Best Practice Guidelines and Template for a National Medication Incident Report Form

This document is intended as a “best practice” guideline and is not to be regarded as a document offering definitive legal advice in relation to the subject matter.

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On behalf of the Irish Medication Safety Network
and in consultation with Irish Medication Safety Network members

About the IMSN

The Irish Medication Safety Network (IMSN) is an independent group of pharmacists and other specialists working in the acute sector, whose principal aim is to improve patient safety with regard to the use of medicines through collaboration, shared learning and action.

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About this Report

In 2009 the World Health Organisation (WHO) published the conceptual framework for the International Classification for Patient Safety (ICPS) which is intended to standardise definitions in order to align reporting systems globally. The conceptual framework aims to provide a comprehensive understanding of the domain of patient safety. It aims to represent a continuous learning and improvement cycle incorporating identification, prevention and reduction of risk.

The Irish Medication Safety Network (IMSN) convened a working group to develop medication incident reporting guidelines. The IMSN guidelines were drafted using the framework developed by the WHO and by building on the systems already in place in Irish hospitals. These guidelines include guidance for completing a Medication Incident Report and descriptions of incident categories (Appendix 1), a sample Medication Incident Report (MIR) template (Appendix 2), and general recommendations to assist a hospital that intends to update its current MIR form or to implement a new MIR form.

Our aim is:
- to develop a template and guidelines for an MIR form for reporting medication safety incidents and near misses in hospitals in Ireland.
- to standardise the description (categories) on medication incident report forms in hospitals around the country. This would facilitate analysis of reports for the identification of common hazards, risks and opportunities and priorities for action on behalf of patient safety in all our hospitals.
- to encourage greater reporting and increase the culture of safety, with the implementation of such a national reporting template.

Background

Incidence studies internationally show that most Adverse Events (AEs) are not the direct result of negligence, carelessness or incompetence of healthcare providers, but rather they are related to deficiencies in organisation, design and processes of care.

Improvements in patient safety and quality of care can be facilitated through incident reporting and the collection of standardised data about medication incidents and near misses. Using data collected we can determine the factors contributing to medication incidents and near misses and establish preventative strategies to minimise the risk of recurrence.

International evidence of medication safety incidents

International studies have reported that adverse events (patient safety events resulting in patient harm) occur in 9 to 16% of hospital admissions. A hospital-based study in the United States determined a rate of adverse drug events (medication errors or adverse drug reactions resulting in patient harm) of 2.3 per 100 admissions, of which 28% were preventable. The Institute of Medicine in the United States estimates:
- 1 medication error per hospitalised patient per day in the United States.
1.5 million preventable adverse drug events per year in the United States\textsuperscript{9}.

7,000 deaths per year from medicine error in US Hospitals\textsuperscript{3}.

### Medication Incident Reporting programmes

Incident reporting provides valuable learning and makes healthcare systems safer for patients\textsuperscript{3}. Many countries have well established reporting systems (Table 1) and are actively engaged in incident reporting initiatives.

#### Table 1: International Incident Reporting Systems

<table>
<thead>
<tr>
<th>Country</th>
<th>Medication Incident Reporting programmes in Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>A variety of reporting activities, including MedMARx®, MedWatch (FDA), National Medication Errors Reporting Program (ISMP MERP)\textsuperscript{10-13}</td>
</tr>
<tr>
<td>Canada</td>
<td>Canadian Medication Incident Reporting and Prevention System (CMIRPS). The collaborating parties of the CMIRPS are: Canadian Institute for Health Information; Health Canada; and Institute for Safe Medication Practices Canada\textsuperscript{14,15}</td>
</tr>
<tr>
<td>Australia</td>
<td>Clinical Incident Management System (AIMS)\textsuperscript{16}</td>
</tr>
<tr>
<td>UK</td>
<td>National Reporting and Learning System (NRLS)\textsuperscript{17}</td>
</tr>
</tbody>
</table>

In Ireland, the Clinical Indemnity Scheme (CIS) managed by the State Claims Agency collects incident and near miss reports from participating public hospitals and maternity hospitals via its STARSweb database. Medication-related incidents/near misses are the highest category of clinical incidents reported via STARSweb, with 10% of reports in 2009\textsuperscript{18}. The Irish Medicines Board (IMB) collects reports from patients and healthcare professionals on adverse drug reactions.

