AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

CLASSIFICATION TOOL
for health service organisations

Consequences of electronic medication management (EMM)-related adverse events and incidents

The Australian Commission on Safety and Quality in Health Care (the Commission) is an Australian Government agency that leads and coordinates national improvements in the safety and quality of health care based on the best available evidence. By working in partnership with patients, carers, clinicians, the Australian, state and territory health systems, the private sector, managers and healthcare organisations, the Commission aims to ensure that the health system is better informed, supported and organised to deliver safe and high-quality care.

The development of standardised taxonomies to describe clinical incidents related to EMM systems continues to be a challenge in Australia and internationally with a multitude of classifications available for implementation.

Australia required a standardised health IT-related incident classification system that provides a unified and consensus-based approach that can be readily applied during the EMM implementation process. This led to the development of **Guidance for hospitals: Classifying EMM-related adverse events and incidents** (the Guidance).

For assessment of the consequences and scale of harm

This classification system may be used to assist with the assessment of the consequences and scale (or magnitude) of EMM related adverse events and incidents. The classification also rates the potential and actual harm associated with these events.

The overall classification of consequences and scale of harm, along with definitions of potential and actual harm in terms of a 'clinical incident'[1] are provided in Table 1.

Background: The consequences classification tool was developed to assist with the assessment of the consequences and scale of harm (potential and actual) associated with the use of EMM systems. It was developed and tested by the Commission alongside other classification schema.

Following testing and feedback, the consequences classification was modified to encompass additional detail including:

- Definitions of actual and potential harm, and
- Reference to data breaches.

The definition of harm and some of the categories for potential consequences of harm have been derived from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) taxonomy of medication errors.[2]

It is the responsibility of an organisation implementing clinical information systems (CIS), for instance, EMM systems, to be able to identify and prevent data breaches that may result from the use of such systems. The significance of the consequences from an incident increases when considered in the context of the 2018 Notifiable Data Breaches scheme.[3, 4]

Since February 2018 the reporting of data breaches has been mandatory. Given the purpose of this classification system, the requirements of the data breach legislation have been built into the definitions of harm.

The harm definitions also include reference to 'sensitive information' such as information about an individual's health which include categories of personal information that are covered by the definition of 'sensitive information' within the Privacy Act (s 6(1)).[5]

Table 1: Consequences, scale and definitions of potential and actual harm

Level 1	Level 2
1. Scale	1.1 Single patient
	1.2 Multiple patients
	1.3 Single staff member
	1.4 Multiple staff
	1.5 Unable to determine scale (for patients or staff)
2. Consequence (actual)	2.1 Incident reached the person and there was a consequence which resulted in death (contributed to or resulted in)
	2.2 Incident reached the person and there was a consequence which resulted in harm (temporary or permanent) which required intervention and/or resulted in an impairment
	2.3 Incident did reach the person but there was no consequence or harm (no symptoms detected; may have required monitoring to confirm)
	2.4 Incident did not reach the person (a 'good catch' or near miss)
	2.5 Unable to determine or assess the consequence(s)

Guidance for completing Table 1's Consequence (actual) – Level 2

Actual harm	Definitions
Harm from a medicine[1]	Harm is defined as temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom, and requiring intervention
Harm from a data breach[2]	Individuals whose *sensitive*[5] personal information is involved in a data breach may be at risk of serious harm, whether that is harm to their physical or mental well-being, financial loss, or damage to their reputation
*'Good catch' or near miss[6]	An event or circumstance that has the potential to cause an incident or critical incident but that did not actually occur due to corrective action and/or timely intervention. [AHRQ Innovations Exchange[7]]

Scale of harm in terms of a 'clinical incident'[1] – colours correspond to Table 1's Consequences (actual) – Level 2.

Harm	Incident
Critical (or extreme)	A clinical incident resulting in patient death
Major (or severe/serious)	A clinical incident resulting in major permanent loss of function
Moderate	A clinical incident resulting in permanent reduction in function
Minor (or mild)	A clinical incident resulting in increased level of care/intervention
Minimum	A clinical incident resulting in no injury
	No harm outcome due to mitigating action (*similar to 'good catch' or near miss)
Insufficient detail[8]	Incident for which report carries insufficient information to evaluate the severity of harm. The report may describe an error or outcome with insufficient information to attribute and/or classify severity of harm of the outcome

References

1. Terminology based upon Table A1 Clinical safety review risk rating matrix from the Medicines View Clinical Safety Review of My Health Record.
2. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) taxonomy of medication errors. https://www.nccmerp.org/sites/default/files/taxonomy2001-07-31.pdf
3. Data breach preparation and response: A guide to managing data breaches in accordance with the Privacy Act 1988 (Cth). February 2018. www.oaic.gov.au/privacy/guidance-and-advice/data-breach-preparation-and-response/
4. Office of the Australian Information Commissioner. Notifiable Data Breaches scheme [Internet] 2018. [cited 18 August 2018] Available from: www.oaic.gov.au/privacy/notifiable-data-breaches/report-a-data-breach/
5. 'Sensitive information' such as information about an individual's health – See s 6(1) of the Privacy Act for categories of personal information that are covered by the definition of 'sensitive information'.
6. Barnard D, Dumkee M, Bains B, Gallivan B. Implementing a good catch program in an integrated health system. Healthc Q. 2006 Oct;9:22–7. https://www.longwoods.com/content/18373
7. AHRQ Health Care Innovations Exchange. Archived Service Delivery Innovation Profile: multifaceted program increases reporting of potential errors, leads to action plans to enhance safety (University of Texas M.D. Anderson Cancer Center). In: AHRQ Health Care Innovations Exchange [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). https://innovations.ahrq.gov/profiles/multifaceted-program-increases-reporting-potential-errors-leads-action-plans-enhance-safety
8. WHO endorsed international classification for patient harm – descriptors of harm severity http://www.who.int/bulletin/volumes/96/7/17-199802/en/ Table 1: http://www.who.int/bulletin/volumes/96/7/BLT-17-199802-table-T1.html

Questions?

For more information, please visit: safetyandquality.gov.au/electronic-medication-management

You can also contact the eHealth and Medication Safety team at: mail@safetyandquality.gov.au