

Implementing a
Bar Coded
Medication
Safety
Program



Pharmacist's Toolkit



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1 Contributors

The American Society of Health-System Pharmacists® Research and Education Foundation wishes to acknowledge the following individuals for their contributions to this project:

Members, ASHP Foundation Expert Panel on the Health-System Use of Machine-Readable Coding

Eva Fowler
Pharmacy Consultant
VAMC
National BCMA Joint Program Office

Brad Ludwig, MS, RPh
Asst. Director, Pharmacy Operations
University of Wisconsin Hospitals and Clinics
Madison, WI

Agatha L. Nolen, MS, DPh, FASHP
Director of Pharmacy
Centennial Medical Center
Nashville, TN

Tim Quigley, RN, MBA
Chief Nurse Executive and Vice President
of Patient Care Services
Spaulding Rehabilitation Hospital
Boston, MA

Paul M. Seelinger, BS Pharm
President
IDentityHealth, Inc.
San Diego, CA

John Tourville, PharmD
Director of Pharmacy
Children's Medical Center of Dallas
Dallas, TX

Special Contributors

David B. Archer, BS Pharm
Director of Information Technology
Centennial Medical Center
Nashville, TN

Susanne Larrabee, RPh
Clinical Pharmacist
Northern Michigan Reg. Health System
Petoskey, MI

Laura Robinson, RN
Robinson Consulting Inc.
Los Gatos, CA

Ronald A. Romard, RPh, MS
Director of Pharmacy Services
Spaulding Rehabilitation Hospital
Boston, MA

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Bellevue, WA, USA 98007-6848 www.seagullscientific.com.

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2 Preface – About this Tool

The *Pharmacist's Toolkit for Implementing a Bar Coding Medication Safety Program* is provided by the American Society of Health-System Pharmacists® Research and Education Foundation and was made possible by an unrestricted educational grant from Omnicell®. To begin development of the tool, in August 2003 the ASHP Foundation assembled a panel of experts on the application of bar coding to prevent medication errors. This panel established the initial framework for this document and served as reviewers as content was developed. Writing, editorial, and project management services were provided by IDentityHealth, Inc. of San Diego, CA.

The objective of this tool is to provide helpful information to pharmacists regarding the planning and implementation of a bedside verification system for medications labeled with machine-readable coding. It will provide valuable and thorough information on preparing the pharmacy and the institution for such a system. It is recommended that pharmacy managers read this document before embarking on the Medication Bar Code Point of Care project and refer to it often during the project.

The ASHP Foundation and the contributors to this tool recognize that bar coding - although seemingly the standard for machine readable coding - is only one type of machine-readable technology. Other symbologies and/or smart chip technologies either exist or are sure to develop during the life of this document. However, to make this tool easier to use and understand, we will use the term "**bar code**" throughout as being representative of machine-readable coding.

By reading this document, the reader will:

1. Have a general understanding of bar coding and wireless networking technology as they relate to the implementation of a Medication Bar Code Point of Care (MBCPC) system.
2. Be better prepared to manage a successful process for planning and implementing a MBCPC system.

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3 Introduction

For the past 15 years, pharmacists and nurses have applied automated systems to solve common problems inherent to the hospital medication use process. Initially with the advent of unit dose dispensing, the need to individually package unit doses of medication spawned the development of desktop packaging machines. The inefficiencies and inaccuracies of manual narcotic control processes led to the development of automated ward-based cabinets that revolutionized controlled substance management in hospitals. The labor intensity of the unit dose cart fill process, an evolving standard of practice for hospital pharmacy, fueled the development of patient-specific packaging systems to support the manual cart fill process and even robotic systems to perform much of the cart fill process automatically. Fortunately, pharmacy information systems had computerized our patient profiles long before automated dispensing systems arrived, allowing interfaces that shared patient-specific medication orders to enhance the effectiveness of automated dispensing machines. As systems such as these entered our daily practices, practitioners began to recognize their ability to impact the safe use of medications, usually positively, but often providing new potential sources of error.

As various pharmacy technologies matured, each became more robust in its capabilities, providing pharmacists with more and more choices for automating the medication use process. Computerized patient profiles led to computerized clinical screening tools for pharmacists and electronically generated MARs for nursing. Decentralized cabinets became profile based, adding enough control for some to adopt them as a replacement for cart fill as the primary method for distributing medications. Robotic systems became faster and addressed a broader area of application, including processes like medication packaging and sterile syringe filling. When properly applied and managed, these sophisticated tools became efficient and highly accurate, allowing pharmacists in many institutions to divorce themselves from some routine dispensing tasks and shift their time to more rewarding clinical roles.

Implementing automated systems within the medication use process is nothing new to hospital pharmacists. So, it may seem that planning a Bar Coded Medication Process (BCMP) and implementing a Medication Bar Code Point of Care (MBCPC) system should be approached much like the implementation of robotics or automated dispensing cabinets. The contributors to this tool respectfully recommend against this assumption. In fact, there are many unique challenges to successfully implementing a MBCPC system. In addition, unlike past implementations of automated systems that were often managed or co-managed at the hospital level by the vendor's field representatives, MBCPC will require full ownership by both pharmacy and nursing beginning with the planning stage and ending – well, actually never ending. As we will learn throughout the *Pharmacist's Toolkit for Implementing Bar Coded Medication Safety Program*, the MBCPC project is truly a different automation challenge.

Contributors to this toolkit - practitioners who are experienced with bar coded medication use processes and pharmacy automation in general – have compiled their thoughts, considerations, and recommendations based on real-life experience. We hope this toolkit will help guide in the planning, implementation, and successful use of this technology in maximizing the prevention of medication errors.

4 Glossary

Term	Definition
5-Rs	Term used to describe the five basic checks when a medication is administered: Right patient, Right med, Right dose, Right route, and Right time.
Bar code	A printed symbol made up of black and white bars; the most common type of machine-readable code that provides a method for data input into an automated system
BCMP	Bar Coded Medication Process; term that describes the hospital's overall medication use process using bar codes to improve medication use accuracy and safety
Check digit	A digit at the end of the data string in a bar code that is calculated based on the other characters in the data string. The check digit is a technical way of insuring against any possibility of misinterpretation by the scanner.
eMAR	An electronic Medication Administration Record
Firmware	The software program that runs on a hardware device, such as a scanner.
MAR	Medication Administration Record – a patient-specific document used by nursing to track the administration of ordered medications; can be totally hand written, printed electronically and maintained as hand written, or fully electronic (eMAR)
MBCPC	Medication Bar Code Point of Care system, an electronic system that allows for bar code scanning at the bedside to check the 5-Rs and typically generates an eMAR or interfaces to another eMAR system. The MBCPC system is part of the hospital's Bar Coded Medication Process (BCMP). "MBCPC" was chosen by contributors to this document as an alternative to the term "bedside scanning" because MBCPC better describes the function of these systems.
NDC	The National Drug Code assigned to the specific product and package size by the Food and Drug Administration (FDA).
PIS	The Pharmacy Information System, or Pharmacy Clinical System, into which medication and IV orders are entered and patient medication profiles are maintained
Scan Code	Another term for the series of characters (data) stored within a machine-readable symbology
Symbology	A type of machine-readable printed symbol, such as a bar code, used to communicate data to an automated system

A complete glossary of technical terms associated with wireless networking, wireless security, and related standards can be found at the **Wi-Fi® Alliance** website at www.wi-fi.org/OpenSection/glossary.asp?TID=2.

5 Technical Background

5.1 Understanding Bar Codes

This section will focus on a basic review of bar codes. Readers should keep in mind that other symbologies, as well as alternative machine-readable technologies, are sure to evolve for use on medication packages. That said, the information on the application of bar coding covered throughout this tool would generally apply to any other future symbology or technology deemed useful to identify a drug product to an automated device. In this section, we will review bar coding in some detail as an example of a machine-readable coding technology.

5.1.1 Bar Codes – A Technical Review

The level of technical understanding of bar coding that a pharmacist should have has been a subject of debate. Some feel that a pharmacist who is implementing a bar coded medication system should have a detailed knowledge of bar code standards and symbologies. Others may feel that, considering the complexity and mass of this information, such detail is not necessary to build an effective medication safety process using bar codes. The truth is probably somewhere in the middle. We propose that the background on bar codes that this chapter will provide is more than enough to help you effectively develop and implement your bar coding program.

Bar codes are by far the most widely recognized machine-readable symbology. The many available types or formats of bar codes can be confusing, but in fact every type of bar code does the same thing – represents a series of characters, the same characters you type from your keyboard. Depending on the type of bar code, these characters may include numbers, letters, and/or special characters. The characters represent data – a piece of information – to be conveyed to an electronic system when the bar code is read. For example, the data stored in a medication bar code will contain a unique number such as an NDC number to identify a manufactured medication, or a hospital-specific code to represent a single patient-specific dose prepared by pharmacy. Bar code scanning, therefore, is simply a fast, highly accurate method of inputting and/or capturing data.

Bar codes are made up of a series of black bars and white spaces. Every character is represented by a different pattern of bars and spaces. When the scanner shines its beam on a bar code, the black bars absorb the light while 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. The scanner then decodes the signal into the characters represented by the bar code and sends the characters to the computer. The software application running on the scanning device looks up the data in a database and returns related (thus the term “relational database”) stored information on the scanned product – in this case a medication. The retrieved information can then be used by the software program to perform tasks, such as to verify and document right drug, dose, and dosage form as ordered, to check allergies or drug interactions, or to notify the user of administration guidelines for the product scanned.

Certain types of bar codes may include “start and stop characters” to indicate the beginning and end of the data string. For example, a Code 39 bar code must begin and end with an asterisk (*) character to be properly read by a scanner. Although “start and stop

characters” are included in these bar codes, they are not considered part of the data when the bar code is read. (Tip: If you create and print a bar code but cannot read it with your scanner, the first thing to check is whether any required start and stop characters were omitted.)

Software programs are available for creating and printing bar codes and bar coded labels. One of the simplest ways to create and print your own bar coded labels is through the use of Windows® or Macintosh® bar code fonts, which allow you to create bar codes using your word processing and spreadsheet programs. These font packages are available from vendors such as Wasp Bar Code Technologies (www.waspbarcode.com) and Worth Data, Inc. (www.barcodehq.com). Software programs from these and other vendors are also available for bar code creation and printing, such as that provided by Zebra Technologies (www.zebra.com) for use with its own line of printers. We’ll discuss more on pharmacy printing of bar codes later in Section 6.7.1 *Getting Bar Codes on All Products*.

Some types of bar codes were developed many years ago. Although there are newer types of bar codes that offer advantages such as smaller size and more data capacity, bar codes that follow older standards are still commonplace in our industry.

There are four general categories of bar code symbology that we will review in more detail:

1. Linear (1-D)
2. Two-dimensional (2-D) Stacked
3. Two-dimensional (2-D) Matrix
4. Composite Reduced Space Symbology

Bar code *density* refers to the number of characters per inch that a bar code can hold. With certain types of bar codes, a *check digit* is an added character at the end of the bar code data that is calculated based on the other characters using a defined mathematical rule. It is used by the scanner to insure an accurate scan. Bar codes that can be scanned either left to right or right to left are considered *bi-directional*, while some are *omni-directional* and can be scanned from any angle.

Additional technical information on bar coding is available from numerous sources, including the standards organizations - the Uniform Code Council (www.uc-council.org) and the Health Industry Communications Council (www.hibcc.org) - and related hardware and software vendors, such as:

- Wasp Bar Code (www.waspbarcode.com/barcode_education)
- Worth Data (www.barcodehq.com/primer.html)
- Seagull Scientific (www.seagullscientific.com)
- Zebra Technologies (www.zebra.com)

5.1.1.1 Linear (1-D) Bar Codes

Currently, almost all bar codes on manufactured medications are linear bar codes. There are several types of linear bar code symbologies, but only some are used by manufacturers or are appropriate for use in pharmacy packaging. In this section, we will provide a basic understanding of various types of linear bar codes.
















Formats for linear bar codes are defined by standard-setting organizations such as the Uniform Code Council (www.uc-council.org) and the Health Industry Business Communications Council (HIBCC) (www.hibcc.org). Linear bar code symbologies look so similar that it is difficult to tell one type of symbology from another on visual examination.

If the MBCPC systems you are considering support only the identification (drug, strength, volume, and dosage form) of a product based on NDC, hospital-specific code, or other unique identifier, a linear bar code is a good choice for your pharmacy-based repackaging and labeling operation. Compared to two-dimensional symbology (2-D) or Composite Reduced Space Symbology (RSS), linear bar codes are the easiest to create, the easiest to read, and perhaps the most “forgiving” when it comes to slight curvatures or crumpled packages. In turn, only a simple, low cost laser scanner is required to read them. For more information on scanners, see Section 5.3.4 Scanners and Firmware.

Key factors in deciding which type of linear bar code to use are:

- Character length and the maximum density (determines label space needed)
- Character types supported – alpha, numeric, or both

These are important due to the need to keep bar codes as small as possible because of limited label space, especially with unit dose packages. The table below roughly compares the proportional sizes of types of bar codes using different identifiers that might be considered viable options for on-site bar code labeling in the pharmacy:

Linear Bar Code Type	10-Digit NDC*	6-digit billing code (numeric)	6-digit mnemonic (alpha/numeric)
Code	0573-2620-48	635412	AVT10T
Code 39	 0573262048	 635412	 AVT10T
Code 128 C/A	 0573262048 (Code 128 C)	 635412 (Code 128 C)	 AVT10T (Code 128 A – allows alpha)
Code 93	 0573262048	 635412	 AVT10T
Interleave 2 of 5	 0573262048 (Even number of digits required)	 635412 (Even number of digits required)	Does not allow alpha characters
Codabar	 0573262048	 635412	Does not allow alpha characters (+/-./\$: are ok)
EAN-13	 3 05732 62048 0	Must have 12-13 numeric characters and prefix = 3	Does not allow alpha characters
UPC-A	 3 05732 62048 0	Must have 10-12 numeric characters and prefix = 3	Does not allow alpha characters

* Data encoded is the actual NDC for Alavert™ Orally Disintegrating Tablet 10mg

Conclusions that can be drawn from this comparison to make pharmacy-printed bar codes smaller:

- Use a numeric identifier and avoid mixing numbers with alpha characters.
- Use the Interleave 2 of 5 or Code 128-C bar codes for numeric identifiers.
- If you must use an alpha-numeric drug mnemonic in the bar code, try Code 93.

Some unit dose packaging systems allow the pharmacist to configure the type of linear bar code to be used. Options are likely to be limited to bar codes that will fit on the packaging machine's label. Fortunately, today's bar code scanners have the ability to read multiple linear bar code formats without special programming. (Your MBCPC vendor should support all of the basic bar code types in the above table, but check with them to be sure.)

Combined with the various types of linear bar codes used by manufacturers, your MBCPC devices will certainly be reading several types of linear bar codes. So, don't hesitate to mix bar code types for various labeling applications to get the smallest labels and best results possible. This will be totally transparent to the end user.

When the day comes that MBCPC systems are able to utilize additional information from the bar code such as lot number and/or expiration date, a linear bar code will probably not be adequate. Although longer linear bar codes could theoretically be designed to hold the added data, linear bar codes would most likely become too large for medication packages and potentially even too large to scan. So, if the additional lot and expiration information becomes the standard for a medication bar code, expect to see significant evolution away from standard linear bar codes in the years to come.

