Canadian Pharmaceutical Bar Coding Project

Medication Bar Code System Implementation Planning

Section I: A Bar Code Primer for Leaders

August 2013 (Final)

Section I: A Bar Code Primer for Leaders

The purpose of this section is to provide a simplistic explanation of Automated Identification and Data Capture (AIDC) and the global standard known as GS1, the use and limitation of some bar code types found within the GS1 standard, and how bar codes can be used within healthcare to safely identify medications and accurately document healthcare practices.

It is hoped readers will be provided with a rudimentary understanding of the AIDC technical process, and feel more confident in working with bar coded medication systems.

A synopsis of Section I is located in the Document Précis section of this document, above.

A Review or Automated Identification

AIDC is a term associated with an automated process of verifying objects or service steps, collecting key information about each as they are performed, followed by documentation of the process and verifications within an electronic record for future reference. *AIDC* is a generic term that incorporates a bar code, RFID tag or other carrier of encoded data, and that can be interpreted by a suitable scanner/reader.

Return to Document Précis PDF

Human Limitations within Complex Practices

Healthcare delivery practices have been based traditionally on human methods passed from one healthcare provider to another. The most common and reliable medication system component was a well-trained healthcare provider exercising vigilance in the face of multiple simultaneous demands, relying heavily on individual human attentiveness usually within a set of written policies and procedures.

Past healthcare practices evolved at a relatively measured pace, so that changing methods could be taught and incorporated into slightly modified practices. More recently, however, the pace of healthcare innovation has become unsupportable by even the most capable healthcare providers. In such an environment of change, individuality of practice has caused a drift away from overall system predictability and reliability. A

higher degree of healthcare provider (HCP) conformity is required for some tasks to ensure standardization of safety practices. [3, 4, 149]

In its ideal form, individual healthcare provider application of cognitive skills should be limited to those clinical areas where such skills are based on knowledge decisions, such as with diagnosis, surgery, supportive and emergent care, and assessment of patient needs. Certain other aspects of healthcare practice are more routine and technical, and best performed within a more standardized practice structure. Simple repetitive medication processes include drug product selection, individual patient dose manipulation (e.g., compounding and calculation), and, importantly, dose administration.

Increasingly, studies have shown that even simple medication processes are error-prone. [17, 18,21,23,77] The reasons for human error are common to all of us, often relating to unintended actions during moments of fatigue, distraction, stress, or multi-tasking. [49, 67] Inadvertent medication errors result in serious harm to a patient, and also loss of confidence in the system and the healthcare provider involved. A more complete discussion of inadvertent error and rates is provided in Section II of this document.

Automating repetitive procedures can provide much needed support for busy healthcare providers. Properly implemented, technology has the ability to assist in the completion of routine important tasks, thus assuring an overall higher level of standardization, reliability and safety within an organization. Benefits accrue to patients, healthcare providers and organizations and, by extension, system-wide improvements to Canadian healthcare.

Machine-Readable Codes and Automated Identification

The term *machine-readable code* may also be referred to as a *data element* or a *key.* It refers to an embedded piece of information contained within a carrier of information known as a *data carrier* (e.g., a bar code). The *data carrier* can be read and interpreted by an automated device known as a reader or scanner.

The embedded *data element* may be in any character format as long as the reader can 'interpret' the characters used. Often the data characters will be numbers only (numeric code), but could also be letters only (alpha code), or a combination of numbers and letters (alpha-numeric code).

In most cases, there is no need for a human to read or interpret the *data element*. In fact, very often the *data element* by itself will be meaningless to a human. It will simply be seen as a string of characters. For example, your Social Insurance Number (SIN) is meaningless without looking up the SIN in an affiliated database or similar list of information. Only when found within that database will the SIN lead to essential information about you.

Reading *machine-readable codes* forms part of a larger quality process known as "*Automated Identification and Data Capture*", or *AIDC.* The *AI* and *DC* are often discussed as separate but highly interdependent steps of a process. Like the SIN example above, the first step in any *automated identification* process is for the reader/scanner to read (or "identify") a *data element* from within a *data carrier*, such as a bar code. Next, with the help of a software program that accompanies the reader/scanner, the system uses the extracted *data*

element to search for additional information about that scanned code ("*data capture*"). The information can be captured into a document usually as part of the process. Examples of *data capture* documents include a store's sales receipt, a store's record of sales, or a required quality control document.

Though many scanned bar codes are associated with a product or part, a bar code and its *data element* may also relate to other business aspects, such as a service being provided, a location, a single step in a process, or a person or animal. Business sectors today have the ability to place a data carrier with its embedded *data element* on almost anything for any reason!

In healthcare, bar codes may be used on medical devices, supplies, room locations, patients, staff members, medication containers, or individual patient doses. *Data capture* can refer to many quality control processes, such as requisitions, documenting a process, and, importantly, patient chart documentation. Figure I-1 shows how a bar code with a *data element* (e.g., GTIN) can provide additional information on a drug product for the purpose of data capture. Such access data elements are often "static" (unchanging) identification codes, which will be discussed later in this section.

