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Barcoding an automatic identification and data capture system in healthcare settings

SK Md Athar Alli

Abstract
The presentation of this work aims to update professionals involved in the healthcare settings on issues associated with the implementation of barcoding technology as a mode of automatic identification and data capture (AIDC) system. AIDC system are called for exploring resources enriched with updated information on principle and technology associated with developing, processing, and implementing barcoding technology for automatic identification of healthcare products/material and capturing and extracting/retrieving data from same. Thereupon the information were studied, summarised and attempted to be presented for convenience and enrichment of stakeholders in the healthcare settings. The contained information will be updating healthcare-setting professionals regarding knowledge, and issues and concerns of business partners and regulatory bodies while implementing barcoding technology as a means of AIDC system in healthcare settings. As a consequence healthcare products/ materials will be handled properly to prevent injury or loss of life and environmental hazards side-by-side to improve performance, productivity and profit of diverse stakeholders in the healthcare settings, ultimately welfare of the mankind.

Keywords: Barcode, barcoding, data capture, symbology, technology, healthcare

1. Introduction

Increased use of computers from 1970s along with need for improved data capture fuelled organisations/ companies for entering data/information manually into the network terminals so as to have accurate information of a product & asset and managing resources. Assorted benefits with capturing and retrieval of data/information electronically and automatically, that is AIDC, had been replacing many manual data entry tasks by barcoding. The technology of barcoding as a AIDC tool ensure data accuracy and credibility, reduce the impact of human errors, faster entry and retrieval, improve convenience and data management, reduce costs, enables product traceability, and many more [1, 4].

The technology of barcoding (also referring AIDC technology, a form of keyless data entry system) is a computer aided process of generating codified information that subsequently printed on a predefined stationary, invariably on a self-adhesive label/ tag which facilitates AIDC for several later applications. The label/ tag, which stores real time data, comprises series of vertical bars or graphical bar pattern (depending on the width and pattern) encoded with numbers, alphabets, and/or special characters in an easily retrievable and interpretable format by human or a barcode reader/scanner [1, 2]. Nowadays printing of barcodes is cheap and the reading technologies are diverse and reliable, and thus AIDC technology plays a vital role in automating many processes, especially the healthcare setting [1, 3].

Barcodes as AIDC tool are widely used in the healthcare and hospital settings. Their use ranging from patient identification (to access patient data, including medical history, drug allergies, etc.) to creating barcoded SOAP Notes to medication management. They are also used to facilitate the separation and indexing of documents that have been imaged in batch scanning applications, track the organisation of species in biology, and integrate with in motion checkweighers to identify the item being weighed in a conveyor line for data collection [1].

Past four decades had witnessed widespread acceptance of barcoding. This led to development of industry standards by major industry groups, like AIAG (automotive), EIA (electronics), HIBCC (healthcare), HAZMAT (chemical), GS1 and HDA (pharmaceutical and supply chain), International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), American National Standards Institute (ANSI), European Committee for Standardization (CEN), and many other. Such standards ensure universal compliance and easy

Identification of product shipments among trading partners in the supply chain as well as ensure that products (like drugs, healthcare products, hazardous chemicals, etc.) are handled properly to prevent injury or loss of life, and environmental hazards [3].

There are multiple barcodes symbologies with different capabilities and usability for diverse applications; and available are multiple barcode printers and scanners with various strengths and weaknesses. Varieties of solutions leave organisation/ traders faced with the challenge of needing to fully understand selection process of the proper equipment for their unique organisational requirements, while adopting AIDC system in the healthcare settings [4].

This paper aims in presenting necessary information to enable organisation/ traders/ stakeholders of the healthcare system to adopt suitable barcoding system complying their own internal requirements and requirements of business partners and regulatory bodies [4].

2. What is Barcode

'Barcode' is a self-contained machine-readable identification labels or a predefined format of dark bars and white spaces of varying width, structured to contain (or encode) a specific piece of information (as alphanumeric and/ or other punctuation symbols) allowing real-time data to be collected accurately and rapidly for an item or object [2].

The encoded information of barcode is readable by a scanner only; the most common is laser barcode scanner. The barcode is not a system but an automated identification tool that upon integration with computer and application software is providing an accurate and readily/ timely support of data requirement for sophisticated management systems thereby improves performance, productivity and profit [2].

3. Application and Advantages of Barcode Technology

Advantages with the use of barcode technology eliminate human errors as in case of manual data entry and diverse unseen. Followings are the important [2]:

a. It increases accuracy of data entry (error free) and provides highest degree of reliability;
b. Improves information availability & retrieval of data and data integrity;
c. It Improves efficiency of the staff, and speed & quality of services as avoids manual entry;
d. Reliable statistics for management information system and management control; and
e. Real time data collection aid effective management of resources and inventories.

4. Barcode Symbologies

The symbology represents mapping between messages and barcode that is the language used to represent or arrange the bars and spaces. Each symbology follows an algorithm for standardising the encoding and storing of the characters. In other words symbologies defines the technical details of a particular type of barcode like the width of bars, character set, method of encoding, checksum specifications, etc. The specification of a symbology includes the encoding of the single digit/ character of the message and the any required start and stop markers into bars and space, the size of the quit zone required to be before and after the barcode, the compilation of a checksum and many other (refer Figure-1) [5]. Arrangement of specifications within symbology can be varied to suit the different applications, accordingly there evolved a number of symbologies over the years [1, 2, 6].

In the early stage, the data (coded information) is represented in barcodes by varying the width and spacing of parallel lines and are retrieved by scanning that is detecting illuminated reflected light by electro optical sensor called barcode scanner/ reader. The bars are darker and non-reflective element while the white gaps are the reflective element of barcode known as inter character gaps/ spaces. In addition a special pattern of bars/ spaces used to identify the end of a barcode symbol is known as stop character. Nowadays these barcodes commonly referred to as linear or one-dimensional (1D) barcodes [2].

Later on, variants of two-dimensional (2D) barcodes were developed, using rectangles, dots, hexagons and other geometric patterns. These barcodes are called matrix codes or 2D barcodes that do not use bars as such, and can be read or deconstructed using application software on mobile devices with inbuilt cameras. The recent surge of 2D barcoding has gained popularity by allowing the scanning straight from Smartphone for a wealth of data [6].

Barcode symbologies differ in qualities like capacity and linearity, making some advantageous for particular usage and industries. The technology of barcoding is advancing day-by-day. Amongst the available more than fifty different coding symbologies, some of the popular one are discussed in subsequent section and are presented with Figure-2 [6].

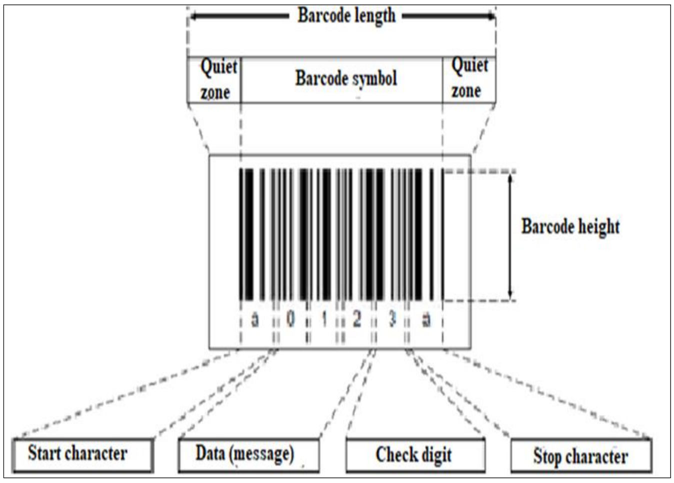


Fig 1: Figure presenting component of linear barcode [27].

