Pharmacist’s Tool kit for Implementing Barcode Medication Administration

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# Table of Contents

**1 - Contributors** ................................................................................................................................. 5

**2 - About this Toolkit** ............................................................................................................................. 5

**3 - Introduction** ........................................................................................................................................ 6

**4 - Glossary** ................................................................................................................................................ 7

**5 - Technical Background** ......................................................................................................................... 8

5.1 Understanding Barcodes .......................................................................................................................... 8

5.1.1 Barcodes—A Technical Review ............................................................................................................. 8

5.1.2 Misconceptions about Manufacturers' Barcodes and NDCs ................................................................. 11

5.1.3 Barcoding Tips for the Pharmacy ........................................................................................................ 12

5.2 System Architecture .................................................................................................................................. 12

5.2.1 Integrated vs. Interfaced ......................................................................................................................... 12

5.2.2 System Servers ....................................................................................................................................... 13

5.2.3 Computer Work Stations and Handheld Devices ................................................................................... 13

5.2.4 Printers ................................................................................................................................................... 14

5.2.5 Scanners<sup>[4]</sup> ................................................................................................................................ 14

5.2.6 Replacement Batteries and Chargers .................................................................................................... 14

5.2.7 Equipment Tracking and Accountability ............................................................................................... 14

5.3 Data Requirements for a BCMA System .................................................................................................... 14

5.3.1 Data Flowing from a Pharmacy System to a BCMA System ................................................................. 15

5.3.2 System and Interface Testing ................................................................................................................ 16

5.3.3 Integration of a BCMA System with Infusion Pumps ............................................................................. 16

**6 - Planning for a Barcode Medication Administration System**<sup>[5]</sup> ......................................................... 17
1 - Contributors

The ASHP Foundation thanks the members of the BCMA Expert Panel and all contributors for their support of this important project. Click here to see a complete list of panel members.

The ASHP Foundation gratefully acknowledges the following for contributions to this project:
Special thanks to Wasp® Bar Code Technologies, 1400 Tenth Street, Plano, TX 75074 www.waspbarcode.com for providing the complimentary copy of Wasp Barcode FontWare used to create the example linear barcodes for this project.[1]

Two-dimensional and GS1 Databar examples for this project were created using the free downloadable demo version of Bartender® 7.1 by Seagull Scientific, Inc., 1616 148th Ave. SE, Bellevue, WA 98007-6848 www.seagullscientific.com. [2]

2 - About this Toolkit

This is the second toolkit about barcoding developed by the American Society of Health-System Pharmacists® Research and Education Foundation. Both were made possible by grants from Omnicell®. To begin development of the first toolkit[3], in August 2003, the Foundation assembled a panel of experts on the application of barcoding to prevent medication errors. That panel established an initial framework for the first document and served as reviewers. A second panel of experts was convened in 2013 to review and update the document, resulting in this second toolkit.

The objective of this toolkit is to provide information about the planning and implementation of a verification system for medications labeled with machine readable coding. The Foundation recognizes that barcoding – although currently seeming to be a standard approach for machine readable coding – is only one type of machine readable technology. Other types of technologies, including smart chips and radio frequency technologies exist now (or may evolve) during the practical life of this document. However, to make this toolkit easier to understand, the term “barcode” is used throughout to be representative of machine readable medium.

It is hoped that the reader of this toolkit will:

1. Gain or strengthen a general understanding of machine readable technology for use in a barcode medication administration (BCMA) system.

2. Be better prepared to plan and implement a BCMA system.
3 - Introduction

Hospital and other health-system pharmacists and nurses have long applied automated systems to resolve common problems inherent in medication use processes. Unit dose dispensing and the need to individually package unit doses of medication stimulated the development of countertop packaging machines. Inefficiencies and inaccuracies in manual controlled substances processes led to the development of automated ward-based vending cabinets. The labor intensity of (and the potential for errors in) unit dose cart filling, fueled the development of robotic cart filling systems. Pharmacy information systems computerized patients’ medication profiles long before such automated devices evolved, which later allowed automated medication profile information interfaces to improve the safety of medication use.

As medication use technologies matured, each became more robust in its capabilities, providing opportunities for automating more aspects of medication use process. Computerized patient profiles led to computerized clinical screening tools for pharmacists and to electronically generated medication dose scheduling and medication administration records (eMARs) for nursing. Ward-based vending cabinets became interfaced with computerized pharmacy systems and enabled remote triggering by pharmacists after medication order reviews. This led some to adopt such cabinets as a replacement for cart delivery as a primary method for distributing medications. Robotic systems became faster and addressed processes such as medication packaging and sterile syringe filling. When properly applied and managed, these tools can be efficient and highly accurate.

Hence, implementing automated systems applied to medication use processes in hospitals is not new. Therefore, it might seem that implementing a BCMA system would be much like the implementation of robotics or automated vending cabinets. The contributors to this toolkit urged that BCMA systems not be approached with that mindset. There are many more challenges inherent in successfully implementing a BCMA system. In addition, unlike implementations of some automated systems that are managed by (or co-managed with) vendors’ field representatives, BCMA systems require full ownership and intense (and sustained) engagement by both pharmacy and nursing. Contributors to this toolkit - practitioners experienced with barcoded medication use and pharmacy automation in general – compiled the thoughts, considerations, and recommendations in this toolkit based on real-life experience.
### 4 - Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-Rs</td>
<td>Term used to describe the five rights of medication administration. Determining these rights prior to the administration is a goal of the medication process: right patient, right medication, right dose, right route, and right time...</td>
</tr>
<tr>
<td>Barcode</td>
<td>A printed symbol made up of black and white lines or bars arranged in a specific pattern; the most common type of machine readable code that provides a method for data input into an automated system.</td>
</tr>
<tr>
<td>Check digit</td>
<td>A digit at the end of the data string in a barcode that is calculated based on the other characters in the data string. The check digit is a technical way of ensuring against misreading by a scanning device.</td>
</tr>
<tr>
<td>CPOE</td>
<td>Computerized Provider Order Entry or Computerized Provider Order Management is a system where providers enter patient care orders electronically, typically for hospitalized patients.</td>
</tr>
<tr>
<td>EHR</td>
<td>An Electronic Health Record or Electronic Medical Record is a systematic computerized record for management of a patient’s medical information and instructions for care. EHRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.</td>
</tr>
<tr>
<td>eMAR</td>
<td>An electronic medication administration record used to document the administration of ordered medications, usually by nursing. The eMAR is one component of the Electronic Health Record (EHR)</td>
</tr>
<tr>
<td>BCMA</td>
<td>Barcode medication administration system, a process utilizing barcode scanning to insure the 5-Rs of medication administration and facilitate the documentation of administration in the eMAR system.</td>
</tr>
<tr>
<td>NDC</td>
<td>The National Drug Code identification number assigned to a specific company, product, and package size by the U.S. Food and Drug Administration (FDA).</td>
</tr>
<tr>
<td>Pharmacy Module</td>
<td>A pharmacy module is an integrated system for tracking and managing patient medication related orders. It is typically a module that is integrated within an EHR.</td>
</tr>
<tr>
<td>Symbology</td>
<td>Any type of machine readable symbol, such as a barcode, used to communicate data to an automated system.</td>
</tr>
</tbody>
</table>
5 - Technical Background

5.1 Understanding Barcodes

This section is a basic review of barcodes. Other symbologies, as well as alternative machine readable technologies, are certain to evolve for use with medication packages. In this section, barcoding is reviewed in some detail as an example of the most common machine readable form.

5.1.1 Barcodes – A Technical Review

Barcodes are the most widely recognized machine readable mediums. There are numerous types and formats of barcodes, but each does the same thing. It represents a series of characters, including numbers, letters, and special characters. Together, the characters represent information to be conveyed to an electronic system, when the barcode is read. For example, the data stored in a medication barcode will contain a unique number such as an NDC number to identify a manufactured medication, or a hospital-specific code to represent a single dose packaged by the pharmacy. Barcode scanning is simply a fast, highly accurate method of inputting and capturing data.

A barcode is made up of a series of black and white spaces. When describing a linear barcode, every character is represented by a different pattern of bars and spaces. When a scanner beam is projected onto a barcode, the black bars absorb light, and the white bars reflect it. The reflected light is captured by a photosensitive detector in the scanner which then decodes the array of bars and spaces, turning them into an electronic signal, which it sends to a computer. A software application running in the system looks up the data in a database and finds related stored information about the scanned product - in this case a medication product. The found information then can be used by the software program to perform tasks, such as to verify and document whether the scanned medication matches the one prescribed and whether the dose and dosage form match what was intended. Interfaced with an information system that includes data about a patient's medication allergies, it can check to determine whether the scanned medication may be a known allergic or contraindicated medication. It can trigger notifications to caregivers about appropriate ways to administer the medication.

Certain types of barcodes include “start and stop characters” to indicate the beginning and end of the data string. For example, a Code 39 barcode must begin and end with an asterisk (*) character in order to be properly read by a scanner. Although start and stop characters are included in these barcodes, they are not considered part of the data when the barcode is read.

**Tip:** If a barcode label printed on site for application to a dose cannot be read with a scanner, it may be because required start and stop characters were omitted.

There are newer types of barcodes that offer advantages, such as smaller size and more data capacity. However, some types of barcodes that were developed many years ago are still commonly used. There are three general categories of barcode symbologies commonly seen on medications:

1. Linear (1-D)
2. Two-dimensional (2-D) Matrix
3. GS1 DataBar, formerly Composite Reduced Space Symbology

Barcode **density** refers to the number of characters per inch that a barcode can represent. With certain
types of barcodes, a check digit is an added character at the end of the barcode that is calculated based on the other characters using a defined mathematical rule. It is used by the scanner to ensure an accurate scan. Barcodes that can be scanned either left to right or right to left are considered bi-directional. Others are omni-directional and can be scanned from any angle and direction.

5.1.1.1 Linear (1-D) Barcodes

There are several types of linear barcode symbologies, but only some are used by medication manufacturers or are appropriate for use in pharmacy packaging. Currently, most of the barcodes on manufactured medications are linear barcodes, but other types of barcodes may be required to meet expanded documentation requirements based on evolving regulations.

Formats for linear barcodes are defined by standard-setting organizations such as GS1 US and the Health Industry Business Communications Council (HIBCC). Linear barcode symbologies look so similar that it is difficult to tell one type of symbology from another on visual examination. Currently, a linear barcode is a good choice for pharmacy-based packaging and labeling, if a BCMA system under consideration supports the identification of a product based on NDC, a hospital-specific code, or some other unique identifier. 2-D barcodes may be beneficial for pharmacy prepared products, but it will depend upon the capability of the scanners utilized.

Two key factors in deciding which type of linear barcode to use are (a) character length and the maximum density (which determine label space required) and (b) character types supported – alpha, numeric, or both. These are important because the barcodes used must be small in order to fit onto limited space, especially with unit dose medication packages. The following table compares the sizes of types of barcodes using different identifiers that might be desired for on-site barcode labeling in the pharmacy.
Some unit dose packaging devices allow the pharmacist to choose the type of linear barcode to be used. Options may be limited to barcodes that will fit on packages for which the device is designed. Fortunately, today's barcode scanners read multiple linear barcode formats. Therefore, it likely will be possible to mix barcode types for various labeling applications in order to obtain the smallest usable labels. Scanning all inventory products will demonstrate medications and packages that could be problematic at the point of care. As requirements and date elements for a barcode have expanded, the utility of a linear barcode is often limiting. A linear barcode might become too large for medication packages and potentially too large to scan.

