Improving Medication Safety: Bedside verification

DRAFT PROJECT OUTLINE

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This paper was prepared by Dr Bruce Anderson PhD. Any errors of fact or interpretation are the responsibility of the author. James Harris of LECG, Elizabeth Plant, Chief Pharmacist at Taranaki DHB, Win Bennett General Manager Funding and Planning at Hawkes Bay DHB, Marilyn Crawley Chief Pharmacist, Dr Robin Youngson, Clinical Director of Waitemata DHB and Gary Hartley of GS1 New Zealand are thanked for reviewing earlier drafts. Also thanked for their input are Pharmac, Quality Improvement Committee, Safety and Quality Use of Medicines Committee, the Health Information Strategy Action Committee, and the Accident Compensation Commission.
MINISTER’S FOREWORD

DHB staff work hard to ensure patients are safe and well looked after while they are in their care. They are dedicated, motivated and highly skilled. But sometimes errors can and do occur.

This project aims to support health professional in the medication administration process by introducing bedside verification of medication. This will reduce the number of adverse medication events and with that reduce the number of patients adversely impacted by those events.

The types of systems that it is proposed to introduce do not remove the need for clinical judgement; rather it supports staff by bringing to their attention a potential error directly before administration. Staff will still need to use their judgement before deciding the appropriate course of action to take following a warning.

Alan Merry and Mary Seddon¹ recently reminded clinicians and policy makers of some wise words by three of the international leaders in improving patient safety; Leape, Berwick and Bates wrote:

For policymakers to wait for incontrovertible proof of the effectiveness before recommending a practice would be a prescription for inaction and an abdication of responsibility. The prudent alternative is to make reasonable judgements based on the best available evidence combined with successful experiences in healthcare. While some errors in these judgements are inevitable, we believe they will be far outweighed by the improvement in patient safety that will result.²

This Government has accepted that the incidence of adverse medication events is unacceptable. This document describes a project aimed to reduce the number of these events and consequently the impact those events have on patients. I am sure that DHB staff and the public will embrace this opportunity to help improve the safety of patients.

* This is an example of a data matrix, two-dimensional barcode. The information to be encoded can be text or raw data. A data matrix symbol can store up to 2,335 alphanumeric characters.

¹ Merry, A., Seddon, M., 2006: Quality improvement in healthcare in New Zealand. Part 2: are our patients safe i and what are we doing about it? The New Zealand Medical Journal, v 119, No 1238
EXECUTIVE SUMMARY

Those working in the New Zealand heath sector are dedicated professional people who strive to provide the best care possible to their patients. However, errors can and do occur despite the best efforts of staff and organisation. Medication\(^3\) errors continue to be a recognised problem in the New Zealand health and disability sectors.

An extrapolation of results by the New Zealand Quality of Healthcare Study\(^4\) (NZQHS) suggests that in New Zealand each year, about 5,000 patients are subject to medication errors. As a result of these errors about 150 patients die, over 400 are permanently disabled, and nearly 3,500 are disabled for less than one year. The magnitude of medication errors estimated in this report for New Zealand is consistent with that experienced in other countries. However, regardless of whether medication errors result in 100, 1,000 or 10,000 deaths, permanent disabilities or other patient impacts, it is important that the New Zealand health sector acts now to put in place additional measures to reduce the incidence of adverse drug events.

Potential medication errors\(^5\) occur throughout the medication process, starting on admission when a clinician records a patient’s medication history. Throughout the medication process, when the clinician prescribes medication to a patient and the prescription is handwritten on a medicine chart.

Prescriptions are either transferred to the hospital pharmacy or dispensed from ward-based stocks. When prescriptions are sent to the pharmacy they are transcribed into the pharmacy information system, the pharmacy then fills, checks and then dispatches the medication to the ward. Alternatively or in conjunction, many hospital pharmacies supply medicines via an imprest system – this is a storage cupboard in the ward which is pre-filled with an agreed selection and quantity of medicines. Nursing staff access this stock according to what is prescribed on the medicine chart i.e. there is no guide to ensure the correctness of the medicines chosen.

The final checks are undertaken usually by nursing staff just prior to the patient receiving the medication and these checks are known as the five rights: “the right medication is given to the right patient in the right dose at the right time by the right route; Conversely, a patient may be injured when;

- the wrong medication is given to a patient or by administering a medication to the wrong patient
- the wrong dose is given
- the medication is administered to a patient who is known to be allergic

\(^3\) In this paper, the terms medication and drug are used interchangeably
\(^5\) *Dorland’s Illustrated Medical Dictionary* (26th Ed.).
- the medication is administered incorrectly or using the wrong formulation (eg, orally instead of by injection)
- the medication is administered at the wrong time or when doses are missed completely.

As an enabler to increasing the penetration of patient safety systems in the United States the Food and Drug Administration mandated the use of linear barcodes on unit of dose for drugs ordinarily used in hospitals. This has allowed for a rapid expansion of the number of hospitals implementing barcode point-of-care and associated medication safety systems. These systems have significantly reduced the number of medication errors and consequently prevented large numbers of patient deaths and injury.

This document discusses a proposal to implement a barcode verification of medication at the point-of-care into New Zealand public hospitals. The draft document is aimed at encouraging conversations and debate on this issue. It is likely that as a result the form of this project will change and the final version will then help guide projects teams in the development of the scope, nature and sequence of any implementation.

For this project to occur several other changes will need to occur including changes to some hospital pharmacy systems - introduce e-prescribing or electronic medication records and the repackaging of pharmaceuticals as unit dose. In isolation each of the components are likely to improve medication safety but the maximum gain is to be obtained from implementing all systems in a coordinated manner. These data capture, decision support and checking systems have been successfully implemented in many hospitals in the United States.

A comprehensive bedside verification of medication using a barcode\(^6\) point-of-patient-care system might work as follows.