A collaborative study of medication safety incidents/near misses was published in December 2009\textsuperscript{19}. Eight Irish hospitals or hospital networks (all members of the Irish Medication Safety network (IMSN)) provided data from voluntary medication safety incidents and near miss reporting programmes for pooled analysis of events occurring between 1\textsuperscript{st} January 2006 and 30\textsuperscript{th} June 2007. A standardised dataset was used to facilitate pooled analysis of reports by patient outcome, stage(s) of the medication use process involved and type of incident or near miss. 6,179 reports were received in total, 95% of which did not involve patient harm.

The majority of Irish hospitals have an incident-reporting programme, and either an in-house bespoke or commercially available database to manage this. Some medication incident reporting is carried out on a generic risk management occurrence form, while others have a specialised MIR form. Reporting systems in Irish hospitals are mainly paper-based, however some web based systems are in operation. Whatever the reporting method i.e. paper based or computerised, the dataset proposed in this report can be adopted by any hospital.
Methodology and Design of MIR Template

In compiling this report the IMSN working group reviewed medication incident forms available from Irish hospitals, guidance from International Standards \cite{1,11,12,13,14,15,16,17} and STARSweb medication incident categories developed by the CIS\cite{18}. On examining all forms/information a basic structure became apparent, with standard sections (Figure 1). Categories from medication incidents were listed and those with similar meanings were referenced together (Appendix 1). As a result a standard minimum dataset was established for inclusion on a national MIR form template. A minimum dataset for a MIR form refers to a core set of data elements required for a comprehensive form that is fit for purpose. The proposed data set aims to go beyond answering the ‘who’ ‘what’ and ‘where’ and endeavours to assist with answering the ‘why’ e.g. why the medication incident occurred. The most relevant definitions to an Irish setting, obtained from international literature were utilised (Appendix 3).

To conform to a national standard dataset, it is recommended that any hospital developing or reviewing a paper based or an electronic MIR form should adopt the template attached (Appendix 2). The template can be made available electronically for hospitals and individual hospitals can brand according to their own specifications e.g. hospital name, crest, colour, etc. If a hospital is updating a current MIR form it should follow these guidelines with regard to the incident details, categorisation, and outcome/action details. Beyond the minimum set of data elements, optional items can be added that provide a hospital with the flexibility to collect data that aligns with local or regional information needs.

The template form is designed with 7 main sections (see Figure 1). Each section has the purpose of eliciting from the reporter as much relevant information about the incident as possible. The form includes narrative sections, to elicit a description of the incident, incident outcome and perceived contributory factors in the reporter’s own words, along with multiple choice sections to elicit contextual details about the incident and its contributory factors.

Contributory factors are the circumstances, actions or influences which are thought to have played a part in the development of the incident or to increase the risk of an incident\cite{20}. The MIR form is also designed to gain background knowledge on the patient’s condition in order to ascertain the level of harm that was possibly caused by the incident and any actions taken to reduce, manage or control any future harm or probability of harm associated with an incident.

Completing MIR forms

When should MIR forms be completed?
A MIR form should be completed as soon as possible after the incident involving medication occurs. All medication incidents, near misses or adverse drug events should be reported so that learning can take place and the potential for such incidents to recur can be reduced. Even if no actual harm came to the patient, or if the incident was averted, it still should be reported (as a ‘near miss’ if it did not reach the patient) as this can help prevent the incident from recurring or causing harm in the future.
Who should complete the form?
Any member of staff working in the hospital may complete the form. It should normally be the person who was involved in the incident.

Figure 1: Outline of the Medication Incident Report (MIR)

1. Patient Details
   - Date, time, location, etc.
   - In/Outpatient, Speciality
   - Stage in Patient Care Process

2. Incident Details
   - Medication involved
   - Event type (incident, near miss or adverse drug reaction)
   - Detection Trigger
   - Free text section
   - Stage in medication use process e.g. administration, prescribing
   - Incident category (the problem), e.g. incorrect drug, incorrect dose
   - Free text section confirms the detail of the tick boxes

3. Outcome of Incident
   - Category of Outcomes
   - Harm/No Harm/Uncertain at time of reporting

4. Treatment Actions Required
   - Treatment / Action
   - Free text section

5. Contributory Factors
   - Description of Contributory Factors (Free text)

6. Reporting details
   - Reported to
   - Patient/Family aware
   - Reported by

7. Follow up Action → Risk Reduction Measures
   - Free text boxes to elicit any additional information

Analysing and Reviewing MIR Forms

Reporting of medication incidents is of little value unless the data are analysed. Analysis normally takes place at a number of levels:

1) Level at which the incident occurred (for example the ward or the patient interface)
2) Organisational level
3) National level
1) Preliminary analysis of the event and contributory factors is carried out locally to ensure MIR forms are completed as accurately and comprehensively as possible at ward or departmental level. Local analysis may lead to identification of risk reduction measures and some hospitals have policies and training for staff in incident analysis to facilitate this process.

