China

Improving medical device management through the use of GS1 standards

Challenge

Managing medical devices, particularly high value ones, is a core part not only of modern hospital management but of ensuring the quality and safety of services. At China's The First Affiliated Hospital of Zhengzhou University, in common with all large hospital facilities, it could be a challenging process. There was a desire to ensure staff were using devices as safely and appropriately as possible; to ensure accurate billing; and to guarantee the traceability of medical devices.

Approach

The hospital implemented new processes for the delivery, acceptance, warehousing and billing of medical devices. These processes were supported by GS1 standards and linked to the operation effective system (OES, used for the management of medical devices) and the hospital information system (HIS, used for billing).

30 minute
reduction in billing time

97%
increase in accuracy of registered information on the use of medical devices

Medical device traceability for both the hospital and governmental supervision department

Improved risk management

Introduction

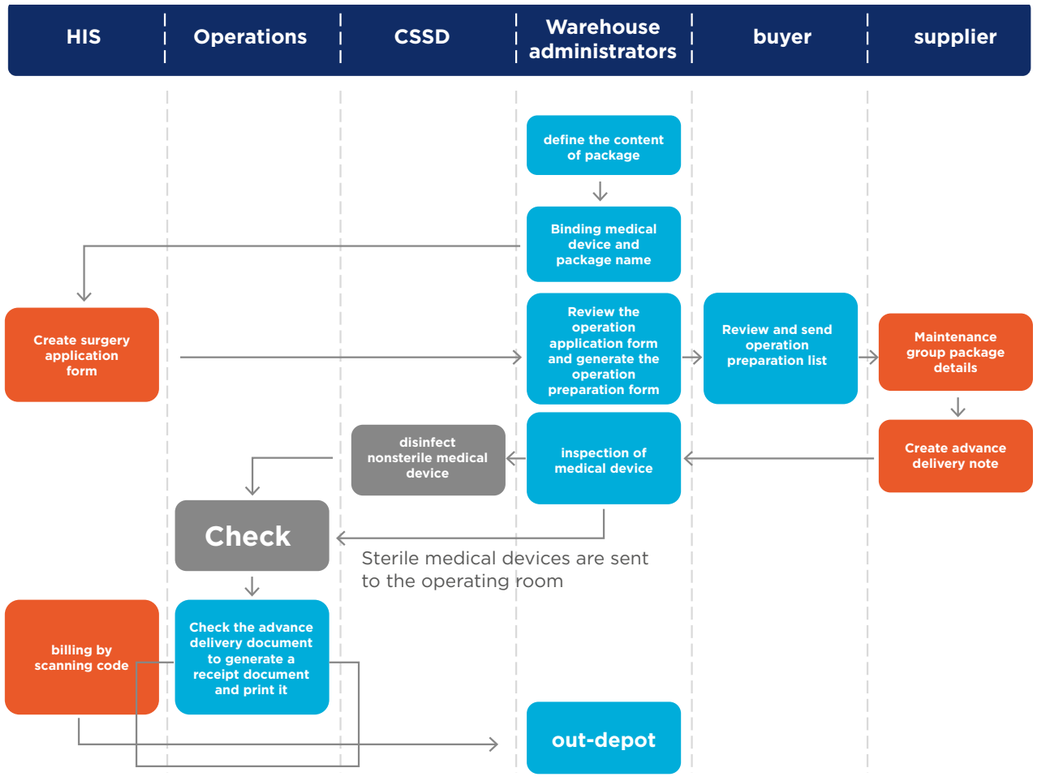
Today, Chinese hospitals must meet new regulations on the supervision and administration of medical devices and on the use of unique device identification for such products. These regulations include strict requirements on traceability.

Traditionally, the management of medical devices in major hospitals has been very challenging. Firstly, submitting, reviewing and summarising the required information about medical devices in clinical departments is inefficient and error-prone. Secondly, many different medical devices are used and products cannot be tracked across the full pathway. Thirdly, the lack of full traceability of medical devices leads to quality risks. Fourthly, information is siloed with little sharing and coordination between departments. Fifthly, there is a lack of information sharing between suppliers and hospitals. Sixthly, it is difficult to oversee the credentials of medical devices and suppliers.

To sum up, the biggest difficulty is the traceability of high-value consumables and the lack of full closed-loop management of medical devices. Most of these issues can be addressed by implementing and using unique device identification (UDI).