- The hospital gives the patient an identification bracelet with a barcode on it. The information in the barcode uniquely identifies the patient and allows for data relating to that patient to be captured and synchronised for example by linking the patient, and clinical staff, to his or her computerised medication record (or on the patient management system). In the future, the system would link to a more comprehensive electronic medical record.
- A medication history is developed with the patient and if needed their General Practitioner. This information is continually updated and then made available (or accessible) at each transition in the patient's care.
- Prescription pharmaceutical and certain over-the-counter drugs would have a barcode on drug packaging/labels and would be available at the unit of dose. The barcode would contain the pharmaceutical's unique identifier number.
- A clinician creates a computerised medication prescription and decision support is available to them at that time flagging incorrect doses, or potentially

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\(^6\) A barcode provides information that is reliably read by a computer. A barcode helps automatic data capture. Technically a barcode is a data carrier for the information encoded in the black and white strips of a linear barcode or the pattern of dots on a two dimensional barcode (see Appendix B for further detail).
dangerous interactions. This prescription is transferred electronically to the hospital pharmacy, where a second series of consistency checks is undertaken (eg, does the prescription match the stated application of that drug and in the correct dose for the patient?). If no problems are encountered, the medication is dispatched to the ward, or profiled into automated drug distribution cabinets available at ward levels.

- The hospital ward has barcode scanners or readers integrated with the hospital's computer systems and are linked to the hospital's patient management system, pharmacy, the patient's electronic medication record and stock inventory.
- Before the medication is administered to a patient, the staff member scans the patient's barcode and a barcode on their own staff identification tag.
- The staff member scans the medication provided by the hospital pharmacy. This scan validates that it is the correct patient, checks that the drug is the same as that prescribed for the patient, in the correct dose, formulation etc.

At each stage of the sequence, data is compared to the patient's electronic medication record. If there is a problem, an error message alerts the staff member, requiring them to stop administration and investigate the problem. As an example, bedside verification could prevent a patient from receiving medication intended for someone else, a child from receiving an adult dosage of a drug, or prevent a patient from mistakenly receiving a duplicate dose of a drug he or she had already received. A bedside verification of medication system also records the time that the patient receives the medication, the person administering and the location of administration. The information collected will ensure more accurate medical records.

While the key patient safety tools in this initiative is the barcode point of care (BPOC) checking there are several other systems that support this approach. For example, BPOC requires drugs to be packaged at the unit of dose level and each medication is individually wrapped and the wrapper has a barcode containing information that uniquely identifies the drug and dose. It is proposed that in the short term unit dose packaging machines be purchased. BPOC systems need to be interoperable with electronic prescribing or electronic medicine charts, patient management and pharmacy information systems. The linking of these systems allows for data to be compared and for checks to be made with other sources of information (such as decision support tools).

A detailed cost utility analysis is available on [www.moh.govt.nz](http://www.moh.govt.nz).
INTRODUCTION

This document examines the extent of the medication error problem in New Zealand and compares this to other jurisdictions. It then goes on to describe an initiative to reduce medication errors by introducing bedside verification of medications using a standardised barcode point-of-care (BPOC) system. A component of this proposal is to also ensure that information can be shared between this and other DHB systems such as pharmacy databases and patient management. It is proposed that this project would involve, at a minimum, all New Zealand public hospitals. While not the focus of this project, it is likely that barcode use on pharmaceuticals and other over-the-counter products would in the future be mandated by regulation as in the United States.

Barcode technology and the associated data integration systems are then discussed. These have been in place in some health systems for some time, and have demonstrated the positive impacts barcode applications have had in clinical health settings and in health supply chains.

MEDICATION ERROR

A medication error can be defined as:\(^7\):

\[\text{Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.}\]

The definition above has three important phrases; preventable, inappropriate use and patient harm.

- Preventable - Only those medication errors that are preventable are considered here. Every individual metabolises medication in different ways and sometimes that results in an unpredictable adverse reaction. On the whole, these events cannot be prevented and therefore are not considered in this project.
- Inappropriate use - involves using a medication in a manner for which it was not intended.
- Patient harm - Some medication errors result in no discernable impact and it is often difficult to identify these events at the time. Critical to the approach taken here is that any harm to a patient only occurs when a medication is actually administered to a patient. The error may have occurred earlier in the medication sequence and not identified before the medication is given to the patient.

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Those involved in medicating patients normally conduct checks to prevent adverse drug events (ADE) but clearly not all checks are successful in identifying possible issues. Types of medication administration errors\(^8\) include:

- the wrong dose
- a medication to a patient who is known to be allergic
- the wrong medication to a patient or administering a medication to the wrong patient
- the medication incorrectly or in the wrong formulation (eg, orally instead of by injection)
- the medication at the wrong time or missing doses.

**Significance of adverse drug events in New Zealand**

Health sector staff are very aware of the potential impacts of adverse drug events and work hard to prevent injury to patients. However, error and omissions do occur and occasionally with disastrous results. The causes of errors often relate to system or process causes and less commonly to individuals. Increased training and improved systems design has reduced error but it is unlikely that further training or systems redesign will eliminate errors.

There is no accurate assessment on the extent or impact of medication errors in New Zealand. However, recent Health and Disability Commissioner reports and media articles have highlighted problems in the administration of pharmaceuticals to patients. One of the few adverse event studies to be conducted in New Zealand was the New Zealand Quality of Healthcare Study (NZQHS)\(^9\). This study investigated adverse events in hospitals by conducting a two stage retrospective review of 6,579 medical records. An adverse event was operationally defined by NZQHS as an unintended injury which resulted in temporary or permanent disability, including increased length of stay and/or financial loss to the patient, and which was caused by health care management rather than the underlying disease process. While not defined by NZQHS, this paper defines an adverse drug event using the same definition of unintended injury as above but with a cause attributable to a medication error\(^10\).

The NZQHS study determined that in-hospital adverse events (as opposed to adverse drug events or medication errors) occurred in just over 10 percent of records reviewed\(^11\). Of those adverse events, approximately 7.5 percent\(^12\) were classified as preventable drug-related adverse events (ADE). This suggests that

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\(^8\) *Dorland's Illustrated Medical Dictionary* (26th Ed.).


\(^10\) An adverse drug event (ADE) or adverse medication event (AME) are definitionally the same as a medication error and used interchangeably.

\(^11\) Other adverse that occurred in the community were identified by the study and these are not considered future here.

0.78 percent of hospital admissions result in a preventable adverse medication event\textsuperscript{13}.

