A Collaborative Study of Medication Safety in Four Irish hospitals

Kirke C., M.Sc. (Clin. Pharm.), MPSIi
Tighe, P., MBA, M.Sc. (Clin. Pharm.) MPSIii
Colohan, G., M.Sc. (Clin. Pharm.), MPSIiii
Harnett, B., M.Sc. (Clin. Pharm.), MPSIiv
Creaton, G., B.Sc. (Pharm.), MPSIiii
Delaney, T., B.Sc. (Pharm.), FPSIi

Abstract

Many Irish hospitals have medication safety initiatives in operation. The aims of these initiatives include collecting incident/near miss reports and using what is learned from incidents/near misses to improve systems to promote medication safety. There has been no national co-ordination of these initiatives. Thus, data collection, analysis and system improvements to avoid repetition of incidents is carried out in various ways in various hospitals and learning from incidents has been confined to the individual hospital in which they occur. A medication safety software package, Analyze-ERR®, was obtained from the Institute of Safe Medication Practices, Canada (ISMP Canada). Four Irish hospitals used this software to record and analyse their medication safety data for a three month period. Aggregate analysis of the data was then performed and is summarised in this paper.

Introduction

Many Irish hospitals have medication safety initiatives in operation. The aims of these initiatives include collecting incident/near miss reports and using what is learned from incidents/near misses to improve systems to promote medication safety. To date, there has been no standardised approach to data collection or data analysis. Aggregate data on medication safety in Ireland has not been published.

Collecting and pooling patient safety information on a national basis is a common and accepted practice. Examples include the Medication Error Reporting Program (MERP) in the USA (run by the United States Pharmacopoeia in association with the Institute for Safe Medication Practices (ISMP)), the National Reporting and Learning System (NRLS) run by the National Patient Safety Agency (NPSA) in the United Kingdom and the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (developed by ISMP Canada, the Canadian Institute for Health Information (CIHI) and Health Canada).

Ireland established enterprise liability under a Clinical Indemnity Scheme (CIS) in 2002 to promote safe patient care, reduce the number of claims and to manage claims in a timely fashion.[1] All enterprises covered by the CIS are required to report all adverse clinical events and near misses on a mandatory basis via a secure web-based Clinical Incident Reporting System, STARSWeb. Medication errors are one category of incidents and near misses that may be reported via STARSWeb. Other risk management incidents/near misses may also be reported, e.g. surgical incidents and infection control incidents. STARSWeb is not currently configured in a format that would have facilitated collecting medication safety data and pooling it for analysis in this pilot study.

A medication safety software package, Analyze-ERR®, was obtained, free of charge, from the Institute of Safe Medication Practices, Canada (ISMP Canada) to facilitate a pilot project to collect and analyse medication safety information in a standardised way in four hospitals in Ireland.

ISMP Canada is an independent Canadian non-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety. Analyze-ERR® is a software documentation tool designed and developed by ISMP Canada for use in institutions to track and analyse medication errors. In Canada, this is followed by a mechanism where users submit data to ISMP Canada, where data are pooled to provide aggregate information on medication errors, e.g. event types, contributory causes. ISMP Canada can then use this data to share the learnings from errors and near misses, including recommendations for prevention of errors, with the healthcare community in Canada.

Aims

The aims of the study were to:

- **use the Analyze-ERR® software to facilitate standardised medication safety data collection and analysis, and**
- **determine whether this software facilitates pooling of information for greater learning.**

i Adelaide and Meath Hospital incorporating the National Children's Hospital, Tallaght, Dublin 24
ii Mater Private Hospital, Eccles Street, Dublin 7
iii Portiuncula Hospital, Ballinasloe, Co Galway
iv St. John's Hospital, St. John's Square, Limerick

Methods

Analyze-ERR® was installed in each of the four hospitals and used to enter and manage medication safety incident/near miss reports collected from January to March 2006. The hospitals involved in the study were:

- **Adelaide & Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH)** – a public voluntary teaching hospital with six hundred beds
- **Mater Private Hospital, Dublin** – a private hospital with two hundred and two beds
- **Portiuncula Hospital, Galway** – a public general hospital with two hundred and ten beds
- **St. John's Hospital, Limerick** – a public voluntary general hospital with one hundred and three beds

Reports included medication errors, adverse drug reactions and hazardous conditions relating to medication. The data was then sent to the project coordinator for pooling and analysis.

