State Claims Agency

Medication Incidents Report

A review of medication incidents reported by Irish acute hospitals (2017-2018)

Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Ghníomhaireacht um Éilimh ar an Stát
State Claims Agency

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Definitions

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.[1]

What is an adverse drug reaction (ADR)?

An ADR is defined as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product.[2]

What is the medication use process?

The medication use process has been described as a five stage process encompassing medication prescribing, transcribing, dispensing, administration and monitoring.[3]

What are high-risk (high alert) medications?

High-risk (high alert) medications are drugs that bear a heightened risk of causing significant patient harm when used in error.[4]

What is the NIMS (National Incident Management System)?

NIMS, the National Incident Management System, is a confidential highly secure web-based incident management tool developed by the SCA for the management of incidents throughout the incident lifecycle. It is used by members of the State indemnity schemes managed by the State Claims Agency (SCA) to fulfil the statutory requirement to report incidents to the SCA, as well as for their own risk management purposes. NIMS is also used by the SCA to support the implementation of its claims and risk management mandates. NIMS facilitates the reporting of incidents, management of incident reviews / investigations, recording of incident review / investigation conclusions and recommendations, tracking of recommendations to closure, and analysis of incident and claims data.

Introduction

Medication incidents are common, potentially devastating for patients and their families and costly for healthcare providers.

It has been estimated that 1-2% of patients admitted to hospitals in the United States (US) every year are harmed by medication errors.[5] The Food and Drug Administration (FDA) estimates that medication errors cost 7,000 lives in the US annually.[6] The annual financial cost of medication errors has been estimated at $3.5 billion in the US[7] and $42 billion worldwide[8]. A recent study of medication incidents in the National Health Service (NHS) in England, across primary and secondary care, estimated that 237 million medication incidents occur at the various stages of the medication use process every year.[3] The same study estimated that avoidable ADRs cause 712 deaths and contribute to 1,708 deaths, and have a financial cost of £98.5 million annually.

Reporting rates do not reflect the incidence of medication incidents. It is estimated that less than 1% of medication errors are reported spontaneously.[9] Higher incident reporting rates are accepted nationally and internationally as evidence of a stronger patient safety culture.[10]

The State Claims Agency (SCA) previously published a report on medication incidents reported by Irish hospitals based on 2016 data.[11] This report, for 2017 and 2018, builds on the work of the earlier report. Data was selected for this report by 'Incident Create Date' rather than 'Date of Incident' as this facilitates expeditious data extraction and more timely evaluation of system engagement, and is in line with international reporting practice.[12] As a result, caution should be exercised when comparing like for like data in this report with the data presented in the previous report.

Methodology

NIMS was searched for medication incidents reported (created) by all Irish acute hospitals (n=50) from 1 January 2017 to 31 December 2018 (inclusive). The data was analysed under various headings.

Results

Medication incidents reported by Irish hospitals, 2013-2018

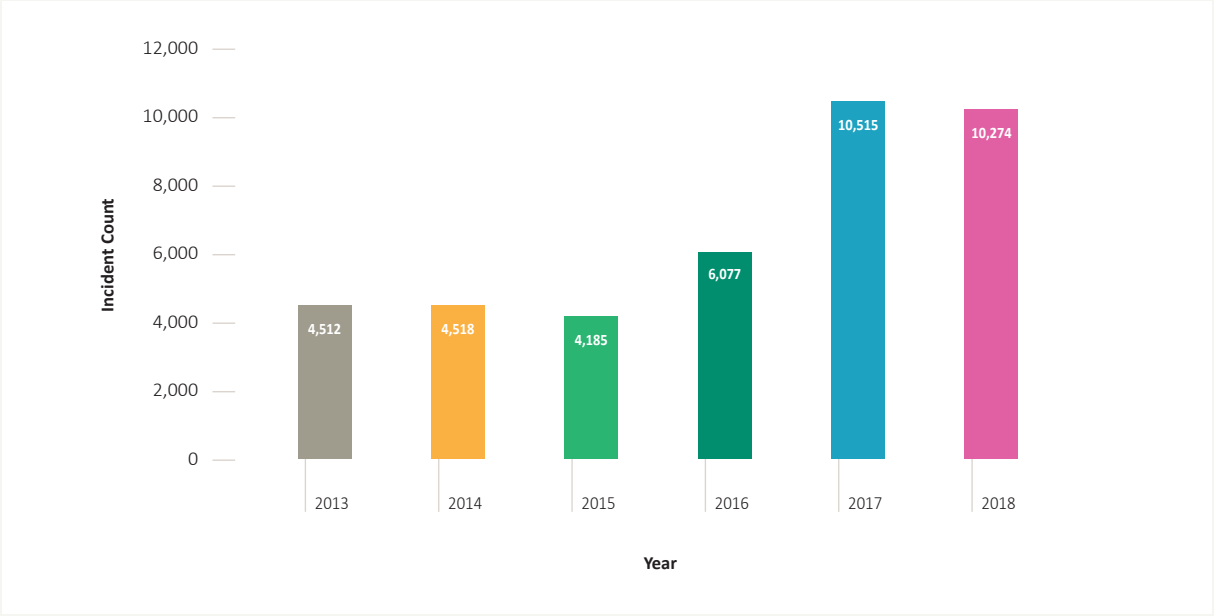

Figure 1. Medication incidents reported by year, 2013-2018 inclusive.

