Chinese Taipei

Using GS1 standards to create Kaohsiung Armed Forces General Hospital's smart medical system

Challenge

Like many other hospitals in Taiwan, KAFGH had a manual process for updating their medical device and material documents.

Approach

Their UDI project introduced three changes:

1. The implementation of auto-identification for medical materials and devices.
2. Improve cost and quantity control of inventory management for medical materials and devices.
3. Introduce traceability of implanted medical devices to patients.

6.9%
lower on hospital costs

Reduce 1,829kg CO^2 emissions per year

0.9%
decrease on the error rate of medical materials by misuse

90.1%
decrease on manual work time

The implementation of auto-identification reduces the chances of human error and means that implanted medical devices can be traced to the patients that have received them. Building on existing uses of GS1's standard for implementing Unique Device Identification (UDI), Kaohsiung Armed Forces General Hospital combined it with the technology of artificial intelligence to effectively improve health quality, ensure patient safety and improve hospital management.

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Introduction/Background

Kaohsiung Armed Forces General Hospital (KAFGH) is located in Kaohsiung city, the biggest city in southern Taiwan island, and provides medical services for all residents in the area as well as emergency rescue and wartime aid. Being in such a unique position, it's been important for KAFGH to lead the way in their use of innovative technologies to better improve the management of the hospital and keep its medical service at its best.

Since 2013, following the promotion of UDI by the Taiwan Food and Drug Administration (TFDA), KAFGH has been using GS1 standards to manage their medical devices, as well as other clinical areas such as medical records. UDI using GS1 standards is also used in the administration of their inventory, distribution, pricing and supply chain.

Kaohsiung Armed Forces General Hospital
740 beds; 1,206 staff/employees

Established in 1945, including: one general hospital and four branches - General Hospital in Kaohsiung city:

- Pingtung Branch: Long term care unit
- Zuoying Branch: Simulated deep sea diving training centre
- Gangshan Branch: Aviation physiological training centre
- Kaohsiung Outpatient centre: Outpatient rehabilitation

Challenge

Like many other domestic hospitals here, KAFGH had a manual process for updating their medical device and material documents. The first aim of their UDI project was to change this in three ways:

- The implementation of auto-identification for medical materials and devices, reducing opportunities for human error and increasing patient safety.
- Improve cost and quantity control of inventory management for medical materials and devices.
- Introduce traceability of implanted medical devices to patients.

Before UDI adoption: manual record keeping

After UDI adoption: a simple scan

From the beginning, KAFGH's UDI project faced some challenges and the following points may help other hospitals that are preparing to implement UDI in the future:

- Involve key stakeholders such as clinicians, nurses, administrators and suppliers at the start of the process.
- Some suppliers will not be willing to label their products using UDI because of concerns about costs and the lack of strong enforcement of the legislation.
- Work with solution providers to enable barcode readers and data collectors to decode the barcodes correctly, so that the information provided through them is accurate. Ensure that hospital IT systems are able to read and process GS1 data. Barcode reader software available in Chinese Taipei is often not able to read GS1 standards, or product information is not being updated into hospital databases by suppliers. It can also be difficult to integrate the new IT system with capability to hold UDI information into existing databases without having to change too much. All of these aspects are worth consideration when choosing which solution providers to collaborate with.
- There can be confusion around the identification contained within the UDI, for example, according to the standards the same item but a different packaging level should have a different UDI. However sometimes the same numbering is incorrectly used for many items. This can make the identification difficult for machines and humans to read.
- The full support of senior management will help with collaboration across all departments when implementing UDI.

Further to the above, KAFGH achieved this by:

- Seeking the support and assistance of our FDA and GS1 Chinese Taipei to understand the benefits of GS1 standards and UDI implementation.
- Organising workshops and seminars for the suppliers of medical materials and devices to explain the reasons behind implementing GS1 standards following the UDI guidance, especially where there are benefits for suppliers e.g. accurate, real-time data on usage and stock from the hospital's inventory management system.
- Creating awareness, engagement and commitment around the concept of UDI in departments where implementation is taking place, providing training and a working group for staff, and inviting them to suggest any improvements they might make.