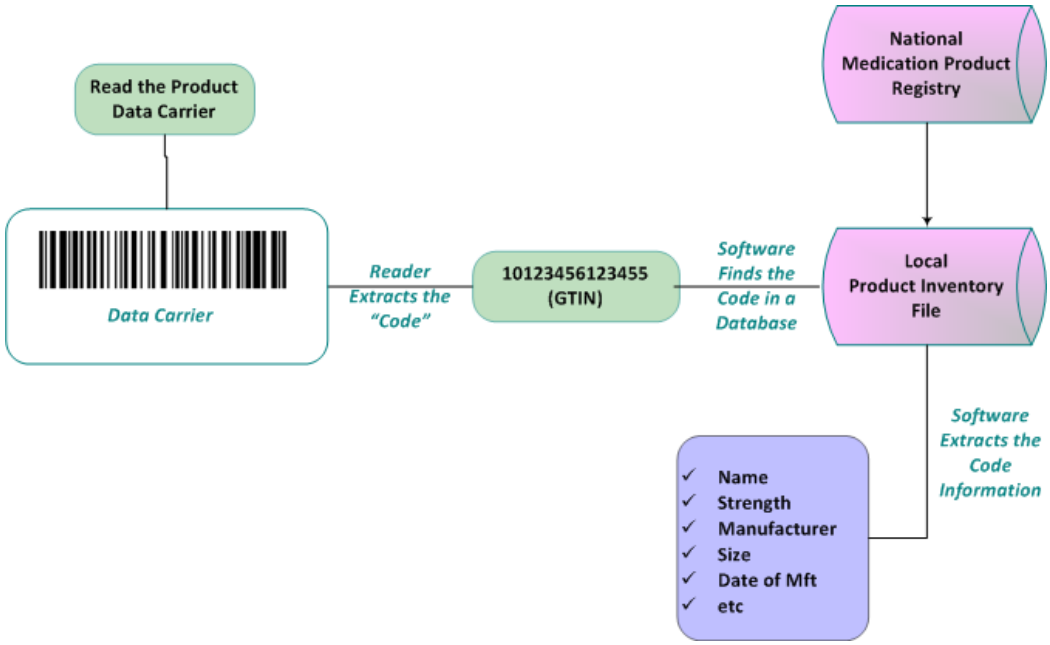

Figure I-1: Reading a Medication *Data element* and Capturing Product Data

Bar Codes and How Do They Differ

A bar code is one type of *data carrier*, and is currently the most common type used within business and healthcare practices. Different bar code types are known as "*symbologies*". The differences can be technically complicated; but suffice it to say, some are better in specific situations.

This section discusses some limitations of some common bar codes to fully accommodate future healthcare practice needs.

Return to Document Précis PDF

Bar Code Types and Quantity of Stored Data

All bar code *symbolo*gies have the ability to carry one or more *data element*s in the form of a short numeric or alphanumeric strings of characters. However, symbologies have differing abilities to hold data, with some being limited in the number of characters.

Many retail operations use the well-known bar code called a "UPC", or Universal Product Code, that we see when we purchase items every day. UPC is an older style of bar code which often finds its main use in simple "sales" processes known as "*Point of Sale*" transactions. In such cases, an item's UPC code is scanned by a reader/scanner, which then places a textual description of the scanned retail product and its printed numeric code onto a printed sales receipt; a process which is repeated for each scanned item in your basket. The system software obtains product descriptions from the store's inventory files (database), and when the purchase basket is empty, the software totals the item costs, calculates sales tax, and provides a net total, a date, and prints (documents) the sales receipt.

The basic bar code *AIDC* process is not any more complicated in healthcare settings. For example, any medical supply item or medication can be scanned and documented. This process will be discussed in detail later.

In our example, the UPC code has limitations. This bar code symbology can only carry up to 12 numeric characters, and can only be scanned/read across the lines: left-to-right or right-to-left. It cannot be scanned top-to-bottom. The UPC is also a relative large bar code which takes up much space on a package, which is often acceptable for many retail items. More advanced bar code symbologies begin to alleviate some of these orientation and spatial constraints.

When a product's *data element* used for a product has only 12 numeric characters almost any symbology, like a UPC, can be chosen for the product's package. However, if additional *data elements* are required within the bar code, it will require that more characters are stored and, as a consequence, only certain symbologies can be used.

Bar Codes Are Not Created Equal

As noted, there are several types of bar codes, each with its own limitations and advantages. Some are more suited for certain segments of business, such as point-of-sale (retail sales), while others can add additional functions in more complex practices such as healthcare.

Healthcare will need additional product information within our healthcare product bar codes, to ensure an accurate and safe process. Additional information will include lot numbers and expiry dates, or other key medication or supply information. As we evolve automated systems to support patients' needs and related healthcare practices, there will be the need to consider other bar code symbologies.

Advanced bar code formats that alleviate some of the UPC constraints include *GS1* DataBar, *GS1* DataBar Stacked, *GS1* DataBar Expanded Stacked, as well as the two-dimensional *GS1* DataMatrix.