2) Given the complexity and clinical nature of medication incidents and frequent organisation-wide applicability of learning from incidents, it is recommended that MIR forms are reviewed and analysed at organisational level. This review and analysis may include:

- critical review of report forms to ensure that the categories selected align with the free text and that the form is completed as intended by the reporter
- incident grading and prioritisation for further review/action
- incident review (in consultation with other healthcare professionals as appropriate) to determine what happened, how and why (using Systems Analysis/Root Cause Analysis techniques) and to determine actions which need to be taken to reduce the risk of recurrence.

As per the WHO Conceptual Framework it is important that analysis captures both mitigating factors which prevent and moderate the progression of an incident toward harming a patient and ameliorating actions taken to make better or compensate any harm after an incident¹.

In addition to analysis of individual incidents as above, trend analysis should be carried out periodically to identify key themes and trends, e.g. specific drugs, as well as processes and procedures that contribute to repetition of individual incidents. Recommendations and actions should be determined to reduce the risk of recurrence.

Analysis at organisational level should incorporate the consequences directly to the organisation such as an increased use of resources to care for the patient, media attention or legal ramifications¹. Hospitals should have a governance process in place to oversee the medication safety process. In many Irish hospitals, this is the responsibility of the Drugs & Therapeutics Committee or Medication Safety Committee.

In a large number of Irish hospitals, pharmacists and/or drug safety personnel play a vital role in reviewing and analysing medication incidents in the above or similar manner, separate to or in coordination with Risk Management or other Quality or Safety personnel. It is the recommendation of the members of the Irish Medication Safety Network that this review and analysis structure is best carried out by or in coordination with pharmacists and/or drug safety personnel.

3) National reporting requirements, e.g. to the Clinical Indemnity Scheme (CIS) via the STARSweb program (for hospitals indemnified by the CIS), to the Irish Medicines Board (IMB) for adverse drug reactions etc., should also be fulfilled. This facilitates national analysis to identify recurring themes across the Irish health care system and in turn informs the development and prioritisation of practical national solutions.

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Grading Medication Incident Report Forms

It is recommended that all incidents be graded. Pharmacists, drug safety personnel or other suitable clinical personnel should carry out risk grading on medication incidents as per hospital policy. Grading systems can capture:

- The actual consequence of the incident
- Potential consequence of the incident
- The likelihood of recurrence of a similar event

The types of grading definition currently in use in Irish hospitals vary and include:

- NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention) index for categorising medication errors\(^2\)
- Risk matrix, e.g. HSE Risk Assessment Tool classification system\(^2\), 5 x 5 matrix of severity and probability (NPSA)\(^4\)
- WHO patient outcome/degree of harm grading\(^1\)
- Specialised definitions developed by individual hospitals.

Conclusion

- The IMSN subgroup recommends that all hospitals collect data on medication incidents. A dataset and a template have been provided to facilitate standardised national reporting of medication incidents.
- It is recommended that all Irish hospitals use this standardised dataset and adopt the template provided (Appendix 2) either in its current format or on a customised hospital form.
- All hospitals should ensure that their MIRs are analysed and acted upon locally.
- Data should be aggregated across hospitals and analysed for trends and recurring patterns.
- Pharmacists and/or drug safety personnel should always be involved in reviewing medication incidents.
### Appendix 1: Guidelines for completion of the Medication Incident Report form

