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International Centre for Health Innovation

# Models for Global Medical Device Supply Chain Standards.

BEST PRACTICES FOR NOMENCLATURE AND UNIQUE DEVICE IDENTIFICATION STANDARDS FOR CANADA

May 2018

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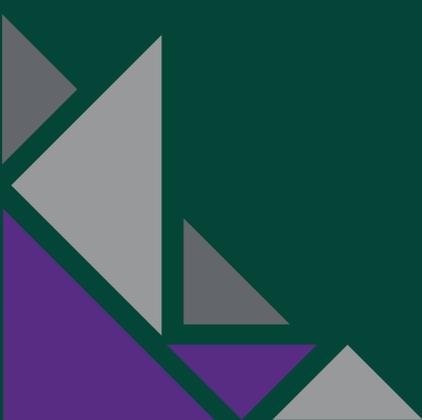
# Executive Summary

Supply chain management and optimization has become a priority area for global health systems due to increasing complexity of healthcare supply chains and the availability of IT solutions capable of automated supply chain management and advanced analytics. Initiatives to promote the efficiency and effectiveness of materials management have been largely motivated by cost savings, but are reaping multiple benefits including promoting patient safety, reducing medical errors, and promoting patient outcomes measurement and tracking.

As health systems are becoming increasingly globalized, particularly related to multi-national device manufacturers, ensuring that all health system product data systems are aligned and interoperable is becoming increasingly important. One approach to managing this challenge is the adoption of global standards which ensure that data systems are using the same terminology and technology so that processes can be standardized internationally. In the healthcare industry, there are two key standards types to identify product information: (1) *unique device identification* (UDI) standards, which standardize product labelling and barcode information; and (2) *nomenclature* standards, which standardize how devices are named and categorized:

▶ **Unique Device Identification** (UDI): A product identifier, usually in the form of a barcode, which has standardized product information such as a device labeller, batch number, serial number, expiration date, and date of manufacture.

▶ **Nomenclature**: A coding system used to describe medical device categories.

The benefits of both UDI and nomenclature standards include reducing medication errors, enabling end-to-end supply chain visibility, facilitating effective product recalls, tracking of medical products, enhancing inventory management, supporting regulatory compliance, and automating reimbursement and replenishment processes.

Adoption of these standards has spread across the United States and Europe, but Canadian adoption has been limited to date. Some Canadian manufacturers are currently subscribing to global standards, particularly multi-national companies, but few hospitals are ready to capture this data. This research engaged the perspectives of 30 health system leaders with expertise in supply chain transformation and UDI and nomenclature standards, in order to meet the following objectives:

▶ Introduce the concepts and benefits of UDI and nomenclature standards;

▶ Identify and examine different current state models for supply chain standardization from multiple countries and industries;

▶ Provide an objective analysis on which standard (or blend of standards) is most efficient from a health system perspective for both UDI and nomenclature;

▶ Make recommendations for the future state standards model selection and design for the Canadian health sector; and

▶ Propose implementation and change management strategies for health sector supply chain standards adoption in Canada for manufacturers, government, and delivery organizations, taking into account enablers, capabilities, and capacity for adoption.

# 1. Unique Device Identification

Unique device identifiers (UDI) are a common, agreed-upon standard used by medical device manufacturers, government regulators, hospitals, and shared services organization (SSO) supply chain managers to track and trace product use. They are typically in the form of a product barcode, which is issued to a manufacturer by a standards organization. Product information (i.e., serial number, batch number, manufacturer, etc.) is uploaded by the manufacturer into a datapool, which is then accessible to healthcare delivery organizations. Healthcare delivery organizations can then link product information to a patient record, leading to complete end-to-end supply chain visibility of specific products.

In Canada, manufacturers, who often sell to multiple countries, are well-positioned to label all of their products with UDI in the near future (3-5 years). Key challenges to address in the midterm include: selecting a common database to upload UDI information to; ensuring that all UDI attributes are clearly defined; and determining processes to label variable units of measure (i.e., ensuring proper labelling on a product case, box, and individual item).

The state of hospital readiness for UDI capture in Canada is much less-developed. Participant interviews revealed that many hospitals are not yet planning to integrate UDI, and most hospitals in Canada do not have the necessary data system integration capabilities to capture UDI. In particular, hospitals need to have their electronic health record (EHR) and enterprise resource planning systems (ERP) fully integrated, and invest in point-of-use barcode scanning in order to prepare for UDI. Aside from IT investments, hospitals need access to one single source to retrieve all UDI information. Currently, hospitals that wish to capture UDI information need to make requests with multiple individual vendors and third-party datapools.

Implementing a UDI policy requires three key decisions:

▶ **Selecting a Policy Model**: This report analysed a variety of national implementations of a UDI policy in the United States and across Europe. Several options for implementing a policy were identified, including a single government body setting overarching standards, a private sector company setting standards mandated by government, or an industry collaboration who develop voluntary standards.

Participants proposed adopting the US Food and Drug Administration (FDA) UDI Rule model. The UDI Rule was implemented in 2014 as a mandatory policy for manufacturers, including a 7-year phased adoption period based on medical device classification. Participant feedback indicates this process was effective and well-received. Participants recommended adding hospitals and SSOs to the scope of the mandate, recommending a similar 7-year adoption timeline for manufacturers, with a 10-year adoption timeline for hospitals (providing time to invest in EHR and ERP system integration).

> **Recommendation:** The US FDA UDI Rule should be adopted for Canadian implementation of UDI standards. Select differences in implementation are highlighted in Section 3.3 Implementation Strategies.

▶ **Selecting a Common UDI Standard:** UDI standards (including what information is required in a barcode, how the information is presented, and how the information is collected) are set by a single standards organization. Standards organizations can be broad in the sectors they serve, or can be specific to a product type. For example, GS1[1] standards are globally available for multiple sectors and multiple product types. Other standards organizations exist which focus on one type of product (i.e., ICCBBA[2] sets standards for blood products) or one specific industry sector (i.e., HIBCC[3] sets standards for the medical device industry). Most standards are interoperable and international. Participants proposed having multiple issuing agencies for UDI, similar to the US approach. However, the main UDI standard should be the GS1 GTIN[4], which already has significant 90%+ adoption in the US.

> **Recommendation:** Adopt the GS1 GTIN as the preferred UDI standard. Other standards should also be accepted, provided that they align and are interoperable with UDI standards.

▶ **Selecting a Common UDI Database:** Rather than sending product information to hospitals directly, manufacturers who subscribe to UDI standards can upload product information to a datapool. Datapools collect and aggregate information from a variety of vendors and share relevant product information with healthcare delivery organizations. This analysis revealed two datapool options that participants felt would work well for Canada: GDSN[5] (a GS1 network of datapools) or GUDID[6] (a US FDA datapool). Participants did not indicate any strong preferences for either of these options, and tradeoffs were given for all options. In particular, participants felt that the global nature of GDSN and the low-cost nature of GUDID were attractive. Participants also noted that having a Canadian-run standard or datapool (i.e., a Canadian version of GUDID) may be met with manufacturer resistance due to the relatively small market size.

> **Recommendation:** Selecting a common datapool will require further investigation. Both GUDID and GDSN options were proposed as effective datapools to adopt. Deciding on one platform for Canada will depend upon a) the willingness of GUDID to expand to Canada, and b) an analysis of Canadian manufacturers to determine how many products are currently tracked in either system.

## 2. Nomenclature Standards

UDI standards ensure that necessary information is provided for each individual product. Nomenclature standards, on the other hand, ensure that similar products can be grouped into like categories. These categories can be used for purposes such as:

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[1] *GS1 is a global not-for-profit standards organization: https://www.gs1.org/*
[2] *International Council for Commonality in Blood Banking Automation: https://www.iccbba.org/*
[3] *Health Industry Business Communications Council: https://www.hibcc.org/*
[4] *Global Trade Item Number: https://www.gs1.org/standards/id-keys/gtin*
[5] *Global Data Synchronization Network: https://www.gs1.org/services/gdsn*
[6] *Global UDI Database: https://gudid.fda.gov/gudid/*

- ▶ Data exchange between manufacturers, regulators, and healthcare authorities
- ▶ Exchange of post-market vigilance information
- ▶ Supporting inventory control in hospital
- ▶ Purchasing and supply chain management[7]

Similar to UDI policy, there are multiple standards organizations that offer nomenclature standards to the healthcare industry globally. The scope of standards organizations for nomenclature is wide. Different standards organizations exist for categorizing medical devices, pharmaceuticals, clinical diagnoses, assistive devices, etc. Selecting which set(s) of standards to use is an ongoing conversation for all health system stakeholders. Globally, medical device nomenclature standard adoption is still relatively low. However, amongst high income countries specifically, 74% have an official nomenclature system: 29% use a nationally developed standard, 27% use the Global Medical Device Nomenclature (GMDN) only, and 12% use the Universal Medical Device Nomenclature System (UMDNS) only.[8] In Canada, there is no standard nomenclature system. Various government bodies have developed internal nomenclature systems, and most hospitals have naming systems that are specific to their organization.

- ▶ **Selecting a Common Nomenclature Standard**: Participants agreed that a Canadian nomenclature standard should be globally-interoperable, and that the GMDN or UMDNS would both work. Both of these standards have strong global adoption, and both have been mandated in a number of countries successfully. The key difference between GMDN and UMDNS is cost, the latter being free to use. Participants did not indicate a strong preference for one system over the other, but due to the no-cost nature of the UMDNS, it was recommended for Canada.

> **Recommendation:** Adopt the UMDNS as the preferred nomenclature standard.

## 3. Implementation Strategies

Adoption of standards will involve long-term system planning for hospitals and SSOs, manufacturers, and government regulators. Participants discussed several high-level strategies to position Canada for UDI and nomenclature standards implementation. Key strategies include:

- ▶ **Assess Hospital/SSO Readiness**: Determine: broad alignment with the proposed UDI/nomenclature standards model; current IT infrastructure available at hospital sites; case study examples of hospital UDI capture; current understanding of UDI/nomenclature standards; resources required for further IT investment; reasonable timelines for standards adoption; and organizations that would be interested in participating in future discussion on standards.

- ▶ **Leverage Quick Wins:** Collect case studies of early success stories for both hospitals and manufacturers, with key emphasis on cost efficiency, patient safety, and patient

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[7] Source: GMDN Agency (2017) GMDN database. Accessed June 2017 at https://www.gmdnagency.org/About/Database
[8] Source: World Health Organization (2017) Global atlas of medical devices. Accessed at
http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/, pg. 72.

outcomes tracking. Educate hospitals on the various benefits of supply chain modernization so it becomes a priority area for cost savings.

▶ **Mandate Adoption:** Similar to the US FDA Rule, a staggered adoption with key project milestones is advised. It is recommended that a mandatory standards adoption begin with manufacturers, then transition to hospitals, GPOs, and SSOs. Timelines should mirror the US FDA Rule, with added allowances for hospitals.

▶ **Build Hospital Item Masters and Case Costing Capabilities:** Few hospitals in Canada are fully utilizing case costing for supply chain management. Even fewer have begun to invest in point-of-use barcode scanning, aside from pharmaceuticals. Participants recommended investing in item master cleansing and case costing capabilities to prepare for UDI capture.

▶ **Prepare for Hospital UDI Integration:** Several best practice guides for hospital UDI integration are available in this report. General strategies include:

1. Establish executive support
2. Form a UDI implementation team including clinicians, supply chain, and IT
3. Develop project communication
4. Assess information systems including ERP and EHR
5. Obtain UDI product data (from GDSN, GUDID, SSO/GPO, or supplier)
6. Engage suppliers for pilot and testing
7. Conduct transactional testing
8. Create standard operating procedures[9]

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**Recommendation:** Health Canada should lead the UDI and nomenclature standards adoption.

▶ 2018-2020: Engagement with key stakeholders (manufacturers, hospitals, SSOs) to determine alignment with strategy, readiness for adoption, and resource requirements
▶ 2020: Publish UDI/nomenclature standards rule
▶ 2023: Class IV medical device implementation (UDI and nomenclature) date
▶ 2025: Class III medical device implementation (UDI and nomenclature) date
▶ 2027: Class II medical device implementation (UDI and nomenclature) date & hospital/SSO EHR/ERP integration date
▶ 2030: Hospital/SSO implementation (UDI and nomenclature) date

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The Canadian health sector's adoption of UDI and nomenclature standards is an inevitable reality that organizations need to begin preparing for today. As global adoption of these standards spreads, they will soon become necessary to participate in the global health sector. The solutions and processes for capturing detailed product information have been well-established, and the market leaders have become apparent in most cases, including the GTIN as a UDI standard, and GMDN and UMDNS as nomenclature standards. Canada is well-positioned to adopt the lessons learned from other jurisdictions, and can expect significant efficiency gains and improvements in patient outcomes upon further investment in supply chain transformation.

