Improving medical device management through the use of GS1 standards

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The First Affiliated Hospital of Zhengzhou University
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01. Introduction of the hospital
02. Difficulties in Medical Device Regulation
03. About UDI
04. Application of UDI in our hospital
PART 01
HOSPITAL INTRODUCTION

The hospital is currently the largest Level-3/Grade-A hospital in China which integrates medical treatment, teaching, research, prevention, health care and recuperation.
The First Affiliated Hospital of Zhengzhou University was established in September 1928, and its predecessor was the affiliated hospital of Henan University Medical College. In 1958, it moved from Kaifeng to Zhengzhou and changed its name to the First Affiliated Hospital of Henan Medical College. It was renamed as the First Affiliated Hospital of Henan Medical University in 1985. In 2000, The hospital was then named as the First Affiliated Hospital of Zhengzhou University, and also known as the First Clinical College of Zhengzhou University.
FIVE DISTRICTS

Homogenization management, standardization construction, and normalization.

Heyi branch (3000 Beds)
Zhengdong distinct (East) branch (5000 Beds)
Huiji (North) branch (500 Beds)
Airport zone (South) branch (2000 Beds)
West branch (Uder Construction)
PART 1

HOSPITAL SCALE

Based on 2022 statistical data

- Beds: 10500
- Clinical Medical Technology Department: 120
- Wards: 279
- Annual Clinic Amount: 63 million
- Annual Discharge Patients: 57.4 million
- Annual Number of Surgeries: 30.1 million

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Based on 2022 statistical data
PART 02
DIFFICULTIES IN MEDICAL DEVICE REGULATION
Article 37 and 9: Medical device using unit shall properly keep the raw materials of Class Ⅲ medical devices purchased and ensure the traceability of the information.
REGISTRATION AND TRACING

- Send the md to the hospital
- Acceptance record product information
- Handwriting
- Manual input
- Code scanning analysis
- Computer input
Recreation and Tracing

Reasons for Difficulty in Regulation

One of the key points of medical device regulation is the recording and tracing of its information.

To follow information well, it is necessary to ensure the accuracy of the information source.

Both handwriting or manual input information, which can lead to errors in all subsequent traceability information, making it difficult to ensure the safety of the device.
PART 03
ABOUT UDI
Unique Medical Device Identification generally shortened to UDI. The U.S. Food and Drug Administration (FDA) created unique device identification, often abbreviated UDI, a rule that requires medical device manufacturers to update their products with a unique device identifier that includes both device and production identifiers (such as expiration date and lot or serial number).

- **UDI** (Unique Device Identification)
  - Based on the GS1 standard.
  -编制结构
- **DI** (DEVICE IDENTIFIER)
  - GTIN (Global Trade Item Number)
  - 全球贸易项目代码
- **PI** (Production Identifier)
  - AI (Application Identifier)
  - 应用标识符
PART 3

CARRIER OF UDI

One-Dimensional Code

QR Code

RFID

EG1: One-dimensional code

EG2: QR Code

EG3: RFID
Origin: The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.

Requirement:
The device labeler must provide the UDI in two forms on labels and packages:

- **Easily readable plain-text**
- **Machine-readable form that uses automatic identification and data capture (AIDC) technology.**

Database: Submit device information to the Global Unique Device Identification Database (GUDID)
July, 2019: The National Medical Products Administration (NMPA), China’s medical device market regulator, has published official Unique Device Identification (UDI) requirements that will take effect October 1, 2019.

Oct, 2019: NMPA launch a UDI pilot program which target high-risk devices and has published “Rules for Unique Device Identification System of Medical Devices”

Requirement:
Uniqueness means that UDI shall comply with the requirements of device identification.

Stability means that UDI shall be co-related to the basic features of the corresponding product, and UDI-DI shall remain the same unless basic characteristics of the product are changed.

Expandability means that UDI shall be able to adapt to the continuous development of regulatory requirements and practical application.
IMPLEMENTATION OF UDI

The implementation of UDI mainly includes 4 links.

1 Coding
The medical device registrant/filer shall choose the code issuing agency to create DI for medical devices and their packages and determine the composition of PI. The registrant/filer should submit DI data when applying for medical device registration, registration change or filing. After the medical devices enters the production process, the registrant/filer should choose the appropriate carrier form to give UDI code to the product body or its packaging.

2 DI Submission
Before the medical device launch and sale, the registrant/filer must upload its DI and related information to the UDI database and be responsible for the dynamic maintenance of the data to ensure the authenticity, accuracy and integrity of DI data.

3 Data sharing
The UDI database shares DI data with operating enterprises, Healthcare providers, relevant government departments and the public in a variety of ways.

4 Data application
The joint use of DI and PI information can realize the accurate identification and recording of the circulation and use of medical devices.
PART 3

BENEFITS OF UDI SYSTEM

EG: UDI on QR Code based on the GS1 Standard — Medical Chitosan
PART 04

Application of UDI in our hospital
Introduce the Information System which named OES to do the management of high value medical device based on UDI.

