Establishment and Application of Medication Barcode System in Taiwan

President, Taiwan Healthcare Automation Association
Honorary President, Taiwan Society of Health-System Pharmacists
Clinical Professor, Kaohsiung Medical University
Director, Department of Pharmacy, Changhua Christian Hospital

Su-Yu Chien, RPh, M.S.
The Only Medical Center with History of 100 Years in Central Taiwan Area
Changhua Christian Hospital Healthcare System

- Hospitals: 10
- Patient beds: 3232
- Staffs: 6358
- Pharmacists: 189

<table>
<thead>
<tr>
<th>Hospitals</th>
<th>1</th>
<th>District Hospitals</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Center</td>
<td>1</td>
<td>Regional Hospitals</td>
<td>2</td>
</tr>
<tr>
<td>Regional Hospitals</td>
<td>2</td>
<td>Specialist Hospital</td>
<td>1</td>
</tr>
</tbody>
</table>
Changhua Christian Hospital
-- Established under God’s Love
Patient Centered Healthcare
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Outline

1. Medication Error can Occur in Any Step of Medical Process
2. Milestones of Taiwan Medication Barcode Project
3. Implementation obstacles
5. Summary & Recommendations
1. Medication Error can Occur in Any Step of Medical Process

- Inventory Management
- Prescribing
- Dispensing
- Administration
- Patient

Outpatient clinic
Inpatient
Medical error is among of the top leading causes of death in the U.S.

Fig. 1. Estimated Deaths Associated with Medical Errors Compared to Leading Causes of Death in the U.S.

- Heart Disease: 727,000
- Cancers: 540,000
- Stroke: 160,000
- Lung Disease: 109,000
- Medical Errors (IOM High Estimate): 98,000
- Accidents: 96,000
- Pneumonia and Flu: 86,000
- Diabetes: 63,000
- Medical Errors (IOM Low Estimate): 44,000
- Suicide: 31,000
- Kidney Disease: 25,000

Deaths in 1997

Source: Adapted from Leatherman et al., 2002

IOM: Institute of Medicine
More than 50% Medication Error Reduction with Barcode Scanning

- With pharmacy bar-code scanning
  - 67% reduction

- With eMAR
  - 100% reduction

- With bar-code eMAR
  - 51% reduction

- With CPOE
  - 55% reduction

Serious Medication Errors

Medication error case per year

- Prescribing 39%
- Transcription 12%
- Dispensing 11%
- Administration 38%

189,000

Source: NEJM 2010; 362; 1698-1707
## 2. Milestones of Taiwan Medication Barcode Project (since 2011)

Purpose: Promote medication safety and efficiency of medication management

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Established standard for medication barcode and user guideline for barcode application</td>
</tr>
<tr>
<td></td>
<td>Hold medication barcode application orientation</td>
</tr>
<tr>
<td>2</td>
<td>Survey of Medication barcode application penetration</td>
</tr>
<tr>
<td></td>
<td>Technical Assistance for Printing Single Unit Barcode</td>
</tr>
<tr>
<td>3</td>
<td>Established barcode application model for hospitals</td>
</tr>
<tr>
<td></td>
<td>Assistance for barcode application in hospital</td>
</tr>
<tr>
<td>4</td>
<td>Recommended higher pricing for reimbursement</td>
</tr>
<tr>
<td>5</td>
<td>Established an online platform for medication barcode and drug information</td>
</tr>
</tbody>
</table>
The package of drug should label generic name, brand name, dosage form, potency, lot number, expiration date.

Every package level should have printed or patched GS1 barcode.

The primary and second level adopt DataMatrix as a carrier.

The third level adopts GS1-128 as a carrier.
**Legislative draft of medication barcoding standard in Taiwan, 2012**

<table>
<thead>
<tr>
<th></th>
<th>Medication Barcode content</th>
<th>Human-Readable content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Level Package</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single unit blister medication</td>
<td>• GTIN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• printed expiration date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• printed lot number</td>
<td></td>
</tr>
<tr>
<td>Blood products, vaccines</td>
<td>• GTIN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• expiration date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• lot number</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary Level Package</strong></td>
<td>• GTIN</td>
<td>Generic name, Chinese/English brand name, potency, lot number, expiration date.</td>
</tr>
<tr>
<td></td>
<td>• expiration date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• lot number</td>
<td></td>
</tr>
<tr>
<td><strong>Tertiary Level Package</strong></td>
<td>• GTIN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• expiration date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• lot number</td>
<td></td>
</tr>
</tbody>
</table>
Technical Assistance for Printing Single Unit Barcode in Taiwan

All passed GSI inspection for adhesiveness and readability

Examples:

