REVIEW OF
MEDICATION INCIDENTS REPORTED IN IRISH HOSPITALS

NATIONAL LEARNING 2016

1. Introduction

Medication errors occur frequently in the hospital setting and place a significant burden on the health system's resources through both errors causing direct harm and those without direct patient harm but which contribute to waste and inefficiency. International literature suggests that one medication error occurs for every five doses given in US hospitals[1] and that 1-2% of patients admitted to US hospitals are harmed by medication errors.[2] United Kingdom figures suggest that less than 1% of medication incidents are spontaneously reported, meaning that many learning opportunities, as a result of these errors, are lost.[3]

In Ireland, acute public hospitals covered by the Clinical Indemnity Scheme (CIS) report incidents, both medication and otherwise, into the National Incident Management System (NIMS), an online, secure, end-to-end risk management portal which was introduced in 2015 to replace the previously used STARSWeb system. This report aims to extract learning from the first full year of medication incident reporting onto NIMS and inform key areas of risk. It also aims to highlight the value of reporting clinical incidents into a centralised platform where issues can be identified, quantified and then disseminated back to the health system so that avoidable patient harm can be minimised.

2. Reporting

In 2016 there were a total of 5,505 medication incidents reported across 50 acute hospitals, resulting in an average of 110 medication incidents per hospital. This represents a significant under-reporting of medication incidents onto the national system, when applying estimated error rates to the number of patient interactions occurring in Irish hospitals daily.

Reported numbers of medication incidents over the previous ten years have been inconsistent with significant inter year variability (Figure 1). Of note, when incident reporting reached a peak in 2011, at which time reporting levels were 49.3% higher than in 2016, the majority of the increase was due to a single pharmacy department reporting all errors notified to it. This illustrates the potential level of incident reporting if hospital pharmacies nationwide were to replicate this proficiency in reporting. It should be acknowledged, however, that clinical pharmacy services are a scarce resource in the Irish health system and that the resources required to report medication incidents at this level often do not exist.
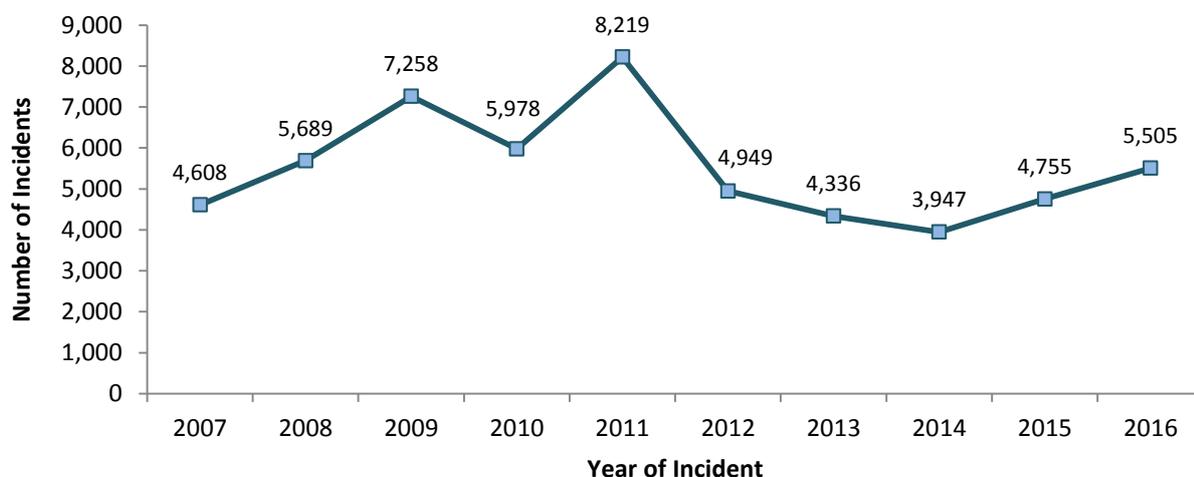

Figure 1: Medication incidents identified in acute hospitals, 2007-2016 inclusive