4.1 Linear Barcode Symbologies

In linear barcoding methodology the encoded information is stored in the relationship of the widths of the bars (spaces) to each other. In most of these symbologies the height of the bars is not relevant, except for some height-modulated Postal Codes (e.g. Australian Post 4-State or USPS Intelligent Mail® Barcode / IM® Barcode) [7]. Linear barcode symbologies can be classified as [1, 2]:

Discrete: Characters in discrete symbologies are composed of n bars and n-1 spaces. These linear barcode has an additional space between characters, which does not convey information, and may have any width as long as it is not confused with the end of the code [1, 2].

Continuous: Characters in continuous symbologies are composed of n bars and n spaces. In this case the barcode is usually abutted with one character ending with a space and the next beginning with a bar, or vice versa. A special end pattern that is bars on both ends is required to end the code [1, 2].

Two-width: A two-width barcode, also called a binary barcode, contains bars and spaces of two widths that are 'wide' and 'narrow'. The precise width of the wide bars and spaces is not essential. Typically it is permitted to be anywhere between 2 and 3 times the width of the narrow equivalents [1, 2].

Many-width: Some other symbologies use either bars of two different heights (e.g. Postnet), or the presence or absence of bars (CPC Binary barcode). Normally these are considered also as binary barcodes [1, 2].

Interleaving: Some symbologies use interleaving in which the first character is encoded using black bars of varying width. The second character is then encoded by varying the width of the white spaces between these bars. Thus characters are encoded in pairs over the same section of the barcode. Example is Interleaved 2 of 5 (ITF) [1].

Some of the common linear symbology formats presented with Figure-2 while their important features are discussed here. Universal Product Code (UPC) has variants UPC-A, UPC-E whereas the European Article Number (EAN) code is available with EAN-13, EAN-8, JAN-13, ISBN, ISSN variants. They find applicability in retail industry. Code 39 is having low data density, ill-suited for very small goods and assets but used in sectors like automotive and defence. A versatile Code 128 is used in supply chain, shipping, transportation, and logistics. Code 93 finds applicability in retail, manufacturing, logistics, electronic components. The ITF code can only encode numbers (not letters) thus suits packaging. Variants of Codabar are Codeabar, Ames Code, NW-7, Monarch, Code 2 of 7, Rationalized Codabar, ANSI/AIM BC3-1995, USD-4, etc. These are used in the logistics, healthcare and education. Most of their usability is in the retail and healthcare settings. MSI Plessey is less dependable, encodes numbers only, and has applicability in retail field. Variants of GS1 Databar are GS1 DataBar Omnidirectional, Stacked Omnidirectional, Truncated, Stacked, Expanded, Expanded Stacked, and may other [1, 2, 7, 8].

4.2 Two-Dimensional Barcode Symbologies

Feature of matrix codes, a 2D barcode symbology, is square or dot-shaped modules arranged on a grid pattern. 2D symbologies also come in circular and other patterns and may employ steganography, hiding modules within an image (for example, DataGlyphs) [1]. These symbologies cannot be read by a laser scanner but must be scanned by an image-based scanner employing a CCD or other digital camera sensor technology [1, 9].

The 2D Barcodes symbologies are capable of storing more information than conventional linear barcode and can embed a hyperlink to a web page. A mobile device with inbuilt camera can be used to read the pattern and browse the linked website, accordingly 2D Barcodes can serve as portable data files, thus enables the user to access information, remotely from the network database, on data such as lot processing, shipment manifest, and serial number/ stock keeping unit [1, 9].

2D Barcodes (Matrix Codes): In these 2D barcode symbologies the information is stored through relevant positioning of black (or white) dots that is encoding information in two dimensions (refer Figure-2). Examples are Maxi Code, Data Matrix or QR Code® [7].

2D Barcodes (Stacked): The stacked or multi-row barcodes store information in two dimensions in which several stacked linear barcodes are used to encode the information and repeat a given linear symbology vertically (refer Figure-2). Examples are PDF417, Codablock F [1, 7].

2D symbology formats using in healthcare settings are presented with Figure-2 while their important features are discussed here. 2D barcode like QR Code® used in retail, entertainment and advertising field while Datamatrix Code and its variant Micro-Datamatrix are used in electronics, retail and Governments sectors. PDF417 with variant Truncated PDF417 will be bulky and used in logistics and Government. AZTEC does not support same range of characters as QR Code® do. It is suitable for transportation, healthcare and other industries [8].

4.3 Composite Codes

Composite codes are developed by combining linear symbologies with 2D (stacked) symbologies (refer Figure-2). The advantage of such codes is that the linear code component encodes the most important information while the 2D component is used for additional data. Examples are GS1 DataBar [7].

Fig 2: Image of important barcode symbologies (linear and two dimensional) [1, 2, 7, 8].

5. AIDC, Barcoding and Health Care Settings

Continual effort to adopt barcode technology among healthcare settings is dating back to the 1970s. In the early 2000s, published reports began to illustrate high rates of medical error (adverse events), the increasing costs of healthcare, and associated patient safety concerns. The fact had grown the desire for barcoding technology, an AIDC system, in healthcare setting as a realistic and applicable solution [10].

The application of AIDC technology in healthcare involves the use of optical machine-readable representation of data in a hospital or healthcare setting, employing barcoding technology. The barcode system based AIDC technology is intended to help in reducing the number of medication errors that occur in hospitals and health care settings. Scanning of barcodes with the use of scanning equipment allow healthcare professionals to ensure that the right drug will be given to the right patient, at the right time, by the right route of administration, and in the right dose. Thus reduce number of medicine and transfusion errors thereby saving healthcare costs [11].

5.1 Application of Barcoding in Healthcare Settings

Barcoding in healthcare settings have a variety of applications, including the followings [10]:

Specimen Collection and Blood Infusion Safety: Healthcare professionals collect specimen (blood, urine, or other) for testing to help diagnose disease, assess health, and monitor medication level. Accurate result associated benefits can be achievable from error-free procedures of specimen collection and reporting testing result. Improper and/or incorrect procedure of specimen collection may lead to erroneous test results that may lead to serious consequences for patients. This may include delayed or inappropriate treatments and incorrect medication adjustments. Barcoding of the blood and other products may allow for reduction of medical error and improve patient safety [10].

Surgical Instrument Identification and Sterilisation: Barcodes may be used to identify the instruments and supplies in kits for surgical procedures. In addition this may ensure compliance with surgeon's preferences for what their kits contains. Barcodes enable to track what is and what is not used on a regular basis thus may allow for hospitals to optimise kit contents for each surgeon. Surgeon's preferences may change over time. Lack of updates to kit and cart contents may result in the purchase of supplies that are never used; this way barcode provides opportunities to reduce costs. Furthermore barcodes on surgical instruments can be used to uniquely identify each instrument which is sterilised individually [10].

Patient Identification: Barcode technology can help prevent medication errors through making accurate and reliable information readily available at the point-of-care. Information can be easily tracked during the stay of the patient relating the drug identification, medication management, infusion safety, specimen collection, any other patient care activity, etc. Wristbands with barcodes containing the information of the patient's medical record or visit number, and any other identifiers have been proven effective to provide proper patient care [10].