<table>
<thead>
<tr>
<th><strong>Medication Incident</strong></th>
<th><strong>Level 1 data</strong></th>
<th><strong>Definition</strong></th>
<th><strong>Level 2 data</strong></th>
<th><strong>Instruction / Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Details</strong></td>
<td></td>
<td></td>
<td><strong>Patient name</strong></td>
<td>Enter the patient’s full name (first and surname)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>M.R.N./Hospital Number/ Medical Record Number/Patient number</strong></td>
<td>Enter the Hospital Number / Medical Record Number (MRN) / Patient number for the particular hospital involved</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Sex</strong></td>
<td>Record the sex of the patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Date of Birth</strong></td>
<td>Record the patient’s date of birth. If you do not know it, record it as accurately as you can using the month and year of birth</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Age</strong></td>
<td>Record the age of the patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Date/s of incident</strong></td>
<td>Record the date as accurately as you can. The event may have run over a few days e.g. missed dose for 3 days 11.07.10 → 13.07.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Time of incident (24 hr clock)</strong></td>
<td>Record the time of the event as accurately as you can using the 24 hr clock</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Inpatient or Outpatient</strong></td>
<td>Tick the appropriate box, indicating if the patient was an inpatient or outpatient at the time of the event</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Ward/Department of patient</strong></td>
<td>Record the ward/department the patient is admitted to at the time of the event e.g. St. John’s Ward</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Exact Location (if different)</strong></td>
<td>Record the exact location. The patient may be admitted to St. Johns Ward however the event may occur in theatre or X-Ray, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tick as appropriate if the event occurred during the patient admission, during hospital stay, while being transferred between wards or at patient discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Consultant and Speciality</strong></td>
<td>State the consultant the patient is under and the speciality at the time of the event e.g. Dr. Joe Bloggs, Cardiology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Referral Speciality and Consultant involved (if applicable)</strong></td>
<td>The event may involve the referral speciality, which may differ from the speciality the patient was admitted under and the healthcare staff ordinarily caring for the patient. Example: if an incorrect dose was administered to an orthopaedic patient by an anaesthetist, the specialty where the event occurred would be Anaesthetics not Orthopaedics</td>
</tr>
<tr>
<td>Medication Incident</td>
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</tr>
<tr>
<td><strong>Level 1 data</strong></td>
<td><strong>Level 2 data</strong></td>
<td><strong>Instruction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incident Details</td>
<td>Patient event/Non-patient event</td>
<td>Patient event or event not directly involving any patient</td>
<td>Tick as appropriate according to the definitions in Appendix 3</td>
<td></td>
</tr>
<tr>
<td>Incident/Near miss/ Adverse Drug Reaction</td>
<td>Incident or near miss or adverse drug reaction</td>
<td></td>
<td>Tick as appropriate according to the definitions in Appendix 3</td>
<td></td>
</tr>
<tr>
<td>Discovered by</td>
<td>Who discovered the event</td>
<td>Tick the profession or description of the person who initially discovered the incident or near miss.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detection Trigger</td>
<td>Detection Trigger</td>
<td>Detail any trigger factor that resulted in the discovery of the event e.g. change in patient condition, chart review, monitor or alarm signal, audit or risk assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Details of drug/s involved</td>
<td>Drug Name/s</td>
<td>Enter the generic or non-proprietary name (with brand name if appropriate) applied to the medicine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose/s</td>
<td>Enter the dose or strength of the medicine involved, e.g. 1 mg /1 ml, or 10 mg, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Route/s</td>
<td>Enter the category that describes the route by which the medicine involved was prescribed e.g. IV, oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frequency</td>
<td>Enter the frequency at which the medication was prescribed e.g. daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Form</td>
<td>Enter the form of the medication, e.g. tablet, capsules, cream, solution, eye drops, etc…</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of the incident (free text)</td>
<td>Factual description of Incident</td>
<td>Describe the patient safety event in your own words. It is important that the information you provide is factual and not simply an opinion. Think about the sequence of events and document them according to the order in which they occurred. End with a description of how the event was concluded.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### Medication Incident

<table>
<thead>
<tr>
<th>Level 1 data</th>
<th>Definition</th>
<th>Level 2 data</th>
<th>Description / Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Details</td>
<td>Stage(s) of the medication process where the incident occurs</td>
<td>Prescribing</td>
<td>The event occurs or originates at the prescribing stage</td>
</tr>
<tr>
<td></td>
<td>Ordering</td>
<td>The event occurs when the medication is ordered by the ward/department from the pharmacy.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharmacy / Dispensing</td>
<td>The event occurs during any of the dispensary processes from procurement through preparation, labelling, delivery to ward e.g. furosemide 40mg labelled as furosemide 20mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Storage</td>
<td>The event occurs during storage of the medication, e.g. not storing at the correct temperature</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Administration</td>
<td>The event occurs at the administration stage of the medication process e.g. a medication being administered once daily when prescribed twice daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
<td>The event occurs at the monitoring stage of the medication process e.g. incorrect interpretation of laboratory results relating to medication therapy; the appropriate monitoring of clinical or laboratory parameters did not take place, incorrect or inappropriate advice or endorsement by clinical pharmacist</td>
<td></td>
</tr>
</tbody>
</table>

