Implementation of Standardized Traceability System
-Expectation of Healthcare Service Providers and Its Users-

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Chikayuki OCHIAI, M. D., D. M. Sc.
Professor, Tokyo Healthcare University
Chairman, GS1 Healthcare Japan
Former Chief Executive, NTT Medical Center Tokyo
The social security-related costs account for more than half of the national general expenditure and for about 1/3 of the general account. Financial sustainability is difficult to exist without reforming the social security system.

### Breakdown of the general account budget in FY2016
(Unit: 100 million yen, %)

- **National debt service payments**: 236,121 (24.4)
- **Distribution of the local allocation tax, etc.**: 152,811 (15.8)
- **General expenditure**: 578,286 (59.8)
- **Social security**: 319,738 (33.1)
- **Public projects**: 59,737 (6.2)
- **Education and advancement of science**: 50,541 (5.2)
- **Defense**: 59,737 (6.2)
- **Others**: 94,690 (9.8)

**General account total annual expenditure**: 967,218 (100.0)

Source: Ministry of Finance
In 2025, the first Baby boomers reach 75-yrs-old. One fifth of Japanese population will consist of people over 75-yrs-old, and one third of it over 65-yrs-old. Although the working population decreases, the population of those who needs medical care increases.
Estimation of the expense for social security

109.5 trillion yen (22.8%)

Total benefits 1.36 times

148.9 trillion yen (24.4%)

Support for child and childcare 4.8 trillion yen (1.0%)

Others 9.0 trillion yen (1.5%)

Long-term care 2.34 times

Long-term care 19.8 trillion yen (3.2%)

Medical Care 54.0 trillion yen (8.9%)

Medical care 1.54 times

Medical Care 35.1 trillion yen (7.3%)

Pension 53.8 trillion yen (11.2%)

Pension 1.12 times

Pension 60.4 trillion yen (9.9%)

GDP 479.6 trillion yen (FY2012)

GDP 1.27 times

GDP 610.6 trillion yen (FY2025)

(Source) Ministry of Health, Labour and Welfare
(Note) Figures in parentheses are percentages of GDP.
Reasons why we need standardized traceability system in the field of healthcare

In the field of Japanese healthcare, in addition to the patient safety and the improvement of quality, “cost efficiency” has become an essential issue as shown in the previous three slides.

If the cost is the same, we should choose the most effective way and if the outcome is the same, we should select the most affordable way.

For solving this issue, we believe that it is vital to establish the globally standardized system making it possible to secure the traceability in the field of healthcare.
We need **standardized traceability system!**

- **Traceability and product identification**
- **Electronic exchange of business document between relevant parties**
- **Exchange of Production information between parties**
We need standardized traceability system!
Brief Summary of Barcode Implementation in Healthcare Industry in Japan

**Medical Devices**

- 1980s
- Guideline (Industry Group)

**Prescription Drugs**

- Start using JAN (EAN-13)

- 2000s
- Database for All Healthcare Products started by MEDIS
  (MEDIS: Medical Information System Development Center)

- 2006
  - Revised Guideline (JFMDA) in 2006

- MHLW issued "Guideline for Barcode Labeling of Medical Devices" in March 2008

- MHLW issued "Implementation Guideline for Barcode Labeling of Prescription Drugs" in September 2006

- Revised in August 2016
Rough sketch of Barcode labeling for prescription drugs

By 2015 July

By 2021 April

Mandatory indication

AI (01) GTIN

AI (01) GTIN

AI (17) Expiration Date and AI (10) Lot No.
Overview about Utilization of GS1 barcode in Japan (Healthcare)

Under the guidance of the government, GS1 Barcode Labeling by the pharmaceutical manufacturers is making great progress, it has been actively used in the distribution scene. However, in hospital and medical fields, it is not used widely at present.