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[9] *Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation. Pg. 28.*

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# Abbreviations

AHRMM – Association for Healthcare Resource & Materials Management

AIAG – Automotive Industry Action Group

AIDC – Automatic Identification and Data Capture

DI – Device Identifier (UDI)

DIN – Drug Identification Number

EDI – Electronic Data Interchange

EHR – Electronic Health Record

ERP – Enterprise Resource Planning

FDA – Food and Drug Administration

GDSN – Global Data Synchronization Network (GS1)

GHX – Global Healthcare Exchange

GMDN – Global Medical Device Nomenclature

GLN – Global Location Number (GS1)

GPO – Group Purchasing Organization

GTIN – Global Trade Item Number (GS1)

GUDID – Global UDI Database (FDA)

HIBCC – Health Industry Business Communications Council

ICCBBA – International Council for Commonality in Blood Banking Automation

PI – Production Identifier (UDI)

RFID – Radio-Frequency Identification

SKU – Stock Keeping Unit

SSO – Shared Services Organization

UDI – Unique Device Identification

UK – United Kingdom

UMDNS – Universal Medical Device Nomenclature System

UNSPSC – United Nations Standard Product and Service Code

UPC – Universal Product Code

US – United States

# Introduction

Globally, supply chain transformation is becoming a priority area for many healthcare systems who are aiming to control rising costs. Initiatives to promote the efficiency and effectiveness of materials management have been largely motivated by cost savings, but are reaping multiple benefits including promoting patient safety, reducing medical errors, and promoting patient outcomes measurement and tracking.

Multiple solutions exist to strengthen healthcare supply chains, including barcoding and RFID technology for point-of-use supply tracking and automated inventory management through data systems integration. However, before hospitals can adopt these technology solutions, some upstream investments are required to align data systems (including ERP and EHR), ensure accuracy of data, and ensure that data is being tracked consistently across organizations.

> **Supply Chain Standards: Lessons from the Grocery Industry**
>
> Consider a grocery store: if grocers were required to label each individual product with a barcode or price tag, it would be much less efficient than using a pre-labelled barcode from the manufacturer – but how does a grocer capture information from a printed barcode on a products? Barcode scanning technology can only identify pricing and product information if the software system understands or "reads" the barcode image, and can link that image to a database with manufacturer information. If grocery stores had to collect this information from each manufacturer individually for each product individually, both grocers and manufacturers would face challenges with the accuracy of the data and the time required for such tasks. This is why, for the past 40 years, grocery stores have used barcode standards. These standards are typically managed by a central organization, who receives product information from manufacturers that is presented in a standardized format, in a database which is made available to retailers globally. Using this approach, the supply costs for both manufactures and grocers are reduced, the visibility and accuracy of supply chain data is enhanced, and automated processes such as product recalling and inventory replenishment can be facilitated.

The healthcare industry has been relatively slow at adopting global standards for supply chain product identification when compared with other industries. In healthcare, there are two key standards to identify product information: (1) *unique device identification* (UDI) standards, which standardize barcode information; and (2) *nomenclature standards*, which standardize how devices are named and categorized.

**Unique Device Identifier (UDI):** "an identifier that adequately identifies a device at the point of distribution and at the point-of-use. A unique device identifier is composed of:

▶ A Device Identifier (DI): a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeller of that device; and

▶ A Production Identifier (PI): a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: the lot or batch, serial number, expiration date, date of manufacture."[10]

**Nomenclature Standards:** "The nomenclature of medical devices is a coding system used to generically identify medical devices and related health products. Having a nomenclature system in place for medical devices facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers."[11]

Adoption of UDI and nomenclature standards for health systems is becoming mandatory in many developed nations, yet approaches to standardization still vary country to country. The lack of a consistent approach to standardization has led to increased inefficiencies for both product vendors and purchasers.

**Target Objectives**

This report aims to meet the following objectives:

▶ Introduces the concepts and benefits of UDI and nomenclature standards;

▶ Identifies and examines different current state models for supply chain standardization from multiple countries and industries;

▶ Provides an objective analysis on which standard (or blend of standards) is most efficient from a health system perspective for both UDI and nomenclature;

▶ Makes recommendations for the future state standards model selection and design for the Canadian health sector; and

▶ Proposes implementation and change management strategies for health sector supply chain standards adoption in Canada for manufacturers, government, and delivery organizations, taking into account enablers, capabilities, and capacity for adoption.

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[10] Source: Aesculap. (2017) Unique device identifier – the UDI ruling and how Aesculap will comply. Accessed at https://www.aesculapusa.com/company/quality-assurance/unique-device-identifier-udi#4

[11] Source: World Health Organization (2018) Nomenclature of medical devices. Accessed at http://www.who.int/medical_devices/innovation/mde_nomenclature/en/

**Target Audience**

This report is intended for:

▸ **Government bodies** who have identified supply chain management as a key priority area for health system improvement. This report provides recommendations based on feedback from industry, healthcare, and government stakeholders regarding policy guidelines for medical device UDI and nomenclature standards.

▸ **Industry vendors** who sell to Canadian purchasers and who are currently investing in standards infrastructure for other jurisdictions (i.e., US FDA UDI Rule). This report provides direction for vendors to select UDI issuing agencies and nomenclature standards based on current Canadian and global trends.

▸ **Hospitals and shared services organizations** (SSOs) who are preparing for automated supply chain management or who want to ensure that existing investments in supply chain management align with national and global trends. This report provides key resources to hospitals and SSOs including an introduction to UDI and nomenclature standards, standards readiness assessment, resource requirements for standards capture, and implementation guidelines.

**Methodology:** A literature review of relevant industry reports on UDI and nomenclature standards was conducted, alongside an industry analysis which examined UDI adoption in the automotive, grocery, retail, and pharmaceutical industries (Appendix 1 – Industry Analysis).

Interviews with 30 health sector participants were conducted with director-level leaders representing the medical device industry (12), government regulators (8), hospital purchasing departments (2), and shared services organizations (8). Participants were asked to share their perspectives regarding UDI and nomenclature standards adoption in Canada, including current state, barriers to adoption, preferred models, and implementation strategies. 5 of the 30 participants were from the United States, the remaining from Canada. Canadian participants were concentrated in Ontario, with some participation from Alberta and British Columbia. Given the contention surrounding UDI and nomenclature standards, participant responses have been anonymized to encourage honest and open dialogue. Interviews were analysed via thematic coding using NVivo software, and general themes are included in this report.

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# 1. Unique Device Identification
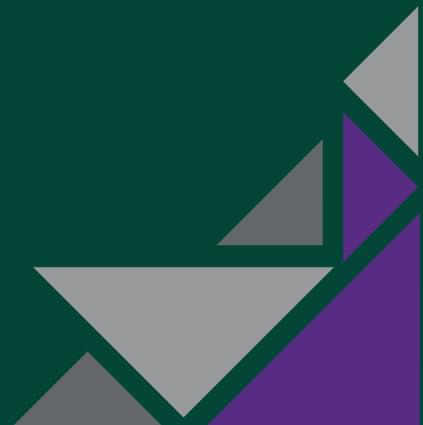
## 1.1 Unique Device Identification

Unique device identifiers (UDI) are a common, agreed-upon standard used by medical device manufacturers, government regulators, and hospital/SSO supply chain managers to track and trace product use. UDIs are comprised of two parts:

- ▶ **Device Identifier (DI)**: a static marker that is specific to a device version or model
- ▶ **Production Identifier (PI)**: a dynamic marker including product expiry date, lot/batch number, serial number, and manufacturing date

The most common type of DI is the GS1 Global Trade Item Number (GTIN), which is used in approximately 90% of medical devices in North America.[13] PIs are a more recent development, and use is growing globally. PIs are less standardized than DIs, and can be granted from a number of approved issuing agencies, which are accredited by certain national standards.



*Figure 1 – UDI components*

*Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation. Pg. 22.*

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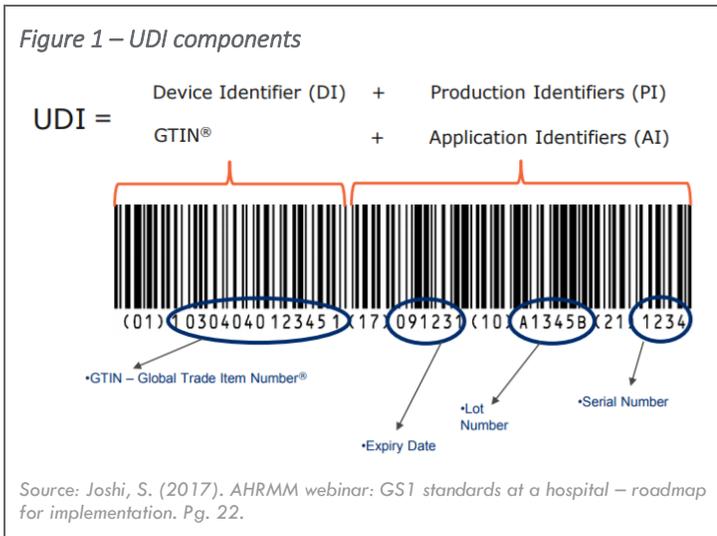
[13] *Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation.*

UDI can be expressed in multiple formats – the most common expressions use GS1 standards, and include the GS1-128 barcode and the GS1 DataMatrix (used when space on packaging is limited). All UDI barcodes are required to have both machine- and human-readable information. The machine-readable component can be expressed through a variety of Automatic Identification and Data Capture (AIDC) methods including barcodes and Radio-Frequency Identification (RFID) tags.



*Figure 2 – UDI common formats*

(01) 1 0304040 12345 1 (17) 101231 (10) ABCD12345 (21) 54321DCBA

GTIN with Serial, Lot & Expiration Date encoded in a GS1-128 Barcode

(01) 1 0304040 12345 1
(17) 101231
(10) ABCD12345
(21) 54321DCBA

GTIN with Serial, Lot & Expiration Date encoded in a GS1 DataMatrix

*Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation. Pg. 24.*

The format of UDI and its basic components are standardized (DI + PI). However, multiple issuing agencies are able to provide specific UDIs to vendors. GS1 is the most commonly used standard amongst medical devices.

Oversight and management of UDI standards involves multiple parties:

▶ **Standards Organizations/Issuing Agencies:** UDI standards (including what information is required in a barcode, how the information is presented, and how the information is collected) are set by a single standards organization. Standards organizations can be broad in the sectors they serve, or can be specific to a product type. For example, GS1 standards are globally available for multiple sectors and multiple product types. Other standards organizations exist which focus on one type of product (i.e., ICCBBA sets standards for blood products) or one specific industry sector (i.e., HIBCC sets standards for the medical device industry). Most standards are interoperable and international.

▶ **Manufacturers:** In some countries, adopting UDI standards is mandatory for manufacturers; in others, manufacturers have the choice to develop their own standards. Regardless, manufacturers must provide product information to healthcare delivery organizations either directly or through a third-party datapool.

▶ **Datapools:** Rather than sending product information to hospitals directly, manufacturers who subscribe to UDI standards can upload product information to a datapool. Datapools collect information from a variety of vendors and share relevant product information with healthcare delivery organizations. Datapools are typically organized around one standard set, but some accept information using multiple standards.

▶ **Healthcare Delivery Organizations:** Delivery organizations such as hospitals are responsible for linking product information to an individual patient. By integrating UDI information with patient charting, full end-to-end supply chain visibility is possible, enabling a variety of benefits, discussed below.

**Benefits of UDI**

The benefits of UDI standardization were discussed with study participants, and confirmed in academic literature, particularly with regards to safety/recalls and cost management (Appendix 2 – Benefits of UDI Standards).

▶ **UDI to Promote Safety:** UDI have the potential to improve patient safety by allowing for faster recalls, ensuring that the right patient is receiving the right product, and the potential for long-term outcomes tracking. UDI have been successfully used to reduce medical product errors (by leveraging an automated check to ensure the product is used on the right patient), facilitate effective product recalls (by immediately identifying which patients received a specific product batch), and ensuring that required products are always available (by providing automated and accurate inventory counts).[14]

*"If there are safety reports or problem reports, it would be very easy to compare between the different countries, it would be much easier to align to see, is it the same batches of devices in Europe, are they the same in Canada or the US. But trying to match up devices, if the similar devices are available on the market, it was very hard minus the UDI. We're hoping that the UDI could bring more of a safety aspect from that perspective to us as a regulator." (Participant 1)*

▶ **UDI to Promote Cost Efficiency:** From a cost efficiency standpoint, UDI bring a new level of transparency to hospital operations. With added data sophistication, hospital procurement departments can ensure that product pricing is fair, can optimize purchasing patterns, and can minimize waste.