Although bar codes may look quite different, the differences among them relate to one or more of the following advancements. The basic function of reading a bar code's *data elements* is no more complicated than that of a simple UPC code.

- A*dditional character lengths* are allowed.
  This allows more and longer *data elements* to be stored directly within the bar code, including some human readable text (if scanned)
- Carry *both numeric and alphabetical* characters (*alpha-numeric*).
  This allows more complex codes to be developed by software programmers and, thereby, more sophisticated human practice needs can be supported.
- The ability to *scan the bar code in any direction* ("*omnidirectional*")
  The package does not need to be oriented to suit the machine reader/scanner; the bar code can be read up/down/left/right and still read properly.
- *Auto-correction of bar code reading.*
  A common frustration occurs when a code fails to be read by a reader/scanner. This is especially the case in mobile scanning devices. By adding auto-correction within a bar code's structure of lines or dots, even if some of the code is not visible (or has been inadvertently erased or rubbed off), the reader may often successfully read the necessary *data elements*.
- Ability to *utilize Application Indicators* to separate different *data element* functions within a bar code's character string. (See discussion later.)
- *One-dimensional and two-dimensional line/dot patterns* that possesses a combination of one and two dimensional parts to the code (a "*composite*" code).

Here is a brief comparison between the GS1 DataMatrix (two-dimensional) bar code symbology and the one-dimensional UPC code symbology described above:

- A DataMatrix can carry up to 3116 numeric, or 2335 alphanumeric, characters, while the UPC only has the ability to carry only 12 or 14 numeric (only) characters.

- A DataMatrix code also has the ability to utilize "*Application Indictors*" to separate multiple *data elements within the same bar code* (see later), while the UPC can carry only one Application Indicator.
- A DataMatrix has inherent auto-correction abilities to reduce failures in reading the bar code, while the UPC does not.
- A DataMatrix also can be printed in a very small print size to fit on small spaces and can even be laser-etched onto surgical instruments or other equipment parts, while the UPC is a large bar code requiring quite large labels for printing.

Appendix I-1 provides the reader with a synopsis of selected bar code symbologies currently approved by the GS1 global *AIDC* application standards organization, which will review later. For healthcare products, including medications, it is very likely that a product's bar code will come from one of the codes approved by *GS1* and shown in Appendix I-1. It is prudent to ensure software systems used in your nursing home care or hospital can read all of these *GS1* code symbologies, and also consider using them on your internal bar coding procedures for patient-specific prescriptions or products.

As a final note, patient-specific identification bar codes are critical to medication dose administration, as well as other delivered healthcare services. Patient identification can be addressed using one of the *GS1*-approved bar code symbologies, such as shown in the Figure I-2 using an in-house assigned unique patient code. As with medication products, a patient Identification identifier (e.g., patient number) can be uniquely assigned as a type of *data element within the patient's electronic health record.*

Figure I-2: Patient-Identification Bar Codes

The same bar code reader that scans a medication product should be able to read/scan the patient ID *data element* on the patient wrist band. The scanned patient *data element* will access a patient database, which will be separate from the medication or prescription database. There, the automated system will extract individual information related to a patient and his/her admission. The specific bar code symbology used on the patient bar code (wristband usually) may be the same or different to that used on his/her medication doses, laboratory blood tubes or requisitions.

It is not the direct purpose of this guide to develop strategies for patient identification coding. Several coding methods can be used. An example of both patient and provider IDs is the GS1 global *AIDC* standard known as the Global Service Relation Number (GSRN). This coding method can be used to establish a unique provider/recipient relationship, for example, between a healthcare provider delivering a service and a patient receiving the service. This particular standard can be applied within any business sector where a service or action is delivered by a provider to a "customer or client", where documentation of the transaction is desirable. Readers are encouraged to read on the application of GSRN, or other methods of identifying patients.

RFID Explained

We should here provide a brief comment on *Radio Frequency Identification* (RFID) chips (or "tags"), which you may also see referred to as "*Electronic Product Codes*" (*EPCs*). Although widespread RFID integration into healthcare product or process *AIDC* is probably several years away, the RFID process will almost certainly have a future within healthcare practices. In the interim, more study of the global health standard, process and cost is needed.

RFID is an electronic microchip that stores data in a method that can be emitted by electronic waves, which can actually pass through some external packaging. The reader (or "*antenna*") picks up the data emitted by the chip and processes the *data element* much like the reader process the code from a printed bar code. An added advantage is that the RFID chip and the *antenna* do not need to be in direct visual line-of-sight of each other. Reading an RFID chip is more "automatic" than reading a bar code, the latter requiring a decision and action by a human to read a bar code.

In theory, multiple items within a basket of items may be readable as a "batch", rather than one-by-one. This "batch reading" may be advantageous in some situations, for example as with healthcare kits. Also, RFID tags permit all *GS1 data elements* to be used, and, in particular, incorporate serial numbers of products easily.