5.2 Barcoding Regulations and Health Care System

Prior to 2000 there is no reference to barcodes. From the initiation of 21st Century, stakeholders across government, provider, practice, and technology have worked together to promote the use of barcodes in healthcare settings. The U. S. Department of Health & Human Services set up a Patient Safety Task Force in 2001. Accordingly there the regulation 21 CFR 606.121(c)(13) is related to blood container labels that states "Container label may bear encoded information in the form of machine readable symbols approved for use by the Director, CBER" [11].

The Drug Supply Chain Security Act 2013 (DSCSA) enforces requirements for an interoperable, electronic system to identify and trace pharmaceutical products throughout their distribution in the United States [12]. In addition, the U. S. Food and Drug Administration (USFDA) regulations require that certain human drug and biological product to have on their labels a linear barcode consisting of, at a minimum, the National Drug Code (NDC) number [13]. The rule also requires the use of machine-readable information on blood and blood component labels (21 CFR 606.121(c) (13)) [12]. The enforced requirements mandates pharmaceutical products must be marked with a NDC, serial number, lot number, and expiration date [12, 13].

In 2011, the USFDA issued guidance that opened the door for using 2D barcode symbologies on vaccine products, allowing manufacturers to replace 1D barcodes with alternative symbologies that capture product identifiers (PID), expiration date, and lot number [14]. The DSCSA also specifies that packages (industrial term is 'lowest saleable units') must be marked with a 2D barcode, and homogeneous cases with either a 2D barcode or linear barcode [12, 15].

California's e-pedigree Law and Drug Pedigree Requirements intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs through creating a track and trace system [16]. The Japanese Government in year 2008 mandated that all medical products must be encoded with a Japan Article Number or JAN, a Global Trade Item Number® (GTIN®), assigned specifically for the Japanese market [17].

The European Commission's Falsified Medicines Directive (Directive 2011/62/EC) aims to fight against counterfeit medicines through serialization and verification. Accordingly those who manufacture, sell, or dispense medications in the European Union have until February 2019 to comply with new track and trace regulations, as outlined in the Directive [18].

The French Club Inter Pharmaceutique 13 (CIP 13) coding legislation requires all prescribed pharmaceutical products distributed in France to print a specified data matrix barcode containing the new CIP13 code, Batch/Lot Number, and expiry date on the outer packaging. And the manufacturer had to find an appropriate technical solution for the serialization number and its carrier such as linear barcode, 2D barcode, and RFID [19].

The Directorate General of Foreign Trade (DGFT), India, issued a public notice on 10th January 2011 regarding implementation of a track and trace system incorporating barcode technology for all drugs and pharmaceutical products exported from India. Accordingly, all export drug and pharmaceutical consignments should be barcoaded at various packaging levels [20].

This mandate is a step towards implementing a traceability system to address challenges associated with counterfeit and ineffective product recall that involves the entire healthcare supply chain, from manufacturers all the way to patients, wholesalers, distributors, exporters and healthcare providers [20].

A critical step in addressing these issues is product identification and data exchange globally, is solving by adopting globally harmonised standards for product identification. Implementation by the regulatory bodies towards traceability calls for use of product serialisation at the secondary level packaging [20].

Serialisation enables building a comprehensive system to track and trace the movement of drugs and pharmaceutical products through the entire supply chain. Identifying every product with unique product number, globally, and by capturing information on its expiry date, batch/lot number, and unique serial number (where applicable) allows tracking of product's lifecycle from production to distribution across borders, all the way to its dispensation to patients at the hospital or the drug store [20].

6. Barcode Symbologies Used in Healthcare Settings

6.1 ITF-14

ITF-14 is a 14-digit number used to identify trade items at various packaging levels, also referred as GTIN®, encodes the GTIN-14. It is based on the Code 2 of 5 Interleaved symbology [7].

6.2 Pharmacode (Laetus-Code®)

The Pharmacode is invented and specified by Laetus® for use in pharmaceutical areas. It supports coloured bars, assigns numeric values to the bars, and used for medicine packing in pharmaceutical field, for small labels. Usually Pharmacode is printed without a human readable text and the data for the bars/ spaces are encoded directly in the property. 'One-Track' and 'Two-Track' are available two variants of these [7].

6.3 Pharma Zentralnummer (PZN)

PZN uses Code 39 as the base symbology is specified by the Informationsstelle für Arzneispezialitäten GmbH. It uses a special check digit and the human readable text always contains the prefix "PZN-" that is not encoded in the barcode data [7].

6.4 Pharmacy Product Number Code (PPN Code)

The content of the PPN Code is specified by the Informationsstelle für Arzneispezialitäten GmbH. It was developed to get unique pharmaceutical product codes on an international level. It embeds the already existing national coding systems, like PZN in Germany [7].

6.5 NTIN Code

The content of the NTIN Code is specified by GS1, is developed for getting unique pharmaceutical product codes on an international level. However this embeds the already existing national coding systems, like PZN in Germany [7].

6.6 QR Code®

QR Code® (ISO standard) formerly QR-Code 2005 is closely similar to QR Code (JIS). QR Code format differs from QR Code (JIS) only in the addition of the facility for symbols to appear in a mirror image orientation, for reflectance reversal (light symbols on dark backgrounds) and the option for specifying alternative character sets to the default [7].

6.7 GS1 DataBar Symbologies or Reduced Space Symbology (RSS) Codes

GS1 developed GS1 DataBar for presenting the NDC using the GTIN® (refer Figure-3(A)). Use of the GTIN® ensures that every variation of a product is allocated a single reference number that is globally unique. Another GS1 identification number is Global Location Number® (GLN®) that identifies physical locations, such as place of departure, place of delivery, and point of storage, adding security and sustainability which is so important when dealing with pharmaceuticals and medical devices [21].

The GTIN® is the globally unique 'GS1 Identification Number' used to identify 'trade items'. Here the trade items are the products and the services that may be priced, ordered or invoiced at any point in the supply chain. GTINs are unique numbers used to identify trade items (i.e. each product type/variant etc.), assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user [20].

A GTIN® is having follow uniqueness [20]:

a. A GTIN® is the unique number that identifies the product or trade item,
b. GTIN® is encoded in a barcode symbology called the data carrier.
c. GTIN® can be an 8, 12, 13 or 14-digit number. However to meet regulatory requirements, the GTINs used to identify primary level items should be in a 14-digit format when encoded in the GS1 DataMatrix barcode.

A GTIN® is created using follow components (refer Figure-3(A)) [20]:

a. Indicator Digit
b. GS1 Company Prefix
c. Item Reference Number
d. Check Digit

Follows are the diverse categories of GS1 DataBar Symbology.