To overcome the drawbacks of traditional management of medical devices, reduce the cost of consumables and form an effective internal control system, The First Affiliated Hospital of Zhengzhou University has established a complete closed-loop system for the management of medical consumables, which works alongside processes in the hospital information system (HIS). It has also implemented full tracking of medical devices, verification of suppliers and devices, information sharing between hospital departments and with suppliers, and all through an entirely online process.

In July 2019, China's National Medical Products Administration (NMPA) and the National Health Commission launched a pilot programme for unique device identification (UDI). The First Affiliated Hospital of Zhengzhou University was one of the pilot sites and so began to introduce a new way of managing medical devices, based on GS1 standards. In 2022, the hospital was selected as a national UDI demonstration unit.



Overall process of consumable management

National regulations require medical institutions to inspect devices on purchase, which mainly involves checking whether the expiry dates and product information are consistent with the information initially supplied.

When the device is then used, clinical staff need to record additional information. In the past, manual registration was mainly used to record the production and use information of medical devices, such as manual registration, computer manual input, etc. There are various risks in manual operation, such as recording the wrong product information, billing errors and low work efficiency.

At The First Affiliated Hospital of Zhengzhou University, these processes are now automated. An updated operation effective system (OES, used for the management of medical devices) can automatically capture the product information and production information of medical devices by processing data from GS1 barcodes. The system searches the UDI database, and generates the corresponding delivery note according to the hospital order. It means all the recorded product information comes from the automatic analysis of a GS1 barcode when the hospital purchases medical devices. When the user department records the use information, it only needs to link the user's information to the product information. This ensures accuracy and greatly reduces the time needed to record use information.

Closed-loop procurement management

Procurement is now a full closed-loop management process, from department order, warehouse checking, supplier delivery, acceptance, to final settlement. The process is similar to selecting products from an online shop, except that the clinical department can only select the medical devices they need from the bidding directory. The purchase plan is pushed to the corresponding warehouse administrator. Following approval, the warehouse administrator pushes it to the medical equipment department. The leader of the medical equipment department generates the corresponding delivery note and pushes it to the supplier after approval. If the administrator finds any errors, or if the quantity requested exceeds the department's average consumption for that item leaving the administrator with queries, he or she can reject the purchase plan.

The supplier can receive the order simultaneously via mobile phone and computer. The order contains the address of the hospital and department, as well as the corresponding name and quantity of medical devices. The supplier generates a delivery note according to the purchase order from the hospital. This is a very important step in the efficient management of medical devices. Suppliers need to fill in a lot of information when generating delivery notes, including production date, expiration date, registration certificate number. If hospitals in turn record this information manually, bit by bit, errors are likely.

The implementation of the UDI solves this problem. The hospital obtains information on devices via scanning the GS1 barcode, which automatically generates batch number, expiration date and other important information. The data is very accurate, which greatly improves efficiency.

The hospital no longer needs the supplier to manually maintain static information on medical devices but can directly scan the code to extract the information and record it in the database.

Warehouse management

The warehouse of the high value medical devices of the operating room will write off and issue medical devices according to the result of code scanning and billing to achieve zero inventory. The entry of medical devices into the secondary warehouse is a virtual warehousing. Only after code scanning and billing are completed, the only associated GS1 code products will be considered as products to be settled by the hospital.

A demonstration of the process is shown in Figure 1.

By binding the hospital billing code to the static code of GS1 (DI part of the UDI) of medical devices, billing can also be completed by scanning the GS1 barcode. This not only ensures the accuracy of billing, but also saves time. In the past, it was necessary to enter the billing code manually. When more consumables were used in surgery, it took a lot of time. Now, scanning the code reduces the time needed for billing by three quarters. In addition, the accuracy of billing has improved by nearly 90%.