5.1.1.2 2-D Stacked Bar Codes

In cases where it is desirable for the bar code to hold more data (e.g., more than 13-14 characters), stacked two-dimensional bar code formats such as PDF417 can be used. These symbols use multiple rows of bars and spaces to encode multiple data elements. It would seem, therefore, that symbols such as PDF417 would be a good choice for medication bar codes containing the NDC, lot number, and expiration date. However, the resulting PDF417 symbol is too large for many medication labels, especially smaller items. The following is an example of a PDF417 2-D bar code used to identify these three data elements for a medication:



PDF417 Bar Code

NDC:	0573-2620-48
Exp. Date:	12/31/00
Lot:	A123B456C789
Encoded as:	(01)0573262048(17)001231(10)A123B456C789

Notice the use of *application identifiers* in parenthesis preceding portions of the encoded data. These identify the characters to follow as the item number [NDC] (01), expiration date (17), and manufacturer lot number (10). As you will see below, application identifiers play a role in data identification in all types of bar codes that can contain multiple data elements and follow the UCC.EAN standards.

5.1.1.3 2-D Matrix Bar Codes

2-D Matrix bar codes like Data Matrix are similar to PDF-417 in their data capacity. However, rather than using a row by 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 bar codes can also be used in a rectangular format. The following is an example of a Data Matrix bar code used to encode the same data as the PDF417 example above:



Data Matrix Bar Code





NDC:	0573-2620-48
Exp. Date:	12/31/00
Lot:	A123B456C789
Encoded as:	(01)0573262048(17)001231(10)A123B456C789

Data Matrix bar codes typically provide a smaller symbol than PDF417 and therefore may be more suitable for some medications. However, the symbol may still be too large for some unit dose packages and small vials.

5.1.1.4 Composite Reduced Space Symbology Bar Codes

Reduced Space Symbology or RSS is a relatively new type of symbology. It was developed for storing more data in a much smaller bar code. Many feel that RSS will quickly become the symbology of choice for manufactured medications now that the FDA requires bar coding on all manufactured packages. As of this writing, at least one manufacturer is using RSS bar codes on some products to encode the drug identifier, lot and expiration information.

As you might suspect, there are several types of RSS bar codes. An RSS bar code can be a very small linear bar code containing only an NDC number, or a stacked combination of linear and 2D bar codes containing the NDC, lot number, and expiration – and even more. The following table shows a few of the key types of RSS symbols and describes their data capacity when used for medications:

RSS Bar Code Type	10-Digit NDC	Lot Number	Expiration Date
Code	0573-2620-48	A123B456C789	12/31/00
RSS-14 	√	-	-
RSS-14 Limited 	√	-	-
RSS-14 Stacked 	√	√	√
RSS-14 Stacked Omni-Directional 	√	√	√

Recent enhancements to off-the-shelf bar coding software now allow the creation of RSS bar codes by even a novice user. Some software programs, such as Seagull Scientific's *Bartender*[®] program, can be used to print RSS bar coded labels or integrated into other software programs, such as that used to operate packaging machines.

For a more accurate comparison of the proportional sizes of 2-D and RSS bar codes, visit the Uniform Code Council's symbol size comparison page at: http://www.uc-council.org/ean_ucc_system/stnds_and_tech/rss_symbol_size_comp.html

5.1.2 Misconceptions about Manufacturers' Bar Codes and NDCs

Some common misconceptions exist related to the use of bar codes on manufactured medications. This section will clarify these issues.

- *Misconception #1: The medication database of the MBCPC system needs to contain a bar code symbol that matches the bar code symbol on the product* – In fact, no such symbols are stored in the medication database. Instead, only the scan code – the data that the symbol represents - needs to be stored there. The scanner reads the bar code and, as explained above, converts the symbol into data; then the associated software program looks for the data, not the symbol, in the medication database.
- *Misconception #2: The data in manufacturers' medication bar codes is always the product NDC number* – It is true that, in some cases, drug manufacturers' bar codes include the 10-digit NDC number as part of the data. For example, some manufacturers use the UCC.EAN-13 (13 character) bar code data standard which is comprised of the lead characters "03" (identifies the product as a pharmaceutical), followed by the 10 digit NDC and a single check digit. Alternatively, the UPC 12-character standard is sometimes used, with a single character "3" rather than "03" as the precursor. In still other cases, the data contained within the bar code does not contain the product NDC at all, but rather will contain some other unique string of numbers assigned by the manufacturer (thus the importance of the proposed FDA regulation on commercial bar codes that will specifically require the NDC as the standard product identifier). In summary, the data contained within a current medication bar code may or may not contain the product NDC.

- *Misconception #3: There are two different NDCs that might be contained in a product bar code* - A common misconception related to NDC numbers is that a product has two "different" NDCs – a 10-character and an 11-character NDC. In fact, there is only one official FDA-issued NDC for each line item. Then how do we end up with 10 and 11 character versions? Well, as we know, the NDC is made up of three parts: manufacturer code - product code - package size code. Since by design, NDCs can have different formats such as 4-4-2, 5-4-1, and 5-3-2 character lengths, data providers have added a zero somewhere within the NDC to synchronize these formats into one 11-character 5-4-2 format. For example, the 4-4-2 NDC 4444-4444-22 becomes 11-digits as **0**4444-4444-22, the 5-4-1 NDC 55555-4444-1 becomes 55555-4444-**0**1, and the 5-3-2 NDC 55555-333-22 becomes 55555-**0**333-22. This does not constitute a different NDC, just a different formatting of the NDC.
- *Misconception #4: Conversion of the NDC from 10 to 11 digits and vice versa eliminates all problems related to uniqueness* - We assume this conversion from 10 to 11 digit formats was intended to avoid potential 10 digit duplicates. However, as pointed out by ScriptPro LLC in their published comment on the proposed FDA regulation (see http://www.scriptpro.com/safety/fda/report/appendix_f.shtml), different 11-digit NDCs can sometimes generate the same 10-digit NDC when the process is reversed and a zero is removed.

5.1.3 Bar Coding Tips for the Pharmacy

In setting up the MBCPC system, the pharmacist will need to decide what unique product identifier will be embedded in the bar code for repackaged oral solids and manually bar coded products, like small injectables and multidose items. For example, these pharmacy-applied bar codes might contain the product NDC (from the original container), the hospital med ID (mnemonic), or billing code to make them unique within the MBCPC formulary. Fact is, to the MBCPC medication database, any of these are acceptable. To the pharmacist, however, this choice is important due to the resulting size of the bar code. So, the following "rules" should be kept in mind:

- The bar code – and the data embedded within it – is only a pointer to the medication information in the MBCPC database.
- Keep the bar code short. The longer the data string in the bar code, the longer the bar code. For this reason, the hospital mnemonic or billing code may be a better choice than the NDC.
- Avoid mixing alpha and numeric characters. With certain types of bar codes, this increases the size. A short numeric data string (e.g., six numeric characters) works well.
- (Optional) Use an even number of numeric characters, such as six characters rather than five. Believe it or not, some bar code types, such as Code 128, may generate a smaller bar code with an even number of characters than with an odd number of fewer characters.
- Trial and error is a good thing. Plan on trying a few different types of bar codes mutually supported by your MBCPC system and your repackaging system. Consider the size of the bar code compared to available label space. Print samples of packages and labels and scan the bar code with the bedside scanner to insure compatibility and a fast, accurate read.

Remembering these tips will help you avoid rework and will get you off to a better start.

5.2 Networking and Communications ¹⁻⁵

For years, we anticipated that Radio Frequency (RF) technology, the same communication technology used by medical systems such as mobile telemetry, would be the carrier for communication with scanning devices at the bedside. The cost and house-wide deployment needs of RF were a potential obstacle to adoption. However, approval of a standard for wireless local area networking (WLAN) and rapid progress made in technological advances with higher data transfer rates have made the promise of bedside computing within reach for most healthcare facilities today.

This chapter will provide a general review of the technical aspects of network communications within the hospital that impact or facilitate a BCMP.

5.2.1 Traditional IS Networking

The current networking standard for healthcare facilities is an Ethernet-based TCP/IP protocol. TCP/IP is the language that devices on the network use to speak with one another. Data is transferred across a twisted pair of fiber optic cable between different points on the network. Bandwidth refers to the speed with which data can be transferred between devices on a network. Traditional Ethernet works at 10MB/sec, while fast-Ethernet, now the common standard, operates at 100MB/sec. Some devices today can transfer data at faster than 1GB/sec. The effective bandwidth is important in determining how much data can be moved around the network, and is particularly important when large packets of data, such as MRI images, are moved across the network.

One of the obvious limitations of facility Local Area Networks (LANs) is their inability to support device mobility. Instead, each device must be physically connected to the network in order to share data. While mobility may not be important when sharing data with an MRI scanner, it can be very important for physiologically monitoring a cardiac patient during transport to and from nursing units and ancillary departments.

Vendors of telemetry systems have successfully taken advantage of the use of Radio Frequency (RF) technology to be able to monitor patients as they move around the facility. RF technology uses radio signals to provide a wireless connection between the monitoring device on the patient and the central monitoring computer system. These RF systems typically use a frequency of the radio spectrum that is dedicated to medical devices and is not subject to interference from other hospital devices that generate radio signals.

5.2.2 Wireless Networks

Wireless Local Area Networks (WLANs) have grown out of the same technology as RF technology. Most wireless networking utilizes radio frequency in the 2.4 GHz band, the only area of the RF spectrum that is reserved for unlicensed devices. The unlicensed nature of this band means that other devices may use a frequency that could interfere with the wireless network. Examples of this are a cordless telephone or a microwave oven. In fact, both cordless phones and microwave ovens are frequently implicated in causing interference with WLAN operation.

WLANs begin with the same networking infrastructure as traditional LANs. They are an adjunct to the Ethernet backbone that exists in the facility, with the addition of a special component called a Wireless Access Point, which is an RF transceiver that sends and receives signals from other wireless devices. Another component is a wireless networking card. Such a card is often installed in a personal computer (PC), but can be part of any

device (e.g., a Personal Digital Assistant or PDA) to provide the built-in functionality of communicating with the wireless access point. While Ethernet and fast-Ethernet are common standards for hard-wired LANs, wireless networking has been slow to adopt standards, and so the ability of devices from different vendors to seamlessly connect is rare.

Today, two common standards in wireless networking are the Institute of Electrical and Electronics Engineers (IEEE) 802.11b standard, which defines connections at a speed of 11MB/sec, and the newer IEEE 802.11g, which defines connections at 54MB/sec. The big weakness in these standards is their failure to include security protocols. Because data traveling across a wireless network is not confined to the cables within the walls of the facility, it is much more prone to potential interception or even corruption. Different vendors have attempted to address these security issues by implementing security protocols within their own devices, but as of yet, no standard has emerged which protects the security and integrity of the data carried in a wireless signal.

A complete glossary of technical terms associated with wireless networking, wireless security, and related standards can be found at the Wi-Fi® Alliance website at www.wi-fi.org/OpenSection/glossary.asp?TID=2.

5.2.3 **Wireless Networking Security**

5.2.3.1 Wi-Fi

The Wi-Fi Alliance is an international, non-profit association of several hundred companies formed in 1999 to certify interoperability of WLAN products based on the 802.11 standards. In contrast, IEEE does not ensure compliance to standards or interoperability between vendor products.

5.2.3.2 Wired Equivalency Protocol (WEP)

Wired Equivalency Protocol (WEP) was designed to provide a combination of security over the access point control, the privacy of the connection, and the integrity of the data transmitted between devices. WEP uses an encryption algorithm to protect the data being transmitted. A hidden pre-shared security key (PSK) is entered into the memory of the wireless access point as well as the wireless network card located in the end device. The security key, along with a plain text phrase, is combined and encrypted, and transmitted by a device which seeks an active wireless connection. The combined packet is received by the wireless access point, decrypted, and the security key is compared to what is stored in memory. While this mechanism is much more secure than using no encryption at all, tools exist that could allow a hacker to decode the encryption algorithm within a matter of hours, potentially compromising the integrity of the wireless network.

Because of the potential for security compromise with 802.11b and 802.11g standards, three new standards are now being formulated to ensure the security and integrity of wireless transmissions. The 802.11i standard will include Enhanced Security Networking (ESN), which will enhance the security of the connection between the end user device and the wireless access point. 802.11f will secure the integrity of the data transferred between two wireless access points from different vendors. And 802.11e will address quality of service issues and will support the use of voice-capable devices over WLANs.

5.2.3.3 Advanced Security Mechanisms

Because of the security flaws in WEP, the IEEE developed the 802.1x authentication standard, which uses dynamic encryption keys rather than the static keys used by WEP. 802.1x uses Extensible Authentication Protocol (EAP), a point-to-point protocol that enhances the effectiveness of the 802.1x standard by enhancing the authentication process, for mutual authentication, forcing the client device to go through the access point to a Remote Authentication Dial-In-User Service (RADIUS) server for authentication. This prevents a potential threat from rogue access points.

TKIP (Temporal Key Integrity Protocol) is an enhanced encryption method that makes data transmission more secure and is backward-compatible with WEP although it also may slow performance.

Wi-Fi Protected Access (WPA) incorporates both 802.1x authentication using EAP and TKIP to ensure that no unauthorized users gain access to the network. It also uses an advanced checksum method to validate data integrity.

For more information on advanced security, see the referenced article available at <http://www.eweek.com/article2/0,1759,1102521,00.asp>.

5.2.4 **The Wireless Networking Security Plan**

Because of security issues - known and unknown – that are inherent with wireless networking, it is critically important that the use of wireless networking within a facility is deployed along with a carefully designed security plan. The plan should outlaw the use of rogue wireless access points (i.e., ones brought into the facility outside of the knowledge of the IS department), because access to the WLAN that is uncontrolled may compromise the entire network. The security plan should outline the controls that must be in place to protect the assignment of security keys (WEP keys) in use and should include the physical security of all access points and wireless network cards. For instance, if an access point or wireless network card is stolen, it may be possible for the thief to discover the security key in use, and then compromise the network. The plan should incorporate three basic security mechanisms to protect the integrity of data on the network:

1. Service Set Identifier (SSID): The SSID is a 32 character unique identifier that is assigned to all data headers in order to ensure that only authorized users are allowed access to the network. The SSID identifies the WLAN, and all clients have to be configured with the SSID in order to access the network.
2. WEP: WEP should be enabled with at least 128 bit encryption.
3. Static IP Addresses: The WLAN should require all devices to use static, pre-defined addresses. Therefore, Dynamic Host Configuration Protocol (DHCP), which allows the network to dynamically assign the IP address of devices attempting to connect to the network, should not be used.

Finally, the plan should address signal “leakage” by providing guidelines on the positioning of Wireless Access Points. The range of WLAN signals sent to and from these access points depends on the specification being used, but in most cases the range exceeds the physical limits of the enterprise. This means that signals can potentially be picked up outside the walls of the facility. Care should be taken to position Wireless Access Points to minimize the amount of RF signal that penetrates outside the building walls.

5.2.5 Deployment of a Wireless Network

Before a wireless network can be deployed, a careful site survey must be conducted to determine the proper equipment to be used and the location of this equipment. Depending on the bandwidth needed on the network, 802.11b or 802.11g equipment is selected. Some vendor equipment is scalable between the two standards and can initially be deployed at 11MB speed then switched to 54MB later as the need arises. Once the bandwidth is determined, the site survey is conducted to identify "dead spots". The planned environment should be created for the site survey. For instance, if the planned system involves the end user working on a PC with a wireless card built into a medication cart, the site survey should be done using this specific equipment. Dead spots are areas where the wireless signal is inadequate to carry the network connection. Wireless signals degrade when passing through dense objects, such as metal, just as other radio signals do. Within a hospital setting, it is not uncommon to find areas with lead-lined walls, making a site survey critical to success. In addition, dead spots can be caused by interference from other sources of 2.4 GHz signals, such as microwave ovens. A careful site survey conducted by a trained information systems staff member will identify dead spots and remediate them prior to the wireless network deployment.

Access points should not be placed on exterior facing walls of the facility, to lessen the chance of RF signals leaking outside the building.

The specific types of wireless access points and wireless network cards should be compatible with other components of the facility IS infrastructure. For example, using the same vendor's equipment for the wireless components as for the wired infrastructure can enable synergistic implementation of security components.

