Adverse events exception reporting 2020/21

Thematic analysis involving always report and review events

Introduction

Te Tāhū Hauora Health Safety & Quality Commission (Te Tāhū Hauora) National Adverse Events Reporting Policy 2017 (the policy) defines an always report and review (ARR) event as an adverse event that can result in serious harm or death but is preventable with strong clinical and organisational systems.

ARRs were first introduced in the 2017 policy and are based on the concept of 'never events', as used by the National Quality Forum (NQF) in the United States of America (known as serious reportable events [SREs]) and England's national health service (NHS). The NQF defines SREs as 'serious, largely preventable, and harmful clinical events, designed to help the health care field assess, measure, and report performance in providing safe care' (National Quality Forum nd). The NHS defines them as 'serious incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers' (NHS England 2018). The NHS (2018) further defines strong systemic protective barriers as 'barriers that must be successful, reliable and comprehensive safeguards or remedies – for example, a uniquely designed connector that stops a medicine being given by the wrong route'.

The underlying premise of ARRs is that they are reviewed, regardless of harm, in the same manner as severity assessment code[1] (SAC) 1 and 2 events. The review enables the organisation to identify system weaknesses and the absence of fundamental safety processes that should be in place to prevent harm.

The thematic analysis informing this paper will review ARR events submitted to Te Tāhū Hauora for the contributory factors found and the recommendations for improvement. It will also make recommendations on the future use of the ARR list.

Thematic analysis

In total, 396 adverse events classified as ARRs were reported to us by district health boards (DHBs) between 1 July 2017 (when the reporting of ARRs was included in the policy) and 30 June 2021. We focused this thematic analysis on wrong consumer and wrong site events, as between them they account for 75 percent of all ARR events reported to us (see Table 1 for a breakdown of reported ARR events). Of the 299 ARR events reported, we received adverse event brief[2] (AEB) part B forms for 177 (59 percent). We analysed a random sample of 62 events from the part B forms submitted, giving us a sample percentage of 35 percent (62/177) of completed events and 21 percent (62/299) of all wrong patient/wrong site ARR events.

Table 1 ARR events reported by DHBs 2017/18–2020/21

ARR category	Number of reported events
Retained item	80
Wrong blood component	7
Wrong consumer/patient	150
Wrong implant/device	4
Wrong implant/prosthesis	3
Wrong procedure	3
Wrong site	149
Total	**396**

The provided contributory factors and recommendations were analysed using the Yorkshire Contributory Factors Framework (YCFF) (Lawton et al 2012).

Table 2 YCFF groupings for ARR events, 2017/18–2020/21

YCFF groupings	Number of events	Examples of contributory factors from AEB part B forms
Active failures	27	• Process not followed • Human error • No sign-out process followed
Task characteristics	9	• Form not well designed • Inadequate process in place • [Provider] followed process, but event still occurred • Multiple systems and forms need to be used concurrently • Procedure was followed, but the procedure was incorrect
Drugs, equipment and supplies	3	• Wrong equipment present • Required equipment not available
Physical environment	1	• Marks on patient obscured due to poor patient access
Individual staff factors	2	• Provider distracted
Workload and staffing issues	1	• Staffing levels below normal
Staff training and education	2	• Lack of knowledge of process

Verbal and written communication	9	• Large amount of patient notes, making it difficult to select correct ones • Poor referral form design
Support from other departments	2	• Inadequate IT processes • IT system difficult to use
Design of equipment, supplies and drugs	1	• Poor equipment relies on individual vigilance
Unable to be classified with information on part B form	5	
Total events	62	

The YCFF enables further grouping of the contributory factors. In this case, the identified factors can be grouped into six broader themes.

Table 3 YCFF themes for reported ARR events 2017/18–2020/21

YCFF theme	Total events	Contributory factors
Active failures	29	• Mistakes • Slips/lapses • Violations
Situational factors	9	• Task characteristics • Individual staff factors
Local working conditions	4	• Drugs, equipment and supplies • Workload and staffing issues
Communication and culture	9	• Verbal and written communication
Organisational factors	5	• Physical environment • Staff training and education • Support from other departments
External factors	1	• Design of equipment, supplies and drugs

Active failures

The largest grouping was active failures, with most reviews in this category highlighting the failure of staff to follow process. Despite identifying where process had not been followed, there was little to no exploration of whether processes were fit for purpose or whether appropriate resources existed to enable staff to follow processes. ‘Work as imagined’ describes how often people who write policies and processes do not understand the environment that people are working in, which results in policies and processes that are difficult or impossible to follow. There is a disconnect between ‘work as imagined’ and ‘work as done’, with work as done describing the adaptation and adjustments staff make to keep consumers and themselves safe and to complete their tasks (Hollnagel et al 2015;

Woodward 2019). In many radiology wrong consumer events, misidentification occurred whether or not procedures were followed. Within these radiology events, there were also occasions where the clinician was either praised for asking the consumer to confirm their identification and procedure details or censured for doing the same thing, depending on whether or not the correct consumer was identified.

