Closing the loop of medication management in hospitals to improve patient safety with barcoding technology on unit dose packaging

POSITION STATEMENT

Introduction

The medication safety benefits for patients of hospitals using electronic medication management systems are well documented as is also that most of these benefits are in the reduced number of errors of administration if closed loop medication management is incorporated into the electronic medication management system. To this end, a small number of Australian hospitals have endeavoured to implement closed loop medication management by adding barcodes to the unit dose of the medication to be administered; however, this is not sustainable for most Australian hospitals. This position statement addresses the issues faced by Australian hospitals in the absence of a standard for barcoding medications at the unit dose level and makes recommendations for such a standard.

SHPA Position

The Society of Hospital Pharmacists of Australia (SHPA) recommends the implementation of barcodes and barcode scanning technology at unit dose, primary packaging and secondary packaging levels for medications. Within hospitals and many other care environments, unit dose barcode scanning would especially support improved patient safety by enabling the introduction of closed loop medication management systems. The scanning of medication barcodes at the patient bedside to confirm that the medication matches the medication order, that it is recorded on the correct patient's medication administration chart, is administered to the correct patient (scanning the patient's wristband), and that it is possible to verify the medication's strength, dosage form and time of administration, are key benefits of this technology. Improvements in other care environments may also be supported through the implementation of these technologies.

Whilst the problem and methods of avoiding medication errors are multifactorial and multidisciplinary, hospital pharmacists are crucial to a safe medications supply chain in hospitals, and in the governance frameworks that support medication safety and quality use of medications. SHPA's position aligns with the Australian Commission on Safety and Quality in Health Care's report on *Barcoding and other scanning technologies to improve medication safety in hospitals*[1] and with the Therapeutics Goods Administration's regulations on improving medication labels[2].

The SHPA acknowledges that achieving the strategic change necessary to ensure unit dose identification for all pharmaceutical products will involve collaboration and cooperation from industry and that this may require prioritisation and transitional arrangements. We feel, however, that based on the learnings from elsewhere globally, the safety of Australian patients and hospital medication processes would be significantly improved as a result of the introduction of unit dose identification and barcoding. We strongly urge further discussion within the industry to develop a plan.

Discussion

Why change is needed to improve the way medications are managed in Australian hospitals

Medications play an important role in healthcare and contribute significantly towards improving health outcomes when used correctly and appropriately. Despite their crucial role, because medications are used so commonly, they are also one of the most common sources of error and adverse events in healthcare. The majority of patients who are hospitalised will be administered at least one medication during their hospital stay[3]. Australian and International studies[4,5] indicate a high prevalence of medication-related problems including medication errors and adverse drug event (ADEs) associated with hospitalisation. Reducing medication-related errors to improve the quality of care has always been a priority for Australian hospital pharmacists.

With increased medication use in Australia, there is a proportional increase in medication-related errors, many of which are avoidable. Medication errors contribute to 250,000 hospital admissions per annum at a cost of $1.4 billion each year to the Australian health system[6]. However, errors in medication supply and administration can be reduced with the use of electronic medication management systems with a closed loop medication management system.

While rates of serious harm are low, errors do affect health outcomes for people and healthcare costs. The prevalence of medication errors is of concern because many of these errors are preventable. One study identified 6.5 adverse events relating to medication use per 100 inpatient admissions; more than 25% of these events were the result of errors and were thought to be preventable[7]. Medication errors can occur at the time of admission to a hospital, when prescriptions are written, when medications are administered, and at the time of discharge.

In a study of the incidence of medication errors at various stages of the medication management process, 34% of errors occurred at the medications administration phase which is where unit dose packing with barcodes may lessen the rate of error. Transcription errors (6%) and dispensing errors (4%) were less common[8]. Errors were much more likely to be picked up if they occurred earlier on in the process as 48% of errors were intercepted at the ordering stage compared to zero at administration[9].

Scanning barcodes at the unit dose level ensures unambiguous identification of medicinal products, by medication name, specific brand, strength and dose form. This provides an additional check to reduce errors in medication administration and may also act as a linkage to a decision support tool during administration. Preliminary studies have suggested the use of barcodes on unit dose packaging of medications can help to reduce medication error rates by 41%[9].

