Pharmaceutical Bar Coding to Improve Patient Safety

Options for Technical Standards in the Canadian Environment

Roundtable Discussion Paper

January 2008

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Preface

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national, not-for-profit agency committed to the advancement of medication safety in all health care settings.

ISMP Canada works collaboratively with the health care community, regulatory agencies and policy makers, patient safety organizations, the pharmaceutical industry, and the public to promote safe medication practices, including but not limited to

- promoting strategies to enhance the safety of medication systems and thus to reduce adverse drug events,

- providing expertise and consultation on medication systems in health service organizations and other health care settings, and

- working with stakeholders to enhance the packaging and labelling of pharmaceutical products.

In keeping with these goals, ISMP Canada and the Canadian Patient Safety Institute (CPSI) hosted a stakeholder meeting in September 2005 to discuss issues related to the packaging and labelling of pharmaceuticals and pre-mixed parenteral solutions. Organizations with interests in medication-related patient safety, such as Canada's Research-Based Pharmaceutical Companies, the Canadian Standards Association, Canadian Emergency Health Services, the Canadian Generic Pharmaceutical Association, the Canadian Society of Hospital Pharmacists, and Health Canada, were represented at the meeting; representatives from AstraZeneca Canada Inc., Baxter Corporation, HealthPRO Procurement Services Inc., Hospira Healthcare Corporation, and Medbuy Corporation also attended. During the discussions, bar coding for pharmaceutical labels (as a component of automatic medication dispensing and/or administration systems) was identified as one of a number of measures that could enhance patient safety.[1]

In early 2006, ISMP Canada was approached by several pharmaceutical companies seeking guidance on the inclusion of bar codes on unit-dose (or unit-of-use) packaging of pharmaceutical products, and this request was the impetus for the preparation of this background paper. This document is intended to stimulate discussion on how pharmaceutical manufacturers can best meet the needs of Canadian health service organizations seeking to improve patient safety by implementing automated identification technologies in medication dispensing and administration systems.

In August 2007, a draft version of this paper was circulated to a wide range of stakeholders, including health care professionals and other end-users, consumer and patient groups, the pharmaceutical industry, regulators, and standards-setting organizations, for input. Feedback received from over 20 individuals and organizations was considered in developing this version of the document which will be used to guide discussion at an invitational stakeholder roundtable scheduled for early 2008.

ISMP Canada hopes that this initiative will lead to the development of *voluntary* national guidelines for manufacturers, in support of bar-code-enabled point-of-care systems that will enhance patient safety in Canadian health care institutions. It should be noted that Health Canada has confirmed that the federal government currently has no plans to mandate bar codes for pharmaceutical labels.

It is important to note that this paper is not intended to analyze the evidence pertaining to the effectiveness of bar coding (or any automated identification technologies) in preventing errors, but rather describes the various components and possible options for standardizing such technology. As stated by the National Coordinating Council for Medication Error Reporting and Prevention, "Before health care practitioners and organizations can benefit from machine-readable codes, the codes must be physically present in a standard format on unit-of-use medication packaging".[2]

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Introduction

Studies conducted in the United States have shown that 34% of medication errors occur at the bedside during medication administration. Unfortunately, very few (2%) of these errors are detected and intercepted before the medication is administered to the patient.[3,4] An additional 10% of medication errors occur during the transcribing of orders and dispensing of medications.[4] It is reasonable to assume that the results would be similar should such studies be conducted in Canada.

Bar code scanning has long been in place in industries outside of the health care sector and more recently has been introduced in some health-care-related industries (such as retail pharmacy and pharmaceutical wholesale operations) to improve supply chain efficiency among trading partners worldwide. In 1987, an American Hospital Association survey showed that bar codes were being used to achieve operational efficiencies in the management of materials in some health care institutions.[5] Almost a decade later, bar coding began to be recognized as a potential tool to improve patient safety, through a wide range of applications including patient identification, verification of medication dispensing and administration, and medical record keeping, all in real time. Bar codes can also complement other initiatives to reduce medication errors, such as computerized prescriber order entry systems.[6]

Twenty-two percent of respondents to a Canadian survey of hospital pharmacists conducted in 2003/04 reported using bar code technology, double the 11% who reported doing so in 2001/02.[4,7] Although Canadian health care facilities have been slow to capitalize on the benefits of bar coding technology for patient safety, use of this technology is increasing steadily.[4] In its 2002 "Call to Action" for pharmaceutical bar coding,[3] the US Institute for Safe Medication Practices stated:

> [T]he principal obstacle to widespread use of bar coding systems at the point of care is a chicken-and-egg issue: Which comes first, unit-dose medications with bar codes on their labels or the implementation by hospitals of the systems designed to read them? Hospitals … have delayed buying the hardware and software necessary to process bar coded information at the bedside because manufacturers do not always provide bar coding of medications at the unit-dose level, while pharmaceutical manufacturers have delayed bar coding such labels on the grounds that so few hospitals are equipped to make effective use of them.

The presence of machine-readable codes in a standardized format on unit-dose[i] medication packages and containers can reduce errors during dispensing and administration of medications but only if health care providers are able to scan and interpret the information in the bar codes.[8] The use of bar coding (arguably the most widely recognized machine-readable identifier)[5,9] in a point-of-care scanning system, combined with a computerized database, allows health care professionals to verify the "five rights"

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[i] A unit-dose medication package is defined as containing a *single dose* of medication to be taken by a patient at a *specific* time, whereas a unit-of-use container refers to a medication package that may be used for a course of therapy (e.g., a seven-day course of therapy for a patient may be dispensed in one *unit-of-use* package).[3]

(i.e., that the right drug, in the right dose and by the right route of administration, is being given to the right patient at the right time).[6]

It is important to note that bar codes are not intended to serve as surrogate product labels. Instead, the alpha/numeric code carried by the bar code functions as a link between the medication about to be administered, the patient about to receive it, and the patient's medication regimen. The use of bar coding to detect errors is possible if medications are labelled with bar codes at the unit-dose level - the actual unit (or dose) to be given to a patient at a specific time.[3]

A hospital-based, bar-code-enabled point-of-care system can work as follows.[10]

- Each patient receives a bar coded identification bracelet. The bar code on the bracelet links the patient with his or her electronic health record, which is maintained by the hospital and which contains information about drug therapy and other medical information.