1. **GS1 DataBar (RSS):** GS1 DataBar is not a specific barcode symbology but a GS1 system based numbering system used to encode the GTIN® with application identifiers. In this barcoding system, the GS1 company prefix is used to generate GTIN® that consists of a packaging indicator (0...9) followed by a 12 digit number (taken from the EAN-13 article number system) and a check digit. The check digit on the 14th position is computed automatically if not provided in the input data (refer Figure-3(A)) [7].
2. **GS1 DataBar Truncated (RSS-14 Truncated)**: This symbology is similar to GS1 DataBar but the height should be at least 13X. Omnidirectional scanning may not be possible [7].
3. **GS1 DataBar Limited (RSS Limited)**: RSS Limited symbology is similar to GS1 DataBar, but it is smaller and limited to a packaging indicator (first digit) 0 or 1 [7].
4. **GS1 DataBar Stacked (RSS-14 Stacked)**: The RSS-14 Stacked symbology is similar to GS1 DataBar, but it is split into two rows to make the symbol smaller. It is used for packaging of pharmaceutical products. Omnidirectional scanning is not possible [7].
5. **GS1 DataBar Stacked Omnidirectional (RSS-14 Stacked Omnidirectional)**: This symbology is similar to GS1 DataBar Stacked and supports omnidirectional scanning [7].
6. **GS1 DataBar Expanded (RSS Expanded):** A variable length symbology that encodes up to 74 numeric or 41 alphabetic characters. Data should be encoded with Application Identifiers. Omnidirectional scanning is possible [7].
7. **GS1 DataBar Expanded Stacked (RSS Expanded Stacked)**: It is stacked version of the GS1 DataBar Expanded symbology. The number of data segments per row can vary between 4 and 22 [7].
8. **GS1 DataBar Composite Symbology**: A GS1 DataBar barcode with an attached 2D component (CC-A or CC-B). The 2D component can encode additional information like lot number, quantity, expiration date [7].
9. **GS1 DataBar Truncated Composite Symbology**: It is a GS1 DataBar Truncated barcode with an attached 2D component (CC-A or CC-B) [7].
10. **GS1 DataBar Limited Composite Symbology**: This is a GS1 DataBar Limited barcode with an attached 2D component (CC-A or CC-B) [7].
11. **GS1 DataBar Stacked Composite Symbology**: A GS1 DataBar Stacked barcode with an attached 2D component (CC-A or CC-B) [7].
12. **GS1 DataBar Stacked Omnidirectional Composite Symbology**: It is a GS1 DataBar Stacked Omnidirectional barcode with an attached 2D component (CC-A or CC-B) [7].
13. **GS1 DataBar Expanded Composite Symbology**: This is a GS1 DataBar Expanded barcode with an attached 2D component (CC-A or CC-B) [7].
14. **GS1 DataBar Expanded Stacked Composite Symbology**: A GS1 DataBar Expanded Stacked barcode with an attached 2D component (CC-A or CC-B) [7].
15. **GS1-128 Composite Symbology**: A GS1-128 barcode with an attached 2D component (CC-A, CC-B or CC-C) [7].

6.8. Health Industry Bar Code (HIBC)

HIBC is an abbreviation for Health Industry Bar Code a standard developed by Health Industry Business Communications Council (HIBCC). The HIBC is a numbering system but not a specific barcode symbology. It is used for product identification codes as well as for worldwide identification of shipping units. HIBCC provides HIBCC Unique Device Identification (UDI) code a uniform barcode labelling standard for products shipped to hospitals and HIBCC Labeler Identification Code (LIC) that identifies each medical product manufacturer and is used as part of the HIBCC barcode. The LIC is issued by HIBCC and is a four-digit alphanumeric number, the first character always being a letter [7, 22, 23].

HIBCC accredited by the ANSI and the CEN. It is also an accredited issuing agency for the UDI program of the USFDA. The HIBC standard is of two categories namely HIBC Supplier Labeling Standard (HIBC SLS) and the HIBC Provider Applications Standard (HIBC PAS) and both standards had been approved by the ANSI [23, 24].

a) HIBC SLS, is the basis for the Universal Product Number, and covers the formats used by suppliers of healthcare products [23].

b) HIBC PAS covers the formats used for internal labelling by health care providers themselves [23].

HIBCC administers and maintains five standards that are related to AIDC in addition to the following systems [24]:

1. The Health Industry Number system,
2. The Labeler Identification Code system, and
3. The Universal Product Number system.

Health Industry Number: It identifies trading partners, including specific health care facilities and locations within them, throughout the health care supply chain. It is a randomly assigned, nine-character, alphanumeric identifier [24].

Labeler Identification Code: The LIC identifies individual device manufacturers. It can be used across multiple product lines. Manufacturers in the LIC database can create identifiers at multiple packaging levels by using the HIBC SLS [24].

Universal Product Number: This identifies medical and surgical products. It can use either the HIBC format (a variable-length alphanumeric code) or the EAN format as standardised as a GS1 GTIN®, which is a fixed-length numeric-only code [24].
The HIBCC UDI has four components to the barcode [25].
1. The Data Identifier,
2. Production Identifier,
3. Supplemental data if desired and
4. A Mod 43 check character.

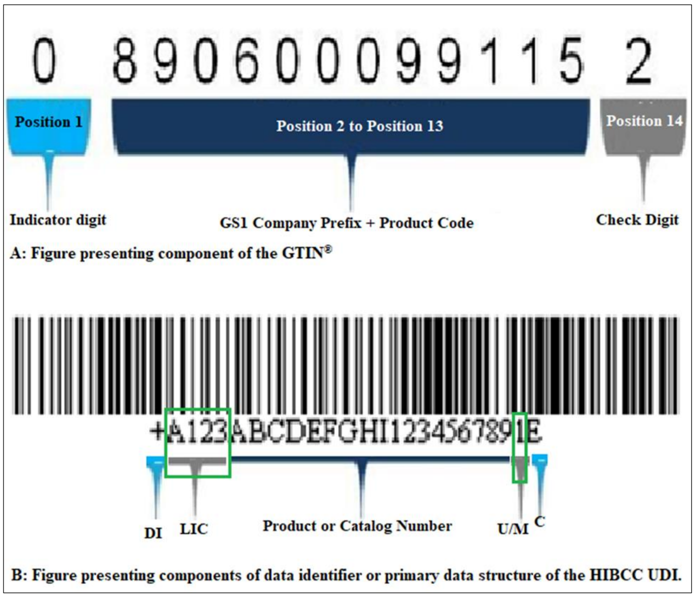
The data identifier or primary data structure is the principal components of the HIBCC UDI. Sub-components of data identifier had been presented with Table-1. Using said tabulated information a data structure for primary barcode "+A123ABCDEFGHI1234567891" is assembled, for illustration (refer Figure-3(B)) [25].
Using the primary data structure and basic barcode symbology several HIBC LIC and/or PAS symbologies can be generated, as enlisted in the Table-2. One of the HIBC symbology generated using data of Table-1 is presented with Figure-3(B).

Table 1: Components of data identifier or primary data structure of the HIBCC UDI [25].

Identifier	Data Type	DB Field Size	Example Data
Device Identifier (DI)	Fixed Character	1	+
Labeler Identification Code (LIC)	Alphanumeric	4	A123
Product or Catalog Number (PCN)	Alphanumeric	1-18	ABCDEFGHI123456789
Unit of Measure Identifier (U/M)	Numeric	1	1
Check Character Mod 43 (C)	Alphanumeric	1	E

Table 2: HIBC LIC and/or PAS symbologies that can be generated using primary data structure [7].