A carefully designed and implemented WLAN can enable patient caregivers the freedom and reliability to access the network, and in turn the MBCPC system database, at the point of patient contact.

5.3 System Hardware

5.3.1 The MBCPC System Main Server

The MBCPC system vendor will probably provide the main server on which the system databases and server based software will run. The server will likely be a rack-mounted box and should be located in the IS department where it will have access to emergency power and tight security. In some cases, the hospital information systems department may prefer to order and install the main server rather than install a server provided by the vendor. In such cases, the vendor will provide hardware specifications for the server.

The MBCPC main server is connected to the hospital network, through which it communicates with MBCPC workstations and/or scanning devices via the hospital network and its wireless access points. It also connects to the interface for ADT and orders via the same network.

Any issues related to the MBCPC main server, such as hardware selection, installation, power requirements, and ongoing support, should be owned by the information systems department from the beginning of the project.

5.3.2 Personal Computer and Laptop Workstations

The system may require the use of portable laptops or stationary PC workstations for nursing areas as well as pharmacy. If the hospital provides this hardware – which may be beneficial in keeping costs down – the vendor should provide hardware specifications for operating system, processor type and speed, memory, ports, hard drive size, video, and any other important parameters. In some cases, network computers already in place may be suitable for running MBCPC workstation applications.

5.3.3 Printers

Printers, most likely residing on the network, will need to be accessible to the MBCPC system for printing medication worksheets and medication administration records for nursing. Like PCs, the vendor should provide printer specifications and existing printers may be adequate.

For information on pharmacy-based printers for generating bar codes, see Section 6.7.1.3.2 Printing Bar Codes to Be Manually Applied.

5.3.4 Scanners and Firmware ¹

The topic of bar code readers can be almost as confusing and intimidating as bar codes, since there are many types and categories of bar code readers. Types of readers include wand scanners, charged coupled device (CCD) scanners, and laser scanners.

5.3.4.1 Wand Scanners

Wand scanners are the oldest and least expensive type of scanner. The wand, shaped somewhat like and held in the hand like a pen, emits a beam of light and must be manually moved – or swiped - across and in contact with the bar code. Reflected light is converted to an electrical signal by a photocell in the wand. Wand scanners require some technique to use, and they do not work well on irregular surfaces, such as curved containers. Wand scanners are not the best choice for reading medication bar codes and, therefore, are not used by the MBCPC vendors.

5.3.4.2 Laser Scanners

Laser scanners work like wand scanners with some major enhancements. Laser scanners send a sweeping beam of laser light over the bar code at about 36 times per second until a successful read occurs. The sweeping beam eliminates the need for the user to swipe across the bar code to read it. Laser scanners can also be used from a convenient distance, such as 3-8 inches away when scanning a medication bar code or even 18 inches away when reading a bar coded wrist band. A successful read is achieved, even on surfaces that are somewhat curved (vials) or flexible (baggies). Like wand scanners, laser scanners convert the reflected light into an electrical signal that is then decoded into the data represented by the bar code.

5.3.4.3 CCD Scanners

CCD scanners work in a very different fashion from wand or laser scanners. CCD scanners capture the entire image of the bar code using a light emitting diode (LED) and an array of light detectors. The image is then converted into an electronic signal identical to that of wand and laser scanners. Until recently, CCD scanners required the scanner to be very

close to the bar code – typically no more than a half inch away. Newer CCD scanners can read bar codes from one-half to seven and one-half inches away.

There are several form factors used by MBCPC vendors for the device used by the caregiver. More on these options will be discussed in Section 6.6.1.2.1 *Product Form Factors*.

The software that operates on handheld devices is commonly referred to as *firmware*. Firmware includes the device's user interface, communications, and scanner support. Scanner support in the firmware will include the ability to read many types of linear and perhaps two-dimensional (2D) bar codes. Support for each type of bar code can typically be turned on or off in the firmware. So, if a bar code is encountered that can't be read, the first step is to investigate whether support for another type of bar code needs to be turned on in the firmware.

5.3.5 Replacement Batteries

Batteries can potentially add significant cost to system maintenance. The specifications, estimated life, sources, and cost for replacement batteries, whether disposable or rechargeable, should be provided in writing by the vendor. Be sure to understand ongoing battery needs as part of the system evaluation.

5.3.6 Equipment Accountability

Some component parts of the MBCPC system, such as handheld Personal Data Assistants (PDAs) or pocket PCs, can have potential value for personal use outside of the hospital. Loss of these devices will result in significant replacement costs. Therefore, theft of these devices may occur if the hospital does not have a sound security system for hospital equipment.

Things to consider in establishing accountability and security for this equipment are:

- Existing hospital policy on equipment accountability (most hospitals have one)
- A documented count of devices at change of shift
- Potential availability of product features designed to assist with device tracking
- The need to inform the security department of the program and get their input
- Past experiences of hospitals using the system you choose

5.4 Interfaces

An *interface* is an electronic connection between two disparate systems through which information is passed and shared. The standard interface protocol (language) used in healthcare is called the Health Level 7 protocol or *HL7*. HL7 defines a standard set of interface messages as well as the content of each message type. By following the HL7 protocol in developing their interface capabilities, system vendors are more readily able to communicate with each other's systems. Although HL7 is an industry standard protocol, it is not a means for a plug-and-play interface. Every interface between systems requires testing and configuration to insure optimal functionality. Luckily, pharmacists need not have detailed familiarity with the HL7 protocol to implement a MBCPC system but should require that all system vendors follow HL7 standards when interfacing to other systems.

The MBCPC system will require a patient profile interface between itself and the pharmacy information system (PIS). For the purpose of this document, PIS will include mainframe clinical systems of which the pharmacy module is a component. Establishing such an

interface requires the cooperation of three key parties – both vendors whose systems will share information and the hospital information systems department. Hospital systems such as these may send and receive information directly to and from each other through specific ports or IP addresses on the hospital network. In some cases, however, an *interface engine* may be employed to manage the flow of information between the data-sharing systems. An interface engine is an application, usually operating on its own computer, connected to the hospital network. It acts as a steppingstone between the systems being interfaced. An interface engine may have the added benefit of giving the information systems department additional control over configuration and fine tuning of the data flowing through the interface. If the interface engine is provided by a third vendor, there are then four key participants working together to create the patient profile interface.

Interfacing should not be confused with *integration*. System integration is more than just the passing of data from one system to another. Integration involves an overlapping of the features of two systems, such as sharing parts of the user interface that interact with both systems.

There are several potential data components of the patient profile interface that supports the MBCPC system. The following sections describe these components based on the direction of data flow between the pharmacy information system (PIS) and the MBCPC system.

5.4.1 **Data Flow from the PIS to the MBCPC System**

For a MBCPC system to accomplish its primary goal of verifying the 5-Rs for all medication therapy, the minimum interface data requirements are:

- ADT
- Allergy Information
- Medication/IV Orders

Enhanced functionality may be available if other information, such as lab results, are also shared. Starting with bar code scanning to verify the 5-Rs is a good start, and additional functionality described in the remainder of this section can always be added if and when necessary.

5.4.1.1 Admission, Discharge, and Transfer (ADT)

The MBCPC system will require a standard ADT interface to track current patients and their real-time bed locations. This part of the interface should be the simplest and easiest to establish because it is identical to those already used by decentralized cabinets and centralized dispensing systems. ADT information will typically come through the PIS but in some cases may come directly from the hospital admissions system.

5.4.1.2 Patient Allergy Information

Allergy information should be considered a minimum requirement for the MBCPC interface. Checking for allergies electronically at the bedside can be a significant patient safety enhancement over a manual allergy checking process, especially when administering a STAT medication prior to pharmacy order entry.

Electronic allergy checking is performed based on therapeutic medication and allergy codes established by medication database vendors.

5.4.1.3 Medication and IV Orders

Editor's Note: There can be confusion among the pharmacy, information systems, nursing, and/or system vendors regarding what comprises a "medication" order vs. an "IV order" when interfaces are discussed. The authors of the *Toolkit* recommend using the term "IVs" to describe parenterals administered based on a rate of infusion and duration, and "medications" for items ordered based on dose and schedule (sig). Therefore, to avoid confusion when discussing automated systems and interfaces, secondary IV medications, such as IV piggybacks, should be considered "medications" and not "IVs". Order entry processes in PIS systems often approach this issue in the same way with secondary IV orders entered as medications rather than IVs.

For the MBCPC system to be a comprehensive medication safety system, it will need to receive all patient medication and IV orders from the PIS system. This includes new orders, order modifications, and discontinuations.

When considering profile interface needs, pharmacy orders can be grouped into four types:

1. Single entity medication orders (only one formulary line item per order)
2. Multiple entity medication orders (more than one formulary line item allowed per order; e.g., an IV Piggyback/Minibag)
3. Single entity IV orders (only one formulary line item per order; e.g., a plain IV bag)
4. Multiple entity IV orders (more than one formulary line item allowed per order; e.g., an admixed IV)

Automated dispensing system profile interfaces often include only single-entity medication orders (#1). Single-entity IV orders (#3) and multiple-entity medication and IV orders (#2 and #4) should also be provided by the interface that feeds data to the MBCPC system. (See Section 6.7.1.3.3 *Products Requiring Manually Applied Bar Codes* for additional information and recommendations on the bar coding of these doses.)

Existing profile interfaces between PIS systems and automated dispensing systems usually exclude single-entity IV orders and any multiple-entity medication or IV orders. So, it is not safe to assume that the interface between your PIS and your automated dispensing systems will be enough to support an all-inclusive MBCPC system. Remember, a comprehensive MBCPC system is important to avoid having dual systems for medication administration and documentation.

Also, do not assume that the information systems department or the MBCPC vendor can easily access an existing profile interface to get order information. Although information systems may have more control of interfaces if an interface engine is in place, there is often a per-interface vendor cost for each and every interface. Consult with your information systems experts on this when planning your system, and be prepared to budget for a new profile interface between the PIS and MBCPC systems that supports all order types mentioned above.

5.4.1.4 Lab and Other Clinical Information

One of the apparent goals of MBCPC systems is to bring information to the nurse at the point of care. Obviously, having access to lab results and/or applying recent lab results to guide appropriate medication use at the point of care would have significant value. However, your project team may prefer to approach the MBCPC project in phases, with medication and IV verification of the 5-Rs along with allergy checking comprising phase I. Additional clinical features can be adopted later. For this reason, the sharing of lab and

other clinical information by the PIS system is likely not a minimum interface requirement for the initial implementation of a MBCPC system.

5.4.2 Data Flow from the MBCPC to the PIS System

5.4.2.1 Medication Administration Documentation

MBCPC systems are designed to do more than just scan medications to verify the 5-Rs at the point of administration. They are also designed to capture medication charting information (including IVs) and provide an electronic medication administration record (eMAR) based on the point of care medication scanning process. These systems generate printed MARs and "worksheets" for nurses designed to replace the MARs typically printed by the PIS. In effect, the MBCPC system's basic framework is designed to be a self-contained, electronic medication safety and documentation system.

It is possible for a MBCPC system to send back information on medication administration transactions to another eMAR system – perhaps the same system that handles order entry for pharmacy. The hospital project team should consider which eMAR option makes the most sense for medication documentation and data analysis in the long term.

5.4.3 Interface Testing

The purpose of this section is to outline the critical importance of interface testing, the conversion from a "testing" environment to a "live" environment, and the establishment of a plan for testing software or hardware upgrades.

To begin, know that the MBCPC vendor and the PIS vendor (or interface engine vendor) will need to collaborate on the establishment of the profile interface. Do not assume that just because your current automated distribution system has a profile interface you already have what you need. In fact, it is highly likely that the data content of the profile interface you have for your automated dispensing system is less complete than what your MBCPC system will require. There is typically an up-front cost and an ongoing maintenance cost to the hospital for each interface, so expect some additional expense. In fact, it is never too early to begin discussions with your PIS and MBCPC vendors regarding interface needs and costs. The interface between the PIS and MBCPC system should first be established on the "test side" of the PIS. This allows interface and process testing and fine tuning to take place without any risk of interfering with live patient data. Once the interface is installed and a test environment is established, thorough testing should be overseen by a person experienced in the interface testing process, preferably someone with a clinical background. This can be a consultant pharmacist provided by the MBCPC vendor, an independent consultant, or a staff pharmacist who is familiar with interface testing. The importance of thorough clinical testing cannot be overstated, and project timelines should never take precedence over validating the accuracy of the interface.

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. The information systems representative will need to admit several test patients to the ADT system to establish a base of test patients, and it should be verified that all patient demographics accurately cross the interface to both the PIS and MBCPC systems. The IS representative will later test transfers, discharges, and other ADT-related transactions used within the hospital. For example, transfers and discharges of patients with and without medications should be tested, and functions such as "readmit" (following discharge in error) should be tested if such a feature is available.

The hospital's pharmacist will need to assist by entering all typical types of medication and IV (LVP) orders and performing all the order management functions of the PIS, including order modifications, placing orders on hold and resuming them, deleting or discontinuing orders. Special order types, such as non-formulary meds, range dosing (e.g., 50-100 mg), multiple units per dose (e.g., two tablets), tapering orders, and the like, should be given special attention during testing. The hospital's nurse should make sure that the medication and IV orders appear correctly on the MBCPC system worksheets and MARs. The nurse should also verify that the expected functionality of the scanning device and MBCPC system in general is achieved. For example, the MBCPC system should appropriately associate ordered doses with due times and correctly document doses given, or not given as the case may be.

Pharmacy has traditionally developed tricks or shortcuts for PIS order entry. Even if the PIS system provided printed MARs for nursing in the past, these order entry habits may not have had an effect on nursing. However, with pharmacy order entry driving the MBCPC system, this is likely to change. As part of the testing process, pharmacy should identify potential order entry problems and define needed order entry process changes that will facilitate the MBCPC system's performance and nurses' use of the system. Getting the advice of your PIS customer support specialist may be helpful when looking for order entry methods, since there are sometimes useful PIS features that pharmacy doesn't use. New order entry rules should be formally documented as pharmacy departmental policy and incorporated into pharmacy training prior to MBCPC system go-live.

Experts recommend that, to test overall interface stability, the live interface should run for several days prior to using the MBCPC system live in a patient care area. The interface testing process should require a sign off of all involved parties – pharmacy, nursing, information systems, PIS vendor, and MBCPC vendor - before the interface is moved to the live PIS environment.

If the MBCPC system does not provide an ongoing, fully functional test environment separate from live data, the MBCPC vendor will need to delete all test data (patients, orders, and transactions) from the MBCPC system database. Maintaining such an ongoing MBCPC system testing environment allows the testing of PIS and/or MBCPC system software and hardware upgrades before applying them to the live patient environment. PIS vendors typically have a built-in test environment, but if your MBCPC vendor does not, it is reasonable for you to insist that a second system be installed and maintained for testing purposes at no additional charge.

There is no more important or more collaborative step in the MBCPC planning and installation process than interface testing.

5.4.4 Integration of MBCPC with Infusion Pumps

So-called *smart pumps* - infusion devices that do much more than just control infusion rates - are demonstrating that they have their own important role in preventing types of errors that a MBCPC system cannot address. These infusion devices allow the user to set clinical parameters for safe administration of IV medications, and they warn the caregiver if the IV drug or dose to be administered is outside of those acceptable parameters.

As of this writing, some infusion device vendors and MBCPC vendors are installing beta sites to test the integration of the functionality of *smart pumps* and MBCPC systems. Therefore, specific features and benefits of integrating or interfacing these products have yet to be

clearly defined and proven. Whether it is feasible for the MBCPC device to allow the caregiver to program an infusion device from its own user interface, or whether the infusion device can send alarms to the MBCPC device, are examples of concepts that will need to be validated. A key issue involving communication between these devices is that infusion devices are FDA-regulated medical devices, whereas MBCPC systems are not. In time, the functionality that the integration of these systems can provide will be better defined.

