Do High-Risk Medicines Alerts Influence Practice?

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ABSTRACT

Background: Medicine-related adverse events are prevalent, costly and mostly preventable. The High Risk Medicines Working Party (Victoria) developed and distributed three high-risk medicines alerts – wrong route of administration of oral medicines, subcutaneous insulin and unfractionated heparin – and accompanying audit tools in 2008 and 2009.

Aims: To determine the impact of the three high-risk medicines alerts on Victorian health services; to assess the clinical relevance and utility of the audit tools; to identify barriers to implementing recommendations; and to obtain feedback and suggestions for future alert topics.

Method: A cross-sectional survey was undertaken from 6 to 31 July 2009 using an online questionnaire. The questionnaire was distributed to 90 metropolitan, regional and rural public health services in Victoria and approximately 200 members of the Quality Use of Medicines Network (Victoria).

Results: Most of the 90 respondents were pharmacists (53%) and nurses (31%). 53 (59%) respondents reported making changes as a result of receiving the high-risk medicines alerts – 21 (40%) concerned the wrong route of administration, 12 (23%) subcutaneous insulin and 7 (13%) unfractionated heparin. Barriers to implementation included time constraints, inadequate staff and resources, excessive paperwork and competing priorities. A minority of respondents indicated some alerts were not relevant to small rural services. Suggestions for improving the audit tools included making them less labour intensive, enabling electronic responses and ensuring their distribution is coordinated with other medicine-related tools.

Conclusion: High-risk medicines alerts and the accompanying audit tools facilitated change but there were some barriers to their implementation, such as time and resource constraints. Not all alerts and audit tools were relevant to all health services.

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INTRODUCTION

Medicines are the most commonly used treatment in health care and are associated with more adverse events than any other treatment (33% of Australian adults take 5 or more medicines).[1] An estimated 1.5 million Australians experience a medicine-related adverse event each year resulting in around 400 000 visits to general practitioners and 140 000 hospital admissions, at an estimated cost of $380 million in 2002.[2,3] Medicine-related errors can occur anywhere in the medicine management pathway.

Medicine-related adverse events are more likely to occur in older people, those with serious illnesses who use multiple medicines, people using high-risk medicines and during care transition between hospital and the community. For example, around 30% of unplanned hospital admissions of older people are associated with medicines.[4] Adverse events can also occur due to errors in the medicine management pathway and when changes to medications are not recorded on discharge summaries or communicated among relevant health professionals.[5]

Many medicine-related adverse events are preventable, e.g. an estimated 1.5 million preventable medicine-related adverse events occur each year in the USA.[1,5,6] Greener[7] developed an hypothesis-generating heuristic estimate that suggested 59% of the 392 000 acute medicine-related hospital admissions in the UK were avoidable. Some strategies for reducing medicine-related adverse events include standardising medicine management processes, improving interdisciplinary communication, health professional and patient education and effective use of technology.[6] The development and distribution of high-risk medicines alerts and bulletins in the US and the UK resulted in national and international systems changes.[3,8,9] Change is critical to the success of such strategies and according to Kotter[10] the key elements of effective change are:

- establishing a sense of urgency among staff responsible for delivering clinical care;
- establishing and supporting key stakeholder (or change champions) to implement change strategies;
- communicating key aspects of the strategy to all stakeholders;
- planning for and creating conditions to achieve short-term successes; and
- consolidating success to encourage ongoing monitoring and improvement.

In July 2006, the interdisciplinary High Risk Medicines Working Party, Quality Use of Medicines Program, Department of Health (Victoria) was established to develop strategies to minimise risks associated with the high-risk medicines described within the acronym: PINCH – potassium, insulin, narcotics, chemotherapy and heparin, as well as address systems for managing high-risk medicines. During 2008 and 2009, three high-risk medicines alerts (wrong route of administration of

oral medicines, subcutaneous insulin, unfractionated heparin) were developed and distributed to 90 Victorian health services.[11] They were primarily developed to inform health services about adverse events concerning these medicines and associated administration systems, and factors that contributed to the adverse events and strategies to prevent future adverse events. The accompanying audit tools were simultaneously developed and distributed to assist health services perform a gap analysis of processes around high-risk medicines usage in relation to the recommendations within the alert.

There are limited data on the impact of high-risk medicines alerts on health services' medicine management systems and the utility of the audit tools in clinical practice. This study aimed to determine the impact of the three high-risk medicines alerts on Victorian health services; to assess the clinical relevance and utility of the audit tools; to identify barriers to implementing recommendations; and to obtain feedback and suggestions for future alert topics.

METHOD

From February 2008 to March 2009, the three high-risk medicines alerts and accompanying audit tools were distributed to the 90 chief executive officers of Victorian metropolitan, regional and rural public health services with a letter requesting they distribute them to the clinical governance, quality use of medicines, drug and therapeutics, and medication safety committees, as well as directors of medical, pharmacy and nursing services. The decision to implement the recommendations in the alerts and audit tools was devolved to the health services, rather than mandated by the Department of Health.

