Clinical Adverse Events Notified to the State Claims Agency under the terms of the Clinical Indemnity Scheme. Incidents occurring between 01/01/2012 and 31/12/2012 – Final Report.
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Foreword

The Clinical Indemnity Scheme (CIS) was established in July 2002, within the State Claims Agency (SCA), with a dual remit of claims management and risk management. Specifically, the CIS has a mandate to:

- Provide clinical indemnity on the basis of “enterprise liability” (i.e. the enterprise assumes liability for all its employees’ alleged clinical negligence).
- Manage claims made against the enterprises in a timely and cost-effective manner.
- Assist the enterprises to reduce the numbers of clinical claims through risk management initiatives.
- Drive and support safe patient care,
- Guide and support clinical risk management in all the enterprises.

Prior to the establishment of the CIS, though individual hospitals and indemnifiers may have collected data regarding adverse events, this was not in the public domain, and did not reflect the national picture.

All enterprises indemnified by the CIS are required to notify any adverse clinical events and “near-misses” occurring in their institutions to the CIS via a confidential, highly secure web-based IT system, the National Adverse Event Management System (NAEMS) formerly known as STARSWeb. National rollout of the NAEMS system commenced in November 2003, and coverage was extended to the entire acute public health sector by end 2006.

Approximately 83,000 adverse events have been consistently notified annually since January 2008. It must be acknowledged, that, as with the majority of incident reporting databases, not all adverse events are notified, for a variety of reasons. However, since 2003, a remarkably consistent profile has emerged, which in turn, mirrors the international experience.

Since feedback is of paramount importance in supporting and encouraging adverse events reporting, a decision has been taken that the SCA will publish annual reports in order to inform provision of better and safer care within the Irish health service.

Dr Ailis Quinlan
Head Clinical Indemnity Scheme
1. Introduction

All patient safety adverse events directly related to service-user treatment or care which did or could have resulted in an adverse outcome must be reported to the Clinical Indemnity Scheme (CIS) via the National Adverse Event Management System (NAEMS) formerly known as STARWeb, by those enterprises that are covered by the scheme. This feedback report provides an overview of the clinical adverse events reported to the State Claims Agency, (SCA) under the terms of the CIS for adverse events occurring between 01/01/2012 and 31/12/2012 and reported onto the system as per reports run on 16/04/2013.

The analysis presented in this report identifies key findings from the adverse events reported. The report reflects the overall national picture and thereafter concentrates on analysis of key adverse event types. The aim of this report is to stimulate discussions at local level in relation to improving the reporting of clinical adverse events so as to provide safer clinical care. As with any data collected, these reports need to be interpreted with necessary caution as there are significant variances in reporting rates across various enterprises within the public health sector in Ireland.

In the Irish public acute healthcare sector alone, over 1.4 million people received either inpatient or day case treatment in 2012 and 1.2 million annual A &E attendances were recorded. This gives a total of approximately 2.6 million patient interactions in the acute sector alone in 2012; yet only 76,842 clinical adverse events which occurred between 01/01/2012 and 31/12/2012 were reported to the SCA by 16/04/2013. Given that over the past 3 years an average of 83,000 clinical adverse events has been notified to the SCA per year there can be no doubt that there is under reporting of clinical adverse events especially when one considers that this represents an adverse event rate of approximately 2.9%, yet the experience in developed countries has been that the frequency of reported adverse event occurrences range between 4-16%. It has been acknowledged internationally that a discrepancy exists between the number of adverse events reported versus the actual number of adverse events. It has been claimed that under-reporting and the near absence of data sharing between healthcare providers is still the rule rather than the exception.

It is important to acknowledge that study methodologies vary significantly internationally, an issue already identified by the World Health Organisation; therefore comparability of data is problematic.

2 Based on Data Report created 16/04/2013
1.1. Data Quality

NAEMS enables enterprises covered under the terms of the CIS to notify their adverse clinical events to the SCA. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the healthcare system.

There are a number of fields within the datasets on the NAEMS system that are mandatory, i.e. they must be completed, and a number of fields where completion is optional. Examples of the mandatory fields are as follows:

- Patient name,
- Specialty and sub specialty associated with adverse event,
- General and specific type of adverse events.
- Date and location of adverse events.