Based on the symbology (data carrier)	Name of the HIBC Symbology	
	LIC	PAS
Code 128, a 1D symbology	HIBC LIC 128	HIBC PAS 128
Code 39, a 1D symbology	HIBC LIC 39	HIBC PAS 39
Data Matrix, a 2D symbology	HIBC LIC Data Matrix	HIBC PAS Data Matrix
QR Code, a 2D symbology	HIBC LIC QR Code	HIBC PAS QR Code
Aztec Code, a 2D symbology	HIBC LIC Aztec Code	HIBC PAS Aztec Code
PDF417, a 2D symbology	HIBC LIC PDF417	HIBC PAS PDF417
MicroPDF417, a 2D symbology	HIBC LIC MicroPDF417	HIBC PAS MicroPDF417
Codablock F, a 2D stacked symbology	HIBC LIC Codablock F	HIBC PAS Codablock F



A: Figure presenting component of the GTIN®
B: Figure presenting components of data identifier or primary data structure of the HIBCC UDI.

Fig 3: Figure presenting component of the GTIN® (A) and the HIBCC UDI (B).

7. Printing of Barcode Labels

Barcodes can be printed on various packaging levels by adoption of two common printing methods [3, 20].
a. Online or inline printing methods, and
b. Offline printing methods.

Online or Inline Printing: Online or inline printing refers to the printing method where the printing and application system is deployed on the production and packaging line itself. This system could be directly connected with an application or 'enterprise resource planning' system that generates and print barcodes in the production process for primary, secondary, and tertiary packaging levels [20].

Offline Printing: Offline printing refers to the printing method where the printing and labelling process is done post production for all levels of packaging that is use of the preprinted barcode label [20].
Preprinted barcode labels bear several limitations like restricted flexibility, unsuitability for inclusion of variable

customer data or combinations of text and barcode information. Ordering preprinted barcode labels from service bureaus are useful and beneficial in operations that require only a low volume of identical labels bearing fixed and non-variable data, often with extensive use of colours or graphics. Organisations with applications requiring high-volume mission-critical labels will find on-demand barcodes worth the initial investment associated with the added value from printing customised information on each label. If they have barcoding systems, can order preprinted labels with the necessary colour, graphics or standardised text (like return addresses on shipping labels); that will be fed through a barcode printer to receive customised labels with variable information [3].

While using preprinted or plain labels, media selection is critical to the success of any barcode integration. The media comprises a variety of ribbons, paper, synthetic labels and tags. However, barcode application, intended life span of the label, and environment to which the label will be exposed all have a direct impact on media selection. It is wiser to pre-test variety of media in an application before purchasing them in bulk quantities [3].

7.1 Barcode Printing Technologies

There are several printing technologies are available for barcode printing. Follows are the some of the most common printing technologies used within the AIDC industry (refer Figure-4) [3, 20]:

1. Dot matrix printing,
2. Inkjet printing,
3. Laser printing, and
4. Thermal printing.
5. Direct thermal printing, and
6. Thermal transfer printing.

Dot matrix printing: Dot matrix technology uses a hammer or pin to transfer pigment from a ribbon onto the substrate/media (refer Figure-4) [3].

Advantages [3]

a. Inexpensive and readily accessible. Uses multi-pass ribbons that can result in reduced overall cost for ribbons and label materials.
b. Can print on virtually any type of form, cheque, or document and can print on wide-web, multi-part (carbon) forms.

Limitations [3]

a. Prints low- to medium-density barcodes that may not meet certain end user requirement.
b. Continuous reuse of ribbon requires close monitoring of ribbon condition for ensuring adequate barcode contrast.
c. Ink saturation of ribbon can result in paper 'bleed' that can cause image distortion.
d. Printed label have limited durability and are not chemical- and/or water-resistant.
e. Printing of single labels associated with significant waste. The design of print carriage in the dot matrix printers, which sitting far below the media, does not allow the label space to be maximized.

Inkjet Printing: Inkjet printing technology works by propelling tiny drops of ink onto the substrate to create the symbol, thus the process does not require contact between the printer and the substrate (refer Figure-4). Inkjet printing process is of two main categories [3, 20]:

Continuous inkjet printing: In this case high-pressure pump creating a continuous stream of ink droplets which are then subjected to an electrostatic field. This results in a controlled, variable electrostatic charge that determines if the ink drop should be printed on the substrate or recycled (leaving a light area) [3, 20].

Drops on demand inkjet printing: Printers in this family particularly suited for high resolution printing which only uses drops of ink that are required to print [3, 20].

Advantages [3]

a. A one step process in case of direct inkjet printing while a two-step process in case of label printing, i.e. printing the label and fixing the label to the product.
b. Some processes are designed for high-volume barcode printing while high-speed inkjet printing suits high-speed production lines as have ability to print 'on-the-fly'.

Limitations [3]

1. Inkjet printing process is often too slow also calls for diligent supervision and maintenance for ensuring consistent print quality and prevents clogging of inkjet.
2. System installation is costly as designed for high-volume barcode printing, and not for individual or small batch printing.
3. Dot placement accuracy and barcode resolution/ density are limited as the print surfaces are in continual motion and due to ink splatter.
4. In most cases water-based inks used therefore label streak, run, or blur when come in contact with water. Whilst use of water insoluble inks often produces a shine that reflects light back to the scanner and barcodes printed on the dark background of corrugated box materials endure from poor contrast. All these rendering barcode with poor readability and sometimes unscannable [3].
5. Requires careful selection of scanning device for ensuring reliable barcode reading.

Laser Printing: Laser printing is an electrostatic digital printing process producing barcode labels with relatively high density and resolution (refer Figure-4) [3, 20].

Advantages [3]

a. Can be serve for printing plain-paper documents and barcoaded document and/or label.
b. Have ability to print high-quality text and graphics on paper documents.
c. Prints barcodes with quite high density and resolution that can be scannable at virtually any wavelength using an infrared scanner.

Limitations [3]

1. Laser technologies are not well suited for industrial or individual-product labelling operations. Laser printer cannot produce single or small labels thus can be wasteful; and toner, drum and supply costs can skyrocket while printing barcodes instead of text materials. In case of long-term, the printing is susceptible to toner flaking and smudging.
2. Adhesives of label for laser printer should have adequate stability under the heat and pressure of the fuser.
3. A laser-printed paper label has limited durability as

printed images are not chemical- and/or water-resistant.

Thermal printing: The most widely used thermal technologies for dedicated barcoding systems are direct thermal printing and thermal transfer printing (refer Figure-4). These printers are best in any of conditions like: point-of-application system, varying label sizes, graphics and scalable text font sizes, high-definition barcodes, compact printers, low operational costs, etc [3, 20].

Direct thermal printing: This technology, noted for their simplicity as eliminates use of ribbon, utilises heat-sensitive media that blackens as it passes under the printhead (refer Figure-4) [3, 20].

Advantages [3]

a. This technology is ideal for applications requiring labels with sharp print quality, good scannability, and short shelf life.
b. Printers of direct thermal technology are simple to operate and enable batch or single label printing with virtually no waste comparing to that based on other technology.
c. Here long-term maintenance costs remain low, as there is no ink, toner, or ribbon to monitor, replenish, or replace, other than the material to be printed.
d. Direct thermal printers are environmental friendly and offer environmental economy, associates with availability of recyclable materials.
e. Printers typically built with high durability comparing dot matrix or laser printers, offering reliable operation in industrial as well as office applications.

Limitations [3]

1. Direct thermal printing process is extremely sensitive to environmental conditions like heat and light (fluorescent and/or direct sunlight).
2. Media used in direct thermal printing remains chemically active after printing, thus the printed labels, tags or ticket stocks should be coated suitably (specifically on the top surface) to resist UV light exposure, chemicals, and abrasions.

