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 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

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.
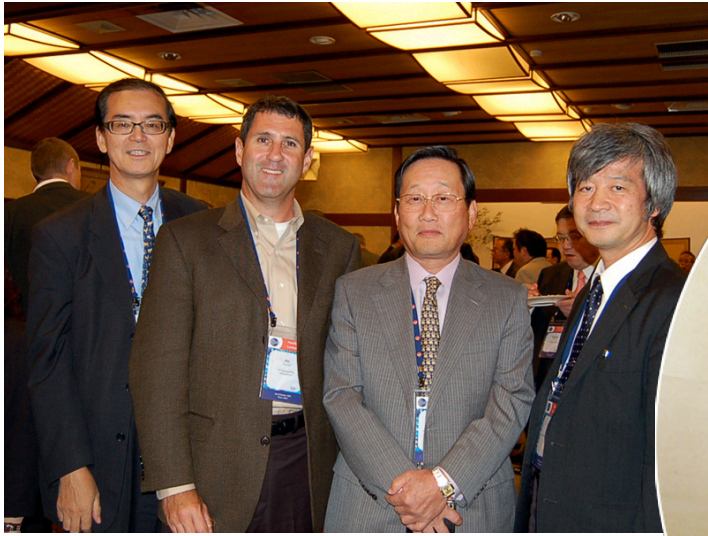
ober 2008

4

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

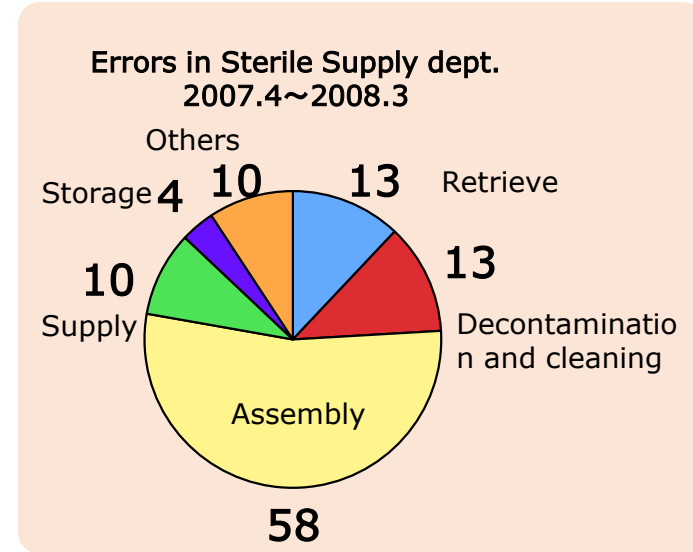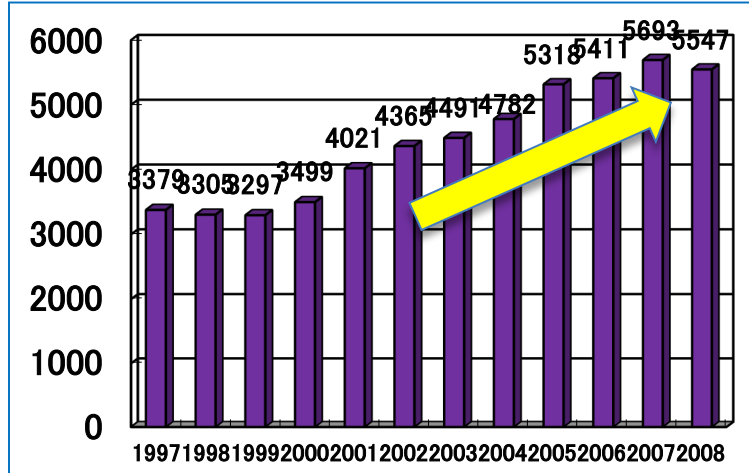# RFID and Bar Code Based Management of Surgical Instruments in a Theater Sterile Supply Unit.

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.