### 5.1.1.2 GS1 Databars

Reduced Space Symbology (RSS) was developed for storing more data in a small barcode. Since its development, the name has formally been changed to GS1 DataBar. A GS1 DataBar code can be a very small linear barcode containing only an NDC number, or a stacked combination of linear and 2D barcodes containing the NDC, lot number, and expiration date, and even more. The following table shows a few of the key types of GS1 DataBar symbols and describes their data capacity when used for medications.

<table>
<thead>
<tr>
<th>Linear Barcode Type</th>
<th>10-Digit NDC*</th>
<th>6-digit billing code (numeric)</th>
<th>6-digit mnemonic (alpha/numeric)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code 39</td>
<td>0573-2620-48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code 128 C/A</td>
<td>0573262048</td>
<td></td>
<td>AVT10T</td>
</tr>
<tr>
<td>Code 93</td>
<td>0573262048</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interleave 2 of 5</td>
<td>0573262048</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codabar</td>
<td>0573262048</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAN-13</td>
<td>053632-620-48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UPC-A</td>
<td>0573262048</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Encoded here is the actual NDC for Alavert™ Orally Disintegrating Tablet 10 mg.*
### 5.1.1.3 2-D Matrix Barcodes

In cases where it is desirable to have a barcode with a large character capacity, a 2-D matrix barcode may be appropriate. Data Matrix barcodes typically provide a small symbol and therefore may be more suitable for some medications. Rather than using a row structure, this symbology spirals outward from the center of the symbol and uses squares or dots rather than bars. Typically seen as squares, Data Matrix barcodes also can be used in a rectangular format. The following is an example of a Data Matrix barcode used to encode an NDC, lot number, and expiration date.

![Data Matrix Barcode](image)

**NDC:** 0573-2620-48  
**Exp. Date:** 12/31/00  
**Lot:** A123B456C789  
**Encoded as:** (01)057326204 8(17)001231(10)A123B456C789

### 5.1.2 Misconceptions about Manufacturers’ Barcodes and NDCs

Some common misconceptions exist related to the use of barcodes on manufactured medications.

**Misconception #1:** The medication database of a BCMA system must contain a barcode symbol that matches the barcode symbol on the product. In fact, no symbols are stored in the BCMA database. Instead, it stores only the barcode data – the string of characters that the symbol represents – Scan Code. The scanner reads the barcode and, as explained above, converts the symbol into data; then the associated software program looks for the data, not the symbol, in the database.
Misconception #2: The data in a manufacturer’s medication barcode is always the product NDC number. FDA regulations stipulate that certain human drug and biological product labels must have a linear barcode that encodes, at a minimum, the product’s NDC number. There are a few exceptions to the rule, however. For example, some over-the-counter products that are not commonly used in hospitals are exempt from the rule. Manufacturers may choose to encode lot numbers, expiration dates, other information, or any combination of information in addition to NDCs as long as the NDC information is contained in a linear barcode.

Misconception #3: The barcode on the outer manufacturer’s packaging is the same as the barcode on the unit of use packaging. The last segment of the NDC is a package identifier. The labeling and barcode on the outer package is for all of the doses in a package (e.g., 25 vials, 100 unit doses), whereas the label and barcode on the individual contents represents the smaller packages. Therefore, they use different characters to identify each - changing the last 2 digits of the NDC. This becomes important when checking to determine whether a particular barcode is readable or applicable within a BCMA system. Storing both barcodes within the BCMA system will allow for a greater chance of a successful scan at the point of care or during pharmacy inventory activities.

5.1.3 Barcoding Tips for the Pharmacy

In setting up a BCMA system, the pharmacist will have to decide what product identifier will be embedded in the barcode for on-site-packaged medications and any other manually barcoded products, such as small injectables and multi-dose items. For example, such pharmacy-applied barcodes might contain the product NDC (from the original container), the hospital’s medication identification (sometimes a mnemonic), or a billing code. The following should be kept in mind.

- It is essential to know the barcode handling capability of the BCMA system (including the scanners used) and to construct codes that are compatible.
- With certain types of barcodes, mixing alpha and numeric characters increases the size of the barcode. A short numeric data string works well.
- It is wise to try different types of barcodes.
- The size of the barcode compared to available label space must be considered. Samples of labels should be printed, applied to actual medication packages, and scanned to make certain they work quickly and accurately without the necessity of multiple scanning attempts.
- The barcode label must fit onto the unit dose or unit of use packaging that will be dispensed and handled by caregivers administering the medication.

5.2 System Architecture

5.2.1 Integrated vs. Interfaced

A hospital information system may include integrated modules that provide medication-related functionality, for example computerized prescriber order entry (CPOE), order entry into a pharmacy system, pharmacy order approval and profiling, an electronic medication administration record (eMAR), a BCMA system, and an electronic medical record (EMR). Another architecture model is for a separate BCMA system interfaced with a hospital’s existing eMAR or with its own eMAR application.

Interfaced systems typically use Health Level Seven (HL7) standard messages to communicate data among systems for admission-discharge-transfers (ADT), CPOE, pharmacy orders, and the BCMA process.
An integrated approach involves using application programming interfaces (APIs) to input and extract data among systems.

Some interface service vendors use screen “scraping” or keystroke emulation to obtain data from one system and input into another. For example, CPOE or pharmacy order information can be taken from screens in a Pharmacy system, converted to a HL7 message, and transmitted to a separate BCMA system. In turn, the BCMA system can send medication administration information via HL7 to an interface service vendor that then emulates a caregiver’s keystrokes and mouse clicks to input data into an EMR/EHR/eMAR. Such interfaces are commonly used for non-medication interfaces in hospitals and can be very effective for BCMA system interfaces as well. However, changes to the screens or other requirements of systems can then cause a need to make changes to and retest the interfaces.

When comparing integrated and interfaced approaches, a BCMA project team must consider the overall pros and cons while keeping a focus on medication use safety. For example, employing a BCMA system provided by the same vendor that supplies the hospital’s EMR typically means that only one medication formulary database has to be maintained to support all medication use modules. Using a separate BCMA system may require maintenance of a separate or duplicate formulary database. The project team should weigh issues such as a potential impact on pharmacy workflow along with potential safety benefits, caregiver workflow and related benefits, and potential broader applications of a separate BCMA system that may have its own integrated EMR and eMAR. Currently, most institutions have implemented an integrated BCMA system, so a stand-alone system is less common. Formulary database interfaces using HL7 messages, specifically via “master file notification” or vendors’ APIs, also may be available if the vendors involved are willing to work together to meet the hospital’s patient safety and workflow goals.

Whether interfaced or integrated approaches are used, the flow of data throughout a hospital’s information systems can be very complex. At the beginning of a BCMA project, a thorough diagram showing message and information flow can be helpful to ensure that all on the hospital’s BCMA team, as well as the vendors involved, have a clear and consistent understanding of necessary information exchanges.

5.2.2 System Servers

A BCMA system may reside within the same computer servers as a hospital’s other information systems, or it may require its own servers. Either way, additional separate servers may be required, or space within shared servers may be set up as virtual machines (virtual servers). This aspect of a BCMA project is managed by the hospital’s information systems staff, which will determine server specifications in consultation with any involved vendors. However, pharmacy and nursing should know whether there is a backup server that will kick in if the main server goes down, how and when the live server will be backed up, whether there is a mirrored live server to kick in if the main server fails, and whether there will be additional servers for ongoing testing of updates and ongoing user training.

5.2.3 Computer Work Stations and Handheld Devices

A BCMA system may require the use of portable or stationary computers for nursing areas as well as pharmacy. If the hospital provides this hardware, the vendor should provide hardware specifications including operating system, processor type and speed, memory and hard disk requirements, and any other computer parameters required by the system. In some cases, computers already in place (e.g., mobile workstations running the hospital’s eMAR system) may be suitable for running BCMA system
applications.

Computer work stations often are mounted on rolling carts or stands located at each patient’s bedside or used just outside a patient’s room. The layout of the facility and medication process workflows should be considered when deciding the locations for BCMA system computer work stations. Some BCMA systems may enable more portability for caregivers by using handheld devices rather than stationary computer work stations. Handheld devices require a location for recharging bays in each department. Whether using computer work stations or charging bays for handheld, these devices used for a BCMA system should be plugged into emergency power outlets. The use of wireless scanners (WIFI or Bluetooth enabled) should be evaluated in all areas where scanning will be utilized to ensure connectivity to the BCMA system. The use of tethered scanners may be desirable in areas where the wireless connectivity is suboptimal. Trialing different devices in ICUs, clinics, and general wards will allow for a mix of devices that will meet the workflow needs of the care providers.

5.2.4 Printers

Printers, most likely residing on the hospital’s information systems, will have to be accessible to a BCMA system for printing medication worksheets and medication administration documents for nursing when needed, such as during down times or when transferring a patient to a patient unit that is not yet using the BCMA system. The vendor should provide printer specifications; existing printers may be adequate.

5.2.5 Scanners

There are many types and categories of barcode scanners. The most common are laser scanners and image scanners. There is plenty of technical information on the Internet about how these types of scanners work. Due to the variety of barcode symbologies used for medications, pharmacists should make sure that scanners used are capable of reading many different barcode types.

5.2.6 Replacement Batteries and Chargers

Batteries and chargers for handheld devices can add significant cost to a BCMA system and to ongoing system maintenance. The specifications, estimated life, sources, and cost for replacement batteries, whether disposable or rechargeable, and the same parameters for chargers should be provided in writing by a BCMA system vendor.

5.2.7 Equipment Tracking and Accountability

Some components of a BCMA system, such as Bluetooth® or tethered scanners and mobile handheld devices, may have value for personal use outside of the hospital. Loss of these devices could result in significant replacement costs. During BCMA system planning, the hospital should consider how it will track equipment and manage accountability for missing components.

5.3 Data Requirements for a BCMA System

In order for a BCMA system to ensure the 5-Rs for all medication therapy, it must, at minimum, include data sets for (a) patient admissions, discharges, and transfers, (b) allergy information, and (c) orders for medications and intravenous fluids (IVs). Enhanced functionality may be enabled if other information (such as clinical laboratory orders and results) is shared. If a BCMA system is interfaced to a hospital’s
overall electronic medical record (EMR) system, additional work may be required for the BCMA system to access desired data.

5.3.1 Data Flowing from a Pharmacy System to a BCMA System

5.3.1.1 Patient Admissions, Discharges, and Transfers

A BCMA system will require patient admission, discharge, and transfer (ADT) information in order to track current patients and their real-time bed locations. If an interface is involved, this may be simple and easy to establish because it should be identical to ADT interfaces already used in the hospital’s information systems. ADT information typically will come through an EMR system but in some cases may come directly from a separate hospital admissions system.

5.3.1.2 Patient Allergy Information

Checking for allergies electronically through a BCMA system at the bedside is a significant patient safety enhancement over a manual allergy checking process. Electronic allergy checking is performed based on medication and allergy codes established by medication database vendors. Although this is important, it often requires further build and customization on the organization’s side to enable the point of care allergy checking. Considerations for medications administered prior to pharmacist verification will need to be manually checked for allergies. The use of free text allergies within the EMR/EHR should be avoided and only coded allergies should be utilized.