By reducing the outcome of an adverse event review to a binary decision of 'process followed' or 'process not followed', we run the risk of missing wider system issues that influence decision-making. This risk is increased by using review methods such as root cause analysis, which promotes a simple linear view of events (Peerally et al 2017) and can miss many factors that may have contributed to an adverse event (Card 2017). The use of alternative review methods, such as the learning review (Pupulidy and Vesel 2017), provides the opportunity to understand the event from the perspective of those involved in it and to aid in meaningful organisational improvement.

Situational factors

None of the reviewed events identified consumer characteristics as a contributory factor, and only two found that individual staff factors were contributors. Both events involving staff factors were attributed to distraction, with one of these events being further attributed to the staff member involved being distracted by the pain the consumer was displaying and the amount of blood present. In this case, the recommendation appears to place the responsibility for the event squarely on the clinician involved, stating, 'The [clinician] has been assisted with strategies to help prevent a repeat incident. Senior clinicians have discussed the case and do not feel any procedural changes are required'. Given the large amount of literature showing the effects of distraction on clinician performance (Westbrook et al 2018; Henneman et al 2018; Santomauro et al 2021), it is disconcerting that distraction is either not looked for or used to identify systemic issues rather than individual failings.

Several events in this category identified inadequate processes, poorly designed workflows and a lack of integrated systems. Unfortunately, there was nothing within the contributory factors (or full reports where provided) that identified the exact issues with the processes, workflows or systems. This lack of detail in the review makes it difficult to create meaningful solutions or system improvements, as there is no description of the current state on which to base improvements.

Local working conditions

Only one review identified a lack of staff as a contributory factor. Based on the submitted information, it is not possible to ascertain whether reviews were overlooking staffing issues or whether staffing levels were adequate within the health and disability sector.

The number of equipment issues reported was also low. As with staffing levels, the submitted information does not allow us to identify whether this area is being overlooked or whether the equipment used in the sector is fit for purpose and in good supply.

Organisational factors

Very few reviews appeared to investigate the physical environment in which the adverse event took place. Only one recommendation addressed making changes to the environment,

although the contributory factors provided for that event did not list the physical environment. Given that the design of hospitals contributes to safety (Joseph and Rashid 2007) and encourages desired behaviours (Lankford et al 2003), more care needs to be taken when designing clinical areas to ensure the physical environment is optimised to support staff.

Only two events listed staff knowledge or education as a contributing factor. This is encouraging, as focusing on individual performance without changing the underlying systems they work in does not lead to sustainable, long-term safety improvements (Dekker 2017). What is less encouraging is that, despite only two of the 62 events reviewed finding that staff knowledge/education was a factor, 40 recommendations were made that involved some form of education, reminders of responsibilities, personal coaching or self-reflection.

External factors

Only one review mentioned the design of the equipment being used as a contributing factor, and no events identified any influences on the event that were external to the organisation. Equipment design issues can be minimised by using a robust human factors-based evaluation process (Fuller et al 2018) prior to purchase and introduction of new equipment. However, this merely guards against introducing poorly designed equipment into local systems and does not guard against poorly designed equipment being available to purchase.

External influences are often higher-level and generated by governments and regulators. In Aotearoa New Zealand, this includes legislation such as the Health and Disability Service (Safety) Act 2001, standards such as Ngā Paerewa Health and Disability Services Standard NZS 8134:2021 and regulatory authority professional standards and national and local procurement processes. It is unsurprising to see no consideration of these higher-level influences, as the most common review methodology used (root cause analysis) is unlikely to identify them. Rather, the use of human factors methods such as learning reviews or AcciMaps (Branford 2011) is required to prompt a focus on meso/micro/macro areas.

Recommendations

The recommendations in the analysed reviews can be grouped into three areas – individual behaviour, policy and process – and factors outside the control of the staff involved in the event, such as equipment design, IT systems and physical layout of clinical spaces. Table 4 shows the numbers of events in each area (there are more recommendations than reviewed events, as many events generated more than one recommendation).