The severity of incidents/near misses was categorised using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) criteria[2] as used on the Analyze-ERR® software (see Fig. 1). In addition to reports regarding medication error, each of the hospitals received reports about adverse drug reactions (ADRs) which did not involve medication error. These reports were also classified into the most pertinent NCC MERP category, i.e. if the ADR resulted in temporary patient harm requiring intervention, it was classified as NCC MERP category E. NCC MERP categories A-B (coloured green in Fig. 1) did not reach the patient, C and D (coloured amber or yellow) reached the patient but did not result in patient harm and categories E-I (coloured red) resulted in increasing levels of patient harm. Harm is defined by NCC MERP as 'Impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom' and corresponds to NCC MERP categories E-I (see Fig. 1).

Results

Five-hundred and ten (510) medication safety incidents/near misses were recorded (mean 128 reports per hospital; range 14-230). Ninety-three percent of the aggregated incident/near miss reports did not result in patient harm (NCC MERP A-D); 7% or 35 incidents resulted in patient harm (NCC MERP E-I) (Fig. 1).

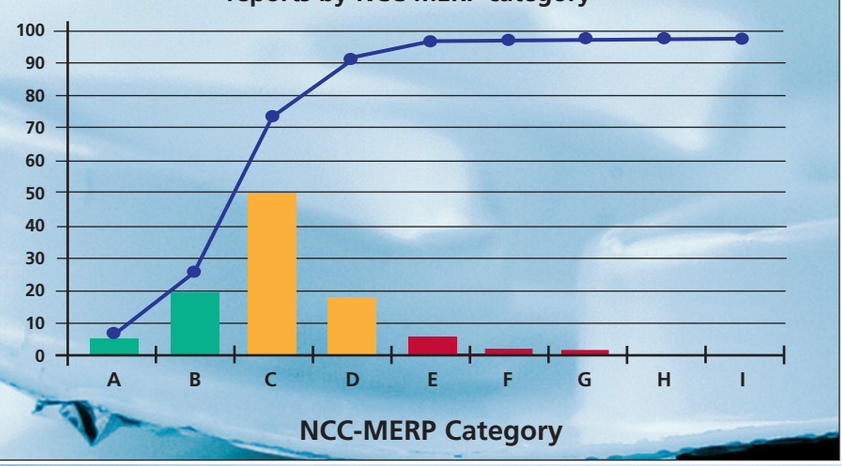
Over 90 drugs were implicated in incident/near miss reports. Enoxaparin, diclofenac, morphine, aspirin and fentanyl resulted in the largest proportion of reports overall. The most frequent drug implicated in reports was enoxaparin, involved in 17 reports (3.3% of the total) (Fig. 2).

The drugs involved in the largest proportion of incidents resulting in patient harm (NCC MERP E-I) were enoxaparin (four reports), paclitaxel (three reports) and amiodarone (three reports) (Fig. 3). Thirty-three (33) drugs were implicated in incident reports resulting in patient harm. Drugs involved in incidents resulting in patient harm were classified by *British National Formulary*[3] categories. The most frequently occurring categories were cardiovascular, malignancy and immunosuppression and anti-infectives. Together, these three categories were responsible for over 55% of incidents resulting in patient harm (Fig. 4).

The stage(s) in the medication use process at which the incident occurred was recorded. An incident/near miss could involve more than one stage, e.g. if a patient was prescribed a drug to which

FIGURE 1

Severity of aggregate incident/near miss reports by NCC-MERP category



***NCCMERP Categories**

- A Circumstances or events that have the capacity to cause a medication error.
- B A medication error drug event occurred but did not reach the patient.
- C A medication error occurred that reached the patient but did not cause patient harm.
- D A medication error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
- E A medication error occurred that may have contributed to or resulted in temporary patient harm and required intervention.
- F A medication error occurred that may have contributed to or resulted in temporary patient harm and required initial or prolonged hospitalization.
- G A medication error occurred that may have contributed to or resulted in permanent patient harm.
- H A medication error occurred that required intervention necessary to sustain life.
- I A medication error occurred that may have contributed to or resulted in the patient's death.