The large spread of medication-related incidents reported from acute hospitals (Figure 2) shows there is much work to be done to ensure that medication incidents identified within hospitals are reported onto the national system and learning extracted at a national level, especially in those hospitals reporting less than 60 medication-related incidents per year. It is envisaged that a combination of improvements to the NIMS system, with greater awareness of both the legislative obligation to report and the benefits of reporting to the national system, will result in increased reporting and learning in the coming years.
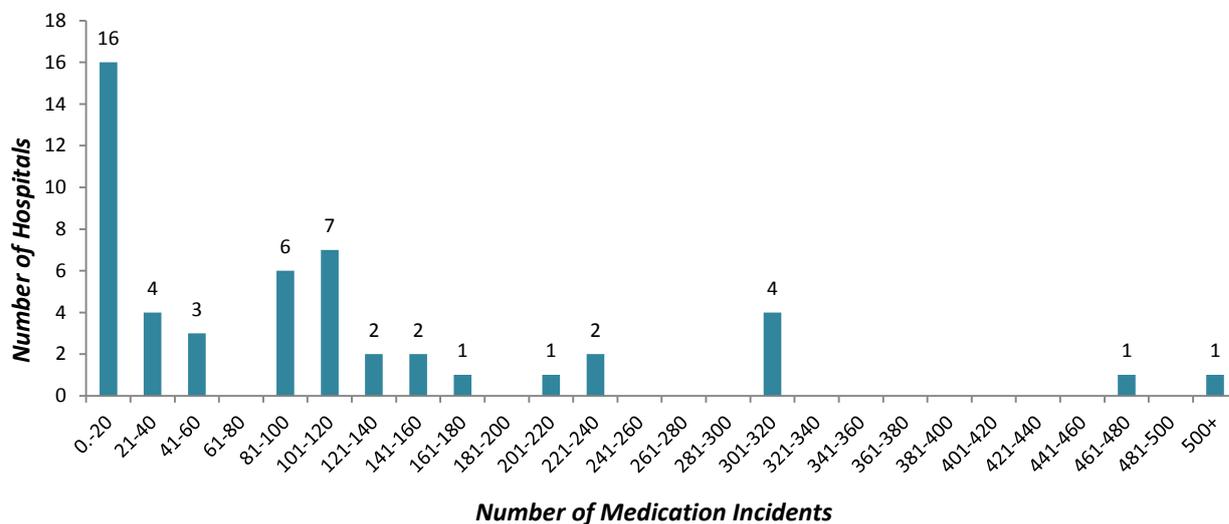

Figure 2: Distribution of medication incidents reported from 50 acute hospitals, 2016

Medication errors occur across all specialities and services within the health system. A recent report published by the State Claims Agency (SCA) identified that medication-related incidents are prominent across major services and sub-services.[4]

3. The Medication Process

In 2016, users had the ability to select from 11 options to assign the "Process" where an incident occurred when categorising a medication incident which, like other incident classifications on the system, was based on the World Health Organisation taxonomy for the classification of patient safety.[5] This represents an important point for data quality as it is the assigned process which informs the cohort of health professionals that can learn from each incident.

Process	Acute Hospitals	Community	NHS
Prescribing	44.1%	20.8%	18.5%
Administration	23.1%	32.4%	50.0%
Preparation/Dispensing	13.7%	21.4%	16.5%
Documentation/Records	5.8%	9.0%	NA
Monitoring	3.3%	3.5%	4.5%
Supply/Ordering/Transport	2.3%	2.1%	NA
Communication/Consent	1.5%	2.9%	NA
Equipment	1.0%	1.4%	NA
Storage	0.7%	1.1%	NA
Presentation/Packaging	0.3%	1.1%	NA
Unknown/Other	4.0%	4.3%	10.5%

Table 1: Proportion of medication incidents by process, 2016

When comparing reporting in Irish acute hospitals to the community sector, and to a large study by the NHS National Reporting and Learning System (NRLS)[3], the large proportion of prescribing incidents is immediately apparent, over double that seen in the community and the NHS (Table 1). Conversely, incidents relating to the administration of medications account for half that seen in the NHS and significantly less than in the community. This difference does not appear to be a product of the category of person reporting as the figures remain similar across the two location areas (Table 2).

A reporting rate of prescribing incidents which is double that of administration is surprising given that medications are administered multiple times for a single prescription, presenting significantly more opportunity for errors in administration. A potential explanation for this is the natural inclination for staff to be more comfortable reporting errors of other categories of staff rather than those they themselves or their colleagues were involved in. The different profile of medications prescribed in the acute setting compared to the community setting would also have some effect on the noted difference, with a greater proportion of medications prescribed in hospitals being either new additions to a regimen or short course treatments, creating more opportunities for error compared to continued prescribing of long term medications.