### Traceability of distribution

<table>
<thead>
<tr>
<th>Pharmaceutical manufacturer</th>
<th>Wholesale</th>
<th>Hospital</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure to connect</td>
<td>Patient ID</td>
<td>Date</td>
<td>Prescriptio n</td>
</tr>
<tr>
<td></td>
<td>Medical device</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| GTIN/Expiry Date/Lot or Serial | Site's own product code | Insurance reimbursement code and more. |

### Utilization of barcode (Sep 2016, by MHLW)

#### Traceability of medical treatment

- **Product Identification**
  - GTIN/Expiry Date/Lot or Serial
  - Medical Devices
  - Primary Package: 86.4%
  - Sales Package (Inner and outer): 94.5%

#### Barcode Labeling of Medical Devices in 2015

<table>
<thead>
<tr>
<th>Medical Devices</th>
<th>Primary Package</th>
<th>Sales Package (Inner and outer)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>86.4%</td>
<td>94.5%</td>
</tr>
</tbody>
</table>

#### Barcode Labeling of Prescription Drugs” in 2015

<table>
<thead>
<tr>
<th>Specific biological products</th>
<th>Injections</th>
<th>Oral medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing Unit</td>
<td>100%</td>
<td>97.5%</td>
</tr>
<tr>
<td>Sales Package</td>
<td>100%</td>
<td>99.8%</td>
</tr>
<tr>
<td></td>
<td>99.9%</td>
<td></td>
</tr>
</tbody>
</table>

Sept. 2016 by MHLW
### Summary of the Survey to Wholesales (distribution of pharmaceuticals)

#### Utilization rate of barcodes in distribution center

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Sales Package</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>2) Outer Package</td>
<td>79.4% ⚫</td>
<td>* All companies replied “not yet” are in preparation</td>
</tr>
</tbody>
</table>

#### Utilization rate of barcodes in their branch office

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Sales Package</td>
<td>81.3% ⚫</td>
<td>* 80% companies replied “not yet” are in preparation</td>
</tr>
<tr>
<td>2) Outer Package</td>
<td>56.3% ⚫</td>
<td></td>
</tr>
</tbody>
</table>

Sept. 2016 by MHLW
Current Situation in Japan (hospitals, medical careers, patients)

Many kinds of identification code including hospital’s private one have already been implemented in most Japanese hospitals.

However, introduction of GS1 identification codes and AIDC technology is still not prevalent.

Almost all medical careers in Japan don’t know “what is GS1?”

For securing traceability in the field of healthcare, standardization of coding from manufactures to healthcare provider is mandatory.

Now, promoting the benefit of GS1 product identification & barcodes and encouraging healthcare providers and hospitals to use them are key issues.
Platform system being proposed by JUMP

- The Japan Usability Medical Information Promotion Conference (JUMP) was born in 2013 for promoting social security numbers in healthcare systems. One of the proposals of the JUMP is to establish the concept and practical use of traceability.
Introduction effect of traceability system

Case study from
NTT Medical Center Tokyo
## NTT Medical Center Tokyo

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beds</td>
<td>606</td>
</tr>
<tr>
<td>Outpatients per day</td>
<td>Approx. 2,117</td>
</tr>
<tr>
<td>Operating rooms</td>
<td>10</td>
</tr>
<tr>
<td>Operations per year</td>
<td>Approx. 5,518</td>
</tr>
<tr>
<td>Nurses in Ope. Dept.</td>
<td>21</td>
</tr>
<tr>
<td>Staff in supply room</td>
<td>10</td>
</tr>
<tr>
<td>Washers</td>
<td>3</td>
</tr>
<tr>
<td>Sterilizers</td>
<td>6</td>
</tr>
<tr>
<td>Surgical containers</td>
<td>Approx. 189</td>
</tr>
<tr>
<td>Medical steel</td>
<td>Approx. 20,000</td>
</tr>
<tr>
<td>instruments (DPM)</td>
<td></td>
</tr>
</tbody>
</table>
Before introducing the traceability system

- The number of surgical operations **continuously increased.**

Management error relating to the SSU occurred in 108 out of 5,712 surgical cases (1.89%) from April 2007 to March 2008. 58 errors were in assembly (53.7%),
UDI for metal instruments
For preventing assembly error
RFID tag on the container
# Decrease of Errors Relating to SSU

<table>
<thead>
<tr>
<th></th>
<th>07.4〜08.3</th>
<th>08.4〜08.7</th>
<th>08.8〜09.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errors</td>
<td>108</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td>Surgeries</td>
<td>5,712</td>
<td>1,913</td>
<td>2,729</td>
</tr>
<tr>
<td>Error ratio</td>
<td>1.89%</td>
<td>1.62%</td>
<td>0.11%</td>
</tr>
</tbody>
</table>

- 07.4〜08.3: before introduction of UDI
- 08.4〜08.7: just after introduction
- 08.8〜09.1: after stuff accustomed to the system
How to manage the use of surgical endoscopes. How to adopt bar code technologies on them.