Passive vs. Non-passive chips

Data elements are written onto the RFID chip electronically, by means of a writer. The code(s) can then be read at different points along a standard process. A passive RFID chip emits its data to a reader (antenna) only when it is irradiated with the reader's radio signal in range, whereupon it will respond with its embedded information code(s). Such a tag is referred to as a "passive" RFID chip because it responds only when it is targeted and asked for its code.

An active tag works differently. It carries an on-board battery. Active RFID chips periodically emit their information into the local surrounding environment.

Finally, RFID chips can of two types. They can be "read only" chips where, for example, a product's serial number is embedded once and never changes, or they can be of the "read/write" variety, where data can be written to, modified, and erased from the tag.

Current RFID Issues and concerns

The most common obstacles to RFID implementation are the need for specialized equipment capable of handling RFID processes, the current lack of a wide-spread use of such equipment in client healthcare facilities, and the cost of implementation. Medication products are not yet available with RFID tags, but studies are underway by major manufacturers.

The global regulatory community, such as the U.S. FDA, continues to study the safety and effectiveness of RFID on products, especially biological products. Also, the business integrity of using RFID tags requires further maturation, so that chips are read only when needed. Problems would

arise if, for example, multiple medications were placed in range of a reader (antenna) and more than one chip (or the wrong chip) was inadvertently read in a process.

In summary, the use of RFID for most medication practices has not yet taken root, but some aspects of healthcare practices are beginning to explore its use. The ISMP Canada Canadian Pharmaceutical Bar Coding Project will continue to monitor the global status of RFID technology in healthcare and the potential value of RFID integration into future practices.

GS1 and *AIDC* Global Standards

International Consensus and the GS1 Global Standard

In a world of global integration and international commerce flow there is a need to use an international language for business transactions. Both the vendor (e.g., manufacturer) and the purchaser (e.g., wholesaler, retail pharmacy, or hospital) must collaboratively ensure that business transaction information is linked efficiently and accurately to products, quantities and costs. It is to both parties' advantage to use the same bar code *AIDC* standard and, if possible, the same database data fields when transacting business.

Several international standards organizations have published *AIDC* standards which define and allow acceptable bar code symbologies, including the *data elements* that can be used within the approved bar codes. Each standards organization develops a method for creating a shared product information database.

The GS1 global *AIDC* standard was endorsed by the *Canadian Pharmaceutical Bar Coding Project*, as well as other Canadian healthcare projects, such as the national vaccine project coordinated by the Public Health Agency of Canada. The Pharmaceutical project's *Joint Technical Statement* (Ver II: 2012) recommends that all healthcare sectors, including pharmaceutical manufacturers, develop bar code (*AIDC)* processes aligned with the GS1 global *AIDC* standard.

The 2012 technical statement can be found and downloaded at the project web page:
http://www.ismp-canada.org/barcoding/index.htm

Return to Document Précis PDF

GS1 Services

GS1 is a global non-profit *AIDC* standards organization that manages may international data standards, including *AIDC* standards. *GS1* standards are employed across a number of businesses ranging from grocery and clothing retailers, agricultural, equipment and healthcare products and processes. Its standard can be applied to many business processes, such as product transfer and sales, provision of services, equipment parts and repair, and document processing. The *GS1 AIDC* standard has begun to be employed within healthcare settings including on commercial medications, but also on vaccines, medical devices, medical/surgical items, and other products. The application of the standard will benefit supply chain and purchasing, as well as patient safety.

GS1 has branch offices in almost every country. Each branch office works with local business sectors to bridge their specific process needs with the global standards. In Canada, GS1 Canada has offices located in Toronto, Montreal and Calgary, offering bilingual services at all offices.

National branches convene as a global network several times annually, where they continue to evolve the global business standards, including *AIDC* standards, to meet the changing needs of business sectors. One such sector is the *GS1* healthcare group. As a result, the global standard evolves in a parallel manner for all international members. GS1 Canada is a member of the *Canadian Pharmaceutical Bar Coding Project's* national advisory committee and its technical task force. http://www.gs1ca.org/home.asp

It is essential for Canadian healthcare to be able to seamless transact between all healthcare sectors because products and services flow from manufacturers through supply chain outlets, to healthcare provider practices such as pharmacy compounding and dispensing, patient care services and, importantly, bedside care. At each step, both patient safety and electronic health record documentation must occur smoothly and accurately. A common *AIDC* standard will help ensure common and safe practices.

Some Key *GS1* Standardized Healthcare *Data elements*

Within the *GS1 AIDC* standard, several *data element* types are defined, some of which are used in healthcare. The following section outlines some key *data element* types.

The difference between static and variable data elements

Certain GS1 *data elements* found within bar codes are referred to as "static" elements. *Static data elements* rarely change for a given product, so that a product's label and bar code can be printed well in advance. In other words, the bar code never changes.

Another *data element* type is referred to as "variable". *Variable data elements* change each and every time an item is produced. An example of such a *variable data element* in your own home would be the serial number on your home electronic devices (e.g., TV or DVD player). In healthcare, *variable data element* examples

include a product's lot number, expiry date, date of manufacture, manufacturing or packaging location (if several plant locations exist), or, again, a product item's uniquely-assigned serial number.