Category of Person Reporting	Acute	Community
Nursing/Midwifery	56.3%	61.5%
Allied Health Professional	37.5%	17.6%
Medical	3.5%	2.4%
General Support	2.1%	18.2%
Legacy Data (Not Known)	0.5%	0%
Other	0.2%	0.3%

Table 2: Category of person reporting medication incidents, 2016

In early 2017, the list of options available under "Process" was refined to remove options which have been shown, through analysis, to cause confusion and limit data quality. The options of "Documentation/Records" and "Communication/Consent" have been removed, as incidents in these categories overwhelmingly related to either prescribing or administration and data quality was suffering as a result of providing users with multiple options to record the same incident. "Presentation/Packaging" was also removed and "Preparation/Dispensing" was renamed "Preparation/Dispensing (Pharmacy)" as data analysis showed that there was possible confusion by front line staff between "Dispensing" and "Administration". The option of "Reconciliation" was added, reflecting the importance of medication reconciliation in the medication use process.

4. Medications and Harm

From early 2017, NIMS has used the Anatomical Therapeutic Chemical Classification System (ATC) to categorise medications with new functionality, allowing users to search for either active ingredient or trade name of a medication. The system automatically assigns three levels of ATC code for the medication selected. For the analysis of 2016 incidents, data was mapped onto this format using data from previously available free text fields and brief descriptions of the incident.

Analysis of medication incidents in the acute setting during 2016 revealed that 29.5% of such incidents did not contain the name of the medication involved. This is possibly due to the National Incident Report Form (NIRF01) not having adequate space to write the specific medication during 2016 and the absence of a function to search from a medication database on the system. It is hoped the addition of the search function in 2017, the addition of specific space on the report form for the medication name and increased education around incident reporting will greatly reduce the number of reports lacking this information.

ATC Level One

The first level of the code indicates the anatomical main group and consists of one letter. The most common level one categories of medication were N - Nervous system (n=992, 18.0%), J - Anti-infectives for systemic use (n=748, 13.6%), B - Blood and blood forming organs (n=653, 11.9%), C - Cardiovascular system (n=342, 6.2%) and A - Alimentary tract and metabolism (n=332, 6.0%), (Figure 3).
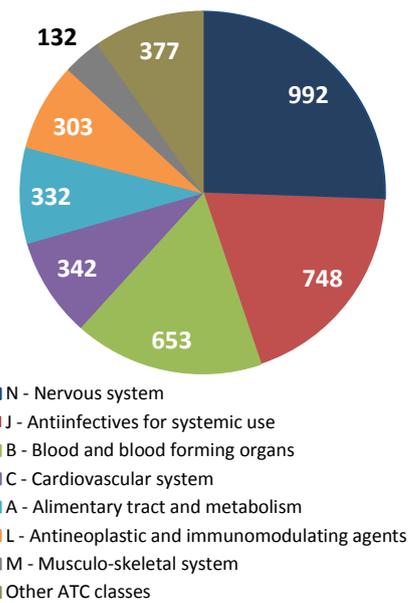
ATC Level Two

Not surprisingly, the most common level two group resulting in medication incidents is J01 - Antibacterials for systemic use (n=646), which is consistent with Ireland being one of the higher per capita consumers of antibacterials throughout the European Union.[6] This high use, coupled with dosing which often falls at times outside a patient's regular medications, results in high numbers of dose omissions/delays in this class (Figure 4).

Legend:
- N - Nervous system
- J - Antiinfectives for systemic use
- B - Blood and blood forming organs
- C - Cardiovascular system
- A - Alimentary tract and metabolism
- L - Antineoplastic and immunomodulating agents
- M - Musculo-skeletal system
- Other ATC classes

