My 10-year journey with GS1 Healthcare Japan

Aiming for improvement of quality and safety in healthcare

Chikayuki OCHIAI, M. D., D. M. Sc.
Professor, Tokyo Healthcare University  Chairman, GS1 Healthcare Japan  Honorary President, NTT Medical Center Tokyo
2019-03-28 Global GS1 Healthcare Noordwijk-Amsterdam Conference
Agenda

- Introduction of myself
- Experiences of UDI implementation in NTT Medical Center Tokyo
- Brief Summary of GS1 Barcodes in Japan
- Activities of GS1 Healthcare Japan
- Current movement of Japanese Government
- Problems to be solved for promoting GS1 Standards in the field of healthcare
My journey to join GS1 Healthcare Japan

1971  Started working as a neurosurgeon.

2002  Became the CEO of NTT Medical Center Tokyo

◆ The first issue to be settled was to create a culture of patient safety.
  ◆ Enabling the staff to work without stress
  ◆ Reducing the workload of the staff to record patient information covering a broad context
   ◆ Introduction of AIDC technologies
     ◆ Enabling accurate recording of use histories of medical devices and pharmaceuticals

2008  GS1 Healthcare Conference Tokyo was held.

2009  GS1 Healthcare Japan was established.
Agenda

• Introduction of myself
• Experiences of UDI implementation in NTT Medical Center Tokyo
• Brief Summary of GS1 Barcodes in Japan
• Activities of GS1 Healthcare Japan
• Current movement of Japanese Government
• Problems to be solved for promoting GS1 Standards in the field of healthcare
RFID and Bar Code Based Management of Surgical Instruments in a Theater Sterile Supply Unit.

Kanto Medical Center NTT EC
Chikayuki Ochiai, M.D.

Happo-en, Tokyo, Japan  Oct. 29th, 2008
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%).
Work flow of SSU

SSU
Sterile Supply Unit

Operation Room

Retrieve
Assortment
Washing / Decontamination

Supply and Storage
Sterilization
Assembly

The Global Language of Business © GS1 2019
Benefits from Direct Part Marking (DPM)

- We could avoid assembly errors by scanning barcodes.
- Working hours were also reduced because it became easy to identify devices.
Direct Part Marking on Each Element of Endoscope for Securing Patient Safety and Traceability

Chikayuki Ochiai  M.D., D.M.Sc.
Chief Executive, NTT Medical Center Tokyo
Dr. Chikayuki Ochai
NTT Medical Center Tokyo
Background  New Technology

2007  3.0mm x 3.0mm

Electrode  Ruler

2011  0.95mm x 2.80mm
## COMPARISON OF TWO TECHNOLOGIES

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>NEWLY DEVELOPED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size of DataMatrix</strong></td>
<td>3.0 mm x 3.0 mm 5.0 mm x 5.0 mm</td>
<td>Min. 0.96 mm x 2.8 mm Max. 2.8 mm x 2.8 mm</td>
</tr>
<tr>
<td><strong>Contents of Code</strong></td>
<td>AI : none</td>
<td>AI : 8004 (GIAI) GS1 Company Prefix + Serial No.</td>
</tr>
<tr>
<td><strong>Objective</strong></td>
<td>One UDI on One Metal Instrument</td>
<td>Individual UDI on Each Element of One Endoscope</td>
</tr>
<tr>
<td><strong>Applicable Material</strong></td>
<td>Stainless steel</td>
<td>Stainless steel Titanium alloy / Resin</td>
</tr>
</tbody>
</table>
Work flow of SSU

SSU
Sterile Supply Unit

Operation Room

Supply and Storage

Sterilization

Assembly

Washing / Decontamination

Assortment

*Retrieve divided into two groups

SCAN

SCAN

*
Adoption of GS1 Standards at NTT Medical Center Tokyo

- Decided to adopt GS1 Standards at NTT Medical Center Tokyo in 2011
- Obtained the first GCP (GS1 Company Prefix) as a hospital in Japan

* Comply with GS1 Standards *

- Extended Direct Part Marking with GS1 DataMatrix containing GIAI to every steel instrument in 2013
Aims of DPM to every steel instrument

To ensure the accurate record of events as follows:

- 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.)
Status of Usage of Metal Instruments by Container

Laparotomy Set of Gynecology

A | B | C
not used | used

Laparotomy Set (middle) of General Surgery

A | B | C | D

Laparotomy Set (large) of General Surgery

A | B | C | D
Benefits from DPM to every steel instrument

- In addition, we could know which instruments weren’t used during surgeries.

