IMPLEMENTATION AND EVALUATION OF A NEW ADVERSE DRUG REACTION MANAGEMENT SYSTEM IN A HOSPITAL NETWORK.

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BACKGROUND

The National Safety and Quality Health Service (NSQHS) Standards require health services to have processes in place for documenting a patient's existing medicine allergies and adverse drug reactions (ADRs). Furthermore, any new ADRs experienced need to be reported in an organisation-wide incident reporting system and to the Therapeutic Goods Administration (TGA)[1]. In November 2020, the organisation established a working group as a way to address known gaps.

AIM/OBJECTIVES

To describe and audit the organisational system implemented to improve ADR reporting in-line with the NSQHS standards.

METHODOLOGY

From June 2021, a new process for documenting, communicating and reporting of new ADRs was implemented (Figure 1).

Patient experiences a new ADR during their admission/encounter

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First Clinician involved to document ADR in patient's Electronic Medical Record

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Clinician (pharmacist, doctor or nurse) to:
1. Provide patient with ADR education, an ADR pamphlet and an ADR alert card (if applicable).
2. Notify ADR pharmacist of ADR

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ADR pharmacist to:
1. Complete VHIMs incident report
2. Submit ADR report to TGA

Figure 1: The new ADR process at Eastern Health as of June 2021

A retrospective, pre-implementation audit was performed from three metropolitan hospitals based on ICD-10 coding in the administrative database with subsequent manual medical records reviewed to ensure all inclusion criteria had been met; to analyse ADR reporting prior to the new ADR management system being analysed. Data collected included patient details, ADR details, ADR reported in the Victorian Health Incident Management System (VHIMS) and to the TGA. This audit was conducted in reverse chronological order from July 2020 until target sample size of 500 was reached (pre).

A post-implementation audit was performed of ADRs reported to the ADR pharmacist following the implementation of the new ADR management system, with the same data points collected (post) (see Figure. 3).

RESULTS

The pre-implementation audit performed showed that almost no ADRs were reported into VHIMs and none to the TGA. An audit of post-implementation of the new ADR management system showed significant improvement in reporting into VHIMs and TGA, as outlined in Table 1.

	Pre-implementation audit	Post-implementation audit
Period	1 July 2018 to 30 June 2020	1 June 2021 to 31 May 2022
Sample size	500	108
ADRs reported in VHIMS	2 (0.4%)	104 (96%)
ADRs reported to the TGA	0 (0%)	96 (89%)

Table 1: ADR reporting compliance

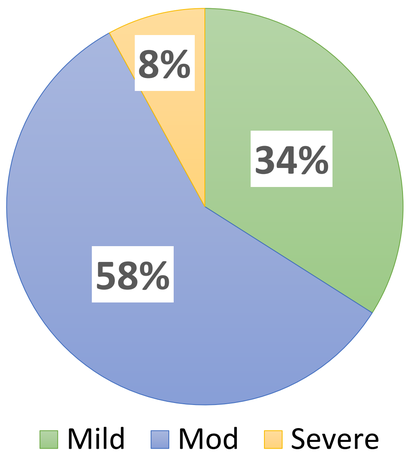
Ten (9%) ADRs that were not reported to the TGA were related to COVID-19 vaccines which required reporting to SafeVic, instead. Two (1.85%) ADRs that required TGA reporting were unintentionally not reported.

DISCUSSION

This review audit and the new system has allowed for improvement works to be carried out at the organisation which includes:

- more robust reporting allowing for trends to be identified and actioned earlier.
- more consistent documentation on Electronic Medical Records.
- improved communication to patients and General Practitioners.
- improved and up-to-date ADR documentation on discharge summaries.
- recognition of more serious adverse effects (as outlined in Figure 2) due to more reliable documentation and recording.

Pre implementation ADR results:
Of 500 ADRS: 170 were mild, 290 moderate and 40 severe



Post implementation ADR results:
Of the 108 ADRs: 28 were mild, 47 moderate and 32 severe

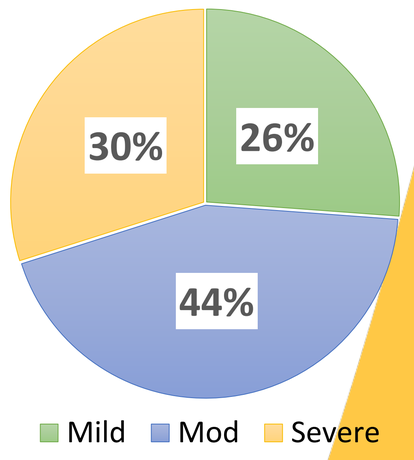
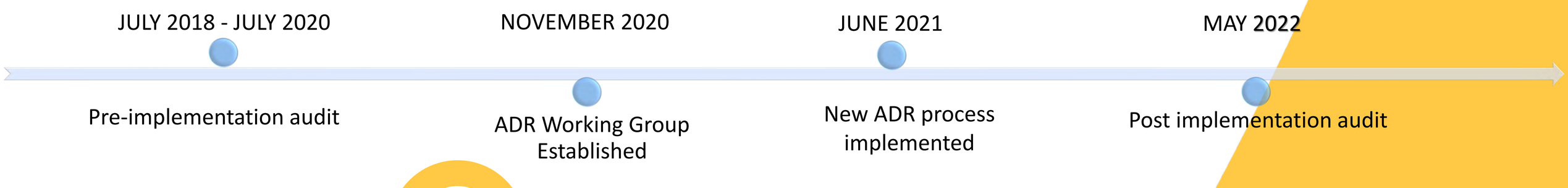


Figure 2: Severity of reported ADRs

CONCLUSION

Improved ADR documentation and reporting systems were successfully implemented to ensure NSQHS standards have be appropriately addressed.
Centralisation of the responsibility for ADR reporting helped improved compliance with the TGA and hospital incidence management requirements.

Figure 3: Timeline of ADR implementation process



Eastern Health

References:
1. Therapeutic Goods Administration (TGA). Reporting adverse events [Internet]. Therapeutic Goods Administration (TGA). Therapeutic Goods Administration (TGA); 2022 [cited 2022Nov16]. Available from: https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events