*"In the healthcare world today, a lot of the ERP systems do not leverage UDI any more than maybe 20-30% of their maximum spend, so **if you've got 70-80% of that spend that isn't being tracked, there's all sorts of issues as far as rebates, missing payment discounts, and invoice reconciliation issues**, so we can do all that UDI because we just upload the contracts, we can upload data including GDSN data if they've got it, and then there's all sorts of procurement analytics and reporting." (Participant 3)*

Once individual hospitals have UDI tracking capacity, greater opportunities for the health system as a whole arise. With the transparency that UDI provides, entire health systems can be optimized, from leveraging economies of scale for purchasing, streamlining product offerings, funding based on outcomes achieved, etc.

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[14] Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation.

*"When you look across the healthcare sector in Canada, if you were to automate all that procurement and do it through UDI, you're looking at bare minimum in my opinion of $2 to $3 billion a year in savings." (Participant 3)*

▸ **UDI to Promote Medical Outcomes Research:** One of the key benefits of UDI visibility is the ability to track patient outcomes through advanced analytics. Capturing UDI requires for hospital electronic health records (EHR) and enterprise resource planning (ERP) systems to be linked. Pairing this with a common language and common standard achieved by UDI policy, outcomes data can be tracked and compared across entire health systems automatically. This will yield a new future for medical research which can be done at a lower cost, at a higher scale, much more quickly.

*"In order for us to truly understand the value of a product we need to be able to track that product and a **UDI will enable us to track a product and eventually measure its clinical effectiveness**. Today we can't do that because we can't actually put the products in the medical record because we have no UDI to do it with." (Participant 22)*

## 1.2 UDI Current State in Canada

Full end-to-end UDI capture requires manufacturers and hospitals/SSOs to invest in supply chain infrastructure and transition data standards to UDI. In Canada, manufacturers and hospitals/SSOs have already begun some investment in UDI capture, at varying rates. Manufacturers, who often sell to multiple countries, are well-positioned to label all of their products with UDI in the near future (3-5 years). For hospitals, significant investments in standardized or interoperable IT infrastructure are required before UDI capture can take place (5-10 years).

**Manufacturer Readiness**

▸ **No Common, Easily Accessible Database:** Most of the larger medical device companies already label their products with UDI, the majority of them using GS1 standards (GTINs). However, the GTINs being used in Canada are often not submitted to a registry or datapool that is easily accessible to hospitals.

*"Most of the products today [in Canada] are marked. What isn't happening right now is we're not reporting that to any individual entity. So unlike in the US where the majority of products are currently reported." (Participant 14)*

Even if manufacturers have GTINs or another UDI in their internal systems, they are not always making the UDI information available to Canadian hospitals, GPOs and SSOs because there is no standard mechanism to do so. Many manufacturers, particularly large global ones, have already made investments in adopting UDI technology, but in Canada, SSOs and GPOs are having difficulties accessing this information.

**Medical Device Industry – Challenges Adopting UDI Standards**

The adoption of UDI standards is not unique to the medical device industry, but there are some key differences unique to the medical device industry which make adopting UDI standards difficult:

▶ **Differences in Interpretation of UDI Attributes:** The medical device industry faces additional challenges due to differences in interpretation of UDI attributes. The broad nature of the medical device industry requires any standards to be either broad enough to allow for multiple interpretations, or be detailed enough to cover most exceptions to the rule. Deciding how to interpret guidelines for labelling can be very time- and resource-intensive.

*" 'Devices' covers a very wide array of things; you've got implants, capital equipment, hospital equipment, a lot of basic bandages – it's this very complex and multidimensional set of products. And then to make matters even more interesting, many devices have accessories that go with them so you have an IV pump, but that IV pump goes on a pole. We spend a lot of time with clients just trying to figure out what do they actually distribute, what is an accessory, what is a replacement part, and where do you draw the lines?" (Participant 2)*

▶ **Private Labelling:** In the healthcare sector, products are not always manufactured by their parent companies. In cases of private labelling and third-party manufacturing, deciding who is responsible for labelling, requires further clarification in any standard.

▶ **Relative Market Size and Global Progress:** Given its relatively small market size, Canada is limited in its UDI mandate options. The state of UDI globally has seen much progress in recent years, and significant investments from the private sector. In order to continue in global markets, Canada's UDI policies must align with global trends.

*"When you look at **Canada, we're less than half a percent of the global population and 1.36% of the global GDP**. So us trying to develop a Canada only standard, when we are right up against the US with a UDI, with a common language, with shared technologies, with companies that have in many cases operations in both countries, and to develop a Canada only standard is just suicidal based on the facts." (Participant 3)*

▶ **High Product Variability:** The nature of the medical device industry requires many individual SKUs, which increases the burden of adopting a common UDI standard.

*"In GDSN today, the last time I looked, there was about 58,000 items registered globally in the GDSN for clinical pharma. Well there's already I think 1.6 million medical devices. Like **for every clinical pharm there's about 50 medical devices**." (Participant 3)*

▶ **Variable Units of Measure:** In healthcare, as versus other industries, supplies are more likely to be delivered in multiple units of measure (i.e., a box of bandages may be comprised of multiple cases, comprised of multiple packs, comprised of individual bandages). Each unit of measure needs to be labelled, but the point at which they are scanned at point-of-use may vary.

*"**The difference in healthcare is that you may have to account for this product in different forms** as the product makes its journey from manufacturing facility through the supply chain down to the hospital. It might be a case at a receiving dock. It might be a box at a hospital shelf and it might be on an each on a patient, and you still have to account for it." (Participant 14)*

**Hospital Readiness**

▶ **Hospitals Attempting to Capture UDI Face Challenges:** For hospitals, few have invested in the technology or cultural shifts required for UDI capture. Hospitals that are attempting to capture UDI currently have to go to multiple sources for product information (compared to the US, for example, which has one common database for all product information).

*"We get our item master attribute data from the vendors, we get it from the manufacturers, we get it from the GPO, HealthPro, we get it from the reps, we get it from the internet – **we scratch and claw for this information because it doesn't exist in one place**." (Participant 22)*

For hospitals who have made investments in technology able to capture UDI data, many currently choose to relabel all barcodes with a standard barcode system that staff have been trained on. This relabeling is often required because of the many types of barcodes on typical medical packaging.

*"We don't use the GTIN to trigger replenishments for a couple of reasons. Number one is it would slow us up if we had to find the barcode on each of these devices. We instead scan a standardized barcode that everyone is trained to use, all of our material handlers that do the replenishment function in the hospitals scan our SAP item level and location barcode because its standardized versus a supply cart that might have 500 different items with varying sizes of barcodes to trigger a replenishment. It would slow us up by as much as 30% in a very time sensitive job." (Participant 11)*

Participants agreed that hospitals could access UDI information directly from the manufacturers. In fact, many hospitals are already receiving this information, but very few have integrated data systems capable of linking UDI information with their ERP and EHR systems.

*"They [hospitals] can get the GTIN information, we [vendors] could send them that information in Excel spreadsheets and so forth but **their benefit is really only achieved by when they establish an electronic compatibility** so that they're not just uploading spreadsheet data, but they would be synchronizing the data directly from the manufacturer to within their institution." (Participant 6)*

▶ **Hospitals Need Investment in IT Solutions:** The process that healthcare delivery organisations need to go through to ensure they are ready for UDI is complex. Looking at technology alone, multiple systems must be established (in particular, EHR and ERP systems), data must be entered and cleansed, and systems must be integrated so they are able to share information. Case studies from two hospitals in Canada indicate that this process can take up to five years, even with funding available. This highlights a need for education, training, and support for delivery organizations to enhance their data systems before a UDI mandate can be implemented.

*"It takes a long time for healthcare providers to begin to think this through and make the necessary changes to their MMIS or ERP. Most of them are referring to our products by either our catalogue number and/or some type of an internal alias, so they don't use the device identifiers or GTINs that we've assigned. I think that's a monumental task for healthcare providers to go through and look at their item master that might be 100,000 or 200,000 products, and begin getting the system set, understanding how device*

*manufacturers have enumerated their products, and begin building that system logic and to learn how to use this." (Participant 15)*

One participant commented that hospital IT services must be heavily involved in discussions about UDI and data compatibility. Hospital departments often underestimate the role that IT plays in supply chain activities, but for UDI integration, they are a necessary component.

*"**IT has to be there front row center**. What's happened over the years is that people have talked about this stuff with good intentions, but then you realize IT plays just an enormous role in this. They understand networking, they understand connectivity, so if they're at the discussion table right at the front I think things will go a lot smoother." (Participant 6)*

▶ **Hospitals Need Further Education on UDI:** Hospitals need to be educated to understand the potential impact of UDI adoption. While many early adopter sites of UDI have invested in order to reduce overall costs, there is a larger potential impact to redesign care pathways with newly found process data. Interviews with participants revealed that many hospitals are still not yet thinking about UDI as a priority area, and some hospitals are not yet familiar with the concept of UDI.

▶ **Hospitals Need Centralized Leadership:** The challenge of encouraging hospitals to build capacity to capture UDI data is further compounded by the fact that all hospitals are currently handling their supply chain management differently. Many are using different systems and are at various stages of analytical sophistication leveraging real-time data. Many hospitals do not yet have centralized purchasing authority.

## 1.3 Barriers to UDI Adoption

The barriers to advancing UDI standardization were discussed, with participants noting the major barriers are the variety of disparate ERP and EHR systems used by health authorities, existing hospital cultural practices of manual ordering through fax, differences in interpretation of UDI attributes, confusion and misinformation about what UDI attributes are or will become mandatory, and waiting for other standards organizations (i.e. US FDA) to develop policy.

▶ **Lack of IT Infrastructure:** The most commonly cited reason participants gave for the lack of adoption of UDI in Canada is the infancy of hospital IT infrastructure in Canada. In order to properly capture UDI data, hospital ERP and EHR systems must be established, item masters must be cleaned, and the systems must be fully integrated. In order to capture UDI data at a system level, ERP and EHR systems must be fully integrated across hospitals and systems.

*"It's a technology issue in as much as they've got **different health authorities in specific provinces using different ERP systems**, but the biggest obstacle is that it's the old habit of using the fax machine to send the faxes and some doctors like picking up the phone and buying stuff directly." (Participant 3)*

▸ **Separation of Hospital and Vendor Supply Chains:** In many hospitals across Ontario, supply chains are still separated by responsibility. Many vendors have little to no involvement in hospital supply chain activities after products have reached the hospital site. Similarly, few hospitals are engaged in upstream supply chains of their vendors.

*"Supply chain to me is something that's ordered and gets to the backdoor of the hospital, not within the hospital." (Participant 13)*

UDI adoption is causing a cultural shift where ownership of end-to-end hospital and vendor supply chains are shared.

▸ **Challenges Communicating UDI Management:** Participant interviews revealed some misinformation regarding UDI implementation in Canada. Some hospitals believed that UDI was already becoming mandatory through GS1 Canada's ECCNet, some believed that Health Canada was already proposing a mandatory UDI policy, and some believed that any UDI solutions would come at a significant cost to hospitals (aside from IT investments).

*"I think GS1 Canada is going out and trying to sell their product, so there's a lot of questions from hospitals saying is Health Canada making this a requirement, but really we're not requiring it, because we're not there yet with our implementation of UDI, and so I think there's a lot of questions." (Participant 1)*

▸ **Lack of Stakeholder Consensus:** In UDI implementations from other jurisdictions, such as the US, at least 1-2 years of wide stakeholder engagement from vendors, hospitals/SSOs, and governments was conducted before a policy was drafted. These engagement sessions have been designed to identify any country-specific requirements, educate all stakeholders about UDI, identify pilot and early adopter sites, and address any stakeholder concerns. A similar process is necessary before a UDI policy can be implemented in Canada.

▸ **Differences in Interpretation of UDI Attributes:** Even once standards have been developed, there are challenges with interpreting UDI attributes, particularly for medical devices. Until a governing body is able to provide guidance on specific interpretation questions, standard adoption may be inconsistent across vendors.

