Medication Incidents MiST Operational Definition

1. Description and Rationale

This measure aims to answer the question:

'How often is a patient harmed due to an error in the process of treatment with medication?'

This therefore, does *not* include events where the patient had an unexpected adverse drug reaction but no error occurred.

Currently information on Medication Incidents (MI) is available in most hospitals through an incident reporting system (e.g. Datix, Safeguard). This is a self-reporting system and it is well recognised that reporting rates vary between hospitals and within different areas of the same hospital. Whilst it is known that a significant number of MIs are not reported, it is currently not possible in most institutions to determine what percentage of MIs are reported and what percentage are not reported. However, where significant harm occurs as a result of a MI, the probability that this will be reported is likely to be much greater. A 'healthy' incident reporting system is one where overall reporting levels are high, but the percentage of incidents reported with significant harm is low.

The National Coordinating Council for Medication Error Reporting and Prevention (MERP - *see appendix 1*) provides a very useful *standardised* method of categorising MIs, in particular with regards to the severity of any harm which may have occurred (levels E - I).

2. Data to report to MiST

I. Number of *reported* MIs per calendar month
II. Percentage of reported MIs in each MERP level (A - I)
III. Percentage of reported MIs in the combined MERP levels [A - D] and [E - I]
IV. Where possible, a breakdown of reported MIs should be provided, reported as a percentage of the total reported, in the following categories *(see appendix 2)*:
    - Prescribing errors/incidents
    - Administration errors/incidents
    - Other errors/incidents

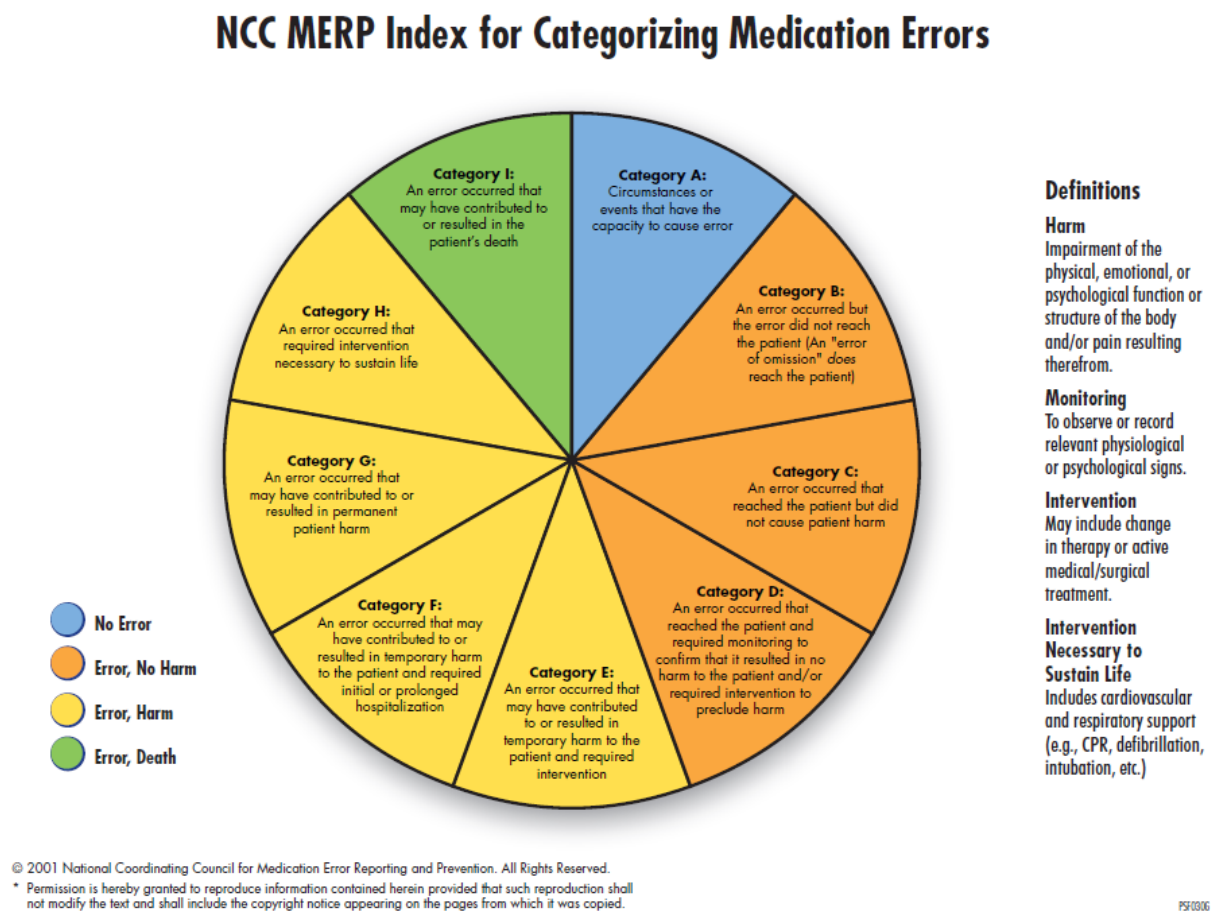
Where available, data should be submitted separately as Whole Hospital data (including PICU) and Paediatric Intensive Care Unit data