Errors in Sterile Supply dept.
2007.4～2008.3

Others 10
Storage 4
Retrieve 13
Supply 10
Decontamination and cleaning 13
Assembly 58

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

Operation Room

SSU
Sterile Supply Unit

Retrieve

Assortment

Washing / Decontamination

Supply and Storage

Sterilization
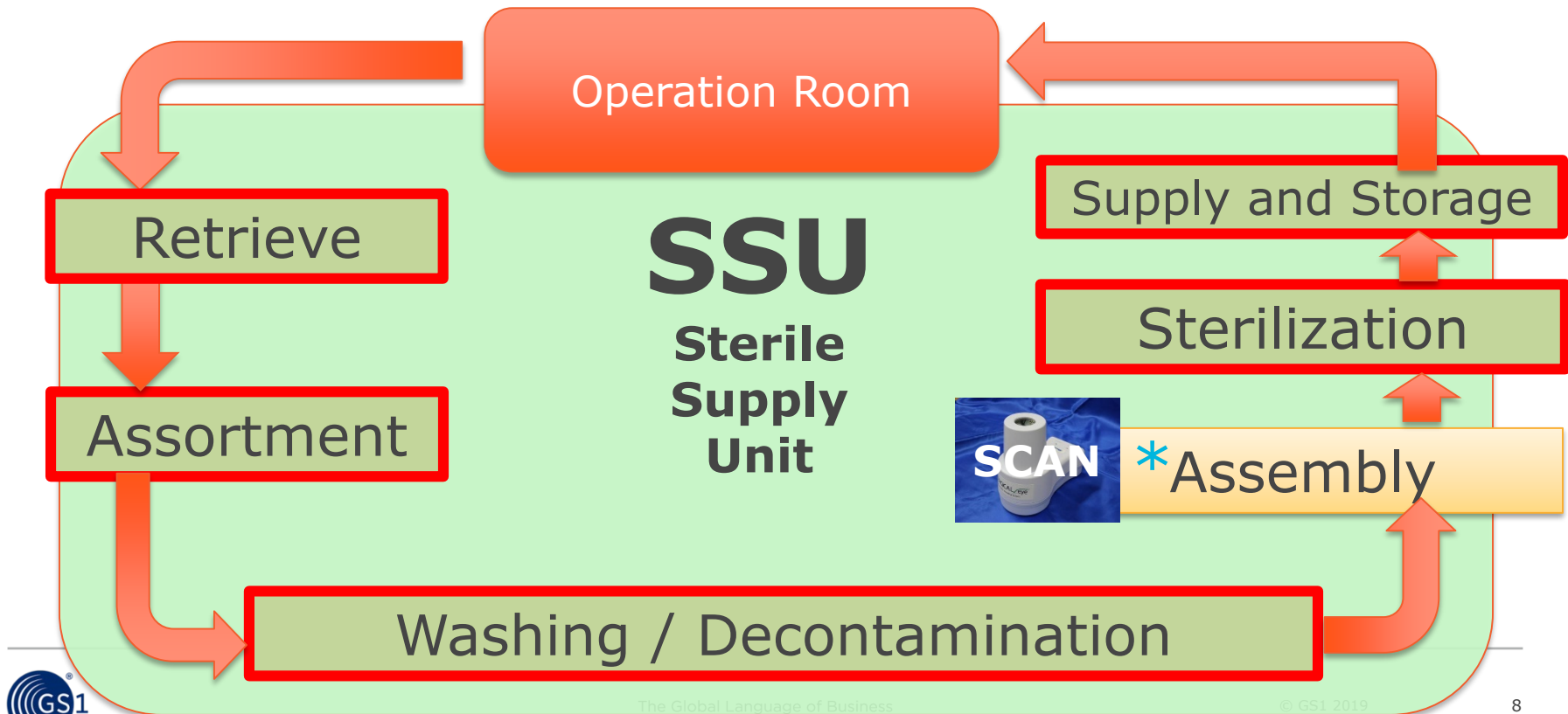
SCAN *Assembly

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.