- Each unit dose of medication (for both prescription and nonprescription drugs) is labelled with a bar code. Although bar codes can be applied by the manufacturer, the repackager, or the pharmacy itself, systems that rely on manufacturer bar coding are considered superior in terms of patient safety, since manufacturers implement quality control procedures that are more stringent and accurate than those available in most health care institutions.[3,6] (This is reflected in the estimated 17% error rate associated with hospital re-labelling that has been reported in the United States.[8])

- At the time the medication is dispensed for a patient, pharmacy staff use a scanner to read the medication's bar code. The computerized database matches this code with the information in the patient's health record, to confirm that the correct medication is being dispensed.

- Before the medication is administered to the patient, the nurse or other health care provider uses a bedside or portable scanner or reader to scan both the bar code on the patient's identification bracelet and the bar code on the label of the unit-dose package of the medication to be administered.

- The computer compares information in the patient's health record with information linked to the medication's bar code. If there is a match, a confirmation is issued, and the medication, dosage, and time of administration are entered automatically into the patient's electronic health record. If the information does not match (e.g., an error in patient identification, medication, dose, dosage form, or administration time), the nurse is alerted by an error message, and a possible adverse event is avoided. This process allows such "near misses" to be captured for analysis, so that the institution can address causes in a systematic way.[11]

The system can also be used to identify health care professionals and others involved in the provision of medication to patients. In these systems, staff members are issued with personal bar codes, which are scanned before transactions involving dispensing or administration of medications.

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In the outpatient setting, the pharmacist or technician scans the medication's bar code and the computer program compares the scanned information with the information in the patient's electronic prescription record. The prescription is released to the patient only if there is a match.

Bar code-enabled medication dispensing and administration can be expected to reduce the incidence of the following medication errors:

- administering the wrong medication or dosage form to a patient
- administering a medication to a patient who is known to be allergic to that particular drug
- administering a medication to the wrong patient
- administering a medication at the wrong time
- duplicating doses

In a fact sheet published on February 25, 2004, the US Food and Drug Administration (FDA) estimated that bar-code-enabled point-of-care systems have the potential to reduce by 50% errors related to the dispensing and administration of medications in hospitals.[10] Evidence to support this projection is now appearing in the literature. For example, in August 2006, the pharmacy manager of a community hospital in Illinois reported that since implementation of a computer-based medication dispensing and administration system (using bar coded unit-dose packaging) the rate of medication errors had declined by 70%.[12] The North Colorado Medical Centre (NCMC), a primary and tertiary care centre in northeastern Colorado, was an early adopter (in 1991) of bar-code-enabled point-of-care technology. In 1995, the NCMC reported that the system had allowed achievement of an overall decrease in medication errors of 71%.[11] A study conducted in 2003 on the benefits of a bar-code-assisted dispensing system in a 735-bed tertiary care academic medical centre in the United States revealed that the overall rate of dispensing errors had been reduced by 96% and potential adverse drug events had declined by 97%.[13]

Although bar codes are widely used in trade and commerce, their use as part of institutional medication dispensing and/or administration systems has been limited. Traditionally, hospitals with unit-dose medication distribution and other systems employing bar code scanning technology (e.g., for billing) have added their own internally printed and generated bar codes to purchased medications.

It has been estimated that the exterior package labels of almost all prescription and nonprescription medications offered for sale in Canada include an identifying bar code. In an audit conducted in 2000 of McKesson Canada's Brampton, Ontario, warehouse, it was determined that of the more than 10 000 stock items checked, approximately 92% carried a bar code on the exterior packaging.[14] However the same does not hold true for inner labels on the unit-dose (or unit-of-use) packaging (e.g. ampoule, vial or blister pack).

There are at present no recognized Canadian guidelines for bar coding developed specifically to apply to medication dispensing and administration, but a number of related initiatives are under way. The Public Health Agency of Canada, for example, is taking steps to develop a consensus on standards for bar coding of vaccines, to facilitate automatic transfer of vaccine-specific information from a national database to an electronic

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client record. As well, there have been developments in this area over the past decade in a number of other jurisdictions. Perhaps we can use the lessons from those experiences to guide the development of voluntary guidelines for Canada.

Discussion Points for Stakeholder Roundtable

ISMP Canada will be seeking to achieve stakeholder consensus on voluntary guidelines for pharmaceutical manufacturers related to the use of bar codes in medication labelling at the unit-dose (or unit-of-use) packaging level.

Key aspects to be addressed in the guidelines include the following topics:

1. *Products to be bar coded*

For discussion purposes, ISMP Canada proposes that the bar code guidelines apply to:

- all prescription drugs for humans with the exception of investigational new drugs and radiopharmaceuticals
- any nonprescription drugs commonly ordered for and administered to hospital inpatients

2. *Packaging and placement of the bar codes*

For discussion purposes, ISMP Canada proposes that bar codes be included on both exterior and interior packaging, as well as on individual blister card bubbles, vials, and small bottles.

3. *Content of the bar codes*

For discussion purposes, ISMP Canada proposes that the following information elements be encoded in the bar code:

- Drug product code
- Drug strength, form
- Manufacturer
- Package size
- Lot number
- Expiry date

4. *Format*

For discussion purposes, ISMP Canada proposes that the data format standards developed by either GS1 or HIBCC be deemed acceptable.

5. *Symbology*

For discussion purposes, ISMP Canada proposes that the guidelines recommend two-dimensional (Data Matrix) symbology.

Overview of Existing Automated Identification Technologies and Standards

Bar Codes

Attributes

Bar codes are used worldwide in supply chain management to identify specific products. A bar code consists of a string of numbers, letters, or special characters, with a series of black and white parallel lines and spaces or mosaics in a checkerboard or honeycomb pattern, representing the numbers, letters, or special characters in a machine-readable form. The characters serve as a reference to a database entry, in much the same way that a vehicle's licence plate is linked to stored information about the vehicle and its owner.[3] Certain types of bar codes include "start and stop" characters (such as an asterisk), to signal the beginning and end of the data string to be read by the scanner.[9]

A "checksum" digit is added at the end of the bar code's data string, calculated from the other characters in the data string. This extra digit is a technical way of preventing misinterpretation by the scanner (caused by, for instance, a mangled label) which might otherwise result in an error.[15]

Bar codes are read by scanners, which may be stationary (like those at store checkout counters) or portable (hand-held wands or pens). Scanners typically transmit the data for one item at a time, but also available are portable battery-operated "batch" scanners, which can store data in memory for later transfer to a host computer, and portable wireless scanners, which can transfer batch data in real time.[16] The portable hand-held scanner is considered the most convenient type for use in hospital settings.[3]

In supply chain applications, computerized bar code scanning systems allow software to link the product to price and other information related to inventory management and to monitor and facilitate the movement of the product through the supply chain. With respect to medication-related applications in health care settings, the bar code's alphanumeric sequence is transmitted to a computerized database, which can be designed to hold information about medication names, dose, concentration, route of administration, and other features (e.g., waste disposal methods).[6]

Bar codes encompass three basic elements: content of the bar code, data format, and symbology.[5]

- *Content* refers to the information encoded in the bar code. In the context of medications, examples of content include the drug name, manufacturer, drug strength and form, expiry date, lot number, and package size and type.[5]

- *Data format* refers to the order in which the data elements representing each content item are arranged. To use a written-language analogy, data format is comparable to sentence structure, where the words are equivalent to the data elements.

