Taiwan

TFDA, CCH and GS1 Taiwan advancing GS1 BarCodes to improve patient safety

ABSTRACT

To prevent medication errors, the Taiwan Food and Drug Administration (TFDA) is developing a regulation that will require printing barcodes on prescription drugs, which will promote the use of automatic identification and data capture to improve patient safety. The Changhua Christian Hospital is deploying and piloting the use of such barcodes in its medication procedures. The TFDA encourages the use of standardised barcodes on pharmaceutical products and plans to mandate the use of GS1 Standards by pharmaceutical manufacturers and hospitals. Barcodes should include the lot number and expiry date, and should allow for the tracking and tracing of a medication prescription, as well as its dispensing and administration.

By **Liang-Chin Wang,** Taiwan Food and Drug Administration

and **Su-Yu Chien,** Changhua Christian Hospital

Medication safety in hospitals

Medication errors are the single most preventable incident that impacts patient safety in hospitals. The Institute of Medicine (IOM) Report 'To Err Is Human - Building a Safer Health System'[1] underlined the importance to reduce medication errors in the U.S. by presenting estimates of the incidence and cost of such errors, as well as evidence on the efficacy of various prevention strategies.

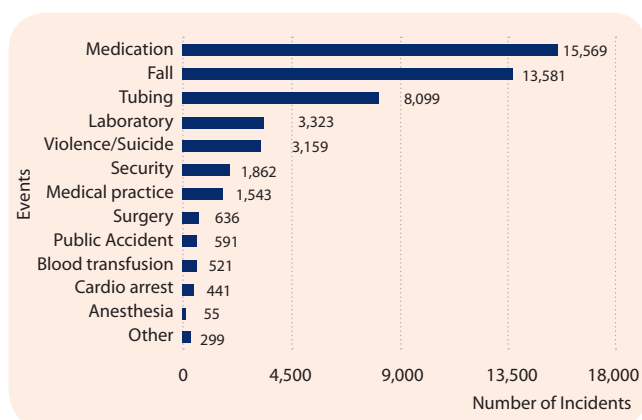To better understand the situation in Taiwan, the Department of Health introduced the Taiwan Patient-safety Reporting (TPR) system in 2003. Reporting by hospitals is voluntary and anonymous. Last year, over 3,900 hospitals reported about 189,000 incidents in the system.

The 2010 Annual Report of the TPR indicated that medication errors are the most common type of incidents that impact patient safety in hospitals.

Improve patient safety and increase efficiency

Unit dose barcodes provide additional safeguard during the dispensing and administration of medication to ensure the 'five rights' — right patient, right medication, right dose, right time, and right route of administration. Numerous hospitals worldwide have proven this is an effective way to prevent medication errors, both for the dispensing pharmacist and the nurse administering the drugs. The nurse scans the barcodes on the patient's wristband and the package of the drug to make sure the right patient gets the right medication.

Increased visibility on product availability also allows for improvement on inventory management, including easy retrieval of products in the pharmacy or another location on the hospital campus, and management of expired or recalled drugs.

In addition, increased supply chain visibility helps pharmaceutical suppliers efficiently manage inventory and distribution.

Events	Number of Incidents
Medication	15,569
Fall	13,581
Tubing	8,099
Laboratory	3,323
Violence/Suicide	3,159
Security	1,862
Medical practice	1,543
Surgery	636
Public Accident	591
Blood transfusion	521
Cardio arrest	441
Anesthesia	55
Other	299

Figure 1. 2010 TPR system Report – Number of incidents by type of event[2]

1 "To Err is Human: Building A Safer Health System" November 1, 1999, Institute of Medicine, http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx
2 http://www.tpr.org.tw/english.htm

Introducing barcodes in the medication process

To improve patient safety, the TFDA seeks to reduce medication errors through the use of barcodes in the medication procedures. Today, only a few hospitals in Taiwan use such a barcode system. The limited availability of barcodes on the packages of prescription drugs and the lack of standardised barcodes are considered the greatest barriers to adopting a barcode system in the medication process.

To this end, the TFDA is planning to mandate the use of standardised barcodes on prescription drugs. The regulation will require pharmaceutical suppliers to put GS1 BarCodes on their packages, with the aim of enabling hospitals to efficiently implement a barcode system in their medication procedures. Furthermore, the TFDA commissioned the Changhua Christian Hospital and GS1 Taiwan to develop a programme to implement barcode systems in hospitals.

The inaugurating meeting of the Taiwan Healthcare Automation Association

In June 2011, a user group was set up by the Taiwan Society of Health-System Pharmacists (TSHP) and GS1 Taiwan. The user group –Taiwan Healthcare Automation Association– consists of representatives from major hospitals, including CCH, National Taiwan University Hospital, Taiwan Veterans General Hospital, and Chang-Gung Memorial Hospital, as well as other stakeholders. GS1 Healthcare Taiwan's objective is to advance the implementation of GS1 Standards to enable automatic identification systems in hospitals.