Pop up the device data

∗

Just scan the barcode

∗

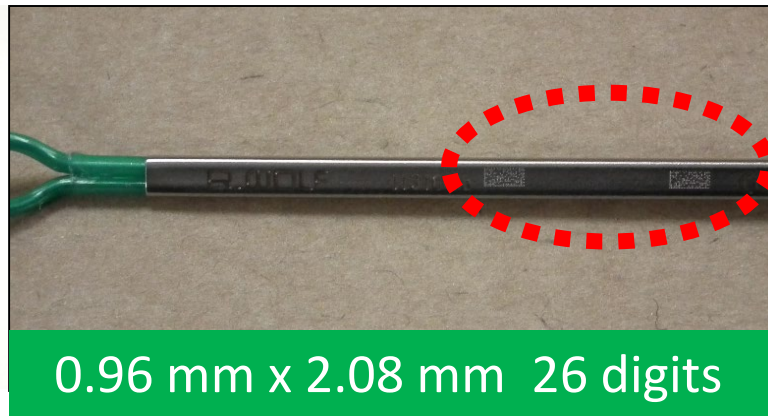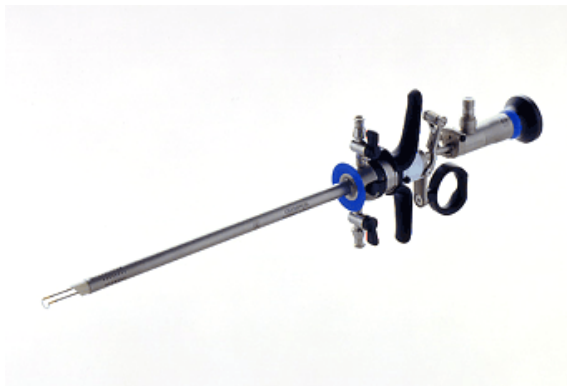| Set Name		1/1
		Surgery Big C
Image		
	Surg. Inst.	Affix
Composition	115	25
No. of Regist.	115	0
No. of Scanned	4	–
Status	Assembling	

GS1 Healthcare
Reference Book
2009/2010

Direct Part Marking on Each Element of Endoscope for Securing Patient Safety and Traceability

0.96 mm x 2.08 mm 26 digits

Chikayuki Ochiai   M.D., D.M.Sc.

Chief Executive, NTT Medical Center Tokyo

New Technology

2007
3.0mm x **3.0**mm

2011
0.95mm x 2.80mm
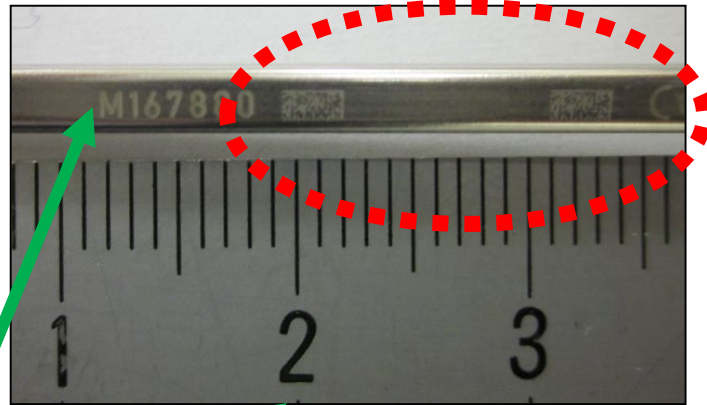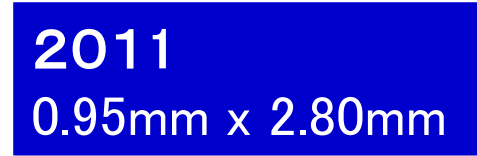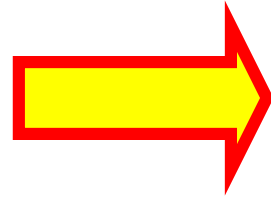
Electrode