Table 4 Themes for recommendations from reported ARR events 2017/18–2020/21

Recommendation type	Number	Examples from submitted reports
Individual behaviour	40	• Remind clinicians of individual responsibilities • Meet with dental therapist to discuss their normal processes • Remind staff of policy • Provide individual coaching to [staff member] • Staff who cared for patient to complete reflections on their care [sic] • Remind staff to be vigilant • Implementation of 'have you checked/expect us to check' posters • Education on '5 rights'[3]
Policy and process	27	• Review forms used • Strengthen process used • Create new SOP [standard operating procedure] • Create checklist • Change checklist
External factors	13	• IT improvements are required across the whole system • Increase staffing levels • Carry out an IT risk assessment • Review the equipment used

Most recommendations were firmly focussed on individual behaviour, with the next biggest category aimed at making work more prescribed. This suggests that the review methods being used are failing to consider the design of the wider system and how individuals interact with it (Isherwood and Waterson 2021) and are instead trying to force individuals to fit within the system, regardless of the usability of the system (Woodward 2019). This approach sees people as a risk to the safe operation of the system and attempts to remove threats and hazards from the system while at the same time becoming increasingly prescriptive in how people can perform their work. This reflects an approach focused on 'human error' rather than considering how the system is designed resulted in 'system-induced error' (Read et al 2021). Safety-II, with its focus on understanding everyday functioning, emphasises the value of people within systems as a positive resource, acknowledging their ability to adapt to hazards, threats and changing work environments (Amalberti and Vincent 2020). Read et al (2021) state that 'Safety II advocates for a much stronger focus on normal performance variability within a system, especially at the higher levels (e.g., government, regulators) who traditionally take a Safety I approach.'

It is disappointing to see such little emphasis on improving the conditions that people work in and the tools that they use. If the system is flawed, it is difficult to be successful, no matter how carefully an individual follows a policy. The apparent focus on individual behaviour also misses the main aim of ARRs, which is to strengthen systems.

Discussion

ARRs are meant to be preventable due to strong clinical and organisational systems. The fact that most recommendations for improvement from the ARR reviews are focused on individual performance and behaviours suggests that either the review process is not identifying these system-level improvements, that the review methods being used do not include a human factors-based approach or that no system-level solutions exist. We feel that system-level solutions most likely do exist; however, the process for identifying them and the commitment to changing the way the system is designed is not embraced. There needs to be consideration of how a human factors expert could work within the DHBs to understand and provide system re-design to prevent harm.

In January 2021, the Healthcare Safety Investigation Branch[4] (HSIB) published a national learning report that analysed their national investigations into adverse events on the never list. They found that the barriers to the never events reviewed were 'neither strong nor systemic' and recommended that:

- the never event list be reviewed
- events that are not preventable be removed
- programmes of work be implemented to find strong and systemic barriers where none are currently available.

When taken together, the results of this analysis and that of the HSIB demonstrate similar results. There is a lack of true system-level barriers to prevent many ARR events from occurring, and those barriers that do exist rely heavily on individuals to manage the risk in the system.

Recommendations for improvement

We have changed our focus over recent years to better reflect the varieties of human work. This is through the learning review methodology that is embedded in a human-factors approach and resilient health care principles:

- health care is a complex adaptive system that operates in the setting of volatility, uncertainty, complexity and ambiguity. All levels of this system influence each other to create the outcomes we see, ie, political, regulatory, financial, clinical and cultural
- safety arises from the ability to adapt flexibly to changing conditions, eg, clinical demands, different contexts, innovations and new threats
- people within the system are the key resource for this adaptability, and it is built on relationships and situated expertise that are built over time
- the system design should support the realities that people face, whether in their work setting (health care staff) or in their daily lives.

This demonstrates the evolving perspective on harm and a move away from finding individuals culpable, to better reflect the complex adaptive, indivisible system within which people work. Incidents are attributed not to the behaviour of an individual component but to how the interactions between the components in the system failed and therefore the system itself failed.

Based on the results of this analysis, the similar work carried out by the HSIB and the literature, we recommend that:

- Te Tāhū Hauora, in conjunction with the wider health and disability sector, reviews the events on the current ARR list and removes any events that do not have strong clinical or organisational systems available to prevent their occurrence
- Te Tāhū Hauora continues to support the health and disability sector to identify strong clinical or organisational systems for events where they do not yet exist, through promotion of the learning review tool and education and review of the national adverse event reporting policy.

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Endnotes

[1] The severity assessment code is a rating to determine the severity of harm to a consumer caused by an adverse event. SAC1 events indicate greater harm, and SAC4 events indicate less harm or a near miss. See our-programmes/adverse-events/publications-and-resources/publication/2937 for more information.

[2] Providers use AEBs to notify Te Tāhū Hauora of adverse events. The part A form is the initial notification and includes non-identifiable demographic data about the consumer, a brief description of what happened and the severity of the event. The part B form provides the factors that contributed to the event and the recommendations made to improve the system because of the review process.

[3] The '5 rights' are a checklist that is intended to reduce or eliminate medication errors. There are also checklists that refer to the 5+3 rights, 6 rights, 8 rights, 9 rights and 10 rights.

[4] The HSIB conducts independent investigations of patient safety concerns in NHS-funded care across England.