The Global Language of Business

An integrated sterilisation management system for traceability and patient safety, using GS1 standards at Fukui Hospital

GS1 Healthcare Webinar

Mr Shingo Kasamatsu,
Department of Medical Informatics, University of Fukui Hospital, Fukui, Japan

September 26, 2019

Welcome and thank you for attending!

- Welcome to our September 2019 webinar.

  Thank you to our guest speaker Mr Shingo Kasamatsu, Department of Medical Informatics, University of Fukui Hospital, Fukui, Japan
- Some housekeeping for today:
  - All attendees will be in listening-only mode
  - If you have questions during the presentation, please type them into the questions area and these will be monitored then answered at the end of the call
- After the webinar:
  - Within a week, the recording will be posted to: http://www.gs1.org/healthcare/hpac_webinars
  - All previous webinars are also posted to this location, so please feel free to use this resource and share the link

GS1 Healthcare Webinars

Forum for thought leaders and adopters of GS1 Healthcare Standards from the global clinical provider environment. The final goal is to improve patient safety, cost efficiency and staff productivity through implementation of GS1 standards.

A forum for sharing and discussion

- The practical realities of implementation of GS1 Standards in the care giving environment in regards to the impact on clinical care and patient interaction

Identification of projects and case studies

- Supporting the adoption of GS1 Standards in healthcare providers and retail pharmacies
- For publication, presentation and sharing

A source of expertise and advice

- To those involved in GS1 standards development, the wider Healthcare stakeholder community and senior executives/decision-makers to gain their buy-in and support for implementation of GS1 Standards

Specific GS1 Healthcare Activities

Webinars

- Monthly webinars open to all stakeholders interested in learning about GS1 standards implementation in the care giving environment.
- http://www.gs1.org/healthcare/hpac_webinars

Awards

- Twice per year
- Provider Implementation Best Case Study Award
- Provider Recognition Award
- The prize: travel & accommodation to attend the next GS1 Healthcare conference
- http://www.gs1.org/healthcare/hpac

GS1 Healthcare also holds two global conferences per year.
The next conference will be in Delhi, India from November 5–7, 2019, with significant Healthcare Provider participation on the agenda.

Presenting today

Mr. Shingo Kasamatsu

- Technical Officer of Faculty of Medical Science, University of Fukui.
- Introduced GS1 standards into the University of Fukui Hospital.
- Spreads the adoption of GS1 standards in the medical field.

UNIVERSITY OF FUKUI

An integrated sterilization management system for traceability and patient safety, using GS1 standards at Fukui Hospital

Shingo Kasamatsu,
Department of Medical Informatics,
University of Fukui Hospital,
Fukui, Japan

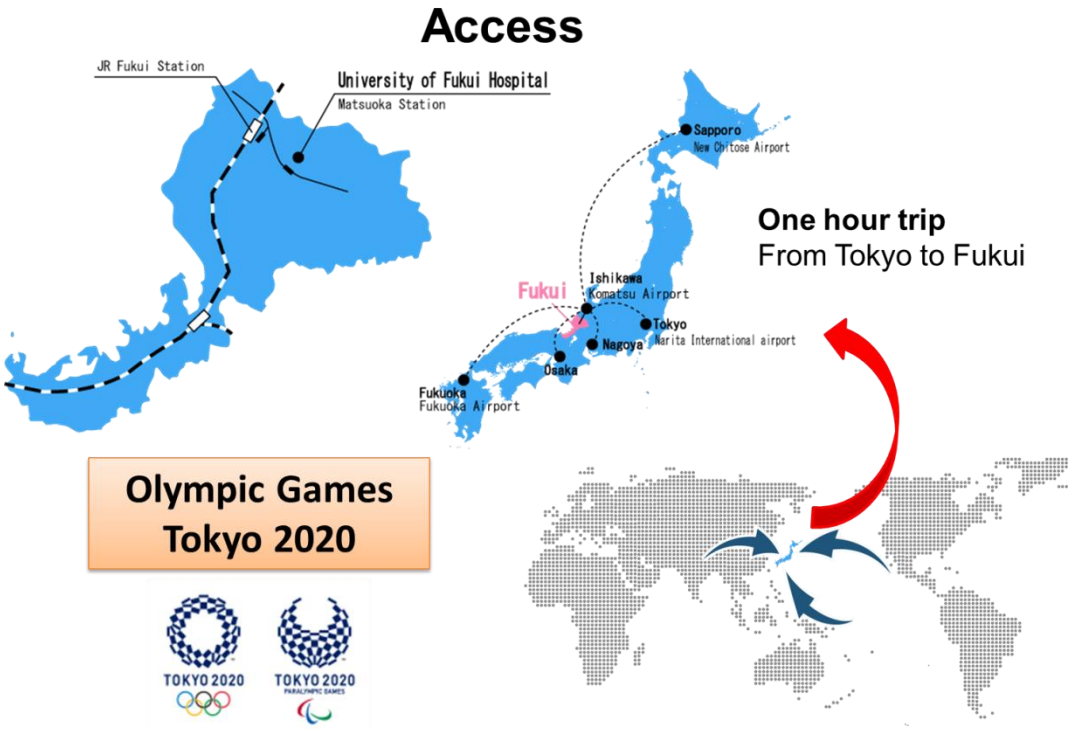
University of Fukui Hospital

Summary of the hospital

Name : University of Fukui Hospital
Date of opening : October 1, 1983
Address: Yoshida-gun, Fukui 910-1193, Japan

