REVIEW ON GLOBAL REGULATORY LANDSCAPE OF UNIQUE DEVICE IDENTIFICATION (UDI) IN MEDICAL DEVICE

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ABSTRACT

The Unique Device Identification (UDI) system is a widely accepted access uniquely determining medical apparatus, boosting post-market surveillance, and improving patient safety. This review article comprehensively examines the landscape surrounding UDI implementation in different countries. With an increasing focus on the harmonization of medical device regulations, this study offers insights into the similarities and disparities in UDI adoption across various regions. The analysis encompasses key aspects of UDI implementation, including regulatory requirements, timelines for compliance, data standards, and enforcement mechanisms. The review covers major markets like the United States, European Union, India, and Global IMDRF countries. It critically evaluates the UDI systems strengths, challenges, and impacts on the healthcare industry and regulatory authorities. Furthermore, the article highlights successful case studies of countries that have effectively integrated UDI into their healthcare systems, leading to improved traceability, reduced counterfeiting, and enhanced patient outcomes. Additionally, it examines the complexities associated with implementing UDI requirements in diverse healthcare settings, such as resource-constrained environments. On completion, this review article presents a comprehensive overview of the regulatory landscape of Unique Device Identification for medical devices in different countries. It emphasizes the importance of continued efforts toward standardization, collaboration,

and adaptation to the dynamic nature of medical technology. In the end, UDI's generalization is vital to guaranteeing patient security and promoting the worldwide medical device industry.

Keywords: IMDRF, AIDC, Safety, Technology, Global

INTRODUCTION:

The diagnosis, treatment, and prevention of disease and sickness all depend on medical technology. From simple medical supplies like gauze and hospital dressing to complex medical equipment like artificial pancreas and heart valves that assist protect and save life, they range in complexity. They include diagnostic technologies that help identify diseases (such as MRIs and in vitro tests) along with healthcare digital innovations (such as therapeutic tools for surgery planning, and closed-loop medication delivery systems). Nearly 18,000 businesses produce approximately 190,000 distinct devices in more than 21,000 device manufacturing facilities globally under the supervision of the United States Food and Drug Administration [1]. Medical equipment range in complexity from basic tongue depressors to computer-assisted (robotic) surgical systems. A medical device is a tool, appliance, machine, implant, or other similar item used to identify, avoid, treat, monitor, or lessen a human medical condition or illness. These tools are essential in healthcare settings and are made to help doctors care for patients more effectively [2]. The UDI system target is

to facilitate it less difficult for medical devices to be properly identified during distribution and use in order to advance a number of public health objectives, including reducing healthcare errors, improving adverse reaction reporting, and swiftly and effectively resolving regulatory recall disputes in the medical device sector. The pharmaceutical sector is crucial to assuring patient safety, product compliance, and market access. Medical device distributors, group purchasing firms, payors, researchers, and others are beginning to use UDI to enhance supply chain effectiveness, track medical devices in the electronic health record, perform comparative effectiveness research, conduct digital purchasing, among other things [3].

Unique Device Identification: In 2012, the United States Food and Drug Administration (FDA) implied Unique Device Identification as a regulation. The most ambitious project has been the development of a worldwide UDI system capable of indisputably identifying a device throughout distribution and usage. Rather of waiting for each jurisdiction to specify the regulatory needs of a UDI system independently, the IMDRF proactive formed

the foundation in 2011 to promote a worldwide standardized system that could be implemented when each jurisdiction rolled out its component of the system **[4]**. The United States Food and Drug Administration (FDA) final regulation for UDI system was established on September 24, 2013, as part of the FDA's standards for safety and surveillance purposes, and since then, UDI has expanded, evolved, and been incorporated into the US and worldwide medical product ecosystems. It offers a robust solution to empower device manufacturers, distributors, and healthcare facilities in enhancing their management of device recalls. A vital and internationally recognized mechanism for identifying medical equipment is the Unique Device Identifier (UDI). In order to ensure patient safety, verification, and compliance with regulations, this system is essential. The UDI is made up of a collection of alphanumeric characters that clearly and unmistakably identify any medical equipment sold today **[5]**. The Device Identifier DI (UDI-DI) and the Production Identifier PI (UDI-PI) are the two main parts of the UDI. Important details regarding the medical equipment are contained in the UDI-DI, often known as the "static" section. This contains specifics like

the name or trade name of the device, its model or version number, and a statement about whether it is marketed as sterile or intended for single-use. The UDI-DI may also include information on the device's maximum number of uses, if sterilization is required prior to use, and the number of devices included in a package. This UDI static component assists manufacturers, regulatory agencies, and healthcare professionals in precisely and consistently identifying certain medical devices, lowering the possibility of mistakes and assuring patient safety. The UDI-PI, often referred to as the "dynamic" part, provides information related to the production and manufacturing of the device. It includes crucial details such as the lot, batch, or serial number, allowing for tracking of individual devices throughout the supply chain. The UDI-PI also contains data about the device's expiration date or date of manufacture, which is critical for ensuring that medical devices are used within their intended timeframe and are not utilized after their expiry date. Furthermore, the UDI-PI includes a distinct identification code, enhancing traceability and enabling quick and accurate identification during recalls or adverse event reporting.