In the medication management process, barcodes can be used from dispensing to administration to address the ‘five rights’ of medication safety, in accordance with the order placed[10]:

1. Right patient
2. Right medication
3. Right time
4. Right dose
5. Right form for the route of administration.

The use of innovative health information technology has been introduced to achieve a closed loop medication management system. At the bedside, barcode technology can be used in real time to verify a patient’s identity before medication administration and to capture the care provider administering the medication. Bedside verification of medications allows nurses to check and document the medication administration to reduce administration errors.

Currently, for most Australian hospitals, verification of medication at the bedside is largely done via a visual check of the product against the prescriber’s order. This is a manual task reliant on the nurse following approved procedures, checking the product label and description, eMAR (electronic Medication Administration Record) description or written order on a paper NIMC (National Inpatient Medication Chart), and interpreting the medication order correctly.

Barcode scanning of medications at the unit dose level would most probably start with unambiguous identification of the product using the Global Trade Item Number (GTIN) allocated to identify this level of the product contained within the GS1 DataMatrix. In future, the barcodes may also include data related to the batch number and expiry date, which will assist in the management of medication alerts and recalls due to improved tracking and tracing of doses within hospitals. The introduction of identification and barcoding including batch number and expiry date information should start at least with secondary packaging to ensure that the end to end supply can better be managed across all processes and be introduced as part of a planned transition program. As it is a requirement for nurses to check the expiry date of the medication prior to administration, it is desirable for barcodes on unit dose packaging to include expiry date to enable digital checking of this. If the information is not able to be contained in the barcode, then it must be available visually.

In hospitals, pharmacists regularly prepare compounded medications such as intravenous solutions, parenteral nutrition and chemotherapy. Scanning of source ingredients

during compounding, repackaging or labelling processes can ensure the labelled doses contain the appropriate ingredients and appropriate records be maintained for compounded medications. This improves the quality, safety and efficiency of health services delivered to patients.

The introduction of unit dose packaging identification aligns with recommendations made by the Australian Commission on Safety and Quality in Health Care and the use of unambiguous identification and barcoding aligns with the Therapeutics Goods Administration's *Therapeutic Goods Order for Prescription Medication Labelling (TG091)*[11] requirements for machine-readable codes. This order will come into effect in September 2020.

Leveraging national infrastructure and global standards

The Australian Digital Health Agency's National Product Catalogue (NPC) is already built with the GTIN as the primary unambiguous identifier for all products. In addition to providing those required for supply chain purposes, it has the capacity within the data fields for the GTIN and relevant data to be provided for the unit level in addition to the secondary pack. Having a manufacturer uniquely identify their products to the level of the unit dose using the GTIN and provide the accurate data related to the product ensures the most comprehensive, consistent and cost-effective action to enable barcode scanning at the bedside as a part of a closed loop medication management system.

The GTIN being available for both the secondary packaging and the unit dose level enables health professionals to scan the outer packaging (secondary packaging) barcode in relevant processes, or the unit dose level for those processes where this is needed. The solution involving manufacturers ensures that there is a nationally standardised system for all medication rather than individual hospitals creating their own internal identification and custom barcodes. In doing so this supports interoperability of technologies and data and ensuring alignment to the national clinical terminology service (NCTS) and the Australian Medications Terminology (AMT) which are mapped to the GTIN, leveraging the benefits of linkages between SMOMED and GS1 standards.

In addition to the ability for us to leverage national infrastructures such as the NPC and NCTS, we also acknowledge that the process to achieve unambiguous identification and barcoding at all levels of a product has already been achieved by the National Blood Authority through their implementation of barcoding requirements for all manufactured products including at unit dose level. They adopted the same global standards we reference within this document and the clear guidelines and transitional approach is one that could be followed for pharmaceuticals.

Successes prove the potential benefits

In recognition of patient safety and the reduction of medication errors, unit dose barcoding has been a regulatory requirement in the USA since 2004 where all pharmaceutical products sold to hospitals must bear a barcode on the smallest unit of use[12]. A USA study found that a barcode medication administration system for inpatient medication cost US$2,000 per moderate or severe medication error prevented. This was less than the cost of additional hospital care resulting from preventable adverse drug events[13]. Similar results have been found in other countries such as The Netherlands, which has implemented unit dose and primary packaging identification.