Of those subject to in-hospital medication error, the severity of the event varies with about 3.1 percent resulting in death, 8.3 percent in permanent disability, 12.5 percent in a disability lasting between one and 12 months and 72 percent in a disability lasting less than one month\textsuperscript{14}. On average an ADE will add seven and a half additional days to a patient’s hospital stay per event. Anecdotally, a significant number of adverse drug events also go unreported, undetected or are assigned to other causes.

An extrapolation of the NZQHS results (methodology and results - Appendix A) indicates that around 5,000 people each year are subject to preventable in-hospital adverse medication events (ADE). Of those ADEs about 150 result in death, over 400 in permanent disabilities, and about 4,000 in short-term disabilities. While care should be exercised over these estimates, they still provide an indication of the extent of the problem.

Of the other studies in New Zealand, a survey of anaesthesiologists in New Zealand identified that 12.5 percent of respondents reported having harmed patients through a drug administration error\textsuperscript{15}. Another study found an overall incidence of drug administration error in anaesthesia in two hospitals reported one error for every 133 anaesthetics\textsuperscript{16}.

\textbf{Other jurisdictions}

An often quoted report in medication safety circles is the United States-based Institute of Medicine’s \textit{To Err is Human}\textsuperscript{17}. This report suggested that there were between 44,000 and 98,000 avoidable patient deaths in the United States each year due to clinical error. Of those deaths, a significant proportion was due to error in medication administration. The report noted clinical studies that assessed reported medication errors in the United States in 1993 at nearly 7,400 deaths.

While there was some argument over the actual number of deaths, the United States Food and Drug Administration concluded that medical errors are a serious public health problem and that the message should not be lost, regardless of whether the annual mortality was 10,000 or 100,000. The Institute of Medicine’s report acted as a trigger for federal agencies to investigate potential interventions to reduce medication errors and the subsequent mandating of barcodes on drugs ordinarily used in Hospitals.

\textsuperscript{13} A proportion of other adverse drug events occurred in the community and led to hospital admission where the error was retrospectively identified in the study of hospital records. The measures proposed in this document will not deal directly with this group

\textsuperscript{14} Does not add to 100% because approximately 4.2% could not be categorised by the NZHQS


\textsuperscript{17} Kohn LT, Corrigan JM, Donaldson MS (eds). 2000. \textit{To Err is Human: Building a Safer Health System}. Washington, DC: Institute of Medicine.
Another study in the United States of America estimated that drug-related errors occur in 20 percent of doses given to patients in hospitals. Other systematic studies have shown that errors occur in prescribing (39 percent), transcribing (12 percent), dispensing (11 percent) and administering drugs (38 percent).

In addition to deaths, there are significant economic costs associated with medication errors. Published estimates cite the direct costs associated with preventable drug related mortality and morbidity at $US76.6B annually and $US177.4B respectively.

In the United Kingdom, the National Health Service (NHS) recently calculated that around 60 patients die each day due to ADEs. The NHS pays out around £400M every year settling clinical negligence claims. The knock-on costs of a high patient risk environment lead to significant costs in additional hospital stays plus clinical negligence claims (eg, the NHS has reported that drug related adverse events cost approximately £500M a year in additional hospital stays alone if this is compounded through not knowing the true extent of medication errors due to inadequate definitions and differing reporting arrangements).

A report of the Pharmaceutical Industry in the United Kingdom, Underpinning Patient Safety, explains the context of this problem:

"Today 50% of the estimated 72,000 deaths in the NHS are caused by medication errors overall. 34% of all medication errors that cause problems for patients are associated with drug administration. Many of the medication errors occur as a result of a lack of machine-readable codes, which significantly increases the risk of human visual identification errors (many packs are of similar name, size and appearance.)"

In Australia, a systematic study of medical/surgical intensive care and general care units of two tertiary hospitals found that 6.5 percent of admissions experienced an ADE and 5.5 percent are potential ADEs. The majority of preventable adverse drug events occurred at the stage of prescribing medication (56 percent) and administration (34 percent).

The data presented for New Zealand by NZQHS (2001) is consistent with that for other countries, and the extrapolation conducted in this report is also consistent with the approaches identified in other reports.

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23 National Patient Safety Agency (NPSA) medication error statistics.
**Where do the errors occur?**

Shown below is a simplified medication sequence with an indication of where within a medication sequence errors occur.

There have been several high profit deaths resulting from errors that occur in medicine reconciliation. On admission to hospital a patient’s medication history is collected. Patients may not know or be able to accurately describe what prescription or complementary medication they are currently using. Also information from the patient’s general practitioner may not be available at the time of admission. As a result DHB staff may not have an accurate picture of potential medication risks. Medicine reconciliation information needs to be updated during patient stay and available during transitions in care (eg moving wards or hospitals etc).

A clinician assesses a patient and prescribes a course of treatment for that patient. This is written, generally by hand on a patient’s medicine chart. A copy of any prescription is faxed to the hospital’s pharmacy where the order is transcribed into a database. A label is generated and in most New Zealand hospitals the medication is filled by a technician and checked by a pharmacist. Alternatively, rather than the pharmacy dispensing the medication nursing staff dispense and administer the medication from standard stocks held on the ward.

As shown below, studies have suggested that a major source of medication error occurs in prescribing. To a large extent checks conducted by pharmacist play an important role in identifying potential medication errors. The pharmacy staffing combinations vary across the country but prescriptions are always required to be checked by a pharmacist before release. In making these checks a pharmacist will assess whether the proposed prescription is appropriate for the patient’s age, weight, sex and for interactions with other drugs that may have been prescribed or taken by the patient.

In many cases there is a delay in this process as pharmacists cannot review every medication chart every day. Often when a new medication prescription is written and the item is held in the imprest stock it may be administered for a short period before a pharmacist reviews the prescription. Pharmacists will check for any obvious contraindications the patient may have to the drug eg: known allergies, impaired renal function.

In some DHBs pharmacy checks are assisted by decision support tools available as part of the pharmacy computer system but this is currently only a very small proportion of hospital pharmacies. In most hospitals, pharmacists also check the medicine chart at ward level and using the clinician’s medical notes to complete a full clinical check relating to the appropriateness of the drug. This is combined with the process occurring in the dispensary. Prescribing errors are meant to be prevented where possible at this stage. Some hospitals also use automated technology to speed up the system and have drugs already available in cabinets at ward level.