In the meantime, the MBCPC system you choose should, at a minimum, have the ability to verify that the right IV is being hung on the right patient when the patient wrist band and the bar code on the IV label are scanned.

Smart pumps and MBCPC systems both make important contributions in making the medication process safer for the patient.

6 Planning for the Bar Coded Medication Process

The decision to implement a bedside bar code medication-use system is often driven by a triggering event or an influential individual or group of individuals. Typically planning, justification, and administrative approval will be required to commit the appropriate institutional monetary and human resources. Contacting MBCPC vendors to arrange a sales presentation will take place during this process, but it probably isn't the best first step. This section will offer guidance that we believe will make you better prepared to contact vendors, present the project for approval, and eventually begin and manage the project.

6.1 Recommended Reading

The contributors recommend you review the references shown below before beginning the planning process.

6.1.1 Assessing Bedside Bar-Coding Readiness

The *Assessing Bedside Bar-Coding Readiness* tool was developed jointly in 2002 by the Institute for Safe Medication Practices (ISMP) and the American Hospital Association, Health Research and Educational Trust. It is one of their *Pathways for Medication Safety* tools. You can download this 54-page document free from the ISMP web site at <http://www.ismp.org/PDF/PathwaySection3.pdf>.

6.1.2 Practical Guide to Bar Coding for Patient Medication Safety

This article was published in the *American Journal of Health-System Pharmacy* on April 15, 2003 (pp. 768 – 779). ASHP members can download it in pdf form at <http://www.ashp.org/public/pubs/ajhp/showFile.cfm?cfid=112559&CFToken=61986905&id=1205&sd=1415>.

6.1.3 JCAHO 2004 National Patient Safety Goals

The Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) 2004 National Patient Safety Goals can be found at <http://www.jcaho.org/accredited+organizations/patient+safety/04+npsg/facts+about+the+04+npsg.htm>

6.2 Creating a Culture for Patient Safety and Awareness

Patient safety is at the forefront of health care organizations from the front line nurse and pharmacist to the hospital CEO. Healthcare today is a high-risk, complex, fast-paced and labor intensive business. These factors have undoubtedly contributed to rising medication error rates. Processes that have worked for many years simply are not safe enough for patients in today's hospital environment.

An error-reporting culture free of fear of reprisal from management and peers is a prerequisite to the foundation of a medication safety program. Such an environment can result in better reporting of errors, and the resulting information can be used to show the need for systems changes.

Organization-wide awareness of the root causes of medication errors can drive the allocation of funds and resources to make necessary changes in the medication-use process. Not only can an investment in process changes improve patient safety, but the investment has a business case as well. Surely, the financial costs to the hospital associated with serious medication errors, especially those that result in litigation, could exceed the cost of implementing new technologies and processes that could avoid such errors.

6.3 Assessing the Hospital's Readiness

Careful!! Adding more and more layers of automation without study, integration, and proper planning may get your MBCPC system off to a shaky start. Therefore, we recommend you begin by conducting a thorough review and assessment based on the current medication processes. This should be done as a basis for determining the best framework (including processes and automation) upon which to add the bedside bar code medication administration system. Keep in mind, the best framework may not necessarily be the current framework.

The best way to approach this is by reading and using the tool *Assessing Bedside Bar-Coding Readiness* which should provide guidance and a standardized approach to forming the Assessment Team and performing the readiness assessment. See Section 6.1.1 *Assessing Bedside Bar-Coding Readiness* for information on obtaining this document.

6.4 Forming Multidisciplinary Project Teams

Two key multidisciplinary teams will be the Assessment Team and the Oversight Team. A pharmacy and a nursing representative should serve as co-chairpersons of these teams to show that the project is equally led by both departments. Together they should schedule routine (e.g., weekly) meetings of the team with planned agendas. When necessary, meetings can be cancelled one day in advance or additional meetings can be scheduled.

6.4.1 The Assessment Team

The *Assessing Bedside Bar-Coding Readiness* tool begins with recommendations for determining Assessment Team membership. The Assessment Team will study and evaluate current medication process workflow and related procedures to determine their preparedness for the use of bar coding. The team should begin the assessment well in advance of MBCPC vendor involvement or implementation activities. Certain members of this team will likely become members of the bar coding Oversight Team that eventually steers the project, so be sure to select them with this in mind.

6.4.1.1.1 Medication Process Review

The Assessment Team should compile a thorough understanding of existing system design and flow for both nursing and pharmacy. To visualize this, the following system components should be depicted and described in multiple process flow charts:

- Medication systems components present in nursing areas, such as stationary medication carts, mobile medication carts, unit-based medication dispensing cabinets, controlled substance storage, IV storage areas, and bedside storage
- Nursing unit logistics, such as centralized medication rooms, pods, and decentralized cabinet location
- Medication systems components in pharmacy, such as robots, other automated dispensers, inventory receiving, repackaging machines, and admixture services

- The current pharmacy distribution processes, such as cart fill, supplemental fill (envelopes or baggies), cabinet replenishment, robotic system replenishment, admixed IV distribution, and delivery methods and times
- Nursing workflow for medication delivery and administration, including medication administration times, MAR print and delivery, witness requirements (e.g., insulin), and pre-bedside medication preparation (e.g., nursing IV admixture)
- Clinical decision support, such as patient care protocols, medication-related rules based on clinical lab values, and other care coordination issues

Keep in mind that current medication system components and processes may vary from one unit or department to another. Therefore, multiple views of system design and flow may be needed. This includes outpatient settings where the MBCPC system will be used to verify that the intended medication is the medication scanned and to record medication administration.

Once the existing medication process framework for the hospital is clearly understood, the various MBCPC system form factors for nursing, such as portable/hand-held devices, computers on wheels (COWs), computerized mobile carts, or bedside-based devices, can be better analyzed. Likewise, the need for changes in medication distribution, storage, access, and administration for each nursing area as well as related nursing workflow and pharmacy workflow in general will become clearer.

The outcome of this analysis should be revisited regularly as the project unfolds.

6.4.2 The Oversight Team

The Oversight Team will include a sub-set of members from the Assessment Team. Having gone through the assessment process, these leaders will already have an appreciation for some of the challenges ahead. The Oversight team will be the agents of change related to the BCMP and, therefore, should consist of individuals who are reliable, responsible, and respected members of their departments. The permanent members of the Oversight Team should minimally include decision-makers from each of the following departments:

- Pharmacy (co-chair)
- Nursing Practice (co-chair)
- Information Systems
- Nursing Education
- Department of Medicine
- Quality Management

In addition, a representative of the following should be assigned as permanent or ad hoc team members as required:

- Respiratory Therapy
- MBCPC vendor
- Purchasing/Materials Management
- Central Supply (if distributing IVs)

The total number of persons on the Oversight Team should be kept to a reasonable number (e.g., maximum of 6-8). Therefore, consider forming smaller teams (see Section 6.4.3 Action Teams) to address specific pieces 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 areas.² 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 who is responsible for team tasks and deadlines. Examples of potential action teams are:

- Bar coding team
 - Identify purchasing changes to procure products already bar coded
 - Assess and make recommendations for onsite packaging equipment needs
 - Assess the potential need for bar codes on PIS labels
 - Ensure processes that result in bar coding of all medications dispensed
- Pharmacy policy and procedure team
 - Assist with system testing
 - Identify needed order entry practice changes to best support passing, scanning, and documenting of bar coded medications
 - Draft new or revised policies and procedures
- Employee and patient identification team (include representatives from Admissions and Human Resources)
 - Determine whether existing bar codes (if any) on employee badges can be used; if necessary, explore methods and make recommendations for bar coding employee badges
 - Identify hospital areas where patient wrist bands are currently applied
 - Identify options and make recommendations for a system of standardized bar coded wrist bands
- Wireless network team
 - Identify wireless/network availability in all areas that need to be serviced by the system, including patient care areas, pharmacy, and training rooms
 - Test signal strength in these areas and make recommendations for network enhancements
- Interface team
 - Plan, implement, and test interfaces for ADT and all medication/IV orders
 - Propose downtime and other technical support policies
- Nursing education team
 - Serve as the hospital's nursing experts
 - Plan and conduct nursing user training, including new hires
- Implementation team
 - Participate in support coverage during evaluation period
 - Plan, schedule, and provide support for roll out
- System evaluation team
 - Collect or gather pre-implementation data on workflow and medication errors
 - Develop and maintain post-implementation project assessment plan (see Section 6.7.9 System Evaluation for more information)
- Purchasing and/or accounting team
 - Provide support for a program cost analysis
 - Assist with development of vendor request for proposal (RFP) and contract
 - Support other teams by identifying sources for materials and disposables, such as labels, packaging film, and wrist bands
- Public relations team
 - Investigate the public relations opportunities of implementing a patient safety system
 - Prepare a press release for release at the end of the evaluation period
 - Prepare the hospital for possible media interest

Assign special action teams to participate when required to identify special challenges or needs and to help implement for their specific areas. Nursing educators often make ideal participants on these teams. Special action teams may include:

- Pediatrics, Neonatal Intensive Care, Labor and Delivery team
- Emergency Department team
- Intensive Care and Cardiac Care team
- Post-Anesthesia Care team
- Respiratory Therapy team

6.5 Pre and Post-Implementation Data Collection

Data related to medication errors and the process for collecting that data before and after system implementation should be identified. Such data should begin with measurement of *errors* and *near errors* based on the 5-Rs – right drug, right dose, right route, right time, right patient. This data will be the basis of quality assurance measurement to indicate how the system is affecting medication safety.

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

6.6 Process for Evaluating and Selecting Vendors

Based upon the operational framework analysis - and especially its resulting understanding of nursing workflow - the Oversight Team should be able to identify potential MBCPC vendors. Key components of the vendor selection process include:

6.6.1 Identifying Acceptable Vendors

6.6.1.1 Vendor Presentations

Potential vendors identified should be invited to present to the Oversight Team. For best results, the Oversight Team should provide each vendor with a brief list of required points to cover during the presentation. Examples may include:

- Company history and demographics (location, number of employees, etc.)
- Overview of pharmacy system components, including formulary database setup and maintenance as well as bar coding capabilities
- Overview of nursing system features and components, including such issues as
 - workflow related to the basic check for the 5-Rs
 - allergy checking
 - electronic documentation features (MAR and other available tools)
 - alerts, such as those that warn if package content differs from ordered dose
 - prompts for collecting clinical data at the time of administration
 - method for alerting the user that the interface is down or behind and patient or order information at the point of care may not be current

- a feature for retroactively associating first doses given by the nurse prior to order entry with the proper order after order entry has occurred
- experience with product integration and interfacing with other systems, including the ability to interface to an existing electronic MAR (if applicable)
- Description of install and ongoing support services and resources
- Hospital network (e.g., wireless) analysis, needs, and estimated costs
- Explanation of how equipment needs are determined, including equipment that is expected to be provided by the hospital (PCs, printers, etc.)
- Number of current installations and references (house-wide and in-progress)
- Recent publications and presentations by successful users
- Description of the service/support program, such as for the replacement of failed hardware
- High-level overview of system costs (purchase vs. lease), including ongoing support costs, included updates vs. upgrades, and hardware replacement costs
- Corporate relationships or agreements that may restrict or limit the hospital's use of another vendor's product (e.g., smart IV pumps)
- Other hospital-specific questions

The allotted time for each presentation should be pre-defined. Two hours per vendor should be more than adequate. It is recommended that presentations be done in close proximity, such as within one week, so that attendees have the information fresh in mind. The team should also consider inviting several prospective pharmacy and nursing end users as well as key decision makers, such as the chief administrator, administrator for clinical services, and chief financial officer, to these presentations.

6.6.1.2 Feature and Functionality Considerations

It is not possible here to provide a detailed list of all features a MBCPC system may provide. These systems are also young in comparison to other automated systems for medications, and their feature sets will surely expand rapidly in the future as more use and customer feedback is obtained. However, there are some recommended core capabilities that a MBCPC system should possess. These include (but are not limited to) the ability to:

- Read the standard linear bar codes types (described in Section 5.1.1.1 *Linear (1-D) Bar Codes*)
- Be upgradeable to read 2D and RSS bar codes (if not already capable)
- Communicate via the hospital network (cabled and wireless)
- Support WPA security (see Section 5.2.3.3 *Advanced Security Mechanisms*) or the minimum security protocol required by your information systems department
- Interface to your PIS and support all types of medication orders including continuous IVs
- Provide features for efficiently managing inventory bar codes and the pharmacy formulary database
- Support interchange of generically equivalent items
- Provide an electronic MAR for medications and IVs (use is optional)
- Interface to another vendor's eMAR and to the hospital's billing system (if required)
- Perform real-time checks for the 5-Rs and for allergies at the time of administration
- Perform clinical checks (interactions, appropriate dose, etc.) deemed necessary by the Oversight Team
- When a discontinued medication is scanned, notify the nurse "Order Discontinued" rather than "Order Not Found" to avoid giving a discontinued medication
- Show interface status (interface down or behind) to notify users when patient and order data may not be current

- Alert the nurse if package content differs from ordered dose and capture the actual amount administered
- Prompts for collecting clinical data (e.g., pulse, blood pressure, etc.) at the time of administration
- Allow the nurse to retroactively associate first doses given prior to order entry with the proper order after order entry has occurred
- Capture data on medication administration process activities, including medication errors averted by the use of the system, and provide reports on these activities that are useful in analyzing the points and potential causes of error
- Be serviceable remotely by the vendor

There are certain additional characteristics of the product or the vendor that merit a special mention, and these are described below.

6.6.1.2.1 Product Form Factors

Already in the initial stages of MBCPC evolution we have seen a few different form factors for MBCPC scanning devices that communicate wirelessly to the system server. Examples include a laptop computer on wheels (COW) with a tethered scanner, a portable handheld device with built-in scanner, and a stationary bedside computer with tethered scanner (possibly with hard-wired network access). There are nursing advantages and disadvantages to each form factor that will vary from hospital to hospital, and potentially from patient care area to patient care area. The process review described in Section 6.4.1.1.1 Medication Process Review should be used as a guide when considering which form factors are suitable for consideration based on the hospital's physical layout and nursing workflow.

6.6.1.2.2 Vendor Experience

There are several MBCPC vendors currently in the marketplace, and it would not be surprising for more to surface considering the potential of this market. So, a key consideration is whether you will consider a vendor with less experience and few if any installations, or if you only consider those vendors that have more experience in the MBCPC market and have a larger number of installations.

A good approach is to determine the product and service satisfaction levels of a vendor's existing or past customers. (Despite the fact that MBCPC is a comparatively young market, cases of de-installation of MBCPC systems and vendor switching have already occurred.) The vendor should be able to provide a reference list of all installed sites, and you should choose the ones you wish to contact. Ask existing customers whether they are house-wide or in pilot and, if so, why and for how long. Also, ask about de-installed sites they may be aware of and contact those sites for their feedback on why the de-installation occurred. (There may be good reasons unrelated to the vendor's product, but then again you may learn of issues that will help you more effectively navigate the vendor selection process.) By checking several references, you should be able to tell whether the vendor's experience is of benefit, or whether their products and/or services are still in an early development mode.

For newer vendors with less experience and minimal installs, ask for detailed information on the company's leaders, including their clinical and engineering leadership. Past experience with pharmacy automation, eMAR systems, and interfacing (patient profile and electronic charting) should raise your level of confidence when considering new players in the market.

6.6.1.2.3 *The Importance of a Test Environment*

A critical but sometimes overlooked issue related to any medication use process automation is the ability of the vendor to provide a permanent test environment for their system. Test environments are commonplace on PIS systems; yet, pharmacy automation vendors have been slow to provide built-in test environments for their systems.