6000 surgeries/y, 10 operating theaters, 600 beds

Access



Fast Facts on University of Fukui Hospital's CSSD team

Annual Performance and Production	2018
CSSD FTEs	**11 FTEs** (1 stand-byes)
Percent of FTEs Certified (*1)	**58.3% (7/12)**
Outpatient procedures	**330,653**
Inpatient volume	**195,378**
Number of Acute Care volume	**17,270**
Baby deliveries	**259**

**1: An average CSSD did not even reach 10% in Japan.*

Fast Facts on University of Fukui Hospital's CSSD team

Other CSSD year-to-date averages	2018
Percentage of sets complete before 7 a.m.	100.0%
Inventory Stock outs	0%
Average instruments/singles processed per week	10,000
Average Case carts processed per week	126
Average Loaners sets per a week	80
Average total department hours worked per week	414 hrs.
Average Overtime hours per week	4.7 hrs.

Summary items are total of CSSD team

Annual Performance and Production

Annual Performance and Production	2013	2014	2015	2016
Number of surgical cases	4,911	5,029	5,025	5,426
GS1 controlled Number of sets/singles assembled/processed	*	4,023	21,872	31,659
Number of case carts assembled/processed	*	3,564	5,462	5,805
GS1 controlled instruments (16,906)*1	*	10,000	16,766	27,745

*1: Initial estimated number of instruments

Background

1. *In 2014, Fukui University Hospital was rebuilding the hospital.*

2. *It was decided to update the CSSD in line with the renewal of the surgery department.*

3. *The practical Guidelines of Surgical medicine was announced in 2009 by the Japanese Association for Operating Technology.*

4. *CSSD decided to ensure traceability of surgical instruments in accordance with these guidelines.*

Why Fukui hospital chose to use GS1 standards

Fukui Hospital needed to ensure the safe use and traceability of instruments used in surgical procedures.

- *The hospital was experiencing an error rate of 3,054 ppm when counting instruments, which introduced risks associated with leaving surgical instruments in a patient's body.*
- *Furthermore, Fukui Hospital wanted to improve efficiencies in its operating rooms and inventory processes.*
- *The hospital's Surgical Center and Central Sterilization department decided to research the concept of direct "marking" instruments with unique identifiers (UDIs) encoded in barcodes.*

Why Fukui hospital chose to use GS1 standards

The Japan Association of Medical Devices Industries (JAMDI) released the Guideline for Marking for Two Dimensional Symbol on Steel Instruments in 2006.

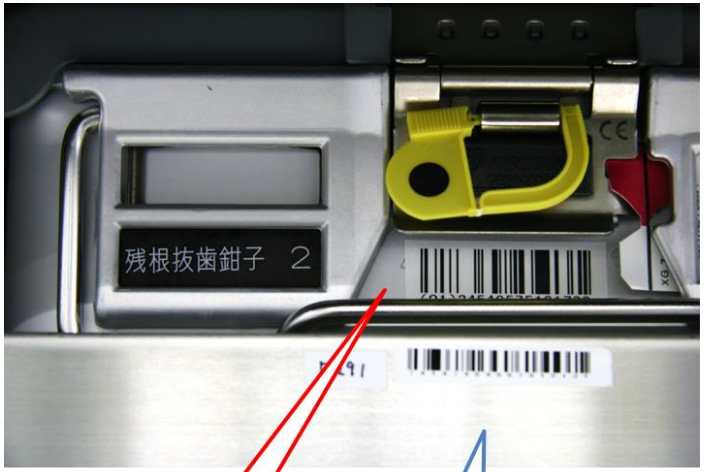
This guideline defines the need for direct marking and using GS1 standards for symbol engraving, recommending the use of GS1 Global Trade Item Numbers plus serial numbers, and direct marking with GS1 DataMatrix barcodes.

Why Fukui hospital chose to use GS1 standards

- *Outside Japan, the International Medical Device Regulators Forum (IMDRF) and the U.S. Food and Drug Administration (FDA) issued the UDI Guidance: Unique Device Identification of Medical Devices and the UDI Final Rules, respectively, in 2013.*
- *Both require the identification of a medical device using Unique Device Identification (UDI).*

For surgical instruments, UDI direct marking is expected to improve patient's safety and optimize patient care.