Note on denominator data:

At present, there is no requirement to submit denominator data. This is for a number of reasons. Firstly, when considering MIs the best denominator to use is the number of administered drug doses/infusions, but this is not routinely collected in most, if any institutions. Patient bed days can be used as a substitute, but institutions vary in the intensity and severity of illness they manage, and organisations with a PICU for example will have a much medication usage per patient bed day. Secondly, as noted above MI data as collected from incident reporting systems is extremely variable since it is entirely reporter dependent. Therefore, differences in MI rates (as determined by number of MIs divided by a defined denominator) are more likely to reflect differences in reporting than they are actual true number of MIs. Finally, the purpose of MiST is not to benchmark institutions, but to share data and methods of good practice. Therefore, by not using a denominator, direct comparisons between institutions will not be possible and the tendency to benchmark will be avoided. Rather, organisations can use submitted data to monitor trends within their own institution, and those organisations with low levels of significant harm (as determined by percentage of reported MIs in the combined MERP level [E - I]) can be encouraged to share insights into their safety culture and methods used to achieve this.

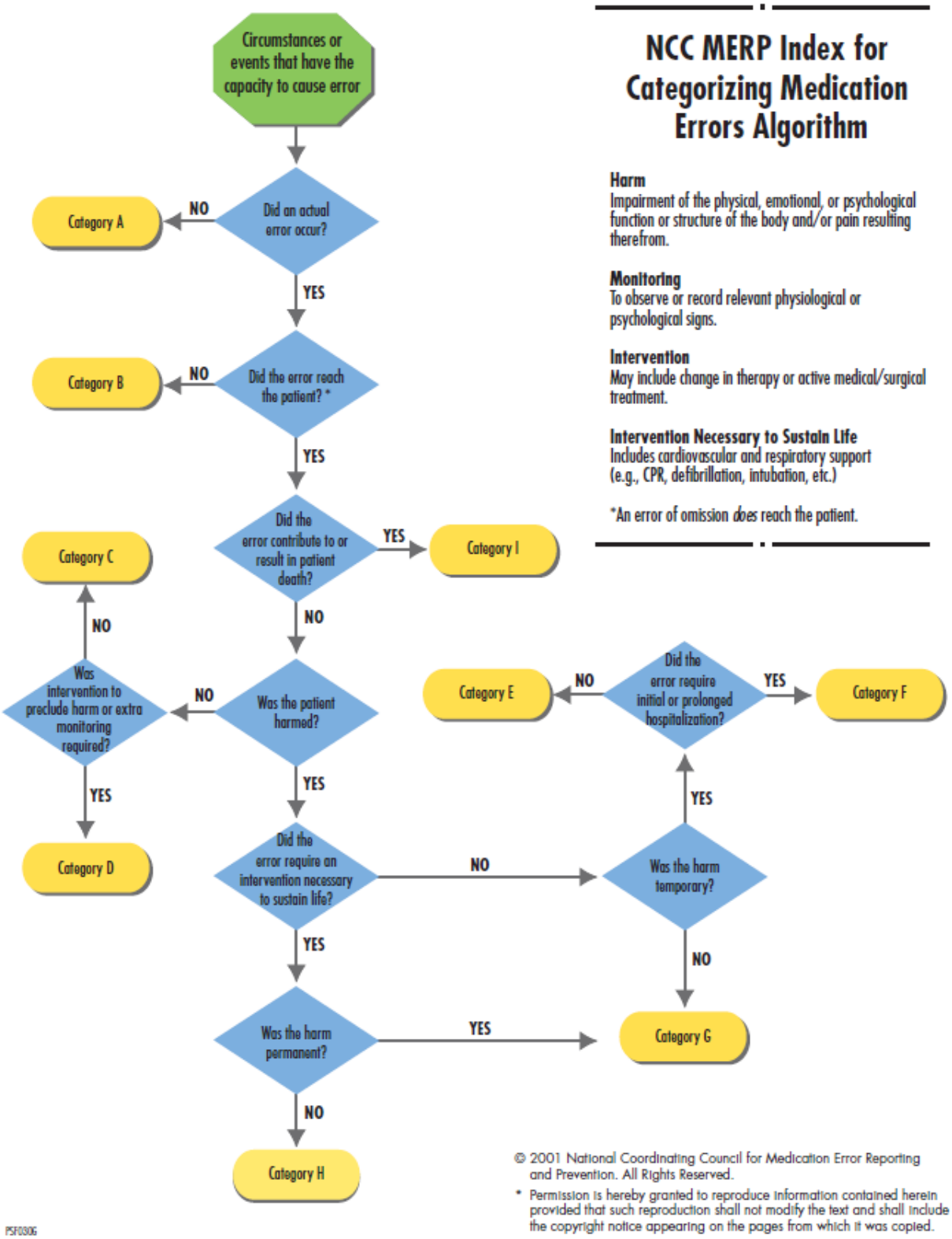
Appendix 1

National Coordinating Council for Medication Error Reporting and Prevention



Incidents where harm occurs fall into MERP categories E - I

The following flow chart is best used when determining the MERP classification of a reported MI:



Appendix 2 - Examples of Medication Incident Classification by Error Type

The following lists are not exhaustive, but are examples of how incidents might be recorded:

- Examples of prescribing incidents might include:
  - Wrong dose or infusion rate prescribed (under or overdose; including lack of appropriate dose adjustments following therapeutic monitoring)
  - Wrong route
  - Wrong frequency
  - Incomplete/Unclear prescription
  - Drug Protocol/Guidance not followed (may include recommended dose adjustments required for renal impairment, prescription of non-compatible diluents or significant drug interactions)
  - Wrong drug prescribed
  - Prescription unintentionally omitted/prescribed late
  - Duplicate drug/drug type
  - Drug contraindicated (e.g. for disease state or allergy)
  - Wrong preparation (e.g. standard release rather than modified release)

- Examples of administration incidents might include:
  - Unintentionally omitted/given late
  - Wrong dose/infusion rate (under or overdose) given where the prescription is correct
  - Wrong route
  - Not signed as given
  - Wrong dilution/preparation/formulation
  - Drug protocol/guidance not followed
  - Extra/repeat dose given
  - Drug incompatability
  - Wrong drug given
  - Drug given without prescription

