The Global Language of Business

# Panel: UDI – changes and benefits in hospitals

36th GS1 Healthcare conference, New Delhi, India

Chaired by Dr. Hajo Reissmann, Head of Medical Supplies Controlling, University Hospital Schleswig-Holstein, Germany
Hennie Mulder, Registered Nurse, Maxima Medical Center, Netherlands
Shingo Kasamatsu, Technical Officer of the Faculty of Medical Science, University of Fukui Hospital, Japan
7 November 2019

## Hennie Mulder

Registered Nurse,
Maxima Medical Center,
Netherlands

Hennie Mulder is a registered nurse with broad experience in hospitals. Hennie is a great ambassador for the implementation of GS1 in hospitals and successfully chairs the GS1 Netherlands healthcare group on traceability. She has established a sound reputation as Operating Room nurse and in leadership.

Since many years, she is Vice-president and treasurer of the Dutch Organization for Perioperative Care (LVO) and editor of OKOperationeel/LVO Journal. Since 1997, she works in the Operating Room and as Quality & Safety coordinator in Maxima Medical Centre, Veldhoven, the Netherlands.


Shingo Kasamatsu

Technical Officer of Faculty of Medical Science,
University of Fukui


After completing the doctoral course at the University of Fukui, he engaged in research on medical information at the School of Medicine.

A person who launched an integrated sterilization management system.

Spreads the adoption of GS1 standards in the medical field.


*E-mail: bhsk@u-fukui.ac.jp*

*LinkedIn: Shin Kasa*

Dr Hajo Reissmann

Head of Medical Supplies Controlling, University Hospital Schleswig-Holstein, Germany

Physician, specialized in Anesthesia and Intensive Care, 20 years of clinical an scientific work in the area. Master of Business Administration in Healthcare. More than 10 years ago migration to a position in hospital administration, i.e. controlling expenditures for medical supplies. 10 years of activities around standardization with GS1. Work in projects promoting AIDC at the point of care.

# Our agenda

- 15 min presentation – H. Mulder
- 15 min presentation – S. Kasamatsu
- 10 min comments – H. Reissmann
- 15 min Q & A from the audience
- 5 min close – H. Reissmann

**Please be ready with your questions!**

The Global Language of Business

# The Unique Device Identifier : For National Implant Registry and OR-nurse scanning

GS1 Healthcare Conference
7 November 2019, New Delhi, India

Hennie Mulder, RN OR nurse

The Global Language of Business


# Maxima Medical Centre and Ministry of Defense
# No conflict with any commercial interest

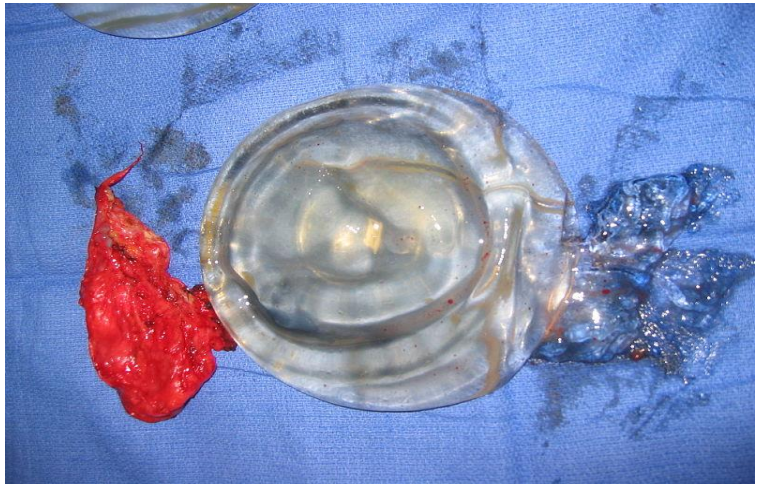
# The new Operating Rooms

# Why a National Implant Registry - L.I.R

## Cause

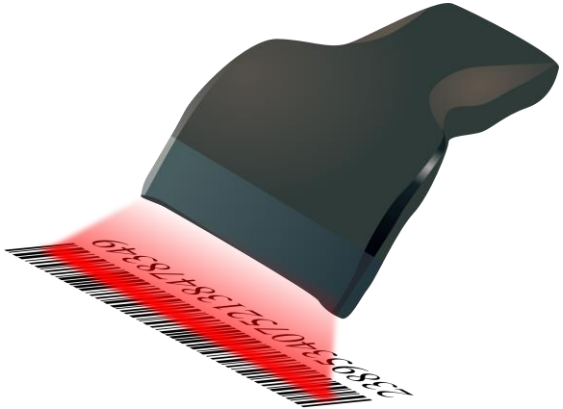
*Patiënt safety and traceability*

*Implementation by 1-1-2020*

# In line with EU MDR

Dutch Agreements on unique coding of medical devices supported by industry, healthcare providers and the ministry of health (ADC)