There were 10,515 medication incidents reported by Irish acute hospitals in 2017 and 10,274 in 2018 (Figure 1; for illustrative purposes the total numbers of medication incidents reported annually from 2013 to 2018 inclusive are presented). This represented 27.4% of all clinical incidents reported in 2017 and 24.9% in 2018 (Table 1). The 2018 total was 2.3% lower than the 2017 total, although this was more than double that recorded in 2015. The percentage of medication incident reports where the medication name was omitted, i.e. left blank, was 11.9% in 2017 and 3.1% in 2018.

Incident Description	2017	2018
Total clinical care incidents	38,415	41,266
Medication incidents	10,515	10,274
Medication incidents as % of total	27.4%	24.9%

Table 1. Medication incidents as percentage of all reported clinical incidents.

Who reports medication incidents?

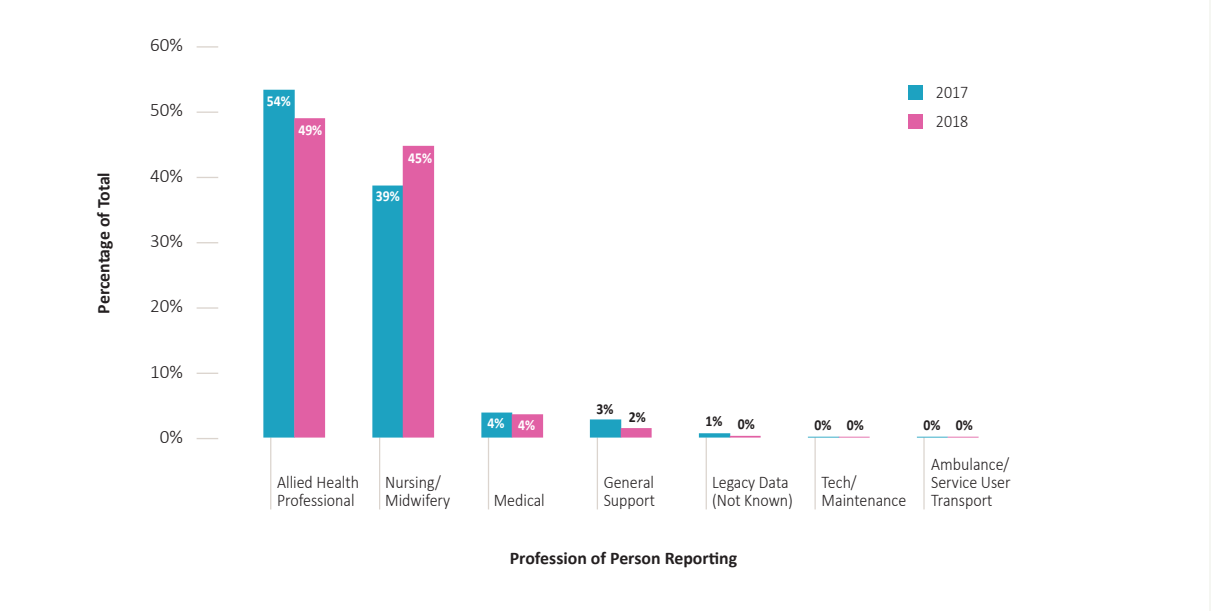

Figure 2. Medication incidents by profession reporting.

Allied health professionals (i.e. health professionals other than doctors, dentists and nurses) were the largest contributors of medication incident reports, submitting more than half of all reports (54%) in 2017 and just under half (49%) in 2018 (Figure 2). Nurses and midwives contributed 39% of medication incident reports in 2017 and 45% in 2018. Medical professionals contributed 4% of medication incident reports in both years, while general support staff contributed 3% in 2017 and 2% in 2018.

Medication incidents by severity

Severity	2017	2018
Extreme	8	10
Major	4	7
Moderate	426	454
Minor	283	212
Negligible	9,794	9,591
Total	**10,515**	**10,274**

Table 2. Medication incidents by severity.

Table 2 shows medication incidents reported in 2017 and 2018 by severity rating. The data is consistent, with incidents similarly distributed across severity categories in both years. The vast majority of medication incidents are reported as negligible severity incidents, i.e. no injury / injury not requiring first aid. The incidence of moderate rated incidents, i.e. injury requiring medical treatment, is approximately double that of minor rated incidents, i.e. injury requiring first aid. In both categories the numbers are in the low hundreds. The incidence of extreme rated incidents, i.e. permanent incapacity / death, is slightly higher than major rated incidents, i.e. long-term incapacity, although the numbers in both these categories are small.