From: US National Co-ordinating Council for Medication Error Reporting and Prevention (NCCMERP) and United States Pharmacopoeia (USP), June 2001

FIGURE 2

Drugs involved in aggregate incident/near miss reports

Drug (generic)	No. of reports	% of reports
Enoxaparin	17	3.3
Diclofenac	14	2.7
Morphine	14	2.7
Aspirin	13	2.5
Fentanyl	12	2.4
Digoxin	9	1.8
Warfarin	9	1.8
Co-amoxiclav	8	1.6
Insulin	8	1.6
Omeprazole	8	1.6

FIGURE 3

Drugs involved in aggregate incident reports resulting in patient harm (NCC MERP E-I)

Drug	No. of reports	% of reports
Enoxaparin	4	8.5
Paclitaxel	3	6.4
Amiodarone	3	6.4
Insulin	2	4.3
Moxifloxacin	2	4.3
Zoledronic acid	2	4.3
Aspirin	2	4.3
Clopidogrel	2	4.3
Tetracaine	2	4.3

they had a documented allergy and the drug was subsequently administered, the incident/near miss would be entered as both a prescribing and an administration error. Prescribing was responsible for nearly 50% of overall incident/near miss reports (Fig. 5), with administration responsible for nearly 30% and dispensing for approximately 10%. The stage(s) involved in incidents resulting in patient harm (NCC MERP E-I) were mainly administration (49%) and prescribing (22%), with 3% due to dispensing (Fig. 6). Sixteen percent of incidents resulting in patient harm were in the 'not applicable' category. These were mainly adverse drug reactions where a stage in the medication use process could not be identified as being involved in the genesis of the incident.

The type of incident/near miss was recorded. The 'other' category was the most frequent type of incident/near miss reported, accounting for 29% of reports overall (Fig. 7) and 44% of incidents resulting in patient harm (NCC MERP E-I) (Fig. 8). A large proportion of this was due to adverse drug reactions and infusion-related reactions, which could not be captured appropriately using the Analyze-ERR® categories. Wrong dose, wrong frequency/rate and dose/drug omission were the next most frequent types (Fig. 7). The monitoring category includes patients being prescribed or administered drugs they had a documented allergy to, drug-drug interactions, contra-indications and clinical monitoring issues.

Of those incidents resulting in patient harm (NCC MERP E-I), the 'other' category accounted for 44% of reports, monitoring for over 22%, and dose/drug omission for 14% (Fig. 8).

FIGURE 4

British National Formulary[2] categories of drugs involved in aggregate incident reports resulting in patient harm (NCC MERP E-I)

BNF Category	No. of Reports	% of of Reports
Cardiovascular	10	21.3
Malignancy, immuno-suppression	9	19.1
Anti-infectives	7	14.9
Endocrine	5	10.6
Anticoagulants	5	10.6
CNS	3	6.4
Anaesthesia	3	6.4
Nutrition and blood	2	4.3
Musculoskeletal and joint	2	4.3
Diagnostics	1	2.1

FIGURE 5

Aggregate incident/near miss reports by stage(s) involved (n=510)

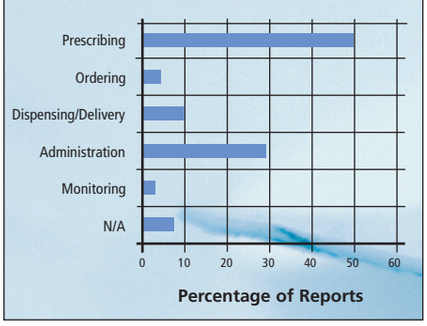
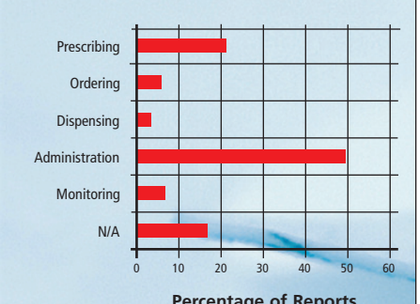


FIGURE 6

Aggregate incident reports resulting in patient harm (NCC MERP E-I) by stage(s) involved (n=35)



Discussion

Standardising data collection and classification by using the Analyze-ERR® database in each of the four hospitals facilitated the first pooled analysis of medication safety incident/near miss data in Ireland.