5.3.1.3 Orders for Medications and Intravenous Fluids

There can be confusion among the staff of pharmacy, information systems, nursing, and system vendors regarding what comprises a “medication order” vs. an “IV order.” Although, pharmacologically, all IVs (of any volume) are medications, this toolkit recommends using the term “IVs” to describe large-volume intravenous solutions administered based on a rate of infusion and duration, and using the term “medications” for all other items (including injections) ordered based on dose and schedule (including supplemental IV medications (less than 100 ml) such as IV piggybacks). Therefore, to avoid confusion when setting up automated systems and interfaces, piggybacks should be classified as “medications” and not as “IVs.” Order entry processes in CPOE and pharmacy systems commonly approach this issue in that way.

A BCMA system must receive all patient medication and IV orders from a pharmacy or CPOE system. This includes new orders, order modifications (e.g., infusion rate changes), cancellations, and discontinuations for all orders. Future capabilities of auto programming infusion devices and utilizing barcode technologies for pump, medication, and patient association will become more important as hospitals adopt this closed loop integration of technologies.

5.3.1.4 Clinical Laboratory Results

One of the goals of a BCMA system is to provide information to the nurse at the point of care. Obviously, having access to clinical laboratory results and applying recent results to guide appropriate medication use at the time of administration has significant value. However, it may be desirable to approach a BCMA project in phases, with medication and IV verification of the 5-Rs along with allergy checking comprising a
first phase. Additional clinical features such as incorporating clinical laboratory results could be adopted later. Input from the lab is important on selecting devices if the use of barcode scanning for specimens is being considered. Capturing glucose test values prior to insulin administration is often required documentation on the patient’s eMAR, so the process will need to fit the nurse’s workflow.

5.3.1.5 Medication Administration Documentation

A BCMA system is designed to do more than just scan medications to ensure the 5-Rs at the point of administration. The system is designed to record medication and IV administration in real time, leading to a more complete and accurate medication administration documentation in the eMAR. Ideally, a BCMA system should not allow a caregiver to bypass scanning except in extreme situations such as during system down time. If bypass scanning occurs, the BCMA system should ask the user for a “reason”.

It is typical for a separate BCMA system to communicate information in real time about medication administration transactions to the hospital’s EMR and eMAR systems and to the systems that handle order entry for CPOE and pharmacy processing. Separate BCMA systems typically offer their own self-contained eMARS. If using a separate BCMA system, the hospital’s project team should consider which eMAR option makes the most sense for medication documentation and data analysis.

5.3.2 System and Interface Testing

If a BCMA system is integrated with a hospital’s EMR system, interfaces between the two systems may not be necessary. However, in either case, thorough testing should include:

- Entering all types of medication and IV orders
- Performing all existing functions of CPOE and pharmacy system order entry
- Order modifications and time changes/rescheduling
- Orders to hold and resume administrations
- Deleting, canceling, or discontinuing orders, including auto-discontinuation
- Orders for non-formulary medications and patients’ own medications
- Range dosing, if allowed (e.g., 50-100 mg)
- Multi-component orders (e.g., a parenteral nutrition fluid plus a piggyback medication)
- Multiple units per dose (e.g., using two tablets for one dose)
- Partial unit per dose (e.g., ½ tablet)
- Tapering orders
- Messages and warnings
- Accurate documentation of all types of one-time, scheduled, and as-needed doses.
- Editing of or canceling previous documentation
- Scanning a medication for administration prior to pharmacy order review and approval
- Determine a process for scanning of non-medications or non-pharmacy supplied products. This could include nutritional feedings and wound care and dressings.

System (or interface) testing requires a team effort. A pharmacist, a nurse, and an information systems representative from the hospital should all play an active role in the testing process. Pharmacy and nursing should work with other departments to ensure that scanners purchased for BCMA may be utilized for other uses (i.e., Blood collection, Blood administration, or enteral formulas).

5.3.3 Integration of a BCMA System with Infusion Pumps
Smart pumps and BCMA systems both make important contributions to safety in medication use. Prospective BCMA system vendors may already have interfaced successfully with smart pumps. If so, it is important to discover what data are shared, what functionalities of either system are affected, and which other hospitals are using the system integrated with smart pumps. Standardization of infusion concentrations, pharmacy dispensing practices, and nursing administration practices are essential to make these systems beneficial.

6 - Planning for a Barcode Medication Administration System[^5]

A decision to implement a BCMA system may be driven by a triggering event, an influential individual or group of individuals, or may be an organization’s approach to achieving “meaningful use,” as part of an incentive plan stipulated by the U.S. federal government.[^6] Use of an electronic health record (EHR) and assistive technologies is specified in stage 2 of the government’s meaningful use incentive program. Typically planning, justification, and administrative approval will be required to commit appropriate resources for a BCMA system. This section offers guidance about managing a BCMA project.

6.1 Recommended Reading

These references are especially recommended before launching a formal planning process for a BCMA system.

- ASHP Statement: Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications
- ASHP Statement: Bar-Code-Enabled Medication Administration Technology
- Guidance for Industry: Bar Code Label Requirements, Food and Drug Administration
6.2 Creating a Culture for Patient Safety and Awareness

Patient safety is a paramount goal in a healthcare organization, from front-line nurses and pharmacists to the organization’s chief executive officer. Moreover, hospital and health-system care is complex and fast-paced and requires intensive expertise. Medications used in those settings are inherently complex and risky.

An error-monitoring culture that focuses on discovering and eliminating system vulnerabilities that could allow errors and in which caregivers are free of fear of reprisal from managers and peers after system-related errors is a prerequisite to the foundation of an effective medication safety program. Such a culture can result in better monitoring of errors, and the resulting information can be used to make appropriate system changes. Organization-wide awareness of the root causes of medication errors can drive the allocation of resources to make necessary changes. The financial costs to the organization associated with serious medication errors, especially those that result in litigation, could exceed the cost of implementing new technologies and processes that could avoid errors.

6.3 Assessing Existing Medication Use Processes

Adding layers of automation without sufficient study, integration, and planning may portend a shaky start to a BCMA system. An important first step should be a thorough review and assessment of existing medication use processes. This should be done as a basis for determining the extent to which automation might enable improvements. Merely automating existing processes may not be enough. It is important that all primary stakeholders in medication use processes be thoroughly engaged in a BCMA project. Project management principles should govern the implementation of the BCMA project.

6.4 Forming Multidisciplinary Project Teams

Two key multidisciplinary teams in a BCMA system implementation will be an assessment team and an oversight team. A pharmacy and a nursing representative should serve as co-chairpersons of these teams. Together they should schedule routine (e.g., weekly) meetings of the teams with planned agendas and documented decisions.

6.4.1 Assessment Team

An assessment team should thoroughly analyze existing system designs and workflows for both nursing and pharmacy. To visualize this, the following system components should be depicted and described in process flow charts.

- Medication system physical components present in nursing areas, such as stationary medication carts, mobile medication carts, patient-unit-based medication vending cabinets, controlled substances storage, IV storage areas, and bedside storage.
- Medication system physical components in pharmacy, such as robots, other automated devices, inventory receiving, packaging machines, and admixture services.
- The current pharmacy distribution processes, such as cart filling, supplemental dispensing (e.g., between times of normal unit dose cart deliveries), cabinet replenishment, robotic system replenishment, admixed IV distribution, and delivery methods and times.
• Nursing workflow for medication administration, including medication administration times, administration documentation, witness procedures (e.g., for insulin doses), and pre-bedside medication preparation (e.g., nursing IV admixture).
• Clinical decision support in pharmacy and nursing, such as pharmacy medication profiles, care protocols, medication-related rules based on clinical laboratory values, and other pertinent care processes.

Existing medication system physical components and processes may vary from one patient unit or department to another. Therefore, multiple views of system designs and workflows may be necessary.

Once existing medication processes are clearly understood. The utility of various potential BCMA system physical components for nursing, such as portable and handheld devices, work stations on wheels or stands, and bedside devices can be better assessed. In that assessment the need for changes in medication distribution, storage, access, and administration for each nursing area as well as related nursing workflow and pharmacy workflow will become clearer.

6.4.2 Oversight Team

An oversight team should include (but not be limited to) a sub-set of members from the assessment team. Having gone through the assessment process, those leaders will already have an appreciation for some of the challenges ahead. Members of an oversight team ultimately will be agents of change for a BCMA project and, therefore, should be individuals who are reliable, responsible, respected, and effective members of their departments. An oversight team should minimally include decision-makers from each of the following departments:

• Pharmacy (co-chair)
• Nursing practice (co-chair)
• Information systems
• Nursing education
• Quality management

A representative of the following should be assigned as permanent or ad hoc team members as required:

• Respiratory therapy
• BCMA system vendor
• Purchasing and materials management
• Central supply (if distributing IVs)
• Other hospital and outpatient departments (e.g., emergency department, anesthesia, procedure units, radiology)

The number of persons on the oversight team should be limited to a reasonable number (e.g., maximum of 6-8). Smaller teams can be created to address specific aspects of the project and to involve more process experts.

6.4.3 Action Teams

Some hospitals have reported success in forming multidisciplinary action teams to target specific project aspects.\(^7\)\(^8\) Using such teams reflects a quality improvement approach that can result in more effective
analysis and planning. Each action team should have a team leader that is responsible for team tasks and deadlines. Examples of potential action teams are:

A Barcoding team could

- Develop a unit dose barcoding strategy for the organization.
- Develop a system for barcode database management for all systems used within the pharmacy, for example BCMA, ADC, and medication storage devices (e.g., carousels).
- Assess medication procurement paths to ensure that all products are barcoded.
- Identify purchasing changes to procure products that are already barcoded.
- Assess and make recommendations for on-site packaging and labeling equipment.
- Identify a method for developing custom barcodes for compounded unit dose items (e.g., suspensions, liquids, and IV admixtures).
- Assess the need for barcodes on pharmacy labels.
- Ensure processes that result in barcoding of all medications dispensed.

A pharmacy policy and procedure and education team could

- Assist with system testing.
- Identify needed order entry and order verification practice changes.
- Draft new or revised policies and procedures.

An employee and patient identification team (including representatives from admissions and human resources) could

- Determine whether existing barcodes (if any) on employee badges can be used to identify workers to a BCMA system. If necessary, explore methods and make recommendations for barcoding employee badges.
- Identify hospital areas where patient wristbands are used.
- Identify options and make recommendations for a system of standardized barcoded wristbands.

A wireless network team could

- Identify wireless availability in all areas that will be served by a BCMA system, including patient care areas, pharmacy, and training rooms.
- Test signal strength in those areas and make recommendations for enhancements.

An interface team could

- Plan, implement, and test interfaces for ADT, other systems, and all medication and IV orders.
- Propose down time and other technical support policies.

A nursing education team could

- Serve as a hospital’s nursing experts about the BCMA system.
- Plan and conduct nursing user training, including for newly hired staff.
An implementation team could

- Participate in support coverage during the development phase.
- Plan, schedule, and provide support during the roll out.

A system evaluation team could

- Collect or gather pre-implementation data on workflows and medication errors.
- Evaluate BCMA system charge-on-administration capabilities and the potential impact on finances.
- Develop and maintain post-implementation project assessments.

A purchasing and accounting team could

- Provide support for a cost analysis of a BCMA system.
- Assist with development of a request for vendors’ proposals and a contract.
- Support other teams by identifying sources for materials and disposables, such as labels, packaging film, and wristbands.