Figure 3: Most common known ATC categories, 2016

The prevalence of incidents relating to B01 - Antithrombotic agents (n=563) in the acute setting may be a result of increased awareness relating to these medications and the risks that they pose to the generally older populations being treated. The under-reporting of medication incidents in general may also explain the significant proportion of actual incidents in this class, as hospitals are more likely to report incidents more severe in nature. The numbers of incidents relating to N02 - Analgesics (n=411) and N05 - Psycholeptics (n=215) are likely to reflect their high consumption in the acute setting.
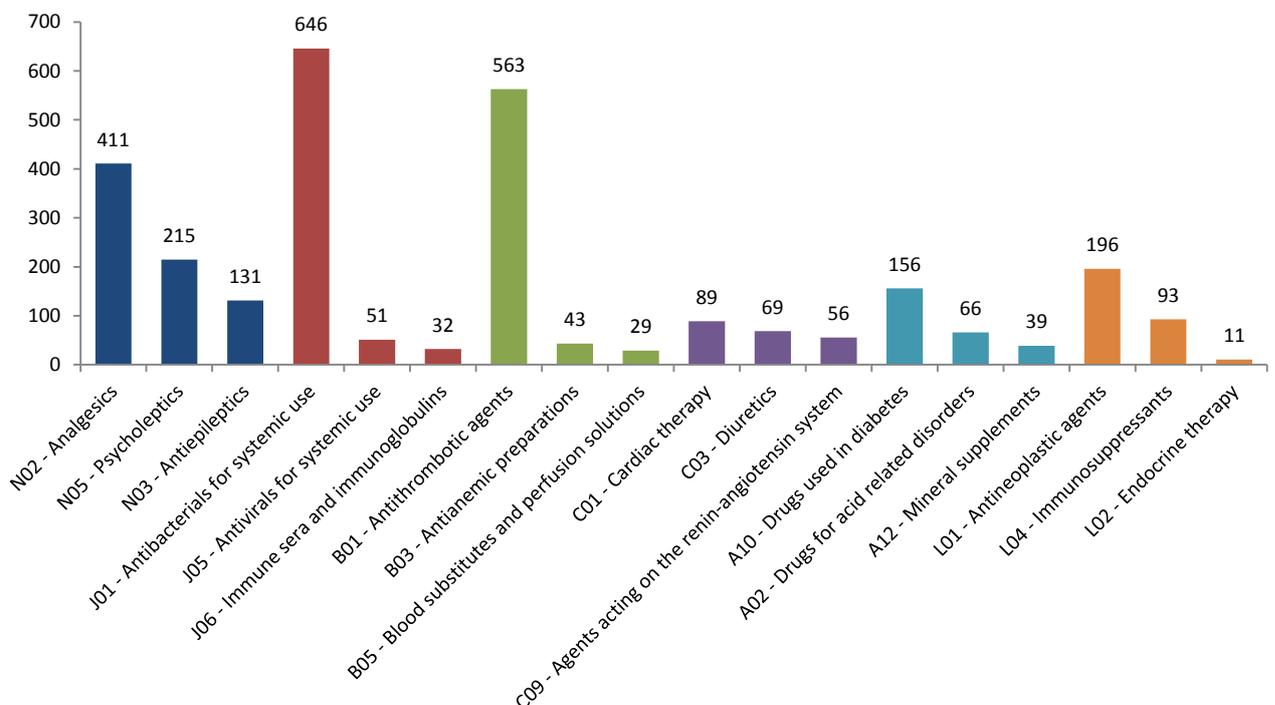
Figure 4: Most common ATC level two categories contained within top five ATC level one categories, 2016

ATC Level Three

At ATC level three, the data reveals classes of medication that are considered high risk. These include N02A - Opioids, B01A - Antithrombotic Agents, A10A - Insulins and Analogues and L04A - Immunosuppressants (Table 3). These classes all contain specific medications which have the potential to cause patient harm when used incorrectly.

ATC Level Three Classes	Count (n)
B01A Antithrombotic Agents	477
J01C Beta-Lactam Antibacterials, Penicillins	255
N02A Opioids	251
N03A Antiepileptics	118
J01X Other Antibacterials	101
N02B Other Analgesics And Antipyretics	99
A10A Insulins And Analogues	91
L01X Other Antineoplastic Agents	91
N05A Antipsychotics	80
L04A Immunosuppressants	80

Table 3: Most common ATC level three categories, 2016

Specific Medications

The twenty most common medications account for 1,500 total incidents in 2016 or 27.2% of all medication incidents. Of the incidents related to the top twenty medications, three were rated extreme (death or permanent incapacity), one rated major (long term incapacity), 91 rated moderate (injury requiring medical treatment) and 32 minor (injury requiring first aid), (Table 4). It is important to note, especially in those incidents with Extreme and Major severity ratings, that these incidents occurred relatively recently and in many cases the exact role the assigned medications played in the ultimate outcome has not yet been established, only that the medication incident has a strong temporal link to the reported patient injury.