Once the checks have been completed the medication is approved and dispensed to the ward where a nurse will administer the medication after checking the "five rights".
The five rights are that the right medication, at the right dose is administered to the right patient by the right route and at the right time. After the medication has been administered the nurse will monitor the condition of the patient and document the medication has been administered. As described earlier, in many New Zealand hospitals, medicines are supplied on imprest from ward stocks and this does not allow for some dispensing checks to occur.

Figure 1: Stages of medication administration and possible error associated with each stage

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Studies in the United States have shown that when clinicians prescribe a medication that there is an error rate of 39 percent, that during transcribing from hand written notes to the pharmacy information system, there is about 12 percent error, that 11 percent error occurs in the dispensing of drugs, and in 38 percent of administrations there is an error.

Each part of the sequence can create its own unique set of errors, individually and/or collectively, by failing to identify problems in the preceding steps or introducing new errors. However, injury or death will only occur when a medication is actually administered (or not administered) to a patient in short the nurse administering the medication is the last line of defence if previous parts of the system have failed. As a consequence about two per cent of patients in New Zealand are subject an adverse drug event (see Appendix A). Many events are non-preventable and about 0.8 percent of adverse drug events are preventable.

THE MEDICATION SAFETY PROJECT PROPOSAL

This proposal is based on the premise that medication error is a serious problem in New Zealand, as it is elsewhere in the world, and regardless of whether the number of patients dying or being injured is 100, 1000 or 10,000, we should act to improve medication safety as soon as possible. Outlined below is a proposal to address medication error in DHB hospitals.

Aim

Improve patient safety by reducing incidence of medication error. Specifically;

- reduce the number of medication errors in New Zealand hospitals

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27 The transcription error described here relates to American data and systems, which can be very different to those used in New Zealand. In the United States clinicians write treatment in the clinical notes, and this is then transcribed onto a chart and ordered from the pharmacy by an assistant. In the United States system the information is also often transcribed again into the pharmacy dispensing system.
• reduce the number of patients who are permanently disabled or die as a result of medication errors

• reduce the costs associated with remedial treatment of the patient injury caused by medication errors.

Objectives

To achieve the aim, components in the medication administration sequence will need to be improved and made consistent across DHBs as well as new systems and processes introduced and all linked to each other. The components are described below and shown in the following diagram.

Key to the success of this patient safety initiative is for it to be owned, driven and championed by clinical staff in DHBs. These clinical staff and other health sector experts have the detailed knowledge to drive appropriate change in medication administration systems. Another factor for the successfully reducing medication errors is ensuring interoperability of each stage in the medication sequence.

In no particular sequence this project includes:

• **Medicine reconciliation.** The development of a standardised processes and tool kits to improve the collection and verification of medicine histories and for systems to record and make available those histories.

• **Standardise hospital medicine information systems.** Emphasis and effort would be primarily into implementing a consistent electronic prescribing system and ensuring that all information systems dealing with medicines are using a consistent dataset of medicines (such as the Unified Data Model\(^ {28} \) (UDM) that is being implemented in the Auckland Region). Once this occurs the pharmacy dispensing system can interface to other systems.

• **Introduce e-medication record or, e-prescribing or a clinician point of entry system;** this changes the prescribing process in DHBs so that the doctor prescribes on-line possibly with decision support checks available at the time of prescribing. This electronic prescription passes through an audit by a pharmacist step providing an electronic medicine chart. Electronic medicine charts provides the definitive information against which the bedside verification system will checked.

• **Package pharmaceuticals at unit of dose with barcodes on wrappers or labels.** In the short to medium term this is likely to involve the purchase and operation of unit dose repackaging machines (phase 1). For the medium to long term (as phase 2) by mandating through rule or regulation the requirement will be for globally standardised barcodes to be printed on pharmaceutical packaging.

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\(^ {28} \) UDM is repository of information about the medicines including formulary. Links branded medicines to generics versions.
- **Introduce bedside verification** using barcode-point-of-care (BPOC) systems to New Zealand public hospitals. As a consequence, **electronic medication administration records** will become available.

- **Link all information systems connected with Medicine Management** including patient management systems, electronic prescribing systems, BPOC systems, and pharmacy dispensing systems, using a common consistent dataset of medicines.

- **Train and support DHB staff** in the operation of these systems and change management of process involved.

- Develop appropriate **data and information standards** across all systems.

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**Figure 2: diagram showing components of the medication safety project**

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Patient Management System (PMS)

Internal data exchange

Medication History (reconciliation)

Prescribe  Transcribe  Review  Approve  Consult  Dispense  Administer  Document

Medication Safety Project

- Standardised medicine reconciliation to record information and systems to access data
- Electronic prescribing or electronic medication chart
- Standardise hospital medicine information systems and medicine data sets
- Bedside verification of medication using barcode point of care, link to PMS and hospital medicine information systems

- Electronic medication administration record

- Drug packaging at Unit of Dose
  - Purchase and operate repackage machines (lifespan 5-10 years)

- New rule/regulation: Mandate unit dose and barcodes on wrappers/labels
  - 1 year development
  - 2 year phase-in period

- Data and information standards
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Description of components

Medicine Reconciliation

Introduction of standardised medicine reconciliation process across DHBs for the recording of medication histories and development of systems that allow for the access that data at the transitions of care.

Electronic medication record, e-prescribing, or full clinician point of entry

Electronic medication record, e-prescribing, and full clinician point of entry (CPOE) are systems where clinicians are provided with tools to assist decision making and the recording of those decisions at the patient’s bedside. In common, each system allows prescribing information to be captured electronically and transmitted to the DHBs pharmacy. At the top end, CPOE provides an electronic tool for clinicians to enter or retrieve data directly from a patient’s electronic record and to make electronic requests for laboratory tests, radiology, specialist referrals and all activities involved in the patient care. Such systems allow direct access to the patient’s latest diagnostic test results such laboratory results, radiology or other diagnostic information. Some systems include decision support information that assists a clinician in deciding the best course of treatment for a patient. E-prescribing focuses primarily on prescribing functions and can assist clinicians with the choice of medication, the dose and possible interaction. In the simplest form of electronic medicine record (or chart) is used to record information on the medicine prescribed.