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There are currently two established standards for data format in health care, one managed by GS1 (an amalgamation of the former Uniform Code Council [UCC] and EAN International) and the other by the Health Information Business Communications Council (HIBCC).[17]

A single format standard is not necessary for medication bar coding, as scanning devices can be programmed to read both formats.[13] More information about the GS1 and HIBCC formats and other standards is contained in the "Standards" section (page 15).

- *Symbology* refers to the number and width of the printed bars and intervening spaces that make up the machine-readable identifier. To use another written-language analogy, the symbology describes the "font" in which the machine-readable code is written. The type and number of characters encoded and the amount of space available for the bar code are some of the factors that determine which type of symbology is most appropriate for a given bar code application.[5]

Three common symbologies are linear bar codes, two-dimensional matrix bar codes, and composite symbologies.

Linear bar codes
Linear bar codes consist of a series of tall printed bars of various widths.[18] Relative to other symbologies, linear bar codes are purportedly the easiest to create and read, and there are reports that they may be the most "forgiving" when packages are curved or crumpled.[9]

Within this classification, two specific symbologies, UPC-A and Code 128, are the most common.[14] Although both are readable by all readily available scanning equipment, UPC-A symbology produces relatively long bar codes, which require more room on the packaging and could therefore be problematic for small unit-dose medication packages. Code 128 produces slightly denser bar codes that allow a greater amount of data to be encoded in a smaller space.[5]

In general, size is the major disadvantage of linear bar codes. Traditional linear bar codes containing more than the unique product identifier (e.g., product lot number and expiration date) would be very large and potentially problematic for application on unit-dose medication packages.[9]

Two-dimensional matrix bar codes
Two-dimensional (2-D) matrix symbologies (e.g., Data Matrix) consist of matrices of printed squares or dots, spiralling outward from the centre of the symbol.[3,6,9] Since vertical and horizontal scanning can be done simultaneously, this type of bar code provides greater data density than the conventional linear type, and the codes themselves can therefore be many times smaller than those in the linear format.[19] Two-dimensional matrix symbologies can be used to print significant amounts of information on very small surfaces.[9]

Composite symbologies

Emerging composite symbologies use a combination of linear and 2-D symbols to encode significant amounts of data in addition to product identification.[17]

Reduced space symbology (RSS) is a relatively new type of linear symbology, developed to store more data in a much smaller area.[9] RSS symbols can be printed on small labels applied to curved surfaces, such as vials, ampoules, and blister packs.[9] Most existing scanners would require upgrading to be able to read RSS bar codes.[5]

Because RSS is capable of handling only primary data (e.g., manufacturer, drug, package level indicator), a new composite symbology has been developed to contain secondary data such as lot number and expiry date. This symbology consists of a portable data file (made up of a number of thinly sliced linear RSS bar codes stacked vertically and containing the secondary data) stacked on top of the main RSS (containing the primary data).[5]

Figure 1: Example of RSS-14 stacked omnidirectional bar code[20]

Standards

Countless product coding systems and standards have been developed by various organizations representing a wide variety of industry constituencies.[3] Some of these have been developed by commercial entities and are of a proprietary nature, whereas others are in line with standards set by the International Organization for Standardization (ISO).

A commercial entity that creates its own code format must maintain the system and police its use in the supply chain, making it applicable only in supply chains completely within the control of the customer or distributor. In addition, proprietary identifiers may not be interoperable with other identifiers and cannot communicate with incompatible systems.[21] Proprietary standards typically require the manual application and/or assignment of a bar code number or tag. However, any stage that involves manual processing introduces the potential for human error and increases the risk of medical error.[14] Therefore, significant advantages accrue when industries can agree on a universal system.

As mentioned earlier in the section on data format, there are currently two leading not-for-profit standards-setting organizations in the health care arena: GS1 and HIBCC.[17] GS1 is headquartered in Brussels, with member countries around the world. HIBCC is based in the United States, with affiliates in Australia, France, and the United Kingdom. In addition, a European Health Industry Business Communications Council is based in The Hague, Netherlands.

There are many similarities and differences between the GS1 and HIBCC systems. Similarities include the following:

- Both assign unique identifiers to the manufacturer or packager, allowing the manufacturer to assign its own product identifier (using criteria determined by the particular system).
- Both provide the same basic information (identification of the manufacturer/labeller, the product, and the packaging level)[17] through their data structures.
- Both offer methods for encoding secondary data, such as lot number, batch number, and expiry date (usually encoded in a separate bar code but occasionally merged with the primary data into one long bar code[17]).

Standards governing the physical and technical appearance of bar codes are managed by the ISO and the International Electrotechnical Commission.

GS1

The GS1 system comprises a standard numbering system and identification carriers to provide users with the means to uniquely identify items, documents, processes, and physical locations in electronic data processing applications.[22] Canada is one of 104 countries with a GS1 member organization, GS1 Canada.

For product identification, the GS1 system relies on the Global Trade Item Number (GTIN), an umbrella term for the family of GS1 numeric codes or data structures[23] that identify products at various packaging levels (e.g., supplier's "selling unit", such as a case or single stock bottle of 500 capsules) to support ordering, warehousing, and other business processes.[24] At present, there are no GTIN standards for the identification of what the organization terms as a "dispensing unit" (e.g., a single tablet or capsule, 1 mL of liquid, or 1 g of ointment).[24] GTINs at the lowest packing level often identify the units sold at the retail level.[25] A proposal to add dispensing unit is now being reviewed by the GS1 Global Healthcare User Group.[14]

A GTIN is 14 digits long and in general consists of:
i. The application identifier, consisting of at least two characters signalling the bar code format.[17]
ii. A package indicator digit, a numeral from 0 to 8 used to identify a particular packaging level.[17]
iii. The company prefix, which is assigned by GS1 to member companies. This is a number of variable lengths, based on the number of GTINs (products) that the company has. For example, a six-digit company prefix indicates that the company has 100 000 products for bar coding.[23]
iv. The item reference number, a five-digit number for the item, which is assigned by the labeller or manufacturer,[17] typically in a specified sequence that is in accordance with GS1-prescribed standards.