### Medication Incident

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</thead>
<tbody>
<tr>
<td>Incident Details</td>
<td>Incident Category</td>
<td>Adverse Drug Reaction or Allergy (no previous history)</td>
<td>The event involves an untoward (unplanned/unexpected) medical reaction that presents during treatment with medication that occurs at doses normally used for the prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function</td>
</tr>
<tr>
<td></td>
<td>Allergy or Intolerance (known)</td>
<td>This event occurs if a known allergen or a medication to which a patient is intolerant is prescribed and/or administered. Note: previously unknown allergies are recorded as Adverse Drug Reactions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contraindication</td>
<td>This event occurs when a patient is prescribed or administered a medication where it is contraindicated due to patient condition, e.g. disease, adverse effects, concomitant drug therapy (drug-drug interaction), interaction with food, e.g. NSAIDs contra-indicated in severe heart failure; anti-hypertensive therapy contra-indicated in patients with profound hypotension etc</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug – Drug/ Drug - Food Interaction</td>
<td>This event occurs when the effects of the drug are changed by the presence of a specific drug or food and results in an unintended interaction</td>
<td></td>
</tr>
</tbody>
</table>
## Medication Incident

<table>
<thead>
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<th>Description / Example</th>
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</thead>
<tbody>
<tr>
<td>Incident Details</td>
<td>Incident Category</td>
<td>Drug not indicated</td>
<td>This event occurs when a drug is prescribed for which there is no apparent indication, where a drug is prescribed prior to confirmation of a treatment plan or despite documentation of a different treatment plan - e.g. prescription of an antimicrobial agent for a patient with no infection or reason for prophylaxis, prescription of chemotherapy for a patient for whom it had been cancelled or who is still awaiting test results.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expired drug</td>
<td>The event involves dispensing, supplying, administering or storing a medicine that is past its use by date.</td>
</tr>
</tbody>
</table>
| | Incorrect dose (over / under / duplicated dose) | | This event involves:  
- Prescribing a medicine at an inappropriate or unintended dose.  
- Dispensing a medicine at an inappropriate dose or at a dose different to that prescribed or ordered.  
- Administering a medicine at an inappropriate dose or at a dose different to that prescribed. |
| | Incorrect drug | | This event involves:  
- Prescribing a medicine that is not the best choice or the intended choice for the subject’s condition, or prescribing an unintended medicine.  
- Dispensing a medicine different from that prescribed or ordered.  
- Administering a medicine different from that prescribed. |
| | Incorrect duration | | The event involves:  
- Prescribing or administering a medicine for a duration that is different from that intended, and/or is practical or appropriate for the subject’s condition e.g. when a drug prescribed for a definitive course is discontinued inappropriately e.g. tapering dose of anti-epileptics stopped abruptly.  
- Dispensing and labelling a medicine for a duration different to that prescribed.  
- Administering a medicine beyond the specified duration of the treatment. |
| | Incorrect formulation / presentation / diluent | | This event occurs when:  
- The incorrect formulation of a drug is used, e.g. OxyNorm® (immediate release oxycodone) instead of OxyContin® (sustained release oxycodone), using the incorrect brand of a drug when the brands are not generically equivalent e.g. Tildiem® 60mg given for Dilzem® SR 60mg.  
- Incorrect diluent refers to when a drug must be reconstituted before administration and the incorrect reconstitution solution or carrier fluid is used. |
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Incident Category</td>
<td></td>
<td>Incorrect frequency</td>
<td>This event involves prescribing or administering a drug more or less frequently than intended; dispensing a drug with the incorrect frequency on the label</td>
</tr>
<tr>
<td>Incorrect labelling / instruction</td>
<td>This event occurs when incorrect or unclear information is included on the label of any product prepared and labelled on the ward, theatre or other department or in the pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect patient</td>
<td>This event occurs when medication is prescribed for, administered to, dispensed to, ordered for or supplied to the wrong patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect quantity</td>
<td>This event involves prescribing, dispensing or administering an incorrect quantity of medicine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Incorrect rate | This event involves:  
  - Prescribing an infusion at a rate different from that intended, and/or that which is practical or appropriate for the subject’s condition  
  - Administering a medicine at an infusion rate different to that prescribed  
  - Dispensing and labelling an infusion for a rate different to that prescribed |
| Incorrect route | This event involves:  
  - Prescribing a medicine by a route different from that intended, and/or that which is practical or appropriate for the subject’s condition  
  - Dispensing a medicine for a route different to that prescribed.  
  - Administering a medicine via a route different to that prescribed |
| Incorrect storage | This event refers to when medication is inappropriately stored, e.g. fridge items not stored correctly in a refrigerator, Misuse of Drugs Act medication not secured in a locked cabinet |
| Incorrect strength/concentration | This event refers to when the incorrect strength of a medication is used e.g. Valsartan/Hydrochlorothiazide available as Co-Diovan in 4 different strengths (160mg/12.5mg, 160mg/25mg, 320mg/12.5mg and 320mg/25mg) and incorrect strength chosen; drug for infusion diluted or reconstituted in an incorrect volume |
| Incorrect time | This event involves:  
  - Prescribing a medicine at a time different from that intended, and/or that which is practical or appropriate for the subject’s condition e.g. midodrine at 10pm  
  - Dispensing and labelling a medicine for a time different to that prescribed.  
  - Administering a medicine at a time different to that prescribed |
| Monitoring inappropriate | This event involves not carrying out the correct monitoring, e.g. not taking vancomycin levels, INR monitored instead of APTT, timing of therapeutic drug monitoring levels inappropriate, leading to difficulties/errors in interpretation |
### Medication Incident