- Examples of ‘other’ MIs might include:
  - Equipment incident (user error, device malfunction, unavailability of device)
  - Medication storage error
  - Drug expired
  - Drug availability
  - Drug monitoring error
  - Labeling error
  - Dispensing/pharmacy error
  - Documentation error

Appendix 3 - Examples of Classifying Medication Incidents Using MERP

The following are examples of how MIs may be classified using the MERP flowchart in appendix 1.

1. A patient received a dose of chemotherapy at approximately 10 times the intended dose. A high dose was prescribed for the mornings and a low dose in the evenings, but the higher dose was administered in the evening in error. There was no evidence of harm to the patient.
    - an error occurred in that the wrong dose was administered (pass A)
    - the error did reach the patient since the wrong dose was administered (pass B)
    - the error did not contribute to or result in death (pass I)
    - there was no evidence of patient harm (move to C/D)
    - no intervention or extra monitoring was required ⇒ **therefore, score as C**

2. Drugs given, but the prescription was noted to be incomplete with no prescriber's signature at the time of administration. The drug information (drug type, route and dose) were correct and appropriate for the patient.
    - an error occurred in that the prescription was incomplete (pass A)
    - the error did not reach the patient since the patient received the correct drug, via the correct route, at the correct dose ⇒ **therefore, score as B**

3. Patient deteriorated requiring intubation and ventilation following recent cardiac surgery. The Registrar discussed with their consultant with the advice given to commence intravenous tazocin and vancomycin for what was felt to be likely sepsis. There was a subsequent delay in administration of antibiotics by over 4 hours, for a number of different reasons (on investigation it was concluded that it would have been possible to administer the antibiotics much sooner than actually occurred). International consensus guidelines state that antibiotics should be commenced within 1 hour of recognition of sepsis, since

delays in administration have been shown to lead to an increased risk of mortality. The patient subsequently died from the sepsis and the investigation concluded that the delay in antibiotic administration contributed to the patient's death.

- an error occurred in that there was a significant delay in antibiotic administration, which is against consensus guidance (pass A)
- the error did reach the patient since they did not receive the antibiotics for over 4 hours (pass B)
- the error was felt (after investigation), to contribute to the patient's death ⇒ **therefore score as I**

4. The burette of the line was noted to be leaking during administration of chemotherapy. The leakage was coming from the clamp although there was no hole visible.
    - there was no error here, but rather an equipment failure that was not predictable, nor preventable ⇒ **therefore score as A**