In Australia, few hospitals such as the St Stephen's Hospital in Queensland and the Royal Children's Hospital in Melbourne currently use a unit dose method of medication administration. Early analysis at St Stephen's Hospital indicates a 22% reduction in medication administration errors[1]. However, health services that opt to repackage medications from commercial preparations to enable unit dose packing and barcoding and scanning at administration do so at significant cost. This involves machinery costs, equipment and packaging costs and staff resources that are not a nationally scalable solution.

With limited hospital pharmacy resources, this represents an opportunity cost for clinical pharmacy services for patients at the bedside. Local health services that undertake this safety and quality measure are unable to scale their operations to collaborate with other health services to improve efficiency and cost-effectiveness. It is for this reason that leadership is required from regulatory bodies and medications sponsors to progress towards unit dose barcoding for the safety of Australian patients.

Conclusion

The introduction of unit dose packaging unambiguous identification and barcoding scanning technology in the hospital medication management process represents a significant safety and quality improvement initiative that will reduce medication-related errors in hospitals through incorrect administration; errors that are potentially fatal.

Without a nationally supported change to mandate that barcodes are available at the medicinal product unit of use there is no feasible way to systematically enable this safety and quality improvement. Barcodes on the unit dose of medications enabling barcoding and scanning technology at administration, ensure that patients benefit from an 'additional check' via systems that are always alert even when busy clinicians and nurses may be tired and distracted.

With the safety of our patients as our priority, we must work with industry to ensure that reasonable timelines are set for these changes to be implemented.

Recommendation

SHPA has recognised the need for improving patient safety and reducing the risk of medication errors in hospitals. To achieve this, SHPA recommends that:

- All medications distributed in Australia have barcodes containing the GTIN on the smallest unit of dose to enable the product to be unambiguously identified when scanned
- Data needed to support the scanning process, including unit dose or primary package, should be provided and managed by the manufacturer / sponsor of the medication within the Australian marketplace
- Over time, the barcodes on all unit doses of medications should also contain the expiry date and batch number
- Therapeutic Goods Administration should update the relevant Therapeutic Goods Orders to mandate barcoding unit dose packaging to be the standard. This would complement their regulations on improving the clarity of medication labels. The existing Therapeutic Goods Order for prescription medications contains exceptions for 'small products' and specific requirements for text size, so an amendment would be needed to ensure that the requirement for identification on unit doses is consistent and clear. It also must have appropriate timelines to implement
- All medications should be identified at the secondary packaging level using a GS1 DataMatrix barcode containing the GTIN, batch and expiry date of the product. Where there are two barcodes (a GS1 DataMatrix and an EAN-13 linear barcode) the GTIN must be the same in both to avoid confusion in the clinical setting
- An appropriate implementation timeline should be defined based on consultation with pharmaceutical manufacturers and other stakeholders to ensure an appropriate and streamlined transition process is undertaken
- All solution providers who need to support pharmaceutical processes in the future will need to ensure that they can effectively and accurately support these measures to ensure the benefits are realised.

VERSION	**1**
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Glossary

Adverse drug event	An adverse event due to a medication. This includes the harm that results from the medication itself (an ADR) and the potential or actual patient harm that comes from errors or system failures associated with the preparation, prescribing, dispensing, distribution or administration of medications (a medication incident).[14]
Australian Medication Terminology (AMT)	A national, standards-based approach to the identification and naming of medications in clinical systems for Australia. The AMT is based on global SNOMED standards.
Barcodes	A barcode is an optical machine-readable representation of data that relates to the object displaying the barcode. Barcodes may be one-dimensional (linear) or two-dimensional (DataMatrix). Barcodes require a special optical reader to scan the information.
Barcodes: One-dimensional or linear	Data is represented by varying the width and spacing of parallel lines. The most common linear barcode on pharmaceuticals in Australia is the EAN-13. It contains the Global Trade Item Number (GTIN) only. 