The availability of a MBCPC test system that interfaces to the PIS test environment should be a requirement and should be stated as such in the RFP. If necessary, the vendor should be required to install a duplicate system and corresponding interface(s) to connect to the PIS test system for ongoing problem solving and testing of new software/hardware releases. Changes to MBCPC system software, firmware, interfaces, or hardware should first be applied to the test system and thoroughly tested by a special action team (see Section 6.4.3 Action Teams) before being implemented in the live environment. The testing process should be documented and the team should sign off before changes are applied to the live system.

In addition, changes to the PIS system that have the potential to impact the MBCPC system should be similarly tested.

6.6.1.3 Site Visits and/or Corporate Visits

The use of site visits to hospitals utilizing a specific vendor's products or visits to the vendor's corporate headquarters can be an informative and important step in the vendor selection process. Visits to hospitals provide better input on user acceptance and system reliability, while corporate visits often allow for hands-on experience with the system in consideration. In some cases, a phone call with nursing and pharmacy contacts that are using the vendor's system can provide more and better information than a vendor-driven site visit.

The time required for the Oversight Team (or its designees) to make these visits should be considered along with the potential advantage of seeing the vendor's system in operation. The ASHP Annual and Mid-Year meetings as well as national nursing meetings such as the American Organization of Nurse Executives (AONE) are also good opportunities for demonstration and hands-on exposure to new products.

Use the approach described in Section 6.6.1.2.2 *Vendor Experience* to gather reference information from a vendor's customers early in the vendor qualification process. Consider site visits as one of the later steps after the list of potential vendors has been narrowed.

6.6.2 **The Request for Proposal (RFP)**

An example RFP is provided in Attachment 3B of the *Assessing Bedside Bar-Coding Readiness* tool (see Section 6.1.1 Assessing Bedside Bar-Coding Readiness).

The following are some important considerations for inclusion in your RFP.

6.6.2.1 System Evaluation Period

Unlike many other automated systems involved in the medication process, MBCPC systems are relatively new. In addition, these systems impact the nursing user more than other automated systems. Although it is important to have a high level of confidence in the vendor selected, an agreed-upon evaluation period might be a good way to start. In turn, if

the vendor has confidence in its products and support, agreeing to an evaluation period should not be an issue.

6.6.2.2 Performance Expectations

The Oversight Team should establish system performance expectations and get sign-off by both the prospective vendor(s) and team members before final vendor selection takes place. These performance standards should relate to system reliability (downtime), customer support, and technical support during the implementation and evaluation phases. Examples* of such standards might include:

- A measure of acceptable MBCPC system downtime, including interfaces, between the 7th day after initial implementation and a future day (e.g., 30th) after implementation, which allows for an initial period of rapid problem-solving when the first unit(s) goes live
- A measure of acceptable hardware failure per time period (e.g., 60 days)
- A nursing satisfaction survey at the 30-day point with an acceptable score
- Ability to read all commercial bar codes

* Examples are not intended to represent industry standards

6.6.2.3 Training and Go-Live Support

Expectations for vendor support during and immediately after implementation should be clearly defined. For example, the vendor might be asked to:

- Participate in all initial user training sessions (nursing, pharmacy, and other)
- Provide 24 hour on site vendor support for the first two consecutive days during which the system is stable and there is no downtime
- Provide 12 hour on site support for the first three days each unit goes live

6.6.2.4 Customer Support

It is recommended that the RFP ask for detailed information on the vendor's customer support services, including but not limited to:

- Onsite support during installation, testing, training and roll out, including a description and number of personnel provided by the vendor, their backgrounds, responsibilities, and roles; request a description of coverage during implementation and rollout, including nights, weekends, and holidays
- Company-based customer support, including user help via phone and email, as well as remote technical support
- User guides and other training and reference tools, including the frequency and method of update
- The update process for software/firmware/hardware fixes and related responsibilities (vendor and hospital)
- A description of the vendor's escalation process for support issues

6.6.2.5 Initial and Ongoing Operating Costs

The RFP should request complete itemized description of all costs, initial and ongoing, such as costs related to:

- The initial system installation
- Interfaces (if not included in #1)
- Hardware
- Networking/wireless installations or improvements

- Shipping and delivery
- Ongoing support fees and database management fees
- Packaging or labeling equipment that can be part of the system purchase
- Consumables (toner, labels, etc.)
- Future upgrade costs (hardware and software)

The terms and conditions for payment should be provided, including a description of the circumstances that determine when billing begins for each phase of the project.

The Oversight Team should use this information to prepare a financial analysis for each vendor under consideration. Indirect cost of supporting the system, such as the cost of repackaging and bar coding medications, may vary for each vendor's system and should be included in each vendor's cost analysis.

6.6.2.6 Ancillary or Contracted Resources

Off-site bar coding services may include packaging and bar coding provided by a licensed re-packager that may or may not be affiliated with the MBCPC vendor or your wholesaler. On the other hand, on-site programs involve offsetting the internal hospital cost by:

- Reducing price or reimbursing the hospital for pharmacy labor dedicated to bar coding
- Providing contract labor (not hospital employed) to do bar coding under the direction of the hospital pharmacy

The RFP should request information on available on-site and off-site programs for repackaging and/or bar coding medications. It will then be possible to compare the cost of these programs to your own estimated cost of additional resources.

6.6.2.7 Choosing a Vendor

Do not lose sight of some basic criteria when narrowing down your list of prospective vendors. Ask yourself these questions before making a decision:

- Does the system meet our minimal requirement (e.g., checking for the 5-Rs and potential allergies)?
- Is the product form factor for the nurse suitable to your nursing care model?
- Is the system simple for nurses to use and, therefore, easy for new users to learn?
- Does the system provide the flexibility nurses need when delivering patient care?
- Does the system support the use of user-friendly medication packaging?
- Does the system enhance the overall medication distribution process?
- Are pharmacy labor requirements reasonable in comparison to the requirements of other systems?
- Can choosing this system keep ongoing costs down and safety benefits up?
- What is the system's reporting capability, and how are the reports used to manage the system and identify potential points of error?

6.7 Pharmacy Planning Considerations

6.7.1 Getting Bar Codes on All Products

This chapter will discuss various approaches for pharmacy to get bar codes on all medications.

6.7.1.1 Commercial Bar Codes

On February 26, 2004, the FDA published its final regulation requiring manufacturers to bar code all medication packages with a linear bar code containing the product NDC number. Newly released products must comply within 60 days of the drug's approval date, while products approved prior to February 26, 2004 need to comply within two years.³

Our hope is that manufacturers will continue to make their drugs available in unit of use packaging, which will help to reduce the amount of repackaging and bar coding necessary in the pharmacy. However, it is safe to assume that repackaging and bar coding on site will always be a part of the pharmacy process for a bar coded medication safety program.

The group purchasing organization (GPO) in which your hospital participates may have already made bar coding a requirement for vendor qualification. However, situations may arise in which a preferred supplier on contract is not providing bar codes that an off-contract supplier of the same generic product could provide. In such cases, you will need to decide whether to repackage and/or bar code the contract brand or purchase off contract until the preferred supplier provides bar codes. In making this decision, consider the differences in product cost, labor, and packaging materials, as well as the importance of supporting your GPO contract.

Check with your GPO for more information on the vendor qualification policy related to bar coding.

6.7.1.2 Contract Re-packagers

Third-party services are available to repackage and bar code products for you. Your wholesaler can provide information on the options available to you through them or an affiliated company. Typically, inventory purchased by the pharmacy is first shipped to a repackaging center, packaged and labeled with bar codes, then shipped to the pharmacy.

These services provide another option for getting bar codes on products. However, be sure to consider the following:

- The price - The cost per dose has been known to be up to 12 cents per dose, so be sure to evaluate this 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? Is it compatible with your distribution system? Will it be user friendly and acceptable to nurses?
- The scope – Consider whether this service may have benefit for select items or all items needing bar codes.

6.7.1.3 Pharmacy On-site Repackaging and Bar Coding

Since many drugs are not commercially available in a unit dose package with a bar code, and since outsourcing your repackaging may be costly, repackaging or manually labeling products with bar codes will probably be an important part of a bar coded medication system. The additional pharmacy resources needed for these processes may vary depending on the pharmacy's current bar coding practices. For example, a pharmacy already bar coding medications for an automated dispensing system that uses bar coding is likely to require less bar coding than a similar pharmacy without such a system.

When choosing repackaging approaches, Pharmacy should consider whether changes in package sizes will impact the storage capacity of decentralized dispensing cabinets. For example, a change that results in reducing the capacity of a key item may necessitate more frequent replenishment of that item and therefore more labor.

In setting up the MBCPC system, the pharmacist will need to decide what unique product identifier will be embedded in the bar code for repackaged products. Decisions on label materials, software, and hardware for these processes are needed early on. The following sections will discuss the use of bar code enabled on-site repackaging systems as well as manual bar coding of drugs that do not require repackaging.

6.7.1.3.1 Oral Solids and Liquids

6.7.1.3.1.1 Manual (Non-Automated) Repackaging

Manual repackaging is the simplest of the oral solid and liquid packaging options. Software provided for use with manual packaging systems should be capable of printing bar codes (be sure to check this with the vendor). Manual systems do not involve the equipment expense of more sophisticated, automated repackaging systems. They have potential application as the first-line oral solid repackaging system or as a supplemental system for low volume packaging needs, such as for specially obtained non-formulary medications.

The **oral solid** packaging process typically involves the use of a sheet of unit dose blisters, a base tray in which the blisters lie during the filling and labeling process, sheets of printable adhesive labels, and a simple software program for designing and printing the labels. The user creates the label template in the software by entering information on the drug to be packaged, including drug description, lot and/or batch number, expiration date of the repackaged dose, and unique product identification number (NDC or hospital 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 sheets, and then places the labels with adhesive side down over the blisters containing the medication. In some cases a roller or similar device is used to uniformly apply pressure to the labels to insure they are fully adhered to the blisters.

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

Although some high-quality inkjet printers can print a bar code of good quality, a 600 dot per inch (dpi) laser printer is recommended for printing high quality bar code symbols.

The type of bar code to be used may be configurable. See Section 5.1 *Understanding Bar Codes* for more information and bar coding tips.

Suppliers of manual repackaging systems for oral solids and liquids include:

- Healthcare Logistics, Circleville, OH (www.hcl-intl.com/mall)
- Medi-Dose/EPS, Inc., Warwick, PA (www.medi-dose.com/catalog/unitdose)

6.7.1.3.1.2 Automated Tabletop Repackaging Systems

Automated tabletop systems for **oral solids** can be much more efficient than manual packaging systems, especially when repackaging larger volumes of doses. These systems also provide a higher quality (Class B or better) package than manual packaging systems. Most hospital pharmacies, large or small, will probably want to minimally employ an automated system such as a tabletop packager for repackaging and bar coding.

Tabletop systems are software driven and keep a log of packaging activities. These systems allow the user to freely assign the date within the bar code and to choose from one or more supported bar code types.

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 bar code. The other film is typically clear, allowing for visual examination of the package content. The films are heat sealed and the strip is perforated to allow separation of individual packages.

Suppliers of tabletop repackaging systems for **oral solids** include:

- Euclid Spiral Paper Tube, Inc., Apple Creek OH (www.euclidspiral.com/medical/euclidspiralmedical-cadet.html)
- Medical Packaging, Inc., Ringoes, NJ (www.medpak.com/mpj/fluidose.htm)
- AutoMed, Vernon Hills, IL (www.automed.com)

Automated tabletop systems for **oral liquids** can be much more efficient than manual packaging systems, especially when repackaging larger volumes of doses. These systems also provide a higher quality (Class B or better) package than manual packaging systems. Most hospital pharmacies, large or small, will probably want to minimally employ an automated system, such as a tabletop packager for repackaging and bar coding.

6.7.1.3.1.3 Interfaced Automated Repackaging Systems

Repackaging systems for oral solids exist that are much more sophisticated than tabletop models. These systems can package and label, including bar codes, based on an interface with the PIS system, centralized dispensing system, and/or decentralized cabinet system. Some, such as McKesson's Standard Bulk Packager for ROBOT-Rx™ and Pyxis' iPAK™II for Homerus™, produce packages designed specifically for their complementary automated centralized dispensing system. Others, like AutoMed's FDS, can package and dispense patient-specific strips of oral solids based on patients' current orders to support a manual cart fill process, or package and dispense many doses of the same medication to support decentralized cabinet replenishment.

These systems are faster, larger, and of course more costly than tabletop packaging systems. However, depending on the hospital's overall pharmacy automation plan, this type of system may be the best choice for optimal system integration and efficiency.

6.7.1.3.2 *Printing Bar Codes to Be Manually Applied*

Your Pharmacy Information System or selected MBCPC system may have the ability to print bar code labels for manual application onto products that do not have commercial bar codes. If not, there are some very simple ways to print bar codes for manual application without incurring significant expense.

The four things to consider when selecting a system for manually printing bar codes are:

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

6.7.1.3.2.1 *What data goes in a manually applied bar code?*

As of this writing, repackaging systems on the market only support the use of a single linear bar code. Therefore, lot and expiration information cannot be included. In the future, it is anticipated that these systems will support Composite RSS symbology or other new symbologies that will allow inclusion of lot and expiration in a relatively small symbol.

Printed bar code labels will need to be manually applied to some very small products, such as mini-vials and ampoules. These products have little space available for a bar code. Therefore, you will need the ability to print very small bar code labels.

To keep the bar code small, a short scan code (the identifier within the bar code) should be used. As shown in the example below using bar code type Interleave 2 of 5, a pharmacy billing code of 6 characters will generate a bar code almost one-half as long as a 10-digit NDC bar code.



If Code 128 is used for an alpha-numeric medication identifier (mnemonic), the bar code roughly compares in size to the same NDC bar code:



As long as these short identifiers are unique to a single formulary item and are entered into the MBCPC system medication database as the *scan code* for the bar code, the scanned medication can be accurately identified. Until drug manufacturers begin to bar code more unit dose products, or until it becomes practical to print RSS bar codes yourself, this may be a good approach for keeping extemporaneous bar codes small.

6.7.1.3.2.2 What type label paper can be used for manually applied labels?

When selecting a bar code label printing approach, be sure to consider the ability of the supplier's label and adhesive to withstand moisture, refrigeration, and freezing. A standard label paper, such as that used for mailing labels, may not be moisture resistant and permanent enough for pharmacy use.

Whatever your approach, be sure you can get labels with an acceptable adhesive. There are several vendors of pharmacy-grade label stock that are now making various sizes of labels for bar coding medications, including the very small labels described in Section 6.7.1.3.2.1 *What data goes in a manually applied bar code?* These include:

- Healthcare Logistics (rolls) (www.hcl-intl.com/mall)
- MeddaLabel, Dallas, TX (www.meddalabel.com)
- The Relizon Company, Dayton, OH (www.relizon.com/PrintSolutions.cfm?ID=2165)

6.7.1.3.2.3 What software can be used to print manually applied bar code labels?

Depending on the format of the label stock – sheets or rolls – select software and/or hardware for printing the labels and storing templates for each medication.

- Printing Sheets (e.g., 8½x11):
 - Use an off-the-shelf MS Windows® bar code font package to print bar code labels from standard Windows applications like Word and Excel, available from several online bar code and scanning equipment suppliers and some local electronics stores. Sheets of label paper can provide a few dozen to a few hundred bar code labels, depending on the individual label size. Both laser printers and inkjet printer deliver good quality bar codes, but tests show that inkjet bar code labels are less moisture resistant and have a tendency to smear. When printing sheets of bar code labels, create alphabetical file folders to store extra labels and reprint when needed.
 - Purchase an inexpensive bar code software printing program, like Wasp Technologies' Labeler V5 (List \$125.00 – supports all basic linear bar code types) or Bartender® by Seagull Scientific (List \$245.00 – also supports 2D and RSS symbology), to print on sheets of label stock.
- Printing Rolls:
 - Local office supply stores typically carry simple, inexpensive label printing machines. Some, such as certain Dymo® models, are capable of printing bar codes on the labels they produce.
 - More sophisticated label printers are available from well-known companies such as Zebra®. These are more expensive than the other options mentioned above but provide a print-on-demand approach for only the quantity of bar code labels desired.