Morphine Sulfate Tab. ®
TFDA, Controlled Substances Pharmaceutical Company

Dipachro S.R.
Film Coated Tab. ®
Taiwan Biotech Co., Ltd
Technical Assistance recipients in Taiwan
**Single Unit Barcoding Examples**
– Taiwanese Pharmaceutical Companies

<table>
<thead>
<tr>
<th>信東</th>
<th>永信</th>
<th>健喬信元</th>
<th>景德</th>
</tr>
</thead>
</table>

![Barcoding Examples](image-url)
### Single Unit Barcoding Examples – Int’l Pharmaceutical Companies

<table>
<thead>
<tr>
<th>AstraZeneca</th>
<th>Bristol-Myers Squibb</th>
<th>Boehringer Ingelheim</th>
<th>Lilly</th>
<th>Lilly</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Sanofi-Aventis</th>
<th>Sanofi-Aventis</th>
<th>TEVA Pharma</th>
<th>UCB</th>
<th>第一三共</th>
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<td><img src="image6.png" alt="Image" /></td>
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<td><img src="image8.png" alt="Image" /></td>
<td><img src="image9.png" alt="Image" /></td>
<td><img src="image10.png" alt="Image" /></td>
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</table>
Medication Barcode Information
Online Platform

- All manufacturers provide drug information using standardized electronic form
- Reduction in information database establishment and maintenance cost for health institutes
Medication Barcode Model for Hospitals in Taiwan
Scope of Medication Barcode System in Hospital

**Inventory Management**
- Inspection and receipt of medication
- Storage and shelving
- Delivering
- Stocktaking

**Dispensing**
- Prescription assessment
- Prescription filling
- Double checking
- Delivering
- Drug information inquiry
- Query patient’s medication use
- Replenishment operation for dispensing machine
- Controlled substance management

**Administration**
- Courier receives medication
- Nurse double checks medication
- Nurse administers medication
Video clip
Concerns from some manufacturers:

- Government authorities in other countries do not require barcode on single medication unit yet
- Technical difficulties
- Additional cost

Government authorities deferred announcement of barcode-printing regulations
## Regulations in some countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Current regulations</th>
</tr>
</thead>
</table>
| **USA** | 2017: Serialized Product Identifiers  
- each package and case  
- human-readable form and on a machine-readable data carrier  
- 2D DataMatrix on Package, Linear or 2D Barcode on Case  
- National Drug Code (NDC), Serial number (SI), lot number, and expiration date |
| **Japan** | General biological products should have GTIN, batch number, and expiration date on secondary and tertiary package; **primary package** should have GTIN  
- Special biological products should have GTIN, batch number, and expiration date on all package |
### Regulations in some countries (Cont.)

<table>
<thead>
<tr>
<th>Country</th>
<th>Current regulations</th>
</tr>
</thead>
</table>
| **Korea** | • 2012: *Special drugs* should have GTIN, batch number, expiration date  
• 2013: *Prescription drugs* should have GTIN, batch number, expiration date  
• 2015: *Prescription drugs* should have GTIN, batch number, expiration date, **serial number**  
• *OTC drugs* need only GTIN |
| **France** | • Only *secondary and tertiary package* need GTIN, batch number, expiration date |
International professional associations strongly recommended the implementation of single unit barcoding in medication packages

ASHP Statements, 2008 --- Bar-Code-Enabled Medication Administration Technology

ASHP believes that pharmaceutical manufacturers should be required to place machine-readable coding that includes the NDC, lot number, and expiration date on all unit dose, unit-of-use, and injectable drug packaging, using symbologies that are readily deciphered by commonly used scanning equipment.

ASHP: The American Society of Health-System Pharmacists

Source: Automation and Information Technology Statements
Barcode Information on the single unit

- Including the identification of the drug (GTIN), the expiration date and the batch number.

- When the production facility is incompatible with an on-line printing of variable data, the barcode can temporarily be limited to the identification of the drug

- No serial number requested on the unit
4. Strategy & Action Plan: intervene both supplier and user concurrently

- Re-search & Establish Barcode Standard
  - Instruct Manufacturers
  - Promote
- Establish Application Model for Hospitals
  - Instruct Hospitals
  - Promote
- Establish Application Model for Community Pharmacies
  - Instruct Community Pharmacies
  - Promote
- Legislate
  - Patient Safety
5. Summary

- Medication barcode application is an important tool to prevent human errors.

- Distinct opinions between pharmacist associations and pharmaceutical manufacturers.

  Patient safety should come first.

- Urge government authorities to pass legislation for mandating single unit barcoding system to ensure patient safety.
6. Recommendations

Consensus → Advocate → Mandate → Patient Safety Achieved

Pharmacy Association (U.S • EU • Asia) → FIP → WHA
Thank you for your attention!