GIAI, GTIN and GLN

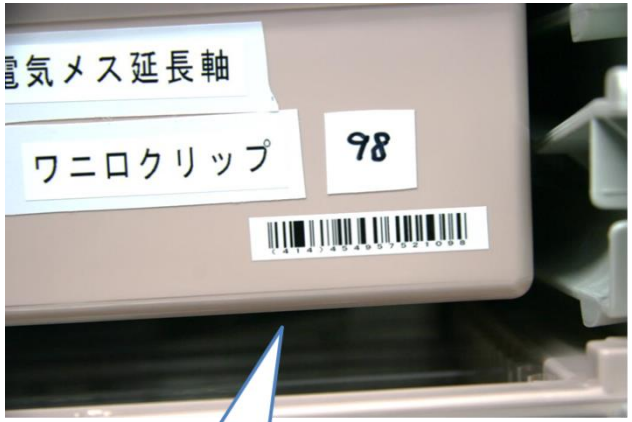


GTIN

GLN

GIAI

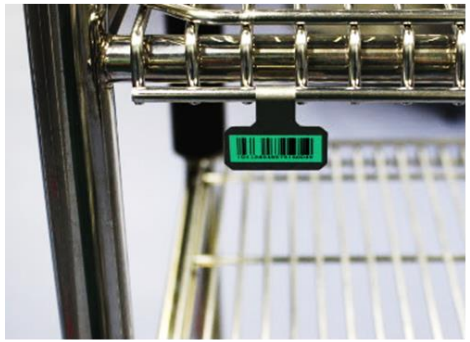
GLN



Rack number

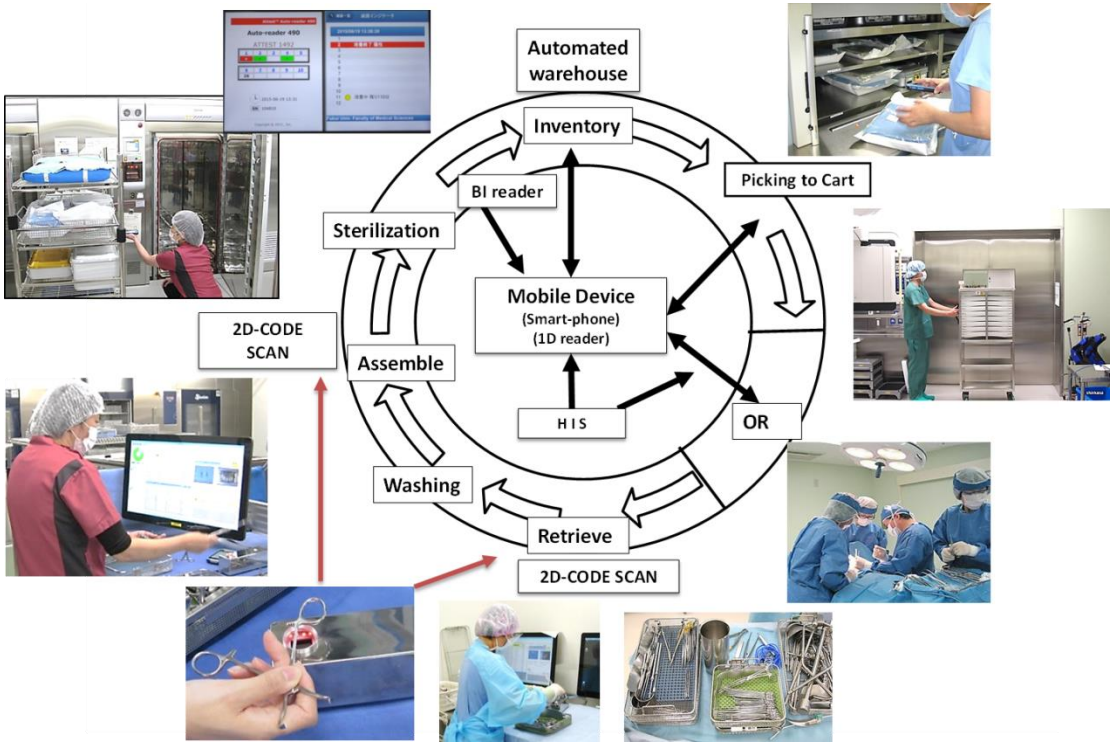
OR number

GS1 Everywhere



GS1 Everywhere

CSSD Work flow



Virtual Tour the CSSD

Engraving Datamatrix

Engraving Datamatrix

Virtual Tour the CSSD

washing&assemble

washing&assemble

Virtual Tour the CSSD

inspection&assemble

inspection&assemble

Virtual Tour the CSSD

sterilization&QC

sterilization&QC

Virtual Tour the CSSD

Picking

Picking

Virtual Tour the CSSD

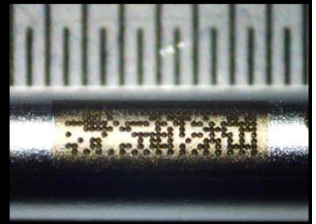
after surgery count

after surgery count

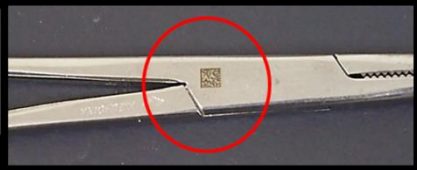
Direct Parts Marking (DPM) in CSSD

- Ideal for fine DPM of small steel instruments
- Suitable for installation in clean areas
- Can be engraved up to about Φ2mm
- Compatible with complex 3D shapes
- High power for engraving to DPM (DataMatrix)