6.7.1.3.3 Products Requiring Manually Applied Bar Codes

6.7.1.3.3.1 Multidose Containers

Although many multidose containers, such as inhalers, topicals, and ophthalmics, come in an outer box or package that is bar coded, keep in mind that this outer package will often be discarded the first time the product is used. Therefore, plan to manually apply bar codes on inner packages for certain multidose products. When determining bar code location, get nursing input to be sure that the bar code is applied in an easily accessible place. For example:

- Many collapsible cream and ointment tubes now have commercial bar codes on the tube itself. Although scanning the commercial bar code may pose some inconvenience if/when these tubes collapse, commercial bar codes may be preferable to manually applied bar codes over the use-life of the product.
- Some inhalant canisters are bar coded, but the bar code may not be accessible for scanning once inserted into the mouthpiece.

6.7.1.3.3.2 Vials, Ampoules, and Respiratory Medications

Until items with a small label surface, like many small (Dosette™) vials, ampoules, and single dose respiratory medications, are bar coded by the manufacturer, they will require manual bar coding by pharmacy. Their unique bar code should contain as few digits as possible, so consider using the hospital identifier (Interleave 2 of 5 bar code) or mnemonic (Code 128 bar code) rather than the NDC in the bar code.

6.7.1.3.3.3 Large Volume IV Solutions

Unlike medication bar codes made up of black and white bars, current bar codes on flexible IV solution containers may be made up of black or blue bars separated by nearly transparent bars. Experience has shown that these bar codes can be difficult for a scanner to read. IV solution manufacturers are aware of this problem and have been talking steps to correct it.

In the interim, test the readability of your IV vendor's flexible container bar codes by using the actual scanner that will be used at the bedside. Scan several containers of various sizes. If the bar code does not read on the first scan at least 90% of the time, manually bar coding these IV solutions should be considered.

If IV solutions are distributed by a department other than pharmacy, such as central supply, it is recommended that pharmacy own and oversee the process of manually affixing a bar code to every container or outer wrap. The quality control measures described in section 6.7.4 Quality Control should be applied to this process.

Manually applied bar code labels or patient-specific bar coded labels generated by the Pharmacy Information System should be applied over the commercial bar code on the IV solution container.

6.7.1.3.4 Patient-Specific Doses, Admixed IVs, and Non-Formulary Medications

One of the biggest challenges in bar coding the medication process is effectively bar coding patient-specific medications. These include:

- A drug or admixture prepared in exact dose or volume to fulfill a specific patient order
- A prepared dose made up of multiple drug line items, such as an admixed IV or oral liquid admixture
- A non-formulary medication that is not part of the PIS and MBCPC system medication data file
- A patient's own medication that is authorized to be used while an inpatient

These patient and order-specific doses cannot be adequately identified using a medication-specific bar code. 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 or considered, and each has its own positive and negative characteristics.

- Bar code contains the **PIS order number** – This approach allows the MBCPC system to match the scanned dose with the PIS order which it is intended to fulfill. Therefore, although accomplishing the goal indirectly, this method can be effective in verifying the 5-Rs when the dose is scanned at the bedside. This method succeeds if PIS order numbers never overlap with other bar code identifiers in use, such as the NDC number, hospital formulary identifier, or hospital billing code.

However, if the PIS system generates a new order number when a medication schedule is changed or when the medication is discontinued and reordered when the patient returns from surgery, this bar coding approach would require that medications dispensed be bar coded again with the new order number. Unfortunately, the process of changing the bar code on an already dispensed dose may be impractical or impossible in some practice settings.

- Bar code contains the **patient identifier and the PIS order number** separated by a delimiting character – This approach allows the MBCPC system to match the scanned dose with the patient and PIS order which it is intended to fulfill. However, unlike the above method, this method is effective even if PIS order numbers overlap with other bar code identifiers. However, like the method above that is also based on the order number, this bar coding approach would require that already dispensed medications be bar coded again with the new order number.
- Bar code contains **patient identifier, medication identifier, and dose**, each separated by a delimiting character - This approach would allow the MBCPC system to match the 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 when the patient returns from surgery, 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 bar code when all three data elements for a single entity order are included. It would also be difficult to implement for a multiple-component order.

The pharmacy should weigh the pros and cons of each of the above approaches and should work with the MBCPC vendor to design the bar coding approach and related procedures to support accurate scanning of patient-specific doses.

Other important considerations related to these approaches are:

- Investigate having your PIS system provide a bar code on labels for patient-specific medications and IVs with the bar code containing the desired elements. This would eliminate the additional work of creating bar codes manually for these items.
 - Check with your information systems department and, if necessary, your PIS vendor for help with order number bar codes.
 - If your PIS system uses product or order categories, inquire whether the desired type of patient-specific bar code can print on PIS labels based on order type or category. Avoid having the PIS system print a bar code when a bar code on the dispensed medication exists. This will ensure that the caregiver sees only one bar code to scan and is not confused by having bar codes on all PIS labels.
- In all cases, the medication contents of the bar coded package or container must still appear in text-readable format.

6.7.1.3.5 *Special Situations for Packaging and Order Entry*

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

6.7.1.3.5.1 *Partial Doses*

The following are two ways to handle medications that are ordered in half tablet doses:

1. Assign a hospital identifier to the half tablet item and enter it into the PIS and MBCPC system as a new line item. Use this line item to order half tablet doses in the PIS. To bar code the half tablet, break the tablets into halves and package them as half tablet per package. Use the hospital identifier for the bar code.
2. Order the medication in the PIS system using the line item for the full tablet and enter the dose amount of half tablet. Then, set up the MBCPC system to notify the nurse that the tablet must be broken in half to achieve the prescribed dose.

Both options have their pros and cons. The first option is more labor intensive for the pharmacy; however it is more in keeping with the concept of unit dose dispensing. It also provides little chance of medication error due to confusion over the half tablet dose. This approach may work well for items used frequently in half tablet doses, but becomes difficult when an unanticipated order for a half tablet dose occurs.

The second option assumes that the PIS and the MBCPC system have the needed features to support the half tablet ordering and the notification to the nurse respectively. This method places the responsibility of breaking the tablet onto the nurse and relies on that person to follow the MBCPC 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 a step in the direction of accuracy and safety. If at all possible, one standard approach to handling half tablet doses should be established. The project team should give careful consideration to the above options in conjunction with the feature sets of the PIS system to decide on the best approach.

6.7.1.3.5.2 *Insulin and Other Pre-prepared Medications*

The less medication preparation (e.g., pouring and drawing up doses) that occurs before going to the bedside, the better and safer the bar coded medication administration process will be. In fact, to best support this process, pharmacy should unit dose and bar code 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 the prime example. It is common for insulin doses to be drawn up in the medication room rather than at the bedside, because best practice dictates that the measured dose should be witnessed by another nurse and so documented.

There are no perfect answers to this issue other than to recommend that witnessing be continued and patient safety take priority over workflow and convenience. Perhaps the best choice is to draw and witness the insulin dose at the bedside just before administration. Or, perhaps the MBCPC system you choose will have a feature to accommodate pre-preparation of these doses. In any event, this issue is an important consideration for the project team and should be raised early in the planning process.

6.7.1.3.5.3 Investigational Drugs

Depending on the type of hospital, the scanning of investigational drugs at the bedside may be a key component of your bar coded medication process. Even if investigational drugs are only used occasionally, establishing a bar coded method for handling them is an important issue to be considered by the project team.

To facilitate proper tracking and documentation of investigational drugs as well as medication safety, the following are recommended:

- Unit dose and bar code all investigational doses when possible.
- Assign a unique line item and hospital identifier to each available strength or size of the investigational drug in both the PIS and MBCPC system medication database. If half tablet doses are required, assign a unique line item for half tablets and follow Option 1 in Section 6.7.1.3.5.1 *Partial Doses* above.
- Prepare patient-specific measured doses when necessary and use the order number in the bar code as described in Section 6.7.1.3.3 *Products Requiring Manually Applied Bar Codes*.
- Continue to fully follow the established investigation protocol. Add bar coding and safety steps to the investigation process without jeopardizing the protocol.

6.7.2 Space Considerations

The implementation of a MBCPC system may have some implications relating to space in the pharmacy. You may wish to plan floor or counter space for the following if you do not already have these in place:

- Bar code enabled oral solid repackaging system (tabletop or floor model)
- Bar code enabled liquid repackaging system (tabletop)
- Work areas for oral solid and/or liquid repackaging
- File space, such as for storing pre-printed bar code labels for manual application
- Work area for applying and checking manually applied bar codes
- Space for the MBCPC pharmacy workstation
- Work area for scanning commercial bar codes upon receipt of orders (see Section 6.7.5 *Medication Database Management* for more information)

6.7.3 Staffing Considerations

Preparing the pharmacy for a MBCPC system will require a significant investment of pharmacy staff time. This will include medication database preparation, inventory and purchasing changes, repackaging and/or bar coding of medications, development of standard bar coding and order entry procedures, and training. One 360-bed hospital recently reported that 600 hours of staff time were required for this process.⁴ 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 the MBCPC system for medications used will eliminate current billing and crediting tasks.⁵

Decisions relating to the use of pharmacy staff are critical to the overall success of the implementation and ongoing management of a MBCPC system and should be incorporated into the redesign of pharmacy workflow. Some important considerations with regard to pharmacy staffing categories are:

- Pharmacy technicians will ordinarily handle purchasing, repackaging, and bar coding functions. If technicians are used in the order entry process, they should be included in redesigning the order entry workflow and trained in process changes.
- Staff pharmacists will be responsible for consistent - and in some cases *new* - order entry practices and other activities such as bar coding quality assurance (checking of repackaging and manually applied bar codes) and bar coding of exceptions (e.g., patient-specific doses, non-formulary medications, and patient's own medications).
- Unit-based clinical and satellite pharmacists can be trained to be a resource for managing and facilitating medication scheduling changes.
- A pharmacy-based nurse dedicated to the program can be a significant asset. This position can serve as a formal liaison between the departments to exemplify the shared ownership of the program. The nurse would help both pharmacy and nursing with work flow and process issues, troubleshoot procedural problems, monitor eMAR documentation, focus on maximizing system benefit, and be responsible for data compilation and analysis for reporting on the system's impact on medication error prevention.

Based on averages obtained in a survey of three general hospitals ranging from 360 to 685 licensed beds, formulas for predicting additional pharmacy staffing needs to support a MBCPC system are.

- Based on licensed beds:
 - Technician time: 0.0029 FTE x number of licensed beds
 - Pharmacist time: 0.0008 FTE x number of licensed beds
- Based on average occupied beds:
 - Technician time: 0.0038 FTE x number of occupied beds
 - Pharmacist time: 0.0011 FTE x number of occupied beds

For example, a hospital of 500 licensed beds might require about 1.5 FTE of technician and 0.5 FTE of pharmacist time.

On the other hand, one pediatric hospital that prepares and bar codes many more patient-specific doses reported the following needs:

- Based on licensed beds:
 - Technician time: 0.0067 FTE x number of licensed beds
 - Pharmacist time: 0.0129 FTE x number of licensed beds
- Based on average occupied beds:
 - Technician time: 0.0083 FTE x number of occupied beds
 - Pharmacist time: 0.0158 FTE x number of occupied beds

Vendors may be able to provide resources to support bar coding by the pharmacy. If interested in these services, they should be mentioned in your request for proposal (see Section 6.6.2.6 Ancillary or Contracted Resources).

6.7.4 Quality Control

A MBCPC program necessitates at least three new quality control steps for pharmacy:

1. The check process for repackaged doses should include a scan of the package bar code to verify that the bar code, text labeling, and medication contained in the package are all correct. The completion of this step should be indicated in the repackaging log.

2. Non-bar coded products to which a bar code is manually applied should be checked and the check process should be documented using the same record-keeping system used for repackaged medications.
3. Products that have bar codes should be scanned as incoming shipments arrive to ensure that the bar code and related product information are present in the MBCPC system database.

This quality control scanning should be done with the same device that will be used to scan medications at the point of administration. Steps 1 and 2 above can be addressed by modifying the existing check process for repackaging to include a scan of the first and last package in a run. A record of the completion of this step should be maintained.

Step 3 is intended to catch brand substitution of generic items by the wholesaler where the brand and bar code have never before been used as well as cases where the manufacturer has changed the bar code to comply with the new FDA regulation.

6.7.5 Medication Database Management

6.7.5.1 Existing Pharmacy Automated Systems

A medication database used by an automated system can be viewed as having two potential components – the *master* medication database and the *active* medication database. The master medication database, typically almost 100,000 medication line items, is provided by a data supplier such as First DataBank, MediSpan, or Multum. Depending on the type of data needed to support a particular automated system, the master database subscription may include medication descriptions (generic/brand name, strength, volume, and dosage form), NDC numbers, allergy codes, drug interactions, generic equivalencies, therapeutic classes, pricing updates, drug images, and more. The master database is updated regularly, such as monthly or quarterly, by the hospital using CDs provided by the data supplier or by downloading the updates from the data supplier's web site. The hospital customer normally does not make changes directly to the data contained in the master database. Not all pharmacy automated systems require the use of a master medication database.

In contrast, 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 the 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 on the length of the description. The active medication database will also allow for assigning 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 cabinet system may be set to require entry of a count each time the medication is accessed by a user.

In some cases, integrated systems provided by the same vendor may share the same master and/or active medication database. However, in more common best-of-breed system environments, each master and/or active medication database must be separately

maintained by the pharmacy. **As a medication safety measure, it is recommended that medication descriptions be synchronized across all systems that are part of the medication process.** In doing so, users will not likely be confused by inconsistent medication descriptions appearing on MARs, pharmacy information system labels, repackaged medication labels, decentralized cabinet displays, and the MBCPC system.

Ongoing maintenance of medication databases for pharmacy automated systems that do not require the use of bar codes 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 less strict a hospital's formulary is, the more labor intensive the ongoing management of medication databases for pharmacy automated systems will be.

6.7.5.2 Point of Care Medication Scanning Systems

To a great extent, the medication databases of a point of care medication scanning system have the same characteristics as that of other pharmacy automated systems. However, the *active* medication database of point of care scanning system requires two additional data components for every shelf item – the bar code identifier and the NDC. Unfortunately, bar code identifiers are not included in the master medication databases available from data suppliers and there is no official global source for this data. Therefore, pharmacy must supply and maintain medication bar code information for the point of care system's active medication database.

During the initial installation of the point of care scanning system, the pharmacy will need to scan every bar-coded shelf item in inventory to properly associate its bar code 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 items and their bar codes can have a many-to-one relationship with a single line item in the active medication database.

Each inventory item must also be linked to a corresponding item in the master medication database to utilize the master database's clinical drug information. By entering each shelf item's 10-digit NDC number into the active medication database, the system will be able to access corresponding drug information from the master database.

In summary, the active medication databases for point of care scanning systems will require the capture of bar codes and NDC numbers for all inventory shelf items. This information must be maintained on an ongoing basis as new shelf items are received or the items will not be identifiable when scanned. See Section 6.7.4 Quality Control for recommendations related to the scanning of incoming shipments.

