

China

Enhancing medical device logistics at The First Affiliated Hospital of Sun Yat-sen University, China

Challenge

Manual coding in SPD management poses risks of errors like incorrect labelling, leading to medical hazards. It also raises costs through human resource and equipment demands. Traditional adverse event reporting is inefficient, burdening departments with excessive paperwork.

Approach

Implementing UDI enhances device traceability, automates inventory management with smart systems and streamlines adverse event reporting. This reduces human error, costs and workload, while boosting oversight and efficiency.



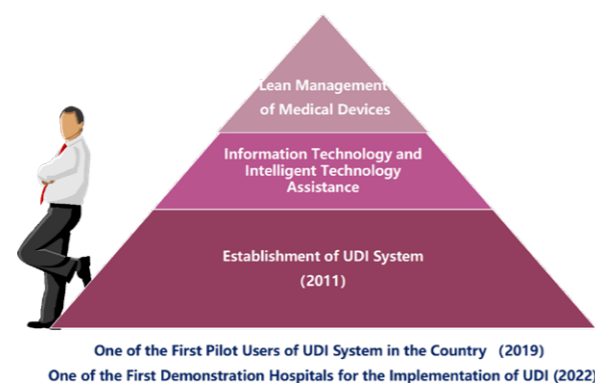
Introduction

The evolving medical industry has made managing medical consumables increasingly complex. Despite the recent boom of supply processing distribution (SPD) in China and the widespread use of Unique Device Identification (UDI), combining UDI and SPD remains a relatively rare and novel practice.

The application of UDI in SPD lean management can significantly enhance medical quality and patient safety by improving the traceability of medical devices throughout their use. UDI facilitates information sharing and exchange among different departments within the medical institution, enhancing coordination and collaboration. It also enables medical institutions to better manage inventory, prevent waste and losses and ensure timely supply of necessary devices.

As an issuing agency for UDI, GS1 provides standards that align with regulatory requirements. The First Affiliated Hospital of Sun Yat-sen University, a pioneer in UDI adoption since 2011, has suc-

cessfully integrated GS1 standards into its device management system. The hospital began implementing SPD in 2023 and combining it with China's *Regulations for the Supervision and Administration of Medical Devices*, providing a compelling case for the joint application of these standards in modern medical practices.



Optimising medical device logistics with GS1 barcodes and UDI integration

The First Affiliated Hospital of Sun Yat-sen University's database spans 1,630 manufacturers and 890 businesses, totalling 103,785 product entries. The main barcoding system used is the GS1-128 barcode, which features several advantages for improving medical device logistics management. This barcode can accommodate a large amount of product data, including the name, specification, batch, validity period and manufacturer of medical devices. This allows all parties in the logistics chain to access key product information swiftly and accurately, eliminating cumbersome manual queries. The GS1-128 barcode also uses standardised coding rules and data formats, ensuring the accuracy and consistency of data and reducing logistics confusion and management problems caused by incorrect information.

The implementation process in the hospital

Managing orders and distribution efficiently is crucial in healthcare, especially when it comes to medical devices. By using Unique Device Identification (UDI), the hospital has created a quality control system that tracks device usage in real-time, sharing supply chain data among stakeholders to ensure efficient monitoring.

When devices are dispatched from suppliers, scanning and recording the UDI code provides all the necessary information about the device, including its name, registration details, category, model, manufacturer, price, production batch number, serial number, production date and expiration date. This information is used to create a detailed electronic delivery note, ensuring that all materials delivered to the hospital meet the required acceptance standards. As a result, staff only need to check the packaging integrity and conduct spot-checks to verify that the physical items match the system information. This makes the acceptance process more efficient and reliable.

UDI also plays a significant role in the acceptance process itself, enhancing how medical devices are verified upon arrival. Scanning the UDI of consumables automatically confirms each product's validity, connecting with the upstream supply chain to log logistics information from suppliers and distributors. This process ensures that both static information (like the device name, registration details and manufacturer) and dynamic data (such as batch numbers, serial numbers, production dates and expiration dates) are accurately parsed and verified. The built-in verification system further ensures that each device

complies with the hospital's selection criteria, quality standards and expiration requirements, creating a comprehensive and accurate purchase inspection record. For instance, at The First Affiliated Hospital of Sun Yat-sen University, the time needed to accept 200 orthopaedic consumables has been reduced from 45 minutes to just two minutes, greatly increasing efficiency and maintaining a 100% acceptance rate.