The data collected show a number of interesting factors worthy of further study or attention. The severity of incidents/near misses reported were categorised as 93% not reaching the patient, or reaching the patient but resulting in no harm, with 7% resulting in patient harm. There were two cases of possible permanent patient harm due to an adverse drug reaction and the other harmful incidents involved temporary harm, from which the patients recovered.

Of the 7% of reports involving patient harm, a large proportion were reports of adverse drug reactions and infusion-related incidents, i.e. they did not involve medication error. Although the Analyze-ERR® database has been developed for the analysis of medication errors and uses the NCC MERP system for classifying medication errors, each of our pilot sites received reports regarding medication errors and adverse drug reactions. This led to difficulty in classifying certain incidents (type of incident, stage(s) involved), resulting in use of the 'other' category for type of incident and the 'not applicable' category for stage(s) involved.

There was a wide distribution of drugs and type of drugs involved in reports. While some drugs such as enoxaparin, diclofenac and aspirin emerged more frequently, they are also used widely in the participating hospitals. The data was not analysed in any greater detail to identify trends in incident reports.

The stage(s) involved in the medication safety incident or near miss provided some interesting information. Although prescribing accounted for nearly 50% of overall reports, it accounted for just over 20% of incidents resulting in patient harm. Conversely, administration was responsible for less than 30% of overall reports but nearly 50% of incidents resulting in patient

FIGURE 7

Type of incident/near miss in aggregate reports (n=510)

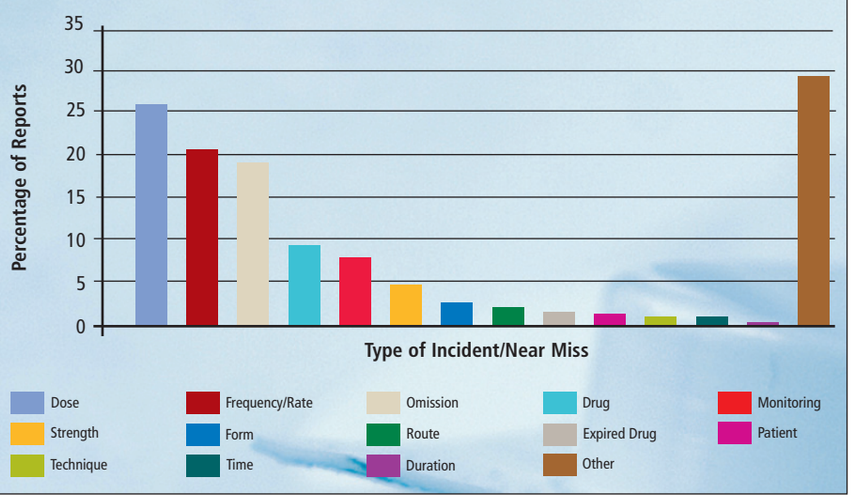
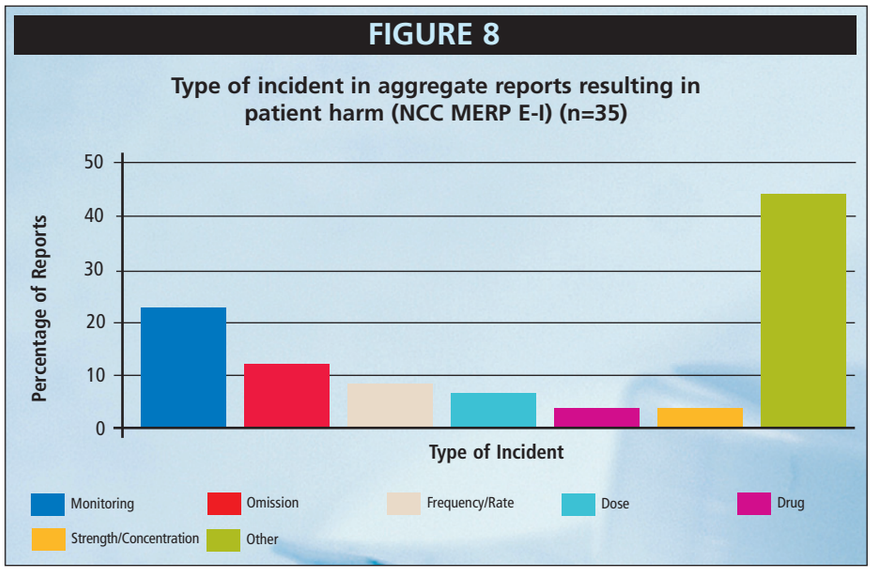