Laser Engraving Technologies



1.2 ×5mm GS1-Datamatrix



2.6 ×2.6mm GS1-Datamatrix

DPM reader

- Optimized for fine DPM of small steel instruments
- Medical grade stainless steel exterior
- Low profile Height to approx. 60mm
- Less than 1/3 the height of other products
- Fully waterproof and can be washed
- 10 DPM-Reader (8 Assembly, 2 Retrieve)

We can assemble while sitting!

Establishment of DPM method for steel instruments

Method review:

- Laser engraving was selected from methods such as laser engraving, dot peen, RFID, and patch seal.
- The purpose was to choose a method that has been successful in long-term use. (i.e. AESCULAP®).
- Dot peen has been used in the past in the aircraft and automobile industries, but a micro size of 3mm or less was not suitable.
- RF-ID cannot be applied to small instruments because it requires embedding and welding.

Preparation before installation

- A system was used to read and confirm the GS1 code when assembling the surgical set.
- Individual identification of all surgical instruments by GS1 Hospital-owned instruments are managed by GIAI.
- Existing instruments were laser engraved with GS1-Datamatrix one by one.

Preparation before installation

- For newly purchased products, we selected equipment that was previously engraved with a GTIN with a serial number.
- Each instrument was laser-engraved with GS1-Datamatrix.
- A serial number was assigned to the surgical container with GIAI.
- A serial number was also given to the basket in the container.
- Surgical carts are also numbered with GIAI.

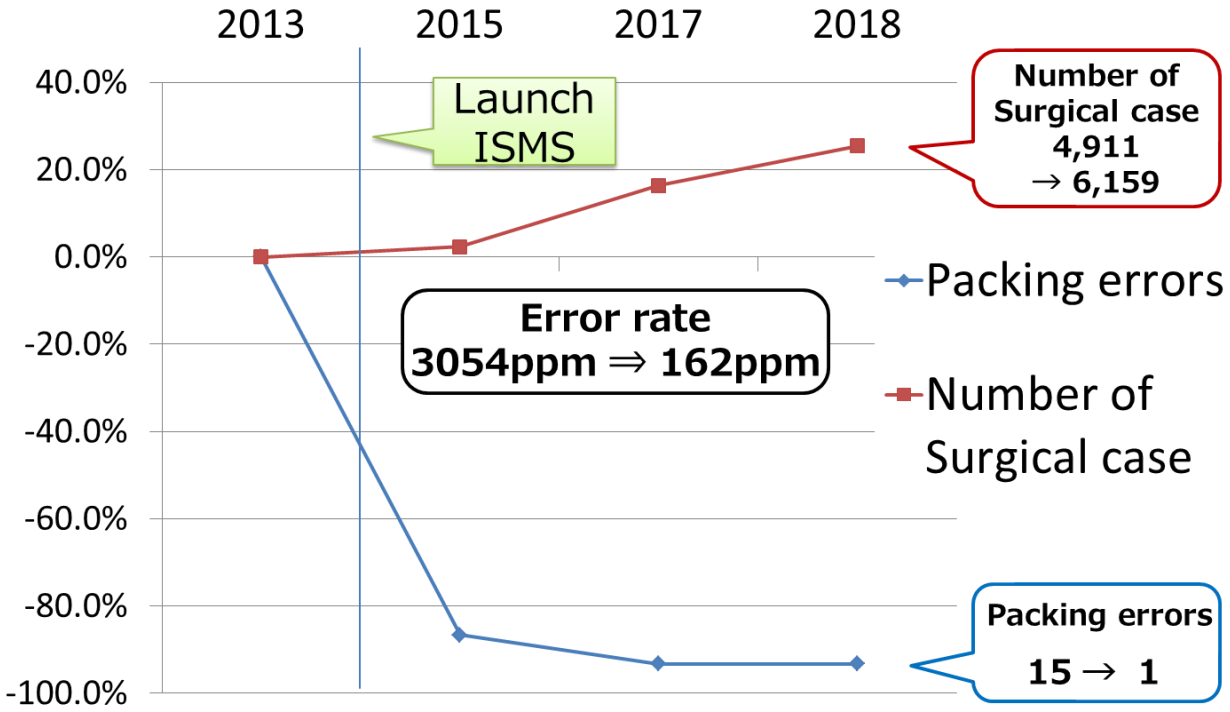
How the error rate with surgical instruments reduced