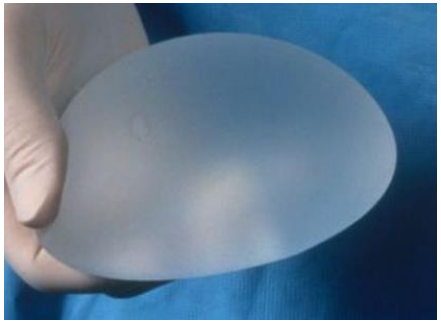
# National implant registry

- Barcode scanning of medical devices

- Facilitates the work of the OR nurse

**&**

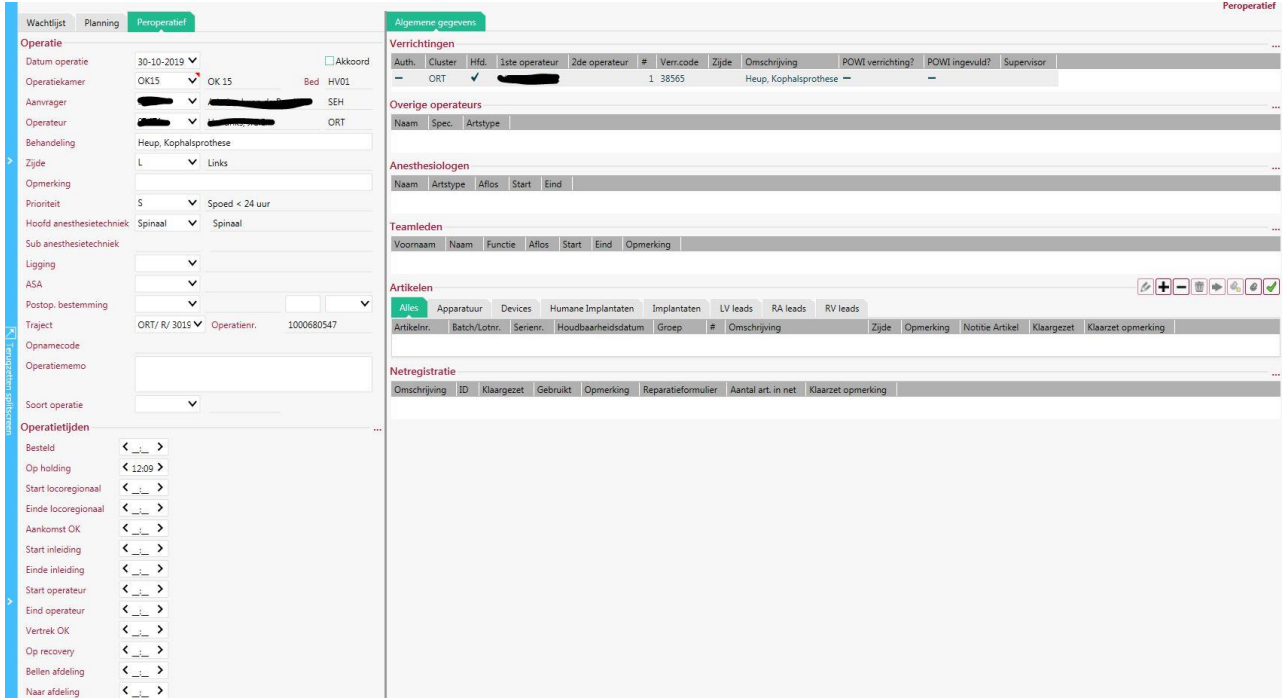
- Traceability within the hospitals
- Direct uploading in implant registry
- (Global) product traceability