Thermal transfer printing: Thermal transfer printing technology works through transmitting heat onto a ribbon (a tape coated with specially designed ink) that then transfers the image onto the label (refer Figure-4) [3, 20].

Advantages [3]

a. Thermal transfer printing technology delivers crispy and high-definition text, graphic, and barcode along with print quality for maximum readability and scannability.
b. This process produces image on unlimited variety of media stock (except multi-form) with stability for long period.
c. Its operation is reliable both in industrial and office applications, and enables printing label either singly and in batch with virtually no waste.
d. Thermal transfer printers are typically more durable and have low long-term maintenance cost comparing dot matrix, inkjet, and laser printers.
e. Printheads of thermal transfer printer have more longevity than direct thermal printers.

Limitations [3]

1. Thermal transfer printers require ribbon thus supply costs are higher than direct thermal printers.
2. Ribbons for thermal transfer printers have poor recyclability, thus single-pass ribbon can be wasteful if little is printed on it.
3. The ribbon and media substrate used in thermal transfer printing must be compatible to have optimum print quality.

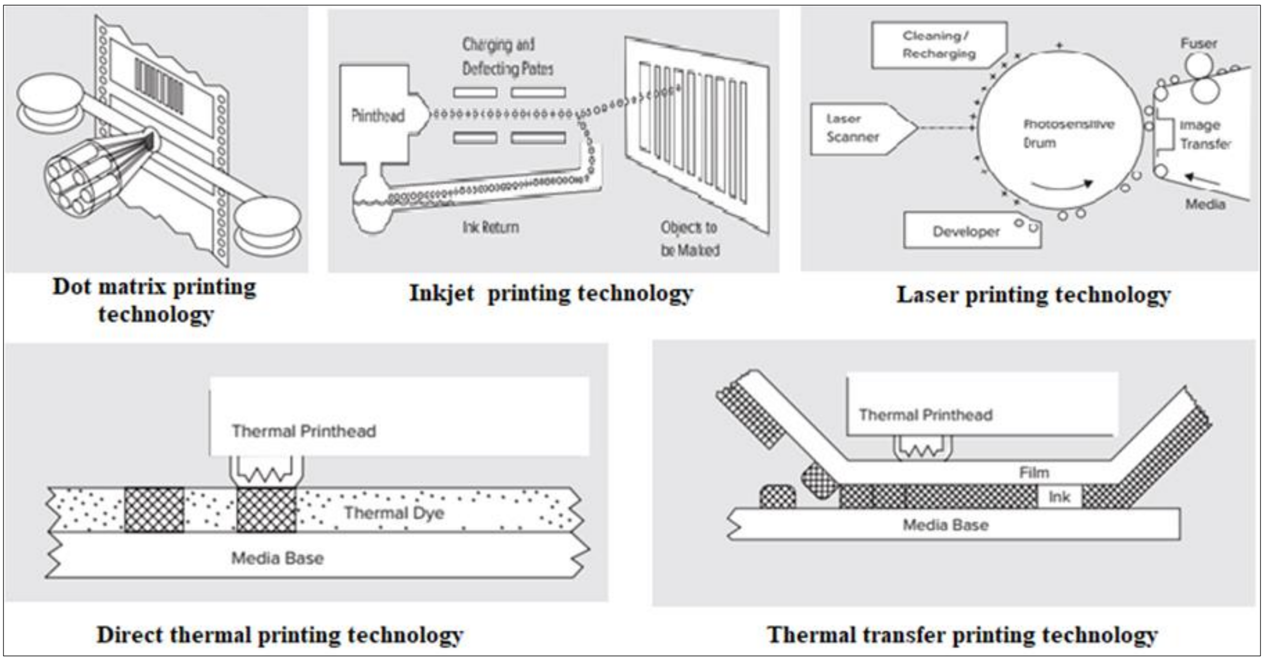


Fig 4: Working principle of most common printing technologies for barcodes.

7.2 Selecting the Right Printer

Selecting the right printer is not as intimidating as it perceived. Judicious analysis of the barcoding functions in specific terms and summarising requirements based on follow points, printer choices can be narrowed considerably [3].

a. Requirement of print resolution, label image durability, print width (that is dimensions of the labels), and the intended usage of the barcode labels.
b. Consider the environments of operation/ location (temperature fluctuation, vibration, high humidity, exposure to chemicals, etc.) and whether the printers be connected to a network or to stand-alone terminals.
c. What's the frequency of change in the label specifications, print volume, minimum printing speed requirements, and printer durability that is anticipated duty cycles for the printers?
d. Environmental conditions that the labels will be exposed to (temperature fluctuation, abrasion, high humidity, exposure to chemicals, etc.).
e. Finally the budget for the project.

8. Automatic Identification and Data Capture

AIDC is doing by affixing a unique barcode to the product/ material followed by using a barcode scanner that encodes and extracts information optically from the barcode. Linear symbologies are read by laser scanners that sweep a light beam across the barcode in a straight line thus reading a slice of the barcode's light-dark patterns. Barcode upon illumination reflects light which is detected by electro-optical sensor and converted into electronical voltage signals. The intensity of reflected light from the dark bars is less than that of spaces (white lines) [2, 26]. In case of laser scanning the laser making multiple passes across the barcode suits for scanning the stacked symbologies [1].

Most 2D codes require an image scanner, which is a barcode scanner also, that algorithmically processes the printed image and converts them into electronic form by shining light into the image and sensing the intensity of light reflection at a point. The image scanners are effectively digital cameras with integrated processors and thus can also capture images including signatures. The image scanners can interface as a keyboard or serial emulation device, via USB, PS-2 or serial connection [1, 2, 9, 26].

Barcode scanners can be categorised in diverse ways, like hand–held, hands-free, fixed-mount, portable data terminals, pen-type or wand barcode scanners, and many more. In addition to these categorisations, most barcode scanners can be classified as laser barcode scanners and image capture barcode scanners. Figure-5 presents commonly used barcode scanner/ reader [26].

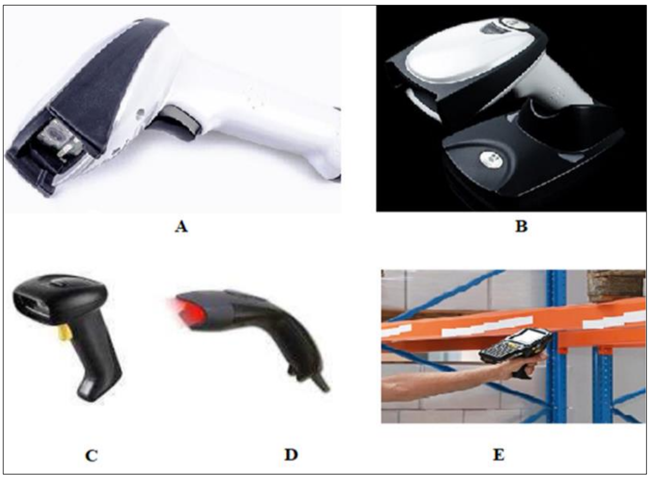


Fig 5: Commonly used barcode scanner/reader.

8.1 Laser Barcode Scanners

These are the most common type of barcode scanners, are generally cost-effective and read only standard 1D barcodes. These scanners have scan pattern that is either a linear or omnidirectional. The omnidirectional have a wider reading area and don't require the user to have the scanner perfectly centred over the barcode at the correct angle thus making them more functional for many applications than scanners with linear scan patterns. With laser scanner there is typically no sweep pattern that can encompass the entire symbol, thus are unsuitable for 2D Symbologies [1, 26].

