on request.
**Please note that Claire O'Regan has left the SCA since writing this article.*

Closed Case Study – Keeping note

In this edition, Catherine Tarrant, Solicitor and Executive Head of Clinical Claims, takes a look back at a case that highlights the importance of careful assessment and taking careful clinical notes.

A patient successfully sued an Irish hospital when a miscarriage was inadvertently caused when a Mirena Coil was inserted while the patient was pregnant. The patient attended hospital, on referral from her General Practitioner, for the purposes of having a Mirena Coil inserted. The insertion was uneventful and the patient was discharged home. Unknown to herself at the time, the patient was in the early stages of pregnancy.

Some weeks later the patient was referred back to the hospital by her General Practitioner as she was complaining of malaise, nausea, tiredness and vaginal bleeding. A scan performed shortly thereafter revealed she was almost 10 weeks pregnant. The patient required admission to hospital where she continued to bleed and two days later passed a visible foetus.

Expert opinion stated that the miscarriage would most likely not have occurred had the Mirena Coil not been inserted while the patient was pregnant. The patient subsequently alleged that she had a major depressive disorder arising out of the miscarriage, and the case was settled for a substantial sum.

In this case there was no note of the patient having been questioned regarding the date of her last menstrual period or her sexual history. The medical staff maintained that they had questioned her regarding these issues and that she had given appropriate answers, but as there was no note of it anywhere in the chart, it was impossible to prove conclusively that these issues had been discussed. She was not advised that she should undergo a pregnancy test if there was any possibility that she may be pregnant. Had she been questioned on these issues, the miscarriage would most likely have been avoided.

This case provides an illustration of the importance of careful assessment of the patient before any procedure is undertaken and the importance of making careful notes of such discussions with the patient. Had the appropriate discussions taken place, this very regrettable outcome may well have been avoided.

Clinical Risk Insights
Noticeboard

NIMS QUERIES AND INFORMATION

+ For general queries, such as how to log an incident, contact the NIMS Helpdesk at **NIMSHelpdesk@ntma.ie** or **01 2384240.**
+ For HSE-related queries, such as system change requests, contact **NIMS@hse.ie.**
+ Additional information on NIMS training and accessing the National Incident Report Forms (NIRFs) can be found at: **https://bit.ly/2M66gqj.**

NATIONAL QUALITY, CLINICAL RISK & PATIENT SAFETY CONFERENCE 2019

Where? RDS Concert Hall Complex, Merrion Road, Dublin

When? Tuesday, 19 November 2019

This national conference aims to educate and inspire those involved in advancing patient and service user safety in health and social care, and will bring together national and international leaders in the field of patient safety to share their expertise and experience. Registration is now open here: **https://bit.ly/2Yah48G**

Closing date for Poster Abstract Submissions: Monday, 14 October 2019.

The Irish Medication Safety Network has issued a safety alert on **CycloGEST – CytoTEC Errors in Pregnancy.** For further information follow this link: **https://bit.ly/2OfYr3l**

Please note that the State Claims Agency has moved! Our new address is:

Treasury Dock
North Wall Quay
Dublin D01 A9T8

To provide feedback or to receive the e-edition of Clinical Risk Insights:

Please get in touch with **clinicalriskinsights@ntma.ie**

Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Ghníomhaireacht um Éilimh ar an Stát
State Claims Agency