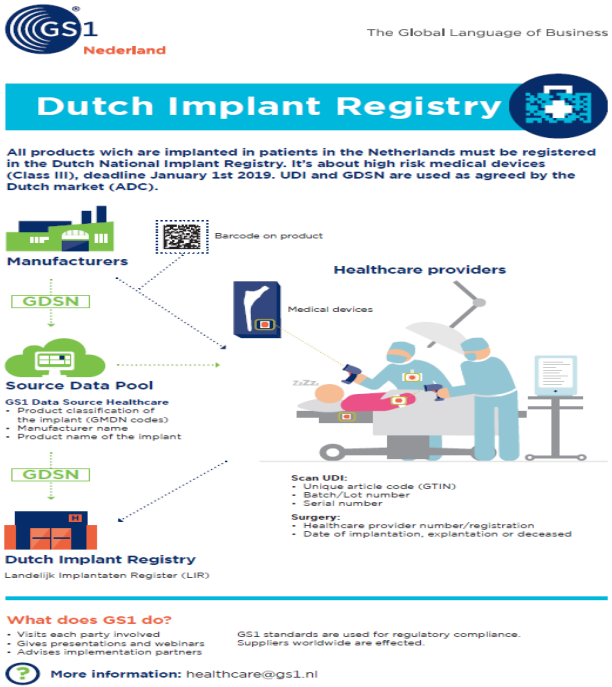


# Why is it so important to have a good barcode

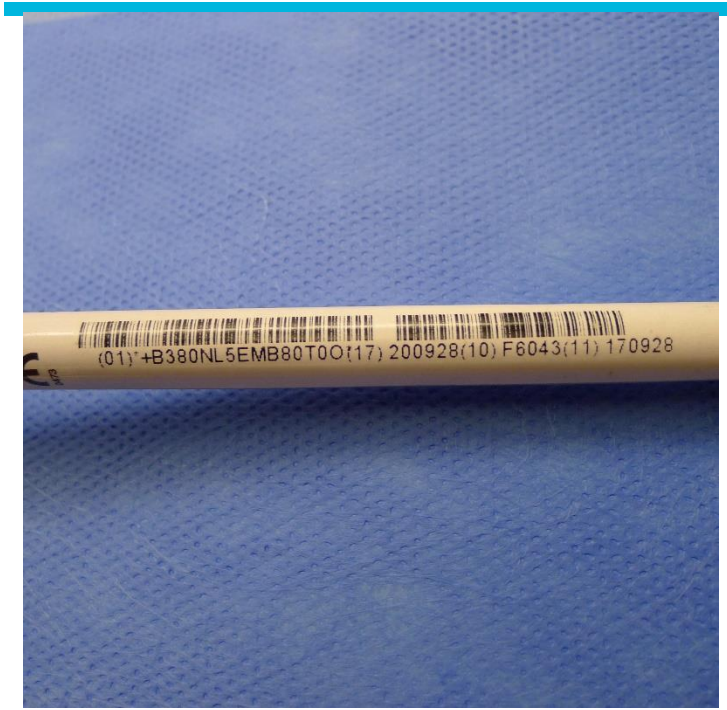

# Scanning is easy but?

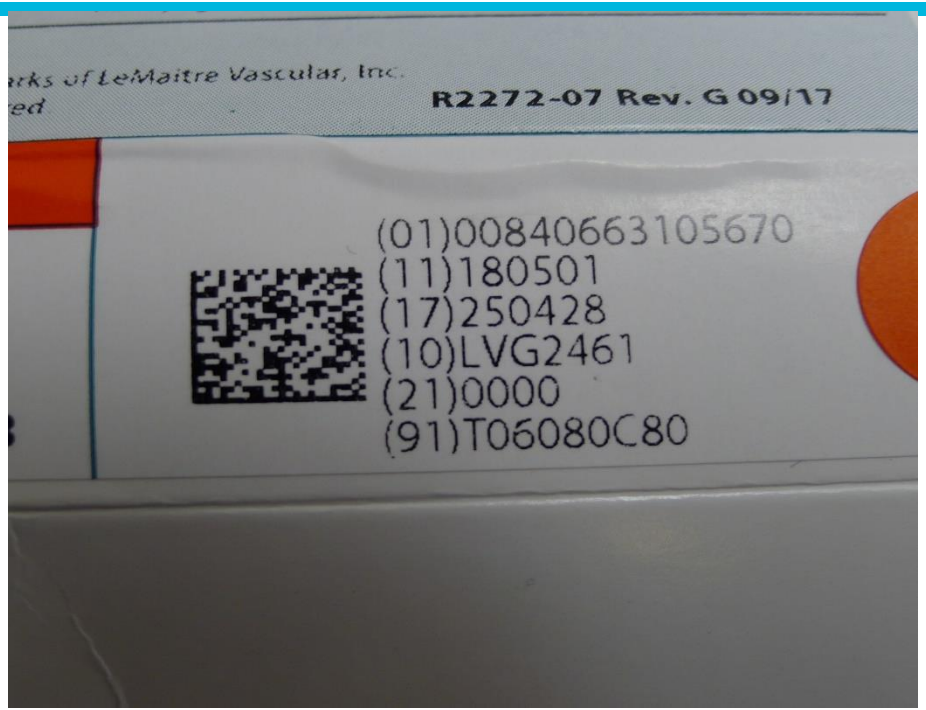

# EHR


Wachtlijst
Planning
Peroperatief
Operatie
Datum operatie
30-10-2019
Akkoord
Operatiekamer
OK15
OK 15
Bed
HV01
Aanvrager
SEH
Operateur
ORT
Behandeling
Heup, Kophalsprothese
Zijde
L
Links
Opmerking
Prioriteit
S
Spoed < 24 uur
Hoofd anesthesietechniek
Spinaal
Spinaal
Sub anesthesietechniek
Ligging
ASA
Postop. bestemming
Traject
ORT/ R/ 3015
Operatienr.
1000680547
Opnamecode
Operatiememo
Soort operatie
Operatietijden
Besteld
Op holding
12:09
Start locoregionaal
Einde locoregionaal
Aankomst OK
Start inleiding
Einde inleiding
Start operateur
Eind operateur
Vertrek OK
Op recovery
Bellen afdeling
Naar afdeling
Algemene gegevens
Peroperatief
Verrichtingen
Auth.
Cluster
Hfd.
1ste operateur
2de operateur
#
Verr.code
Zijde
Omschrijving
POWI verrichting?
POWI ingevuld?
Supervisor
ORT
1
38565
Heup, Kophalsprothese
Overige operateurs
Naam
Spec.
Artstype
Anesthesiologen
Naam
Artstype
Aflos
Start
Eind
Teamleden
Voornaam
Naam
Functie
Aflos
Start
Eind
Opmerking
Artikelen
Alles
Apparatuur
Devices
Humane Implantaten
Implantaten
LV leads
RA leads
RV leads
Artikelnr.
Batch/Lotnr.
Serienr.
Houdbaarheidsdatum
Groep
#
Omschrijving
Zijde
Opmerking
Notitie Artikel
Klaargezet
Klaarzet opmerking
Netregistratie
Omschrijving
ID
Klaargezet
Gebruikt
Opmerking
Reparatieformulier
Aantal art. in net
Klaarzet opmerking

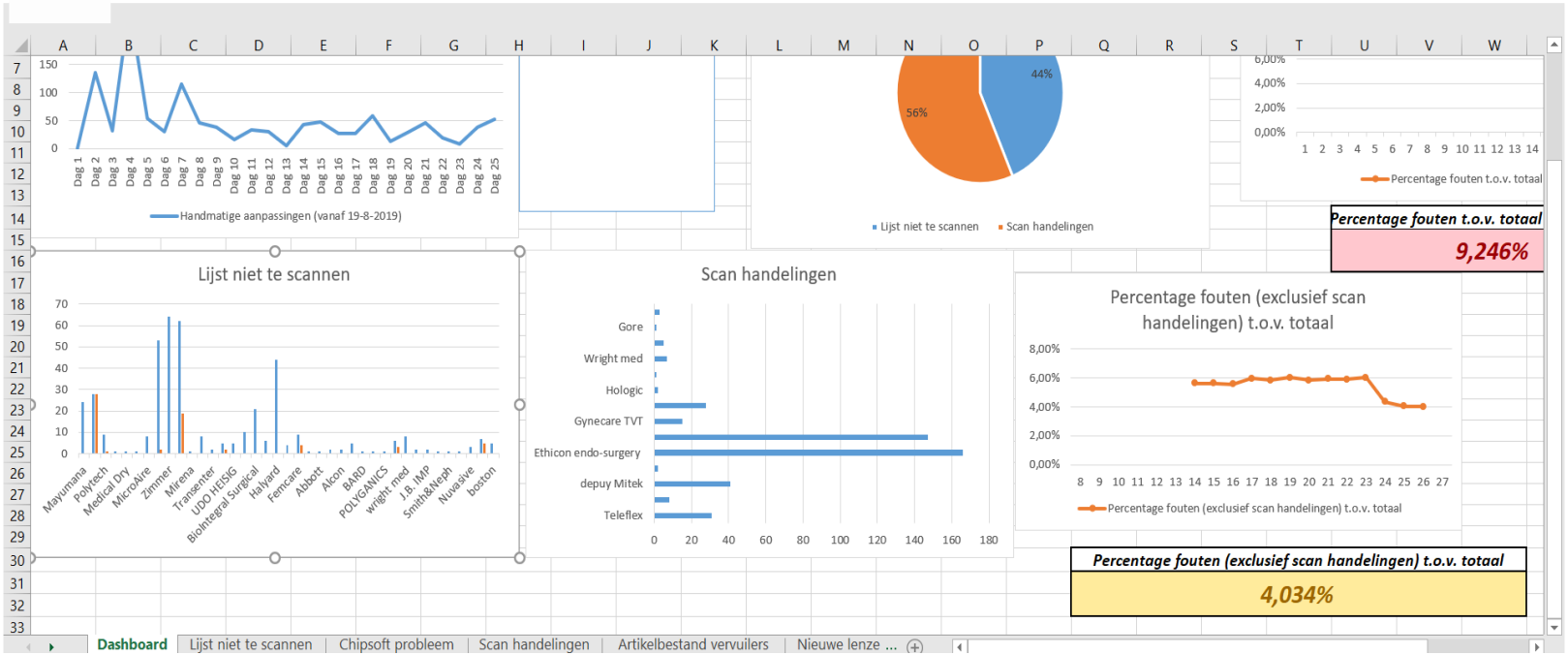

GS1 Nederland
The Global Language of Business
Dutch Implant Registry
All products wich are implanted in patients in the Netherlands must be registered in the Dutch National Implant Registry. It's about high risk medical devices (Class III), deadline January 1st 2019. UDI and GDSN are used as agreed by the Dutch market (ADC).
Manufacturers
Barcode on product
GDSN
Source Data Pool
GS1 Data Source Healthcare
• Product classification of the implant (GMDN codes)
• Manufacturer name
• Product name of the implant
GDSN
Dutch Implant Registry
Landelijk Implantaten Register (LIR)
Healthcare providers
Medical devices
Scan UDI:
• Unique article code (GTIN)
• Batch/Lot number
• Serial number
Surgery:
• Healthcare provider number/registration
• Date of implantation, explantation or deceased
What does GS1 do?
• Visits each party involved
• Gives presentations and webinars
• Advises implementation partners
GS1 standards are used for regulatory compliance. Suppliers worldwide are effected.
More information: healthcare@gs1.nl