8.2 Image Barcode Scanners

These are more sophisticated than laser barcode scanners. Instead of using a laser, these uses image capture technology to scan barcodes and digital image processing functionality to decode them. However these are also more costly, although they come at a wide range of prices [26].

8.3 Hand Held Linear Scanners

A handheld barcode scanner is any scanner that is held in the hand of the user during operation. Most handheld scanners are designed like a handgun, with a grip and a trigger to activate the scanning operation. The handheld barcode scanner having their own full-blown operating system running, also termed as 'Mobile Computer', can be corded, cordless, 1D, 2D, or connected to a iOS/ Android Smartphone/ tablet (refer Figure-5(E)) [2].

8.4 Mobile Barcode Scanner

Barcode scanning mobile applications are another option, where a Smartphone or tablet PC serves as a barcode reader through the use of a downloaded application. Many of these applications allow users to scan multiple symbologies including 1D, 2D, QR codes, and many others [26].

8.5 Barcode Scanner Selection Criteria

The following technicality/ features will help in defining unique requirements while selecting a barcode scanner [9, 26]:

a. What symbologies need to scan, linear and/or 2D barcodes, barcode printing method and barcode density, and typical scanning distance that is distance from the scanner to the barcode [4, 26].
b. If the equipment is linear or image-based scanner and how often scanners will be used? [4, 26]
c. Environmental factors: Ruggedness requirement, for indoor and/or outdoor use, exposure to/ use in extreme cold or heat, subject to corrosive/ harsh chemicals. Scanning application with potentially hazardous conditions (indoor or outdoor) and outdoor calls and for more durable model with an IP rating of IP54 or IP65 [4, 26].
d. Consider the scanner features for mobility, compatibility, connectivity (like fixed, mobile, mounted, motion activated scanning requirement, tethered or cordless), self-contained software, incorporated Bluetooth/ Wi-Fi technology, with/ without USB/ serial/ PS-2 keyboard connection, inbuilt programmable symbol selection, implementing keyboard emulation, and many others [4, 26].
e. End user considerations: Ease of use, weight, durability, reliability, cleanability, fluid resistant/ waterproof, and power and charging requirements like requirement of power supply, battery life, and battery backup [4, 26].
f. Efficient receiving: Trade units may be marked with the

GTIN® only with no secondary identifier or symbology thus may be encoded in an ITF symbology. Instances calls for inclusion of secondary identifier on logistical or product units like batch/lot number, expiry date, best before date, and/or production date. Thus requirement is the use of the GS1-128 symbology, as ITF is incapable of encoding secondary information. Scanning equipment for the pallet and case level may not call for 2D or 3D image-based scanners. However, if situation warrants to scan below the case level (for instance, cases opened and product repacked for distribution), image scanners be considered/ recommended. The variations in these situations depends on the receiving process touch points that includes [4]:

1. Receiving from manufacturer,
2. Pick and pack from distribution centre to provider,
3. Receiving at provider, and
4. Inventory management.

9. Quality Control of Barcodes

Developing and implementing barcode technology as AIDC tool with 100% reliability, it is common for producers and users of barcodes to have a quality management system which includes verification and validation of barcodes. Thus need is the examination of scannability and the quality of the barcode in comparison to standards and specifications of user and/or regulatory bodies. The processes of verification and validation will improve the effectiveness of a labelling program, as it involves evaluating very different elements of the barcode [1, 27].

For linear barcodes testing parameters are edge contrast, minimum edge contrast, symbol contrast, modulation, inter-character gap, defects, and decodability. While for 2D matrix symbols look at the parameters like symbol contrast, modulation, decodability, unused error correction, fixed (finder) pattern damage, grid non-uniformity, axial non-uniformity, and many others. Depending on the parameter, each is graded with ANSI test grade from 0.0 to 4.0 (F to A), or given a pass or fail mark [1].

9.1 Barcode Verification

Barcode verification ensures readability, regardless of who is scanning the symbology, also provides feedback on the quality of barcodes thereby controlling and improving the barcode production process. Barcode verification, conceptualises 'Standards-Based Quality Measures', is the process of confirming the data content format within the barcode meets specific application standards as well the print quality of a barcode using ISO, IEC and/or ANSI standards [27].

As per ANSI standards the barcodes are graded with letter grades A, B, C, D, and F. Relating to quality A is the highest and F is the lowest. The ISO/IEC standard provides numeric grades that range from 4.0 to 0.0. The grade 4.0 is highest quality while the 0.0 is the lowest quality. The ISO grades provide a higher data granularity comparing ANSI grades. ISO/IEC 15416 standard covers 1D barcode whilst ISO/IEC 15415 covers 2D barcodes. An ISO score of 1.5 and ANSI grade C is considered 'passing' for most applications. There also application-specific standards, like the GS1 General Specifications or MailMark for the UK Post Office. These systems are having their own requirement that can be confirmed via barcode verification [27].

9.2 Barcode Validation

Barcode validation confirms that the correct barcode information is applied to the correct product is a concept of matching the right data to the right product. The validation process may include checking the size of barcode and its position on the final product/ package, and ensuring that other packaging elements are non-interfering with scanning. Barcode validation may include evaluations of after use (abuse) testing parameters such as sunlight, abrasion, impact, moisture, etc. The barcodes are validated according to the rules created by the company performing the validation [1, 27].

9.3 Verification and Validation of Barcodes

Barcodes play an increasingly important role in AIDC process, in diverse industries. For ensuring that vitally important factors are the barcodes be consistently read and contain the correct data. Barcode verification processes use standards based measures to ensure that the barcode can be read with any scanner at any location. In the other hand barcode validation ensures that the right barcode label or mark has been applied to the right product, and contains the right data. The integration of barcode verification and validation is the basis for 'Mission-Critical Quality Control' in labelling and production processes [27].

Comparing verification validation does not follow stringent or defined standards but is equally important to ensure the success of a barcode labelling/ marking program. If the barcode is encoded with incorrect data and/or is applied to the wrong item or package, there could be a number of operational failures like inaccurate shipments, returns, repackaging, chargeback, and other costly errors. The results of validation test are more subjective in nature, and necessarily cannot ensure the scannability of barcode. A poorly printed barcode could pass a validation test, as it contains the right data, but will fail a verification test. The points on barcode verification versus barcode validation presented with Table-3 [27].

In the field of pharmaceutical and medical device, and healthcare setting the consequences of improperly labelling are even more critical. For example in the retail sector, the improper labelling of pharmaceutical or medical device, that is product label with incorrect barcode data, can affect sales and profitability or result in product recall [27].

Table 3: Difference between verification and validation.

Barcode Verification	Barcode Validation
▪ Ensures print quality and scannability of the barcode.	▪ Evaluates accuracy of the barcode data and correctness of label and labelling the product.
▪ The process is standards-based.	▪ The process is subjective and based on requirements of user/company/regulations.
▪ Requires purpose-built verification systems.	▪ Can be performed using any scanning equipment.