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A check digit at the end of the bar code is calculated from the other characters in the data string. This extra digit is a technical way of preventing misinterpretation of the code by the scanner.[9]

GTINs are structured to ensure that each is unique, but they are not significant (i.e., the number itself is not a descriptive code for anything) and are simply used as unique identifiers to access information contained in a database.

Although the GTIN is a 14-digit number, its data carrier (i.e., the bar code) may have a 8-, 12-, 13-, or 14-digit number, according to the database structure used: GTIN-8, GTIN-12, GTIN-13, or GTIN-14, respectively.[21,23]

Figure 2: Example of linear bar code with encoded GTIN[26]

Unique GTINs are assigned to distinguish trade items according to differences "relative to the trading process". Thus, if a buyer needs to distinguish a new trade item[ii] from an old trade item, a new GTIN must be assigned.[25]

As Canada's GS1 member organization, GS1 Canada distributes and maintains all company prefixes licensed to Canadian member companies. It also maintains the ECCnet Registry, a national product registry developed to allow trading partners (retailers and manufacturers) to synchronize product data and thus to improve supply chain efficiency.[20]

Health Industry Business Communications Council (HIBCC)

HIBCC's initial mandate, to develop a uniform bar code system for product identification, resulted in the Health Industry Bar Code (HIBC) Standard. This standard consists of two parts:

- HIBC Supplier Labelling Standard (HIBC SLS), which specifies the primary data structure (used by suppliers of products)
- HIBC Provider Standard, which specifies the formats to be used for internal labelling (e.g., for identification of patients) by health care providers.[27]

[ii] Defined by GS1 as any product or service for which there is a need to retrieve predefined information, encompassing individual items and their various packaging configurations.

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The HIBC SLS allows a variable-length alphanumeric code for primary identification of pharmaceuticals, with the option of coding for secondary information critical to health care processes, such as lot, batch, and serial numbers, expiration date, and a secure link character.

An HIBC/LIC primary data structure is 8 to 20 characters long,[17] consisting of:

i. A flag character (+), signalling that the bar code follows the HIBC data structure.
ii. A four-character company prefix called the Labeller Identification Code (LIC), which is assigned by HIBCC to its members. The first character is a letter, and the rest are typically numerals.[17]
iii. A product identifier, assigned by the member. It can be 1 to 13 characters long, consisting of letters, numerals, or a combination.[17]
iv. A single character for unit of measure, indicating the particular packaging level (0 to 9, where 0 is the lowest, "unit-of-use" level).

A single check digit follows at the end.

The HIBC code (the data) can be encoded on multiple types of one- and two-dimensional data carriers, including linear bar codes and Data Matrix.

HIBCC has also developed the Health Industry Number (HIN) database and system, a numbering system that focuses on health care providers and that can accommodate the unique attributes of health care entities, such as the identification of multiple locations within hospitals and multiple practices of individual practitioners.

+A123BJC5D6E71G

Figure 3: Primary data structure for the HIBC/LIC standard, indicating the labeller, the product code, and the unit of measure

+83278F8G9H0J2G%

Figure 4: Secondary data structure for the HIBC/LIC standard, indicating quantity and/or expiration date and/or lot, batch, or serial number

+H123NDC55555333220/$$0101ABC1238

	8 = check character
	ABC123 = lot number
	0101 = expiration date MMYY format
	$$ = lot and expiration date format flag
	0 = unit of measure indicator (for a unit-dose package)
	NDC5555533322 = number that identifies the specific product
	H123 = labeller ID code (manufacturer, wholesaler, repackager)
	+ = health industry bar code flag character
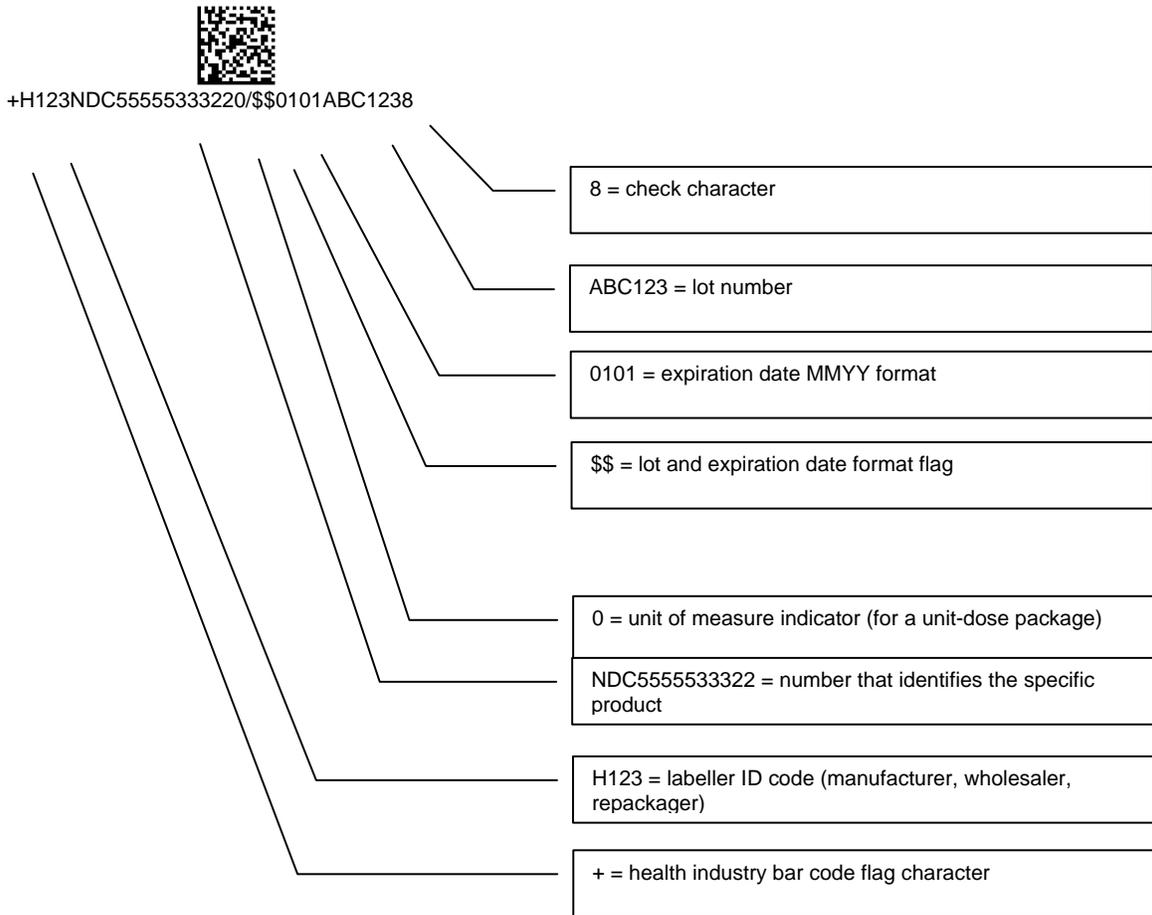
Figure 5: Example of an HIBCC Data Matrix bar code for a unit-dose package