Medication incidents by stage of the medication use process

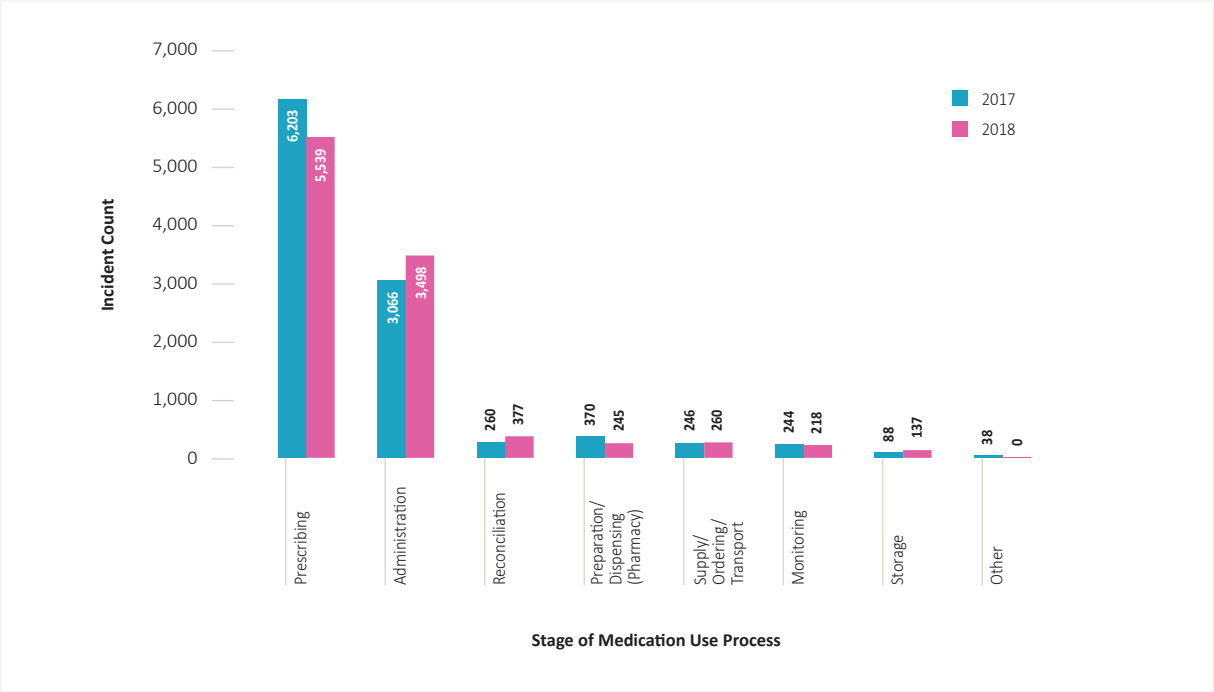

Figure 3. Medication incidents by stage of process.

Prescribing errors accounted for the majority of medication incidents created in both 2017 (59.0%) and 2018 (53.9%). Administration errors accounted for 29.2% in 2017 and 34.0% in 2018. Other stages of the medication use process accounted for significantly less medication incidents in both years (Figure 3).