Barcodes: Two-dimensional or DataMatrix	Data is represented using rectangles, dots, hexagons and other geometric patterns. 2D barcodes can contain alpha-numerical information. The most commonly used 2D barcode on pharmaceuticals is the GS1 DataMatrix. It contains the Global Trade Item Number (GTIN) but can also contain other data elements, most commonly Batch/Lot, Expiry Date and Serial Number. QR codes are also often used to provide links to consumer medicines information, but are not used for product identification or supply chain applications	
Closed Loop Medication Management	The use of technology in the medication management process, from ordering through to administration. Aims to minimise manual selection, input and transcription, to reduce human effort and some risks of human error[1].	
Global Trade Item Number (GTIN)	The GTIN is used to identify any item (often referred to as trade item or physical product) upon which there is a need to retrieve pre-defined information at any point in the 'supply chain'. For pharmaceutical products this includes but is not limited to manufacturing, distribution, dispensing, administration, patient records, and recall processes. GTIN is one of the GS1 global identification standards.	
Medicinal Product	A substance or combination of substances that may be administered to human beings for the treatment or prevention of disease, with the view of making a medical diagnosis or to restore correct or modify physiological functions.	
Primary Packaging	The primary packaging of a medication is the blister pack in which a medication is contained (in contrast to the medications packet, which is secondary packaging), or the physical syringe, vial or ampoule.	
Secondary Packaging	The level of packaging containing more than one primary package or a group of primary packages. The secondary packaging is the packaging outside the primary packaging, perhaps used to group primary packages together.	
Unit Dose	Contains one discrete pharmaceutical dose form (i.e. tablet, a volume of liquid, or the immediate package of a medical device such as a syringe). This is the immediate container in which a manufacturer item is contained.	

References

1. Bainbridge, M., & Askew, D. (2017). Barcoding and other scanning technologies to improve medication safety in hospitals. Sydney: ACSQHC.
2. Therapeutics Goods Administration. (2017). Australia's medication labels are becoming clearer. Retrieved from https://www.tga.gov.au/australias-medication-labels-are-becoming-clearer
3. Roughead, E. E., Semple, S. J., & Rosenfeld, E. (2016). The extent of medication errors and adverse drug reactions throughout the patient journey in acute care in Australia. *International Journal of Evidence-Based Healthcare*, 14(Issue 3: Medication Safety Issue), 113-122. doi:10.1097/xeb.0000000000000075
4. Dean, B., Schachter, M., Vincent, C., & Barber, N. (2002). Prescribing errors in hospital inpatients: their incidence and clinical significance. *Quality & Safety in Health Care*, 11(4), 340–344. http://doi.org/10.1136/qhc.11.4.340
5. Roughead, E. E., & Semple, S. J. (2009). Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002–2008. *Australia and New Zealand Health Policy*, 6(1), 18. doi:10.1186/1743-8462-6-18
6. Pharmaceutical Society of Australia. (2019). Medicine Safety: Take Care. Canberra: PSA
7. Bates, D., Leape, L., & Cullen, D. (1998). Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors. *JAMA*, 280(15), 1311-1316. doi: 10.1001/jama.280.15.1311
8. Bates, D., Cullen, D., & Laird, N. (1995). Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA: The Journal Of The American Medical Association*, 274(1), 29-34. doi: 10.1001/jama.274.1.29
9. Poon, E. G., Keohane, C. A., Yoon, C. S., Ditmore, M., Bane, A., Levtzion-Korach, O., . . . Gandhi, T. K. (2010). Effect of Bar-Code Technology on the Safety of Medication Administration. *New England Journal of Medication*, 362(18), 1698-1707. doi:10.1056/NEJMsa0907115
10. Institute for Safe Medication Practices (US). (2007). The five rights: a destination without a map [Internet]. Horsham, Pennsylvania: ISMP (US).
11. Therapeutic Goods Administration. (2018). Therapeutic Goods Order for Prescription Medication Labelling (TG091. Department of Health. Australian Government.
12. Food and Drug Administration. (2004). *Bar Code Label Requirement for Human Drug Products and Biological Products*. Food and Drug Administration.
13. Sakowski, J., & Ketchel, A. (2013). The cost of implementing inpatient bar code medication administration. Am J Manag Care., 19(2), 38-45.
14. The Society of Hospital Pharmacists of Australia. (2013). Standards of Practice for Clinical Pharmacy Services. Journal of Pharmacy Practice and Research, 43(2).