A public relations team could

- Investigate the public relations opportunities in implementing an improved patient safety system.
- Prepare a press release at the end of the initial evaluation period.
- Prepare the hospital for possible media interest.

Other action teams can be established when required to identify and address special challenges. Nursing educators often make ideal participants on these teams. Special action teams may include:

- Pediatrics, neonatal intensive care, labor and delivery
- Emergency department
- Intensive care and cardiac care
- Operating rooms and anesthesia
- Post-anesthesia care
- Respiratory therapy
- Psychiatry
- Infusion centers
- Outpatient departments

6.5 Pre and Post-Implementation Data Collection

Data related to medication errors and the processes for collecting the data before and after system implementation should be identified. Such data could include patient barcode scanning rates, medication barcode scanning rates, and BCMA system flags, including near misses. These data will be the basis of quality assurance measurement to indicate how the system is affecting medication use safety. Additionally, if the organization chooses to use a charge-on-administration process, charge capture reports should be created and reviewed regularly.

Collection of post-BCMA system data most likely will be automated by the BCMA system itself. The
process for collecting pre-BCMA system data, if not already in place, should be initiated well in advance (e.g., 2-3 months) of a BCMA system implementation. Pre-BCMA system data should be carefully collected through the hospital’s medication error reporting system as well as by direct observation. Observation may catch an error or near error that would have gone undetected or unreported.

6.6 Pharmacy Considerations

There are various methods to achieve barcoding of all medication doses. They include buying unit dose barcoded medications from manufacturers, using an outsourced licensed re-packager, and barcoding unit doses in-house. Developing a unit dose barcoding strategy is unique to every organization and often is driven by organization size, pharmacy storage, and funding. Additional Staff or allocating pharmacist or pharmacy technician time to handle BCMA issues like training new barcodes or trouble-shooting nursing barcodes problem reports may be required.

6.6.1 Manufacturers’ Barcodes

In 2004, FDA established a regulation requiring manufacturers to barcode all medication packages with a linear barcode containing, at a minimum, the product NDC number. [9] The FDA released a guidance document in 2011 that addresses some of the complexities in adding a barcode to pharmaceuticals. While this regulation was a good step, it had several limitations.

- It specified that the NDC number be used in a linear barcode. Many manufacturers incorporate additional data and/or characters into the barcode, which may change the barcode with every purchase made by a pharmacy - - effectively requiring the hospital’s medication use databases to be updated with each new purchase. Changes to the data encoded within the barcode do not change frequently, but hospitals may need to scan products upon receipt to capture these changes prior to dispensing or compounding.
- There was no requirement to include lot numbers or expiration dates in the barcodes. Some BCMA systems, though, may have the ability to read lot numbers and expiration dates from barcodes (typically DataBar type), if this information is included in the barcode.
- There was no requirement in the regulation manufactures are required to produce unit dose packages. Manufactures bear an expense to barcode unit doses, so they are “dis incentivized” to do so. Therefore, some choose to produce only multi-dose packages.
- Specification that the barcode must be linear limits the character potential of the barcode and creates a label-space burden on packages. Many manufacturers have elected to use reduced space symbology (RSS) type barcodes (DataBar) to add NDC-containing barcodes on small products (unit-dose packages, ampules, suppositories, etc.).

A group purchasing organization (GPO) contracted with a hospital may make barcoding a requirement for vendor qualification. However, situations may arise in which a contracted preferred vendor does not provide barcoded items that an off-contract vendor of the same medication can provide. In such cases, it will be necessary to decide whether to barcode (in-house) the contracted “brand” or to purchase off-contract products until the preferred vendor provides barcodes. In making this decision, one must consider the differences in product costs, labor, packaging materials, as well as the importance of supporting a GPO contract. It is important to know a GPO’s vendor qualification policy related to barcoding and unit dose barcoding.

6.6.2 Outsourced Unit Dose Packaging
Licensed outsourced services are available to package and barcode unit doses. Wholesalers can provide information on the options available, sometimes directly from the wholesaler or through an affiliate. During outsourcing, inventory purchased by a pharmacy typically is first shipped to the packaging center, packaged there and labeled with barcodes, and then shipped to the pharmacy. While such services provide an option for getting barcodes onto products, pharmacists should be mindful of the following.

- Is the service licensed for repackaging?
- The cost per dose. This must be evaluated carefully against the cost of on-site packaging equipment, labor, and materials.
- The final package: Will the final package be an overwrap, a blister, or some other form usable in an organization’s medication use processes? Will package sizes be compatible with the organization’s medication distribution system? Will packages be user friendly and acceptable to nurses?
- Is the barcode of good quality (e.g., ability to resist smudging)?
- Are there adequate quality assurance procedures in place at the repackager? What is the repackager’s error rate, and how are errors reported to customers?
- Will such a service have benefit for select items or all items needing barcodes?

### 6.6.3 Pharmacy On-site Unit Dose Packaging and Barcoding

Since many medications are not commercially available in a unit dose package with a barcode, and since outsourcing such packaging may be costly, packaging unit doses and manually labeling products with barcodes in-house likely will be an important part of a BCMA program. The additional pharmacy resources required for these processes will vary depending on the pharmacy’s current barcoding practices. For example, a pharmacy already barcoding medications for a robotic filling system is likely to require less new barcoding than a similar pharmacy without such a system.

When choosing unit dose packaging approaches, pharmacy should consider whether changes in package sizes will affect the storage capacity of decentralized vending cabinets. For example, a change that results in a larger package that reduces the storage capacity of a key item may necessitate more frequent replenishment of that item and therefore more labor.

In setting up a BCMA system, pharmacy will have to decide what unique product identifier will be embedded in the barcode for pharmacy packaged products. Decisions will be required about label materials, software, and hardware for these processes. The following sections discuss the use of barcoding in on-site packaging as well as manual barcoding of some medications that do not require such packaging.

#### 6.6.3.1 Manual (Non-Automated) Pharmacy Packaging

Manual packaging is the simplest of the unit dose packaging options. Software provided for use with manual packaging equipment should be capable of printing barcodes. The size and type of barcodes available through the system should be configurable. Manual systems do not involve the equipment expense of more sophisticated, automated packaging systems. They have utility as a first-line packaging approach or as a supplemental system for low volume packaging, such as for specially obtained non-formulary medications.

An oral solid unit dose packaging process typically involves the use of a card of unsealed unit dose
blisters, a base tray in which the blister card is fitted during the filling and labeling process, sheets of printable adhesive labels, and a software program for designing and printing the labels. The user creates the label in the system’s software by entering information about the medication to be packaged, including the medication’s name, lot number, expiration date, and a product identification barcode embedding a NDC or a hospital-assigned number. The labels are then printed in sheets. The user manually places the oral solids into the blisters, removes the backing from the adhesive label sheet, and then places the label sheet onto the blister card (an action that seals the doses into the blisters).

Manual packaging systems for unit dose oral liquids are available. Some involve a plastic cup to which an adhesive seal or crimped lid is applied to seal the contents. The user inserts the amount of liquid desired into the unit dose container using a manual pump, permanently caps and seals the unit, and labels the product with a label that contains a barcode. Others use a syringe-like single dose container (oral syringe) which, despite looking somewhat like a syringe for injection, does not allow a needle to be connected. An adapter is inserted into the mouth of the reservoir liquid medication bottle and individual oral syringes are then filled by withdrawing liquid through the adapter. The oral syringe is then labeled, including barcoding.

Manual packaging of unit dose syringes can be done by drawing appropriate volumes into individual syringes from an ampule or multi-dose vial.

6.6.3.2 Automated Countertop Pharmacy Packaging

Automated countertop packaging systems for unit dose oral solids can be more efficient than manual packaging systems, especially when packaging large numbers of doses. These systems may provide a higher quality package than manual packaging systems. Oral solid systems provide either a manual or semi-automated feed of tablets or capsules. The tablets or capsules are fed between two films, one of which is opaque and labeled with the product information and barcode. The other film side typically is transparent, allowing for visual examination of the package content. The films are heat sealed, and the strip is perforated to allow separation of individual packages.

Automated countertop systems for oral liquids and multiple, syringe filling are available and can be more efficient than manual packaging systems, especially when packaging large numbers of doses.

The size of the equipment, storage of supplies, final product configuration, cost of equipment and supplies, final product quality, and database management all should be considered when choosing a unit dose packaging system.

6.6.3.3 Interfaced Automated Pharmacy Packaging

Packaging systems for unit doses exist that are much more sophisticated than countertop models. These systems can package and label, including barcodes, based on an interface with a pharmacy system, centralized dispensing system, and decentralized vending cabinets. These systems are faster, larger, and more costly than countertop packaging systems. However, depending on the overall pharmacy volume and automation plan, this type of system may be the most efficient.

6.6.3.4 Printing Barcodes to Be Manually Applied
A pharmacy system or BCMA system may have the ability to print barcode labels for manual application onto products that do not have commercial barcodes. Four things to consider are:

- Deciding what identifier to put into the barcode
- Finding a label paper backed with a “pharmacy-grade” adhesive with templates available for printing very small barcode labels
- Selecting a software application for printing the barcodes
- Selecting a printer

6.6.3.5 What Data Go into a Manually Applied Barcode?

In order to determine the type of barcode symbology and barcode content to be used in manually applied barcodes, it is important to understand the capabilities of the BCMA system with respect to barcodes. Once system capabilities are known, it is best to employ a consistent barcode content strategy that can be easily taught to pharmacy packaging and labeling personnel and incorporated into pharmacy policies and procedures. Depending on the size of the item being labeled, the symbology of the barcode may vary.

6.6.3.6 Multi-Use Containers

Multi-use products are intended to be utilized for one patient used multiple times or for the duration of their hospitalization. Although many multi-use containers, such as inhalers, topicals, and ophthalmics, come in an outer box or package that is barcoded, the outer package often will be discarded the first time the product is used. Therefore, it will be necessary to manually apply barcodes on inner packages for certain multi-use products. When determining barcode label placement, nursing input should be obtained to be sure that the barcode is applied in an easily accessible place. The use of a system generated barcode for administration purposes may be effective, but education with the nursing staff to ensure the correct barcode is utilized for administration is essential.

Many collapsible cream and ointment tubes have commercial barcodes on them. Although scanning the commercial barcode may pose some inconvenience when these tubes collapse, commercial barcodes may be preferable to manually applied barcodes during the use-life of the product. Some inhalant canisters are barcoded, but the barcode may not be accessible for scanning once a canister is inserted into a mouthpiece.

6.6.3.7 Vials, Ampules, Syringes, and Respiratory Meds

Until items with a small label area (such as many small vials, ampules, syringes, and single dose respiratory medications), are barcoded by manufacturers, they will require manual barcoding by pharmacy. The use of DataBar/RSS barcode symbologies has made it rare for pharmacies to add additional barcodes to these products. On occasion, it still may be necessary to repackage or re-label these products to ensure a positive scan.

6.6.3.8 Large Volume Intravenous Fluids

The readability of barcodes on IV vendors’ flexible containers should be tested using the actual scanner that will be used at the bedside and in the pharmacy. Several containers of various sizes should be scanned. If the barcodes do not read on the first scan at least 90% of the time, manually barcoding these
items should be considered. Some IV products may have more than one manufacturer-applied barcode on each item. In such cases, knowing which barcode to scan becomes a teaching point for workers. The scan ability of these products has improved with changes to the placement of the barcode on the infusion bag and the use of alternative style barcodes. Confusion may exist with the nursing staff if multiple barcodes are on the infusion bag.