*"We have people whose job it is at FDA to review the data, assess the quality, and interact with the manufacturers if something seems not right. So some of the monitoring can be done that way. Some other parts of it really are more of an industry convergence, if we look at cardiovascular stents, as a larger ecosystem, we have to come to an agreement on how are we going to describe the clinically relevant sizes of cardiovascular stents so that we can all do it the same way because to date, different people have interpreted that differently. So some of its being done by FDA, some of its more of an industry focused activity or kind of broader ecosystem kind of activity." (Participant 2)*

# 2. Nomenclature Standards
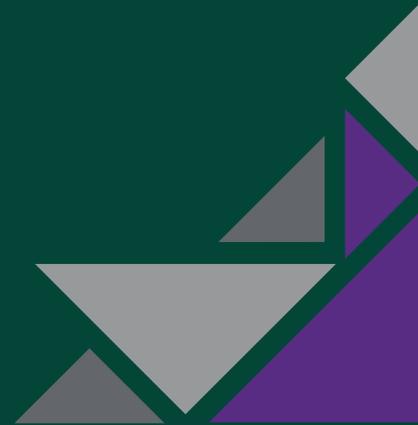
## 2.1 Nomenclature Standards

UDI standards ensure that basic product information is shared across supply chains, including individual, unique product serial numbers, batch numbers, manufacturer information, etc. Simply put, UDI standards ensure that necessary information is provided for each individual product. The adoption and disciplined use of nomenclature standards, on the other hand, ensure that similar products can be grouped into like categories, greatly enhancing the efficient and effective management of inventory and reduction in supply chain costs.

"Device categorization is a data element that allows for analysis of device behavior at a higher level than that provided by a device identifier, company name or brand name. It provides the ability to search across a device type or category (containing like devices) to see trends or signals you couldn't otherwise see."[15] The main purpose of nomenclature standards is to provide health authorities and regulators, healthcare providers, manufacturers, and other stakeholders with a common naming system that can be used to exchange medical device information and support patient safety for:

- Data exchange between manufacturers, regulators, and healthcare authorities
- Exchange of post-market vigilance information
- Supporting inventory control in hospital
- Purchasing and supply chain management[16]

UDI standards allow for full end-to-end supply chain visibility of individual products. Nomenclature standards allow for comparison and evaluation of similar product groupings. As product datasets become increasingly complex, the way that products are individually and collectively coded in the system becomes more important.

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**Application of Nomenclature Standards**

Consider a hospital that is trying to control costs for diabetes management. Managers could search their product databases and patient records for "insulin pumps", but how would they know if they've captured all of the pumps that have been used in a given time period? Some pumps may have been entered into the patient chart as a "personal insulin pump" or an "implantable insulin pump", or an abbreviated PIP or IIP. Without a standard nomenclature, category management would require knowing all possible names and descriptions for every product. This becomes very complicated and inefficient given the amount of medical jargon, off-label usage, and number of products in healthcare. Now consider a health system funder that is trying to control diabetes management costs for an entire region. Even if individual hospitals have standard naming systems, how would you compare across multiple hospitals?

The complexity of healthcare systems and the number of stakeholders involved in an increasingly globalized market now requires some agreement on a common language for inventory descriptions. Nomenclature standards meet this demand by providing a common language with clear guidelines for categorizing and naming individual products. If adopted, nomenclature standard can vastly reduce inventory management complexity.

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[15] Source: AHRMM (2016). Device categorization: GMDN/SNOMED terminologies. Accessed June 2017 at http://www.ahrmm.org/resources/learning-udi-community/pdfs/work-groups/device-categorization-work-group-summary-statement-103116.pdf

[16] Source: GMDN Agency (2017) GMDN database. Accessed June 2017 at https://www.gmdnagency.org/About/Database

Similar to UDI policy, there are numerous standards organizations worldwide that offer nomenclature standards to the healthcare industry (see Table 1). Different standards organizations exist for categorizing medical devices, pharmaceuticals, clinical diagnoses, assistive devices, etc. Selecting which set(s) of standards to use is an ongoing conversation for all health system stakeholders.

*Table 1 – Nomenclature Standards Organizations*

| | Global Medical Device Nomenclature (GMDN) | Universal Medical Device Nomenclature System (UMDNS) | United Nations Standard Product and Service Code (UNSPSC) |
|---|---|---|---|
| Governance | GMDN Agency | ECRI Institute, not-for-profit | Owned by the UN Development Programme, managed by GS1 US, not-for-profit |
| Intended Purpose | To give a common generic descriptor for medical devices having similar features, characteristics and intended use. | To facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. | To construct a global product classification reference framework. |
| Countries where Nomenclature Use is Mandatory | Australia, Japan, Italy, Greece, Poland, Czech Republic, Estonia, Portugal, Turkey, Croatia, Peru, Mozambique | Hong Kong, Israel, Jordan, Panama, Switzerland | N/A |
| Endorsement | Global Harmonization Task Force, European Commission EUDAMED, US FDA, Australian Therapeutic Goods Administration, Japanese Ministry of Health, Labour, and Welfare | Asian Harmonization Working Party, Healthcare Information and Management Systems Society, Committee on Data Standards for Patient Safety of the US Institute of Medicine | Coalition for Healthcare eStandards, Industry Data Exchange Association, Petroleum Industry Data Exchange, RosettaNet Consortium |
| Cost | Regulators: Free<br>Industry: >100 EUR/year<br>Providers: 600 EUR/year | Free | Regulators: $1200-$1800/year<br>Industry: $350/year<br>Providers: $350/year |

*Source: World Health Organization (2011) Nomenclature of medical devices. Accessed June 2017 at http://www.who.int/medical_devices/innovation/mde_nomenclature/en/*

**Benefits of Nomenclature Standards**

Nomenclature standards "provide a standardized nomenclature for medical devices and diagnostics to improve identification and unambiguous data exchange between authorities, manufacturers, healthcare providers, and conformity assessment bodies to support patient safety."[17] Primary benefits of nomenclature standards include:

▶ Communication and record keeping between manufacturers and regulatory bodies;
▶ Collation of post-market surveillance data; and
▶ Inventory management analysis.

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[17] *Source: White, J., Carolan-Rees, G. (2013) Current state of medical device nomenclature and taxonomy systems in the UK. Journal of the Royal Society of Medicine. 0: 1-7. Pg. 3.*

Ultimately, these benefits lead to a more efficient and effective system, allowing for greater optimization and cost reduction. Previous work has highlighted the following key characteristics of an effective device categorization code set:

- "Includes a transparent change control and versioning process that proactively communicates change details to allow effective use of terms within downstream systems (Health IT, registries, etc.);
- Includes best practice guidelines that define unambiguous ways to assign device categories;
- Aligns with or improves existing device type code set;
- Has ability to include reference to regulatory requirements associated with a particular model/version of a device; and
- Includes representation of all existing device types and is up-to-date with those in commercial distribution."[18]

Research participants commented that they have seen the benefits of standardized nomenclature through the pharmaceutical industry in Canada, which already uses global standards:

> *"Our unique challenge as a plan is that we are national in scope, as opposed to pharmacy, pharmacy is universal, it's the same DIN that all use. It's a lot simpler, a lot cleaner." (Participant 28)*

> *"I think about pharmacy and I think we've got 18 to 20 pharmaceutical companies that are functioning off of a common nomenclature, so even though they make a product that's different and has a different DIN, it's still classified in a way that there is commonality between the different manufacturers. We need to get to that place too so that we can structure common product lines, common things over multiple manufacturers." (Participant 29)*

## 2.2 Nomenclature Standards Current State in Canada

Despite the agreed upon benefits of nomenclature standards, adoption in Canada is still limited. For this reason, the adjudication process involved in approving and funding medical equipment and products is costly and time intensive. Under the current system, reimbursers must adjudicate each claim individually. However, technological advancements and nomenclature standards now make it possible for much of the adjudication process to be automated and standardized. By leveraging nomenclature standards, reimbursers can ensure that automated reimbursements abide by the healthcare delivery organization contracts (i.e., if hospital A has established a spending limit for a specific device category, purchase orders would automatically be linked to that device category, with a notification sent to either the reimbursers or purchaser when the limit is reached). Under this system, the adjudication process is faster, thereby ensuring clients get their products faster and

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[18] *Source: AHRMM (2016). Device categorization: GMDN/SNOMED terminologies. Accessed June 2017 at http://www.ahrmm.org/resources/learning-udi-community/pdfs/work-groups/device-categorization-work-group-summary-statement-103116.pdf*

distributors are paid faster. Multiple reimbursers have expressed an interest in leveraging nomenclature standards for automatic reimbursement, but most Canadian reimbursers are still using internally-developed standards which are not universally interoperable.

Similar to hospitals re-labeling products in place of UDI, most tracking systems are currently using internally-developed nomenclature standards, making comparisons across organizations challenging:

> *"We categorize in seven different categories. Audiology, prosthetics, general medical supplies and equipment, orthotics, some vision aids, so we have 580 codes and we have divided them into some broad categories and within that we have subdivided them. But those categories and subcategories are not related at all to the particular item code for that particular item – **that number is just arbitrarily attached to that particular item**." (Participant 30)*

Globally, countries are increasingly implementing mandatory nomenclature standard policies. Most of the mandatory nomenclature standard requirements have come from European countries. However, unlike UDI which is dominated by GS1 GTIN and GDSN, there are three widely used nomenclature standards with no clear market leader: GMDN, UMDNS, and UNSPSC.

*Figure 3 – Global nomenclature standards for medical devices*
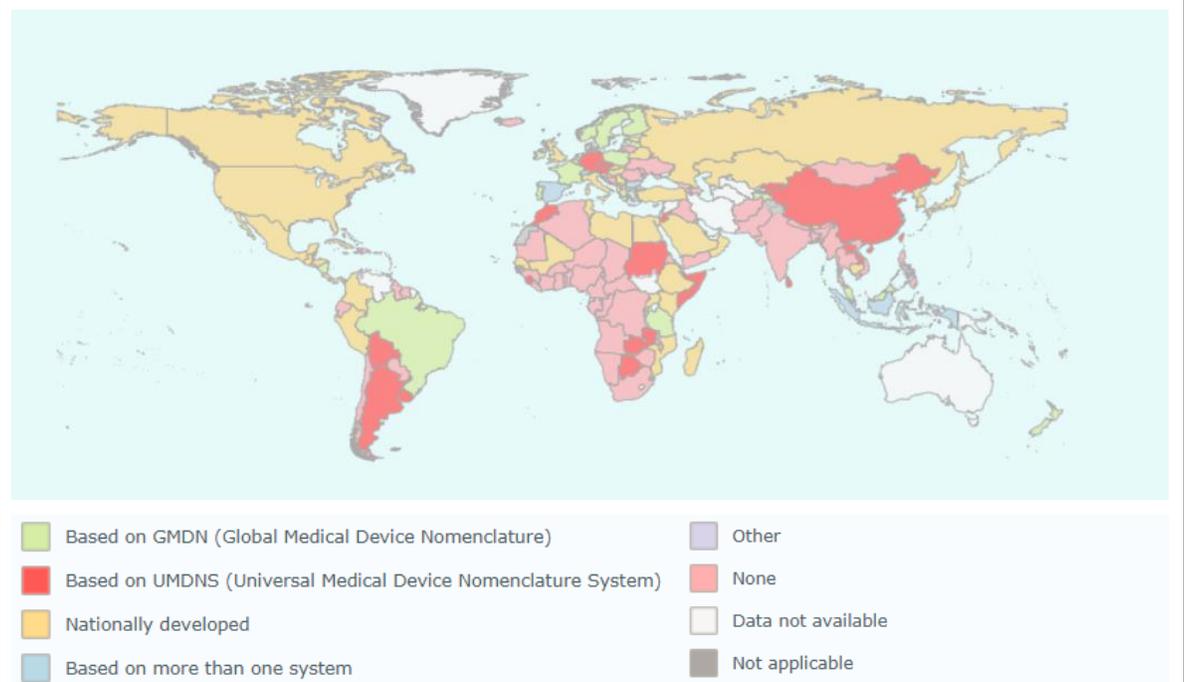


Legend:
- Based on GMDN (Global Medical Device Nomenclature)
- Based on UMDNS (Universal Medical Device Nomenclature System)
- Nationally developed
- Based on more than one system
- Other
- None
- Data not available
- Not applicable

*Source: World Health Organization (2017) Global atlas of medical devices. Accessed at http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/, pg. 71.*

Globally, nomenclature standard adoption is still relatively low (51%). However, amongst high income countries specifically, 74% have an official nomenclature system: 29% use a nationally developed standard, 27% use GMDN only, and 12% use UMDNS only (see Figure 4).[19]



*Figure 4 – Aggregate global nomenclature standards for medical devices*
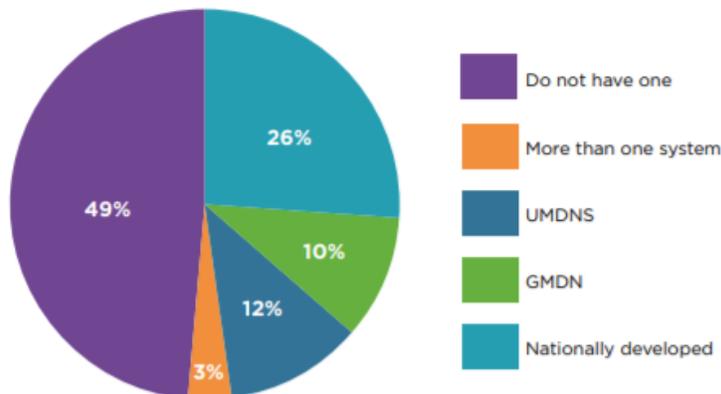
Source: World Health Organization (2017) Global atlas of medical devices. Accessed at http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/, pg. 71.