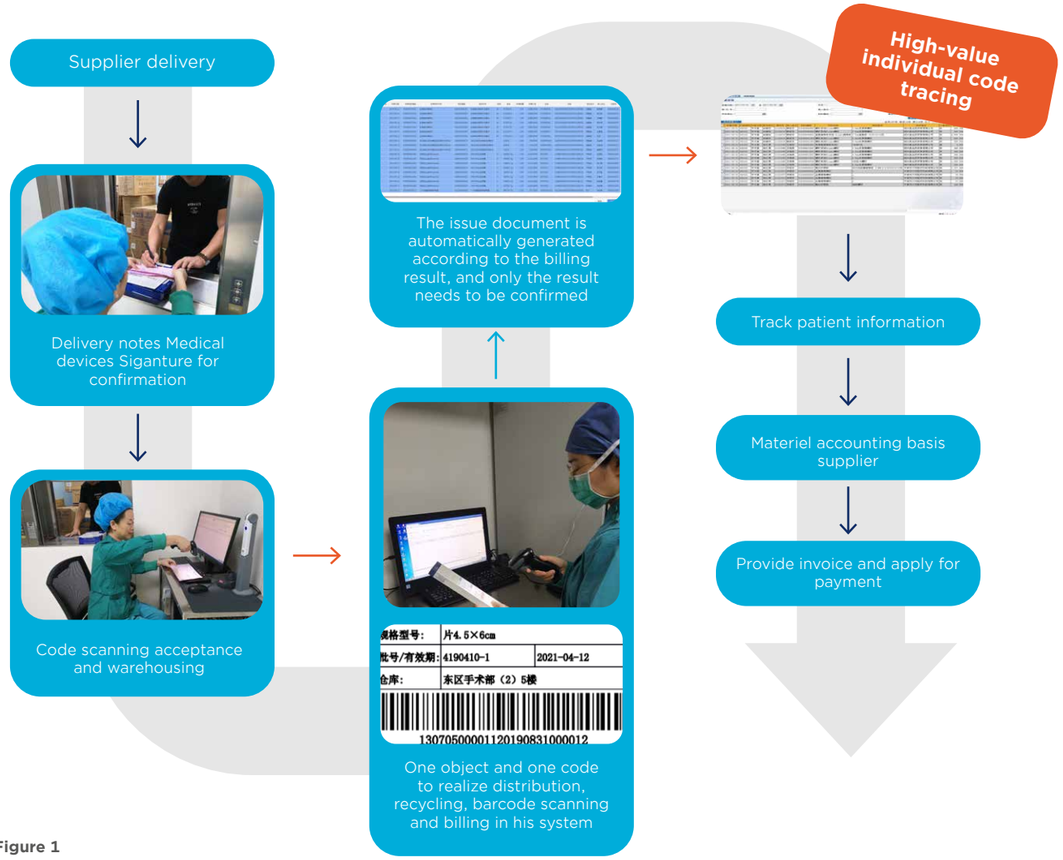


Figure 1

Next steps

At present, The First Affiliated Hospital of Zhengzhou University only manages class III (high value) medical devices in this way. It is hoped that government departments, medical institutions and medical device manufacturers can jointly promote the implementation of UDI, so that more medical devices can be assigned with GS1 barcodes that can be scanned.

There are plans to develop the hospital's OES to draw more information from the GS1 barcode: for instance, it could automatically store and analyse the quantity of a product, and it can scan multiple products for billing at one time by using a Serial Shipping Container Code (SSCC).

Conclusion

The application of unique identification of medical devices has improved the management of high-value medical devices at The First Affiliated Hospital of Zhengzhou University. Staff efficiency has increased, medical errors fallen, and the hospital now better meets laws and regulations in this area. It is hoped that GS1 standards can increasingly be used on medical devices, more effective information can be identified, and more departments such as food and drug administration department, customs and taxation can cooperate to create a larger data platform and promote the safe and rational use of medical devices for the patient.

About the author

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Simeng is an engineer in the medical equipment department of The First Affiliated Hospital of Zhengzhou University, the largest hospital in China. She graduated from Macquarie University and holds a double master's degree. Simeng has four years' experience in managing medical devices, including writing the hospital's procedures in this area, and in promoting the implement of the UDI on medical devices. She is a member of several groups in the academic community on medical equipment and has been invited to speak on the topic at many meetings.

Local coordination

Xue Wang (Shirley Wang)
Engineer, Promotion Department, GS1 China

Xue Wang joined GS1 China in 2012 and has been responsible for UDI promotion since 2019. She has worked with colleagues from 47 branches to establish UDI pilots and to develop UDI guides. She took the lead in organising more than 30 national and regional UDI training sessions, covering 200,000 participants in total. Xue holds a bachelor of logistics management from Air Force Command College.

About the organisation

The First Affiliated Hospital of Zhengzhou University (hospital) was initially 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, under the support of the central government, the former Zhengzhou University, Zhengzhou Technology University and Henan Medical University merged. The hospital was then named as the First Affiliated Hospital of Zhengzhou University, and also known as the First Clinical College of Zhengzhou University. In 2012, it was established as the hospital co-sponsored by the province and the Ministry of Health. In 2017, clinical medicine was selected in the national list of world-class universities and first-class disciplines. The hospital is currently the largest Level-3/Grade-A hospital in China, integrating treatment, teaching, research, prevention, healthcare and recuperation.

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