If IV solutions are distributed by a department other than pharmacy, such as central supply, it is recommended that pharmacy oversee the process of barcode database maintenance and manually affixing barcodes to containers or outer wrappings. If a manual barcode is to be used instead of a manufacturer’s barcode, it is important to consider placement of the barcode on the product. In general, manually applied barcode labels should be applied over the commercial barcode(s). Complicating the scanning of large volume infusion solutions is the backorders and drug shortages of products. Care is required to ensure that all solutions being utilized within an institution have a barcode that has been added to the BCMA or pharmacy module to ensure proper scanning.

### 6.6.3.9 Patient-Specific Doses

One of the biggest challenges is barcoding patient-specific medications. These include:

- A medication or admixture custom prepared in an exact dose or volume to fulfill a specific patient order
- A prepared dose made up of multiple medication line items (each of which must be documented and billed), such as an admixed IV or an oral liquid mixture
- A non-formulary medication that is not part of the pharmacy system and BCMA system medication database
- A patient’s own medication that is authorized to be used while an inpatient

Often, these patient and order-specific doses cannot be adequately identified using a medication-specific barcode. Therefore, an alternate method must be used that associates the prepared dose with the intended patient and the appropriate order. The approaches described below have been used. Each has advantages and disadvantages.

- The barcode contains the patient identifier and the pharmacy system order number separated by a delimiting character. This approach allows a BCMA system to match the scanned dose with the patient and pharmacy system order that it is intended to fulfill. Unlike the method above, this method is effective even if pharmacy system order numbers overlap with other barcode identifiers. However, like the method above that is based on the order number, this barcoding approach would require already dispensed medications to be barcoded again with a new order number when a medication schedule is changed or when a medication is discontinued and reordered.

- The barcode contains a patient identifier, medication order identifier, and dose, each separated by a delimiting character. This approach allows a BCMA system to match a scanned dose with the patient, the ordered medication, and the specific dose ordered. The benefit of this approach is that a change in the order number, such as when a medication schedule is changed or when an order is discontinued and the same medication and dose are reordered (e.g., when a patient is transferred between units), will have no effect, and doses dispensed for the previous order can be scanned and accepted to fulfill the new order. Unfortunately, this method may result in a long barcode when all three data elements are included. It also would be difficult to implement for a multiple-medication
The barcode contains the pharmacy system order number. This approach allows a BCMA system to match the scanned dose with the pharmacy system order that it is intended to fulfill. This method can succeed if pharmacy system numbers do not overlap with other barcode identifiers, such as the NDC number, hospital formulary database identifier, or hospital billing code. However, if the pharmacy system generates a new order number when a medication schedule is changed or when the medication is discontinued and reordered (e.g., when a patient is transferred between patient units), this barcoding approach would require that medications already dispensed be barcoded again with a new order number. Unfortunately, the process of changing the barcode on an already dispensed dose may be impractical or impossible in some practice settings.

The pros and cons of the above approaches should be weighed. Pharmacy should work with the BCMA vendor to design the barcoding approach and related procedures.

Other important considerations related to these approaches are:

- The pharmacy system automatically provides a barcoded label for patient-specific medications and IVs using a barcode that contains all the desired elements. This would eliminate the additional work of manually creating barcodes for these items.
- If a pharmacy system uses product or order categories, it might be possible for the desired type of patient-specific barcode to be printed on pharmacy system labels. However, caution should be exerted to ensure that a product does not bear more than one barcode.
- In all cases, the medication contents of the barcoded package or container should appear in text-readable format.
- The different label types the pharmacy system can create should be researched: with barcode, without barcode, and with different label sizes.
- The types of labels used for printing and the placement of the barcode on the label should be investigated. Is it a continuous label? Can die-cut labels be used?

The following are important considerations for a BCMA project team and should be raised early in the planning process.

**6.6.3.10 Partial Doses**

Following are two ways to handle medications that are ordered in half tablet doses.

- A hospital identifier can be assigned to the half tablet item and entered into a pharmacy system and a BCMA system as a distinct line item. This line item can be used to order half tablet doses in the pharmacy system. To barcode the half tablet, the tablet can be cut into halves and packaged as a half tablet per package. A unique barcode will then be assigned for the half-tablet product.

- The medication can be ordered in a pharmacy system using the line item for a full tablet and entering the dose amount of half a tablet. A full tablet is dispensed. Then the BCMA system can be set to notify the nurse that the tablet must be broken in half to achieve the prescribed dose and the remaining half tablet wasted.
Both options have advantages and disadvantages. The first option is more labor intensive for the pharmacy; however it is more in keeping with the concept of unit dose dispensing. It reduces the chance for medication error due to confusion about the half tablet dose. This approach may work well for items used frequently in half tablet doses, but it becomes difficult when an unanticipated order for a half tablet dose occurs.

The second option assumes that a pharmacy system and a BCMA system have the necessary features to support half tablet ordering and notification to the nurse. This method places the responsibility of breaking the tablet onto the nurse and relies on that person to comply with a BCMA system warning. If this approach used, it is recommended that the nurse be required to acknowledge the notification by indicating that a half tablet dose will be given. Consistency is an important factor in accuracy and safety. If possible, a standard approach to handling half tablet doses should be established. A BCMA project team should give careful consideration to the above options in conjunction with the feature sets of available pharmacy and BCMA systems to decide on the best approach.

### 6.6.3.11 Insulin

The less medication preparation (e.g., pouring and drawing up doses) that occurs before going to the bedside, the better and safer a BCMA system will be. To best support this process, pharmacy should unit dose and barcode virtually everything, including oral liquids and injectables. However, in certain situations, providing a unit dose or even a pharmacy-prepared patient-specific dose may be impossible. Insulin is a prime example. There are multiple dispensing methodologies for insulin, including use of patient-specific pens, patient-specific vials, or multiple-dose vials for many patients. Doses may have to be drawn up based on bedside determinations of blood glucose levels. In preparation for administration, it is common for insulin doses to be drawn up in a medication room rather than at the bedside. In this practice, what barcode could the nurse scan, and how can the dose administered be documented in the eMAR?

### 6.6.3.12 Isolation Patients

What will be the BCMA process for nurses administering medications to patients in isolation? There are no perfect answers to these issues other than to recommend that patient safety must take priority over workflow convenience. The movement of a “dirty” scanner from one patient’s room to another should be limited. The hospital policy and procedures for patient isolation should be followed with medication scanners consistently as other equipment.

### 6.6.3.13 Investigational Medications

Depending on the type of hospital, the scanning of investigational medications at the bedside may be a substantial component of medication use. Even if investigational medications are used only occasionally, establishing a barcoding method for handling them is important. To facilitate proper tracking and documentation of investigational medications as well as medication safety, the following are recommended:

- All investigational medication doses should be unit dose packaged and barcoded.
- The BCMA system vendor should be consulted for recommendations about use of investigational medications.
• A unique line item and hospital identifier should be assigned to each available strength or size of the investigational medication in both the pharmacy system and BCMA system. If half tablet doses are required, a unique line item for half tablets should be assigned, and the processes above about partial doses should be followed.
• Patient-specific measured doses should be prepared when necessary using the order number in the barcode as suggested in the section about products requiring manually applied barcodes. The established investigation protocol must be followed at all times. Barcoding and BCMA systems can be added to the investigation process without jeopardizing protocols.

6.6.4 Space Considerations

The implementation of a BCMA system may have some pharmacy space implications. Floor and counter space for the following should be planned.

• A barcode-enabled unit dose oral solid packaging system (countertop or floor model)
• A barcode-enabled unit dose liquid packaging system (countertop)
• A barcode-enabled syringe filling system
• Work areas for packaging oral solids, oral liquids, and syringes
• File space, such as for production records and storing pre-printed barcode labels for manual application
• A work area for applying and checking manually applied barcodes
• A space for a BCMA system work station
• A work area for scanning commercial barcodes upon receipt of shipments into inventory

6.6.5 Staffing Considerations

Preparing the pharmacy for a BCMA system may require a significant investment of pharmacy staff time. This will include medication database preparation and maintenance, inventory and purchasing changes, packaging and barcoding of medications, development or alteration of standard order entry or verification procedures, and training. One 360-bed hospital reported that 600 hours of staff time were required initially for this process. In addition, pharmacy staff time will be required to support the system on an ongoing basis. Some of this staff time may be offset, such as in cases where billing by a BCMA system for medications administered might eliminate current billing and crediting tasks.5

Some important considerations are:

• Pharmacy technicians will ordinarily handle purchasing, packaging, and barcoding functions. They will be engaged in dispensing and barcode reading of unused doses returned to stock. If technicians are used in an order entry process, they should be included in redesigning the order entry workflow and should be trained about the process changes.
• Pharmacists will be responsible for consistent - and in some cases new - order entry or verification practices and other activities such as quality assurance of barcoding (checking of packaging and manually applied barcodes) and barcoding of patient-specific doses, non-formulary medications, and patients’ own medications.
• Pharmacists can be a resource for managing and facilitating medication scheduling changes.
• A pharmacy-based nurse dedicated to a BCMA system can be a significant asset. This person can serve as a formal liaison between pharmacy and nursing. The nurse can help both pharmacy and nursing with workflow and process issues, troubleshoot procedural problems, monitor eMAR
documentation, and focus on maximizing system benefits.

- A staff member should be assigned responsibility for data compilation and analysis with respect to reporting about the system’s impact on medication error prevention.
- Organizations that have a teaching program should consider how to incorporate pharmacy students or residents with a BCMA system implementation and ongoing operation.

Vendors may be able to provide resources to support barcoding by the pharmacy. If the pharmacy is interested in these services, they should be specified in a request for proposal.

### 6.6.6 Quality Control

A BCMA system necessitates at least three new quality control steps for pharmacy.

- The check process for unit doses packaged on-site should include a scan of the package barcode to verify that the barcode, text labeling, and medication contained in the packages are all correct. The completion of this step should be recorded in a packaging log.
- Non-barcoded products to which a barcode is then manually applied should be checked, and the check process should be documented using the same record-keeping system used for on-site packaged medications.
- Purchased products that have barcodes should be scanned as incoming shipments arrive to ensure that the necessary product information is present in the pharmacy system and BCMA system databases.

Quality control scanning should be done with the same device that will be used to scan medications at the point of administration. The first two actions above can be modified to include a scan of the first and last package in a run. Again, a record of the completion of this should be maintained.

The third action above is intended to catch changes in the manufacturers of generic items shipped by a wholesaler where the “brand” and barcode have never before been used. It also helps catch instances where a manufacturer has changed its barcode content.

### 6.6.7 Medication Database Management

#### 6.6.7.1 Existing Pharmacy Automated Systems

A medication database used by an automated system can be viewed as having two potential components – a master medication database and an active medication database. A master medication database, typically almost 100,000 medication line items, is provided by a data supplier such as First DataBank™, MediSpan®, or CernerMultum®. Depending on the type of data required to support a particular automated system, the master database may include medication descriptions (generic and brand name, strength, volume, and dosage form), NDC numbers, allergy codes, medication interactions, generic equivalencies, therapeutic classes, pricing updates, drug product images, and more. Master databases are updated regularly, such as monthly or quarterly. Not all pharmacy automated systems require the use of a master medication database.