## 2.3 Barriers to Nomenclature Standards Adoption

The barriers to nomenclature standards adoption are similar to the barriers to UDI standards adoption including a lack of IT infrastructure, challenges communicating nomenclature management, and a need for increased stakeholder engagement and buy-in. Additional barriers unique to nomenclature standards include:

▸ **Lack of Consistent Approach across Canada Necessitates Manual Adjudication:** For funders or purchasers responsible for multiple hospitals (i.e., SSOs, GPOs, federal funding programs), comparing product use across hospitals is currently a challenge as each individual healthcare delivery organization is using slightly different naming systems. Without a common standard, the language used is inconsistent across provinces, requiring multiple parallel processes for reimbursement. One participant responsible for delivering health services to populations that are under federal jurisdiction noted:

*"You might have one nomenclature with an association in Alberta but then you might have a different nomenclature with ADP in Ontario. As a national program there's issues with*

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[19] Source: World Health Organization (2017) Global atlas of medical devices. Accessed at http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/, pg. 72.

*everyone using their own nomenclature and trying to get to something that's got some commonality to it is a real challenge." (Participant 30)*

▸ **Global Manufacturers using Disparate Systems:** The naming of medical devices is typically the responsibility of the manufacturer. It is primarily vendors that need to agree on nomenclature standards to enable automated tracking. With a European-led push for globally-interoperable nomenclature standards, large multinational medical device companies are beginning to invest in UMDNS and GMDN systems.

*"I think that over time we've had conversations with [our clients] about their frustrations with the lack of automation with our program and the need for a push on the industry side to move to some sort of standardized identifiers and nomenclature." (Participant 28)*

▸ **Leadership Uncertainty:** Unlike UDI standards, which can be mandated by Health Canada at a system level, leadership of nomenclature standards is less clear. There are multiple federal and provincial bodies responsible for reimbursement and market post-surveillance that would benefit from nomenclature standardization, but participants were unclear which body would be best-positioned to lead adoption.

# 3. Proposed Standard Models
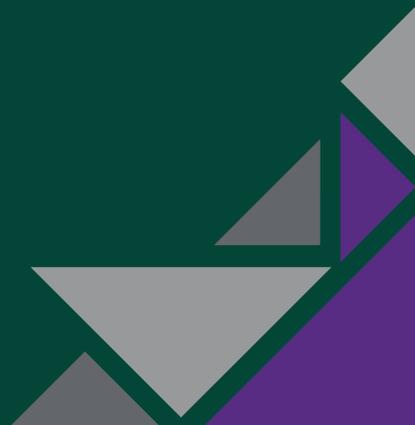
## 3.1 Proposed Standards Principles

Interview participants were asked about standards principles and values to guide implementation. Universality, interoperability, and affordability were highlighted as key principles of an optimal standards strategy. Participants felt that both UDI and nomenclature standards should be global, rather than having separate national standards which would cause redundancies for multi-national companies. Participants felt that standards should be interoperable so that only the base criteria are mandatory, leaving room for multiple standards organizations and issuing agencies to compete to add value through optional added services. Participants felt that standards should be affordable to both manufacturers and healthcare delivery organizations in order to facilitate adoption.

▶ **Universality**: The most stressed recommendation for standards policy in Canada was to ensure that the Canadian UDI and nomenclature policy aligns with global trends. Participants recognized that Canada is a small part of a much larger global healthcare network, and standards must reflect global progress. This principle was suggested by government, vendor, and hospital/SSO participants alike.

*"It's our hope that it's a **rational harmonized** role and it's not something completely different than what we're doing in the US or Europe or elsewhere." (Participant 15)*

*"The more universal that system can be, the better it is because at the end of the day if it is used across a larger and larger population base, it just makes it more practical and less chance of error and the cost of administering and managing and training will drop." (Participant 13)*

Participants explained that there are no Canadian-specific attributes which would prohibit the use of an internationally-operable standards system. One participant commented that bilingual fields are a Canadian-specific attribute, but industry participants confirmed that global standards have the capacity to add additional fields, which could be used for French language descriptors.

*"I am **not aware of any Canadian requirements because of the uniqueness of our country** or territory or healthcare system that would require us to have and go to the expense of having our own separate identification system or UDI for medical devices." (Participant 13)*

*"Don't try to ask for Canadian only attributes or if they do, make sure it's absolutely critical." (Participant 14)*

▶ **Interoperability**: Participants did not think that there necessarily has to be just one standard, but that multiple standards can co-exist as long as they are interoperable. Participants noted that the ability of standards databases to communicate with one another will become increasingly important as UDIs are incorporated into clinical patient records, allowing for novel data analysis.

*"Down the road where UDI is incorporated into patient records and we want to start amalgamating data or accumulating data, it's best if everybody had the same language*

*so if Health Canada decides to have a registry for UDI that that registry would mirror up with the GUDID or the European one." (Participant 6)*

Several jurisdictions have developed systems which allow for multiple standards (i.e., GS1, HIBCC, ICCBBA in the US). Having multiple standards has not proven problematic in these jurisdictions, provided that the standards are interoperable. Global trends indicate that multiple standards are required for medical devices, pharmaceuticals, tissue products, and blood products, therefore having one common standard for all of healthcare is not yet feasible, but interoperability is.

▶ **Affordability**: Participants reinforced the idea that adopting and using standards must be affordable for both manufacturers and healthcare delivery organizations. Aside from the upfront investments required for leveraging UDI, participants felt that accessing and submitting UDI information from a central database must be low cost or no cost to suppliers and healthcare delivery organizations. Industry participants, in particular, showed some concerns regarding other jurisdictions who have chosen to mandate national UDI registries at significant cost to vendors. This becomes problematic as global manufacturers must subscribe to multiple registries in order to maintain global distribution.

Further, participants generally agreed that any added costs to industry will likely be passed down to the end users and health systems.

*"I think a policy in order to minimize a cost on the industry, and I'm very interested in minimizing costs on the industry, there's **no such thing as a cost that can be on a manufacturer that doesn't get felt by the end users**. So the policy needs to minimize the cost on the manufacturers and for that I would suggest that the closest we can get to the American policy the better, because those companies are already spending their money on implementing the American policy." (Participant 22)*

One of the key challenges in adopting UDI standards across Canada will be an issue of funding. Interviews revealed that hospitals and manufacturers are generally unwilling to pay on an ongoing basis for UDI issuing and access. Hospital participants also commented on their challenges funding the back-office data investments required to capture UDI data.

*"The big struggle that we had in Canada is that suppliers were reluctant to pay to [upload UDI information to a database], which I understand, yet hospitals feel they can't pay to access which I also understand, so then that comes back to what funds this thing?" (Participant 7)*

▶ **Clear Intention/Design:** Much of the contention surrounding supply chain standardization regards defining how the data will be used and by whom. Manufacturers have some concerns that proprietary information could be included in standards. Hospitals have some concerns that linking product information with patient information will raise privacy concerns for patient information. One key principle of a successful standards strategy must be to clearly define the data's intended purpose, design, and ownership.

*"It's one thing to be able to say we need these unique identifiers in order to do recalls, that's very different than we need these unique identifiers because we want to know what was used on every individual patient. So I think there's got to be some kind of triage*

*around how are you going to use the data and what's the value from the data before you dive into applying broad policies across things." (Participant 12)*

▸ **Near 100% Adoption:** All participants agreed that the benefits of UDI are severely limited if the entire system is not capturing this data and using the same standards and language. Many participants stressed the importance of including both manufacturers and healthcare delivery organizations in the adoption of UDI standards, even if healthcare delivery organizations adopt standards later than manufacturers.

*"One of the big challenges we're having in Canada now is that we're a lot further behind than the US in terms of the technological systems that hospitals have, so even trying to embed UDI into an existing hospital framework right now is just not possible because none of the systems within the hospitals talk to one another and we just haven't reached that level of data sophistication, so one of the big questions we've been trying to tackle is **how you implement some kind of UDI policy forcing manufacturers and governments to start using that, but still embed some kind of element that would require healthcare delivery organizations to use that data as well**, even if it's much further down the line."*
*(Participant 15)*

▸ **Role of Standards Organizations and Datapools as Neutral Brokers:** The role of standards organizations and datapools was discussed extensively by participants. All participants expressed concerns at the growing role standards organizations are taking, in particular, decisions to make separate national standards in addition to global standards, and decisions to make these national standards mandatory in some jurisdictions.

*"When I look at GS1 or HIBCC or any of the standards organizations or issuing agencies, **where I think they get off the path is when they start getting in to commercial activities and I just don't think it's their role** and I think it confuses the conversation. The standards organizations are supposed to be neutral and when you start driving financial activities, I think it gets very confused. That's one of the reasons that in the US we took the model that we did, where the database was neutral. It was an FDA sponsored activity. It doesn't cost anyone anything to put the data in. It doesn't cost anyone anything to get the data back out again. We don't care which standards organization you use." (Participant 2)*

## 3.2 Policy Models

In order to achieve full UDI capture in Canada, three key decisions must be made: (1) an overall policy model (i.e., mandate standards vs. voluntary participation); (2) selecting a common standard (i.e., GMDN vs. UMDNS vs. national standard for nomenclature, GTIN vs. national standard for UDI); and, (3) selecting a common database for UDI (i.e., GDSN vs. GUDID vs. national database).

**Selecting a Policy Model - US FDA UDI Rule**

There are several different models available in order to drive global standardization of supply chain standards. These include, but are not limited to:

▸ A single government body (i.e., US FDA or Health Canada) setting overarching standards, allowing for multiple private sector UDI and nomenclature issuing agencies;

▸ A single private sector company setting standards, with mandatory use from product vendors and purchasers;

▸ A collaboration of large product vendor companies who collectively develop common standards; and

▸ A single translating body (public or private) that collects vendor UDIs and nomenclature information and translates them to a standardized version for purchasers

Several participants spoke of the global impact that the US FDA UDI Rule has had, particularly as global suppliers and regulators are sharing common elements of the FDA Rule. Participants generally agreed that the FDA's approach has been a success, and recommended that Canada adopt a similar approach. Globally, many countries have adopted similar approaches to the US FDA.

> *"The US was really the founder of UDI. Even Europe is pretty much marrying up with what the US FDA has done." (Participant 6)*

Participants generally recommended following the FDA's UDI model, with some exceptions noted below.

▸ **Mandate Hospital Adoption:** Participants noted the unique capacity Canada has to do a full-scale implementation of supply chain standards across the entire health system. One common criticism of the US FDA Rule was that the FDA had no control over hospital implementation, so uptake has been poor. They have been very successful in their implementation from the manufacturing sector, but participants stressed the importance of full, system-wide implementation to capture the full benefits of UDI.

> *"Because of the nature of government, potentially [the Canadian government] could enact all of those [standards for manufacturers and hospitals] at once and if they were to do that, it would be much more powerful because there would be more of a unifying feature behind this." (Participant 14)*

▶ **Prevent Multiple DIs:** Some concerns were raised about the potential for having multiple device identifiers (DIs) for the same product. The level of visibility reaped from having a UDI standard will be new for many manufacturers, who have previously been unaccustomed to sharing data and having it linked with patient outcomes. A cultural shift will have to take place which will see the burden of product evidence being shifted from manufacturer reporting to public patient outcome data. One potential way in which a small group of manufacturers have been working around this in the US is to have multiple DIs for the same product (i.e., if they are shipped to different jurisdictions, if they are used for multiple clinical purposes, etc.). This issue is currently being addressed by AHRMM, and Canada should consider findings when they are released in 2018.