The American Hospital Association, the Pharmaceutical Research and Manufacturers Association, the American Society for Automation in Pharmacy, the Association of Healthcare Resource and Materials Management, and the Healthcare Distribution Management Association are all members of the HIBCC.[28] HIBCC standards and services are administered globally by an international network of affiliate offices.

HIBCC and the HIBC standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization and are endorsed by the ISO and the FDA.
The term "Universal Product Number" (UPN) is an umbrella term that refers to the two bar code data formats established by GS1 and HIBCC.[17] The UPN database is a repository of the product catalogues of individual companies; the database contains all currently assigned UPNs, with a description of each product and package-level information.[27]

The most recent edition (scheduled for publication in 2007) of the US Institute of Medicine's Quality Chasm Series, entitled *Preventing Medication Errors*,[8] advises:

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Another area requiring standardization is the bar codes used for drug labels and bar-code medication administration systems. … A commonly used standard that scanners can easily read will have a greater impact on patient safety than a unique symbology that few scanners are programmed to read.

A number of different stakeholders—drug manufacturers, distributors, re-packagers/re-labelers, manufacturers of bar-code medication administration systems and hospitals—utilize bar codes on drug products. As with the lack of a common drug nomenclature, there is no single, common bar-code standard or symbology. Among hospitals, re-packagers, and vendors of bar-code medication administration systems up to six different barcode standards are being used, with its own special characteristics, features, and methods for encoding product information. This situation creates several problems. First, the lack of a common standard drives costs up throughout the drug delivery system, particularly for hospitals that incur costs to re-package/re-label drugs to the unit dose level and/or purchase additional software or technology to read the different bar codes. Second, error rates associated with hospital re-labeling are estimated at 17% nationwide, increasing the risk of ADEs [adverse drug events]. Third, the multitude of standards inhibits integration of clinical systems. Designation of a single, common bar-code standard could resolve these problems.

Radio Frequency Identification

Radio frequency identification (RFID) is another type of automated identification technology that can serve as an alternative to bar coding. An RFID label (tag) is made up of a radio transmitter chip or transponder, which records and retrieves information by means of radio waves. With this type of identification, a special interrogating wand is used to scan the label. The wand emits a radio wave that is received by the label, which in turn transmits back the information it contains.[29] Accordingly, information can be captured remotely, without tactile or visual (line of sight) contact.[19] Identification badges that open doors when waved in front of a reader contain such RFID chips, as do anti-theft devices attached to clothing in retail settings (which must be removed before the purchaser leaves the store). [29] Whereas bar code scanners can read only one bar code at a time, RFID readers can process dozens or even hundreds of labels at once.[30]

As an emerging technology, RFID is still relatively new. Despite definite advantages, its implementation is reportedly more expensive[19] than that of bar coding[iii] and concerns have been expressed about interference between wireless physiologic monitors and the radio signals from RFID chips.[29] For these reasons, ISMP Canada is not proposing RFID technology as an automatic identification option for medication dispensing and/or administration systems in Canada at this time.

Despite its limitations for medication dispensing and administration, use of RFID technology in drug supply chains (as the backbone of "e-pedigree" systems) to combat

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[iii] Two-dimensional bar code labels cost less than 1¢ each; RFID "smart labels" range from 18¢ to 50¢ each, depending on quantities. Two-dimensional readers range from Can$1750 to Can$3000, and RFID readers cost Can$3300 to Can$3500.[29,31]

counterfeit drug importation, is of growing interest to many industry stakeholders. For example, as of January 1, 2007, the state of California required prescription medications distributed within its borders to be accompanied by an electronic pedigree, and since December 2005, the US pharmaceutical manufacturer Pfizer has been operating a pilot project whereby RFID chips are implanted in pallets, cases, and bottles of one of its "high counterfeit risk" medications for shipment to two distributors.[32]

Near-Infrared Spectroscopy

Another new automatic identification technology is near-infrared spectroscopy (NIR). For each prescription, a tablet or capsule is placed within a scanning device. During the scan, the medication reflects infrared light in a manner unique to the product's individual composition, providing a one-of-a-kind spectral signature or "fingerprint", which is recorded and stored in a database. When a drug is scanned before administration to a patient, the resulting fingerprint will be cross-referenced with the database of products. If the two are not an exact match, the "error" (mismatch) is flagged to the user. NIR is also used to identify counterfeit drugs. The technology can be integrated with existing dispensing systems to ensure that the appropriate drug is being dispensed to the correct patient.[15]

Canadian Pharmaceutical Bar Coding Initiatives

Automated Identification of Vaccines Project (Public Health Agency of Canada)

The Public Health Agency of Canada initiated the Automated Identification of Vaccines Project in response to a 1999 recommendation of the National Advisory Committee on Immunization that "bar codes [be incorporated] into vaccine product labelling to improve immunization record keeping and inventory management".[33] Accurate and complete record keeping (including vaccine lot numbers and expiry dates) is considered essential to vaccine safety, as it allows for identification of those vaccinated and the vaccinations received, tracking of inventory, and follow-up for vaccines that may be associated with adverse events or that may have been recalled.[34]

Since 1999, consultations have been held with vaccine manufacturers, international partners, and other stakeholders, and a pilot project to assess the impact of vaccine bar coding on workflow and data capture was carried out in 2005.

Proposed standards for bar coding vaccine products

- *Content:* A 14-digit GTIN will be encoded, along with lot number and expiry date.[33] An early feasibility study recommended that the Drug Identification Number (DIN)[iv] of the vaccine be encoded in the bar code; however, the GTIN was later proposed for this purpose, to support universal compatibility.[35]

- *Format:* Code 128 data encoding standard is proposed for encoding the content of the bar code.

