



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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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)¹ 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 risk¹.

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 care².

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 misses³. Using data collected we can determine the factors contributing to medication incidents and near misses and establish preventative strategies to minimise the risk of recurrence³.

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 admissions⁴⁻⁷. 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 preventable⁸. The Institute of Medicine in the United States estimates:

- 1 medication error per hospitalised patient per day in the United States⁹

- 1.5 million preventable adverse drug events per year in the United States⁹
- 7,000 deaths per year from medicine error in US Hospitals³.

Medication Incident Reporting programmes

Incident reporting provides valuable learning and makes healthcare systems safer for patients³. Many countries have well established reporting systems (Table 1) and are actively engaged in incident reporting initiatives.

Table 1: International Incident Reporting Systems

Country	Medication Incident Reporting programmes in Hospitals
USA	A variety of reporting activities, including MedMARx®, MedWatch (FDA), National Medication Errors Reporting Program (ISMP MERP) ¹⁰⁻¹³
Canada	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 ^{14,15}
Australia	Clinical Incident Management System (AIMS) ¹⁶
UK	National Reporting and Learning System (NRLS) ¹⁷

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 2009¹⁸. 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 2009¹⁹. Eight Irish hospitals or hospital networks (all members of the Irish Medication Safety network (IMSNI)) provided data from voluntary medication safety incidents and near miss reporting programmes for pooled analysis of events occurring between 1st January 2006 and 30th 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^{1,11,12,13,14,15,16,17} and STARSweb medication incident categories developed by the CIS¹⁸. 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 incident²⁰. 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

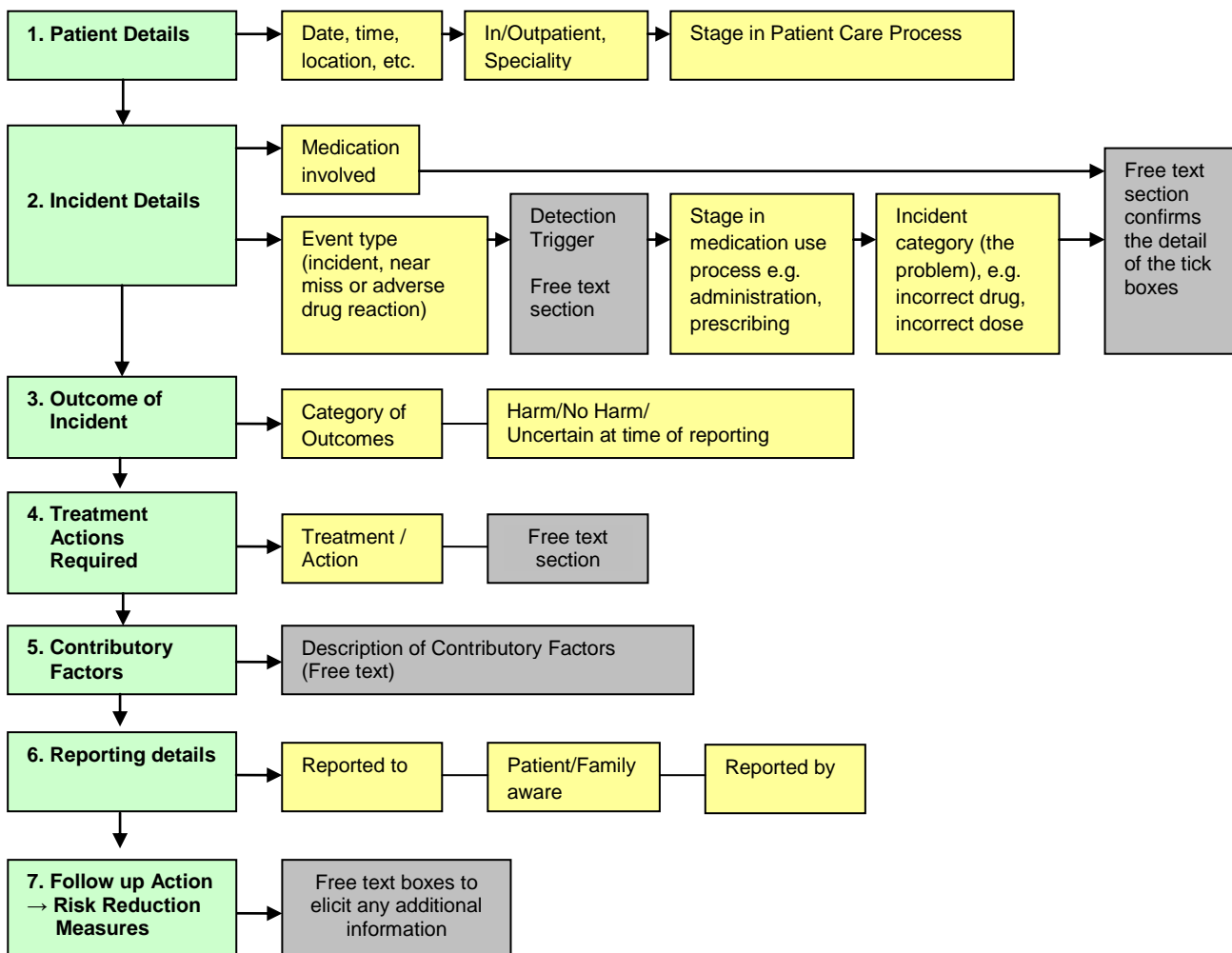
When should MIR forms be completed?