Solution

As mentioned, the main challenge for data visibility remains the ability to use UDI data throughout the whole network of the hospital's existing databases. This is why it was important to make sure that the UDI could be captured efficiently and accurately by all systems that required supply data for one purpose or another, including for interoperability purposes and for updating of the electronic patient record.

Since 2016, KAFGH has been working with XuZhen Medical Co., Ltd., which provides a GS1 standards and UDI cloud solution: Chronos®. This includes the use of Artificial Intelligence (AI), with patented algorithms and machine/deep learning, to enhance cloud computing's UDI capabilities in clinical medical environments. This allows the hospital to automatically complete the synchronisation of data feeding services, including clinical medical information system, supply chain management system, the hospital management system and the logistics system.

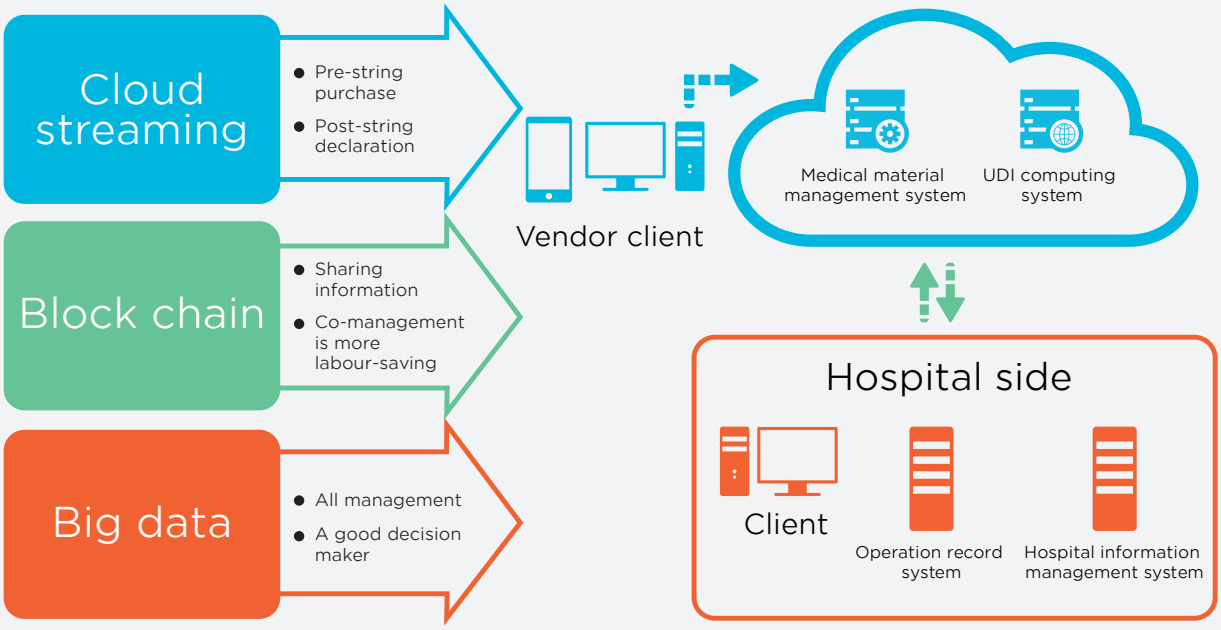
Steps

The first thing KAFGH did was to upgrade their information system to XuZhen's Chronos® so they could manage medical materials and medical devices through UDI implementation. This meant that with one scan, the management of all their clinical, and any other related processes, was automated. Chronos® is also compatible with all existing information systems in the hospital so no additional integration had to take place. Training was also provided so that hospital staff could quickly use the new tools and processes.

At the same time, KAFGH also worked with suppliers to highlight the benefits of implementing GS1 standards and UDI labeling guidelines for them, including the real-time online consignment stock management interface that is specially designed for suppliers by XuZhen's Chronos®.