Arguably, it is not possible to introduce BPOC without a consistent, comprehensive and reliable source of information on the patient medicine history and what is currently prescribed to the patient. Checks at the time of administration would use information in an electronic medication chart, e-prescribing system or CPOE.

There are many benefits to the full CPOE, however, it is costly, takes longer to introduce and is not as easy to implement as e-prescribing or e-medicine record. The decision support component of CPOE can be costly to develop and maintain. However, if this option is chosen the development and maintenance of CPOE should be undertaken by a single provider for all DHBs. This would ensure consistency across New Zealand and reduce ongoing support costs.

At this time it is proposed that electronic prescribing or medicine record are introduced. Part of introducing e-prescribing will be to ensure that there is a consistent dataset of medicines that all information systems involved in medicine management access. As with most parts of this project there are a number of barriers to overcome including legislative requirements over the signing of

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29 Neuenschwander, M., and Wisz, M, 2006; To the Bedside 2: An Expanded Review of Barcode Point of Care Solutions. The Neuenschwander Company

prescriptions, absence of a consistent medicines classification and possible public and patient concerns over the use of electronic signatures.

**Standardise hospital medicine information systems**

Currently, DHB pharmacies use seven different electronic pharmacy information systems with the most popular brands being Windose and Ascribe. Also in use are DOS-based systems and other locally developed proprietary software. While most of these systems link to DHB patient management systems (PMS) there is no ability for medicine administration information to be stored and subsequently accessed. Also, the information contained in pharmacy information systems is often incomplete because it does not record administration details and in many situations staff are able to dispense from ward stocks (as opposed to from the central pharmacy). The costs and patient risks associated with linking different and non-standard pharmacy systems of varying quality and application to a BPOC system are likely to be prohibitive. An alternative solution is to standardise DHB pharmacy information systems or arguably more importantly, hospital medication administration systems. To do this DHB pharmacists would lead a peer group to decide through an international tender on the preferred pharmacy information system and the connection of this to other DHB systems. This group would also lead the implementation of the chosen system to DHBs and train key personnel in its operation.

**Introduce unit dose packaging**

The main wholesalers and distributors of pharmaceuticals to DHBs are Health Support Ltd (HSL), Pharmaceutical Wholesalers Ltd (PWL) and ProPharma. Pharmaceuticals are not packaged at the unit dose level in New Zealand and are not labelled at that level with barcodes. In order to maximise the use of BPOC systems, pharmaceuticals would need to be packaged at unit of dose and labelled with barcodes on the wrapper or label. This could be achieved by requiring unit doses packaging with barcodes in supply contracts or by mandating the requirement through rules or regulations. Both these measures take time to implement and therefore should form part of a later phase. A rapid means of achieving unit dose packaging would be through the purchase of robotic repackaging machines.

Depending on size and functionality, a repackaging machine costs between $250,000 - $500,000. Not every DHB would need a repackaging machine and it would be more cost effective to purchase a limited number and regionally locate them (at for example six sites). From those sites unit dose drugs would be distributed to DHB pharmacies. Another alternative would be for the medication distribution companies to make strategic business decisions to offer medication packed at unit of dose.

The establishment of repackaging centres will require the development of stringent quality control and validation processes. Also, establishing repackaging centres will require the development of a logistic network in order to supply DHBs and to manage risks associated the deliver appropriate stocks to DHB pharmacies. Once
again these implementation issues would be the responsibility of a project team probably lead by a pharmacist with experience in these areas.

*Introduce bedside verification with barcode point of care systems to public hospitals*

A barcode point-of-care system allows for consistency checking between a clinician’s prescription on the patient’s electronic medicine chart (generally at the bedside), with the medication order prepared by the dispensing pharmacy (or taken from ward imprest stocks), and to the medication’s delivery to the bedside where it is administered by clinical staff at the bedside. Barcoding of medication at unit dose allows for the medication to be reliably and uniquely identified and matched to the clinician’s original prescription, to the correct patient, and a record of when a particular medication was administered is electronically recorded. System rules can provide a warning should information from any part of the sequence be inconsistent with the patient’s records or other pharmacy rules. This would also be activated if the patient was documented as allergic to the medicine. Medication administration is unable to continue until resolved. Some barcode symbologies (Appendix B) can also allow for important traceability or quality control such as batch and expiry date information to be recorded automatically.

Barcode point of care systems have been used in the United States of America for some time and there are a number of companies that supply modular, off-the-shelf systems. Issues for consideration include;

- choice of bedside verification system
- selection and functionality of the equipment that will be used
- how the system will be rolled out
- staff support and training of all associated systems
- ongoing software support and systems maintenance

As a consequence of introducing BPOC systems, medication administration records will become electronic and the linking of this information to other information systems would improve patient care and safety.

*Link all systems to the DHB patient management system*

As outlined, DHBs currently use seven different patient management systems and the most commonly used is IBA (seven users) followed by PIMS (five users). As described above, currently the hospital pharmacy information system, medication administration system and medication records are not linked to hospital patient management system (PMS). Patient management systems contain only demographic information on the patient and their ward location within the hospital. Currently neither electronic medication records nor electronic administration records are in use in DHB hospitals. Hospital pharmacy dispensing systems are usually interfaced to the Patient Management System but PMS does not store medicine administration information. At best, the information currently in the hospital pharmacy system is a subset of the prescription orders that are a handwritten

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31 Except a partial implementation in those DHBs that use the Pyxis medication dispensing machines
medicine chart. That is because many prescriptions are filled from ward imprest stocks and this information is not added to the hospital pharmacy system.

Pharmacist advise that the pharmacy information systems do not contain accurate, up to date record of medicines prescribed or administered. As a consequence, patient information that may impact on the medication decisions may not be available to the prescribing clinicians or pharmacist approving orders eg allergies, or age, sex and weight, liver or renal function of the patient. This information would be best included in electronic prescribing or similar system.