# Some challenges



# Issues reported while recording in EHR



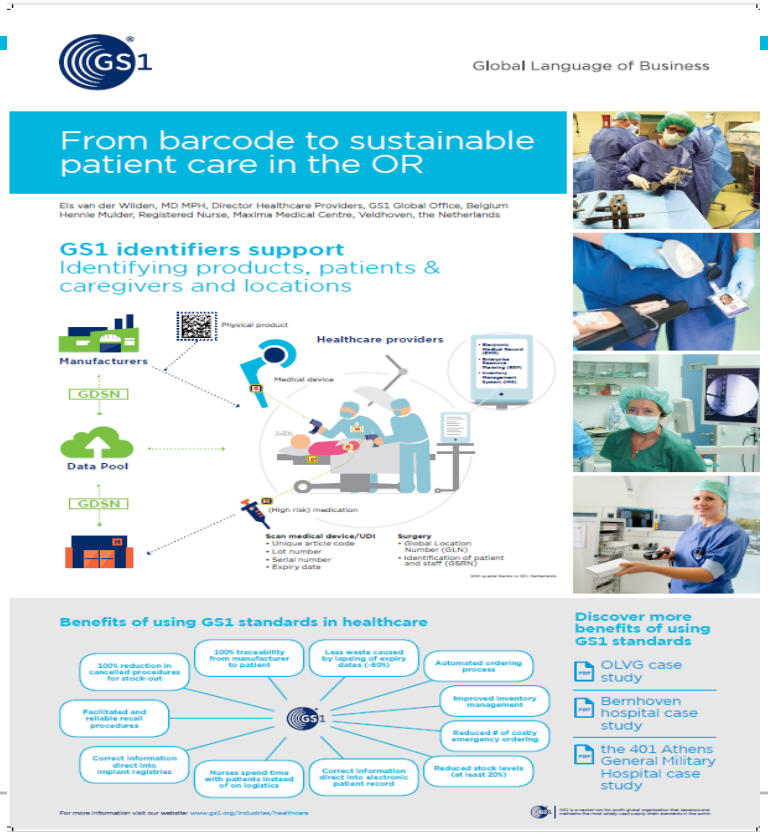
# How the EU Medical Device Regulation helps

- UDI on every medical device available => scannable
- Ease registration in EHR
- Less issues with non-scans
- Facilitate recall

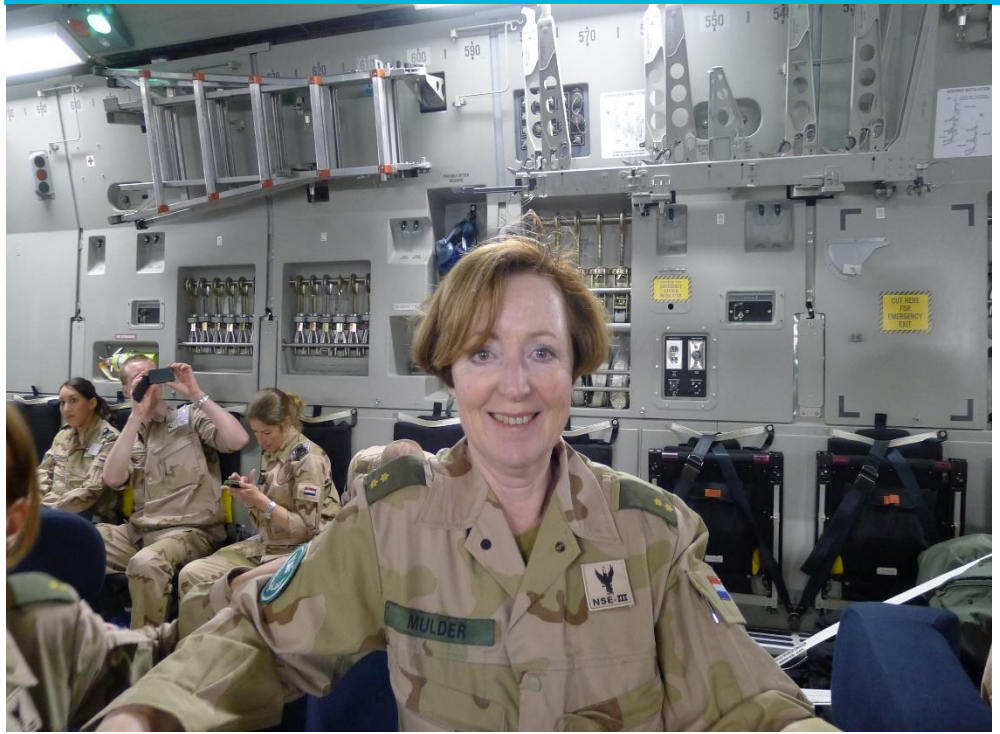
- Comply to National Implant Registry

- **Patient safety**

# How a barcode can facilitate a nurse



# So .....




# Contact details

**Hennie Mulder**

**Registered or nurse and board member of the Dutch OR Nurses Association**

- T +31(0)62366157
- E h.mulder@mmc.nl

The Global Language of Business

# 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

# 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**

# 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*

# Background

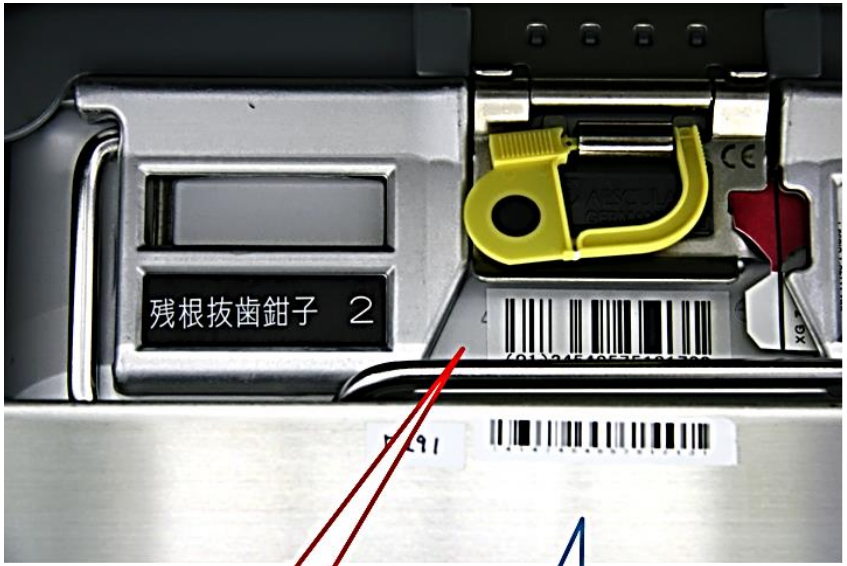
1. *In 2014, Fukui University Hospital was rebuilding the hospital.*