The alerts and audit tools were also posted on the High Risk Medicines' web site at the time they were distributed to the chief executive officers. They were also distributed via e-mail to stakeholders such as the directors and deputy directors of pharmacy, quality managers and the Victorian Quality Use of Medicines Network.

The alerts and accompanying audit tools were circulated at the following times: wrong route of administration in February 2008; subcutaneous insulin in December 2008; and unfractionated heparin in March 2009. Health services were expected to implement the alerts to comply with Victoria's clinical governance framework, which expects known clinical risks to be addressed proactively.[12] The audits could be completed before, during or after the implementation of the recommendations as they provided a gap analysis of processes that needed to be addressed.

A cross-sectional survey was undertaken from 6 to 31 July 2009 using an online questionnaire developed for the study. The questionnaire consisted of 12 questions: mixture of five-point Likert scales and open-ended and closed questions. Face and content validity of the questionnaire were established with a panel of experts (pharmacists, nurses, a general practitioner, a physician) prior to dissemination.

Participants were informed about how the data would be used and that completing and returning the questionnaire would be taken as consent to use the data.

Data were analysed using descriptive statistics including frequencies and percentages. Content analysis of the open-ended questions was undertaken using the five-step framework method: becoming familiar with the data, identifying a thematic framework, indexing and charting key themes, and mapping and interpreting the findings.[13] Two of the authors independently undertook analysis in NVivo (version 1.2.142) and then discussed the findings until they reached consensus.

RESULTS

Most of the 90 respondents were pharmacists (53%) and nurses (31%), and the remaining 16% were administrators or 'other'. Most respondents were also involved in implementing the alerts and undertaking the audits in their health services. The number of responses was fairly evenly distributed among the three alerts (Table 1). As the responses were anonymous it was not possible to determine their origin or whether multiple responses were returned from the same organisation.

Table 1. Responses to the three high-risk medicines alert

Alert	No. of responses (n = 90)
Wrong route of administration	35%
Subcutaneous insulin	29%
Unfractionated heparin	30%

Influence on Practice

The majority of respondents (86%) noted that the alerts helped identify areas that needed improvement in their organisations and 90% noted that the alerts improved patient safety. Fifty-nine per cent of respondents made changes to existing practices and/or policies as a result of receiving the alerts. Of these, 40% concerned the wrong route of administration, 23% subcutaneous insulin and 13% unfractionated heparin alerts (Table 2).

Responses to the open-ended questions suggested that the alerts and audit tools acted as catalysts for change by bringing the high-risk medicines to the attention of health professionals. They enhanced interdisciplinary discussion and resulted in review of and changes to practices and policies. One respondent stated: *'The audit was a very valuable tool and it made the process of 'change' in our hospital so much easier'*.

Respondents noted that planned, targeted staff education, completing audits and improving staff medication knowledge and competence were necessary to the change process. As a result of the alerts, some hospitals included medicines alerts and high-risk medicines information in orientation packs for new staff.

Some respondents noted that their hospitals were preparing to make changes in response to locally identified needs regarding high-risk medicines before they received the alerts and audit tools. They reported that the alerts supported the need for change in their hospitals. While others reported that the alerts were important education tools. For example, one respondent indicated that their hospital was not aware dispensers for administering oral medicines were available before they received the wrong route of administration alert.

Table 2. Actions prompted by the high-risk medicines alerts

Outcomes prompted by the alerts
Subcutaneous Insulin
New insulin medication chart developed and aligned with the National Inpatient Medication Chart.
Medicine labelling and range of insulins stocked rationalised.
Insulin protocols collated and reviewed.
Insulin incidents reviewed.
Policies for managing hypoglycaemia developed or revised and the contents of 'hypo' kits reviewed.
Insulin promoted as a high-risk medicine.
Policies revised to highlight that insulin doses must be prescribed in units rather than 'IU'.
Wrong Route of Administration of Oral Medicines
Oral dispensers introduced to administer oral liquid medicines via percutaneous endoscopic gastrostomy tubes.
Policies for administering oral liquid medicines revised.
Staff education and orientation programs used to increase awareness of risks associated with oral medicines administered via non-oral routes and introduce changes to existing practices and products.
Alerts discussed in clinical risk management committee meetings.
Unfractionated Heparin
Anticoagulant protocols reviewed.
Product labelling and range of heparins stocked rationalised.
Recommendations incorporated into revised heparin infusion chart.

Barriers to Implementing the Alerts

Forty-two respondents did not answer the question about barriers to implementing the alerts. Of the 48 people that responded, 48% indicated there were no barriers and 52% cited a number of barriers (Table 3). Some respondents reported a lot of time-consuming preliminary work was needed to implement an alert and audit plan such as preparing education material and disseminating messages to all clinical staff.

Table 3. Barriers to implementing recommendations in the alerts

Perceived barriers
Time constraints.
Insufficient resources including staff with the relevant expertise.
Processes for changing policies such as the need for committees and working parties to approve implementing the alerts and the implementation process.
Availability of materials, products and suitable storage space.
No governing body to influence change in general practice.
Alerts focused on medicines rarely used in some services.
Receiving several alerts in a short time frame.
Competing priorities, e.g. clinical load.
Limited availability and difficulty sourcing oral dispensers and their cost at the time of the wrong route of administration alert.