Surgical laparotomy set (large)

Number of components: 126pcs

47.9% Used
52.1% Not Used
Total 5,040 pcs

34.5% Used
65.5% Not Used
Total 4,080 pcs

Benefits from DPM to every steel instrument:

downsized the number of devices 30% or more
Agenda

• Introduction of myself
• Experiences of UDI implementation in NTT Medical Center Tokyo
• Brief Summery of GS1 Barcodes in Japan
• Activities of GS1 Healthcare Japan
• Current movement of Japanese Government
• Problems to be solved for promoting GS1 Standards in the field of healthcare
Brief Summary of GS1 Barcodes in Japan

Medical Devices

1980s

Start using JAN (EAN-13)

1999

Guideline (Industry Group)

2000

Database for All Healthcare Products started by MEDIS

(MEDIS: Medical Information System Development Center)

2001

2006

Revised Guideline (JFMDA) in 2006

2008

MHLW issued “Guideline for Barcode Labeling of Medical Devices” in March 2008

2009

2010

2016


Revised in August 2016

Prescription Drugs

2018

The National UDI conference was held from 2016 to 2018

2019

Japan Medical Traceability Promotion Council was established in 2018
Barcoding ratio to prescription drugs and medical devices

<table>
<thead>
<tr>
<th></th>
<th>Primary Packages</th>
<th>Sales Packages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescription Drugs</strong></td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Medical Devices</strong></td>
<td>84.1%</td>
<td>97.7%</td>
</tr>
</tbody>
</table>

*Not yet 100% but almost 100%*

https://www.mhlw.go.jp/stf/newpage_01668.html
https://www.mhlw.go.jp/content/10807000/000361190.pdf
Agenda

• Introduction of myself
• Experiences of UDI implementation in NTT Medical Center Tokyo
• Brief Summery of GS1 Barcodes in Japan
• Activities of GS1 Healthcare Japan
• Current movement of Japanese Government
• Problems to be solved for promoting GS1 Standards in the field of healthcare
GS1 Healthcare Japan was established in 2009

- More than 100 members from manufacturers, wholesalers, and medical institutions
- I became the second chairman after late Prof. Kaihara in 2011.
- GS1 Healthcare Japan hosts an Annual Healthcare Conference every spring to promote GS1 Standards. The number of participants has been increasing.
- Published several guidelines for the accurate usage of GS1 Barcodes.

GS1 Healthcare Japan

Promotion Work Group

Standardization Work Group

Solution Study Work Group
Let me show you a video

Simple Scan for safer, more effective healthcare

http://www.dsri.jp/gshealth/disclosure/movie.html
Test Calculation of the benefits

• According to the president of this hospital where we took the Video, the hospital achieved **4.67hrs/day** reduction of work hours for verification and mixing of injections.

• 4.67hrs/day = **30,000 dollars/year**

• In Japan, there are 2,000 hospitals with more than 200 beds

• If all those hospitals introduce the same system, it will bring a **6 million dollars/year** cost cut.

• There are more than 5,000 hospitals with less than 200 beds.

• I believe at least a **10 million dollars/year** cost cut will be achieved if those hospitals also introduce the system.
Agenda

• Introduction of myself
• Experiences of UDI implementation in NTT Medical Center Tokyo
• Brief Summery of GS1 Barcodes in Japan
• Activities of GS1 Healthcare Japan
• Current movement of Japanese Government
• Problems to be solved for promoting GS1 Standards in the field of healthcare
Opinions about pharmaceuticals and medical device policy

4. Enhancement of governance: production, distribution, and sale of pharmaceuticals and medical devices
   (3) Improvement of safety
      2 Traceability

- From the perspective of medical safety, it is important to improve traceability with barcodes to manage data of pharmaceuticals and medical devices, trace usage histories, and prevent human errors. To encourage the safety measures mentioned above, we concluded that it is appropriate to make it mandatory to place international standard barcodes on containers or capsule, and sales packages.

- We have to consider differences of types or features of pharmaceuticals and medical devices, and penetration of current coding standard including OTC drugs when making barcode placement mandatory.