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.*

# GIAI, GTIN and GLN





GTIN

GLN

GIAI

# GS1 Everywhere

# GS1 Everywhere

# CSSD Work flow

Counts

Wash・Steril.

Mobile

Surgery

CART picking

# Virtual Tour the CSSD

*after surgery count*

# Virtual Tour the CSSD

*washing&assemble*

# Virtual Tour the CSSD

*sterilization&QC*

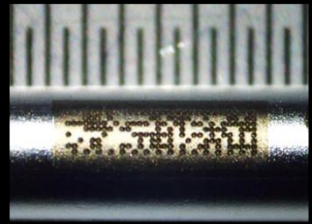
# Virtual Tour the CSSD

*Picking*

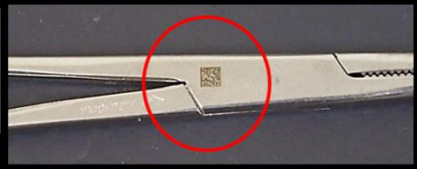
# Direct Parts Marking ( DPM ) in CSSD

- 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*



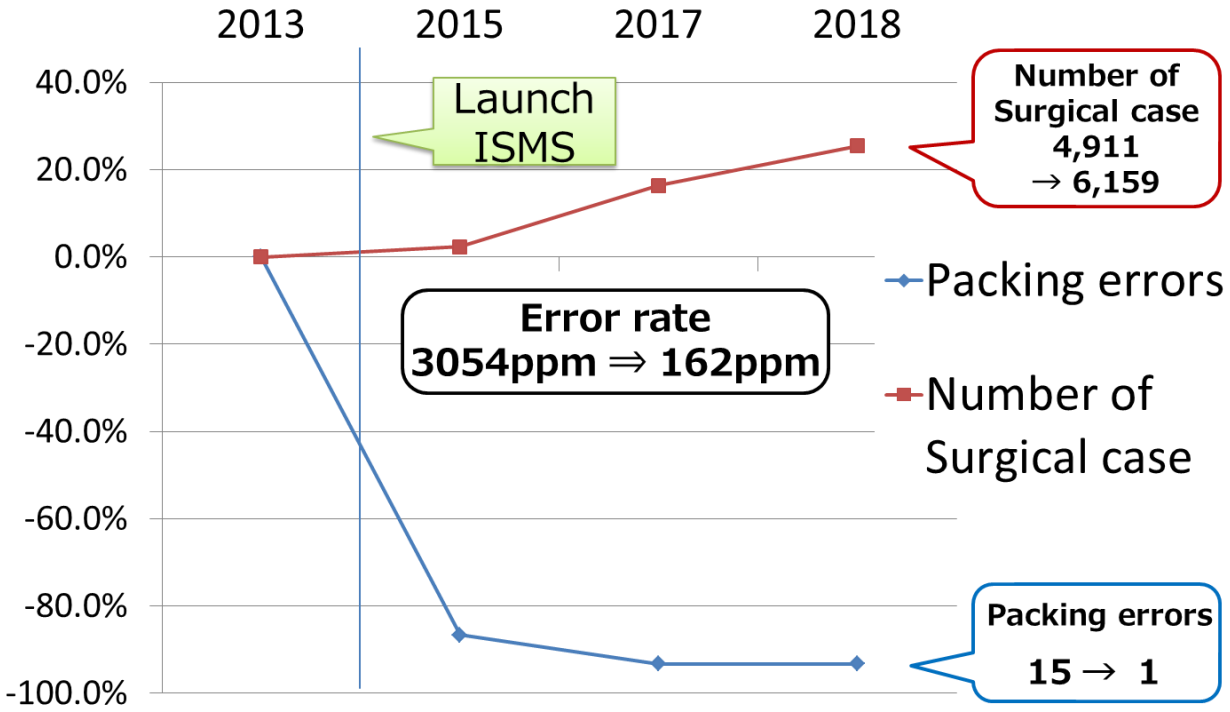
*2.6 ×2.6mm GS1-Datamatrix*