The interface of the suppliers.

The interface of the hospital.

Establish the information interaction between the suppliers and the hospital.
PART 4

DATA BASE

The Hospital Port

Medical Insurance Code Database of NHSA

The Supplier Port

UDI Database of NMPA
## UDI Database of NMPA

### Search Results: 威高 (20889条记录)

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<th>医疗器械唯一标识编码体系名称</th>
<th>最小销售单元中使用单元的数量</th>
<th>医疗器械注册人/备案人名称</th>
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The supplier maintains UDI for the winning product on the supplier page (selected from the national UDI database)
PART 4  Selected from the national UDI database
PART 4

The hospital port audits the UDI codes pushed by suppliers to prevent issues such as incorrect products or models from being pushed.
The clinical department submits the demand for medical consumables online, and after being reviewed by the Medical Equipment Department, the order will be summarized and sent to the supplier. The supplier can receive the order information on their phone or computer.
Suppliers generate delivery notes based on hospital orders and need to fill in product related information. These can be automatically filled out by scanning UDI parsing based on GS1 rules, saving time, improving efficiency, and ensuring accuracy.
PART 4

The delivery notes

郑州大学第一附属医院送货单

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<th>名称</th>
<th>生厂家</th>
<th>规格</th>
<th>型号</th>
<th>单位</th>
<th>数量</th>
<th>单价</th>
<th>金额</th>
<th>生产批号</th>
<th>产品有效期</th>
<th>灭菌批号</th>
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本页数量小计: 1
本页金额小计: 

合计数量: 6
合计金额: 

通知人: 供应商: 医学装备部验收人: 库房验收人: 2 - 2
When medical devices are accepted and stored in the secondary warehouse of the operating room, the nurse needs to scan the UDI and bind their name and operating room number through PDA to collect them. Only medical devices collected by scanning the UDI can be charged during surgery, and medical devices that have not been scanned and bound cannot be charged during the surgery.

PART 4
Can better manage the secondary warehouse, prevent exchange, and more accurately complete the billing of surgical medical devices.

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</table>

### Materials

**Material 1**
- Name: 外科生物补片
- Code: 33286
- Price: 8360.00
- Quantity: 1

**Material 2**
- Name: 电凝器
- Code: 41545
- Price: 19500.00
- Quantity: 1

### Scanned Details

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<tr>
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<th>Code</th>
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<td>41545</td>
<td>19500.00</td>
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</tbody>
</table>

### Warehouse Management

- **Scan**: Scanner with UDI scanner feature
- **Bind**: Nurse binds name and operating room number to scanned UDI
- **Charge**: Only scanned and bound devices can be charged during surgery

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*Note: Images show examples of scanning and binding for surgical medical devices.*
PART 4

After the medical devices are charged, the nurse will print the "Medical Usage Registration Form" and attach the original label of the medical devices to the "Label Sticking Page". These documents will be placed in the patient's case and permanently saved. The product information in the document is sourced from the information scanned and analyzed during acceptance registration by scanning the UDI based on the GS1 standards.

These documents are required by Chinese regulations to be stored in the case.
The hospital can check all information of the product by the system including the GS1 code, the Serial number of a specific device, the Expiration date of a specific device and so on.
PART 4  The Closed -loop management of High Value Medical Device

The nurse lace the order based on the inventory.

Hospital Charging Code

Sattlement

Scan for charging and recording the information.

GS1 Code

The buyer Check the order and send to the suppliers.

Hospital Code

The suppliers scanning the GS1 code and get the Hospital Code and Delivery Slip.

The inspection of the medical device

Fxxxxxxxxxx
The establishment of UDI system:

1 will help to improve the informatization level to establish a traceability system, improve the management efficiency for enterprises, promoting high-quality development of the medical device industry.

2 will help distribution enterprises to establish modern logistics systems, realizing the transparency, visualization and intelligence of the medical device supply chain.

3 will help healthcare providers to strengthen the risk management and control of the clinical use of medical device usage, reduce device errors, ensure the safety of patients’ medical device usage.

4 will help medical device regulatory departments to build big data for device supervision. It can realize that medical devices can be traced and tracked, the responsibility can be investigated, achieving smart supervision.

5 will help the health, medical insurance, customs, and other departments to raise the clinical use of medical devices, bidding and purchasing, medical insurance settlement, import clearance, and other links’ management efficiency.

6 will help the public feel reliable when purchasing and using medical devices.
PART 4

A laser-powered, microchip-based technology enables scanning of implant usage from inside the sterile field. Scan technology can be implemented on device tray.
A touchscreen-enabled solution for preparing, managing, and documenting orthopedic implants and trays through sterile processing, all the way to the point of care. Built on our platform, uses either RFID or barcode scanning software to identify each tray and its contents, and document the utilization of each implant.
UDI system will promote the realization of smart medical device supervision and social co-governance, help the industrial transforming upgrading and healthy developing, provide the public with safer and more efficient medical services and will give people a stronger sense of fulfillment, happiness and security.
Thanks!