Medication incidents by incident category

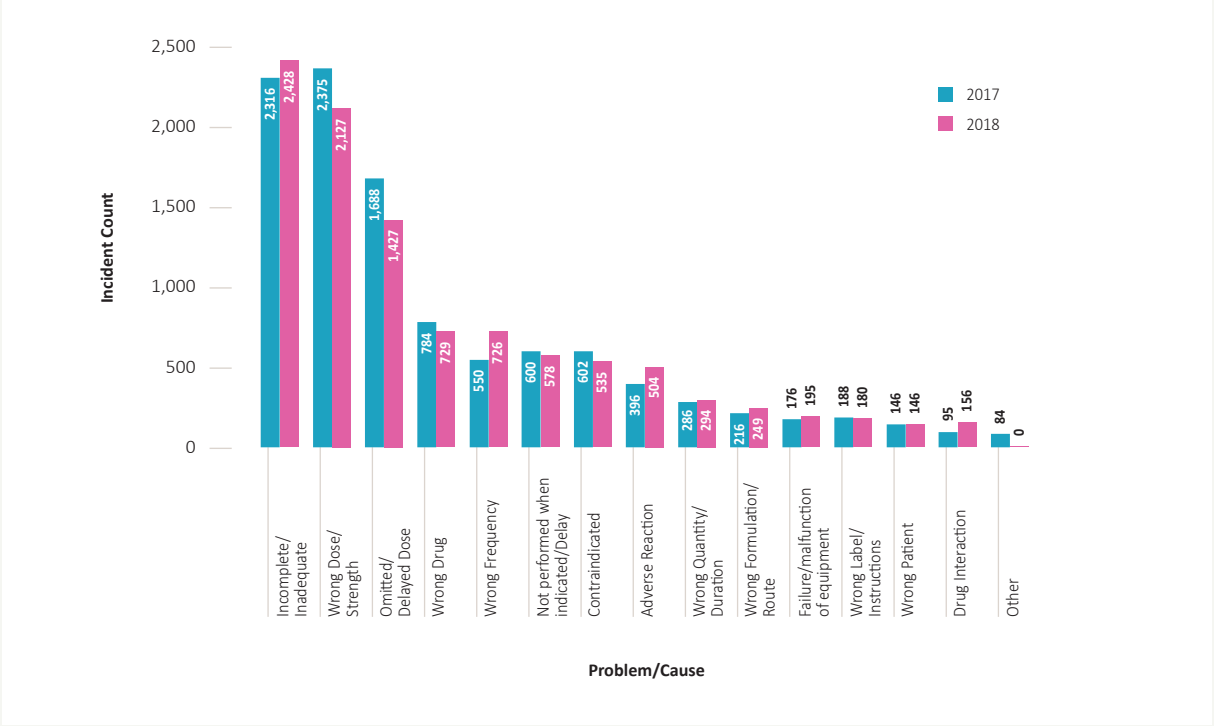

Figure 4. Medication incidents by incident category.

The data was analysed by incident category (problem / cause on NIMS; Figure 4). The largest incident category over the two year period was 'incomplete / inadequate', which was selected in 22.0% of medication incidents in 2017 and 23.6% in 2018.* 'Wrong dose / strength' was the second largest incident category over the two years, accounting for 22.6% of incidents in 2017 and 20.7% in 2018. Omitted / delayed dose was the third largest incident category in this dataset, accounting for 16.1% of incidents in 2017 and 13.9% of incidents in 2018. Combined, these three incident categories accounted for 60.7% of medication incidents by category in 2017 and 58.2% in 2018. Other incident categories accounted for smaller numbers of medication incidents.

* Incomplete / inadequate is an incident category frequently selected when there has been an omission or inadequacy in the medication use process e.g. prescribing which omits the dose, route or frequency of a medication.

Top 10 medication groups at ATC level 3

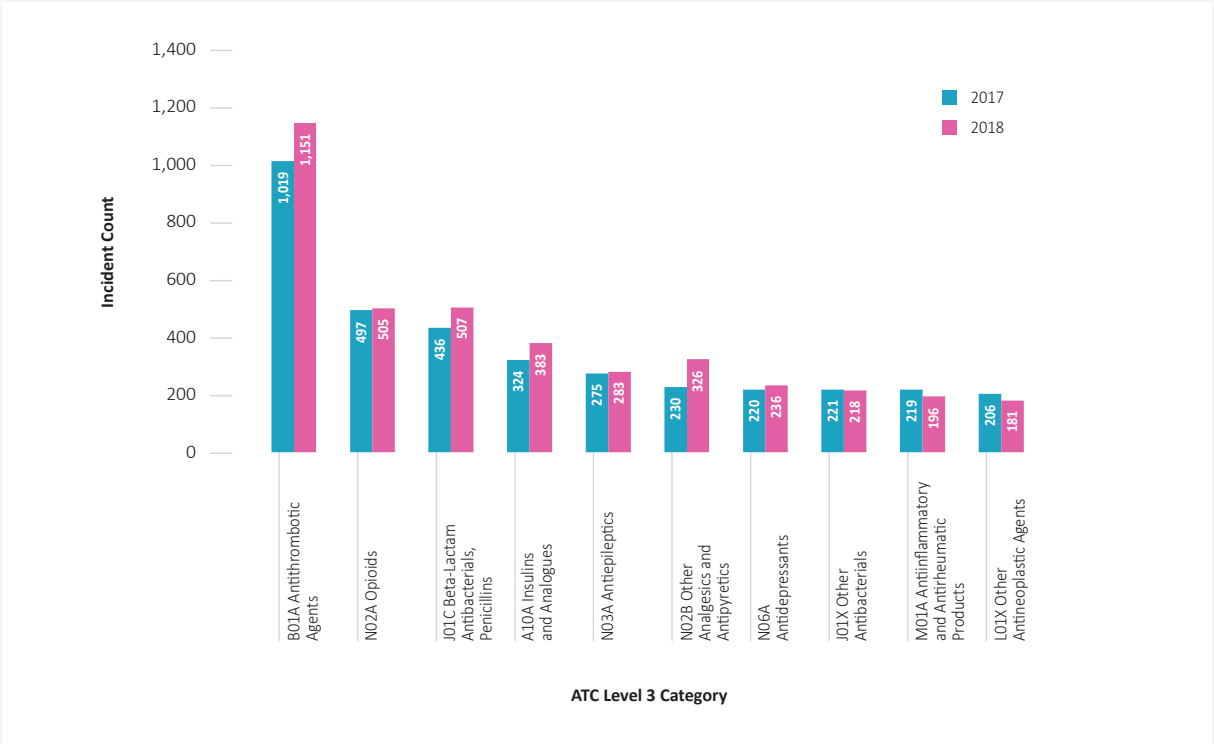

Figure 5. Top 10 medication groups at ATC level 3.