# 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 )

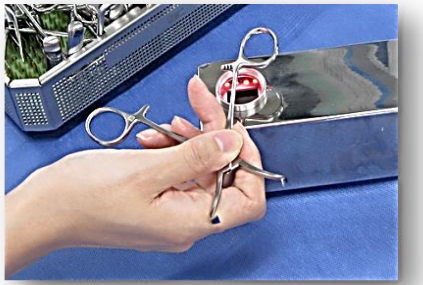
*We can assemble while sitting!*

# 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

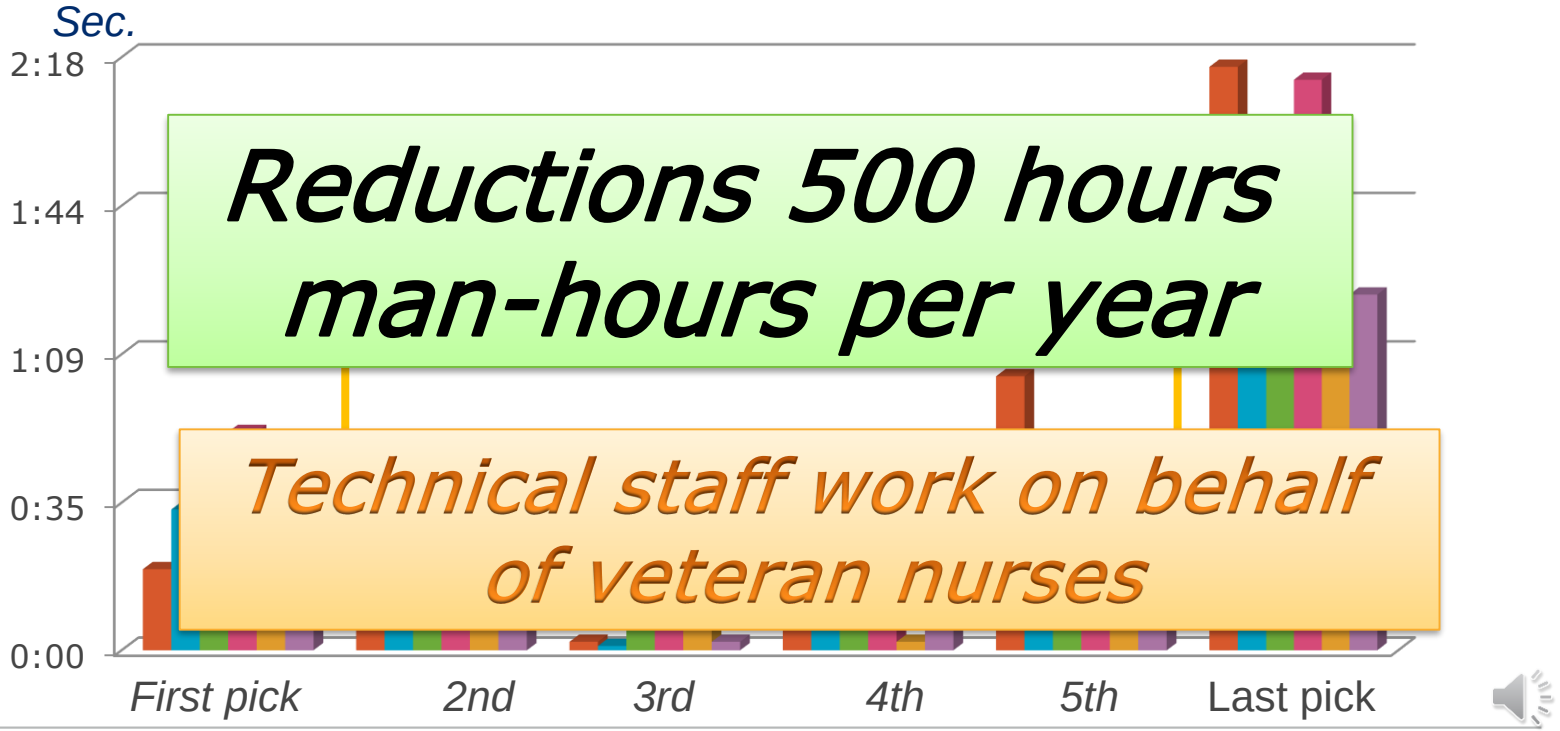


# Operational results in Assemble

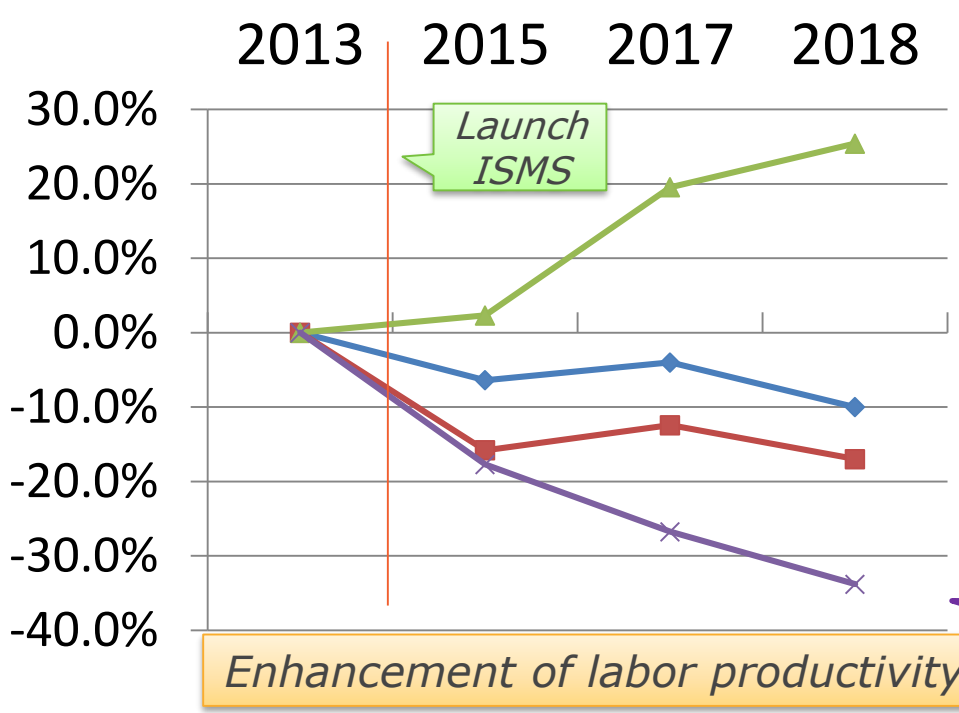
*1,000,000 Scan/year*

# Operational results on Picking

# Picking cycle time becomes short



# Cost-benefit analysis

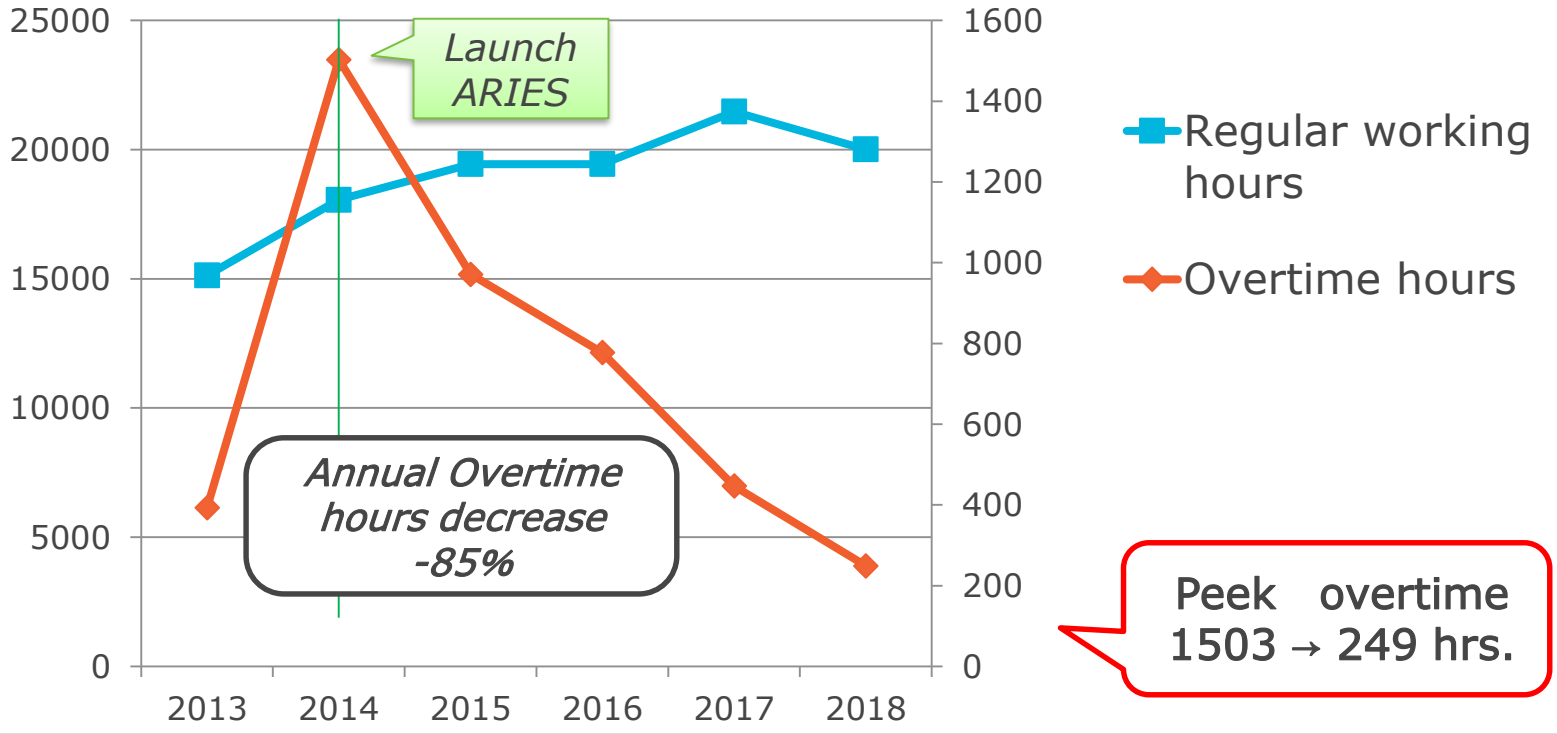



hours worked
Labor costs
Surgical case
Unit costs

*Labor Costs per Surgical Case -34%*

*$ 145.50 → $ 97.36*

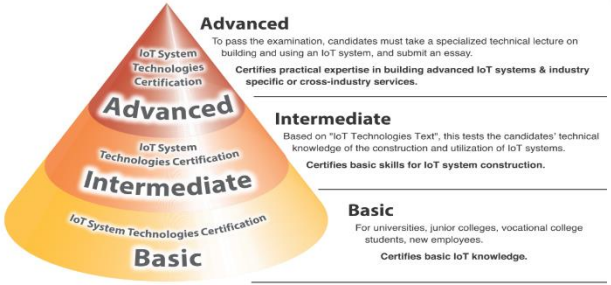
# Work style change by improvement of labor productivity



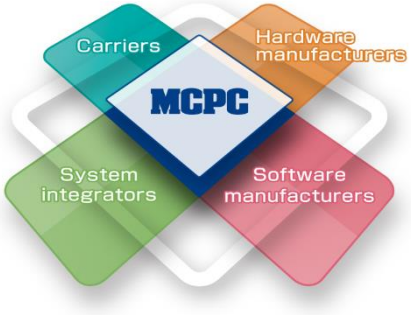