Integrating UDI with smart technology optimises warehouse management, enabling efficient tracking of consumables throughout their lifecycle.

There are three types of related intelligent recognition devices: barcode recognition devices, such as one-dimensional barcode scanners and two-dimensional barcode scanners; RFID (Radio Frequency Identification) devices, such as handheld RFID scanning devices or customised RFID batch recognition devices such as intelligent cabinets, walls and rooms; and optical character recognition (OCR) devices, such as OCR cameras. In the central warehouse, UDI information manages the entry, storage and distribution of medical consumables. In department-level warehouses, tracking is enhanced with intelligent cabinets, smart storage solutions, scanning devices and RFID technology. These tools help maintain detailed records of consumable usage and ensure accurate inventory management.

Access to storage areas is secured using smart IC cards, fingerprints, facial recognition and finger vein identification. Smart sensing technology provides real-time inventory data, preventing waste through expiration date alerts and reducing losses with anti-theft alarms. The system also supports automatic replenishment alerts when inventory levels are low and allows for comprehensive inventory queries and reports, whether monthly, quarterly or annually.

Intelligent inventory management of consumables



Through customized intelligent equipment, refined management of consumables such as sutures, guidewire catheters, and hemostatic material can be achieved

The UDI system also improves the management of consumable use. By scanning the UDI barcode, electronic records are created whenever consumables are used on patients. This process starts with a quality inspection of the device and the

creation of a clinical application registration system. Clinical staff scan the UDI barcode to input product information, which is then linked to patient data and treatment details from the hospital information system (HIS) and clinical information system (CIS). This integration ensures that all medical device information, patient data and treatment records are interconnected, providing a complete and accurate clinical application record. This approach not only guarantees traceability for safety and quality management, but also ensures compliance with regulatory requirements. As such, UDI code has become a common basic language at The First Affiliated Hospital of Sun Yat-sen University, from the acceptance and pre-operation inspection before use to the post-operation records and charges afterwards.

Based on the UDI code, through the SPD system and mobile nursing linkage (Inpatient Wards)



Similarly, integrating UDI streamlines the billing and settlement processes. Automatic identification and data capture (AIDC) technology links physical items to their corresponding information, ensuring consistency across purchasing, usage and billing. Mobile nursing billing enables better management of consumables: before using products in clinical departments, nurses use a PDA to scan the patient's wristband, which retrieves information from the HIS. They then scan the consumables' barcodes, enabling the system to automatically identify the relevant charges and transmit this data to the HIS. This process completes the issuance of consumables, generates billing and links it to the patient's information, creating a comprehensive usage record and enabling two-way traceability.



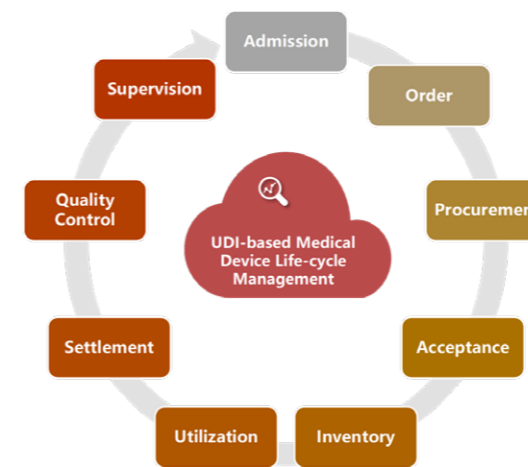
Once the safe use of medical consumables is confirmed, the system updates the hospital information system for billing and logs the transaction in the hospital resource planning (HRP) material management system. This integration supports both single and monthly settlements, ensuring that products used are accurately billed and that insurance claims are reviewed for compliance.