NIMS classifies medications according to the WHO anatomic, therapeutic, chemical (ATC) classification system.[13] Figure 5 shows the top 10 medication groups at ATC level 3, i.e. pharmacologic or therapeutic subgroup. Antithrombotic agents comprised 9.7% of all medication incidents reported in 2017 and 11.2% in 2018. The number of antithrombotic incidents is more than twice the number of the next most frequently implicated group, opioids, which are followed by penicillins, insulins and antiepileptics.

Top 10 drugs involved in medication incidents

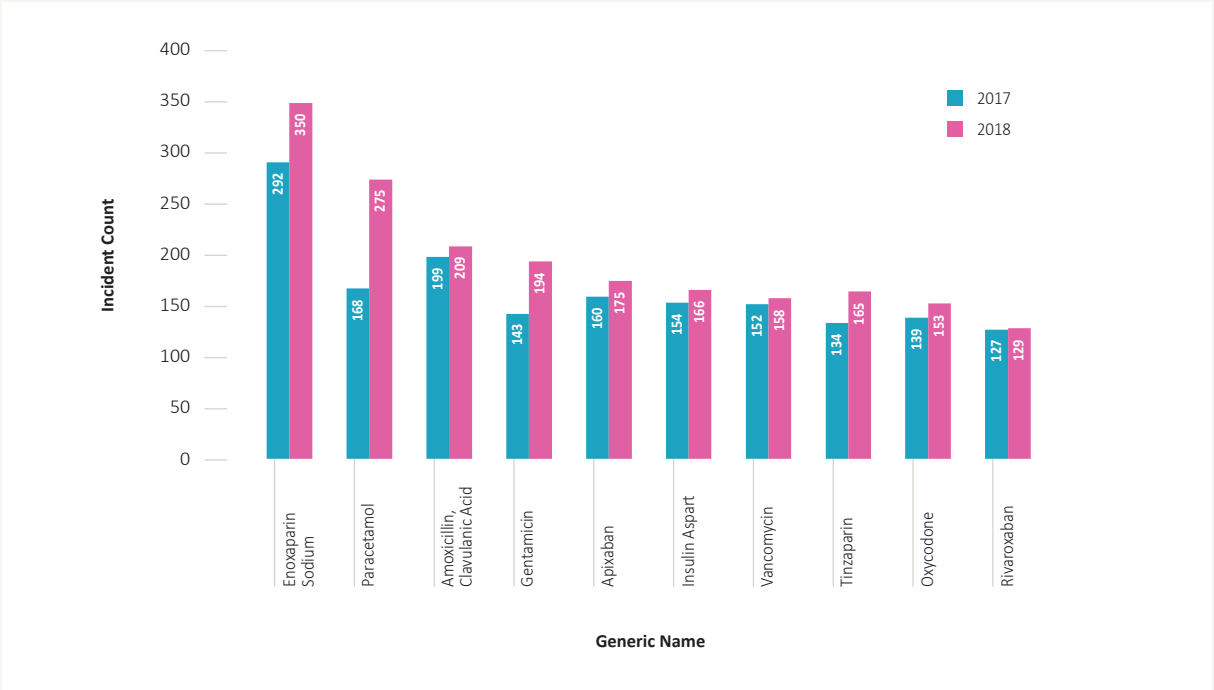

Figure 6. Top 10 drugs involved in medication incidents.

The data was analysed by generic name (Figure 6). The individual medications identified reflect the medication groups at ATC level 3 (Figure 5). There are four antithrombotic agents in the top 10 including enoxaparin (2.8% of all medication incidents reported in 2017 and 3.4% in 2018), apixaban, tinzaparin and rivaroxaban.

Paracetamol incidents are the second highest by number associated with a single agent over the review period and show an increase in 2018 compared to 2017. There are three antibiotics, namely amoxicillin / clavulanic acid, gentamicin and vancomycin, in the top 10. The other agents to feature in the top 10 are insulin aspart and the opioid, oxycodone.