Some of the bar code symbologies discussed above (e.g., UPC codes) can only handle *data elements* that do not change (i.e., *static data elements*), while other bar codes (e.g., DataMatrix) can accommodate both *static* and *variable data elements* occurring within an embedded data character string.

Common data elements and product "Application Identifiers"

There are very many *data elements* used in business; however few are likely to be found within a medication bar code. Each different *data element* type has a corresponding assigned "*Application Identifier*".

Application Identifiers (AI)

When multiple *data elements* appear within a single bar code, they appear as a long string of characters. To separate the individual *data elements*, and to make them readable as distinct and separate *data elements* by a reader/scanner, they are each preceded by a two or three digit flag called an "*Application Identifier*" (*AI*).

AI codes are also defined within the *GS1 AIDC* standard. In additional to telling a bar code reader where a *data element* begins within a sometimes long character string, the *AI* also informs the reader what type of *data element* it is about to read, and its format. For example, if a product's expiry date is located within a bar code character string, it will be preceded by the *AI* code 17. The following are just some *GS1* examples which may be used within a product's bar code:

AI 01 = *Global Trade Item Number* (*GTIN*)
AI 10 = Lot or Batch Number
AI 17 = Expiry Date (YYMMDD)
AI 21 = Serial Number
AI 30 = Quantity in the package

Packaging levels defined by *GS1*

The *GS1 AIDC* standard also defines and numbers four packaging levels:

Pallet
Case or Shipping Unit: A package/case of Secondary units
(e.g., a case of 12 boxes of 10 vials)
Secondary: A package of Primary units
(e.g., a box of 10 vials)
Primary: The unit of use level of a product.
(e.g., one vial)

Each level is assigned a *GS1* packaging level number, which is included in the product's identifier code, *GTIN*. (See *GTIN* description below.)

The *Global Trade Item Number* (*GTIN*) (Static Data Element)

Key among all product *data element*s is one known as the "*Global Trade Item Number*", or "*GTIN*". It is a globally unique identification code for any product produced, including its packaging level. In medication terms, *GTIN* is a more specific code than the Health Canada *Drug Identification Number* (*DIN*). Its length varies from 8 to the currently recommended 14 character length.

Inclusion of *GTIN* on all marketed pharmaceutical packaging levels in Canada has been recommended to pharmaceutical manufacturers since December 1, 2012.

Using the 14-character length example, the *GTIN* contains (Figure I-3):

- Product packaging level digit
- Company identifier (prefix)
- Company's Product Number Category
- Company's Internal Product Number
- Final "check digit" number to ensure GTIN number is read properly

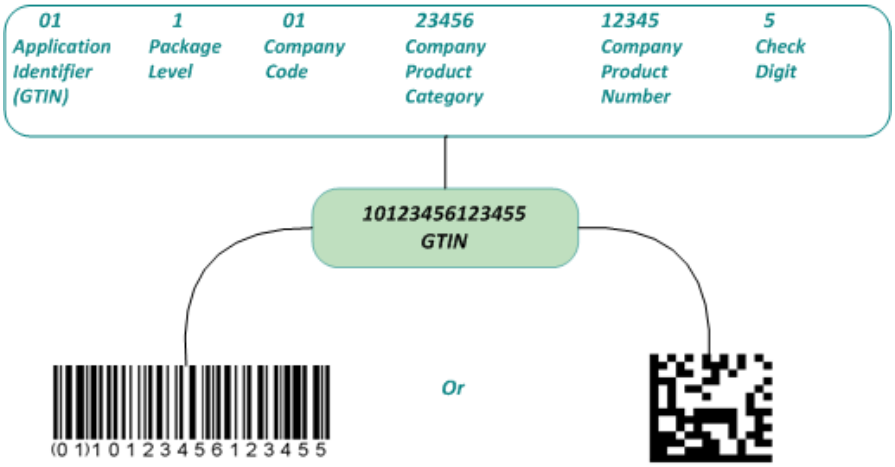

Figure I-3: GTIN-14 Composition

The *Global Location Number* (*GLN*) (Static *Data Element*)

This GS1 *data element* indicates the location of the product's origination, or last location, depending on the use of the *GLN* code. It can indicate the source of the product, and can be added as an additional *data element* within a bar code, but is not required at this time.

Expiry Date (Variable *Data Element*)

The product "Expiry Date" can be included in a bar code string and can thus be used to identify whether the product is usable or not. This *data element* is recommended in Canada by December 2017.

Lot or *Batch Number* (Variable *Data Element*)

The specific lot or batch number assigned by the company can be included within a bar code. This *data element* is recommended in Canada by December 2017.

Global "*Serialization*" Efforts

International healthcare jurisdictions are reviewing the future use of medication product serial numbers, which are seen as an important means of controlling and validating the safe medication chain. It is a future operational practice concept, but one which is already taking root in certain countries.

When serialization is fully developed it will create a continuous string of documented "ownership" of a medication from the manufacturer through warehousing, shipping companies, and, potentially, hospitals and pharmacies to the patient. Its use will greatly assist in the global endeavour to combat counterfeit medication practices. The product serial number will be unique to each vial or unit of medication, much like your home DVD player has a unique serial number. It should be noted that the initial serialization efforts may be limited to a case or secondary packaging level.