The rate of completion for the optional fields is presented in Figure 1. As can be seen, the highest level of non-completion relates to fields associated with risk analysis of the adverse events failure to complete these fields limits the level of meaningful analysis and feedback that can be provided to the system. Therefore, the analysis contained within this report needs to be viewed with caution, as it is reflective only of the information provided to the SCA via the notification system.

![Figure 1: Completion Rate Non-mandatory Data Fields Clinical Adverse Events 01/01/2012 - 31/12/2012.](image-url)
Figure 2 gives a breakdown of all clinical adverse events occurring in 2012 as reported to NAEMS by 16/04/2013; unsurprisingly, and reflecting international norms and data from previous years, slips/trips and falls were the most commonly reported adverse events in 2012.

**Figure 2: Breakdown of Adverse Events Occurring between 01/01/2012 – 31/12/2012 & Reported by 16/04/2013**
1.2. Adverse Events reported by Specialty

As can be seen in Table 1, the Top 5 Specialties responsible for 73.7% of the adverse events reported are from the specialties of Medicine, Disability, Mental Health, Obstetrics and Elderly Services.

Table 1: Adverse Events Reported by Specialty

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>25</td>
</tr>
<tr>
<td>Disability</td>
<td>16.4</td>
</tr>
<tr>
<td>Mental Health</td>
<td>12.4</td>
</tr>
<tr>
<td>Obstetrics</td>
<td>10.1</td>
</tr>
<tr>
<td>Elderly Services</td>
<td>9.8</td>
</tr>
<tr>
<td>Surgery</td>
<td>9.4</td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>3.1</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>3.1</td>
</tr>
<tr>
<td>Community Health Services</td>
<td>1.7</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>1.3</td>
</tr>
<tr>
<td>Haematology</td>
<td>0.9</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>0.9</td>
</tr>
<tr>
<td>Radiology</td>
<td>0.8</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>0.5</td>
</tr>
<tr>
<td>Allied Professional Services</td>
<td>0.4</td>
</tr>
<tr>
<td>Laboratory Services</td>
<td>0.2</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
A breakdown of the Top 5 types of Adverse Events reported by these specialties is presented in Figure 3 and further detailed in Appendix 1.

**Figure 3: Top 5 specialty reporters by Adverse Events type occurring in 2012 & reported by 16/04/2013**
1.3. Adverse Events Reported by Staff category.

The staff category reporting the adverse event was not recorded in 23.4% of the cases reviewed. The category of staff reporting the adverse events in the remaining 76.6% is presented in Figure 4.

As can be seen, the specialty of nursing/midwifery continues to be the most prolific reporter of clinical adverse events, however this is not surprising when one considers that of the over 101,000 staff employed within the public health sector in Ireland⁵, 34.1% are nursing/midwifery and 8.2% are doctors/dentists⁶. The number of adverse events recorded as being reported by medical staff remains the same at 3%. Further analysis of the adverse events reported by medical staff established that the type of adverse events reported were in-patient care/treatment categories (with medication adverse events being the leading category of incident reported at 26.1%) whereas over a third of adverse events reported by nursing staff related to slips trips and falls (34.3%). Of all the adverse events reported onto NAEMS for 2012, it is encouraging to find that medical staff reported over 9.9% of all peri operative/peri procedure related adverse events (n=1837), 7.8% of all medication related adverse events (n=6017), 6.1% of all peri-natal adverse events (n=5585), 5.7% of all diagnosis related adverse events (n=1364) and 3.2% of all treatment related adverse events (n=5300).

A breakdown of the Top 10 type of adverse events reported by discipline, both medical and nursing staff respectively is represented in Figures 5 and 6.