<table>
<thead>
<tr>
<th>Level 1 data</th>
<th>Definition</th>
<th>Level 2 data</th>
<th>Description / Example</th>
</tr>
</thead>
</table>
| Incident Details   | Incident Category           | Omitted/missed drug/dose                                      | This event occurs when a:  
- Patient is not prescribed a drug/dose that they should receive  
- Medication is not dispensed as ordered in time for patient to receive a due dose  
- Failure to administer a prescribed dose to a patient when due. This excludes patients who refuse, or a decision not to administer                                                                                     |
|                    | Therapeutic duplication     |                                                              | This event occurs when a drug is prescribed more than once or when more than one agent in a particular therapeutic class is erroneously prescribed for a patient, e.g. paracetamol and Solpadol®, diclofenac prescribed for a patient already on naproxen, enoxaparin prescribed for a patient already on dabigatran |
|                    | Other                       |                                                              | This event includes any incident category that may not be accurately described by any of the above categories. The ‘OTHER’ category must only be used when no other alternative category is available                                          |
| Pump Incident Details, if relevant | Asset Tag Number |                                                               | Details the Pump number or asset number assigned by individual hospitals for equipment                                                                                                                                  |
|                    | Brand and Name of Equipment |                                                              | Details the name and brand of the pump or other equipment involved in the incident                                                                                                                                    |

### Medication Incident

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<tr>
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<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome of Incident</td>
<td>Resulted in harm</td>
<td></td>
<td>Detail if the event resulted in patient harm/no harm or clearly specify if the outcome is unknown at the time of reporting</td>
</tr>
<tr>
<td></td>
<td>Treatment/Monitoring Required</td>
<td></td>
<td>Detail the outcome of the event and specify if any treatment action / monitoring was required as a result of the event</td>
</tr>
</tbody>
</table>