The active medication database is a hospital-specific medication database of typically between 1,000 and 3,000 approved formulary products. The active medication database may be a stand-alone data set or it
may be a subset of a master medication database with links to the master database’s drug information. The active medication database typically includes shortened medication descriptions as well as hospital-specific medication identifier codes by which medications are ordered and identified. Certain components of an automated system’s active medication database, such as hospital-defined medication descriptions, may be edited or updated freely by the pharmacy without affecting the master database. The ability to create shortened medication descriptions for each formulary line item is important, since automated systems typically have technical or practical limitations about the length of the descriptions they can handle. The active medication database will allow unique functionality settings to govern how the system manages each line item. For example, a line item in the active medication database for a decentralized vending cabinet system may be set to require entry of a count each time the cabinet medication is accessed by a user.

In some cases, integrated systems provided by the same vendor may share the same master and active medication databases. However, in most cases a database separate from the master must be established and maintained by the pharmacy. As a safety measure, it is recommended that medication descriptions be the same across all systems that are part of medication use processes. In doing this, users will not be confronted with inconsistent medication descriptions appearing on eMARS, pharmacy system displays, on-site packaged medication labels, decentralized vending cabinet displays, and in a BCMA system. Ongoing maintenance of medication databases involves:

- Regularly updating the data supplier’s master medication database files (if applicable)
- Entering a new medication into all active medication databases when it is approved for formulary status
- Adjusting settings for an existing formulary item in a system’s active medication database when necessary

In general, the broader a hospital’s formulary is, the more labor intensive the ongoing management of medication databases will be for related automated systems.

### 6.6.7.2 BCMA Systems

To a great extent, the medication databases of a BCMA system have the same characteristics as in other pharmacy automated systems. However, the active medication database of a point of care scanning system requires two additional data components for every item – the barcode identifier and the NDC. Unfortunately, barcode identifiers are not included in the master medication databases available from data suppliers, and there is no official global source for such data. Therefore, in most instances, the pharmacy must supply and maintain medication barcode information for a BCMA system’s active medication database. Some wholesalers are developing services that may provide a file of purchased barcodes (tied to necessary related information data) and ready for import into a BCMA system. There are also commercial systems that reside in the scanning system that can “translate” a vendor’s NDC and verify a product.

During the initial installation of a BCMA system, the pharmacy will have to scan every barcoded shelf item in inventory to properly associate its barcode with a line item in the system’s active medication database. Unlike other data associations where a one-to-one relationship exists, such as a formulary line item and its hospital identifier code, generically equivalent inventory with items and their barcodes can have a many-to-one relationship with a single line item in the active medication database. This information
must be maintained on an ongoing basis as new shelf items are received; otherwise items will not be identifiable when scanned.

6.6.8 Revising Order Entry Procedures

The use of an integrated CPOE, pharmacy and BCMA system is the current desired state to ensure that all systems are performing in a safe and efficient manner. Pharmacy order verification form a CPOE system should occur prior to a nurse administering a medication with a BCMA system. Therefore, if a BCMA system schedules doses to be administered, the nurse will be administering medications based on those order entries. The use of standard frequencies with defaulted start times will improve the scheduling within the BCMA system, but exceptions will need to be considered based on patient preference or condition. For this reason, some order entry practices may have to be adjusted to accommodate nursing and patient needs. In addition to the situations described in previous sections, the following should be considered.

- First dose scheduling. Order entry or verification often will default the first scheduled dose to the next standard dosing time based on the hospital’s defined dosing schedules. However, the nurse may have to administer a first dose before the order entry process can create such a schedule or before a next regularly scheduled time. Pharmacy and nursing should establish a method for handling this scenario. Possible resolutions include:
  
  o Pharmacy enters a special first dose order and a routinely scheduled order. For example, pharmacy may have to enter orders (a) for a dose now and (b) for doses twice a day to enable administration of both doses on the first day.
  
  o The nurse administers the first dose as a non-ordered or “override” dose before the first scheduled time. Efforts should be made to minimize any administration of medication prior to pharmacist verification.

- Schedule changes. The nurse may decide that scheduled times for a specific medication should be adjusted. Nursing and pharmacy should establish a standard means for communicating the time exceptions.

- Non-formulary medication. Rather than add a formulary line item for a rarely used non-formulary medication, in some BCMA systems, pharmacy can enter the order into a pharmacy system using a virtual line item called “non-formulary medication.” It may be possible to describe the exact medication in a comment area, and that description then can appear on the label and in the eMAR. If this process was followed in a point of care scanning environment, this item might be dispensed without a barcode (undesirable). If a non-formulary medication is to be utilized and BCMA is desired, it should be added to the pharmacy module.

- Patient’s own medication. A patient’s own medications, if allowed by hospital policy, should be barcoded and scanned like all other medications. The medication then can be handled routinely based on its formulary status.

  o If the medication is a formulary item. The order can be entered and the medication can be dispensed from barcoded pharmacy stock, or a medication-specific barcode can be applied to the patient’s medication container.
  
  o If the medication is not a formulary item. The order can be entered and the barcoding process for non-formulary medications can be used.
• Procedures should be established for handling medications obtained by an override process by nursing, such as from an automated vending cabinet.

It is important that detailed, written pharmacy order entry and verification procedures be developed. These procedures must be used uniformly by all members of the pharmacy staff and should be used as a tool for training new staff members.

6.6.9 Down Time Procedures

Occasional planned down time is necessary with any automated system. Problems that sometimes occur during planned down time can be avoided through coordination and communication among departments.

If unplanned system down time occurs, it is essential to follow a pre-decided standard contingency procedure designed to minimize adverse effects on patient care. A down time procedure for a BCMA system may be significantly different if the pharmacy system also is down. In such a case, the pharmacy system down time procedure should be followed. New orders will have to be tracked manually and then entered into the pharmacy system as soon as possible when service resumes. If the pharmacy system is operational and only the pharmacy system’s interface to the BCMA system is down, nursing must be informed immediately that patient and order information in the BCMA system is not current. BCMA systems should be designed to notify users when the interface with a pharmacy system is down or slow.

In cases where the BCMA system (but not the pharmacy system) is down, pharmacy processes related to the electronic management of barcoded inventory, such as barcode scanning of incoming items, scanning after products are packaged and labeled, and BCMA formulary database updates, should be suspended until the BCMA system returns to service. If barcodes on newly received, on-site packaged, or relabeled products must be checked, the pharmacy should manually verify barcodes based on the text description of the barcode content that usually appears just below the barcode symbol. Barcodes for each new item and each processed batch (e.g., on-site packaged) should be scanned for readability and quality when the BCMA system returns to service. This approach is important because safety depends on all those data being complete and any data that flows through into the BCMA process being correct. In short, the pharmacy and BCMA systems must be synchronized.

Finally, the pharmacy and information systems department should keep an adequate back up supply of BCMA devices available if a pharmacy scanner or BCMA system device fails.

6.6.10 Pharmacy Staff Training

As with other automated systems, effective training of the pharmacy staff is crucial for success and consistency. Following are some recommendations that, working closely with a BCMA system vendor, will help achieve a successful training experience.

• Introduction to the BCMA system should include a focus on hospital patient safety initiatives, the Joint Commission (TJC) recommendations, and regulatory requirements that support the need for minimizing error-prone circumstances.
• Training tools, such as user guides, videos, and other training aids, should be obtained from the BCMA system vendor.
• A pharmacist, such as the oversight team co-chairperson, and the BCMA system vendor should jointly
conduct an early training session to focus specifically on the necessary pharmacy activities.

- If experienced consultants are available, their input should be obtained about training content.
- Pharmacy managers should incorporate BCMA system training into training for newly hired staff.
- A time and place must be chosen for BCMA system training. Access to fully functional equipment will be required at that location.
- In addition to BCMA pharmacy training, the pharmacy staff should receive the nurse user training. New steps in the medication use process, such as the need for nursing to request a pharmacy system schedule change on a medication order, should be identified, and pharmacy responsibilities should be defined.
- A reasonable amount of time should be scheduled for the training session, including time for hands-on practice and a question and answer period.
- Certificates of completion should be issued for the training, and the training should be documented in each employee’s education record.
- All changes to current policies and procedures should be addressed, including:
  - Procedures for planned and unplanned down time
  - On-site packaging and barcoding procedures
  - Order entry procedures
  - Troubleshooting procedures, including identifying and logging problems, assessing problems and attempting resolution (if applicable), contacting internal (e.g., information systems) or external (vendor) help desks when necessary, and documenting problem resolution.
- Pharmacy staff should be provided with a clear understanding of the privilege levels and controls inherent in the automated systems.
  - Key privileges, such as creating users and editing formulary items, should be restricted to a limited number of people (e.g., two).
  - Other functions, such as verifying barcodes on incoming shipments, likely will be applicable to all users.
  - Pharmacy should determine privilege assignments in advance of training.

A vendor representative, preferably someone with clinical experience, should assist with training and be available to answer questions. However, it is recommended that a pharmacist conduct and oversee pharmacy training. Pharmacy needs to understand nursing workflows to best trouble shoot any issues that arise when he/she administers a medication. Having the pharmacists on the project team attends nursing training, and some of the nurses attend pharmacy training could help address issues that may arise post go-live.

The information systems department should be made aware of the clinical and safety importance that the BCMA system has to nursing, pharmacy, and patients. It is recommended that information systems staff attend a pharmacy training session to get an overall understanding of the pharmacy components of the system and related pharmacy procedures. Such a session can be scheduled in conjunction with pharmacy training or independently.

6.6.11 System Evaluation (POST-Implementation)

A system evaluation action team should closely monitor for the proper use of the BCMA system and all related processes. To do so effectively, a process flow measurement system can be developed. Process flow measurement should identify process problems and work-arounds that may develop that may diminish safety benefits.
Examples of work-arounds that have been seen with point of care medication scanning systems include:

- Extra barcoded patient wristbands are created to avoid having to scan the patient-worn wristband. In some cases, these are taped to a bed rail or wall in the patient room. In other cases, they are kept in the medication room so that the user can scan medications before going to the patient.
- Medications are removed from barcoded packages in a medication room, and the empty packages are scanned later after medications are administered.
- Medication scanning is bypassed altogether and medications are documented later.
- A medication is administered by indicating it is a “non-barcoded medication” (a feature of some systems) when the medication is, in fact, barcoded.

The monitoring process should help identify the process issues that cause users to develop work-arounds. As an example, if no process existed for a nurse to initiate a schedule adjustment for a scheduled medication, the nurse may have given the medication but scanned it as given at a standard time. This process problem should be addressed. Clear procedures should be established for all users of the BCMA system, and reports should be generated and reviewed to identify trends in using the system effectively.

6.6.12 Regulatory Considerations

FDA regulations exist for barcoding of medications by manufacturers, but they do not apply to pharmacy on-site packaging. State boards of pharmacy, not the FDA, regulate pharmacy practice. The addition of a barcode to a hospital-prepared medication package should not affect the pharmacy’s ability to comply with existing state regulations. If outsourced packaging and barcoding is needed, the pharmacy should contract with a licensed medication repackager for this service.

Non-24-hour pharmacy service will necessitate those doses for medication orders written during off hours be scanned and administered prior to pharmacy order entry the following morning. Pharmacy should work with nursing to establish a procedure to reconcile such doses with orders written during off hours and the orders that are eventually entered.