	# of errors	# of surgeries per year	Error rate (ppm)
2013: Before ISMS	**15**	**4,911**	**3,054**
2015: After initial implementation	**2**	**5,025**	**398**
2017: After full implementation	**1**	**5,871**	**175**
2018: Stable operation	**1**	**6,159**	**162**

2013-2018 Prevention of errors in counting

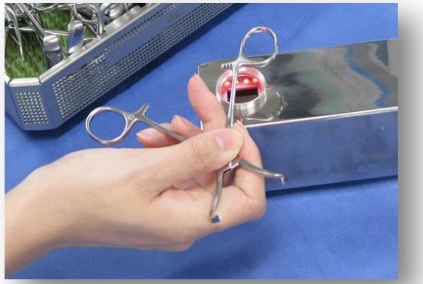
Source: University of Fukui Hospital Surgical Center

How the error rate with surgical instruments reduced

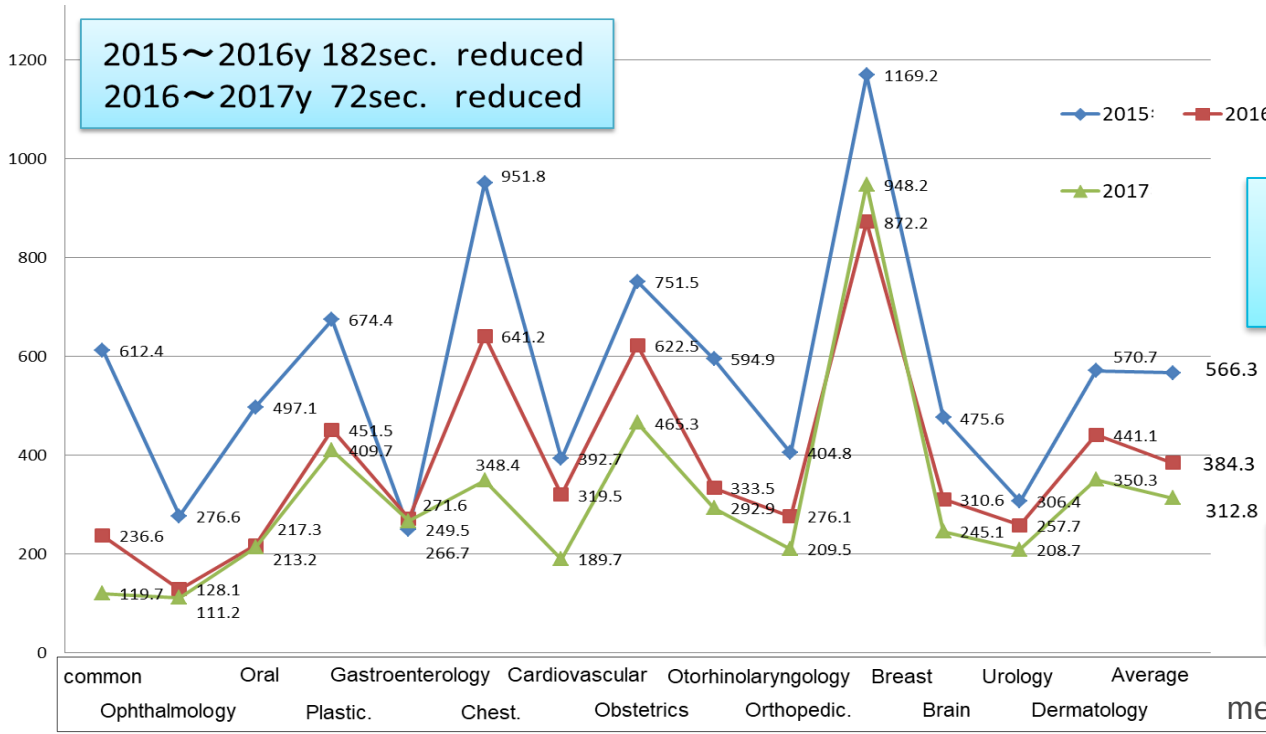


Reduce Assembly time ~ but keep Inspection reliability ~

- ✓ Read the GS1 code each instruments
- ✓ Check for residual contamination, good movement and sharpness.
- ✓ After all instruments have been checked, the set assembly is complete