- *Symbology:* Two-dimensional data matrix symbology is proposed for encoding the required information onto the primary vaccine package. As a minimum, a one-dimensional linear bar code should be used to encode the required data on the secondary packaging.[35]

  Two peel-off labels, each containing the Data Matrix bar code and human-readable information (the vaccine trade name, GTIN, expiry date, and lot number), should be provided for each unit dose of vaccine enclosed in a secondary vaccine package.[35] The labels could be affixed to the primary vaccine package (placed so as not to obscure or replace the information already on the package), and the user could peel off the label, place it on a flat surface in the patient's medical record or immunization card, and scan the bar code either before or after administration of the vaccine.[35]

[iv] Drug Identification Numbers (DINs) are the numbers assigned by Health Canada's Therapeutic Products Directorate to prescription and nonprescription drugs that have been approved for sale in Canada. The DIN is unique to Canada and confirms that the product has undergone and passed a review of its formulation, labelling, and instructions for use. The DIN is also a tool to help Health Canada conduct follow-up for products already on the market and products that have been recalled, carry out inspections, and conduct quality monitoring. Numbers are assigned sequentially.[36]

In parallel with the work on bar coding standards for vaccines is the development of a Vaccine Identification Database System (VIDS). This database or repository, to be maintained by the Public Health Agency of Canada, is being created to "facilitate the electronic retrieval and transfer of vaccine information to client immunization registries through use of bar code scanning or manual entries".[35] At this point in the development of the database, it includes the following information for every vaccine licensed for use in Canada: trade name, product description, DIN, manufacturer identity, active ingredients, agent or antigen, route of administration, lot number, dose, and all known contraindications.[35]

The Automated Identification of Vaccines Project is a work in progress. During a stakeholder meeting held on January 10 and 11, 2007, issues to be addressed and priorities for resolution were identified, roles and responsibilities of participants were specified, and other potential stakeholders were identified.

Retail Pharmacy Task Force (GS1 Canada)

GS1 Canada recently established the Retail Pharmacy Task Force, which comprises representatives from a number of retail pharmacy chains, consolidated distributors (pharmaceutical wholesalers) and manufacturers, and a pharmacy automation vendor,[24] to update the pharmaceutical field attributes for the ECCnet Registry and to consider the automatic identification of "dispensing units" within medication packages.[14]

In addition to identifying the necessary field attributes to support data synchronization within the pharmacy sector, the committee has developed and submitted a global recommendation to create a GTIN structure at the individual dispensing-unit level.[14] The task force noted that when a medication reaches a retail pharmacy, it is no longer handled in the supplier's selling unit (e.g., a case or bottle of 500 tablets); instead, the selling unit is split up before reaching the end-user (in other words, a specific number of tablets or a set volume of fluid will be taken from the stock bottle to be dispensed to the consumer, according to the prescription). Currently, pharmacy automation systems store information at the package level and must extrapolate from this information to determine information (such as quantity) about the dispensing unit, using the product's DIN or the package's GTIN and dividing by the package volume or count. Since each system employs its own standards, this extrapolation is done by several parties at a number of points in the supply chain. Without a common source or standard for information about dispensing units, errors and discrepancies can arise. The task force has concluded that a "solution to this issue in Canada is required" to support:

- the dispensing process
- inventory tracking
- return and disposal of medications (in quantities that are less than the supplier unit)
- regulatory reporting (e.g., for narcotics)
- adjudication of claims by third-party payers
- administration of medications in institutions (i.e., to reduce medication errors)[24]

At a July 2006 meeting, the potential for encoding a medication's DIN in an automatic identification system was discussed; it was agreed that a new GTIN level, assigned at the dispensing unit (or "zero level" of the packaging hierarchy), would better meet the needs of pharmaceutical trading partners.[24] GS1 Canada noted that DINs are linked to specific drugs and their strength or concentration, but not to attributes such as colour, flavour, or specific units of measure.[24] The organization has concluded that "the DIN … does not suffice in all cases to identify or validate the drug dispensed to the degree that the health care systems, health care professionals and consumers need".

GS1 Canada's Retail Pharmacy Task Force has submitted its recommendation to the Global Healthcare User Group for consideration as an adopted standard.[14] The work of the task force continues.

Pharmacy Directors' Network, Alberta

In May 2007, the Pharmacy Directors' Network began discussing the feasibility of an initiative to develop a common provincial standard for bar coding pharmaceuticals in the absence of a national system. Benefits of bar code harmonization on a provincial level identified by the Directors include supporting:

- improved data management within the health regions
- centralized inventory management on a regional or even province-wide basis
- ability of centralized/regional pharmacy production facilities to supply products to other regions, including logistical support in times of critical medication shortages (e.g., pandemic infection)
- great efficiencies in the contracting process for pharmaceuticals, most of which is currently done on a province-wide basis (e.g., tracking purchase volumes on a facility, region and provincial level, and assess contract performance)
- development of a unified provincial reporting model to track, trend, report on and react to issues that affect patient medication safety in the institutional care settings, with potential for integration with the developing NetCare system
- potential for standardization of medication error reporting on a provincial basis using the product bar code
- improved patient care when patients are transferred between facilities or regions by ensuring that medications are identified in a consistent manner regardless of where they are dispensed

To-date, the Directors have completed a short technical assessment survey to identify the pharmacy information systems deployed throughout the province, and their capabilities to support use of pharmaceutical bar coding for both inventory management and point-of-care applications.

Further work on the Alberta provincial bar coding initiative has been put on hold temporarily, pending the overall direction and outcomes of the January 2008 stakeholder roundtable discussions sponsored by ISMP Canada and CPSI.[50]

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Example Manufacturer Bar Coding Initiative for Injectable Products – Sandoz Canada Inc.

In November 2003, subsequent to the FDA's March 2003 proposal to require bar codes on pharmaceuticals, Sandoz Canada Inc. decided to move forward with bar codes on all of the company's injectable product labels (in both Canada and the United States).

Given the need for bar code symbology to be small enough for printing on small-volume parenteral products, the company chose RSS Limited symbology for its ampoule and vial bar coding. The RSS bar code encodes unique 14-digit data strings made up of:

- an indicator digit to identify the packaging level
- 12 digits comprising the company prefix assigned by GS1 Canada (057513 in this case) and the item reference number (assigned by the company) and
- a check digit (calculated from the preceding 13 digits)

For the Canadian market, the company uses its own internal product codes, which are specific to the formulation and the format. As previously stated, DINs cannot be used because they are specific to a formulation, not a format.