Focus areas

Focus area 1: medication incidents involving antithrombotic agents

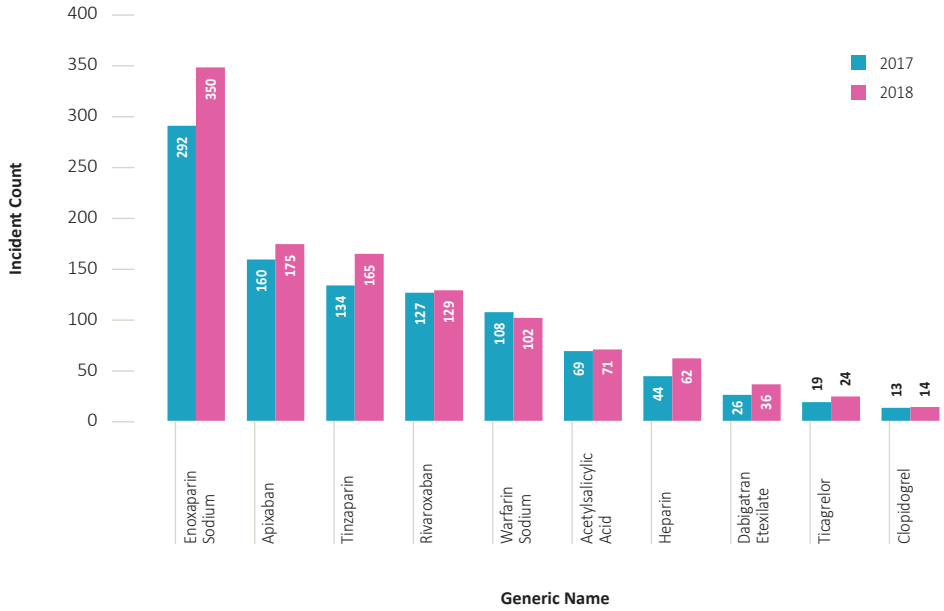

Figure 7. Top 10 antithrombotic agents involved in medication incidents.

Antithrombotics were the ATC level 3 group involved in the largest number of medication incidents in this review (Figure 5) and contributed four of the top 10 most commonly implicated drugs (Figure 6). This prompted further analysis of antithrombotic medication incidents.

Figure 7 shows the top 10 antithrombotic agents involved in medication incidents in 2017 and 2018. Enoxaparin is associated with twice as many medication incidents as the next most commonly implicated agents, and the annual figures for enoxaparin have more than doubled since a similar study in 2016.[11] Other heparins, namely tinzaparin and unfractionated heparin, featured in third and seventh places respectively.

The direct acting oral anticoagulants (DOACs), apixaban and rivaroxaban, appear in second and fourth places respectively. Annual figures for apixaban and rivaroxaban have almost tripled compared to the 2016 figures.[11] While this increase may reflect increasing usage, an increase of this order is a cause for concern and merits ongoing review.

Warfarin is in fifth position and is notable as it was the only agent in this series to see a reduction in medication incidents in 2018 compared to 2017, although this may reflect declining use. Aspirin (acetylsalicylic acid) featured in sixth place whilst dabigatran, ticagelor and clopidogrel were associated with smaller numbers of incidents.

Focus area 2: paracetamol incidents

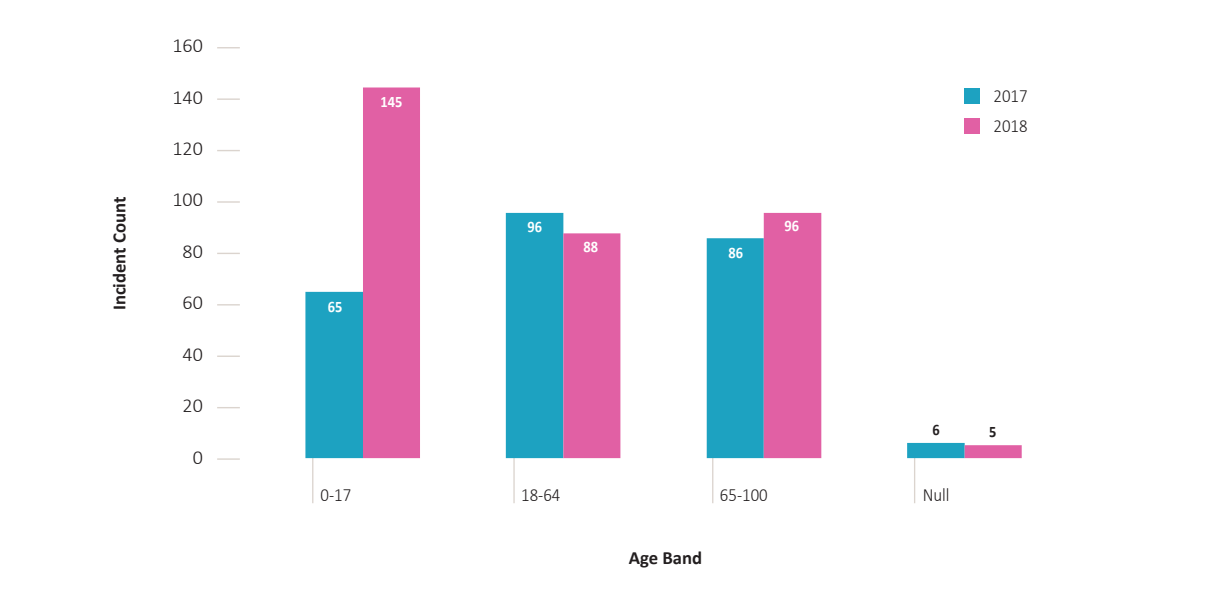

Figure 8. Paracetamol incidents by age band.