Ruler

COMPARISON OF TWO TECHNOLOGIES

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

Work flow of SSU

SCAN

Operation Room

SSU

Sterile Supply Unit

Supply and Storage

Sterilization

*Retrieve divided into two groups

Assortment

SCAN * Assembly

Washing / Decontamination
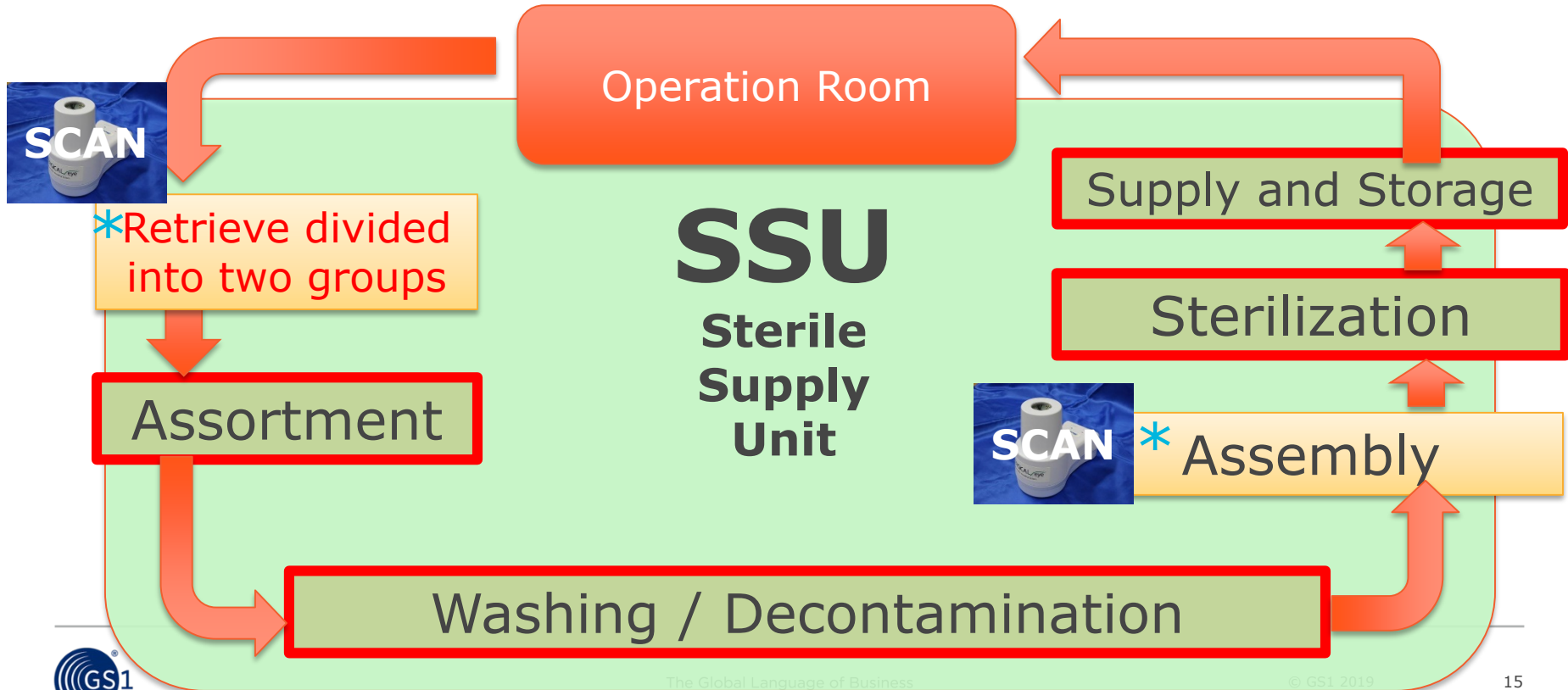
Adoption of GS1 Standards at NTT Medical Center Tokyo

- 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
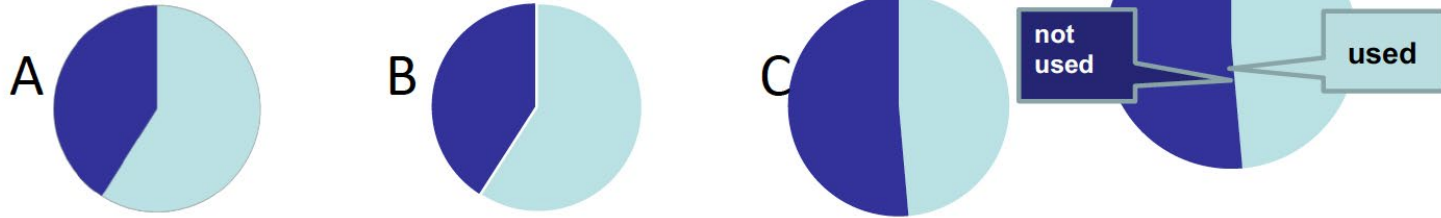
Laparotomy Set (middle) of General Surgery

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.