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)



Analysing and Reviewing MIR Forms

Reporting of medication incidents is of little value unless the data are analysed²¹. 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.

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 errors²²
- Risk matrix, e.g. HSE Risk Assessment Tool classification system²³, 5 x 5 matrix of severity and probability (NPSA)²⁴
- WHO patient outcome/degree of harm grading¹
- 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

Medication Incident			
Level 1 data	Definition	Level 2 data	Instruction / Description
Patient Details	Patient demographics and details of the patient's location and medical history at the time of the incident	Patient name	Enter the patient's full name (first and surname)
		M.R.N./Hospital Number/ Medical Record Number/Patient number	Enter the Hospital Number / Medical Record Number (MRN) / Patient number for the particular hospital involved
		Male/Female	Record the sex of the patient
		Date of Birth	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
		Age	Record the age of the patient
		Date/s of incident	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
		Time of incident (24 hr clock)	Record the time of the event as accurately as you can using the 24 hr clock
		Inpatient or Outpatient	Tick the appropriate box, indicating if the patient was an inpatient or outpatient at the time of the event
		Ward/Department of patient	Record the ward/department the patient is admitted to at the time of the event e.g. St. John's Ward
		Exact Location (if different)	Record the exact location. The patient may be admitted to St. Johns Ward however the event may occur in theatre or X-Ray, etc.
		Stage in Patient Care	Tick as appropriate if the event occurred during the patient admission, during hospital stay, while being transferred between wards or at patient discharge
		Consultant and Speciality	State the consultant the patient is under and the speciality at the time of the event e.g. Dr. Joe Bloggs, Cardiology
Referral Speciality and Consultant involved (if applicable)	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 speciality where the event occurred would be Anaesthetics not Orthopaedics		

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Medication Incident			
Level 1 data	Definition	Level 2 data	Instruction
Incident Details	Patient event/Non-patient event	Patient event or event not directly involving any patient	Tick as appropriate according to the definitions in Appendix 3
	Incident/Near miss/ Adverse Drug Reaction	Incident or near miss or adverse drug reaction	Tick as appropriate according to the definitions in Appendix 3
	Discovered by	Who discovered the event	Tick the profession or description of the person who initially discovered the incident or near miss.
	Detection Trigger	Detection Trigger	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
	Details of drug/s involved	Drug Name/s	Enter the generic or non-proprietary name (with brand name if appropriate) applied to the medicine
		Dose/s	Enter the dose or strength of the medicine involved, e.g. 1 mg /1 ml, or 10 mg, etc.
		Route/s	Enter the category that describes the route by which the medicine involved was prescribed e.g. IV, oral
		Frequency	Enter the frequency at which the medication was prescribed e.g. daily
	Form	Enter the form of the medication, e.g. tablet, capsules, cream, solution, eye drops, etc...	
Description of the incident (free text)	Factual description of incident	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.	