Analysis of the most common medications involved in incidents identifies specific areas of risk within class B01A – Antithrombotic agents, with Heparins (Enoxaparin, Heparin and Tinzaparin), Direct Acting Oral Anticoagulants (Apixaban, Rivaroxaban) and Warfarin all prominent within the 20 most common medications. These medications, whilst used frequently, are considered high risk due to the potentially catastrophic nature of harm which can result from errors involving these agents, as evidenced by incident severity ratings (Table 4). This is particularly true in the case of Direct Acting Oral Anticoagulants (DOACs) where options for managing DOAC induced bleeding are extremely limited. The specific nature of these incidents as well as risk management considerations are further analysed in the following section.

Other specific areas of interest within the most common medications are antibiotics with narrow therapeutic indexes (Vancomycin, Gentamicin). These medications present significant risks to patients where small differences in blood concentration may lead to serious therapeutic failures or adverse reactions.

The prominence of opioid based analgesics is representative of common, well known issues with these medications. Analysis found 28 incidents relating to Morphine and 21 relating to Oxycodone dose/strength errors. Confusion between different dose forms of Oxycodone (Oxynorm®/Oxycontin®) is also prominent.

Medication Name	Extreme	Major	Moderate	Minor	Negligible	Total
Enoxaparin sodium	1		2		142	**145**
Amoxicillin || clavulanic acid			11	2	108	**121**
Paracetamol	1		4	2	111	**118**
Morphine sulphate			9	4	93	**106**
Vancomycin			5	3	85	**93**
Oxycodone			5	4	80	**89**
Gentamicin			14	3	71	**88**
Heparin	1		5	1	79	**86**
Warfarin sodium		1	1	1	80	**83**
Piperacillin || Tazobactam			6	5	63	**74**
Benzylpenicillin sodium			8		59	**67**
Apixaban			2	1	63	**66**
Diclofenac			5	2	53	**60**
Insulin aspart			1	1	47	**49**
Fentanyl			4	2	39	**45**
Rivaroxaban			3	1	41	**45**
Tinzaparin			3		40	**43**
Methotrexate			2		41	**43**
Furosemide			1		40	**41**
Acetylsalicylic acid (Aspirin)					38	**38**

Table 4: Twenty most common medications involved in incidents reported in acute hospitals, 2016

Penicillin-based antibiotics such as Benzylpenicillin, Amoxicillin + Clavulanic Acid and Piperacillin + Tazobactam account for a large number of incidents which would not be unexpected due to their widespread use. Of those incidents that resulted in harm, 57.7% (n=26) related to allergic reactions. The risk associated with allergy related incidents is discussed in the following section.

International comparison with the NRLS data shows similarities with medications associated with causing harm.[3] The NRLS study lists Opioids, Antibiotics, Warfarin, Low Molecular Weight Heparins, Insulin, Non-Steroidal Anti-inflammatories and Methotrexate all within the list of the 13 medications that most commonly cause harm. These 13 medications are also represented within the 20 most common medications in this study. It should be noted, however, that the data presented here is of a significantly smaller sample size.

5. Areas of Risk

Anticoagulant Prescribing

Detailed analysis of incidents involving anticoagulants identifies the following main areas of risk where preventable errors occurred during 2016:

- Inappropriate dosing of Low Molecular Weight Heparins (LMWHs) and Direct Acting Oral Anticoagulants (DOACs) in specific populations, especially in older persons and in patients with poor renal function.
- Therapeutic duplication through co-prescribing of LMWHs with contra-indicated DOACs, resulting in increased risk of bleeding.
- Omission of regular anticoagulants on discharge resulting in increased risk of stroke and thromboembolism.

Use of Antibiotics with Narrow Therapeutic Indexes

Gentamicin and Vancomycin were prominent in the ten most common medications causing incidents, with specific focus on the prescribing and monitoring of correct doses of these antibiotics. Sub-optimal dosing can lead to increased patient morbidity and mortality and increased bacterial resistance. Over-dosage can lead to temporary or permanent kidney damage, loss of hearing or balance disturbance. These medications are both widely used and extremely important on the front line with Gentamicin being used to treat an estimated 15,000 patients per annum in Irish hospitals.[7] Common risk situations included:

- Not adjusting initial dosing for patients with poor kidney function.
- Delay in the measurement of pre-dose levels prior to 2nd dose in patients with unstable kidney function or prior to 2nd/3rd dose in patients with stable kidney function.