In the US market, the FDA-assigned 10-digit National Drug Code (NDC) is used rather than the GS1 company prefix and item reference number. (When used in a bar code, the NDC number is prefixed by the numeral 3, which indicates that the FDA assigned the labeller code, rather than GS1).

Example of RSS bar codes for injectable products:

	United States	Canada
Product	**ABC (10 x 2 mL)**	**DEF (1 x 50 mL)**
Product identification number(s)	54643 58200 (NDC)	0057513 (company prefix assigned by GS1 Canada) and 8070 (company-assigned product code)
Data string encoded in RSS symbology	**1 035464358200 1**	**1 005751308070 5**
Breakdown of data string	**1 03**5464358200 **1** **1 = unit-of-use packaging level** **0 = zero filling authorized only at the left side of the code** **3 = indicates that FDA assigned the labeller code** **5464358200 = NDC** **1 = digit calculated by GS1 software**	**1 0**05751308070 **5** **1 = unit-of-use packaging level** **0 = zero filling authorized only at the left side of the code** **057513 = GS1 company prefix** **08070 = Sandoz internal product code** **5 = digit calculated by GS1 software**

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Other Pharmaceutical Bar Coding Initiatives

Australia

Bar coding of pharmaceuticals is not mandatory in Australia. The Therapeutics Goods Administration registers pharmaceutical products by assigning an Australian Registered Therapeutic Good (ARTG) number. This number is generally assigned to a type of drug, but the packaging is not specified. Therefore, manufacturers can use the same ARTG number for different types of packaging for a single drug, which makes this number unsuitable for use as a unique product identifier for unit-dose packaging.[37] Most drugs distributed to Australia are bar coded according to the GTIN, but this applies only to the smallest selling unit, not at the unit-dose level. Product lot numbers and expiry dates are not commonly encoded.[37]

Israel

In general, unit-dose packaging is not common in hospitals in Israel. Instead, the pharmacy department sends original packages to hospital wards, and nurses remove medication from these packages for administration to the patient. The government has made general suggestions that medication packages be marked with bar code labels.

Japan

Japan has mandated that all medical products be encoded with a Japan Article Number (JAN), which is a GTIN assigned specifically for the Japanese market. Bar coding is applied to the selling unit. The nine-character JAN company prefix reportedly poses some challenges for unit-dose coding, since the lengthy company prefix only leaves three digits for coding all products from a particular company. Neither lot number nor expiry date is required.[37]

New Zealand

The New Zealand government is reportedly considering a universal system of bar coding for medicines at the unit-dose level, with point-of-care scanning.[38] Bar coding of pharmaceuticals is not mandatory.

United Kingdom and Europe

In 2005, Britain's National Health Service (NHS) signalled that bar codes (used as part of systems to reduce medication error) may become compulsory in the United Kingdom in the future.[39] European Article Numbers (EANs) are commonly incorporated in medication labelling by drug manufacturers.[40] Expiry date and lot numbers are not encoded.[41] In February 2007, Britain's Ministry of Health issued *Coding for Success*, which recommends that medicines and devices supplied to the NHS be coded using the GS1 systems.[52]

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has recommended the use of 2D data matrix codes (containing the GTIN, batch number,

expiry and possibly a unique pack identifier)[50] and the Council of Europe report recommends these be implemented on unit packaging, such as ampoules and vials.[51]

United States

<u>Veterans Affairs</u>

In 1994, the US Department of Veterans Affairs (VA) developed and piloted a bar coded medication administration system for its medical centres, and by 2000 the technology had been implemented in 163 VA centres.[42] A VA hospital spokesperson has estimated that the system prevented almost 380 000 medication errors over a 5-year period.[43] The VA medical centre in Topeka, Kansas, reported that implementation of bar coding reduced its medication error rate by 86% over a 9-year period.[44]

<u>National Coordinating Council for Medication Error Reporting and Prevention</u>

The mission of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) is to maximize the safe use of medications by all stakeholders and to increase awareness of medication errors through open communication, promotion of strategies for preventing medication errors, and increased reporting. Member organizations include the American Health Care Association, the American Hospital Association, the FDA, and the US Institute for Safe Medication Practices.

In 2001, the NCC MERP developed recommendations for promoting and standardizing bar coding on medication packaging as a means to reduce errors.[45] Features addressed in the recommendations include the following:

- *Packaging and placement:* Bar code labels should be placed on the labels of immediate unit-of-use containers of all "commercially available prescription and non-prescription medications, in any dosage form". "Unit-of-use" containers are defined as including single-unit, single-dose, unit-dose, unit-of-use, multiple-unit, and multiple-dose containers. NCC MERP also recommends that bar code labels be placed on the immediate container or carton and the shelf keeping unit (SKU).[2]

- *Encoded information:* The bar code should include the NDC number (as the unique product identifier), as well as the lot number and expiration date. Lot numbers are crucial in the event of product recalls, and the inclusion of the expiration date ensures that patients do not receive outdated medications.[2]

- *Symbology:* The three data elements (NDC number, lot number, and expiry date) should be bar coded using "existing symbologies". As an example, it is suggested that the NDC number be encoded in a linear bar code, with the lot number and expiration date encoded in a two-dimensional code.[2]

Food and Drug Administration

In December 2001, the FDA announced its intention to require machine-readable codes on drug and biological product labels, as part of a strategy to reduce medication errors in hospitals and other health care settings.[6]

The FDA held a public meeting to discuss aspects of the potential requirements in July 2002. There was widespread support for a bar code requirement, but opinions varied regarding the information to be encoded. The FDA published a proposed rule in the *Federal Register* in March 2003. The proposal generated approximately 190 comments, almost all of them supporting the rule in whole or in part.[45]

The FDA published a final rule, entitled "Bar Code Label Requirements for Human Drug Products and Biological Products", in the *Federal Register* on February 26, 2004. The final rule requires linear bar codes containing the drug's NDC number on most prescription drugs and any nonprescription drugs "commonly used in hospitals" and dispensed pursuant to an order. The rule became effective on April 26, 2006.[6]

The presence of machine-readable codes in a standardized format on all medication packages and containers can reduce errors during medication dispensing and administration. According to the FDA, use of a bar code system has the potential to reduce by 50% the occurrence of preventable adverse drug events that originate in the dispensing and administration stages of the medication use process.[6]

The rule incorporates features related to products, packaging and placement, encoded information, and symbology.