Medication Incident			
Level 1 data	Definition	Level 2 data	Description / Example
Incident Details	Stage(s) of the medication process where the incident occurs	Prescribing	The event occurs or originates at the prescribing stage
		Ordering	The event occurs when the medication is ordered by the ward/department from the pharmacy.
		Pharmacy / Dispensing	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
		Storage	The event occurs during storage of the medication, e.g. not storing at the correct temperature
		Administration	The event occurs at the administration stage of the medication process e.g. a medication being administered once daily when prescribed twice daily
		Monitoring	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

Medication Incident			
Level 1 data	Definition	Level 2 data	Description / Example
Incident Details	Incident Category	Adverse Drug Reaction or Allergy (no previous history)	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
		Allergy or Intolerance (known)	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
		Contraindication	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
		Drug – Drug/ Drug - Food Interaction	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

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Medication Incident			
Level 1 data	Definition	Level 2 data	Description / Example
Incident Details	Incident Category	Drug not indicated	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
		Expired drug	The event involves dispensing, supplying, administering or storing a medicine that is past its use by date
		Incorrect dose (over / under / duplicated dose)	This event involves: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 : <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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

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Medication Incident			
Level 1 data	Definition	Level 2 data	Description / Example
Incident Details	Incident Category	Incorrect frequency	This event involves prescribing or administering a drug more or less frequently than intended; dispensing a drug with the incorrect frequency on the label
		Incorrect labelling / instruction	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
		Incorrect patient	This event occurs when medication is prescribed for, administered to, dispensed to, ordered for or supplied to the wrong patient
		Incorrect quantity	This event involves prescribing, dispensing or administering an incorrect quantity of medicine
		Incorrect rate	This event involves: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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		

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Medication Incident			
Level 1 data	Definition	Level 2 data	Description / Example
Incident Details	Incident Category	Omitted/missed drug/dose	This event occurs when a: <ul style="list-style-type: none"> • 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			
Level 1 data	Definition	Level 2 data	Instruction
Outcome of Incident	Resulted in harm		Detail if the event resulted in patient harm/no harm or clearly specify if the outcome is unknown at the time of reporting
	Treatment/Monitoring Required		Detail the outcome of the event and specify if any treatment action / monitoring was required as a result of the event

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Medication Incident			
Level 1 data	Definition / Type	Level 2 data	Description / Example
<p>Contributory Factors</p> <p>Some of the prompts outlined here may assist in describing the contributing factors involved</p>	<p>Factors that may have contributed to the incident/ near miss</p> <p>Staff Factors</p>	Error/Slip/Lapse	
		Calculation Error	This occurs when an incorrect dose is prescribed, administered or dispensed due to a calculation mistake
		Rewrite Error	This refers to when a prescription is not transcribed or rewritten correctly
		Drug Continued/Discontinued in Error	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 inappropriately e.g. patient on Tinzaparin stopped before INR therapeutic for 2 days.
		Documentation Ambiguous/Incomplete	This occurs when inadequate documentation in nursing or medical notes contributes to the event. Examples include: <ul style="list-style-type: none"> administering a medicine as prescribed but failing to document the administration on the subject's drug chart or other treatment record. prescribing a medicine in a manner where the prescriber's intention is not clear or prescription is incomplete, e.g. no signature.
		Incorrect Administration Times Circled	This occurs when incorrect/absent circling of times on the medication chart contributes to the event
		Incorrect Endorsement	This occurs when the medication order has incorrect additional instructions endorsed by a doctor, nurse or pharmacist.
		Incorrect Labelling	This refers to when an incident involves unclear or absent labelling by staff
		Lack of or Mis-communication	The occurs as a result of incomplete, misheard, misunderstood instructions
Lack of Knowledge of Drug/Patient	This arises due to staff being unfamiliar with the medication or the patient's medical history		

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Medication Incident			
Level 1 data	Definition / Type	Level 2 data	Description / Example
Contributory Factors	Staff Factors, continued	Lack of Knowledge of / Failure to adjust for Patient Factors	This arises due to staff being unfamiliar with adjusting medications relative to the patient's condition
		Personal/Health/Behavioural Factors	This arises if a staff members personal status, health or behavioural factors contribute to a medication incident occurring.
		Policy/Procedure Not Followed	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
	Patient Factors	Behavioural Factors	This occurs if a patient's behaviour contributes to the medication incident
		Communication Difficulties	This occurs if there is a difficulty in communicating with the patient e.g. literacy or cognitive related factors involved
		Complexity of Condition	This occurs if a patient's medical requirements are complex in nature
		Non Compliance	This occurs if a patient is non compliant with instructions or medications
		Perception/Understanding	This occurs if a patient's lack of perception or understanding contributes to an incident
		Unauthorised Self Administration	This refers to when a patient has administered a drug to him or herself without informing medical/nursing staff
	Environmental Factors	Interruptions	This occurs when interruptions by staff, telephone, patients, visitors etc cause a distraction which contributes to an event occurring
		Lighting/Noise/Clutter	This occurs when defects in lighting, distraction of noise or a cluttered work environment contribute to the event
		Physical Environment	This occurs when the event happened as a result of the work environment causing a workflow problem