This workstream would involve the purchase or development of a hospital medicine administration system. This would include a single location (database) where information on the patient and their medication would be held and available to those involved in prescribing, approving, dispensing, and administering medication. Whether this database is an expansion of the PMS, pharmacy information system or a prescribing system will be in consultation with users.

Train and support DHB staff on the operation of these systems

A key to the successful implementation of any medication safety system is that the introduction is led and championed by hospital staff, specifically clinicians, pharmacists and nurses. Ultimately, these are the people that know the issues and will end up using the system. This approach allows for problems to be identified quickly and appropriate remedies to be developed in conjunction with knowledgeable specialists.

With the introduction of any new processes or technology, training and change management are critical components to ensure a successful rollout. Training will be provided to users of the system and supporting reference documentation made available. A project helpline could also be set-up for use within the initial period after go-live. Also within this component, the approach to rolling out these changed processes will be defined and agreed upon. Once again all of this will require ownership by key individuals and those individuals will be engaged within the project from the offset.

Develop appropriate data and information standards across all systems.

Standardisation of data and information across all systems will allow for interoperability at local, regional and global levels. The standards developed will sit underneath purchasing decisions and allow for integration with existing and future systems. At this time, it is envisaged that the Health Information Strategy Action Committee will have a lead role in the standards development.

Mandate for barcodes to be included on pharmaceutical packaging

It is possible that in the future barcodes may need to be mandated on packaging and manufactures would package at the unit of dose. This process is likely to take some time and therefore this component should occur as a second phase. If the decision
is made to require, by rule or regulation, the adoption of barcodes on medicines then a phase-in period is recommended to allow manufacturers to amend labels. In the mean time a centralised purchase of unit dose repackaging machines would allow the system to be implemented quickly. This would provide time for medicine regulators to develop draft regulations, consult widely on the proposal and then phase in any new rule.

It is acknowledged that there are likely to be some compliance costs associated with the introduction of new regulations. It is also likely that any rule would need to apply across all pharmaceuticals and as a result would include those used in hospital as well as those dispensed by community pharmacists or aged residential care facilities. Issues such as the possible application of a rule to over-the-counter goods would also be considered in any regulation.

**Implementation of proposal**

As described above, bedside verification using bar coding is seen as a key tool to reduce medication errors. In themselves, barcodes are only an information carrier, a means of storing data in a standardised format. This standardisation then allows for data collection, checking and verification. Using internationally standardised barcodes allows for the exchange of medication data.

Key to the success of any implementation is sound planning. A project team consisting of nursing, pharmacy and other clinical staff, drawn from DHBs, would provide balanced representation and form the core for planning and implementation. It is likely that these specialists will lead components of the project; for example the DHB pharmacy systems will be lead by a DHB chief pharmacist with advice from a DHB pharmacist group. Specialist will be supported by project managers. Also of importance will be the involvement of information system specialist from DHBs and ensuring that currently IS systems, or planned systems are considered.

The draft document is aimed at encouraging conversations and debate on this issue. It is likely that as a result of those conversations there will be changes to the scope and extent of the project. The final version will help guide projects teams in the development of the scope, nature and sequence of any implementation. Once detailed planning has been completed tender specifications will be developed, followed by tender processes and system selection. A suggested sequence of implementation would see e-prescribing, hospital medicine information systems and of unit dose repackaging centres established followed by bedside verification systems. Finally, changes to rules or regulations to mandate barcodes on medication. Each stage will be lead by sector specialists with input from a broad range of other health sector experts.

**CONCLUSION – THE NEED TO ACT**

There are significant patient safety gains to be made from the introduction of barcode point of care systems. The gains have been proven following the introduction of the system in other countries. The best patient safety gains will be made from bar
coding pharmaceuticals at the point of patient contact, as this is where any error
would have the most adverse impact on a patient. The maximum gain is from bar
coding pharmaceuticals at individual unit dose level.

Benefits from adopting this technology accrue in lives saved and injuries prevented. Benefits also occur in economic terms by reducing the number of extra days of hospital care required through reducing adverse drug events, reducing potential medical misadventure claims to ACC and improving the DHB pharmaceutical supply chain.
APPENDIX A:

Introduction

This analysis is premised on the basic assumption that medication errors do occur in New Zealand hospitals and that to date the extent of the problem has not been determined. Below is an attempt to estimate the magnitude of these events and the possible impacts on patients. There are limitations with this estimate and the major one is that there is only one recent New Zealand-based study has considered the causes of medical error (with medication error as part of it)\(^{32,33}\). Details of this study are described in the body of this report.

Extent of medication errors in New Zealand public hospitals

Using the methodologies adopted by the United States Food and Drug Administration and the results of the NZQHS study, an assessment of the possible extent and impact of adverse drug events (ADEs) can be made for New Zealand. The methodology used is described below and summarised in Table 1. Percentage values below are from the NZQHS and other papers published using the results of the original NZQHS results\(^{34}\).

Firstly, an estimate of the number of adverse drug events is calculated by multiplying the percentage of adverse events that occurred inside public hospitals (B) by the percentage of all adverse events which are preventable, drug related, and occurred inside public hospitals (C). This suggests that preventable in-hospital adverse drug events occur in 0.78% of admissions (D). The number of inpatient hospital admissions for 2004/05 is multiplied by percentage of ADEs per admission (see Table A-1, AxD). This provides an estimate of the 4,871 New Zealand-wide total of in-hospital ADEs (E).

Table A-1: Assessment of the possible extent and impact of ADEs in New Zealand

| Estimated inpatient public hospital admission 2004/05\(^{35}\) | A | 624,540 |
| Percent of public hospital admissions associated with an in-hospital adverse event (AE)\(^{36}\) | B | 10.40% |
| Percent of those in-hospital adverse events that are drug-related AE (ADE)\(^{37}\) | C | 7.50% |


\(^{33}\) There are other academic articles that consider narrower components of medication administration such as Merry, A.F., 1995: Anaesthetists, errors in drug administration and the law. New Zealand Medical Journal, v108, No 1000, p185-187


Percent of public hospital admissions per annum associated with an adverse drug event (ADE) | BxC=D | 0.78%
---|---|---
Estimated New Zealand-wide ADEs per annum | AxD=E | 4,871

The severity of an adverse drug event may vary from no reaction to a mild rash or irritation to permanent disability or death. As the primary reference deals only with adverse drug events where patient harmed has occurred, the estimate of impact does not account for medication administration errors where no impact occurs.