Products
Manufacturers, repackagers, relabellers, and private label distributors of human prescription drug products and nonprescription drug products regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to the provisions of the final rule, unless they are exempt from the establishment registration and drug listing requirements in the Federal Food, Drug, and Cosmetic Act.[45]

The law contains several exemptions (such as licensed pharmacies) and allows other exemptions upon a finding that registration is not necessary to protect the public health. Thus, distributors who do nothing to the drug itself are exempt from the establishment registration requirement and, by extension, the bar code requirement. Hospitals, clinics, and public health agencies are also exempt.[6]

Bar codes must appear on the labels of the following products:[6]

- All human prescription drugs (including vaccines and diluents), with the exception of drug samples, investigational new drugs, allergenic extracts, medical gases, intrauterine contraceptive devices regulated as drugs, prescription drugs sold directly to patients, low-density polyethylene form fill and seal containers, and radiopharmaceuticals.
- Nonprescription drugs commonly used in hospitals and dispensed pursuant to an order. (Through an exercise of enforcement discretion, the FDA does not require

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bar codes to appear on nonprescription drugs that are distributed in low-density polyethylene containers.)

- Biological products.

The FDA declined to require bar codes on medical devices. Reasons cited for this decision were the fact that there is no numbering system for devices comparable to the NDC for drugs, and there is insufficient evidence that devices are associated with medication errors.[45]

Packaging and placement
Bar codes must appear on the drug's label, which under federal legislation is defined as the product's immediate container *and* the outside container or wrapper, *unless* the bar code is readily visible and machine readable through the outside wrapper or container. If the bar code cannot be easily read by a machine through a product's over-wrap, the over-wrap must also include the bar code.

If perforated blister cells are individually labelled, each one must contain the bar code. Because the rule stipulates that the bar code must remain intact under normal conditions of use, it cannot be printed across blister pack perforations.[6]

There are no blanket exemptions for small containers (e.g., suppositories, small vials, prefilled syringes). However, firms are permitted to apply for specific exemptions if it can be shown that putting a bar code on a product is technologically not feasible *or* that it would adversely affect the drug's safety, effectiveness, purity, or potency *and* that the problem cannot be solved by package redesign or use of an over-wrap. The FDA reports that RSS has made bar coding possible on vials as small as 1 mL.[6]

The FDA reports that before implementation of the final rule, the majority of pharmaceutical products already had the NDC number encoded in a bar code, which appeared on the exterior of the package. The final rule (which requires placement of the bar code on the drug label) will result in bar codes appearing on both exterior and interior packaging, as well as on individual blister card bubbles, vials, and small bottles.[6]

Encoded information
Bar codes must encode the drug's unique NDC number. Currently the NDC is a 10-digit number consisting of three parts:

- the labeller code, identifying the manufacturer or distributor (assigned by the FDA; four or five characters in length[46])
- the product code, identifying the drug product (three or four characters long[46])
- the package code, identifying the trade package size and type (one or two characters in length[46])

Establishments are now able to assign their own product and package codes. The FDA maintains a database of all NDC numbers and makes this database available for use by commercial computerized systems that can provide bedside bar code identification.

Because firms can assign NDC numbers to their own products, the current NDC number system has a potential limitation when different dosages are administered from a single

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package or when partial dosages are administered. For example, if a drug package contains 20 tablets, the NDC number reflects a package of 20. If only one tablet is administered to a patient; scanning the NDC number would not record the correct dose but would show the correct dosage form and correct drug.

The FDA intends to correct this problem through a separate rule (published in the *Federal Register* on August 29, 2006) that will enable the agency to assign the entire NDC number, to ensure that each is unique and appropriate to the drug and package type.[45]

During development of the rule, a request was made to allow firms to use Universal Product Code or UPC (now known as GTIN) numbers in place of or in addition to NDC numbers for nonprescription drugs. The FDA declined to allow this, because GTIN numbers, although used in the retail setting, do not necessarily identify unique drug products. For instance, if a nonprescription drug product is reformulated with a different ingredient, the manufacturer can use the same GTIN number but must assign a different NDC number.[6]

Although the US Institute for Safe Medication Practices, the NCC MERP, the American Society of Health-System Pharmacists, and other organizations interested in patient safety advocated for inclusion of the lot number and expiry date in the product bar code, the FDA declined to mandate this information.[47] The FDA acknowledged that this information would be helpful to facilitate drug recalls, but noted that it could not be proven that the additional patient safety benefits derived from including these details would warrant the associated implementation costs. This information may be included on drug product labelling on a voluntary basis, and the use of other machine-readable formats to encode the additional optional information is allowed.[6]

Symbology
Linear bar codes, meeting standards set by GS1 or the HIBCC, are specifically prescribed by the rule, and alternative identification technologies (e.g., RFID chips or two-dimensional symbology) cannot be substituted. This means that the NDC number can be encoded in either EAN.UCC or HIBCC format, with visual presentation in a linear bar code.

The FDA does not issue guidance related to bar code quality (e.g., size, symbol quality, reflectance), but relies instead on the standards set by other organizations (e.g., GS1, American Society for Testing and Materials).

It should be noted that other automatic identification technologies capable of encoding the NDC number were considered by the FDA. However, given that linear bar coding is a proven, established, and relatively user-friendly technology, one that is less expensive than newer emerging technologies, a decision was taken to support this particular technology.[6] Furthermore, prescribing a single technology (rather than allowing for flexibility) was considered necessary to encourage hospitals and others to implement bar code systems.[6]

Amendments to allow for the use of newer technologies (as an alternative to linear bar coding) will be considered during future revision processes. It has been reported that some US stakeholders are currently seeking to have the FDA rule revised to allow for the use of

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symbologies other than linear bar coding and thus to provide the capacity to encode additional amounts of information.[8]

Multi-jurisdictional: GS1 Global Healthcare User Group

The global Healthcare User Group (HUG), described as a voluntary group of GS1 members and invited supply chain participants, was established in July 2005 to "lead the utilization and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety",[39] using bar codes and RFID.[48]

As of August 2006, HUG's 100 members included senior executives from a number of multinational pharmaceutical companies, hospitals in Europe and the United Kingdom, medical device manufacturers, transportation companies, wholesalers, and associations and regulatory bodies (e.g., the NHS and US and European associations of medical device manufacturers). The Public Health Agency of Canada also participates.[14]

HUG recently initiated processes to develop GTIN allocation rules and other standards to promote the uptake of GS1 systems in health care applications[49] and to define automatic identification data requirements to support patient safety.[48] In April 2007, HUG issued a position statement advocating a global approach in the development and implementation of standards for automatic product identification in health care.[14]

GS1 Canada has also launched a local Healthcare User Group for Canada.

GS1 Canada's Retail Pharmacy Task Force (described previously) will be providing input into HUG's work.[3]

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