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⁵ Health Service Executive Annual Report and Financial Statements 2012.
⁶ [www.hse.ie/eng/staff/resources/employment_reports/census](http://www.hse.ie/eng/staff/resources/employment_reports/census) accessed 20/06/2013
1.4. Further Details Section

This section on the NAEMS system enables a free text description of the adverse events to be recorded. Although this data field was completed in over 94% of the adverse events reviewed, the quality of the information recorded varies significantly. It is essential that a summary objective description of the adverse events is recorded to provide a clearer picture of the adverse events and thus enable more detailed analysis of the adverse events, if appropriate.
1.5 Risk Rating

Risk rating of adverse events is to be undertaken by enterprises in order to determine the actual or potential impact of the adverse events and the likelihood of recurrence. As illustrated in Figure 1, the data field for risk rating of the adverse events was completed in 49.6% of the adverse events included in this review; the breakdown of the risk rating is as outlined in Table 2.

**Table 2: Risk rating of Adverse Events.**

<table>
<thead>
<tr>
<th>Risk Rating</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not stated</td>
<td>50.6</td>
</tr>
<tr>
<td>High</td>
<td>0.7</td>
</tr>
<tr>
<td>Moderate</td>
<td>13.7</td>
</tr>
<tr>
<td>Low</td>
<td>19.1</td>
</tr>
<tr>
<td>Very Low</td>
<td>15.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
2.0 Overview of adverse events and near misses notified to the State Claims Agency, under the terms of the Clinical Indemnity Scheme, occurring between 01/01/2012 and 31/12/2012 and reported by 16/04/2013.

76,842 clinical adverse events which occurred between 01/01/2012 and 31/12/2012 were reported to the SCA through NAEMS by 16/04/2013. Slips/trips/falls consistently represents the highest category of reported clinical adverse events, accounting for 33.3% of all adverse events included in this analysis. In recent years, there has been an increasing trend upwards of reported clinical adverse events related to violence / harassment / aggression, representing 12.9% of all clinical adverse events in 2012. Medication adverse events, (accounting for 7.8%) remains within the top 3 types of reported adverse events.

![Figure 7: Top 5 Incident Types Occurring between 01/01/2012 and 31/12/2012 & Reported by 16/04/2013]

The remainder of this report will concentrate on the following adverse events types:
- Falls
- Violence/ harassment/ aggression
- Medication
- Peri-natal
- Treatment
- Diagnosis

These topics were selected as they represent the top types of adverse events in both incident types reported and claims submitted. While diagnosis adverse events have routinely appeared in the Top 5 in the past, this year this category was replaced by Violence/Harassment/Aggression, however given the significant implication and impact of missed diagnosis it is imperative that it continues to be considered an integral part of this report and is therefore included.

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7 Based on Data Report created 16/04/2013
2.1 Slips Trips & Falls

Slips/Trips/Falls consistently represents the highest category of clinical adverse events reported, accounting for 25,577 or 33.3% of all events included in this analysis.

The majority of falls reported are occurring in the specialities of Medicine 37.7%, Elderly Services 20.6%, Disability 11.8%, Mental Health 11.1% and Surgery 8.3% as illustrated in Figure 8.

![Figure 8: Specialty in which fall occurred](image)

There are currently nine options available for recording the specific nature of the falls Adverse Events as illustrated in Figure 9; 48% related to falls whilst mobilising without supervision and 11.4% whilst mobilising with supervision. 34.7% of these events involved the service user falling from equipment such as beds, chairs, hoists etc. and the remaining 5.9% were classified as “other”.

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Figure 9: Slips, trips and falls by Specific Nature of Event
2.2 Violence/ Harassment/ Aggression

9943 adverse events related to violence/ harassment and aggression were reported as occurring in 2012, accounting for 12.9% of all clinical adverse events notified. 8 Events of this nature can affect service users, staff and members of the public. 83.7% of these events occurred within the disability and mental health services, (Figure 10) and in such circumstances, only those adverse events in which the service user was the perpetrator are classified as clinical events.

![Figure 10: Violence/ Harassment/ Aggression Adverse Events by Specialty](image)

![Figure 11: Staff Category Reporting Violence/Harassment Adverse Events](image)

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8 Based on Data Report created 16/04/2013
2.3 Medication

6017 medication related adverse events were reported in 2012, accounting for 7.8% of all events reported. The highest category of medication adverse events was in relation to incorrect reconciliation of medication on admission/discharge/transfer at 21.8%. The Top 5 medication type adverse events are represented in Figure 12. The category “Other” has been selected in 11.3% of the medication adverse events recorded at enterprise level despite the fact that a significant number of these could be categorised under the available options for medication adverse events.