One of the most significant challenges when implementing barcode systems in hospitals is the necessity to invest in an infrastructure for an electronic medication administration system, and the cost of maintaining and upgrading the system. This issue may be addressed by government subsidies.

The challenge for pharmaceutical suppliers lies in solving technical issues, such as ensuring barcode printing quality on a blister pack and the difficulty that comes with printing a barcode on a unit dose package. The user group is looking into these issues, with GS1 Taiwan providing technical support throughout the implementation process. The user group is also looking into recommendations to increase health insurance payments to cover the additional cost of barcoding.

Prescription drugs

The primary and secondary package stages of prescription drugs are required to apply one of the GS1 Data Carriers to encode Global Trade Item Number (GTIN). Multi-packs and cases stages are required to have GTIN, expiry date, and lot / batch numbers or serial number with GS1-128.

Packaging hierarchy		GS1 Identification Key	Additional Data	Data Carrier
Primary package		GTIN - AI(01)	• Lot/Batch Number* - AI(10) • Expiry Date* - AI(17)	GS1 Data Carriers (Lot/ batch Number and Expiry Date are Optional)
Secondary package		GTIN -AI(01)	• Lot/Batch Number* - AI(10) • Expiry Date* - AI(17)	GS1 Data Carriers (Lot/ batch Number and Expiry Date are Optional)
Multi-packs		GTIN -AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17)	GS1-128
Cases		GTIN - AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17)	GS1-128

Figure 2: Taiwan Healthcare Automation Association recommendation to the TFDA for prescription drugs

* Instead of encoding the lot/batch number and expiry date into data carriers on the primary and secondary packages of prescription drugs, pharmaceutical manufacturers just need to print these two elements in a human-readable way on the packages.
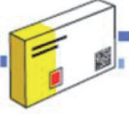
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Packaging hierarchy		GS1 Identification Key	Additional Data	Data Carrier
Primary package		GTIN - AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17) • Serial Number* - AI(21)	GS1 Data Carriers
Secondary package		GTIN -AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17)	GS1 Data Carriers
Multi-packs		GTIN -AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17)	GS1-128
Cases		GTIN - AI(01)	• Lot/Batch Number - AI(10) • Expiry Date - AI(17)	GS1-128

Figure 3: Taiwan Healthcare Automation Association recommendation to the TFDA for controlled drugs, blood products and vaccines.

*: The data carriers on all levels of the package of controlled drugs, blood products and vaccines must include serial numbers.

Controlled drugs, blood products and vaccines

Controlled drugs, blood products and vaccines are required to utilise GS1-128 and other GS1 Data Carriers to encode the necessary product and production identification, including the GTIN, expiry date, and batch/lot numbers on every level of packaging. Furthermore, the data carriers on all levels of packaging of controlled drugs, blood products and vaccines must include serial numbers.

Conclusion

The TFDA's regulation on medication safety will require the implementation of GS1 BarCodes on prescription drug packaging. Most pharmaceutical suppliers, domestic and international, have already implemented GS1 Standards on certain packaging levels to manage their supply chain. This will help them to comply with the upcoming requirements.

Moreover, Taiwan Healthcare Automation Association's guidelines will guide stakeholders to follow global standards of medication barcoding at various packaging levels.

About the Taiwan Food and Drug Administration (TFDA)

The TFDA's mission is to ensure food and drug safety and to lead the nation into a new era of food and drug management. The TFDA was established by the Department of Health in 2010. It consolidated four governmental bodies, including the Bureau of Food Safety, the Bureau of Pharmaceutical Affairs, the Bureau of Food and Drug Analysis and the Bureau of Controlled Drugs. This organisational reform was needed to streamline the process from policy planning to execution, and to increase administration efficiency.

About the Changhua Christian Hospital (CCH)

CCH was established in 1896. It has grown under the selfless contributions of overseas missionaries and has continued growing to the present day. CCH consists of ten branch hospitals, totaling 3,232 beds and 6,358 employees.

ABOUT THE AUTHOR

Liang-Chin Wang works at the Taiwanese Department of Health as a TFDA Officer for over 20 years and has gained experiences in GS1 Standards and barcodes.

Su-Yu Chien is director of the pharmacy department at CCH. She is also a professor at the School of Pharmacy of the Kaohsiung Medical University. As investigator of the Joint Commission on Hospital Accreditation, Department of Health, Taiwan, she has been involved in many governmental projects. She is a member of the Quality of Pharmacy Service Promotion Committee, Department of Health, Taiwan and of the Drug Pricing Committee, Bureau of National Health Insurance, Taiwan.

Co-author: **Shawn Chen**, currently works for GS1 Taiwan as Project Manager of Professional Service Department.