6.7.6 **Revising Order Entry Procedures**

Pharmacy order entry will provide medication order information, including dose scheduling to the point of care scanning system. Therefore, if the point of care scanning system schedules doses to be given, more than ever before the nurse will be administering medications based on the pharmacy entry and scheduling of medication orders. For this

reason, pharmacy may need to change some order entry practices to better accommodate nursing and patient needs. In addition to the situations described in Section 6.7.1.3.5 Special Situations for Packaging and Order Entry, the following should also be considered:

- First dose scheduling – PIS order entry will often default the first scheduled dose to the next dosing time based on defined dosing schedules. However, the nurse is likely to give a first dose before the first dose scheduled when the order is entered in to the PIS. Pharmacy and nursing should establish a method for handling this scenario. Possible resolutions include:
 - Pharmacy will enter a special first dose order followed by the routinely scheduled order. For example, pharmacy may need to enter orders for a dose NOW and for doses BID to allow for administration of both BID doses on the first day.
 - The nurse will administer the first dose as a non-ordered or “override” dose before the first scheduled time.
- 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 needed schedule changes.
- Range dosing – Although discouraged, range dosing, especially for pain medications, is often still used. Depending on the features of the PIS and the point of care scanning system, pharmacy may need to enter the minimum and maximum dose of the range differently than in the past. Check with your system vendors to determine how range dosing is supported.
- Non-formulary medications – Rather than add a formulary line item for a rarely used non-formulary medication, pharmacy often enters the order into the PIS using a virtual line item called Non-Formulary Med. In such cases, the description of the specific medication is noted in the PIS order comment area, and this description appears on the label and the MAR. If this process were followed in a point of care scanning environment, this item would likely be dispensed without a bar code.
- Patient’s own medications – A patient’s own medications, if allowed by hospital policy, should be bar coded and scanned like all other medications. These can be handled based on their formulary status:
 - Medication is a formulary item – Enter the order and dispense the medication from bar coded pharmacy stock, or temporarily affix a medication-specific bar code to the patient’s prescription vial.
 - Medication is not a formulary item – Follow the order entry and bar coding process established for all non-formulary medications.

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

6.7.7 Pharmacy Downtime Procedures

Occasional planned downtime is necessary with any automated system. Problems that sometimes occur during planned downtime can be avoided through coordination and communication between departments. See Section 8.2 General Downtime Procedures for more information on planned downtime.

Should unplanned system downtime occur, a clear escalation procedure designed to minimize the adverse effects of the downtime on patient care activities is essential. The MBCPC downtime procedure for pharmacy will be significantly different if the PIS is down. In such a case, the PIS downtime procedure should be followed. New orders will need to be tracked manually and entered into the PIS system as soon as possible when service is

returned. If the PIS is operational and the PIS interface to the MBCPC is down, nursing must be informed immediately that patient and order information in the MBCPC is not current. As mentioned previously in this document, MBCPC systems should have a feature that automatically notifies users when the interface is down or behind.

For cases where the MBCPC is down, pharmacy should establish clear downtime procedures. If possible, processes related to the electronic management of bar coded inventory, such as bar code scanning of incoming items, scanning after product repackaging and labeling, and MBCPC formulary updates, should be held until the MBCPC returns to service. If bar codes on newly received, repackaged, or relabeled products must be checked, the pharmacy should attempt to visually verify the bar code based on the text description of the bar code content which usually appears just below the bar code symbol. Bar codes for each new item and each processed batch should still be scanned for readability and quality when the MBCPC system returns to service.

Finally, the pharmacy and/or information systems department should keep an adequate back up supply of MBCPC devices available should a pharmacy scanner or MBCPC computer fail for reasons related to hardware.

6.7.8 Pharmacy Staff Training

As with other automated systems, effective training of the pharmacy staff is crucial for success and consistency. The following are some recommendations that, when working closely with your MBCPC vendor, will help achieve a successful training experience:

- Introduction to the system should include focus on hospital patient safety initiatives, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommendations, and regulatory requirements that support the need for changing current error-prone systems.
- Training tools, such as user guides, videos, CDs, and other training aids, should be obtained from your MBCPC vendor.
- A pharmacist, such as the Oversight Team co-chair person, and the MBCPC vendor should jointly conduct an early training session to focus specifically on the pharmacy bar coding initiative.
- If experienced consultants are available, obtain their input on training content.
- Pharmacy managers should incorporate MBCPC system training into new hire systems training.
- Decide where and when MBCPC training should be held. Access to fully functional equipment will be required at this location.
- In addition to MBCPC pharmacy training, the pharmacy staff should also receive the nurse user training. New steps in the medication use process, such as the need for nursing to request a PIS schedule change on a medication order, should be identified and pharmacy responsibilities defined.
- A reasonable amount of time should be scheduled for the training session, including time for hands-on practice and a question/answer period.
- Remember to issue certificates of completion for the training and to record the training in the employee's education record.
- Cover all changes to current policies and procedures, including:
 - Procedures for planned and unplanned downtime
 - Repackaging and bar coding procedures (see Section 6.7.1.3)

- Pharmacy On-site Repackaging and Bar Coding)
- Order entry procedures (see Section 6.7.6 Revising Order Entry Procedures)
- Troubleshooting procedures, including
 - Identifying and logging problems
 - Assessing the problem and attempting resolution (if applicable)
 - Contacting internal (e.g., information systems) or external (vendor) help desk if necessary
 - Documenting problem resolution
- Provide pharmacy staff with a clear understanding of the privilege levels and controls provided by the automated system.
 - Key privileges, such as creating users and editing formulary items, should be restricted to a limited number (e.g., two) of power users.
 - Other functions, such as verifying bar codes on incoming shipments, will likely be applicable to all users.
 - To enhance the effectiveness of training, pharmacy should determine privilege assignments in advance of training.
- Include an explanation of HIPAA regulations related to MBCPC technology. See Section 6.8.11 Privacy and HIPAA for more information.

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 conducts and oversees pharmacy training.

Information systems should be made aware of the clinical importance that the system has to nursing, pharmacy, and the patient. It is recommended that information systems 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.

6.7.9 System Evaluation

The System Evaluation action team should closely monitor for the proper use of the system and all related processes. To do so effectively, a process flow measurement system may need to be developed. Process flow measurement should identify process problems and “work-arounds” that may develop. Such bad practices circumvent the safety benefit of bar codes scanning.

Examples of work-arounds that have already been seen with point of care medication scanning systems include:

- Extra bar coded 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 bar coded packages in the med room, and the empty packages are scanned later after meds are passed.
- Medication scanning is bypassed altogether and medications are documented later.
- Giving a medication by indicating it is a “non-bar coded medication” (a feature of some systems) when the medication is in fact bar coded.

The measurement system should also help identify the process issues that cause users to develop certain 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 later time. The team should strive to address these process problems and to recommend process improvements to permanently eliminate such issues.

If the MBCPC allows the administration of non-bar coded products, it may, in effect, be providing a built in work-around that could (and probably will) be used inappropriately. The contributors to this tool advise that all medications be bar coded without exception, and that system features allowing the option to bypass scanning the medication bar code be carefully evaluated. Minimally, electronic documentation should reflect when a dose is given without scanning, and nursing procedures for administering a dose with an unreadable bar code should be established.

6.7.10 Regulatory Considerations

Although the FDA has proposed a regulation for bar coding of medications by manufacturers, that regulation does not apply to pharmacy onsite repackaging. State boards of pharmacy, not the FDA, regulate pharmacy practice. So far, no board actions related to pharmacy bar coding have been reported.

The addition of a bar code to an internal medication package should not impact the pharmacy's ability to comply with existing state regulations. However, keep in mind that repackaged medications, including those repackaged with bar codes, cannot be transferred or sold to other facilities. If an external packaging and bar coding help is needed, the pharmacy should contract with a licensed medication repackaging company for this service.

Non-24-hour pharmacy service will necessitate doses for medication orders written during off hours to be scanned and given prior to order entry the following morning. Pharmacy should work with nursing to establish a procedure for reconciling doses given prior to order entry against new orders received during off hours.

6.8 Nursing Planning Considerations⁶⁷

6.8.1 Nursing Workflow Implications

Studies have shown that the process of ordering, confirming, preparing, dispensing, and administering a medication has multiple potential points of failure. Not only are there dozens of steps in nursing medication administration workflow, some medications also require separate and distinct steps to administer. Nurses are accountable for 'walking the last mile' in the medication process. It is the nurse who is the last check between accurate medication therapy and potential medication error. Therefore, a thorough understanding of the nursing medication process and workflow should be obtained before making any technology decisions.

A recommended first step in selecting a product form factor for a point of care medication scanning system that would best fit your nursing organization is to map and study the current medication administration process using flowcharts. The differences in the delivery 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 is accountable for gathering along the route of 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 considered. Existing policies and procedures for medication administration should be up-to-date and available for reference during this investigation,

and an assessment of whether or not these procedures are being followed is essential before proceeding. Updated policies and procedures can also serve as a valuable point of reference for evaluating technology that is a good match for your nursing organization.

Space restrictions that may interfere with process changes under consideration should be identified and taken into consideration. See Section 6.8.5 Space Considerations for Nursing for more information.

High-risk medication workflows will require special attention since errors with these types of administrations are more likely to cause serious adverse drug events. The list below provides medications the Institute for Safe Medication Practices considers as high alert medications or categories:

- IV calcium (as gluceptate, gluconate, or chloride)
- Chemotherapeutic agents
- Chloral hydrate and drugs used for pediatric ambulatory sedation
- Digoxin
- Heparin
- Hypertonic saline
- Insulin
- Potassium chloride

Finally, be sure to consider workflow impact for non-nursing practitioners who administer medications, such as physicians or respiratory therapists. It is recommended that these practitioners follow the same medication verification and documentation practices as nurses.

6.8.2 Bar Coding the Patient

The MBCPC system will require that a unique bar coded identifier, such as a bar coded wrist band, be attached to each patient. This bar code will be scanned to identify the patient prior to the administration of a medication. Determining how and when the bar code gets applied to the patient is an important consideration, especially if your hospital currently does not use wrist bands that are bar coded.

There are several vendors available that can provide bar coded wrist bands. These include the following companies:

- PDC Corporation (www.pdcorp.com/healthcare/barcode_solutions.html)
- Zebra Technologies (www.lifesciences.zebra.com/health-services.htm)
- Datacard Group (www2.datacard.com/solutions_for/healthcare/health_identification.shtm)

If a bar coded wrist band system is new to the hospital, one or more systems can be evaluated during the point of care medication scanning system evaluation period. During the evaluation period, only patients in the pilot areas will need bar coded wrist bands. Therefore, an interim process for creating wrist bands and affixing them to patients on pilot units is an appropriate and practical approach.

Prior to the start of the evaluation period, a policy restricting the printing of duplicate bar coded wrist bands should be established. This is important to prevent dangerous work-arounds that have been known to occur with duplicate bar coded wrist bands being scanned away from the point of direct patient care.

6.8.3 Impact on Nurse Staffing

According to experts who have studied the impact of MBCPC systems on nurse staffing levels, automating patient care processes and providing alerts and other decision support tools to reduce errors should not significantly impact staffing in the long term. One published study reported that a MBCPC system was expanded hospital-wide in a six-month timeframe and 2.4 additional nursing full time equivalents (FTE) were added.⁸ Since MBCPC systems automatically document medication administration as it is occurring, it is likely to reduce charting time spent before or after the medication event in comparison to manual or other electronic charting methods. Keep in mind, however, that there initially will be time and labor costs associated with setting up and implementing the system. Some ongoing nursing labor investment related to training and support should also be expected.

6.8.4 Nurse Training and Support

6.8.4.1 Training of Nurse Users

The time needed for training staff nurses may vary based on the design, form factor, and user-friendliness of the MBCPC system selected. For example, systems that are menu driven may require more training time than those that step the user through each process. The following are some recommended approaches that, working closely with your MBCPC vendor, will help achieve a successful training experience:

- Introduction to the system should include focus on hospital patient safety initiatives, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommendations, and regulatory requirements that support the need for changing current error-prone systems.
- Training tools, such as user guides, videos, CDs, and other training aids, should be available from your MBCPC vendor.
- Make sure that dedicated MBCPC equipment is planned for and reserved for ongoing user training.
- Hospital nurses, such as nursing education instructors, and the MBCPC vendor jointly conduct initial training sessions while the technology is still being learned. During system roll out, nursing should gradually assume the training role with less help from the vendor.
- If experienced professional consultants are available, obtain their input on training content.
- Nursing education instructors should incorporate MBCPC system training into new hire systems training.
- Decide where and when training should be held. Access to fully functional equipment will be required at this location. A location away from the patient care area is recommended for uninterrupted learning. Consider the advantage of focused training before or after regular work shift, even if overtime applies.
- Establish a reasonable amount of time for the training session, including time for hands-on practice and a question/answer period.
- Remember to issue certificates of completion for the training and to record the training in the employee's education record.
- Cover all changes to current policies and procedures, including procedures for planned and unplanned downtime (see Section 6.8.13 Nursing Downtime Procedures
- Include an explanation of HIPAA regulations related to MBCPC technology (see Section 6.8.11 Privacy and HIPAA for more information).

6.8.4.2 Go-Live and Ongoing Support

Initial support of the new system should include a collaborative effort by information systems, nursing and pharmacy as well as the MBCPC vendor. Whereas the average age of nurses has increased and some suspect that the average technical awareness of nurses has decreased, this may not be true if your hospital already uses other technologies to which users are accustomed. In any case, care should be taken to acknowledge and accommodate users with varying levels of technical aptitude.

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

An ongoing nursing support plan for the MBCPC system should be developed, communicated, and clearly understood by the nursing staff. It should include who the 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 the vendor customer support department when necessary.

6.8.5 **Space Considerations for Nursing**

Since MBCPC systems are used at various points in the nursing medication administration workflow, special attention to nursing unit and bedside space constraints should be considered when determining which MBCPC form factor will work best for nursing. It is recommended that space be assessed during the review of nursing workflow described in Section 6.8.1 Nursing Workflow Implications. Space availability at each step of the medication administration process should be examined in relation to product form factor. For example, there may be ample room for the needed MBCPC equipment at the bedside but not enough space in a medication room for the same equipment when the nurse is preparing medications or IVs, assuming the equipment may be needed during preparation. Additionally, equipment will require a designated storage place with access to an emergency-power electrical source for recharging batteries or for storage when not in use. The space chosen should not interfere with other activities and must meet safety requirements established for patient care areas.

The Computer on Wheels (COW) was the form factor of the first generation MBCPC systems in the mid-1990s and still exists today. The device involves a laptop computer with wireless networking and a tethered bar code reader mounted on a rolling cart or stand. Logistics to consider with a COW form factor are:

- Space available in the patient room and/or at the patient bedside
- Space available in other areas where medications are prepared (if applicable)
- Electrical sources
- Number of units required to service the nursing unit and related storage space when not in use
- Whether the vendor will load their software onto the hospital's own PCs, and whether you can continue to run other applications on the same PC to help save space
- Whether hand-held devices are also needed when circumstances prevent the use of the COW

Some MBCPC systems involve the use of wireless hand-held devices such as personal data assistants (PDAs) or custom-designed devices made specifically for point of care medication scanning and documentation. These hand-held devices may have limited capabilities and, therefore, work in tandem with a nearby network-enabled PC, notebook or laptop with additional features. Typically, the requirement for the number of computers (PCs, notebooks, etc.) with hand-held based systems is less than with systems using the COW form factor and, therefore, they require less dedicated space on the nursing unit.

Still another MBCPC form factor is one that uses a stationary computer at the patient bedside. Flat-screen PCs are mounted on a wall or pole near the bedside. Tethered or wireless bar code scanners communicate with these stationary systems. In some cases, storage space is provided in the base of the device to allow the elimination of the typical bedside cabinet. Stationary bedside systems may require supplemental hand-held devices for use when medicating ambulatory patients and those hand-held devices will require dedicated space for storage and recharge when not in use. These systems are capable of also being used for other purposes, such as computerized physician order entry (CPOE) or patient entertainment.

In summary, nursing should carefully assess the space requirements for various MBCPC form factors as part of the vendor selection process.