Figure 12: Top 5 medication Adverse Events

Figure 13: Medication Adverse Events by Specialty
2.4 Peri-natal

5270 peri-natal adverse events were reported in 2012, representing 6.4% of all events types. Figure 14 gives a breakdown of reported peri-natal events by looking at specific incident types with post-partum haemorrhage and perineal tear joint leaders at 14.7% each.

![Figure 14: Incident type specific peri-natal Adverse Events](image)

As expected the most prolific reporters of peri-natal events are nursing/midwifery staff as illustrated in Figure 15.

![Figure 15: Staff Category Reporting Peri-natal Adverse Events](image)
Figures 16 and 17 illustrate the Top 5 peri-natal adverse events reported by medical and nursing/midwifery disciplines and the differences between the incident types reported.

**Figure 16: Top 5 Peri-natal Adverse Events Reported by Medical Staff**

- Perineal tear (3rd & 4th degree) (incl breakdown of perineum) - 46.5%
- Shoulder Dystocia - 14.6%
- Post-partum haemorrhage - 12.9%
- Birth injury incl instrument injury - 5.0%
- Other - 4.4%

**Figure 17: Top 5 Peri-natal Adverse Events Reported by Midwives**

- Post-partum haemorrhage - 14.6%
- Apgar <5@1, 7@5, cord BE <12, pH<7.2 - 14.2%
- Unexpected transfer to SCBU/NICU - 13.5%
- Other - 13.0%
- Perineal tear (3rd & 4th degree) (incl breakdown of perineum) - 12.0%
2.5 Treatment

5,300 treatment related adverse events were reported as occurring in 2012, over half (50.8%) of which were reported from the specialty of Medicine and Surgery as illustrated in Figure 18.

It could be argued that a significant amount of the categorisations for patient safety adverse events are treatment related, however there is a specific category available for events identified as being treatment related with 16 specific options available for individual categorisation. It is therefore unfortunate that the category “other” has been the option selected in 31.7% of the treatment adverse events reported as illustrated in Figure 19 as this gives very little if any meaningful data.
The Speciality of Emergency Medicine reported 30.5% of delay/failure to treat events as seen in Figure 20, however this is not surprising given the fact that Emergency Departments provide 24/7 access to undifferentiated emergency and urgent presentations across the entire spectrum of medical, surgical, trauma and behavioural conditions.

Figure 20: Delay/failure to treat by Top 5 Specialties

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http://www.ifem.cc/about_IFEM.aspx accessed 31/07/2013
2.6 Diagnosis

1,364 diagnosis-related adverse events which occurred in 2012 were reported. Although this represents only 1.8% of all adverse events for 2012, it is important to note that 11% of all claims submitted in 2012 were in relation to diagnosis.

When consideration is given to the potential for diagnosis-related events to occur in a health system that treats millions of patients per year, there is a likelihood of significant under-reporting of these. Figure 21 illustrates the Top 5 Specialties involved in reported diagnosis adverse events with Paediatrics being marginally ahead at 18.9%.

![Figure 21: Diagnosis Adverse Events by Specialty](image)

As can be seen in Figure 22, mislabelled samples was the most frequent type of adverse event reported at 34.3%. The implications of incorrect sample labelling on both the patient and the service is significant as the impact in the delayed diagnosis, recall of patient(s), additional tests leads to an increased burden on an already stretched services. And yet labelling of samples is considered a basic task; this is an issue that if addressed could have a major impact on the service and patient safety requiring very little if any resources.

![Figure 22: Diagnosis Adverse Events by Incident Type Specific](image)
Figure 23 illustrates the monthly breakdown of all diagnosis adverse events reported with noticeable increases in the months of May and November. A similar picture can be seen in each of the Top 5 Specialties where a breakdown of diagnosis adverse events by month of occurrence is included in Appendix 2.