Of the estimated 4,800 adverse drug events each year in New Zealand about 150 may result in the patient dying and about another 400 are permanently disabled (Table A-2). An further estimate of 4,000 patients are subject to other less severe impacts with disabilities lasting less than 12 months or less the one month. The small number of patients that were subject to a medication error had insufficient details in their patient's record on which the NZQHS reviewers could assess the impact of the ADE.

Implementing bedside verification of drugs using barcode point-of-care and associated systems in the United States has shown a reduction in adverse drug events of between 65-86 percent (average 78.2 percent). This means that the measures proposed in this initiative could result in 3,166 - 4,189 errors being prevented in New Zealand (ie, 3,166 - 4,189 people subject to medication errors would not have to have experienced unnecessary pain, disability or death). The extrapolation above, and in Table A-2, does not deal with the other medication errors where there has been no observable impact.

Table A-2: Adverse drug events per annum by severity of impact and possible reduction following the introduction of measures proposed in this document

<table>
<thead>
<tr>
<th>Type of Adverse Drug Event (ADE)</th>
<th>Percent ADE by Type (%)</th>
<th>Number of Patients impacted</th>
<th>Reduction due to BPOC (65%)</th>
<th>Reduction due to BPOC (78%)</th>
<th>Reduction with BPOC (86%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADEs each year resulting in death</td>
<td>3.1%</td>
<td>151</td>
<td>98</td>
<td>118</td>
<td>130</td>
</tr>
<tr>
<td>ADEs each year resulting in permanent disability</td>
<td>8.3%</td>
<td>404</td>
<td>263</td>
<td>315</td>
<td>348</td>
</tr>
<tr>
<td>ADEs each year resulting in disability lasting between 1-12 months</td>
<td>12.5%</td>
<td>609</td>
<td>396</td>
<td>475</td>
<td>524</td>
</tr>
<tr>
<td>ADEs each year resulting in disability lasting less than 1 month</td>
<td>71.9%</td>
<td>3,505</td>
<td>2,277</td>
<td>2,732</td>
<td>3,012</td>
</tr>
</tbody>
</table>

ADEs each year with undefined impact

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>4.2%</th>
<th>205</th>
<th>133</th>
<th>160</th>
<th>176</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTALS</td>
<td></td>
<td>4,871</td>
<td>3,166</td>
<td>3,800</td>
<td>4,189</td>
<td></td>
</tr>
</tbody>
</table>

The breakdown above does uses preventable, in-hospital adverse medication events. Some adverse reactions to medications occur, not because of error, but because of the way people metabolise some medications or due to unknown allergies. These events are defined as non-preventable. At this time there are no systems (that includes BPOC) that can identify or prevent these potential events. Recalling the definition provided in the beginning of this report, a medication error only relates to preventable events.

**How do New Zealand’s results compare internationally?**

**Australia**

In 2003, the then Federal Minister of Health and Aging, Senator Kay Paterson announced that medication error was one of the most common causes of unintentional harm in Australia, resulting in an estimated 80,000 hospital admissions every year.

A systematic study undertaken in medical/surgical intensive care and general care units of two tertiary hospitals found that 6.5 percent of admissions experienced an ADE\(^{41}\) and 5.5 percent are potential ADEs\(^{42}\). The majority of preventable ADEs occurred at the stage of medication ordering (56 percent) and administration (34 percent).

**United States**

As outlined earlier, it was suggested in the Institute of Medicine’s report *To Err is Human* that there are between 44,000 and 98,000 avoidable patient deaths in the United States each year due to medical error\(^{43}\). Of those deaths, a significant proportion is due to errors in drug administration. The report to *Err is Human* noted clinical studies that assessed reported medication errors in the United States in 1993 at nearly 7400 deaths. While there was some argument over the actual number of deaths, the United States Food and Drug Administration concluded that medical errors are a serious public health problem and that the message should not be lost, regardless of whether the annual mortality was 10,000 or 100,000.

In another study it was estimated that drug-related errors occur in 20 percent of doses given to patients in hospitals\(^{44}\). Other systematic studies have shown that

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errors occur in prescribing (22 percent), transcribing (11 percent), dispensing (10 percent) and administering drugs (51 percent). In addition to deaths, there are significant economic costs associated with medication errors. Published estimates cite the direct costs associated with preventable drug-related mortality and morbidity at $US76.6B annually and $US177.4B respectively.

United Kingdom

In the United Kingdom, the National Health Service (NHS) has recently calculated that around 60 patients die each day due to ADEs. The NHS pays out around £400M every year settling clinical negligence claims. The knock-on costs of a high patient risk environment lead to significant costs in additional hospital stays plus clinical negligence claims (eg, the NHS has reported that drug-related adverse events cost approximately £500M a year in additional hospital stays alone; this is compounded through not knowing the true extent of medication errors due to inadequate definitions and differing reporting arrangements).

A report of the Pharmaceutical Industry in the United Kingdom, Underpinning Patient Safety, explains the context of this problem:

Today 50% of the estimated 72,000 deaths in the NHS are caused by medication errors overall. 34% of all medication errors that cause problems for patients are associated with drug administration. Many of the medication errors occur as a result of a lack of machine-readable codes, which significantly increases the risk of human visual identification errors (Many packs are of similar name, size and appearance.)

Table 2 reports the findings of the 2002 Commonwealth Fund International Health Policy Survey for Sicker Adults in United States, Canada, the United Kingdom, Australia and New Zealand. The data shows similarity in the percentage of medication errors between the countries involved in the survey.

Table 2: Medication and Medical Errors Among Sicker Adults in Five Counties, 2002

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49 National Patient Safety Agency (NPSA) medication error statistics.
As shown above, the data presented for New Zealand by Davis et al. (2001) is consistent with that for other countries, and that the extrapolation conducted in this report is also consistent with the approaches identified in other reports.