# The prize of Ministry of Internal Affairs and Communications

2019 MCPC award

Grand prize




Winner



# More information Let's look!

# Drive New Generation

*The near future of CSSD*

*Thanks so much*

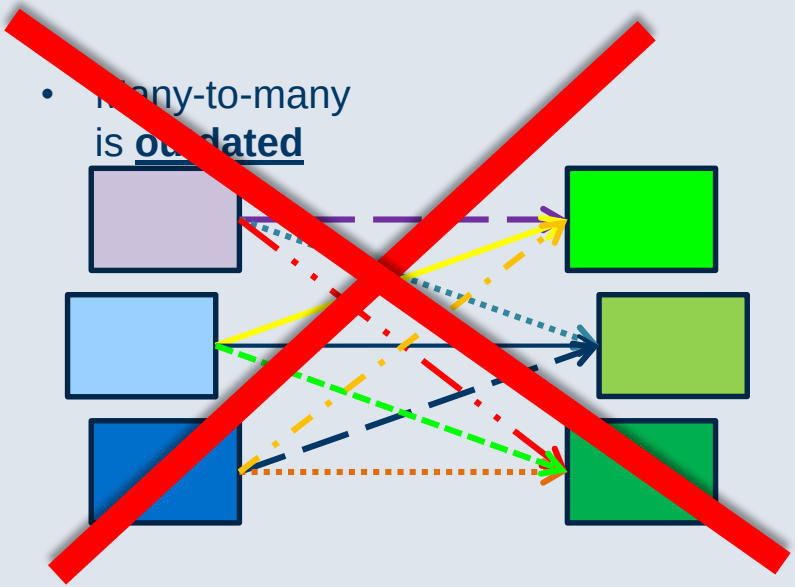
# Concluding remarks

## Unique Device Identification → a mixed blessing

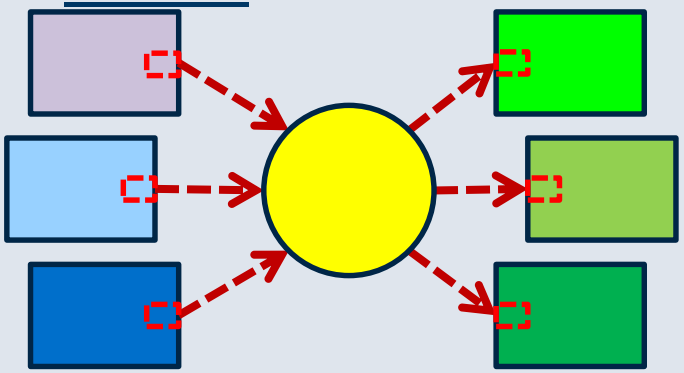
- *Nice*: Good identifiers make logistics and clinical processes much safer and easier
- *But*: There is a flipside
  - Data hungry administrators and regulators are aware of that → rising demands for recording of events
  - Acquisition and administration of master data (UDI and more) comes at a price