*"I don't think all vendors are excited about having a national repository that identifies if they have had a good outcome with their product. So I think there may be some interest in having different DI numbers for the same product because it's a lot harder then to collect that picture." (Participant 21)*

**Recommendation:** The US FDA UDI Rule should be adopted for Canadian implementation of UDI standards. Select differences in implementation are highlighted in Section 3.3 Implementation Strategies.

**Selecting a Common UDI Standard – GS1 GTIN**

*GS1 GTIN*

Most participants agreed that most existing standards would work for Canadian UDI. The US FDA's policy has leveraged multiple issuing agencies (GS1, HIBCC, and ICCBBA), who all must meet common requirements. The overwhelming majority of global medical device products use the GTIN, or an internally-developed vendor label (ICCBBA is for blood products only, and HIBCC is a market minority). Most participants agreed that the most commonly used standard, and the most commonly recommended standard, is the GS1 GTIN.

*"**From our perspective we've made the assumption GS1 is really the only practical alternative in the market** and so we would say that we support GS1 standards. There's some things they don't have in there that we think they should, but at the end of the day I don't really see anybody else who's going to be able to develop a standard and bring it forward." (Participant 12)*

Participants also felt, however, that having multiple issuing agencies, as done in the US, should be encouraged, as long as they are interoperable.

*"I often just hear GS1 [being proposed as the main standard] so I think it's important to recognize that in the OR, if the US has accepted three standards, then that's what we're going to see on our products and we have to insure that those three standards are all documented in the patient record." (Participant 21)*

**Lessons from GS1 Canada**

Another standard frequently raised by study participants was GS1 Canada, who have developed a combination standard and datapool called ECCNet. Participants recognized the benefits of many of the value-added services that GS1 Canada offers. However, participants expressed concerns with the precedent set by jurisdictions such as the UK and Australia, where value-added services were mandated either by government or large hospital systems. Concerns were raised regarding GS1 Canada's efforts to create a national registry, rather than a globally interoperable one. Participants also recognized the leading role that GS1 Canada has taken in advancing UDI policy, but expressed some concerns that this position could present the potential to act as a conflict of interest given their investment in value-added services and monitoring.

▸ **Risk of Alienating Medical Device Companies with National Requirements:** In general, participants felt that a mandatory national standard, run by a non-government organization, raised concerns about fairness and control of data. The ECCNet platform was not designed to be globally interoperable, so multinational medical device companies are resistant to adoption.

*"They're [GS1 Canada] trying to develop a Canada-only standard for barcoding that can be used for recall, it can be used for identifying products, it can be used for some supply chain applications within hospitals. And you look at what they [hospitals] buy; its med devices and med surg. that would be my guess 80-85% of what they buy, and I can tell you right now that the medical device industry is absolutely not going to support a Canada-only barcode system and a Canada-only UDI." (Participant 4)*

**Recommendation:** Adopt the GS1 GTIN as the preferred UDI standard. Other standards should also be accepted, provided that they align and are interoperable with UDI standards.

**Selecting a Common UDI Database – GUDID or GDSN**

Two options for UDI databases were proposed by participants: GUDID and GSDN.

*GUDID*

The Global UDI Database (GUDID) is a government-run datapool for UDI information. Run by the FDA, members submit UDI information to the database, which is then made available to delivery organizations at no cost. Participants generally spoke positively of the US FDA's approach to UDI standardization. Many participants recommended copying the GUDID system from the US, or simply extending the same platform to the Canadian market over a phased implementation. Several key principles were recommended:

▸ **Control Publishing of Sensitive Information:** Several participants highlighted privacy concerns regarding a public UDI database. Careful attention must be paid to which attributes are published, who has access to which data, and protection of proprietary data.

*"The only caveat is that if we're tying in patient records we certainly don't want to have patient information floating around to various parts of the world." (Participant 6)*

▶ **Neutral, Not-for-Profit Database:** Participants agreed that a government-owned and government-led database would be the best option for Canada.

> *"It would make more sense for this to be administered by the Canadian government as opposed to an individual entity simply because in the US there are multiple standards out there. There's HIBCC and then there's also the ICCBBA, so it doesn't make sense for any individual standards body to administer the standard because you need to have at least two or three." (Participant 14)*

In addition to recommending a government-run database (similar to or an extension of the GUDID system in the US), one other database was proposed as an alternative, the GS1 GDSN.

*GDSN*

GS1's Global Data Synchronization Network (GDSN) is a data network that allow companies to synchronize and share data based on GS1 standards. It is comprised of 38 data pools worldwide that are linked through the Global Registry. Organizations upload standardized data related to their products and services, which are then shared real-time with trading partners using the network.[20] The GDSN aim is to on ensure data accuracy and consistency: accuracy is achieved by validating the data against standards and business rules, and consistency is achieved by having a set format of data each company must use.[21]

Worldwide there are 38 data pools.[22] 1WorldSync is the largest data pool, comprising 40% of worldwide trading partners, and is a GS1 subsidiary formed in 2012 by a merger of the US and German GS1 data pools.[23] There are a number of other private data pools, including Commport Communications International, a Canadian company, and GHX Health ConneXion, a healthcare-focused data pool that aims to reduce the costs of GDSN implementation.[24] Additionally, many of the GS1 national organizations operate their own data pools. Up until 2015, GS1 Canada was among these countries, but its network subsequently subsumed into 1WorldSync. GHX was the company that originally hosted GS1 Canada's data pool, but when GDSN standards were updated in 2015, chose not to recertify.[25] In press releases GS1 Canada stated that a goal of the move was to "enhance their capability to support medical device manufacturers."[26]

Information related to the costs to access the GDSN data pools was difficult to find, as 1WorldSync and other data pool providers do not release them publicly. The Global Registry itself, operated by GS1, functions on a cost-recovery basis, and bills the data pools themselves. Each data pool is charged a US$15,000 subscription fee, and the remaining

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[20] *Source: GS1 Canada (2017) GS1 Canada GDSN. http://www.gs1ca.org/pages/n/gdsn/index.asp*
[21] *Source: Lansa (2017) What is global data synchronization. http://www.lansa.com/pim/gdsn.htm*
[22] *Source: GS1 (2017) GS1 global registry statistics.*
  *http://www.gs1.org/sites/default/files/docs/gdsn/stats/gdsn_dp_activity.pdf*
[23] *Source: GS1 (2017) Certified data pools. http://www.gs1.org/gdsn/certified-data-pools*
[24] *Source: GHX (2017) Health ConneXion. http://ghx.com/solutions/supplier-products/health-connexion/*
[25] *Source: GS1 Canada (2015) GS1 Canada – 1WorldSync partnership. http://www.gs1ca.org/files/1WorldSync-FAQ-en-fr.pdf*
[26] *Source: Feeney, B., Wilkinson, L. (2015) GS1 Canada announces partnership with global data solutions leader 1WorldSync to power GS1 Canada GDSN. http://www.prweb.com/releases/2015/03/prweb12610349.htm*

costs are allocated based on the number of trading partners and data transfers each pool has in a year.[27]

In 2015, the last year Canada-only data was available, 316 companies used the GDSN, with almost 20,000 GTIN's registered. GS1 publishes a list of all companies worldwide enrolled in the GDSN, and a number of major Canadian companies and healthcare organizations are members. These organizations include HealthPro Procurement Services Inc, MedBuy, 3M Canada, Plexxus, Shared Services West, Healthcare Materials Management Services and Mohawk Shared Services, along with a number of other international healthcare and medical device companies.

Participants in Canada noted that the GDSN has the capacity to act as the global standard and datapool for Canadian health systems. Participants suggested that GDSN could be the mandatory portion of UDI policy, opening up a secondary market for certification and supply chain management services as an optional, value-added services. Making the value-added services optional allows for companies of different sizes to find appropriate solutions (i.e. small companies using third party certification vs. large companies hiring in-house certifiers).

▶ **GDSN has Full Functionality**: *"If you go back to the old GDSN there were some attributes that were hard coded that weren't in the GDSN. But the GDSN now has the backend flexibility to add new attributes very, very quickly and easily. It is not fact that the GDSN cannot handle any of those attributes because they can. We handle French language today. We handle images today. All automated and they're in URL tags."* (Participant 3)

▶ **Affordability:** For companies who have already invested in GDSN for other jurisdictions, the cost to deal in Canada is already covered. Unlike GUDID, however, there is a small cost for delivery organizations.

*"We have successfully shared data through GDSN and its worked, its worked absolutely fine and I know we got stalled a couple of times because there are some desired data attributes that we don't have in the US and for those we're unable to provide them, but as a generalization — it's worked. It's worked out fine when they asked us to share data through GDSN, we can send it through. It doesn't cost us one cent more to send it through to Canada."* (Participant 15)

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[27] *Source: GS1 (2015) GDSN 2015 financial model.*
*http://www.gs1.org/docs/gdsn/support/2015_GDSN_Financial_Model_Bulletin.pdf*

Key differences between the GUDID and GDSN are included in Figure 5 below.

Figure 5 – GUDID vs. GDSN

|  | **GUDID** | **GDSN** |
|---|---|---|
| Focus | Regulatory | Commercial, Clinical, & Regulatory |
| Country | US | All (Global) |
| Entry Point | via FDA tools | Any one of 31 global GDSN Certified Data Pools |
| Item Types Included | Medical Devices Only | Any item type (Medical Device, Pharmaceutical, Food, Janitorial, etc.) |
| Required by | FDA | GPOs, and other healthcare recipients |
| Pricing Message | N/A | Can be shared via GDSN Price message |
| Supply side sharing mechanism | Push- Public access to almost all data | Push- Permissions based control |
| Demand side sharing mechanism | Pull- Users manually download and manipulation of file | Push- File pushed (real time or preset schedule), permissions based control |

*Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation. Pg. 48.*

**Recommendation:** Selecting a common datapool will require further investigation. This analysis revealed two options that participants felt would work well for Canada: GDSN or GUDID. Participants did not indicate any strong preferences for either of these options, and tradeoffs were given for all options. In particular, participants felt that the global nature of GDSN and the low-cost nature of GUDID were attractive. Participants also noted that having a Canadian-run standard or datapool (i.e., a Canadian version of GUDID) may be met with manufacturer resistance due to the relatively small market size. Deciding on one platform for Canada will depend upon a) the willingness of GUDID to expand to Canada, and b) an analysis of Canadian manufacturers to determine how many products are currently tracked in either systems.

**Selecting a Common Nomenclature Standard – UMDNS or GMDN**

Participants agreed that a Canadian nomenclature standard should be globally-interoperable, and that the GMDN or UMDNS would both work. Both of these standards have strong global adoption, and both have been mandated in a number of countries successfully. The key difference between GMDN and UMDNS is cost, the latter being free to use. GMDN has a small fee for both manufacturers and delivery organizations. Participants did not indicate a strong preference for one system over the other, but due to the no-cost nature of the UMDNS, it was proposed as the standard for Canada.

**Recommendation:** Adopt the UMDNS as the preferred nomenclature standard.

## 3.3 Implementation Strategies

The purpose of this report is to recommend UDI and nomenclature standards sets and high level approaches for adoption. Implementation strategies for specific standard sets have been documented in the literature, and the following resources should be considered when adopting a new standard:

> **Tip:** Additional implementation resources for hospitals include:
>
> ‣ GTIN Adoption & Usage Model: Implementation Roadmap for US Healthcare Supply Chain
> ‣ GTIN Maturity Model and Industry Roadmap
> ‣ Provider GLN Tool Kit, Provider GTIN Tool Kit, Provider GDSN Tool Kit
> ‣ GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2
> ‣ Best Practice Guide for Implementing GLN in Trace, Chargeback & Rebate Processes
> ‣ GS1 Standards – Overview of Global Data Synchronization Network (GDSN)
> ‣ GLN 101 for Healthcare Location Identification
> ‣ Improving Healthcare Business Processes
> ‣ GS1 Standards & Hospital Supply Chain Operations

Adoption of standards will involve long-term system planning for hospitals and SSOs, manufacturers, and government regulators. Participants discussed several high-level strategies to position Canada for UDI and nomenclature standards implementation.

‣ **Assess Hospital/SSO Readiness**: Determine: broad alignment with the proposed UDI/nomenclature standards model; current IT infrastructure available at hospital sites; case study examples of hospital UDI capture; current understanding of UDI/nomenclature standards; resources required for further IT investment; reasonable timelines for standards adoption; and organizations that would be interested in participating in future discussion on standards.