- We request marketing authorization to record their product data to database and we have to encourage safety measures using barcodes in medical institutions.
Barcoding will be mandatory

- **Medical Devices**
  - 2006: MHLW issued “Guideline for Barcode Labeling of Medical Devices” in March 2008
  - 2016: Revised in August 2016

- **Prescription Drugs**
  - 2006
  - 2008
  - 2009
  - 2010
  - 2016

*On 19th March, The Cabinet of Japan submitted the amendment draft of “Pharmaceuticals and Medical Devices Act” to the National Diet.*
Agenda

• Introduction of myself
• Experiences of UDI implementation in NTT Medical Center Tokyo
• Brief Summary of GS1 Barcodes in Japan
• Activities of GS1 Healthcare Japan
• Current movement of Japanese Government
• Problems to be solved for promoting GS1 Standards in the field of healthcare
Present status

• Several hospitals have already implemented traceability systems using GS1 barcodes in Japan.

• However,

∗ - Those hospitals have, without exception, enthusiastic specialists who have adequate knowledge not only on healthcare staff’s business process but also on information systems.

∗ - Usual hospitals hardly find such specialists among their staff.
Prevalent views on GS1 barcodes among healthcare staff

• What is GS1? Is it GS1 or GSI?
  - Barcoding will be mandatory but GS1 Barcodes are not popular among healthcare staff.

• Even if they know GS1 Barcodes, their opinions are below;
  - If barcoding ratio is not 100%, we cannot use barcodes.
  - We find “Unit of Use” packages without a barcode on them. It is inadequate for our use at point of care.
  - I have no idea what I should do to implement GS1 Barcodes
My request to barcode labelers to overcome such a prevalent view

**Simplification is needed**

- Many kind of barcodes on one package
  - Most of healthcare staff usually don’t know which one is the GS1 Barcode.
  - Multiple barcodes cause confusion.
- Two or more GS1-128 on one package
  - We don’t know which one is the barcode encoded GTIN.
- Hidden barcodes
  - Sometimes a barcode is labeled at the bottom (or back) of medical devices.
  - Hard to find and scan them.
To healthcare providers

✓ In the aging society, the number of healthcare staff is decreasing!

✓ If you are aiming for providing satisfaction for patients and your staff •••••

  ✴ I am sure that GS1 Standards will play a key roll.
  ✴ Do something, do anything... Just make a start!
What GS1 Healthcare should do

- It is necessary to provide much more opportunities for hospital managers in order to inform them how to utilize GS1 Barcodes.

✓ Who should be involved in the planning process
✓ How to change their old business process to new one
✓ How to create their own data-base
✓ How to negotiate with solution providers
✓ etc.
My current activity in order to overcome these obstacles

- A new conference with medical associations called “Japan Medical Traceability Promotion Council (JMTPC)” was organized in 2018.

- JMTPC is conducting pilot projects to establish medical traceability in Japan, through which projects the council tries to provide advices to utilize GS1 barcodes without difficulty for healthcare staff.

- “Medical Traceability” means adequate disclosure of information all over the healthcare products. It not only secures patient’s right-to-know but also clarifies accountability of all stakeholders in the field of healthcare from suppliers to providers.

- The ultimate purpose of JMTPC is to create a platform system as cloud computing to which every stakeholder can access.
Platform system being proposed by JMTPC

By accessing the platform, every stakeholder from manufacturers to patients and their families becomes possible to record and check all medical product data.

Flow of Products

Pharmaceutical Companies & Medical Equipment Makers

Wholesalers

Hospitals

Pharmacies

Patient Safety

Standardized DB

Check

Registration

Check

Registration

Check

Registration

Check

Registration

Platform system for medical traceability (Cloud)

Making the information collectable and extractable throughout the flow of products

In the event of Natural Disaster

Appropriate transport of healthcare products

Urgent support to the damaged area

Prevention of Counterfeit

Alert

Portal

Electronic Prescription

Utilization of Big Data

RFID tags & Bar codes

Traceability

Patient ID Card
My journey with GS1 Healthcare Japan

- As the CEO of NTT Medical Center Tokyo, I started my journey to find the way to improve patient safety as well as medical efficiency.

- And now, as the chairman of GS1 Healthcare Japan, I am still roving the way to promote traceability systems in the field of healthcare.

- I believe, however, the dawn is just around the corner.

The answer is always

My mission is to encourage the usage of GS1 Barcodes
Thank you for your kind attention.

Contact address
ochiai-ind@umin.ac.jp

GS1 Healthcare Japan
http://www.dsri.jp/gshealth/

Japan Medical Traceability Promotion Council (JMTPC)
https://jmtpc.jp/