Penicillin Allergy

Penicillin-based antibiotics accounted for 41.7% of all antibiotic consumption in hospitals in Ireland[6], which, when combined with a significant cohort of patients who self-report penicillin allergy, represents an area of considerable risk in the Irish health system.

In 2016, there were 283 incidents relating to penicillin-based antibiotics, 30 of which caused harm and 48 of which related to their use being contra-indicated, mostly by allergy. These incidents represent preventable patient harm and an opportunity to enhance patient safety.

Recommendations
• The importance of education around, and compliance with, HSE policy on Healthcare Records Management[8], particularly in relation to the requirement to record allergy status accurately is reinforced.
• Clinical Pharmacy services, where available, are utilised on medical rounds.
• Patients are educated regarding the presence and severity of their allergy status and the medications which correspond to that allergy status.
• Care is taken to prescribe medications by generic name, rather than brand name, as name recognition can act as an important safety net in these cases.

6. Conclusion

A high rate of incident reporting is considered a marker of a strong patient safety culture. It is hoped that continued uptake of the National Incident Management System (NIMS) will facilitate both the SCA and the healthcare system to ensure that widespread learning occurs in response to incidents in all areas. This is especially important for medication errors which have a widespread impact on patient safety and quality of care, both nationally and internationally.

To mitigate risk regarding medication incidents, it is of utmost importance that Clinical Pharmacy services be made available, not only to identify, report and disseminate learning from incidents, but to add medication expertise to multi-disciplinary teams in clinical settings. International data shows that the clinical pharmacist is a crucial part of the health care team contributing to increased quality of care at the least expense whilst minimising preventable patient harm.[9]

Further overall measures for the prevention of medication incidents identified in a recent SCA report[4] included:
- Medication Reconciliation at the time of patient transfer.
- Implementation of a medication safety training and education programme for doctors and nurses with audited outcomes.
- Implementation of the Electronic Healthcare Record with Clinical Decision Support and Computerised Physician Order Entry.
- Introduction of a national drug kardex in all hospitals and healthcare services.

References

1. Mansur JM. Medication Safety Systems and the Important Role of Pharmacists. Drugs Aging. 2016 Mar; 33(3): 213-21.

2. Routledge PA. Safe prescribing: a titanic challenge. Br J Clin Pharmacol. 2012 Oct; 74(4): 676–684.

3. Cousins DH, Gerrett D & Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005-2010). Br J Clin Pharmacol. 2012 Oct; 74(4): 597-604.

4. Slattery D, Walsh D, O'Byrne Maguire I, et al. National Clinical Incidents, Claims and Costs Report. Lessons learned, a five year review: 2010-2014 [Internet]. Dublin: State Claims Agency; 2017 [cited 2017 June 27]. Available from: http://stateclaims.ie/wp-content/uploads/2017/05/State-Claims-Agency-National-Clinical-Incidents-Claims-and-Costs-Report.pdf

5. World Health Organisation. Conceptual Framework for the International Classification for Patient Safety [Internet]. WHO; 2009 [cited 2017 September 15]. Available from: http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf

6. European Centre for Disease Prevention and Control. Distribution of Antibacterials for Systemic Use (ATC group J01) in the hospital sector in Ireland, reporting year 2014 [Internet]. ECDC; 2014 [cited 2017 September 15]. Available from: https://ecdc.europa.eu/en/antimicrobial-consumption/database/rates-country

7. Royal College of Physicians of Ireland. Updated gentamicin guidelines for adult and paediatric settings now available [Internet]. Dublin: RCPI; 2016 [updated 2016 December 5; cited 2017 June 27]. Available from: https://www.rcpi.ie/news/releases/updated-gentamicin-guidelines-for-adult-and-paediatric-settings-now-available/

8. Health Service Executive. HSE Standards and Recommended Practices for Healthcare Records Management [Internet]. Dublin: HSE; 2011 [cited 2017 November 22]. Available from: http://www.hse.ie/eng/about/Who/QID/Quality_and_Patient_Safety_Documents/v3.pdf

9. Glassman P. Clinical Pharmacist's Role in Preventing Adverse Drug Events: Brief Update Review. In: Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices [Internet]. Agency for Healthcare Research and Quality (US); 2013 [cited 2017 June 27]. Available from: https://archive.ahrq.gov/research/findings/evidence-based-reports/ptsafetyIIchap4.pdf

Author

Matthew Kennedy, Clinical Risk Adviser, Clinical Risk Unit, State Claims Agency.