‣ **Leverage Quick Wins:** Collect case studies of success stories for both hospitals and manufacturers, with key emphasis on cost efficiency, patient safety, and patient outcomes tracking. Educate hospitals on the various benefits of supply chain modernization so it becomes a priority area for cost savings.

*"I think that it's important for [policymakers] that they search as quickly as possible for positive use cases of why this is important and how this is helpful, because if you do that, that will just reinforce the message. They'll want to use that to advertise as much as possible." (Participant 14)*

‣ **Mandate Adoption:** Mandating adoption can be used in tandem with leveraging quick wins, and should be used to set timelines for adoption. Pilot projects can be run to find quick wins and sort out any problems that may arise in Canadian systems, but a mandated UDI adoption policy would require hospitals to adopt the required technology in a timely manner.

*"I actually think it needs to be a 'thou shalt do it or you won't be able to do business', so you need to give companies and organizations runway and time to get there, but let's*

*do what the grocery industry did and basically say 'if you want to do business you must have this in place and this is what you must have in place by this date... I'm not a believer that an organic, let's just hope everyone will see the value of these things would work." (Participant 12)*

- **Phased Approach (Staggered Milestones):** Similar to the US FDA Rule, a staggered adoption with key project milestones is advised. Participants discussed the FDA's approach and indicated that it was successful. All participants recommended a similar process for Canada.

  *"If Health Canada intends to acquire this for healthcare providers, it would also make sense that they make this a requirement when they first release the regulation. It wouldn't make sense five years later to tell hospitals that it's an expectation that they're going to use it, but it would make sense for that to be a requirement up front or at least while you'd need to give device manufacturers time to get all this set and get this implemented, it would make sense to explain it or communicate it up front for healthcare providers so at least they would know it's becoming an expectation and I think they would start to get involved right up front." (Participant 16)*

- **Manufacturers First, Then Hospitals:** It is recommended that a mandatory standards adoption begin with manufacturers, and then transition to hospitals, GPOs, and SSOs. Manufacturers generally have a UDI in place for the majority of their products, even if it doesn't meet the specific requirements of an individual government. However, healthcare delivery organizations in Canada have greater variability in terms of their readiness for capturing UDI and nomenclature data. By incenting hospitals to adopt standards without having the manufacturers near 100% adoption will create additional, unnecessary challenges. One participant predicted that if manufacturers are not the first milestone, hospital responses may include *"we can't do it, there's no use because the manufacturers aren't there." (Participant 12)*

  *"We've reached out to a lot of hospitals and a lot of GPOs and SSOs, but a lot of them are either not actively pursuing more UDI engagements, or just aren't aware of it yet, so it seems like **on the delivery side of things it's not quite as developed as on the industry side of things**, so when we're looking at proposing some kind of policy to Health Canada, on the industry side of things it seems like everybody agrees that the approach that the US FDA has taken seems to be one that would likely work for Canada, but now on the delivery side of things talking with a few hospitals that we've talked to, it's really not ready for that yet at that level and there's a lot of things that have to happen on a hospital side before that big policy can be enacted." (Participant 8)*

- **Funding for Hospitals:** Hospital participants indicated a need for additional funding, particularly for IT investment. An analysis of other national UDI and nomenclature strategies did not identify any significant government spending on hospital IT solutions, but also did not reveal any jurisdictions with 100% adoption from hospitals. Additional funding would likely speed up implementation and adoption, but may not be required in all cases. Some funding for barcode scanning technology may be required however.

  *"In Canada, **healthcare providers investing, means governments spending money**. So if governments are not willing to spend money then there can be no effective UDI policy or there can be no implementation of an effective UDI policy." (Participant 22)*

**Hospitals/SSOs**

Several strategies specific to hospitals were recommended in order to prepare for UDI integration.

▸ **Build Hospital Item Masters and Case Costing Capabilities:** The main recommendation from participants related to hospital preparedness for UDI capture was investing in item master cleansing and case costing capabilities. The current state of hospital supply chains in Canada varies greatly, but few organizations are fully utilizing case costing for supply chain management. Even fewer have begun to invest in point-of-use barcode scanning, aside from pharmaceuticals. Participants noted that this process, once organizational buy-in is obtained, can take up to five years to complete.

*"It's more than just the clinical EHR… they could easily put a field in there and you put your thirteen digit GTIN in that field. That's the easy part. **The hard part is creating all the functionality at the point of use.** The scanners and the RFID readers and how are we going to get that information into the system, how are we going to say that that product has now been used on that patient? So all the scanning and that type of infrastructure has to be put in place."* (Participant 22)

*"Another reason why [the federal government] has been procrastinating is they realize that the **IT infrastructure within hospitals aren't capable**, so for them to come out with any kind of edict or ruling would really be unfair to the healthcare system because they make some authorization that you need to have this and then the IT structure is not in place for the hospitals. **It really comes down to they really need to upgrade their IT structures.**"* (Participant 6)

▸ **Connect Similar Hospitals:** Connect hospitals investing in IT with other hospitals who have similar IT infrastructure (i.e., EHR and ERP systems), and collaborate for initial UDI adoption.

▸ **Assess Current State UDI Readiness:** Conduct an assessment of organizational preparedness for UDI capture. GS1's *GTIN Adoption & Usage Model* identifies the key people, process, and technology requirements for UDI capture and ways to assess readiness. A high-level summary is included in Figure 6.

Figure 6 – Hospital standard readiness assessment

| | Level One **Awareness** | Level Two **People and Process** | Level Three **Systems and Partners** | Level Four **Transact and Extend** | Level Five **Optimize** |
|---|---|---|---|---|---|
| | *Communicate and Educate* | *Enumerate and Develop Accuracy Processes* | *Align Systems and Attributes* | *Use GTINs instead of Proprietary Numbers* | *Maintain and Share* |
| **People** | ▪ Assess impending regulatory requirements, and ability to meet or exceed requirements.<br>▪ Commit to implement.<br>▪ Inform organization and supply chain partners. | ▪ Educate Customer Service, Sales Reps, and Procurement teams on GTIN as well as company requirements and capabilities. | ▪ Prioritize trading partners for implementation of standards in transactions. | ▪ Identify any new skill sets required and include in succession planning and hiring.<br>▪ Develop Subject Matter Experts and transition skills appropriately. | ▪ Tie KPI's to standards adoption / utilization in respective area of responsibility. |
| **Process** | ▪ Understand the benefits beyond compliance. | ▪ Enumerate all products.<br>▪ Develop and maintain SOPs for master data management. | ▪ Include contract terms and conditions that call for GS1 Standards on all products. | ▪ Use GTINs and other GS1 Standards in a majority of, if not all, transactions. | ▪ Maintain, share, & access products and attributes via a shared data catalog (e.g. GDSN). |
| **Technology** | ▪ Assess current technology capabilities for standards usage. | ▪ Develop process to promote accuracy and usability of GTIN at all packaging levels. | ▪ Align IT capabilities internally and externally. | ▪ Assure technology infrastructure and plan can support standards across various systems. | ▪ Develop and integrate systems to synchronize with master data using GTIN. |

*Source: GS1 US (2017). GTIN adoption & usage model: implementation roadmap for US healthcare supply chain. Accessed at https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=830&language=en-US&PortalId=0&TabId=134. Pg. 8.*

▸ **Prepare for UDI Integration:** Several best practice guides for hospital UDI integration are available (recommendations below). General project implementation strategies include:

1. Establish executive support
2. Form a UDI implementation team including clinicians, supply chain, and IT
3. Develop project communication
4. Assess information systems including ERP and EHR
5. Obtain UDI product data (from GDSN, GUDID, SSO/GPO, or Supplier)
6. Engage suppliers for pilot and testing
7. Conduct transactional testing
8. Create standard operating procedures[28]

**Timelines**

Participants recommended a similar timeline to the US FDA UDI Rule (see Figure 7). The FDA UDI Final Rule established key deadlines for manufacturers to capture all UDI data (Appendix 3 – Industry Compliance Timeline, & Appendix 4 – FDA UDI Compliance Dates). The timelines in the US were originally proposed as a five-year plan, which was later extended to a seven-year plan (extended deadline for UDI capture on Class 1 medical device products). Participants recommended waiting until the US implementation is complete (2020) before beginning a Canadian implementation. In the meantime, the government should begin engaging stakeholders to discuss the proposed standards strategy and work through any challenges. Implementation in the US indicated that this engagement process can take up to two years.

> *"We should wait and we should let [the US] work through it because we are about 2% of the spend of US product, and the tail is not going to wag the dog. We are not going to change the rules and the manufacturers are not going to label based on our spend."* (Participant 8)



*Figure 7 – FDA hospital compliance timeline*

**2017-2019**

- Assess information system capability to store and capture the Global Trade Item Number® (GTIN®) in Enterprise Resource Planning (ERP) and UDI in Electronic Health Record (EHR) systems
- Assess scanning capabilities
- Obtain product data (including GTIN and other attributes)
- Map item master database fields with GTIN

- Conduct transactional testing
- Engage suppliers for pilot and testing
- Integrate supply chain and clinical systems
- Document UDI at the point of care
- Integrate new device labels (UDI) and new pharmaceutical labels (DSCSA) into point of care and scanning systems

*Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital – roadmap for implementation. Pg. 17.*

Participants included in this study felt that the US state of UDI readiness was higher than in Canada because of the experience hospitals have with case-costing. Participants noted that in the American health system, billing practices necessitate accurate case costing and EHR/ERP integration. In Canada, the timelines for UDI adoption need to include time for hospital IT system investment. This study proposes adopting the same adoption timelines as the US model, with few exceptions:

▸ **Include Nomenclature Standards:** The process for adopting nomenclature standards and UDI standards are relatively similar for manufacturers. For this reason, it is recommended that nomenclature standards and UDI standards be mandated simultaneously. Timelines for nomenclature standards should align with UDI standards, as proposed in the FDA model.

▸ **Include Hospitals in Integration Plan:** In the US model, the mandated UDI policy was directed towards manufacturers. Participants in this study noted that the true

benefit of UDI is only possible with full end-to-end adoption. For this reason, it is recommended that hospitals are included in the UDI and nomenclature standards mandate. Participants felt that a reasonable timeline to be capturing UDI and nomenclature standards at each hospital was ten years.

**Recommendation:** Health Canada should lead the UDI and nomenclature standards adoption in Canada.

- ▶ 2018 – 2020: Engagement with key stakeholders (manufacturers, hospitals, SSOs) to determine alignment with strategy, readiness for adoption, and resource requirements.
- ▶ 2020: Publish UDI/nomenclature standards Rule.
- ▶ 2023: Class IV medical device implementation (UDI and nomenclature) date
- ▶ 2025: Class III medical device implementation (UDI and nomenclature) date
- ▶ 2027: Class II medical device implementation (UDI and nomenclature) date & hospital/SSO EHR/ERP integration date
- ▶ 2030: Hospital/SSO implementation (UDI and nomenclature) date

The Canadian health sector's adoption of UDI and nomenclature standards is an inevitable reality that organizations need to begin preparing for today. As global adoption of these standards spreads, they will soon become necessary to participate in the global health sector. The solutions and processes for capturing detailed product information have been well-established, and the market leaders have become apparent in most cases, including the GTIN as a UDI standard, and GMDN and UMDNS as nomenclature standards. Canada is well-positioned to adopt the lessons learned from other jurisdictions, and can expect significant efficiency gains and improvements in patient outcomes upon further investment in supply chain transformation.

# Appendices
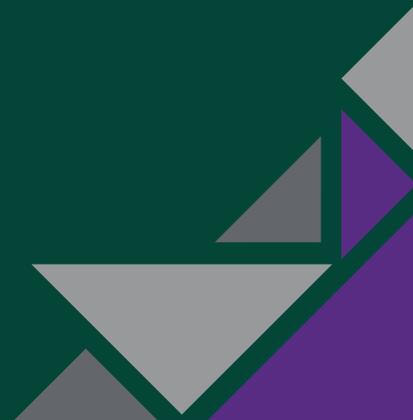
# Appendix 1 – Industry Analysis

**Automotive Industry**

▸ Interoperability challenges between multiple sets of standards and/or applications can be managed by consortia through industry trade or technical associations, or with the help of a standards organization. However, the effectiveness of voluntary organizations can be limited if discussions are dominated by large players and/or if any key stakeholders are not engaged.