Supervision, management and training assessment

In clinical application management, UDI accurately and comprehensively records all data related to the use of medical devices, providing a clear, closed-loop view of their lifecycle. This system helps the hospital to monitor and analyse the use of medical consumables effectively. When managing adverse events, scanning the UDI barcode provides detailed information quickly, including the type of consumable, patient usage, the number of uses, the manufacturers and suppliers and inventory levels. This not only makes it easier to report adverse events, but also enhances traceability of specific devices through UDI code tracking, allowing issues to be quickly identified and resolved.

By linking UDI with logistics, financial data and other information flows, the hospital has been able to create a comprehensive view of medical consumables. With the technical support of SPD - such as multi-tenant applications, distributed processing, distributed storage and high-speed cache applications - alongside data from consumables, hospital operations, suppliers and smart hardware, a robust business intelligence reporting system has been developed. This system uses UDI-related usage data and statistical analysis to conduct detailed monitoring, analysis and personalised evaluation. With the UDI verification mechanism in place, the system can also provide early warnings for any abnormal use of high-value medical consumables, enhancing overall management and safety.

UDI-enhanced SPD management: Streamlining efficiency, safety and traceability in healthcare



UDI provides detailed information about medical devices, which helps the whole SPD management streamline processes, increase efficiency, accurately track inventory and keep patients safe. Through UDI, teams can monitor devices in real-time while standardising operations and optimising inventory management, all of which promote lean management. This combination enhances the quality of medical services at The First Affiliated Hospital of Sun Yat-sen University, reducing both risks and costs.

Using UDI also allows the hospital to trace medical devices throughout their entire lifecycle, reducing the errors that can occur with manual data entry. For example, staff may accidentally paste the wrong code, leading to medical risks and medical errors. With UDI, each device is identified by its original manufacturer code, reducing these risks and ensuring greater accuracy. Through UDI, the costs associated with manual coding in SPD are reduced, leading to more efficient management.

Integrating smart technology with SPD and UDI provides additional benefits to inventory management. The UDI RFID tag more accurately records details such as the effective period and batch number, which are crucial for timely expiration warnings. 'Smart cabinets' track individually labelled items stored in the cabinet, including lot numbers and expiry dates, and are a crucial tool for managing information about medical implants and other high-value inventory. Smart cabinets can alert staff before items expire, preventing the use of outdated supplies and ensuring patient safety. Through intelligent

sensing, these smart cabinets can accurately identify, track and manage stored medical devices and monitor inventory in real time, boosting management efficiency. They can also automate restocking based on usage and demand, improving the accuracy and timeliness of inventory replenishment.

Additionally, the process of reporting adverse events involving medical devices is simplified with UDI. By scanning the UDI code, the SPD system can link directly to patient information and display in-hospital product information, while scanning the batch code provides all relevant batch information. This improves reporting efficiency and reduces workload on staff.

The benefits of implementing GS1 standards

The National Medical Products Administration (NMPA) launched the China UDI Database on 10 December 2019, and as of August 2024, more than 93% of enterprises choose GS1 standards for UDI implementation. Our hospital began using GS1 in 2011 and is one of the first hospitals in China to use UDI. After years of application, 98% of medical devices that have implemented UDI have adopted GS1 standards, which has brought great benefits to the management of medical consumables in the hospital.

Industry-wide benefits:

- Global recognition and acceptance: GS1 standards are widely recognised and used globally, ensuring compatibility and interoperability with a large number of organisations and systems.
- Industry best practices: GS1 standards are developed based on industry expertise and best practices, providing a reliable and efficient framework.
- Streamlined supply chain management: GS1 standards optimise inventory management, enhance product tracking and improve data exchange across the supply chain.
- Enhanced traceability and transparency: GS1 standards enable better traceability of products, which is crucial for quality control, recalls and meeting regulatory requirements.
- Cost-effectiveness: By adhering to established standards, organisations can potentially reduce costs associated with custom solutions and integration efforts.
- Data accuracy and consistency: GS1 standards ensure accurate and consistent product data, minimising errors and misunderstandings.