6.8.6 Electronic Charting Issues

Since MBCPC systems gather medication use and related clinical data during the process of giving medications, they are ideal for populating an electronic medication administration record (eMAR). MBCPC systems have a built-in eMAR but should also be capable of sending this medication charting information to another eMAR system. The challenge is ensuring that all the components that make up the eMAR come together in one document that can be used as a permanent part of the patient record.

6.8.6.1 Identifying the Patient

As mentioned previously the patient must be recognized by the system electronically and therefore the admitting process must identify all patients, whether they enter the hospital system as inpatients or outpatients, in the same way. Patient demographics, including key identifiers such as permanent medical record number and unique visit number, must be shared through the ADT interface to the MBCPC system. Outpatient records, including medications and orders, should not follow the patient to the inpatient record and vice-versa. In cases where patient confidentiality is essential, there is a need to block certain patient information from being viewable or printable within hospital systems. For example, a psychiatric patient that is being treated on an outpatient basis may be admitted for a surgery unrelated to the patient's psychiatric condition. When a permanent patient medical record numbering system is used, a unique patient visit number is assigned for each incident of care. Therefore, consider whether the bar code on the patient wrist band should contain the patient's medical record number, visit number, or both for proper identification to the MBCPC system.

Finally, it is recommended that nursing strive for consistency of format for both inpatient and outpatient eMARs.

6.8.6.2 Identifying the Caregiver

The eMAR must accurately capture the caregiver for all medication transactions. Therefore, all caregivers that administer medications to patients need to be identified electronically to the MBCPC system. Although employee ID badges often contain magnetic stripes, a bar code on the employee badge is typically used for identification in a MBCPC system.

6.8.6.3 Capturing Data for the Medication Event

Since clinical observations and assessments happen at the same time as medication administration, the MBCPC system should allow users to capture this data during administration to be recorded in the eMAR. Typically, nursing policies and procedures are already in place to define the clinical data points that need to be captured. When planning for the MBCPC system, a thorough review of these charting requirements is recommended to ensure they are able to be captured by the MBCPC system.

A potential benefit of a MBCPC system is real-time billing for medications and related bar coded items used during medication administration. For example, scanning IV tubing sets when IV lines are changed could generate charges for these supplies. This could result in additional revenues. Perhaps just as importantly, capturing the use of such supplies can result in more accurate case-costing information.

Finally, if implementing a MBCPC involves using an eMAR for the first time, consider the impact that an eMAR may have on physicians and processes that take place to support their practices. Educate the physicians on how their access to information may change, hopefully for the better, when the MBCPC system is implemented.

6.8.7 **Medications Given by Non-nursing Personnel**

Care should be taken to design the MBCPC system and related processes to support non-nursing practitioners that may give medications in your setting. For example, in some hospitals, physicians may administer certain medications to patients. It is highly desirable for physicians to verify and document medication administration in the same manner as nurses. This would necessitate their training and use of the MBCPC system.

If the hospital is a teaching institution, student nurses pose a unique challenge. To address it, 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 need the ability to use the MBCPC system to pass medications. Inquire whether the MBCPC system provides privilege level controls that will allow student nurses to pass medications under the direction of a registered nurse. An example of such a privilege level control would be to require a witness before finalizing the user's medication transactions.

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

6.8.8 Patient Isolation

Patient isolation poses a challenge when equipment is shared by nurses and taken into patient rooms. The MBCPC system will be no exception. Even if a handheld device or other MBCPC equipment is restricted for use on one isolation patient, sooner or later the devices need to be put back into the pool of shared devices. Make sure the devices can be cleaned and that the hospital procedure for cleaning devices after isolation use is followed. Also, consider asking the MBCPC vendor for a custom disposable cover or similar barrier for their device when it is used for an isolation patient.

6.8.9 Challenges of Specialty Nursing Areas and Special Situations

Although medications administered in specialty departments typically are given without entry of an electronic medication order, you should consider having all departments where medications are administered use the same system and follow the same general procedures for medication administration and documentation. For example, departments like Post-Anesthesia Care Unit, Radiology, Emergency Department, and Cardiac Catheterization Lab should use the MBCPC system and eMAR for recording medications administered during tests or treatments.

Although an automated check for the 5-Rs is not possible without an electronic order entry, there are still valuable safety checks that can be gained by using the MBCPC system in these areas, such as screening for allergy, appropriate dose, and drug interactions. In addition, the capture of accurate billing information at the point of care in these departments may be a benefit. Therefore, consider how the MBCPC system could be used in specialty areas and may impact workflow. Be prepared to recommend process changes if required to maximize the benefit of the system.

In special circumstances, such as a code or other emergency situation defined by the hospital, scanning of the bar code at the actual time of administration may not be possible or practical. A secondary method for electronically documenting medications used during these incidents must be available in the MBCPC system.

6.8.10 Management of Hardware Devices

Although device management is not a new challenge for the hospital or for nursing, the MBCPC system may require some additional controls. Depending on its form factor, certain MBCPC equipment may have a higher potential for diversion than other hospital equipment. For example, systems that use an off-the-shelf PDA or scanner may have "street value" due to their ability to operate personal applications like spreadsheets, calendars, and word processors.

Since MBCPC equipment generally does not need to leave the department to which it is issued, a daily or shift-to-shift equipment accountability check should be conducted and the results of that check recorded.

6.8.11 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. With the compliance date of October 16, 2003, hospitals have implemented proactive steps to protect the confidentiality of hard copy and electronic medical record

content within the hospital and, if applicable, outside the facility. These steps include implementation of:

- Physical safeguards, such as
 - Controls for electronic media
 - Maintenance and proper disposal of records
 - Workstation access security
 - Data encryption and decryption techniques
- Security administration safeguards, such as
 - Data trending analysis
 - Disaster recovery planning
 - Backup planning
 - Password management
 - Incident procedures
 - Security awareness and training
 - Workforce clearance
- Technical safeguards, such as
 - System testing and revisions
 - Audit controls
 - Strict control over remote system access
 - System design integrity
- Strategy, assessment, and remediation steps, such as
 - Corporate compliance with HIPPA regulations
 - Risk assessment
 - Gap analysis strategies to maintain compliance with regulations
- Information systems standards, such as
 - Standards for transaction data
 - Establishing code sets and identifiers
 - Consents, authorization and disclosures
 - Privacy notifications practices
 - Enforcement of privacy laws
- CPOE considerations, such as
 - Requirements and design to support privacy
 - Medication decision support and legislation
- Patient safety and reduction of medication error efforts, such as
 - MBCPC systems to verify the 5-Rs
 - Improve process sophistication
 - FDA regulations on bar coding

Two questions need to be asked when evaluating MBCPC systems for nursing use related to HIPAA:

- What features or attributes does a MBCPC system possess that demonstrates it is sensitive to patient privacy?
- What responsibilities will the hospital have to maintain patient privacy within the system?

It is recommended that the above questions be used when evaluating HIPAA-preparedness of a MBCPC system. Additional tools to assist in determining HIPAA compliance are provided by WebInservice® (www.webinservice.com).

6.8.12 Occupational Health

Another form factor-related issue to understand is how the physical user interface occurs.

Any system having potential for repetitive body motion on the part of the user should be carefully studied. Evaluation, and perhaps research through due diligence in speaking with existing users, will help determine whether a risk of injury due to repetitive tasks. Injuries involving personal computer components such as the keyboards and mouse are known risks. The potential for risk associated with PDAs and other hand-held devices used when delivering patient care is relatively new and not well studied. In fact, the only apparent sources of such feedback are the facilities and users that have used these systems for a significant period of time.

There is no known health risk associated with the operation of wireless networking signals such as those that meet 802.11b or 802.11g standards. Mobile MBCPC devices, such as laptop computers on carts or rolling stands, may pose a risk in some work areas by crowding the work environment and therefore causing a physical hazard to patients, visitors, or health care providers. Assessing the space in these areas and choosing the right hardware form factor and configuration will help reduce occupational health risks.

6.8.13 Nursing Downtime Procedures

Occasional planned downtime is necessary with any automated system. Problems that sometimes occur during planned downtime can be avoided through coordination and communication between departments. See Section 8.2 General Downtime Procedures for more information on planned downtime.

Should unplanned system downtime occur, a clear escalation procedure designed to minimize the adverse effects of the downtime on patient care activities. The downtime policy and procedure should call for nurses to immediately revert to a manual method of medication verification and documentation if an unplanned downtime occurs, and this manual method should be described in detail in a related procedure. Nursing must also have a consistent medication information source (electronic or paper) to guide medication administration if a system failure occurs. Whether a system failure is a single or multiple system failure that brings the MBCPC system down, the MBCPC downtime procedure should be followed.

Features for retrospectively documenting a dose administered during a downtime period may be available in some MBCPC systems. For example, the system may provide an option to document administration of a medication outside of the usual bedside bar code scanning process. Such a feature may help capture medication events that occur during planned and unplanned downtime. However, if used inappropriately, such a capability can also create an undesirable user work-around.

7 Managing the Implementation

7.1 The Development Period

Point of care medication scanning is still a relatively young technology. Therefore, it is appropriate to employ a development period in a limited area (e.g., one nursing unit) before formally signing off on acceptance and expansion of the system. With MBCPC system implementation, the term development period 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 period is important for validating the system’s technical capabilities, usability, user acceptance, and related work flow changes. During the development period, system and interface bugs 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 unit that utilizes many medications and IVs of varying types, such as a medical/surgical unit, is a good choice as the pilot unit. Specialty units, such as ICU or pediatrics, should probably be avoided when considering pilot 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 onsite support at the initiation of the pilot. The go-live support team should consider providing coverage on off shifts, such as night and weekend shifts, to assist users who work only those shifts.

There is no recommended length for a development period. Instead, the number of issues identified will determine its duration. However, the Oversight Team should consider establishing a length of time (e.g., two weeks) during which there will be no major issues before the development period will be considered ended.

7.2 The Roll-Out Plan

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

The roll-out plan should include:

- Weekly expansion to new areas
- Scheduled unit conferences and training in new areas the week before the go-live date
- Support coverage

8 Special Considerations

8.1 Data Analysis⁹

The purpose of this section is to outline the importance of data management and to describe the steps necessary to develop a comprehensive plan for data collection, data interpretation, and process improvement activities for the MBCPC system.

8.1.1 Importance of Data Management

Proper data management and analysis is critical to the continued success and optimization of a MBCPC safety program. Data gleaned from the MBCPC system should be integrated with traditional performance improvement methods to provide the information needed to achieve the goal of safer medication use.

8.1.2 Data Collection

Prior to implementation, a multidisciplinary group, such as the System Evaluation action team (made up of representatives from pharmacy, nursing, and performance improvement), should determine the person(s) responsible for collection and review of all applicable data. The content of reports available from the MBCPC system can be used to decide who should be responsible for reviewing, analyzing, and disseminating each report. Information from the MBCPC system focuses on potential opportunities for improvement in various aspects of drug therapy management.

8.1.3 Data Interpretation

Error prevention data will be produced by the MBCPC system in the form of warning messages (wrong dose, wrong drug, 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 clinical 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. The final filtered data should be able to be exported from the MBCPC system for trending and further analysis if needed.

8.1.4 Reporting

Monthly reports detailing the impact of the MBCPC system on medication administration activities and patient safety can be very useful to pharmacy, nurse managers, respiratory therapy, and specifically the System Evaluation action team. Established groups such as the Pharmacy and Therapeutics Committee, Nursing Executive Committee, Patient Safety Committee, and Performance Improvement Committee may be interested in receiving quarterly summary reports of medication safety information. These reports include, but are not 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 to date.

8.1.5 Data Driven Process Improvement

Information derived from MBCPC system reports can be utilized on an ongoing basis to make further 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. Such an analysis may also identify problematic medications or issues with the drug distribution system. This data should help to pinpoint additional training needs for pharmacy or nursing and can be used to identify workflow and 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 prevented stratifies the data for focused process improvement, shows the system's impact on patient safety, and indicates the system's overall value to the hospital and its patients.

8.2 General Downtime Procedures

Since hospitals have used technology for years, your hospital should already have procedures for planned and unplanned downtime for the network and for individual systems where necessary. Understanding the differences between planned and unplanned downtime is necessary to properly plan for their occurrence.

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

The process for planned MBCPC system downtime should begin with adequate notification of system users to allow them to plan ahead. For example, nurses will need to know during what period medication administration will need to be tracked manually and when the system will be ready for these manual events to be subsequently recorded. For a MBCPC system, it is recommended that three days notice be given to all patient care areas and to pharmacy before a planned downtime occurs.

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

Departmental policy and procedure should clearly describe the process to be followed for unplanned downtime. For further recommendations on unplanned downtime, see Sections 6.7.7 Pharmacy Downtime Procedures and 6.8.13 Nursing Downtime Procedures.

8.3 Unique Hospital Characteristics

Certain hospital characteristics will impact the MBCPC system and should be considered when planning and developing policy and procedure. Examples of such characteristics include:

- Pharmacy service hours – If the pharmacy is not a 24-hour service, PIS order entry will not occur during off hours and therefore the order information that drives the MBCPC will not be current. The MBCPC should allow the administration of “non-ordered medications” with a feature for retroactively associating the doses given with an order

after order entry has occurred. In addition, pharmacy should ensure that medications that may be accessed to fulfill a new order during hours when the pharmacy is closed are bar coded.

- Outsourced pharmacy services – If the pharmacy uses outsourced services, such as an IV admixture service or repackaging service, those services should be involved in planning for bar coding to support the MBCPC.

8.4 Physician Involvement

As an important aspect of a multidisciplinary approach, one or more physicians should be involved in the planning process. In turn, these physicians should keep the medical staff informed of issues and progress related to the MBCPC system. For example, in many hospitals, implementation of the MBCPC system will be the physicians' first exposure to an electronic MAR. Whether an electronic or manual MAR was used previously, changes in format or layout of this and other documents used by physicians may change, so having them involved from the start will help ensure their buy-in and a successful implementation.

8.5 Potential State-Specific Issues

Issues that may impact the MBCPC project are:

- The allowable ratio of pharmacy technicians to pharmacists
- Rules governing the activities of a certified technician working under the supervision or direction of a pharmacist
- Rules governing the access of medications when the pharmacy is closed

In some states, requirements may exist for the investigation of medication errors and appropriate follow up action. In such cases, reports and documents generated by the MBCPC system may provide information that is helpful for tracking activities leading up to and including the time of the error.

8.6 Media Coverage

Hospitals that implement a MBCPC system may consider the project an opportunity to tout their commitment to patient safety. The public relations team for the project should be formed early in the process and chaired by a member of the hospital's Public Relations staff. A press release at the conclusion of the evaluation period is a good first step to creating interest amongst the local media, including newspapers, television stations, and radio stations. The press release should be aimed at delivering a message to the local community that the medication bar coding program is supported organization-wide and that the hospital is committed to implementing the safest possible systems for its patients.

Although the subject of medication safety should be a positive topic for media relations, it may also raise questions about the potential that previous systems were less safe. Questions about medication error rates are likely. The benefit of disseminating medication error data to any outside source should be carefully analyzed. It is strongly recommended that sharing of such information be approved in writing by hospital administration before being distributed.

In summary, the public relations team and hospital administration must carefully plan the content of press releases and media encounters related to the medication safety project.

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- ⁹ Larrabee, S. Understanding and Applying Medication Bar Code Technology: Pharmacy Challenges, *American Society of Health System Pharmacists Mid-Year Clinical Meeting*, New Orleans, 2004.

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

Bridge Medical, An AmerisourceBergen Company (www.BridgeMedical.com)
Cerner Corporation (www.cerner.com)
intelliDOT Corporation (www.intellidot.net)
McKesson Automation, a Business Unit of McKesson Corporation (www.mckesson.com)
Omnicell (www.omnicell.com)
Pyxis Corporation, A Cardinal Health Company (www.pyxis.com)