Various international healthcare jurisdictions are enacting laws entitled "ePedigree", which will require information to be submitted using a product's serial number to a database that will track and ensure that product distributed is not counterfeit, misbranded or diverted (stolen) product. Some drug products have been known to be susceptible to drug diversion and/or counterfeiting. The enactment of such laws should increase public confidence that their medication is effective and authentic.

The future use and application of medication product serial numbers will be reviewed in 2013 by ISMP Canada, after review of global regulation in this process.

System Requirements for Bar Code Use

Return to Document Précis PDF

Types of Readers

It is not the purpose of this document to provide an extensive review of readers, their specific functionality, or utilization issues.

There are several basic types of bar code readers, but these can be divided into two categories: *light-based* readers and *camera-type* readers.

> *Light-based* readers work by illuminating the contrasting lines of a bar code, such as on a one-dimensional bar code. The contrasting optical density pattern of light (created from the contrast between dark lines and white spaces) returning into the reader is converted into electrical patterns within the reader. These are, in turn, translated into the data character string.
>
> Though some older 2D bar codes may be read by *light-based* readers, *camera-type* readers are required for newer two-dimensional bar codes (e.g., DataMatrix). *Camera-type* readers have an array of light sensors, like a matrix, which captures the pattern of dots within the 2D code. This pattern is converted into data character string.

It is noteworthy that smaller electronic devices, like digital phones, can be used as camera-type readers, and may play a part in the future of healthcare practice. However, currently the differing abilities to auto-focus on an image mean that only certain two-dimensional bar codes lend themselves to reading by such mobile 'cameras'. The *GS1* DataMatrix code can be used, as can a recently-approved *GS1* code called "QR code". (QR codes are popular for rapid access to marketing websites from printed journals, posters and advertisements. QR codes are included in *GS1*-approved symbologies for non-healthcare items purchased by consumers or hospitals.)

Most readers acquired today can read both one-dimensional and two-dimensional codes, but care should be taken to ensure any purchased reader can read bar codes reliably. And, with some readers, they may require that a certain bar code symbology be enabled prior to use. Also, system coordination can fail as a result of multiple reader types, some of which may be different in functionality or read capabilities.

Typical problems with readers and bar codes

The most common reader concern encountered by bar code users is the apparent inability to capture and utilize some bar codes on products. This can become frustrating to the user and potentially lead to user

dissatisfaction and non-compliance. Occasionally a bar-coded item may need to be passed several times under a reader, or the distance between the bar code and the reader face may need to be accurately maintained to keep the readable bar code image in focus.

In mobile practices such as with nursing care, as opposed to desktop practices, unsuccessful reads are a concern that point to the need for fine-tuning reader effectiveness and efficiency. Also, it is important that the reader is chosen carefully, and set-up to read the appropriate bar codes used within the medication system. During implementation, user comfort with reader vagaries should be addressed with the staff.

Unsuccessful reads can also be due to the bar code itself, not the reader. Such variability includes the background of the product label, or the reader's rate of bar code pick-up on certain packaging. Our project's technical statement and other similar standards recommend that pharmaceutical manufacturers ensure a product's bar code readability. Manufacturers follow international technical guidelines and perform standardized readability tests as part of their packaging approval requirements. Some bar codes may inadvertently be eroded due to treatment by solutions during healthcare practices, and labels are tested to reasonably resist such erosion.

Items with small radii or small labeling surfaces, such as a 1 to 5 mL medication ampoule or vial, have may be difficult to read due to the tight radius (bending) of the bar code. This problem can also occur with patient arm bands, especially of small weight neonates, but re-orientation of the bar code direction can often help.

Health and industry sectors continue to identify and collaborate on solutions to known issues. Organizations must ensure the readers utilized are appropriate, easy to use, and that there are not multiple types of readers such that the medication system bar codes cannot be utilized at all points of the medication chain.

Some additional bar code reader implementation issues related to poor reader set-up configuration and product labelling will also be provided in Section III.

Software for Bar Code Medication Practices

The Importance of Complementary Software

Just as a bar code cannot be used unless it can be read, a *data element* extracted by a reader cannot be used unless the reader can relay the *data element* via a software program which connects to a database of information. The software, in turn, used the *data element* to link to product descriptors, and then applies various functionality (safety) steps related to the medication process and health record documentation.

Software is the integrating engine linking the printed bar code (or RFID chip) with the practice functionality that supports patient needs and healthcare providers. Software can perform several important safety tasks along the medication chain and prescription process. For example, it will verify a product and access its product information as a basic minimum function. It can also seek and obtain important ancillary information about the safe use of the product or the appropriateness for that specific patient. Other functions include:

- Automated calculations
- Verification of the correct medication selection based on a patient's medication record (health record)
- Warnings of unsafe situations or patient monitoring requirements
- Confirmation of the completed and approved process
- Accessing patient education material
- Documentation of the process in the Electronic Health Record (EHR)
- Automatic notification of recalled or quarantined medication batches

The Medication Flow Chain and Prescription Process

To this point we have focused solely on medication verification at the patient dose administration level. In fact, the same bar code (or RFID chip) is utilized at every step in a long chain of events, as shown in Figure I-4. It sequentially enhances system conformity and efficiency, product verification, accurate quality documentation. In short, bar codes and software enhance patient safety by avoiding many preventable human errors.