(01)	(17)	(10)	(21)
Device Identifier	**Expiration Date**	**Lot Number**	**Serial Number**

Figure 1: Unique Device Identification

Forms of UDI

According to the UDI Rule, the UDI on the product label and product packaging must be displayed in both plain-text and AIDC technology formats (21 CFR 801.40). Furthermore, under 21 CFR 801.45, some devices must be directly labelled **[6]**. The UDI immediately marked on the device itself for those devices may be delivered by either or both easily accessible plain-text or AIDC technology, or any other technology that provides the UDI of the device on demand (21 CFR 801.45).

1. Easily readable plain-text**:** The UDI must incorporate the Device Identifier (DI) and, if applicable, the Production Identifier (PI) in a clear and easily accessible plain-text format. Equally important is the inclusion of data delimiter(s) for the DI and PI in the UDI's readable plain-text form. Omitting these data delimiters could hinder individuals from accurately identifying the device using the plain-text version of the UDI. The plain-text version of the UDI, conveniently available, should be positioned below or in close proximity to the AIDC technology version and may be presented as format of one line or more than a one lines of text.

2. AIDC**:** As stated in 21 CFR 801.3, AIDC encompasses any technology capable of transmitting a device's UDI or the DI component of a UDI in a manner which can be input into a patient's electronic patient record or other detailed plan for solving a problem with computer through a machine-learning process. The UDI, or its AIDC version, need to be presented in a manner that can be look through by a scanner capable of interpreting bar codes or other AIDC technologies (21 CFR 801.3 and 801.40) **[7]**.

Table 1: Key Element of UDI System

Element 1	Assignment of UDI Consisting of: 1.Basic UDI-DI 2.UDI-DI and UDI-PI 3. Packaging UDI
Element 2	Using UDI Career to place UDI on a device or packaging
Element 3	UDI information storage by economical drivers
Element 4	UDI database for information access

Benefits of Unique Device Identification

The system holds the potential to significantly boost the healthcare sector's ability to provide patients with secure and high-quality care. Both major healthcare organizations and consumers stand to gain from improved medical device tracking across various healthcare settings, resulting in enhanced efficiency and reduced expenses. The benefits of implementing UDI throughout the medical industry are considerable, and though achieving full implementation may be challenging, there are relatively straightforward steps that can be taken immediately to begin realizing many of these advantages **[8]**.

A system of this type can provide several benefits **[9, 10]**. A few examples:

a. Patient Safety Risk Prevention: By utilizing UDI, medical device manufacturers can enhance patient safety risk prevention by swiftly notifying authorized users about potential issues that may require the removal of a medical device from service. Additionally, it allows for the dissemination of information regarding the continued safe use of the medical device, thereby reducing risks to patients.

b. Adverse event notification: Within the hospital, recording and prompt communication of anomalous occurrences and adverse event notifications to the FDA and manufacturer to increase efficiency and patient safety.

c. Use tracking: UDI enables optimized tracking and renewing of diagnostics system necessities lowering expenses.

The UDI system aims to enhance medical device identification by making it possible to quickly and conclusively identify a device as well as some important qualities relevant to an equipment's security and efficient usage. To take full advantage of the benefits of the UDI system, UDIs must be incorporated with data sources throughout the healthcare sector, such as the supply chain, electronic health records, and databases **[11]**.
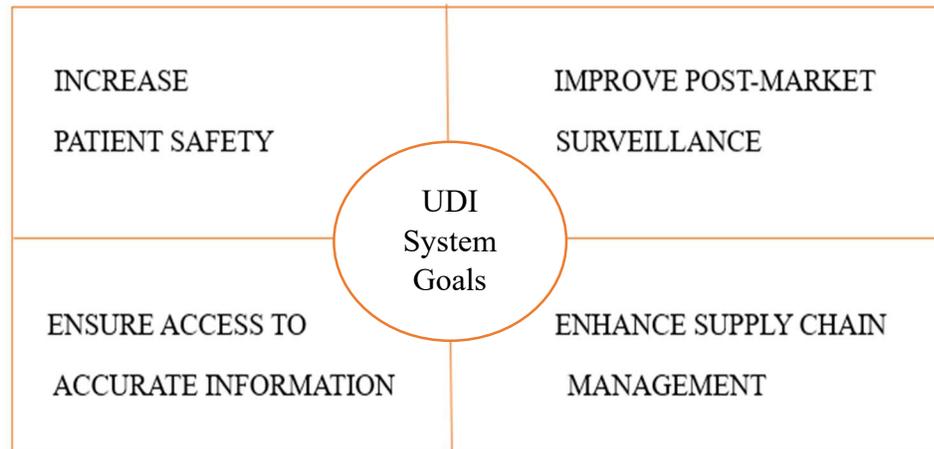
Figure 2: UDI System Goals

Unique Device Identification issuing entities

The FDA has accredited several issuing entities to assign UDIs to medical devices. These entities are known as "Issuing Agencies." Some of the recognized Issuing Agencies for UDIs include:

1. GS1: GS1 is the most commonly used issuing entity for UDI. The non-profit company GS1 does business with the leading international system for trade item identification. They are an impartial international forum for the partnership that brings along business executives, policymakers, academics, and associations to create standards-based solutions to deal with the difficulties of data interchange. A company that subscribes to GS1 is given a "GS1 Company Prefix" and GS1 maintains a range of "Item Reference" numbers for the company to use in relation to its product line. For the subscription, GS1 charges a higher initial price and a reduced annual renewal rate. Most makers of medical devices work with GS1 [12].