Hospital benefits:

- Hospital-wide acceptance: With more than 10 years of experience in implementing UDI, the entire hospital team is familiar with GS1 standards and supports them.
- Strong implementation foundation: Thanks to supportive policies, more manufacturers are now using GS1 standards in their products, making it easier for the hospital to adopt and integrate these standards.



The use of UDI in the healthcare system has the potential to significantly enhance patient safety, streamline operations and data-sharing and elevate quality of care. In our hospital, the traceability rate for the entire lifecycle of high-value consumables has reached 100%. By using UDI for reporting, we log more than 150 adverse events annually. This greatly improves efficiency, minimises waste and advances our analytics capabilities for medical devices. By embracing this system and working together, we can fully harness the benefits of UDI and make a positive impact on the healthcare industry.

Next steps and conclusion

Looking ahead, The First Affiliated Hospital of Sun Yat-sen University aims to lead UDI implementation by creating a comprehensive guide for other medical institutions, drawing on its own successful practices. This guide will help establish clear UDI system specifications, promoting better management practices across healthcare settings. The hospital also aims to establish standards that will improve the precision of device management and accelerate the digital transformation of the medical device industry.

To further support these efforts, the hospital will create a UDI training demonstration base for leadership and staff training. This centre will offer courses, guided visits and hands-on guidance to nurture new talents and share the hospital's expertise. The First Affiliated Hospital of Sun Yat-sen University will document its UDI implementation models in academic papers and patents, boosting both its academic and social impact.

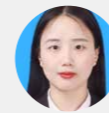
Collaboration will be key as the hospital unites various stakeholders to drive the digital transformation of medical devices. Part of this effort will involve exploring innovative uses of UDI in healthcare, particularly in integrating different data sources to enable seamless data sharing. This will enhance decision-making capabilities for traceability, usage monitoring, cost control, evaluation, reporting and recall management through advanced data analytics and risk prediction.

Finally, the First Affiliated Hospital of Sun Yat-sen University intends to explore the application of other GS1 standards, such as using the Global Service Relation Number (GSRN) for tracking medical staff and patients and the Global Location Number (GLN) for identifying specific locations like wards or operating rooms. By embracing these steps, the hospital will continue leading the way in digital innovation while driving better patient care and operational efficiency..

About the authors



Tan Jiawen, is a staff member of the Medical Engineering Department of the First Affiliated Hospital of Sun Yat-sen University, engaged in research on intelligent management and evaluation of medical consumables. Tan's research focuses on the application of UDI in medical consumables, access management of medical consumables, and evaluation and optimisation of the use of medical consumables.



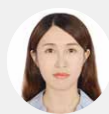
Miao Jiaqing, took up a position in the medical consumables department of the Medical Engineering Department of the First Affiliated Hospital of Sun Yat-sen University in 2019. Miao's main research field is medical device management. This includes UDI-based SPD supply chain models for hospital medical consumables, centralised procurement management of medical consumables, evaluation of medical consumables usage and research on consumables access and procurement.

About the organisation



The First Affiliated Hospital of Sun Yat-sen University, originally known as the Affiliated Hospital of Guangdong Public Institution of Medicine, was founded in 1910 by Dr Paul Jerome Todd (an American medical missionary) with 40 Western doctors. It is composed of the Headquarters, East Division and Hui ya Hospital. The Hospital is an important base for research, medical service, medical education, preventive care and rehabilitation in South China. It is well known for its high quality and excellent service in China and Southeast Asia.

About the authors



Yu Donglan, Director of the Medical Engineering Department of the First Affiliated Hospital of Sun Yat-sen University, is an experienced engineer specialising in the application of UDI for medical device management. Yu's research focuses on the intelligent management of medical devices, quality control throughout their lifecycle and the performance and operation management of medical equipment.



Wu Lihua, the section chief of the medical consumables department of the Medical Engineering Department of the First Affiliated Hospital of Sun Yat-sen University, has 15 years of management experience in medical device management. She is responsible for the management of medical consumables in the hospital. Her main research is the application of the UDI of medical devices in the whole lifecycle management of medical consumables.