6.7 Nursing Considerations

6.7.1 Nursing Workflow

The process of ordering, confirming, preparing, dispensing, and administering a medication has multiple potential points of failure. There are many steps in nursing medication administration, and some medications require extra steps to administer them. Nurses work at the final check point between accurate medication therapy and potential medication errors. Therefore, a thorough understanding of the nursing medication processes should be developed before implementing a BCMA system.

As noted in 6.4.1, a recommended first step in a BCMA system selection and implementation is to map and study the current medication administration process using flowcharts. Differences in the administration of various types of medications should be understood. Where medications are stored, retrieved, and prepared should be depicted. Necessary retrieval of non-pharmacy items and patient information, including clinical information that the nurse must collect and document during administration (e.g., finger stick blood sugar checked before insulin administration, or digoxin level and
apical heart rate checked prior to digoxin administration) should be noted. Existing policies and procedures for medication administration should be up to-date and available for reference during this analysis, and an assessment of whether or not these procedures are being followed is essential before proceeding. Updated policies and procedures can serve as a valuable point of reference for evaluating BCMA technology that may be a good match for nursing processes. Space limitations may affect process changes and should be identified.

High-risk medication workflows require special attention since errors with these medications are more likely to cause serious adverse drug events. The Institute for Safe Medication Practices has identified the following as high alert medications or categories.

ISMP’s List of High Alert Medications.\textsuperscript{[14]}

- IV calcium (as gluconate or chloride)
- Antineoplastic ("chemotherapy") agents
- Chloral hydrate and medications used for pediatric ambulatory sedation
- Digoxin
- Heparin
- Hypertonic saline
- Insulin
- Potassium chloride

Finally, workflows must be considered for non-nursing practitioners who administer medications, such as physicians and respiratory therapists. It is recommended that these practitioners follow the same medication verification and documentation practices as nurses.

\textbf{6.7.2 Barcoding the Patient}

A BCMA system will require that a barcoded wristband be attached to each patient at the time of admission. Many hospitals limit the area/location or personnel who may print patient ID bands to minimize extra bands or incorrect bands being utilized. The wristband barcode should be scanned to identify the patient prior to the administration of each medication or during each group of medications to be administered. There may be patient populations that will make attaching a barcode to the patient difficult (premature infants, burn patients, behavioral health patients), so each institution should evaluate their patient population and develop alternative strategies if these patients are to be admitted. A process needs to be determined to ensure that the correct patient receive the correct barcoded ID band.

\textbf{6.7.3 Nurse Staffing}

A BCMA system that includes alerts and other decision support tools to reduce errors should not significantly impact staffing. Since BCMA systems automatically document medication administration as it occurs, it is likely to reduce charting time after medication administration in comparison to manual or other electronic charting methods. There will be time and labor costs, however, associated with setting up and implementing a BCMA system. Some ongoing nursing labor investment related to training and support should be expected.
6.7.4 Nurse Training

The time required for training staff nurses may vary based on the design and user-friendliness of the BCMA system selected. Following are some recommended approaches that, working closely with a BCMA vendor, will help achieve a successful training experience.

- Introduction to the BCMA system should include a focus on hospital patient safety initiatives, TJC recommendations, and regulatory requirements that support the need for minimizing error-prone circumstances.
- Training tools, such as user guides, videos, and other training aids, should be obtained from the BCMA system vendor.
- BCMA system equipment should be reserved for ongoing user training.
- Hospital nurses, such as nursing education instructors, and the BCMA vendor should jointly conduct initial training sessions while the technology is being learned. During system roll out, nursing should gradually assume the training role with less help from the vendor.
- If experienced consultants are available, their input should be obtained about training content.
- Nursing education instructors should incorporate BCMA system training into training for newly hired staff.
- A time and place must be chosen for BCMA system training. Access to fully functional equipment will be required at that location. A location away from the patient care area is recommended for uninterrupted learning. Training before or after regular work shifts should be considered, even if overtime applies.
- A reasonable amount of time for the training session should be allotted, including time for hands-on practice and a question and answer period.
- Certificates of completion should be issued for the training, and the training should be documented in each employee’s education record.
- All changes to current policies and procedures should be addressed, including procedures for planned and unplanned down time.
- Explanation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations should be included related to BCMA system technology.

6.7.5 Go-Live and Ongoing Support

Support of a BCMA system during a go-live phase requires a collaborative effort by information systems, nursing, pharmacy, and the BCMA vendor. Care should be taken to accommodate users with varying levels of technical experience.

Appropriate support-staff levels should be considered during the first several days if not weeks of implementation, since much learning will be gained from real patient care experience. Staff nurses have reported stress when first using a BCMA system in the presence of patients, so having support help available is important to user acceptance in the early stages.

An ongoing nursing support plan for the BCMA system should be developed, communicated, and clearly understood by the nursing staff. It should specify whom a nurse should contact when procedural questions arise, when troubleshooting help is needed, or when system failures occur. The support plan should include an escalation process, beginning with internal hospital support and escalating to a readily accessible vendor customer support department when necessary.
6.7.6 Space Considerations for Nursing

Since BCMA systems are used at various points in medication administration, special attention to nursing unit and bedside space constraints should be considered when selecting BCMA system equipment. Space availability at each step of the medication administration process should be examined. For example, there may be sufficient space for required BCMA system equipment at the bedside but not enough space in a medication room for necessary BCMA equipment when the nurse is preparing medications or IVs. Additionally, equipment will require a designated storage place with access to an emergency-power electrical source for recharging batteries and for storage when not in use. The spaces chosen should not interfere with other activities and must meet safety requirements established for patient care areas.

Work stations on rolling carts or stands were common in the early generations of BCMA systems in the mid-1990s and still exist today. These devices typically include a laptop computer with wireless networking capability and a tethered or Bluetooth® barcode reader. Some things to consider with such devices are:

- How easily the rolling carts or stands fit through doorways
- Space available in patient rooms and at the bedside
- Space available in other areas where medications are prepared (if applicable)
- Electrical sources
- The number of devices required to serve the nursing unit
- Storage space when not in use
- Whether the BCMA system vendor will load software onto the hospital’s own computers (e.g. laptops) and whether it will be possible to run other applications on the same computers to help save space
- Whether handheld devices will be used when circumstances prevent the use of rolling carts or stands
- How cleaning will be done and infection control standards will be maintained

Some BCMA systems use wireless handheld devices. Sometimes when handheld devices are used, the requirement for the number of other computers is less than with systems using stationary work stations or work stations on rolling carts or stands.

Some BCMA systems use a stationary computer at the bedside. Flat-screen computers can be mounted on a wall or stand near the bedside. Tethered or Bluetooth® barcode scanners may communicate with these stationary components. Stationary bedside components may require supplemental handheld devices for use when medicating ambulatory patients. Handheld devices require dedicated space for storage and recharging when not in use. These devices may be capable of use for other purposes, such as CPOE and other nursing documentation.

Per HIPAA, the protection of personal health information from view by visitors and other patients must be considered when any systems are used.

6.7.7 Electronic Charting

It is important to ensure that all the components that make up the eMAR come together in one view that will become the permanent patient record. It is essential that the eMAR facilitate the documentation of medication administration. The use of an EHR will allow for other disciplines to view medication
administration in a view that will facilitate assimilation of that information to drive patient care. Determining the documentation comments and exception comments for BCMA should be considered when designing the system.

6.7.7.1 Identifying the Patient

The patient must be recognized by the system electronically. Therefore, the admitting process must identify all patients, whether they enter the hospital system as inpatients (fully admitted or admitted “for observation”) or outpatients, in the same electronic manner (usually barcoding). Patient information, including key identifiers such as a medical record number and unique visit number, must be shared through an admissions-discharges-transfers interface with a BCMA system. When a patient medical record numbering system is used, a unique patient visit number is assigned for each incident of care. It must be decided whether the barcode on the patient wristband will contain the patient’s medical record number, visit number, or both for proper identification of the patient by a BCMA system.

It is recommended that nursing strive for consistency of format for both inpatient and outpatient eMARs.

6.7.7.2 Identifying the Caregiver

An eMAR must accurately identify and record the caregiver for all medication administrations. Therefore, all caregivers that administer medications to patients have to be identified electronically to a BCMA system. Although employee ID badges often contain magnetic stripes, a barcode on the employee badge is may be used for user identification by a BCMA system. Many hospitals use proximity readers and/or biometrics to determine the identity of the nurse during medication administration. The use of a user ID and password are typically still required to gain access to the EHR software prior to the nurse begins any actions in the BCMA module.

6.7.7.3 Data about the Medication Administration Event

Since clinical observations and assessments happen at the same time as medication administration, a BCMA system should allow users to capture those data during administration to be recorded in the EMR. Typically, nursing policies and procedures are already in place to define the clinical data that should be captured. When planning for a BCMA system, a thorough review of these charting requirements is necessary in order to ensure that the necessary information can be captured.

It is useful for a BCMA system to enable reconciliation between what is dispensed and what is administered. It also is useful for a BCMA system to capture real-time billing information about medications administered, based on the NDCs of scanned products in order to fulfill billing requirements of the Centers for Medicare and Medicaid Services (CMS).

6.7.8 Medications Administered by Non-Nursing Personnel

A BCMA system and related processes must support non-nursing practitioners that administer medications. As noted earlier, for example, in some hospitals, physicians may administer certain medications to patients. Again, it is highly desirable for physicians to verify and document medication administration in the same manner as nurses. Considerations should be determined for medical staff that routinely administers medications, such as anesthesiologists. Physicians administering medications as part of a procedure or for sedation may require training for use of the BCMA system. If these providers
do not use the BCMA system, the patient’s nurse may be required to document to the administration of the medication on the eMAR by proxy. Other providers may have a limited scope of medication administration, but should also be included in the use of the BCMA system (i.e., radiology technicians, respiratory therapists, perfusionists, etc.).

In a teaching institution, student nurses pose a challenge with BCMA systems. In addressing this, the relationship between the school of nursing and the hospital should be clearly understood. In some cases, students as well as the instructors who oversee them may have to use a BCMA system to administer medications. It is important to know whether the BCMA system can provide privilege level controls that will allow student nurses to administer medications under the direction of a staff nurse. An example of such a privilege level control would be to require a documented witness before finalizing a student nurse’s medication administration transactions.

It is recommended that respiratory therapists use the BCMA system for verifying and documenting medications used during respiratory treatments and to document patient training about the use of inhalation devices. The medications used by respiratory therapists may be dispensed by pharmacy directly for a patient, or they may be provided to the respiratory therapy department as stocked medications. In either case, point of care administration and clinical data gathering for respiratory medication events should be consistent with nursing medication practices.

**6.7.9 Infection Control**

Infection control challenges exist when shared equipment is moved in and out of patient rooms. A BCMA system is no exception. It is important that BCMA system devices can be cleaned using effective hospital-grade cleaning agents. Also it is important that the cleaning procedure is followed after devices are used in isolation rooms. The BCMA system vendor should be asked for custom disposable covers or similar barriers for devices when used for isolation patients.