# Master Data from external sources: Communication

- Many-to-many
  is **outdated**



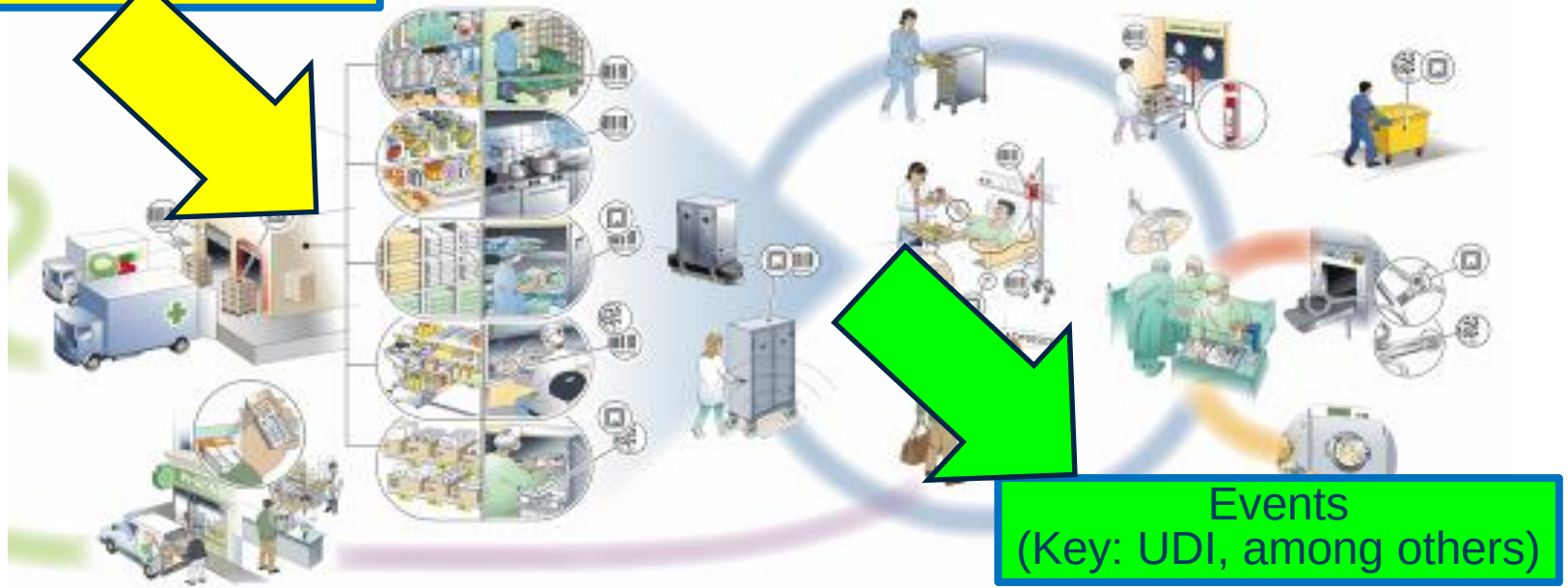
- One-to-many (data hub)
  is **the future**



UNIVERSITÄTSKLINIKUM
Schleswig-Holstein

The Global Language of Business

Master Data (UDI!)



Events
(Key: UDI, among others)

Goal: Smooth flow of people, things & information

UNIVERSITÄTSKLINIKUM
Schleswig-Holstein

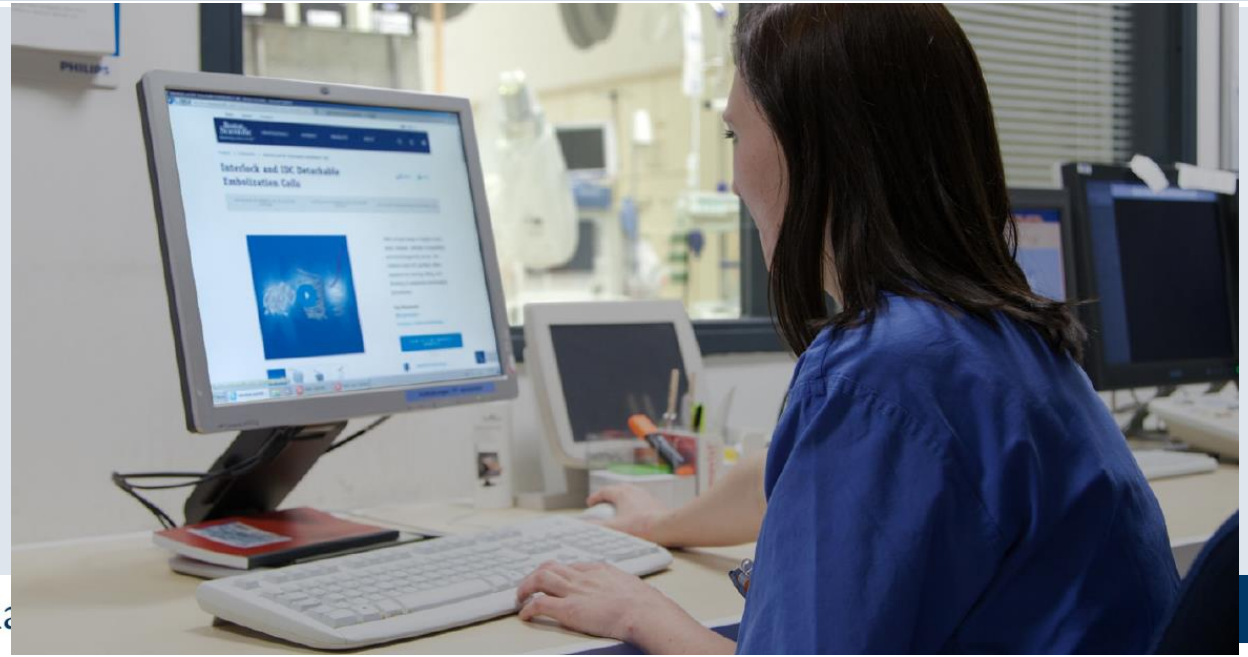
The Global Language of Business

# GS1 Digital Link
# → connecting objects to their digtal twins

UNIVERSITÄTSKLINIKUM
Schleswig-Holstein

The Global Language of Business

# GS1 Digital Link
# → connecting objects to their digtal twins



Wissen scha

# Questions from the audience

## Some messages to take away

- Due to various activities by regulators, manufacturers, standardisation organisations, and solution providers identification of things at the point of care has become easier.
- Hospital have to adapt (and to invest) to reap the benefits.
- Enhancements are in the pipeline.