Lastly, XuZhen's Chronos® connected internally to each system of the different departments in the hospital, so that they'd get the right data as they need it, and also to provide the required information needed for the public database, owned by the TFDA, for product authentication.

UDI system architecture



What is achieved above is an intelligent management system with three supportive ICT features:
1. cloud streaming **2.** block chain technology **3.** opportunity for big data analysis

Material inventory

Smart capability managing general medical supplies, consumables, high-value implants

Reduce the managing burden of administration personnel

Clear and simple accounting

Less procurement process

Less expired inventory in hospital

Clinical utilisation

One scan and easy use

Significantly reduce the problems of out-of-stock

Lower the cost

Healthcare practitioners

Improve the accuracy of health insurance declaration

Reduce medical loss of hospital

Provide complete Electronic Medical Records (EMRs)

Suppliers

Precise reconciliation

Prediction of inventory replenishment

Logistics information of product delivery

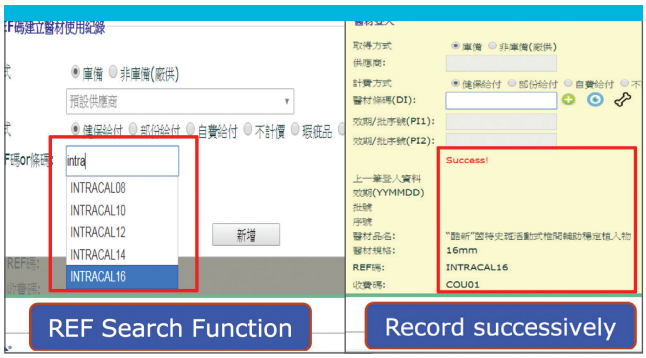
At this stage, KAFGH has already implemented UDI-based information systems for all existing 16 surgical operation rooms from different divisions across the whole hospital.

As a result of their work so far, more than 90% of medical materials and devices can be identified by scanning their UDI barcodes; less than 10% could not be identified. In those instances, the system can retrieve the correct product data from the cloud using the reference number shown on the box. Both marking/labeling can be read by the readers so the patient record can be updated. The software provides a constant link to the TFDA database of product permits which every medical product must apply for and be registered before launching to the Chinese Taipei market. There is still a small percentage of bulk medical materials without UDI, such as cotton buds, gauze, bandages etc. Here, KAFGH would use the GTIN in the EAN-13 barcode to identify them.

The three areas that need to be considered when implementing UDI are:

1. Products without UDI labels

Use reference number when UDI not available



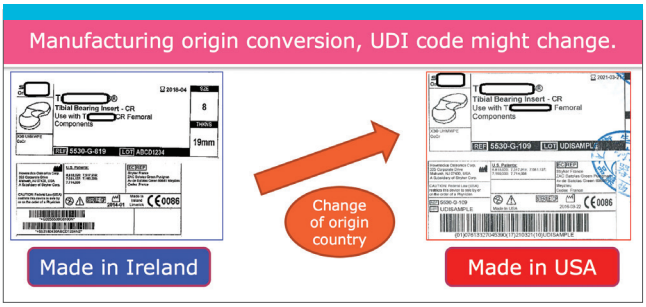
Solution system screens using reference number to check

2. Same product items but with a different package level

Package type	Package level	DI code
Single package	0	04711234560012
Two in package	0	04711234560029
10 in package	0	04711234560036
A box of 48 groups of 2 into the packaging	1	14711234560026
A box of 48 groups of 10 into the pack-aging	1	14711234560033

Same product items but UDI changes, which are identified as same product grouping by Chronos® Artificial Intelligence

3. Same product items show same company brand but different origin of production (different country code)



Same product items but UDI changes, which are identified as same product grouping by Chronos® Artificial Intelligence

Products without a match in the system are suspended as suspicious products and technicians then confirm whether a warning notice to the company or to TFDA is needed. That's another way the new system provides such control, improving protection against counterfeiting for hospitals and for patients.