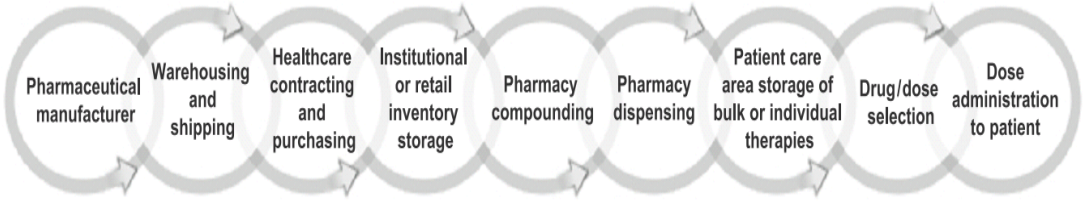

Figure I-4: Medication Flow Chain

Of course, bar code software functionality at each link in the chain is different and specific to the detailed process at that step. However, the basic *AIDC* process described earlier in this section is similar. It includes: product identification and documentation, automated calculations of when small portions inventory units are used, and safety verification against standardized patient records, standard recipes, or standard protocols.

The *Canadian Pharmaceutical Bar Code Project* in 2012 issued a *minimal software functionality checklist* to assist technology providers and healthcare providers to develop and acquire information and automated systems that optimize bar code system potential. The functional checklist is available at the ISMP Canada website, or by clicking on the document image below.

The figure below shows simplistically how software integrates practices at the medication dose administration stage, often referred to as the "*Bar Code Medication Administration*" stage, or *BCMA*. Figure I-5 demonstrates how a scanned medication item is verified and related data captured into the health record, whether within a community-based care facility or an inpatient/ambulatory facility.

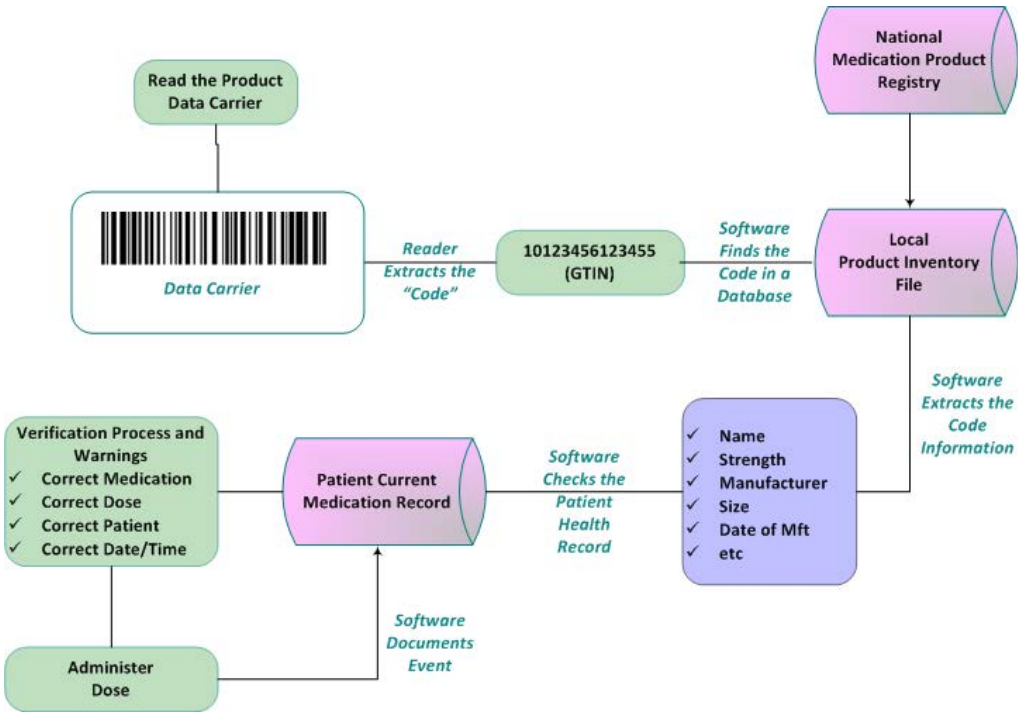

Figure I-5: Simplified *BCMA* System *AIDC* Functionality

Though it is not a primary focus of this resource guide, the establishment of a robust and reliable method of patient bar code identification is a precursor to an effective *BCMA* system. Organizations must ensure that the patient ID system is carefully chosen and implemented, as it is used for critical healthcare practices, or applied services, other than medication practices.

In Section II, a more detailed review of bar code safety functionality and effectiveness is described for points along the medication flow chain and prescription processes.