A set of endoscope is usually composed of more than 20 elements including very fine devices.
New Technology

2007
3.0 mm x 3.0 mm

Electrode of endoscope

2011
0.95 mm x 2.80 mm
Work flow of SSU

SSU: sterile supply unit

OR
(Operation Room)

retieve divided into two groups

assortment

washing/decontamination

supply and storage

sterilization

assembly

SSU
Frequency of the use of each element

- Needle electrode: 1
- Roller electrode: 1
- Loop electrode 24 f r (30,M): 1
- Loop electrode 24 f r (30,S): 1
- Loop electrode 24 f r (30,S): 1
- Biopsy forceps: 10
- Bridge (for 70°): 9
- Handle (passive): 9
- Intermittent sheath: 9
- Silicone tube: 0
- Irrigation adaptor: 6
- Light guide (with a connector): 5
- Bipolar cord: 0
- E scalpel cord: 9
- Optical mandolin 24 f r: 10
- TURis handle (passive): 0
- Mandolin 24 f r: 12
- Mandolin 24 f r: 12
- With a rotary cock attached: 10
- Continuous sheath 24 f r: 14
- Irrigation sheath 26 f r: 13
- Scope 30P: 16
Brief history of our trials

• First trial (2008~)
  – Introduction of bar code technologies in SSU at the process of assembly for metal instruments

• Second trial (2011~)
  – Development of very small-sized direct part marking applicable to the element of surgical endoscopy
  – Introduction of bar code reading at the process of retrieve in addition to assembly

• Third trial (2013~)
  – Implementation of bar code reading at the process of assembly and retrieve for all metal instruments
結果の概要

**Laparotomy Set (large) of General Surgery E**

- **Laparotomy Set (large) of General Surgery E**
- **July 2014〜Oct. 2014**
- **Frequency of Use**: 30 times
- **Composition**: 140 metal instruments
- **Instruments used**: 51%
- **Instruments not used**: 49%

### 平均の使用回数と未使用回数

<table>
<thead>
<tr>
<th>計数</th>
<th>使用回数</th>
<th>未使用回数</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,320</td>
<td>2,585 (51%)</td>
<td>2,735 (49%)</td>
</tr>
</tbody>
</table>

### 抽出セット

- ① 小児用腸鉗子（直） 2
- ② 小児用腸鉗子（曲） 2
- ③ 腸鉗子（直） 2
- ④ 腸鉗子（曲） 2
- ⑤ 胃鉗子（直） 1
- ⑥ 胃鉗子（曲） 1

合計: 10本
Status of Usage of Metal Instruments by Container

Laparotomy Set of Gynecology

Laparotomy Set (middle) of General Surgery

Laparotomy Set (large) of General Surgery
Strive to downsize the set of instruments

Surgical laparotomy (large)

- Average usage level: 47.9% of 5,040pcs
- Total usage level: 65.5% of 4,080pcs

Number of components:
- 126pcs before downsizing
- 98pcs after downsizing

It realized to reduce the number of devices 30% or more.
Introduction effect of traceability system

- Cost optimization based on work data
  - Reduction of working hours for washing and assembly

>> Reduction of labor costs

Trend in labor rates and number of workers

Trend in labor costs and number of surgical operations

Enhancing the efficiency of hospital management.
Tracking of the event history

- When the surgery started and ended
- When and by whom instruments were retrieved and washed.
- Which instruments are in each container
- How often instruments are being used
- When and which instruments have been repaired
- When, how and by whom the container were set, sterilized and stored
- In which patient the instruments were used (AIDS, Creutzfeld-Jakob disease, etc.)
Thank you for your kind attention.
Thank you for your kind attention.