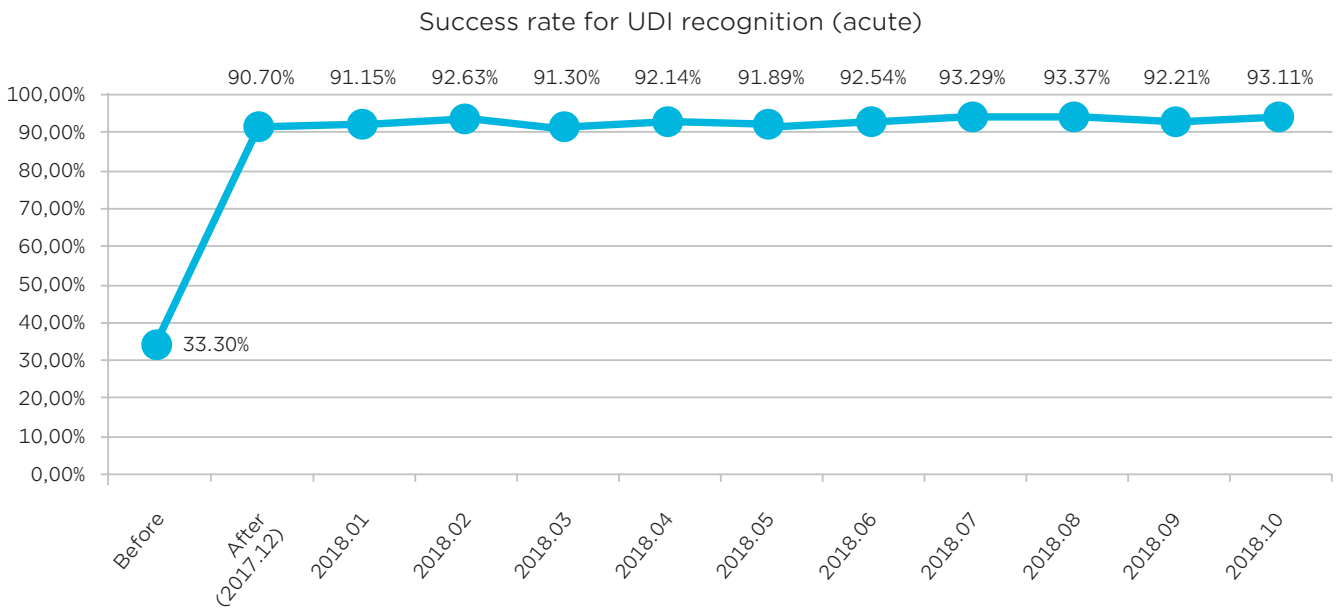
Benefits

All stakeholders in the healthcare supply chain have benefitted from KAFGH's experience of UDI implementation. Above all, the automation has released healthcare professionals' time back to care, where they previously would have been busy with traditional manual administration and management. The system's traceability has enhanced patient safety by using GS1 standards and UDI to correctly identify products with a simple scan of barcode.

Moreover, UDI helps showcase all levels of inventory information for both the hospital and all suppliers. This prevents issues around undersupplying or oversupplying products by offering a clear, real-time picture of patients' (or surgeons' / physicians') usage, so as to ensure a seamless supply.

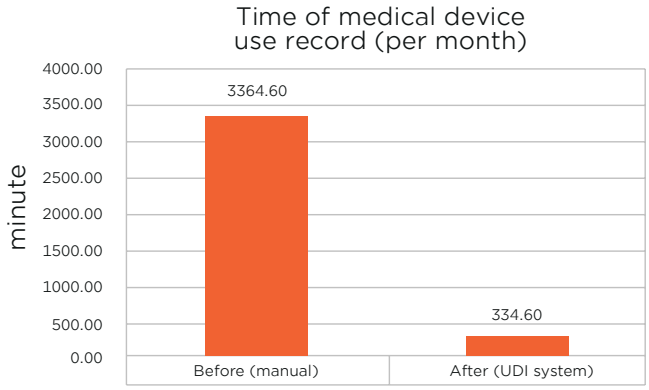
Quantitative indicators:

1. Above 90% success rate on UDI recognition right after solution implementation



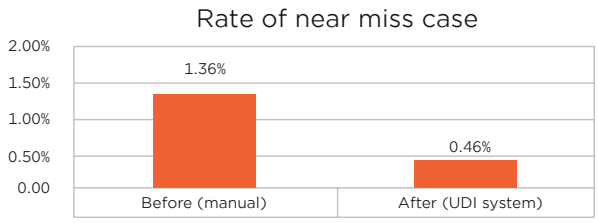
Category	2017.12	2018.01	2018.02	2018.03	2018.04	2018.05	2018.06	2018.07	2018.08	2018.09
Item number (should be identified)	140	192	285	437	369	518	456	462	377	398
Class 1 medical device	0	4	5	12	10	4	12	12	9	1
Human donation organisation	0	2	0	1	2	0	0	0	0	0
Drug	2	3	5	6	2	4	1	5	4	1
No UDI label (suppliers don't supply)	2	4	5	12	10	30	21	14	10	22
UDI system error	9	4	6	7	5	0	0	0	2	7
Item number (successfully identified)	127	175	264	399	340	480	422	431	352	367
Success rate for UDI recognition (%)	**90.7**	**91.2**	**92.6**	**91.3**	**91.1**	**91.9**	**92.5**	**93.3**	**93.4**	**92.2**

2. 90.1% decrease on manual work time (including administration management man-hours and medical recording man-hours)



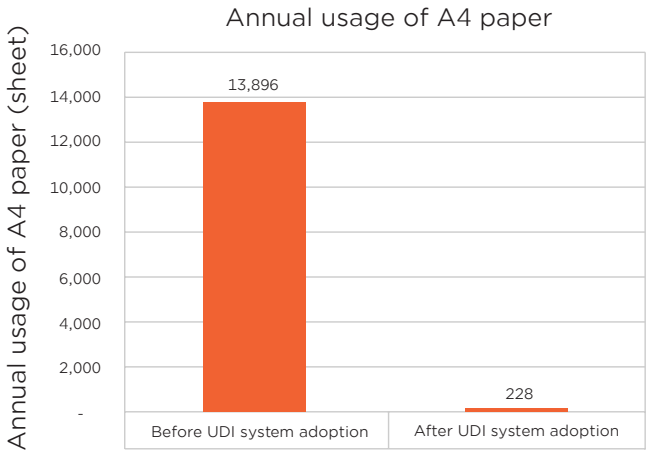
90.1% decrease (3364.60 minutes down to 334.60 minutes.)

3. 0.9% decrease on the error rate of medical materials by misuse



0.9% decrease (From 1.36% down to 0.46%)

4. Save 13,668 A4 papers ($) and reduce 1,829kg co_2 emission per year



Save 13,668 A4 papers
(From 13,896 sheets down to 228 sheets)

5. 6.9% lower on hospital cost

Paper cost down	273.44 USD per year
Salary cost down	4734.61 USD per year
Near miss cost down	3891.05 USD per year
Patient safety cost	Incalculable and priceless

Qualitative benefits:

- The product transparency after implementation reduces the issues and problems of consignment products.
- Lessen the number of administrative tasks for clinicians and nurses, leaving them to focus on the care of patients.
- Ensure full traceability of medical devices and products to patients.
- Improve internal data sharing between information systems and databases so as to advance hospital management.

Conclusion

Today, hospitals in Chinese Taipei are using multiple information systems, each designed for the different needs of each department. The challenge for IT departments, therefore, is to enable the use of product IDs across this complicated infrastructure. UDI offers a unique chance to capitalise on a standard used all the way through to the patient and beyond.

KAFGH's UDI project is an incredible achievement in Taiwan as it finally standardises documentation processing and reporting throughout a hospital, with data captured efficiently and accurately by UDI and used by all their existing systems. Following on from this success, the next stage for KAFGH will be to apply unique identification to the full life cycle of drug dispensing, using barcodes like the GS1 DataMatrix, in their hospital.