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Level 1 data	Definition / Type	Level 2 data	Description / Example
Contributory Factors	Organisational Service Factors	Multiple Prescription Sheets	This occurs as a result of a patient having more than one prescription sheet
		Policy/Protocol or Guidelines Not Available/Accessible	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
		References Not Available/ Accessible/ Outdated	This occurs when references are unavailable or outdated and as a result contribute to a medication incident
		Staffing Levels/Workload	This may occur when insufficient staffing levels are in place
		Staff Training/Experience/Supervision Deficit	The event occurs due to insufficient training on the medication or process or inexperienced staff carrying out the task without supervision
	External Factors	Drug Packaging/Label Related	This occurs when packaging or faulty drug identification contributes to the event
		Equipment Design Factor	This refers to when equipment design or misprogramming contributes to the event
		Sound Alike – Look Alike Drugs (SALAD)	This involves prescribing, dispensing or administering an incorrect drug with a similar name to the intended drug e.g. Omesar® and Omacor®
		Services/Systems/Policies Requirements	This occurs when there are insufficient or unsatisfactory services/systems/policies from external regulators
	Other		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

Medication Incident			
Level 1 data	Definition	Level 2 data	Instruction
Follow up Actions	Actions that reduce, manage or control future risk	Risk Reduction Measures	Please detail any actions taken to reduce recurrence of the event

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Appendix 2: MIR Template

XXXXXXX Hospital

Medication Incident Report Template

Report No:

Analyze Err No:

STARS Incident ID:

Patient event Non-Patient event

Patient Details

Patient Name:

M.R.N.: Male Female

Date of Birth: Age:

Affix Addressograph

Date/s of Incident: →

Time of Incident (24 hr clock):

Inpatient Outpatient

Ward/Department of patient:

Exact location (if different):

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/alarm, 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)
<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>

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) <input type="checkbox"/>	Incorrect drug <input type="checkbox"/>	Incorrect rate <input type="checkbox"/>
Allergy/Intolerance (previously known) <input type="checkbox"/>	Incorrect duration <input type="checkbox"/>	Incorrect route <input type="checkbox"/>
Contraindication <input type="checkbox"/>	Incorrect formulation / presentation / diluent <input type="checkbox"/>	Incorrect storage <input type="checkbox"/>
Drug/Drug - Drug/Food Interaction <input type="checkbox"/>	Incorrect frequency <input type="checkbox"/>	Incorrect strength / concentration <input type="checkbox"/>
Drug not indicated <input type="checkbox"/>	Incorrect labelling / instruction <input type="checkbox"/>	Incorrect time <input type="checkbox"/>
Expired drug <input type="checkbox"/>	Incorrect patient <input type="checkbox"/>	Monitoring inappropriate <input type="checkbox"/>
Incorrect dose (over/under/duplicated dose) <input type="checkbox"/>	Incorrect quantity <input type="checkbox"/>	Omitted / missed drug / dose <input type="checkbox"/>
		Therapeutic duplication <input type="checkbox"/>
		Other <input type="text"/>

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	<input type="text"/>	Job Description/Title:	<input type="text"/>
PRINT NAME	<input type="text"/>	Date reported to doctor/other:	<input type="text"/>
Contact Bleep/extension	<input type="text"/>	Date MIR Form filled in:	<input type="text"/>
e-mail	<input type="text"/>		

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

Official Use Only: Date Received: D D M M Y Y Y Y Date Reviewed: D D M M Y Y Y Y

Patient Outcome, Degree of Harm: None Mild Moderate Severe Death

Likelihood of Recurrence: Risk Rating: NCC MERP Index:

Signature: Job Description/Title:

*Designed by a subgroup of the Irish Medication Safety Network, see www.imsn.ie
Approved 11/3/2014*

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.¹

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^{25,26}.
- An error in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome (i.e. injury to the patient)²⁷.

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 started¹.

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 function²⁸.
- ASHP²⁹ defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that:
 - Requires discontinuing the drug (therapeutic or diagnostic),
 - Requires changing the drug therapy,
 - Requires modifying the dose (except for minor dosage adjustments),
 - Necessitates admission to a hospital,
 - Prolongs stay in a health care facility,
 - Necessitates supportive treatment,
 - Significantly complicates diagnosis,
 - Negatively affects prognosis, or
 - 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 outcome²⁸.
- 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 incident²⁰.

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.

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