There was a 63.7% increase in paracetamol-related incidents in 2018 compared to 2017 (Figure 6). Paracetamol is widely used in hospitals in oral, intravenous and rectal forms, and, when used at therapeutic doses, is generally considered safe. The significant increase in paracetamol associated incidents warranted further investigation.

Analysis of paracetamol incident data revealed that there was a 36.3% increase in prescribing incidents, a 29.9% increase in wrong dose / strength incidents and a 123.1% increase in incidents in those aged 0-17 years in 2018 compared to 2017 (Figure 8). This increase in the 0-17 age band is in contrast to the other two age bands in which the yearly totals are broadly similar. Null represents reports in which the patient's age was omitted. Possible reasons for the doubling of incidents in children include the complicated dosing regimen based on age and the availability of multiple formulations. However, these factors have not changed in recent years.

Focus area 3: penicillin allergy

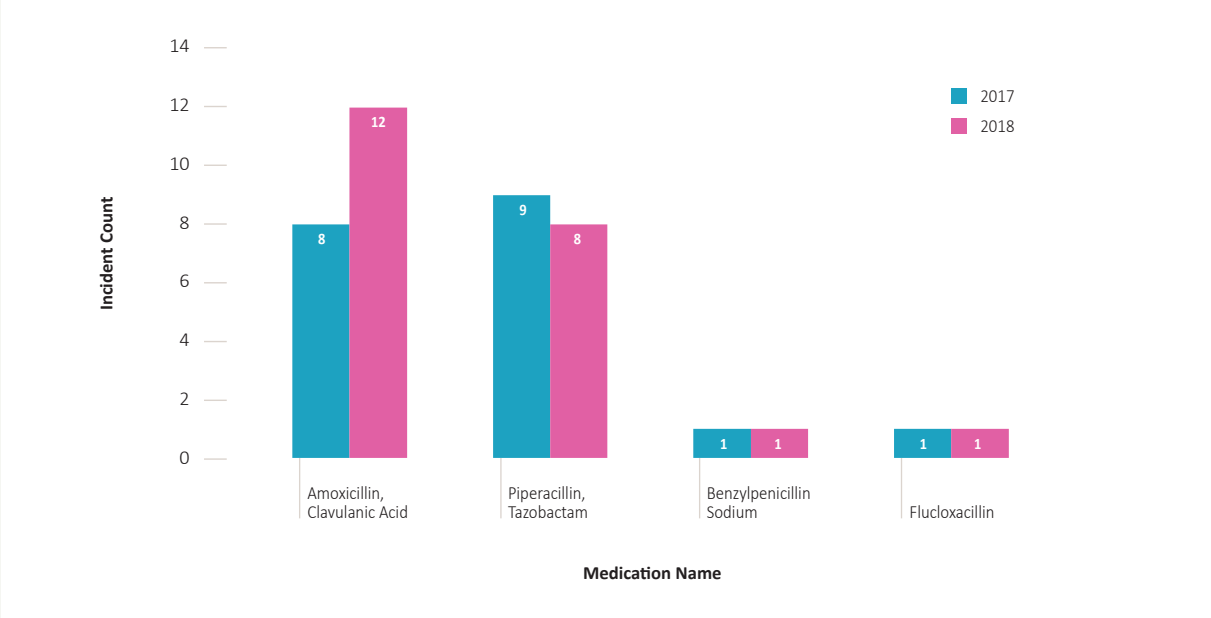

Figure 9. Penicillin allergy incidents by generic name and year.

Allergy is a well-recognised adverse effect of penicillin antibiotics. Nonetheless, the SCA continues to receive reports of allergic reactions to penicillins, including in patients with a previously documented penicillin allergy. This prompted further analysis of penicillin allergy incidents.

Figure 9 shows penicillin allergy incidents by generic name and by year. There were 41 penicillin allergy incidents reported by Irish acute hospitals over the two year period. The patient's allergy status was previously known in 15 (37%) of these incidents. Co-amoxiclav and piperacillin / tazobactam accounted for 90% of penicillin allergy incidents.[14]

Discussion

The WHO launched the third global patient safety challenge entitled 'Medication Without Harm' in 2017 with the stated aim of reducing severe, avoidable harm related to medication by 50% over five years.[8] This SCA report contributes information on medication incidents reported by Irish acute hospitals in 2017 and 2018. It demonstrates the benefits of clinical incident reporting and the potential for national learning that NIMS affords the Irish healthcare system.

There has been a welcome increase in medication incident reporting since 2016. This may be due, in part, to improvements in NIMS functionality. Medication incident reporting appeared to plateau in 2018. However, in line with international evidence, it is likely that medication incidents remain under-reported. In 2018, 24.9% of all reported clinical incidents were medication incidents, which compares well with medication incidents accounting for 9.7% of all patient safety incidents in a six year review of National Health Service (NHS) data in England and Wales.[9]

A significant data quality challenge has been the submission of medication incident reports to NIMS in which the medication name has been omitted, i.e. left blank. The percentage of such reports dropped to 3.1% in 2018 and this represents a marked improvement on the 2016 figure of 29.5%.[11] This finding may reflect the addition of medication name search functionality to NIMS in early 2017.