![Graph showing Diagnosis Events by Month of Occurrence (n=1364)]
3. Conclusion and Recommendations

“From the beginning of their training, healthcare professionals are taught that errors are unacceptable: no diagnosis, allergy or previous medical problem can be missed, every test must be tracked down, every medication dose must be exactly right. Despite this, in every healthcare system errors do happen, sometimes with serious or even fatal consequences for patients and their families. When such adverse incidents occur there must be a system in place that ensures that all those affected are informed and cared for, and that there is analysis and learning from the error to try to prevent the recurrence of such an Adverse Events. The dissemination of learning throughout the system is crucial to minimising error and protecting future patients.” Dr Deirdre Madden (2008)

The analysis presented in this report represents the key findings identified from the adverse events reported. The report reflects the overall national picture and analysis of key adverse event types. The aim of this report is to stimulate discussions at local level in relation to improving the reporting of clinical adverse events so as to provide safer clinical care. What is evident throughout is that there is a significant level of under reporting of clinical adverse events. There is a limited amount of information contained within the adverse event report to enable detailed analysis; information related to the adverse event reported onto the database is not being updated following completion of local analysis; information related to the extent of injury is not updated when the level of harm becomes evident, e.g. on receipt of diagnostic information.

Understanding the underlying system factors that lead to patient harm and fixing them leads to improved safety.

Recommendations

The following recommendations are based on the findings contained within the report. These are not placed in any order of priority, and remain consistent with recommendations from previous reports.

1. Data entered by enterprises needs to be updated to reflect any additional information in relation to the incident that is identified following any local risk management assessments/interventions etc. All adverse events should be allocated a risk rating, severity of injury and likelihood of recurrence.

2. HSE Managers and organisational management, to include Clinical Leads, could use risk ratings, outcomes, contributory factors and actions taken as derived from adverse event reported data (in conjunction with risk assessments, audit, complaints and claims data) as performance measurement indicators to measure progress being made nationally, regionally, and locally with respect to adverse event prevention.

3. Clinical Managers and Risk Managers should ensure that the quality and quantity of data submitted via incident reporting is sufficient to allow for meaningful trend analyses and the actioning of targeted interventions to reduce adverse events and thus prevent injuries.

4. The HSE, in conjunction with the SCA and in collaboration with professional/specialist colleges could use the findings of this study to promote reporting of all adverse event types amongst all categories of staff, but in particular, doctors through targeted quality and risk education initiatives, integrated quality and safety committees, clinical audit meetings, morbidity and mortality meetings, conferences and academic exchanges.

5. Professional/specialist colleges and regulatory bodies need to address the cultural barriers to adverse event reporting amongst their members/organizations, at undergraduate and post-graduate levels.

6. Given that a mislabelled sample was found to be the most frequently reported adverse event under diagnosis related adverse events, it is imperative that staff are made aware of the frequency of this fundamental error and organisations need to put measures in place to reduce the incidence of such adverse events occurring. The implications of incorrect sample labelling on both the patient and the service is significant as the impact of the delayed diagnosis, recall of patient(s) and additional tests leads to an increased burden on an already stretched service.
APPENDIX 1: Incident Type Reported by Specialty (Top 5)

Figure 24: Adverse Event Type Reported by Specialty of Medicine

Figure 25: Adverse Event Type Reported by Disability Services
Figure 26: Adverse Event Type Reported by Mental Health Services

Figure 27: Adverse Event Type Reported by Obstetrics
Figure 28: Adverse Type Reported by Surgery
APPENDIX 2: Diagnosis Adverse Events by Month of Occurrence (Top 5 Specialties)

Figure 29: Diagnosis Related Adverse Events in Medicine by Month of Occurrence

Figure 30: Diagnosis Related Adverse Events in Emergency Medicine by Month of Occurrence
Figure 31: Diagnosis Related Adverse Events in Obstetrics by Month of Occurrence

Figure 32: Diagnosis Related Adverse Events in Paediatrics by Month of Occurrence
Figure 33: Diagnosis Related Adverse Events in Surgical Services by Month of Occurrence