Successful implementation of the recommendations in the alerts and completing the audits required interdisciplinary support and collaboration. Some respondents described difficulties when establishing the audit process, which was interpreted as 'telling people how to do their work', which the respondents noted reflected the 'power relationships' among health professionals. Respondents who provided feedback about 'barriers' suggested 'management direction and support' was essential to successful implementation. Some respondents commented that general practitioners were reluctant to adhere to the recommendations, for example not following the directive to write 'units' when prescribing insulin doses and using 'IU'.

While the audit tool was considered to be 'great for large health services' there was a suggestion that they could be tailored to suit small rural health services.

Improving Alerts and Future Topics

A number of suggestions for improving the alerts and audit tools were received, which will be considered when developing future topics for the high-risk medicines alerts program (Table 4). The majority (79%) of respondents noted it would be useful if the completed audits could be submitted electronically to a central database for benchmarking purposes. Topics suggested for future alerts included: insulin infusions; cytotoxics; opioids; pumps; processes for recording allergies; clinical handover; labelling and packaging; omission of medicines; and neonatal nasogastric feeds.

Table 4. Respondents verbatim suggestions for improving alerts and audit tools

Suggested improvements
Alerts
Increase awareness.
Recognise not all alerts apply to all hospitals.
Acknowledge that specific competencies are unworkable.
Ensure the time the alerts are distributed is consistent with other medicine-related initiatives such as the insulin alert and the insulin chart being developed so that changes can be implemented simultaneously.
Extend the dissemination network.
Provide a hypoglycaemia management policy.
Audit Tools
Recognise small health services may use some high-risk medicines infrequently.
Make them less labour intensive.
Time the distribution to synchronise with other tools such as insulin charts.
Develop a process to enable the audit tool to be completed online.
Conduct a staff survey.

DISCUSSION

Although the overall response rate could not be determined, the range and content provided valuable qualitative information on the impact, implementation and future recommendations for alert development. Implementing the three alerts and undertaking the audits were in various stages of completion in most health services at the time of the survey, which could have impacted on the type and amount of information provided, and the number of responses received.

Most of the respondents were pharmacists and nurses, possibly because they undertake the bulk of the medicine-related activities (excluding prescribing) in hospitals. The responses suggest pharmacists and nurses are noticeably active in managing system change to improve safe and effective use of high-risk medicines.

Respondents noted that the alerts and audit tools acted as catalysts for change in their hospitals. The alerts appeared to have stimulated health services to assess their performance and share information to make it easier for others to learn from their successes and failures and help foster a culture of safety. Self-assessment, sharing information and fostering a culture of safety are key recommendations of the Institute of Medicine.[6]

Interestingly, Kotter's key elements of change, i.e. creating a sense of urgency, support, communication and planning, were consistent with the change management strategies highlighted by respondents to be important contributors to effective implementation of the alerts.[10] Significantly, changes were made to policies as a result of the three alerts, for example insulin charts, product rationalisation and availability of dispensers for administering oral liquid medicines via gastrostomy tubes. However, the factors that drove the change were not explored in this study. The role of the alerts as change agents requires further investigation.

Some respondents reported insulin doses were still being written as 'IU' instead of 'units'. Although the magnitude of the problem is unknown, it is of concern, given the large amount of education on this topic that has been targeted to health professionals. Additionally, the two case studies on the subcutaneous insulin alert highlighted serious adverse events associated with writing insulin doses as 'IU'.

Competing priorities and timeframes of the alert dissemination (three in 12 months) were reported to be barriers to implementation. These alerts were distributed over a year after the implementation of the National Inpatient Medication Chart and national compulsory alerts for potassium and vincristine. These prior experiences were useful to inform the future national approach to alert development.

Small rural health services reported that some alerts were not relevant to them because of the low usage of the drug concerned. However, infrequent use of high-risk medicines in these health services may increase risks and necessitate vigilance and adherence to the alert recommendations.

Respondents cited a number of other perceived barriers that are similar to those encountered in other aspects of health care.[1] Most concerned time and resource constraints and local issues such as storage space.

Seventy-one per cent of respondents indicated that the content of the alerts were relevant to their health service. In addition, topics for future alerts were also suggested, which included other high-risk medicines, delivery systems and documentation. Constructive feedback for improving the alerts and audit tools to increase their utility will inform future delivery of the high-risk medicines alert program and other medicine-related communication. The findings highlight the need for targeted staff education to improve medicine safety when the alert recommendations are being implemented.

The limitations of qualitative self-report studies and the small sample size need to be considered when interpreting the results and their implications for practice. The survey was conducted four months after the third alert was disseminated and may not have allowed sufficient time for the recommendations to be fully considered and implemented.

In conclusion, high-risk medicines alerts and the accompanying audit tools facilitated change but their were some barriers to their implementation, such as time and resource constraints. Not all alerts and audit tools were relevant to all health services.

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