Reminders and Warnings

Software can selectively integrate reminders to healthcare providers based on known medication treatment plans and site policies. This process may remind a healthcare provider when a medication event is due, to avoid late or missed doses, or may remind healthcare providers of necessary checks prior to administering medication (such as the latest laboratory results). Routine required patient monitoring, such as checking a patient's blood pressure, respiration rates or hydration, may also be prompted.

Warnings related to wrong drug, wrong patient, allergies, dosage, etc can all be ranked or customized by an organization to include only those that are deemed essential for patient safety.

Of course, warnings must be handled carefully. Literature has reviewed the pros and cons of warnings. Though warnings can enhance patient safety, too many warnings may cause operator "alert fatigue", and may unnecessarily interfere with the flow of healthcare. It is not the purpose of this Primer to discuss warnings in great detail; however it is recommended that the reader review literature related to the appropriate use of warnings.

Automated Calculations

In pharmacy operations especially, complex recipes or formulae involving only part inventory units are common, and can quite often involve high-alert medications of concern. A recipe, for example, can be automated to ensure selection of correct ingredient(s), accurate calculation of the portion (volume) of the inventory unit required, and documentation of quality assurance information. These safety functionalities can also apply to nursing practices, where such practices are required.

This is especially critical in those recipes produced by pharmacy and that involve medications with the potential for catastrophic patient harm. These are often produced in pre-prepared batches, and represent an increasingly common safety practice in healthcare.

Interoperability and Accessing Relational Databases

An intriguing development concerns the ability of software to obtain ancillary information related to a medication product from distant, or "relational", databases. Software using the same medication *GTIN data element*, can access external databases, where the *GTIN* code is used to cross-link various databases. Such databases and information uses are potentially many:

- Health Canada product monographs and national "Black Box" warnings.
- Approved Clinical Information including Drug Interaction and Dosing Information.
- Laboratory Interactions or Warnings.
- Parenteral Policies and Infusion information.
- High Resolution product images.
- Approved locally-approved or commercial patient counselling information.
- Educational videos.

The term 'interoperability' is used to denote the ability of two software systems to exchange simple information for use by one system, or both.

Data Capture

Return to Document Précis PDF

How a Bar Code Reader Finds Data

As indicated in the Figure 4, above, using *GTIN* allows system software to find detailed product information from a local product inventory file. The product data within this file can be obtained from a national standardized pharmaceutical product registry. GS1 Canada maintains such a database which complies with global data field standards. It is known as *ECCnet Registry,* and has been recommended by this Project as the primary medication product descriptor data repository. It contains a great deal of information on most marketed Canadian pharmaceutical products. Other similar databases also exist which may also comply with the global rules for standardized data fields.

Both the national and local product databases can contain as many as 50 or more product data fields. Which data fields are relevant to patient care practices are, of course, a local decision when setting up the local software/inventory system. However, it is comforting to know that data fields will increasingly become standardized to global standards, thus allowing more consistent data flow and quality documentation.

Documentation within the Patient's Health Record and Sharing Information

One exciting aspect of a pan-Canadian bar code and data standard is that information on a patient's health record will increasingly become more standardized in its structure. The alignment of both database data fields and product data descriptions between healthcare systems should greatly facilitate the transfer of important patient healthcare information.

This information, in turn, can more seamlessly flow upward into future regional, provincial and national patient health records (Canada Health Infoway), populated from many different healthcare sources within community and institutional settings.

A good start to help to build interoperability between healthcare systems, and the transfer of patient health records to provincial and national health records, is a the point of system procurement. The Project's Supplement B (Software Functionality) to its Joint Technical Statement (ver II: 2012) is a good place to begin. Discuss data synchronization and software safety functionality with your prospective technology providers.

Appendix I-1: Bar Code Types

(Excerpted from: http://www.gs1.org/barcodes/technical/bar_code_types/#ean_upc)

Return to Document Précis PDF

Bar Code Symbology	Summarized Features
UPC A (GTIN 12) 	• One-dimensional • Omnidirectional • 12 Character (others exist for 8 and 13 character versions also) • Numeric characters Only • Allows GTIN-12 (12 character GTINs only) • Point of Sale
GS1 DataBar (GTIN 14) 	• One-dimensional • Omnidirectional • 14 Character (GTIN 12 or 13 character versions are also allowed, if the GTIN number is padded with zeroes (0) on the left to make up the full 14 character string) • Numeric characters Only • Allows GS1 Application Identifiers (GTIN and others)
GS1 DataBar Expanded 	• One-dimensional • Omnidirectional • 74 Numeric or 41 alphanumeric • Allows GS1 Application Identifiers (GTIN and others)
GS1- DataBar Composite 	• Mixed one-dimensional and two-dimensional • Allows GS1 Application Identifiers (GTIN and others)
GS1 Data Matrix 	• Two-dimensional, compact • Can be etched on metal • 3116 Numeric or 2335 alphanumeric • Allows GS1 Application Identifiers (GTIN and others) • Camera-based readers required
GS1 QR Codes 	• Approved for product or customer information (e.g., information websites) • Not approved yet for use in product automated identification.