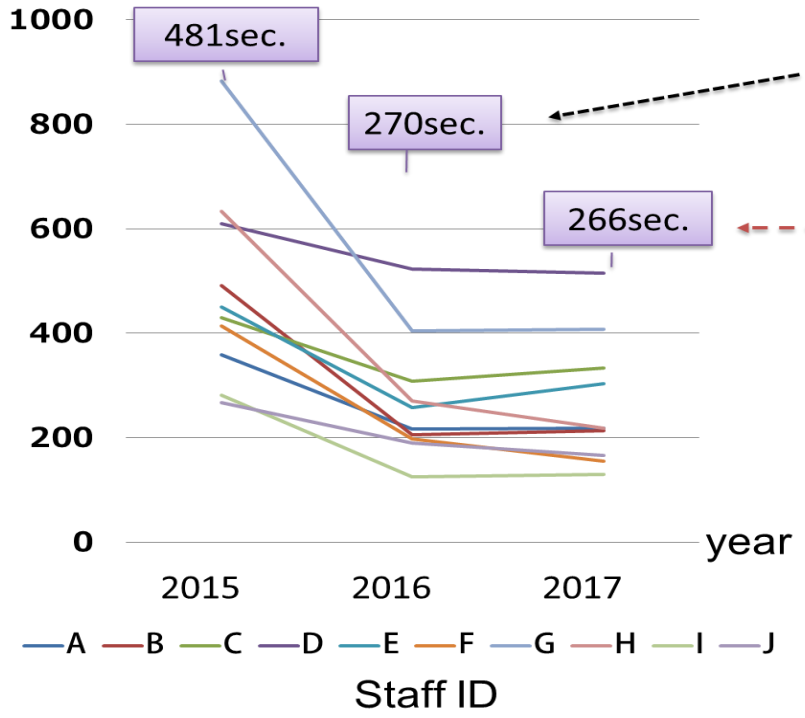
Average assembly time per Container/Set by medical specialty



The container list was reviewed using statistical methods, the number of extra instruments has decreased.

The number of scanning for marked small instruments increased

Average assembly time for each staff ID



- Improve the method for that work and skill
- As system instauration progressed, the set assembly time was reduced by an average of 215 seconds

ISMS can check the inventory assets Jan. 11,2018

- Solution

  Implementation of GS1 Standards

  ✓ GTIN,GIAI,GLN

- Results

  Number of instruments 31,078pcs.(100%)

  ✓ In use : 24,307 (78.2%)

  ✓ Stock: 6,571 (21.1%)

  ✓ Under repair : 200 (0.64%)

Types of assemble sets
1,764

Types of instruments
4,027

- In 2018,

We started managing the number of devices in wards / outpatients.

Reduce cost of inventory

When New order

4-Same Endoscope

It was enough to purchase one Endoscope.

Reduced urology inventory.

Same functional Device but different Manufacturer

Reduce inventory cost 10,000€

medical specialty	Device name	Aries 運用開始	使用回数	準備回数	未使用	使用率（144日換算）	運用期間
泌 Uro	TURis1	2015/2/20	93	111	18	28.70%	2年3ヶ月
泌 Uro	TURis2	2015/2/23	66	83	17	20.30%	2年3ヶ月
泌 Uro	TURis3	2015/2/20	87	114	27	26.85%	2年3ヶ月
泌 Uro	TURis4	2015/4/20	76	90	14	25.33%	2年1ヶ月
泌 Urology	TUR1 Endoscope1	2015/2/23	6	53	47	1.85%	2年3ヶ月
泌 Urology	TUR2 Endoscope2	2015/2/24	5	56	51	1.54%	2年3ヶ月
泌 Urology	TUR3 Endoscope3	なし	0	0	0	0%	0
泌 Urology	TUR4 Endoscope4	2015/2/23	1	53	52	0.31%	2年3ヶ月
Gyneco	NE Resectoscope1	2015/10/22	45	60	15	19.73%	1年7ヶ月
Gyneco	Resectoscope2	2015/12/25	14	23	9	6.86%	1年5ケ月