**Conclusion**

It is acknowledged that the extrapolation here has limitations, in the small sample size, and the need to extrapolate those result to a broader population. However, it is the only systematic study on adverse events in New Zealand public hospitals. Yet when comparing these results to other clinical study from overseas it is apparent that the magnitude of adverse drug events appears consistent.

It could be argued that the magnitude of medication errors is not as large as suggested here or that the methodology used to calculating the impact is flawed. Similar claims were made in the United States when the Institute of Medicine released *To Err is Human* citing 98,000 deaths resulting from medical error (which included adverse drug events) annually. At the time, no one argued that medical error was a problem or that the issue needed addressing. However, at the time there was considerable debate on the report itself, the different definitions of what constituted a medical error, the methodology of the studies used to calculate the extent of the problem and the magnitude of medical error.

The IOM report authors did acknowledge the limitations of their study and those on which they based their interpretations\(^5\). Many responded to the criticisms and supported the IOM reports conclusions with pragmatic responses such as it would be unfortunate, however, to allow the assertion that the magnitude of the problem of medical errors (preventable or otherwise) is grossly exaggerated to cloud the

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message and blunt the impact of the IOM report [To Err is Human]. Whether the annual mortality is 10,000 or 100,000, medical errors are a serious public health problem. Likewise in New Zealand, we should not lose sight of the conclusion that medication errors are an issue and that we have an opportunity to put in place measures to reduce their incidence.

As with any health intervention and especially one as expensive as this it is appropriate to ask the question is this problem of such a magnitude that when compared to others problems it is sufficiently serious to warrant intervention or should the resources be devoted to some other intervention that will have a greater impact?. Effectively, this asks how sensitive this initiative is to the number of patients impacted by adverse drug events.

A test of the sensitivity of the assumption of number of ADEs prevented under this proposal is provided in the sensitivity analysis of the associated cost utility analysis. That analysis suggests that the break-even of reduced events; where there is no net saving from introducing bedside verification is about 29 percent reduction. This level of investment still compares well to average cost per QALY of Pharmac intervention of $12,117 in 2004/05 (see Figure 1 of the Cost Utility Analysis).

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52 Honig, P., Philips, J., Woodcock, J., 2000; letter to the editor, How Many Deaths Are Due to Medical Errors? Journal of the American Medical Association, 284, 2187-2188.
APPENDIX B

Types of barcodes

This Appendix shows some of the current standardised barcode forms currently in use. A barcode represents data in a machine-readable form and provides a method for information to be read reliably by a computer. A barcode thus facilitates *automatic data capture*. Technically a barcode is a *data carrier* for the information encoded in the black and white bars (strips) of a linear barcode or the pattern of small square dots on a *two dimensional* barcode. Ideally barcodes are printed on products by the manufacturer (known as *supplier originated marking*). The most common barcode is the EAN 13 barcode (often referred internationally as EAN/UPC 13) and the number encoded in this barcode is called a Global Trade Item Number (GTIN). A GTIN is globally unique and thus will uniquely identify the product to which the barcode is attached.

**EAN-13** is a product identification structure used by the GS1 system; also known as the Global Trade Item Number (GTIN). The GTIN is an 8 to 14-digit fixed length numeric, and incorporates an indicator digit (or logistic variant), the GS1 company prefix, product code and check digit. Note that manufacturer code and product code lengths vary.

**GS1-128** is a very high-density barcode symbology, and a variant of code 128. It is used extensively worldwide in shipping and packaging industries. It is used for alphanumeric or numeric-only barcodes. GS1-128 is used extensively as product identification at container and pallet levels in retail markets. (Previously known as EAN/UCC-128)

**GS1 DataBar (previously known as Reduced Space Symbology RSS)**

GS1 DataBar is a family of linear symbology capable of encoding the 14-digit Global Trade Item Number (GTIN). DataBar is designed to bring the benefits of full product identification, as well as other supply chain applications, to space-constrained situations where existing linear symbologies could not normally be used.

**GS1 DataBar Omni-directional (previously known as RSS-14)** This compact linear symbol encodes a full 14-digit GTIN and, optionally, a code indicating a link with a two-dimensional symbol carrying supplementary information. DataBar can be scanned omni-directionally.
GS1 DataBar Stacked omni-directional (previously known as RSS-14 Stacked)
This version of the RSS symbology also encodes a 14-digit GTIN. It is presented in two stacked segments. This feature enables making optimal use of space available. DataBar Stacked has two versions, a truncated version used for small item marking applications and a taller one, designed to be read by omni-directional scanners.

GS1 DataBar Limited (previously known as RSS Limited) ï The DataBar Limited version encodes 14-digits with the restriction that the first digit (indicator) has the value of either 1 or 0. Therefore it cannot encode the full range of UCC/EAN-14 numbers. It cannot be scanned in an omnidirectional scanning environment.

GS1 DataBar Expanded (previously known as RSS Expanded) - The DataBar Expanded version encodes up to 74 numeric or 41 alphabetic characters. The symbol encodes the GTIN or another GS1 identification number, plus additional data as required. It can be scanned omni-directionally.

Composite Symbology ï DataBar barcodes can be combined with a unique 2D Composite Component to form GS1 composite symbology. This enables identification and supply chain management capabilities for organisations limited by other solutions. Composite Symbology consists of a linear symbol accompanied by a two-dimensional symbol printed on top of the linear. This can be any existing linear symbology, including DataBar. The linear symbol acts as a finder pattern for the 2D symbol, allowing the 2D component to be kept very small.

Data Matrix ï A two dimensional matrix symbology used for small items. The code provides for batch number and expiry date information among other identifiable information. Used at point-of-use where other supplemental information is required and where space is very limited.

RFID and the Electronic Product Code (RFID/EPC)
RFID stands for radio frequency identification. It is a technology that has existed for decades. At a simple level, it involves tags that emit radio signals and devices called readers which pick those signals up. The Electronic Product Code (EPC) is the next generation of product identification. The EPC is a simple, compact ‘license plate’ that uniquely identifies objects (items, cases, pallets, locations, etc) in the supply chain. Like many current numbering schemes used in commerce, the EPC is divided into numbers that identify the manufacturer and product type. However, the EPC uses an extra set of digits ï a serial number ï to identify unique items.