9.4 Barcode Verifier Standards

The ISO defined 'Barcode Verifier Standards' initially in ISO/IEC 15426-1 (linear) and ISO/IEC 15426-2 (2D), which is repealed by ISO/IEC 15416 (linear) and ISO/IEC 15415 (2D). The European Standard EN 1635 has been withdrawn and replaced by ISO/IEC 15416. The original United States barcode quality specification was ANSI X3.182 (UPCs used in the US– ANSI/UCC5). As of 2011 the ISO workgroup JTC1 SC31 was developing a Direct Part Marking quality standard: ISO/IEC TR 29158 [1].

There are a variety of verification and validation solutions available, including wide range of models and price points. Integration partners can provide expert guidance in finding the right solution for industry and application, as well as integrating verification and validation into existing labelling and production processes [27].

10. Healthcare Settings and AIDC Concerns

Implementation of mature technology involving barcodes as an AIDC tool is appreciated by economists. However, there are concerns with the use/ implementation of improper AIDC technology in healthcare settings [10].

1. From the technological standpoint, linear barcode symbologies have their limitations with regards to their size, memory capacity to store data, and standards that are put in place (like the 10-digit NDC number) [10].
2. There is an escape with 2D symbologies, providing smaller barcodes for healthcare materials and tools or memory capacity to store larger amount of data. As a result, there has been a lot of attention on the use of 2D barcode labels [10].
3. However, nowadays there exist older models of barcode scanners in the healthcare setting are unable to read compact symbologies like RSS composite, or 2D symbologies. A fact as a solution is recent models of smart phones is capable to read all known barcodes using respective applications [10].
4. AIDC will impact the workflow process positively. However the workflow interruptions may be resulting from fatigue and frustration among clinical professional when having insufficient support of information technology. Workarounds are common issue with the use of many technological devices/ systems. Some examples leading to workarounds in a clinical setting results out of barcoding technology may include (but are not limited to) adherence to outdated equipment [10].

The concerns in nutshell are [10]:

a. Formalising clinical professional autonomy to document decisions;
b. Support is too slow to respond in clinical routine, especially emergencies;
c. Software limits in flexibility with dosing orders;
d. Sequencing the monitored medication delivery window and prioritizing other patient care activities; and
e. Equipment problems like missing armbands, illegible barcodes, and others are summarised as insufficient data quality.

All concerns may be traced to inadequate methods or insufficient tools with a non-covered demand for support by modern information technologies. Actualised decision for equipping the mobile work serves to overcome limitations originated from legacy equipment [10].

11. Future of AIDC in Healthcare Settings

Barcodes as AIDC tool are an important part of the drug safety infrastructure adopted by regulatory authorities, globally. Amongst the diverse available barcode symbologies the 2D barcodes capture more data elements and occupy less space than a linear barcode side-by-side is improving accuracy and completeness when the encoaded data of the barcode is captured or extracted by scanning. In addition, the 2D barcode symbologies facilitate the accurate tracking of PID by the regulatory authorities as well as help healthcare providers in capturing accurate and complete data about inventory and administration of healthcare products like pharmaceuticals, drugs, vaccine, and many others [10, 14].

Barcoding as an AIDC technology in healthcare is eventually underway to shift over to the use of 2D symbologies to adapt the size restrictions and the growing need for large amounts of data. Furthermore, current guidance allows for a PID, such as the NDC, a lot number and an expiration date on 2D barcoded healthcare products. Due to availability of same (diverse data) on vaccine vial and syringe labels, these data are often captured manually into an Electronic Medical Record or Immunisation Information System by a provider at inventory and administration. This is so soon becoming a reality with the use of mobile phones and is bound to play crucial role in the development of 'mHealth' [10, 14].

In the AIDC process the barcoding, as a mature reliable technology, will continue to be adopted within the healthcare setting to improve the quality of patient care. However, growing attention on radio-frequency identification (RFID) systems are expected to be the future competitor for barcoding in this field. However the simplicity, universality, and low cost of barcodes will limit the role of RFID. Still barcoding will continue to play a prominent role with RFID and will likely integrate with RFID to form a hybrid system. In this case, barcoding (1D and 2D) will continue to have advantages over RFID (specifically passive RFID) due to follow reasons [1, 10]:

a. Barcoding is cheaper than RFID, thus price of passive RFID must be lowered to become competitor, and;
b. Barcode technology is ideally suited for tasks where a human being is stationary and objects are moving, for instance, blood sample collection and labelling.

Organisations involved in health care system should encourage the use of 2D barcoded products, incorporate 2D barcoding into their workflow, adjust software for 2D barcode functionality, and support the continued adoption of 2D barcode scanning at the point of care in order to improve data quality and efficiency in their facilities. Encourage integration of 2D barcode symbologies on pharmaceuticals/ drugs and promote consistency of use among healthcare professionals. Adopt activities to promote the adoption of 2D barcodes by requesting the healthcare information system vendors to integrate 2D barcode functions into their systems, train staff to adopt them, develop a scanning protocol for 2D barcode symbologies, perform regular testing for assessing working efficiency of scanners (e.g., scan 2D barcode into a word processing document to validate output), support scanner configuration, troubleshooting and continuing education as needed [14].

12. Conclusion

Implication of AIDC through barcoding, by itself is not system but an identification tool, will provide an accurate and timely support of the data requirement for the sophisticated management systems and improve resource management and efficiency of healthcare settings.

Healthcare products required to be treated differently than consumer products, as human safety requirements apply and they are monitored by the government. Thus labels for patient use must be error-free, and must contain specific, required information. Furthermore during transfer/ movement of healthcare product/ drug through the supply chain it will come across various touch points where information needs to be automatically captured and shared with the regulatory authorities, and other stakeholders.

There been diverse barcoding systems for medical products and the industry needs to standardise on one system. Most in the healthcare industry agree that using different barcoding systems is not efficient and do they really need to pick just one as which option is better, but the more difficult task is selecting one option as the standard. However, most of the regulatory authorities has not backed any option, but has concentrated more on the concept of developing a UDI system for pharmaceuticals and medical devices. However HIBC meets mostly the unique needs of the healthcare and medical and pharmaceutical manufacturing industries.

Ensure that the bacoding system performing complying the validation and verification protocols. Furthermore ensure that scanners selected are capable of scanning and decoding 2D Matrix barcode symbology and 1D barcode symbology, complying prevailing guidelines. Use of standards-based verifier is must thus perform verification using purpose-built barcode verifiers (that meet ISO/IEC standards). Calibrate these verifiers on a regular basis to ensure proper operation. Calibration should be performed usually using Calibrated Conformance Test Card, in which each barcode symbology specification includes a reference decode algorithm. Reading barcode with a regular scanner is not verification; as this cannot guarantee that another scanner along the supply chain in further stage can also read that code.

Thus to facilitate AIDC, barcode scanners and/or portable data terminals should be used within warehouses, point of shipping, and many other touch points/ terminals to capture the data by scanning the barcode labels. Accordingly, organisations may have diverse barcode scanning requirements. For instance, warehouse receiving may require a portable, hand-held scanner or a floor mounted portal which is fixed to the docking bay. In other hand, point of sale requirements may not be same, due to the employment of different symbologies for product identification. All these issues required to be complying.

Since the majority of pharmaceutical products have a multi-year lifecycle, expectation to realise the full impact of serialisation is not prior to 2022. Thus serialisation will be a gradual process. We must continue to work out issues and adjust processes to experience the benefits of complete, accurate product data. This knowledge will help manufacturers to fix these barcodes and ensure compliance with standards failure will impact the entire supply chain, in the upcoming years.

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