▸ Information system integration is not evolving within industry supply chains; however, the business case for better integration has been evidenced in the automotive industry for several years and for more than a decade in the electronics sector. Under inefficient integration, systems are put in place to automate information inputs and flows, but the unavailability of a suitable standards infrastructure leads to excessive capital investment, duplication of effort, higher than optimal staffing and support levels, and inadequate organizational flexibility.[29]

▸ The automotive industry has collectively worked together with AIAG to ensure that standards and their development remain non-competitive and can be discussed in an open forum.

▸ In the automotive industry, many large manufacturers (such as Ford) use global standards as a base for their supply chain management, and add company-specific attributes to gain a competitive advantage in supply chain.

▸ Across North America, supply chain management and standards were largely managed by a collective of large automobile companies until the US government became involved in 2000 in response to multiple recall scandals. Recall legislation has acted as an incentive for automobile companies to invest in barcoding individual parts, allowing for easy identification and limited scope of recall.

**Grocery Industry**

▸ The benefits of global standardization extend beyond cost savings for individual companies. In the grocery industry, the benefits of global standardization have far exceeded initial expectations, with unanticipated benefits including support of larger product assortments, improved forecasting and in-store marketing and promotion, more efficient end-to-end supply chain operations, and customer analysis through loyalty programs.[30]

▸ One common challenge with global grocery standards identified in the literature is a systemic bias towards larger companies. As global standards requirements become increasingly complex, small companies are faced with increased costs of compliance, which can be prohibitive to the company, ultimately leading to a market where either smaller companies are unable to compete, or where the costs of supply chain standards are passed on to the consumer to preserve margin. This effect was further compounded by private standards in particular, which have a tendency to be more expensive and more complex than global standards managed publically.

▸ Despite the stability of the grocery industry and its long-time adoption of global standards, as the industry continues to evolve so does its requirement for standards. Existing GS1 standards are currently lacking when it comes to random-weight and variable-measure items, highlighting the need for continuous and iterative standards improvement.

▸ The benefits of increasing the rigidity of standards and certification requirements are limited in the grocery industry. The limitations of codes of practice and performance standards alone as a way of improving worker and supplier conditions are increasingly recognized.[31]

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[29] Source: *National Institute of Standards & Technology (2004) Economic impact of inadequate infrastructure for supply chain integration. https://www.nist.gov/sites/default/files/documents/director/planning/report04-2.pdf*

## Retail Industry

▶ A key difference between healthcare and retail is that a few major retailers can set expectations and requirements for consumer packaged goods suppliers, while manufacturers in the healthcare sector represent the largest and most global segment.[32]

▶ Consumer expectations of retail supply chain management are moving towards increased transparency, visibility, and standardization. Rigorous supply chain management has become a key competitive advantage for many companies who are able to meet the increasing demands of consumers.

▶ Global cross-industry standards often need to be customized/specialized to allow for industry-specific tracking. For the retail industry, the high volume of manufacturers, distributers, and retailers requires that EDI standards be enhanced. Similarly, the high variability in supply chain management applications requires complex interoperability standards.

## Pharmaceutical Industry

▶ Barcoding practices within the pharmaceutical industry began in the 1980's, and were driven primarily by industry until the mid-2000's when governments began enacting legislation to promote their use and accuracy.

▶ Concerns about creating a standards monopoly have been raised by several parties. For standards bodies which have proprietary interests, it is important to define which attributes are necessary and should be made mandatory, and which attributes are a value-added service to be left to the discretion of the manufacturer. Compelling manufacturers to adopt private standards when a public standard exists and is sufficient can violate antitrust laws.

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[30] Source: McKinsey (2012) Strength in unity: The promise of global standards in healthcare.
http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf
[31] Source: Tallontire, A., Vorley, B. (2005) Achieving fairness in trading between supermarkets and their agrifood supply chains.
UK Food Group. http://www.eldis.org/go/home&id=19705&type=Document#.WMbb6G_yv3g
[32] Source: McKinsey (2012) Strength in unity: The promise of global standards in healthcare.
http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

# Appendix 2 — Benefits of UDI Standards

## Safety and Quality of Care

| Challenge | Standards-Based Solutions |
|---|---|
| **Preventable errors** | GS1 product identifiers facilitate bedside verification and point-of-care scanning, which decreases the number of preventable medication/medical errors. |
| **Non-value added tasks** | Patients and families choose providers based on quality of care. The use of GS1 Standards helps streamline operational processes, so your team can focus on delivering the best patient care. |
| **Getting the right product to the right patient** | GS1 Standards enable the accurate identification of products, facilitating caregivers' efforts to ensure that the right product is available for patient care at the time it is needed. |
| **Managing Electronic Health Records (EHRs)** | The use of product and location identifiers helps ensure accurate treatment documentation and future interpretation of that information. |
| **Manual records and requests** | Reducing the number of hand-written orders, instructions, etc. by clinicians and other hospital staff and replacing this with automatic data capture reduces errors and allows for communication between automated order entry and supply chain systems, improving accuracy and increasing efficiency. |

## Operational Efficiency

| Challenge | Standards-Based Solutions |
|---|---|
| **Cash flow issues** | GS1 Standards streamline chargeback and rebate processing, reducing the amount of money sitting in unresolved sales accounts. |
| **Inaccurate pricing** | Use of standardized location and product identifiers helps ensure that hospitals receive correct contract prices on products ordered and received. |
| **Monitoring expiration dates of inventory** | Use of product identifiers in association with secondary information (such as lot, expiration date, and/or serial number) facilitates better inventory management. |
| **Difficulty in capturing patient charges** | Use of standardized product identifiers tied to a given patient simplifies the patient charge capture process. |
| **Need to re-label products** | Reducing the number of hand-written orders, instructions, etc. by clinicians and other hospital staff and replacing this with automatic data capture reduces errors and allows for communication between automated order entry and supply chain systems, improving accuracy and increasing efficiency. |
| **Difficulty in asset and instrument tracking** | Use of standardized product and location identifiers in conjunction with auto ID technology greatly reduces the incidence of missing equipment and/or expense of purchasing or renting equipment, while facilitating better instrument tracking and maintenance. |

## Regulation Compliance and Risk Management

| Challenge | Standards-Based Solutions |
|---|---|
| **Increased tax on medical devices** | Increased efficiency across the supply chain, made possible by using GS1 Standards, will help offset the cost of recent medical device taxes. |
| **Recall process is difficult to optimize** | Use of standardized product and location identifiers enables a more efficient product recall process. |
| **FDA Unique Device Identification (UDI) Regulation** | Use of standardized product identifiers prepares systems to support UDI requirements. |
| **Drug Supply Chain Security Act (DSCSA)** | Use of GS1 Standards prepares systems to support upcoming traceability requirements. |

*Source: GS1 US (2016). Modernize your supply chain to improve patient safety and reduce costs. Accessed at https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=736&language=en-US&PortalId=0&TabId=134. Pg. 3.*

# Appendix 3 – Industry Compliance Timeline
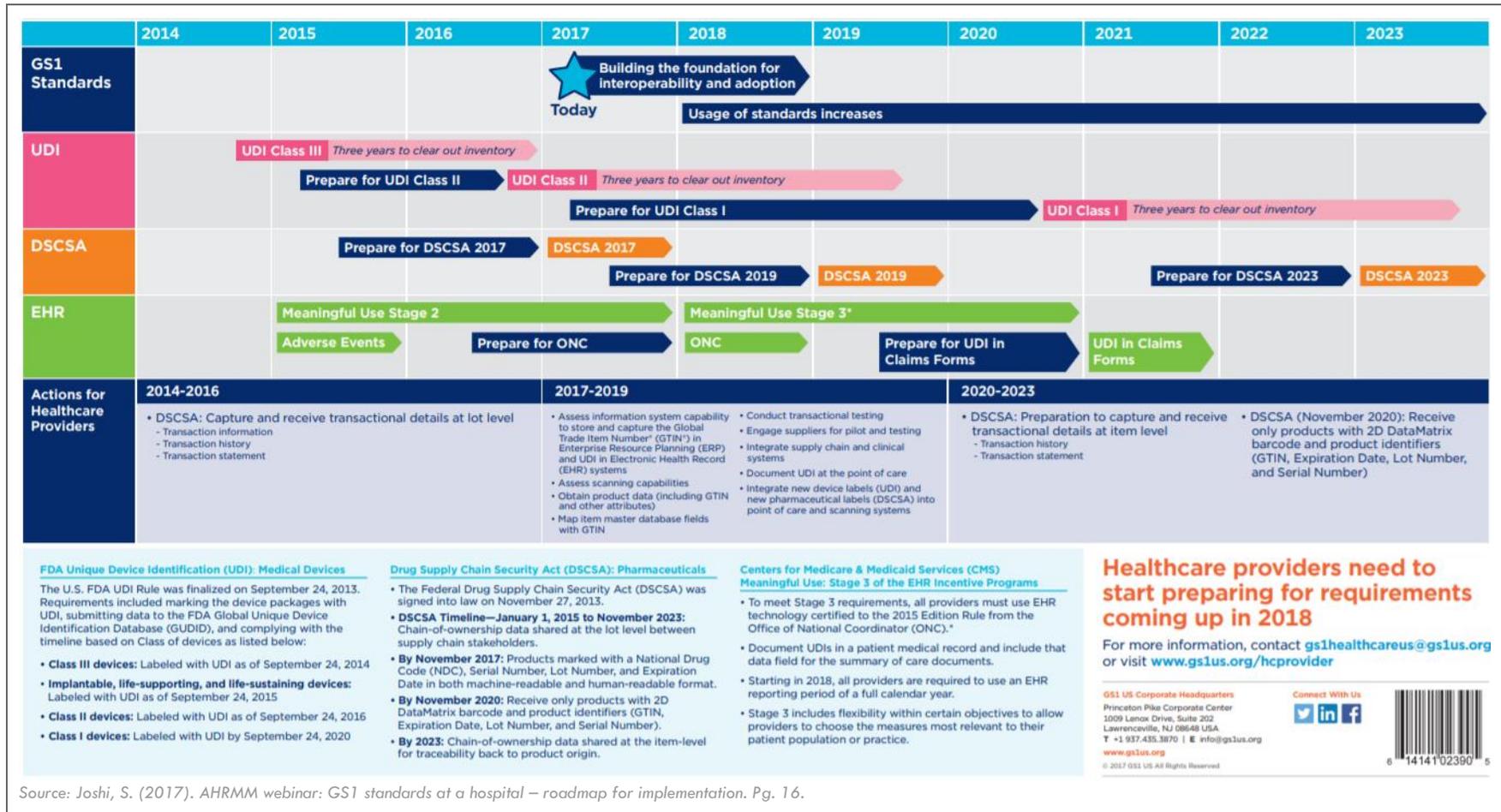


*Source: Joshi, S. (2017). AHRMM webinar: GS1 standards at a hospital — roadmap for implementation. Pg. 16.*

# Appendix 4 – FDA UDI Compliance Dates

| Compliance Date | Requirement |
|---|---|
| 1 year after publication of the final rule (September 24, 2014) | The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20.* <br> Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. <br> A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b). |
| 2 years after publication of the final rule (September 24, 2015) | The labels and packages of <u>implantable, life-supporting, and life-sustaining devices</u> must bear a UDI. § 801.20. <br> Dates on the labels of these devices must be formatted as required by § 801.18. |
| | A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. <br> Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b). |
| | Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. |
| 3 years after publication of the final rule (September 24, 2016) | Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. |
| | The labels and packages of class II medical devices must bear a UDI. § 801.20. <br> Dates on the labels of these devices must be formatted as required by § 801.18. <br> Class II stand-alone software must provide its UDI as required by § 801.50(b). |
| | Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. |
| 5 years after publication of the final rule (September 24, 2018) | A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. |
| | The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20. <br> Dates on the labels of <u>all</u> devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18. |
| | Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. <br> Class I stand-alone software must provide its UDI as required by § 801.50(b). |
| 7 years after publication of the final rule (September 24, 2020)** | Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. |

*§ numbers indicate Code of Federal Regulation from the UDI Final Rule.*
*\*\*The initial target deadline for Class 1 devices was 2018, which was later extended to 2020.*
*Source: US Food and Drug Administration (2018). Compliance dates for UDI requirements. Accessed at*
*   https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm.*

**Ivey International Centre for Health Innovation**
Ivey Business School at Western University
1255 Western Road
London, ON, Canada
N6G 0N1
P| 519 661 2111 ext. 87959
E| healthinnovation@ivey.ca
www.ivey.ca/healthinnovation

Contact: Alexander Smith, Research Associate, asmith@ivey.ca

www.twitter.com/iveyhealth

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