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Medication Incident

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<th>Description / Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contributory Factors</td>
<td>Factors that may have contributed to the incident/near miss</td>
<td>Error/Slip/Lapse</td>
<td>This occurs when an incorrect dose is prescribed, administered or dispensed due to a calculation mistake.</td>
</tr>
<tr>
<td>Staff Factors</td>
<td>Calculation Error</td>
<td>This refers to when a prescription is not transcribed or rewritten correctly.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rewrite Error</td>
<td>This refers to when a drug prescribed for a definitive course has been ineffective or has caused adverse effects but has not been discontinued appropriately or when a drug is not cancelled appropriately for a procedure e.g. warfarin not held before surgery or when a drug prescribed for a definitive course is discontinued incorrectly.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug Continued/Discontinued in Error</td>
<td>This refers to when a medicine as prescribed but failing to document the administration on the subject’s drug chart or other treatment record.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Documentation Ambiguous/Incomplete</td>
<td>This occurs when inadequate documentation in nursing or medical notes contributes to the event. Examples include:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incorrect Administration Times Circled</td>
<td>• administering a medicine in a manner where the prescriber’s intention is not clear or prescription is incomplete, e.g. no signature.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incorrect Endorsement</td>
<td>This occurs when the medication order has incorrect additional instructions endorsed by a doctor, nurse or pharmacist.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incorrect Labelling</td>
<td>This refers to when an incident involves unclear or absent labelling by staff.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lack of or Mis-communication</td>
<td>This occurs as a result of incomplete, misheard, misunderstood instructions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lack of Knowledge of Drug/Patient</td>
<td>This arises due to staff being unfamiliar with the medication or the patient’s medical history.</td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Contributory Factors</td>
<td>Staff Factors, continued</td>
<td>Lack of Knowledge of / Failure to adjust for Patient Factors</td>
<td>This arises due to staff being unfamiliar with adjusting medications relative to the patient’s condition.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Personal/Health/Behavioural Factors</td>
<td>This arises if a staff member’s personal status, health or behavioural factors contribute to a medication incident occurring.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Policy/Procedure Not Followed</td>
<td>This occurs when a policy/procedure was not followed e.g. when double checking of procedure, equipment or medication is not undertaken or due to the use of unauthorised abbreviations or decimal points with no leading zero (e.g. iu instead of units and .5g instead of 500 milligrams) or if non-generic prescribing contributed to the incident.</td>
</tr>
<tr>
<td></td>
<td>Patient Factors</td>
<td>Behavioural Factors</td>
<td>This occurs if a patient’s behaviour contributes to the medication incident.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Communication Difficulties</td>
<td>This occurs if there is a difficulty in communicating with the patient e.g. literacy or cognitive related factors involved.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Complexity of Condition</td>
<td>This occurs if a patient’s medical requirements are complex in nature.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non Compliance</td>
<td>This occurs if a patient is non-compliant with instructions or medications.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perception/Understanding</td>
<td>This occurs if a patient’s lack of perception or understanding contributes to an incident.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unauthorised Self Administration</td>
<td>This refers to if a patient has administered a drug to him or herself without informing medical/nursing staff.</td>
</tr>
<tr>
<td>Environmental Factors</td>
<td>Interruptions</td>
<td>This occurs when interruptions by staff, telephone, patients, visitors etc cause a distraction which contributes to an event occurring.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lighting/Noise/Clutter</td>
<td>This occurs when defects in lighting, distraction of noise or a cluttered work environment contribute to the event.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical Environment</td>
<td>This occurs when the event happened as a result of the work environment causing a workflow problem.</td>
<td></td>
</tr>
<tr>
<td>Level 1 data</td>
<td>Definition / Type</td>
<td>Level 2 data</td>
<td>Description / Example</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Contributory Factors</td>
<td>Organisational Service Factors</td>
<td>Multiple Prescription Sheets</td>
<td>This occurs as a result of a patient having more than one prescription sheet</td>
</tr>
<tr>
<td></td>
<td>Policy/Protocol or Guidelines</td>
<td>Not Available/Accessible</td>
<td>This occurs when the organisation has no policy/protocol or guideline available to staff to assist them in their work processes and this is a contributory factor in a medication incident</td>
</tr>
<tr>
<td></td>
<td>References Not Available/ Accessible/ Outdated</td>
<td></td>
<td>This occurs when references are unavailable or outdated and as a result contribute to a medication incident</td>
</tr>
<tr>
<td></td>
<td>Staffing Levels/Workload</td>
<td></td>
<td>This may occur when insufficient staffing levels are in place</td>
</tr>
<tr>
<td></td>
<td>Staff Training/Experience/Supervision Deficit</td>
<td></td>
<td>The event occurs due to insufficient training on the medication or process or inexperienced staff carrying out the task without supervision</td>
</tr>
<tr>
<td>External Factors</td>
<td>Drug Packaging/Label Related</td>
<td></td>
<td>This occurs when packaging or faulty drug identification contributes to the event</td>
</tr>
<tr>
<td></td>
<td>Equipment Design Factor</td>
<td></td>
<td>This refers to when equipment design or misprogramming contributes to the event</td>
</tr>
<tr>
<td></td>
<td>Sound Alike – Look Alike Drugs (SALAD)</td>
<td></td>
<td>This involves prescribing, dispensing or administering an incorrect drug with a similar name to the intended drug e.g. Omesar® and Omacor®</td>
</tr>
<tr>
<td></td>
<td>Services/Systems/Policies Requirements</td>
<td></td>
<td>This occurs when there are insufficient or unsatisfactory services/systems/policies from external regulators</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>This includes any contributory factor that may not be accurately described by any of the above factors. The ‘OTHER’ contributory factor must only be used when no other alternative factor is available</td>
</tr>
</tbody>
</table>

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Follow up Actions</td>
<td>Actions that reduce, manage or control future risk</td>
<td>Risk Reduction Measures</td>
<td>Please detail any actions taken to reduce recurrence of the event</td>
</tr>
</tbody>
</table>

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Appendix 2: MIR Template

XXX XXXXX Hospital

Medication Incident Report Template

Report No: ____________
Analyze Err No: ____________
STARS Incident ID: ____________