2. HIBCC: In order to offer a standard for data transfer via universal bar code labeling, the health sector Business Communications Council (HIBCC), a nonprofit organization supported and funded by the health sector, was founded in 1983. A Labeler Identification Code (LIC) is provided to a company once it has made a one-time subscription payment to HIBCC. The company creates and assigns Product/Catalog Numbers (PCN) to its product line without charging additional fees [13].

3. ICCBBA: The World Health Organization (WHO) and the ICCBBA are both non-governmental organizations. Internationally consistency to enable the transfer, transfusion, or transplantation of medicinal items of human origin is provided by the ISBT 128 standard, which is adopted in more than 75 countries. Additionally, it encrypts data on biological products in a way that makes it possible for the data to be accurately and consistently transmitted from one computer system to another **[14]**.

Unique Device Identification (UDI) regulations varied among different countries. One of the first countries to adopt UDI legislation was the United States, whose Food and Drug Administration (FDA) mandates that majority of medical devices have a unique identification for tracking and safety purposes **[15]**. The Medical Device Regulation (MDR) and of Vitro Diagnostic Medical Devices Regulation (IVDR) of the European Union (EU) set forth UDI standards to enhance healthcare device traceability and post-market supervision. India and Global IMDRF also introduced UDI regulations to enhance device identification and patient safety **[16]**.

UDI regulations in different countries

Table 2: Comparative study of UDI system in different nations [17, 18]

Country (Regulatory Body)	Classification	Standard and Time	Label Requirements	Data Reporting System
USA (USFDA)	**Class I - low-risk devices** **Class II - moderate-risk devices** **Class III - high-risk Devices**	**GS1, HIBCC & ICCBBA (2013)**	**Device Identifier (UI), Production Identifiers (PI)**	**GUDID**
Europe (EMA)	**Class I - low-risk devices** **Class IIa - low-medium risk devices** **Class IIb - medium-high risk devices** **Class III - high-risk devices**	**GS1, HIBCC & ICCBBA (2015/2016)**	**DI, PI to Unit of Use (UoU) Level**	**EUDAMED Database**
India (CDSCO)	**Class A - Low-risk devices** **Class B - Low-medium-risk devices** **Class C - Medium– high-risk devices** **Class D - High-risk devices**	**GS1 (2012)**	**DI, PI to Unit of Use (UoU) Level**	**Procurement Ministry of Health and Family Welfare**
Global (IMDRF)	**Class A: Low risk** **Class B: low-moderate risk** **Class C: Moderate-high risk** **Class D: High risk**	**GS1 & HIBCC (2013)**	**DI, PI to Unit of Use (UoU) Level**	**UDI-IMDRF**

Future Perspective

Increased health benefits are a result of expanding technology in healthcare systems. Greater identification leads to fewer medical device recalls, fewer malpractice claims, less counterfeiting, more accurate product evaluations, and greater public health. The UDI system is useful for gathering, storing, and extracting information on medical devices for identification and tracking that is safe and efficient [19]. A unified regulatory framework for UDI is intended to be implemented internationally in the near future for optimal utilization. Although there may be difficulties at first for manufacturers to follow new laws that will impact their system and cost. With continued usage, however, its advantages will outweigh its appliance's worth. In order to help the healthcare system monitor medical devices and gather patient information more quickly, the IMDRF anticipates requiring the UDI system in the near future.

CONCLUSION

With each passing year, innovation and advanced technologies reach higher levels. They are improving their effectiveness and efficiency by coming up with creative solutions to difficulties. The UDI application strategy can assist reduce the gap and enable healthcare systems to promote enhanced patient device safety and efficacy. The most recent technology utilized to monitor the movement of products and gather patient data is the Unique Device Identification system. It has demonstrated benefits in supplying realistic items, improving patient safety, and speeding up product recalls. Because it will simplify the method of monitoring and tracking the whereabouts of a medical product, use of the UDI system must be particularly advantageous for community of clinical engineers. Different techniques have already emerged, despite the fact that the FDA and EU have the same methodology or desire of tracking medical devices. Additionally, GUDID APIs make it simple for healthcare systems to incorporate GUDID inquiries into their current IT frameworks. Together, labelers, users, and regulators can identify particular devices at every stage of their life cycle, from labeling to patient usage.

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CONFLICT OF INTEREST

The authors declare no conflict of interest among themselves.

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