The key to success remains the ability to leverage UDI throughout the healthcare supply chain. Once implemented, KAFGH have seen benefits such as:

1. Improved inventory management

Once all medical devices have a scanable barcode, inventory management is no longer an arduous process, susceptible to human error. It provides real-time, online analytics regarding cost, recalls and waste. This empowers healthcare providers to reduce waste significantly, audit inventory easily, and stock their facilities effectively.

2. More time with patients

Instead of manually filling out device information on forms or trying to hunt down the model of a medical device, the scanable and readable UDI label makes this information readily available. The automation of the process on data entry and electronic medical records releases more time to physicians and nurses to focus on their patients.

3. More informed patient treatment

UDI ensures that all information regarding an implanted medical device is retained. This enhances the analysis of devices on the market by providing a standard and clear way to document the device use in electronic health records, clinical information systems, claim data sources and registries. It helps doctors to better respond to a patient's unique needs by retrieving more detailed information accordingly.

4. Better assessment of device performance

A UDI solution like KAFGH's provides a lot of trackable data for medical devices, which doctors can use to assess medical implants by looking at the health outcomes by the model of device, the hospital where it was implanted, and in some cases the physician who performed the surgery. Through more accurate reporting, reviewing and analysing of adverse event reports, problem devices can be identified and corrected more quickly. Additionally, a more robust post-market surveillance system can be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.

5. Reduction in medical errors

Scanning a UDI barcode makes it easy for healthcare professionals to rapidly and precisely identify a device and obtain important information concerning the characteristics of the device. This helps the reduction of medical errors by enabling an additional level of verification before a medical device is used or implanted in a patient. This extra authentication helps prevent mix-ups, which can have harmful or even deadly consequences.

6. Faster recalls

The UDI system eliminates all guesswork by providing data transparency that allows manufacturers, distributors and healthcare facilities to effectively manage medical device recalls. Using a simple scan, medical professionals can quickly see if medical devices in their facilities are included in a recall, and remove those devices from use.

7. Reduction in counterfeiting

UDI barcodes lock a medical device into a chain of custody process. With UDI, medical devices are controlled from the manufacturer to the distributor, to the healthcare provider, and all the way to patient use. This means medical devices are checked at multiple points, especially for KAFGH, where the UDI solution provides powerful features to screen suspicious products or forgeries. This greatly reduces the possibility of a counterfeit device entering clinical usage.

About the authors

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Superindendent
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General Ko is currently the superintendent of Kaohsiung Armed Forces General Hospital. He makes sure KAFGH pass strict requirements of patient safety and spares no effort to continue promoting the hospital's quality improvement work.
He is also one of the most important decision makers of KAFGH's UDI technology promotion.

Dr. Shih-Chung Huang
Physician of cardiology
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Dr. Huang is currently the attending physician of cardiology and the chief of the Teaching and Research Centre in Kaohsiung Armed Forces General Hospital. One of his responsibilities is to encourage his team members to cooperate with other departments to achieve the best results.

Dr. Kingsley Huang
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Dr. Huang is a postdoctoral research fellow of the Institute of Clinical Medicine, National Yang-Ming University in Chinese Taipei. Meanwhile, he is also a chief technology officer of XuZhen Medical Company Limited, which helps integrate clinical systems with UDI concepts using his innovative solutions to medical merchandise management.

Major YI-Liang Shih
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Major Shih is currently not only the medical material supply officer of Kaohsiung Armed Forces General Hospital, but also is a pharmacist. Since 2014, he has been responsible for the development and promotion of UDI technology in KAFGH. He's also one of KAFGH's key implementers of technology promotion.

About the organisation

XuZhen Chronos®
A GS1 standards and UDI oriented cloud solution developed by Xu Zhen Medical Co., Ltd. the start-up company with strong strengths and worldwide ambitions aiming to provide IoT, blockchain and cloud technologies as a solution to empower the outstanding medical services in major medical institutions. www.xuzhen.com.tw