Patient Details

Patient Name: ____________
M.R.N: ____________
Date of Birth: ____________

Male   Female

Date(s) of Incident: ____________

Time of Incident (24 hr clock): ____________

Inpatient   Outpatient

Stage in Patient Care:
Admission   During stay   Patient transfer   Discharge

Consultant/Specialty: ____________
Referral Specialty and Consultant involved (if applicable):

Incident Details

Event Type - please tick:
Incident (reached patient)   Near Miss (did not reach pt)   Adverse Drug Reaction

Discovered by: Nurse   Doctor   Pharmacist   Patient/Family   Visitor   AHP   Other

Detection Trigger: Please detail in plain English how the incident was discovered e.g. chart review, change in patient status, via a monitor/alar, audit review or assessment

Details of relevant drug(s) involved (total drug history not required):

Drug Name/s   Dose/s   Route/s   Frequency   Form (e.g. tab, patch, etc)

Brief factual description of incident (in plain English):

*Please include a copy of prescription if possible/relevant

Stage(s) of the process where incident / near miss occurred:

Prescribing   Ordering   Pharmacy / Dispensing

Storage   Administration   Monitoring
Incident Category: Medication Incident related to:
- Adverse Drug Reaction / Allergy (no previous history)
- Allergy/Intolerance (previously known)
- Contraindication
- Drug/Drug - Drug/Food Interaction
- Drug not indicated
- Expired drug
- Incorrect dose (over/under/duplicated dose)

Pump Incident Detail (if relevant): Brand Name of Equipment

Asset tag Number

Patient Outcome - Resulted in Harm: Yes [ ] No [ ] Uncertain at time of reporting [ ]

Outcome of incident and Treatment / Monitoring Required e.g. X-Ray, blood test, ECG, dressings, new medications:

Contributory Factors:
The purpose of incident reporting is to improve quality and enhance patient safety. Therefore, it would be very helpful if you would describe briefly, in plain English, any factors which you feel may have contributed to the incident.

Reported to: Name: [ ] Verbal [ ] Written Communication

NCHD / Consultant / Manager / Pharmacy / Other (circle as appropriate)

Patient/Family Aware: Yes [ ] No [ ]

Reported by: Nurse [ ] Doctor [ ] Pharmacist [ ] Patient/Family [ ] Visitor [ ] AHP [ ] Other [ ]

Follow-up Actions/ Risk Reduction Measures:

Undertaken: [ ]

Recommended: [ ]

SIGNATURE: [ ]

Job Description/Title: [ ]

PRINT NAME: [ ]

Contact Bleep/extension: [ ]

e-mail: [ ]

Date reported to doctor/other: [ ]

Date MIR Form filled in: [ ]

Please fill out the form as completely as possible and send to:

Official Use Only: Date Received: [ ]

Date Reviewed: [ ]

Patient Outcome, Degree of Harm: None [ ] Mid [ ] Moderate [ ] Severe [ ] Death

Likelihood of Recurrence: Risk Rating: NCC MERP Index:

Signature: [ ]

Designed by a subgroup of the Irish Medication Safety Network, see www.imsn.ie

Approved 11/3/2014

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Appendix 3: Definitions

Incident (or adverse incident):
- Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.

Medication error
- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging and nomenclature, compounding. An error in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome (i.e. injury to the patient).

Near Miss
- An incident which did not reach the patient e.g. Penicillin being prescribed for a penicillin-allergic patient, but the allergy being discovered before the patient got the drug, or being connected to the wrong patient’s intravenous line, but the error was detected before the infusion started.

Adverse Drug Reaction
- A response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. ASHP defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that:
  1. Requires discontinuing the drug (therapeutic or diagnostic),
  2. Requires changing the drug therapy,
  3. Requires modifying the dose (except for minor dosage adjustments),
  4. Necessitates admission to a hospital,
  5. Prolongs stay in a health care facility,
  6. Necessitates supportive treatment,
  7. Significantly complicates diagnosis,
  8. Negatively affects prognosis, or
  9. Results in temporary or permanent harm, disability, or death.
Consistent with this definition, an **allergic reaction** (an immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug) and an **idiosyncratic reaction** (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.

**Contributing factor:**
- An antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome\(^\text{28}\).  
- A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident\(^\text{20}\).

**Patient event:**  
An event which directly involves one or more patients.

**Non-patient event:**  
An event which does not directly involve any patient, such as a storage or delivery issue.
References


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