**6.7.10 Specialty Nursing Areas and Other Special Situations**

Although medications administered in specialty departments sometimes must be administered without entry of an electronic medication order, the hospital should consider having all departments where medications are administered use the same BCMA system and follow the same general procedures for medication administration and documentation. For example, areas like a post-anesthesia care unit, radiology, an emergency department, and a cardiac catheterization lab should use the BCMA system and eMAR for recording medications administered during procedures. Although an automated check for the 5-Rs is not possible without an electronic order entry, there still are valuable safety checks that can be gained by using the BCMA system in these areas, such as screening for allergies, appropriate dose ranges, and medication interactions. In addition, the capture of accurate CMS billing information at the point of care in these departments may be a benefit. Therefore, it should be considered how the BCMA system could be used in specialty areas and may impact workflow there. Process changes may be required to maximize the benefits.

In special circumstances, such as a cardiopulmonary resuscitation or other emergency situations defined by the hospital, scanning of a barcode at the actual time of administration may not be possible or practical. A secondary method for electronically documenting medications used during these incidents should be devised.
6.7.11 Management of Hardware Devices

Although device management is not a new challenge for hospitals or for nursing, a BCMA system may require some additional controls. Certain BCMA equipment may have a potential for diversion. For example, certain mobile devices may have personal utility if they can operate applications like spreadsheets, calendars, and word processors. In these cases, the hospital should consider using a mechanism for tracking and updating these devices remotely.

6.7.12 Privacy and HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was established to regulate the way healthcare facilities transmit, store, and access personal health information. Since the compliance date of October 16, 2003, hospitals have implemented steps to protect the confidentiality of hard copy and electronic medical record content within the hospital and, if applicable, outside the facility. These steps have included implementation of:

• Physical safeguards, such as
  o Controls for electronic media
  o Maintenance and proper disposal of records
  o Work station access security
• Security administration safeguards, such as
  o Data trending analysis
  o Disaster recovery planning
  o Backup planning
  o Password management
  o Incident procedures
  o Security awareness and training
  o Workforce clearance
• Technical safeguards, such as
  o System testing and revisions
  o Audit controls
  o Strict control over remote system access
  o System design integrity
  o Data encryption and decryption techniques
• Strategy, assessment, and remediation steps, such as
  o Corporate compliance with HIPAA regulations
  o Risk assessment
  o Gap analyses to assess compliance with regulations
• Information systems standards, such as
  o Standards for transaction data
  o Establishing code sets and identifiers
  o Consents, authorizations, and disclosures
  o Privacy notification practices
  o Adherence to privacy laws
• CPOE considerations, such as
  o Requirements and designs to support privacy
  o Medication decision support
• Patient safety and reduction of medication error efforts, such as
  o Using BCMA systems to verify the 5-Rs
  o Improving process sophistication
  o Compliance with FDA regulations about barcoding

Two general questions should be asked when evaluating BCMA systems for nursing use related to HIPAA.

• What features and attributes does a BCMA system possess that demonstrate it is sensitive to patient privacy?
• What responsibilities will the hospital have to maintain patient privacy within the system?

6.7.13 Occupational Hazards

Another factor to understand is how the physical user interface occurs. Any system requiring repetitive body motions on the part of a user should be carefully studied. Evaluation, and perhaps research through speaking with existing users in other settings, will help determine whether there is a risk of injury due to repetitive tasks.

Some BCMA devices, such as laptop computers on rolling carts or stands, may pose a risk in some work areas by crowding the work environment and therefore causing encumbrances or a tripping hazard to patients, visitors, or healthcare providers. Assessing the space in these areas and choosing the right hardware will help reduce hazards.

6.7.14 Nursing Down Time Procedures

Occasional planned down time is necessary with any automated system. Problems that sometimes occur during planned down time can be avoided through coordination and communication among departments.

If unplanned system down time occurs, it is essential to follow a pre-decided standard contingency procedure designed to minimize adverse effects on patient care. The down time procedure should call for nurses to immediately revert to a manual method of medication verification and documentation. This manual method should be described in detail in a related procedure. Nursing must have a consistent medication information source (electronic or paper) to guide medication administration if a system failure occurs.

Features for retrospectively documenting a dose administered during a down time may be available in some BCMA systems. For example, the system may provide an option to document administration of a medication outside of the usual bedside barcode scanning process. Such a feature may help capture medication events that occur during planned and unplanned down time. However, if used inappropriately, such a capability can create an opportunity for work-arounds.

7 - Managing the Implementation

7.1 The Development Phase

The impact of a BCMA system on organizational workflow is different for every organization and
sometimes different for different departments within an organization. Therefore, it may be appropriate to employ a development phase in a limited area (e.g., one nursing unit) before formally signing off on acceptance and expansion of a BCMA system. The term “development phase” is preferred over “evaluation” or “trial” because it avoids implications that the technology might be temporary and better defines the purpose of the project phase.

The development phase is important for validating the system’s technical capabilities, usability, user acceptance, and related workflow. During the development phase, system and interface problems can be resolved by the vendor, and process adjustments can be made by the hospital. This is a significant step in the implementation process and should not be rushed.

A patient unit that utilizes many medications and IVs of varying types, such as a medical-surgical unit, is a good choice as an initial go-live unit. Specialty units, such as intensive care units or pediatrics, probably should be avoided as first go-live units because they present special issues that will be easier to address once experience with the system is gained.

In addition to support from pharmacy, nursing, and information systems, the vendor should provide both technical and clinical on-site support at the initiation of a BCMA system’s go-live. A go-live support team should provide coverage on night and weekend shifts to assist users who work only those shifts.

There is no recommended length for a development phase. Instead, the number and depth of issues identified will determine its duration. However, the oversight team should consider establishing a length of time (e.g., two weeks) during which no major issues are found before the development phase will be considered ended.

7.2 The Roll-Out

A roll-out plan should be finalized during the development phase so that, once that phase has concluded, roll-out can begin almost immediately. To minimize the time during which two systems are in use, and to begin taking advantage of the safety benefits of a BCMA system, roll out to the entire hospital should be completed as rapidly as possible.

The roll-out plan should include weekly expansion to additional areas, scheduled patient unit conferences and training in new areas the week before the go-live date, and support staffing.

8 - Special Considerations

8.1 Data Analysis\[^{15}\]

8.1.1 Importance of Data Management

Proper data management and analysis are critical to the continued success and optimization of a BCMA system. Data gleaned from a BCMA system should be integrated with traditional performance improvement methods to provide the information necessary to achieve the goal of safe medication use.
8.1.2 Data Collection

Prior to implementation, a multidisciplinary group, such as a system evaluation action team (made up of representatives from pharmacy, nursing, and performance improvement), should determine the person(s) responsible for collecting and reviewing applicable data. The content of reports available from a BCMA system can be used to decide who should be responsible for reviewing, analyzing, and disseminating each report. Information from a BCMA system will reveal opportunities for improvement.

8.1.3 Data Interpretation

Error prevention data will be produced by a BCMA system in the form of warning messages (wrong dose, wrong medication, order status, dose omitted, etc.). It is imperative to understand the factors that influence the types and number of warnings generated. There will not be a direct one-to-one correlation between warnings received and errors prevented. Daily review of the data combined with consistent application of methods to eliminate false positives will be essential for capturing meaningful information. This is especially crucial if multiple individuals are responsible for data collection and interpretations. It should be possible for data to be exported from a BCMA system for trending and further analysis if needed.

8.1.4 Reporting

Reports detailing the impact of a BCMA system on medication administration activities and patient safety can be useful to pharmacy, nurse managers, respiratory therapy, and a system evaluation action team. Established hospital groups such as the Pharmacy and Therapeutics Committee, Nursing Executive Committee, Patient Safety Committee, and Performance Improvement Committee may be interested in receiving quarterly summaries of medication safety information. These reports should include, but not be limited to, the number of doses administered and errors prevented each month, the types of errors prevented, the potential severity of errors prevented, the medications involved, and the process improvements made.

8.1.5 Data-Driven Process Improvement

Information derived from BCMA system reports can be utilized on an ongoing basis to make process improvements. For example, root cause analysis of the data may indicate that a review of policies and procedures relating to medication administration is needed. Similarly, an analysis may identify problematic medications or issues with the medication distribution system. The data should help to pinpoint additional training needs for pharmacy or nursing and can be used to identify workflow or staffing issues. Application of a severity index, such as the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) severity scale, to errors occurring and prevented will help stratify data for focused process improvements.

It is important for organizations to set clear requirements for use of a BCMA system and hold staff accountable for adherence.

8.2 General Down Time Procedures

Since hospitals have used computer technology for years, most hospitals have procedures for planned
and unplanned down times for both overall networks and for individual systems. Understanding the differences between planned and unplanned down time is necessary to properly plan for their occurrence.

Planned down time requires multi-department collaboration and a planned sequence of events. Occasionally, the information systems department, sometimes with system vendors, will take systems down to perform routine maintenance, to improve performance, to upgrade hardware or software, or to move equipment to a new location. BCMA systems are no exception.

The process for planned BCMA system down times should begin with adequate notification of system users to allow them to plan ahead. For example, nurses will have to know during which period’s medication administration must be scheduled and documented manually and when the system will be restored in order to carry out necessary tasks. For a BCMA system, it is recommended that at least three days’ notice be given to patient care areas and to pharmacy before a planned down time occurs.

The information system department should be sensitive about scheduling planned down time during periods of high system use, such as times when medication administration is occurring and when a patient census is high. Scheduling planned down time on a weekend during the late evening or at night when fewer doses are being administered should be considered.

Departmental policies and procedures should clearly describe the process to be followed for unplanned down time, both for hardware or software down time.

8.3 Unique Hospital Characteristics

Certain hospital characteristics will affect a BCMA system and should be considered when planning and developing policies and procedures. Examples of such characteristics include:

• Pharmacy service hours. If the pharmacy is not a 24-hour service, pharmacy system order entry will not occur during off hours and therefore the order information that drives a BCMA system will not be current. In such a case, the BCMA system will have to allow the administration of “non-ordered medications” with a feature for retroactively associating the doses administered with orders after order entry has occurred. In addition, pharmacy should ensure that medications are barcoded that may be accessed to fulfill a new order during hours when the pharmacy is closed.

• Outsourced pharmacy services – If the pharmacy uses outsourced services, such as an IV admixture service, after-hours order entry service, or repackaging service, those services should be involved in planning for barcoding to support a BCMA system.

The use of BCMA outside the inpatient nursing unit should be considered based on the types of clinics, departments, and procedural areas existing within the institution. The pre-existence of pharmacy services in these areas may ensure a smooth implementation of BCMA. The patient volumes, through put, and types of medications being utilized should be studies prior to any implementation. Equipment that is suitable for inpatient use, may not be useful in these other environments.
9 - References


The following vendor web sites were visited during the course of this project:

Allscripts - http://www.allscripts.com
BD/CareFusion Corporation - http://www.carefusion.com/
Capsa Solutions - http://www.capsasolutions.com/
Cerner Corporation - http://www.cerner.com/
CliniComp, Intl - http://www.clinicomputer.com/
CPSI - http://www.cpsi.com/
Epic - http://www.epic.com/
GS1 US - http://www.gs1us.org/
Health Industry Business Communications Council - http://www.hibcc.org/
Netsmart Technologies - http://www.ntst.com/
Omnicell, Inc - http://www.omnicell.com/
QuadraMed Corporation - http://www.quadramed.com/
Siemens Healthcare - http://usa.healthcare.siemens.com/infrastructure-it
Softwriters, Inc - http://www.softwriters.com/
Talyst, Inc. - http://www.talyst.com/
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