Average usage level

Used

Not Used

Surgical laparotomy set (large)

47.9%

Total 5,040 pcs

52.1%
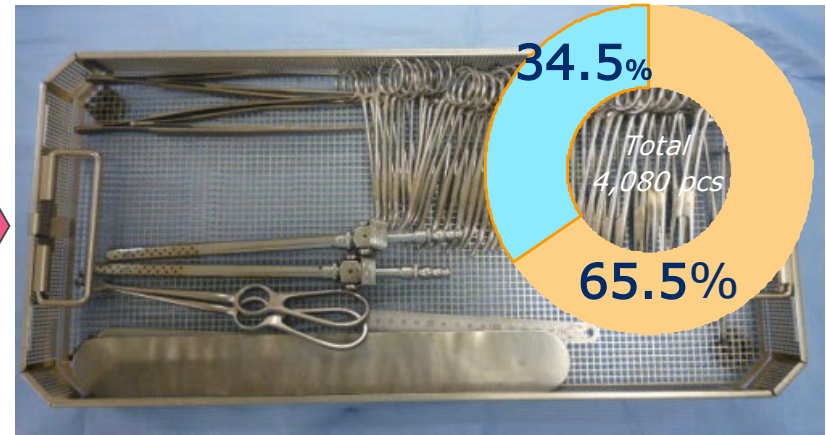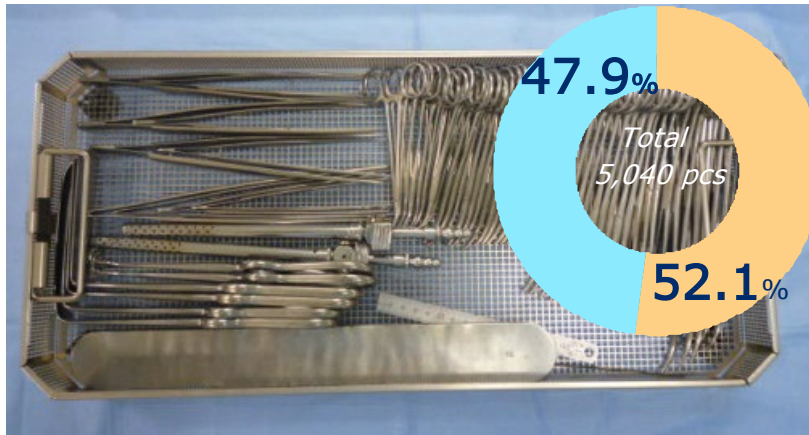
Number of components
126pcs

34.5%

Total 4,080 pcs

65.5%

Number of components
98pcs

* downsized the number of devices 30% or more

Agenda

- Introduction of myself
- Experiences of UDI implementation in NTT Medical Center Tokyo
- Brief Summmery 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 Summery of GS1 Barcodes in Japan

Medical Devices	Prescription Drugs

1980s ‖	Start using JAN (EAN-13)
1999	
2000	Guideline (Industry Group)
2001	Database for All Healthcare Products started by MEDIS
	(MEDIS: Medical Information System Development Center)
2006	Revised Guideline (JFMDA) in 2006
2008	
2009	**MHLW issued "Guideline for Barcode Labeling of Medical Devices" in March 2008**
2010	
2016	

Prescription Drugs column:

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

Revised in August 2016

The National UDI conference was held from 2016 to 2018

2018

2019 Japan Medical Traceability Promotion Council was established in 2018

Barcoding ratio to prescription drugs and medical devices

Prescription Drugs	Primary Packages	Sales Packages
	100%	100%

Medical Devices	Primary Packages	Sales Packages
	84.1%	97.7%

* Not yet 100% but almost 100%

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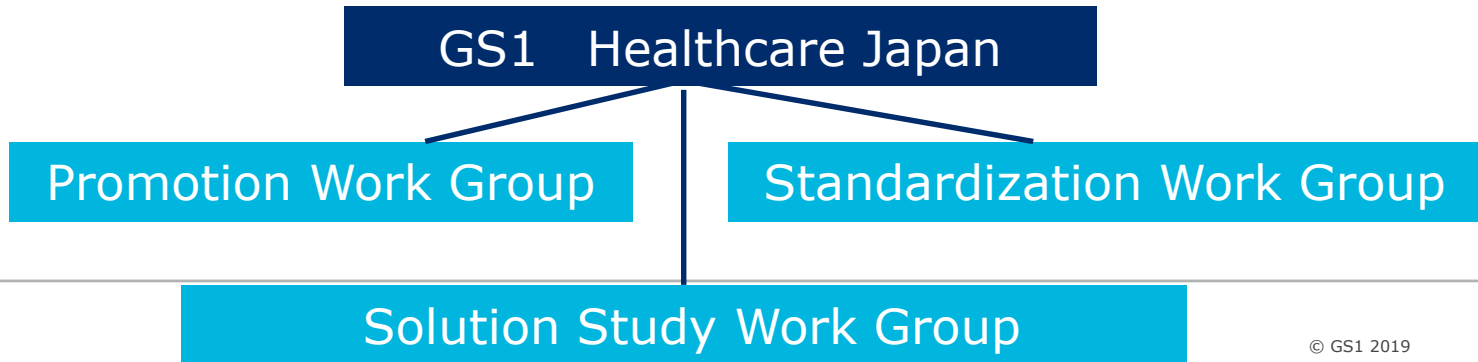
Agenda

- 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

GS1 Japan
Healthcare
The Global Language of Business

医療機器等への
ダイレクトマーキング運用ガイド
Ver. 1.0

READY FOR
UDI!

GS1ヘルスケアジャパン協議会

GS1 Japan

The Global Language of Business

医療機器等のための
UDI対応バーコード表示ガイド
2017年6月 第2版

READY FOR
UDI!

一般財団法人 流通システム開発センター
The Distribution Systems Research Institute (DSRI)

GS1 Japan
Healthcare
The Global Language of Business

医療機器本体へのバーコード表示
－活用メリットと表示位置の考え方－
Ver. 1.0

UDI

GS1ヘルスケアジャパン協議会

GS1 Japan ｜ GS1 ヘルスケアジャパン協議会

Simple Scan
安全で効率的な医療の実現のために

医薬品・医療機器等に表示された GS1 標準バーコード を Scan して読み取ることで
取り間違いや誤使用の防止、トレーサビリティの確保、医療従事者の負担軽減、過剰な医療機器の
利用とコスト削減など様々な効果が得られます。

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

Conclusion by the national committee of the MHLW

Dec. 25, 2018

* **Opinions about pharmaceuticals and medical device policy**

Tentative translation

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.

Published on Dec. 25 2018
By The Committee on Pharmaceuticals and Medical Devices
the Health Science Council of MHWL

● 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	Prescription Drugs

2006
2008
2009
2010
2016

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

*

2019

**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 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

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 GSl 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.
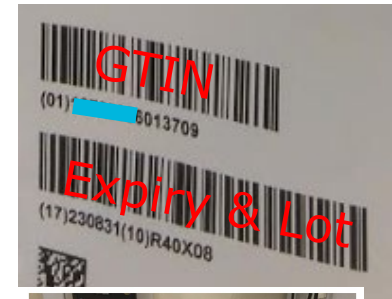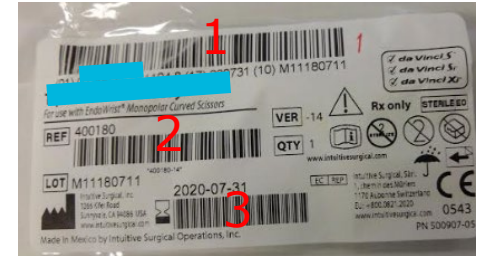
To healthcare providers

- ✓ 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

医療トレーサビリティ推進協議会
Japan Medical Traceability Promotion Council

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

Patient Safety

Pharmaceutical Companies & Medical Equipment Makers

Wholesalers

Hospitals

Docto r Patie nt

Pharmacies

Pharmaci st Patien

Electronic Medical Diary

In the event of Natural Disaster

Appropriate transport of healthcare products

Urgent support to the damaged area

check registration check registration check registration check registration

Standardized DB

Platform system for medical traceability（Cloud）

Making the information collectable and extractable throughout the flow of products

Alert

Portal

Electronic Prescription

Utilization of Big Data

Prevention of Counterfeit

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

GS1®

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/