Allied health professionals reported half of all medication incidents over the two year period. The majority of reports from these staff groups are most likely generated by clinical pharmacists, although the professional grade breakdown is not available. A further four in 10 medication incident reports were submitted by nurses and midwives. The report reveals low incident reporting system engagement by doctors, who contributed just 4% of medication incident reports in both 2017 and 2018. This is consistent with the findings of the previous SCA report.[11]

Prescribing incidents accounted for 59% of all medication incidents in 2017 and 53.9% in 2018. Prevalence of prescribing incidents was also a feature of the previous SCA report on medication incidents.[11] This may be related to the staff groups reporting medication incidents. Clinical pharmacists, undertaking prescription review on daily ward rounds, are in a position to detect, address and report prescribing incidents but may be unaware of administration errors which often occur outside of their ward visits. Nonetheless, the high level of prescribing incidents is of concern. There is evidence that training, experience and practice reduce prescribing errors by hospital doctors.[4] Undergraduate medical training colleges have an important role to play in ensuring that doctors are equipped with the necessary skills to prescribe safely from the beginning of their careers. It is notable that the introduction of a standardised national in-patient prescription chart in Australia was associated with a reduction in prescribing errors.[4]

The top three incident categories identified in this report were, in descending order, 'incomplete / inadequate, 'wrong dose / strength' and 'omitted / delayed dose'. 'Incomplete / inadequate' is linked to the large number of prescribing incidents in the data and is frequently selected when the prescriber has omitted important prescription details such as dose, route or frequency. In a six year review of NHS data in England and Wales, the largest incident categories, accounting for 15.6% and 15.2% of medication incidents respectively, were 'omitted and delayed medicine' and 'wrong dose or strength'.[9]

The medication groups most frequently encountered on medication incident reports in 2017 and 2018 were, in descending order, antithrombotics, opioids, penicillins, insulins and antiepileptics. In a similar study in 2016 the most commonly implicated medication groups were antithrombotics, penicillins, opioids, antiepileptics and 'other antibacterials'.[11] Medications most frequently associated with fatal and severe harm outcomes in a six year analysis of NHS incident data were opioids, antibiotics, warfarin, low molecular weight heparin (both classed here as antithrombotics) and insulin.[9]

The medication groups most commonly implicated in medication incident reports in this study broadly reflect those medications commonly found on lists of high-risk (high alert) medications. Hospitals should direct their risk mitigation strategies at these medication groups. It is notable that high-risk (high alert) medications were a focus of recent Health Information and Quality Authority (HIQA) medication safety inspections in hospitals.[15]

Clinical pharmacy services and medicines reconciliation at transitions in care have been demonstrated to reduce medication errors.[16] Electronic healthcare records and other electronic solutions such as computerised physician order entry, automated dispensing cabinets and barcoding also have the potential to improve medication safety. The SCA endorses and welcomes such solutions.

What can hospitals do to improve medication safety?

✔	Ensure **medication reconciliation** at transfers between care settings.
✔	Ensure clinical areas have access to **clinical pharmacy services**.
✔	Develop a **safe prescribing guide** to ensure non-consultant hospital doctors have access to evidence-based current prescribing guidelines.
✔	Ensure availability of a **recognised reference source(s)** at the point of prescribing.
✔	Consider use of **standardised in-patient prescription charts.**
✔	Provide medication safety **education and training** for health and social care professionals.
✔	Encourage **medication incident reporting** and timely uploading to NIMS to allow detection of trends and clusters at both local and national level.
✔	**Empower the patient or carer** through participation in programmes such as the HSE's 'Know, Check, Ask' safer medicines campaign.[17]

Conclusions

Medication incident reporting by Irish acute hospitals in the period 2017-2018 has improved significantly since a similar SCA report for 2016[11], even allowing for changes in the data selection methodology. Over 20,000 medication incidents were reported in this two year period and the number of incidents logged without a medication name has progressively decreased. This increased volume and quality of information has produced a valuable dataset upon which this report has drawn to reveal the nature and extent of medication incidents in Irish acute hospitals.

The report signposts areas for improvement in medication incident reporting such as the relatively low system engagement of medical staff compared to other healthcare professionals. The report also highlights the medications and medication groups which are more commonly associated with medication incidents, where targeted risk mitigation strategies will have greatest impact in improving patient safety. As Ireland moves to embrace the challenge of the WHO's 2017 Medication Without Harm, healthcare providers are encouraged to act on the learning contained in this report to improve the safety of their medication systems for the benefit of patients, staff and their organisations.

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All data in this report is accurate as of 31 December 2018, with the exception of penicillin allergy data (focus area 3) which is correct as of 28 May 2019.

Prepared:

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