FIGURE 8



harm. Dispensing accounted for 10% of the overall figure but just 3% of incidents resulting in patient harm. The way that medication safety incident/near miss data is collected in a hospital can influence these figures significantly. Pharmacy staff are likely to report primarily dispensing and prescribing errors, whereas nursing staff are more likely to report administration errors. In our pilot group, approximately 65% of reports overall were submitted by pharmacy staff and 35% by nursing staff.

The most frequent types of incident reported were wrong dose, wrong frequency/rate and dose omission. Wrong dose could involve error at the prescribing, ordering, dispensing or administration stages. Wrong frequency/rate and dose omission could involve prescribing or administration. However, it is interesting to note that of those incidents resulting in patient harm, the 'monitoring' category accounted for over 20% of incidents. Many of these incidents involved allergic reactions, i.e. a medication that the patient was allergic to was prescribed and administered, resulting in an allergic reaction to the patient. In addition, this category included situations where patient factors were not taken into consideration when prescribing and/or administering drugs, e.g. there was a contra-indication or caution to the use of the drug in that patient or a drug-drug interaction.

The pilot was conducted over a very short time period and with limited resources. Comparison of the pilot data with published data from other countries was not carried out at this stage. It is clear that further collection and analysis of Irish medication safety information would be useful to identify trends and issues requiring attention.

Following the pilot project, feedback has been given to ISMP Canada. Overall, the pilot group found Analyze-ERR® very helpful for collecting and analysing their medication safety data and will continue to use it for this purpose. The pilot group were pleased to be able to share medication safety information with their colleagues. A number of issues were raised which ISMP Canada feel could be addressed should the pilot lead to a more permanent solution for Ireland. These include the need to adapt the database to the Irish medication use system and to incorporate information on adverse drug reactions.

For Analyze-ERR® to function optimally in the Irish setting, a central Irish Analyze-ERR® database is needed. This means that each institution would send their anonymised data to the central database, thus compiling Irish data. The individual hospitals could then compare their data to the overall Irish data. The value of such comparisons would include reassurance locally that the data collected is 'normal' or valid data. In addition, it could be used to identify when local data is out of line with general trends, e.g. if data is being entered under different categories by different participants, whether the professions reporting lead to more of particular types of reports, whether the participating organisation is identifying a high or low proportion of incidents resulting in harm (and that if the number is very low, whether some important information is being missed by the reporting system). In addition to the advantages to individual hospitals, having reliable, internationally comparable statistics on medication safety events would be of great value to the Irish health system.

The pilot group has presented to the State Claims Agency, which operates the Clinical Indemnity Scheme (CIS). Currently, medication safety incidents/near misses need to be entered by organisations indemnified by the CIS to STARSWeb in addition to Analyze-ERR®. The CIS is investigating ways of improving the quality of medication safety information available to them and is liaising with the pilot group to facilitate this.

Conclusion

Using a standardised, medication safety-specific database to record medication safety incident/near miss data facilitated aggregate analysis. Standardising the medication safety data collected by hospitals and having an appropriately resourced facility to house a central database would facilitate analysis of medication safety data for Ireland and comparison with international information.

Acknowledgements

The pilot group would like to acknowledge David U, Robert Lam and colleagues in ISMP Canada for providing us with the Analzye-ERR® software and user support.

References ~

1 Clinical Indemnity Scheme Newsletter, Nov 2006. Available from http://www.stateclaims.ie (last accessed on 18/12/06)

2 National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) criteria. Available from http://www.nccmerp.org (last accessed 18/12/2006)

3 British National Formulary, 51st Edition, March 2006, British Medical Association, Royal Pharmaceutical Society of Great Britain