Operational results on retrieve

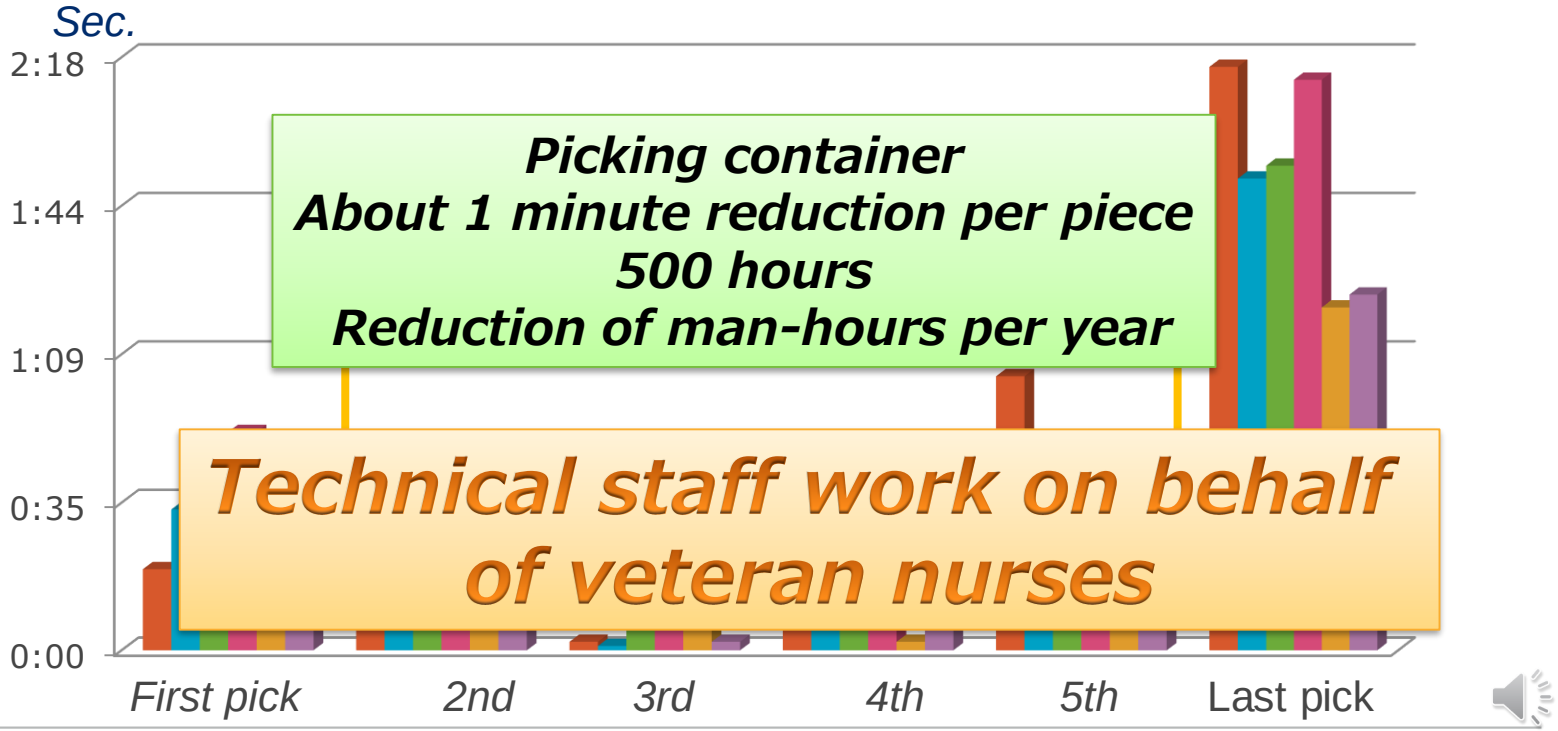
500,000 scan/year

Operational results in Assemble

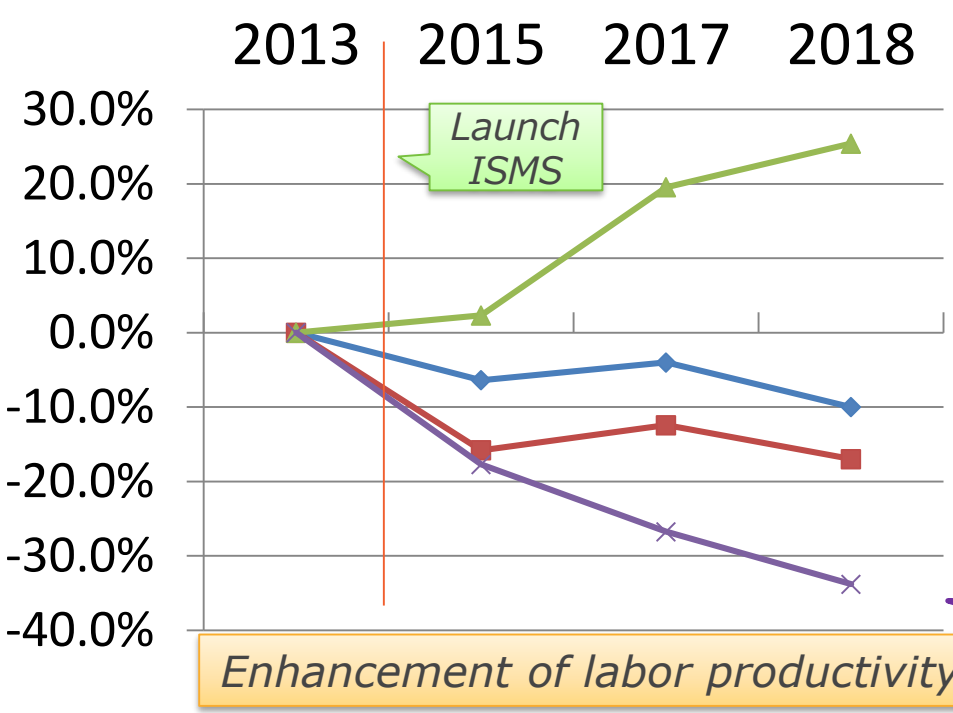
500,000 Scan/year

Operational results on Picking

Picking cycle time becomes short



Cost-benefit analysis



hours worked

Labor costs

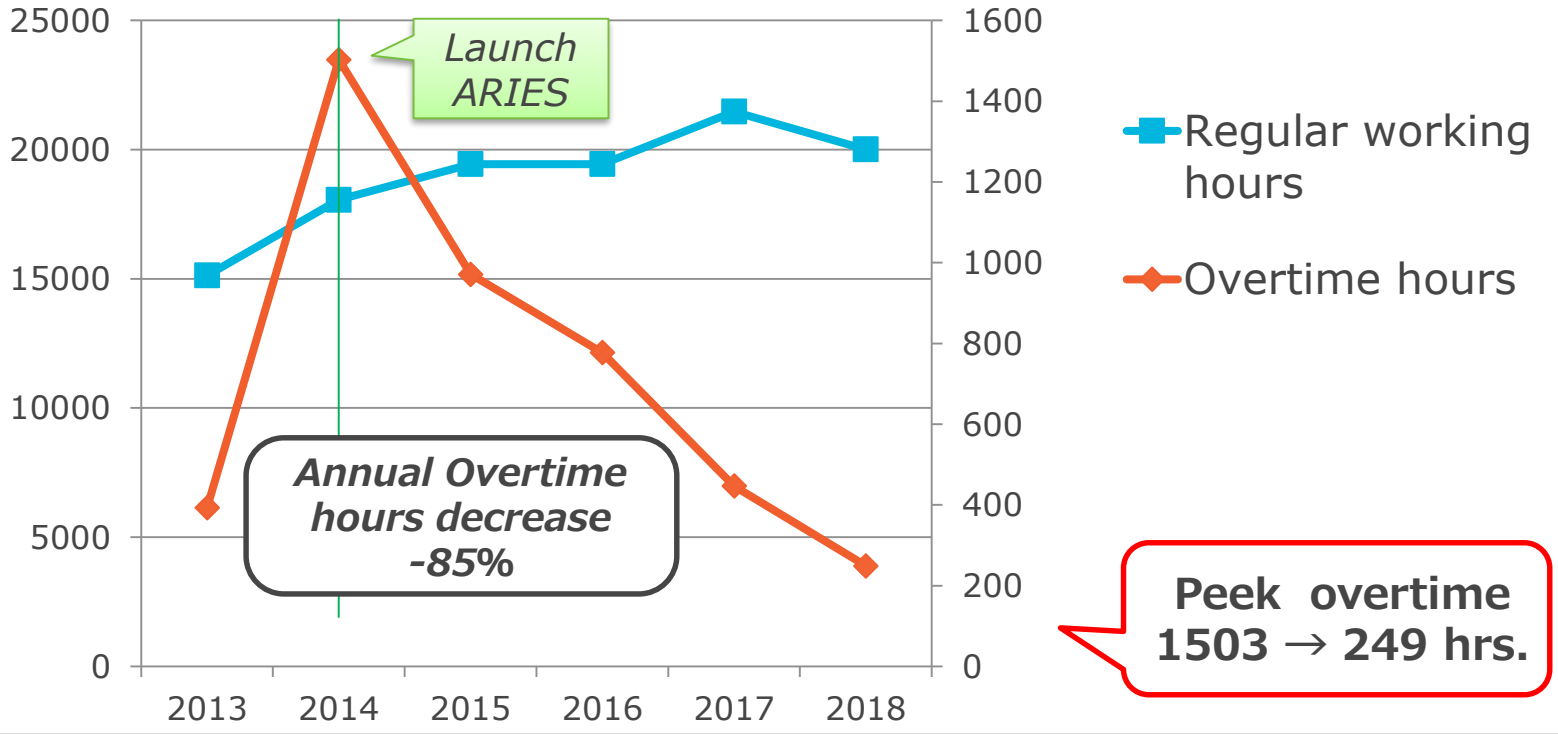
Surgical case

Unit costs

Labor Costs per Surgical Case -34%

$ 145.50 → $ 97.36

Work style change by improvement of labor productivity



Hard ROI

Quantitatively evaluate

Cost reduction / efficiency

item	Annual reduction*1	Reduction rate
Work cost*2	56.7 man-hours	-33.8%
Labor cost reduction*2	267,000₫	-33.8%
Overtime hours*3	1,254hrs.	-85.0%
Assembly error loss*4	18,600₫	-93.9%

Increase in revenue and customers

item	Increased in period	Rate of increase
Number of Surgery*1	1,248	25.4%
revenue*1	31,700,000₫	25.9%

**1 Comparison with 2013 (Correction for Number of surgical case)*

**2 Working days 244days, 7.5hrs,/day*

**3 Difference between 2014 and 2018 CSSD division overtimes*

**4 If a device assembly error is found in the operating room, the delay loss is converted into an amount.*

Soft ROI

- UDI has made it possible to centrally manage instruments.
- Inventory instruments can be used effectively.
- The low-performance instrument was replaced with another set by referring to the data on the use of the surgical instrument set.
- It led to the reduction of unnecessary expenses.

- No more rushing to reprocess a few instrument sets.
- The instrument can be used with sufficient maintenance.
- It is possible to provide safe surgical instruments.

Drive New Generation

The near future of CSSD

Thanks so much

GS1 Healthcare webinar:
Questions and contact details

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