令和３年度　厚生労働行政推進調査事業費補助金（地域医療基盤開発推進研究事業）

第６回　医療機関における医療安全および業務効率化に資する医薬品・医療機器のトレーサビリティ確立に向けた研究　班会議

議 事 次 第

日時：令和 4 年 1 月 25 日（火）午後 17:00～19:00
場所：国立国際医療研究センター第一会議室／
Microsoft Teams による WEB 会議併用

1．　国際的な医療用バーコード活用の現状（英語－日本語同時通訳）

- Dr. Claire Clarke ご紹介
- Overview of Electronic Patient Record’s and GS1 standards use
  （Claire Clarke , Director of Healthcare Engagement, GS1 Global Office）
- ディスカッション（Q＆A）

2．　前回からの進捗報告

3．　事務連絡

【配布資料】
資料１　委員名簿
資料２　GS1 Global EPR's for Japan FINAL（Dr. Claire Clarke 発表資料）
資料３

January25, 2022

令和３年度　厚生労働行政推進調査事業費補助金（地域医療基盤開発推進研究事業）

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委員名簿

【研究班】（敬称略、氏名五十音順）

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折井 孝男	東日本電信電話株式会社関東病院 薬剤部 シニアファーマシスト
笠松 眞吾	福井大学 学術研究院医学系部門救急講座 特命助教
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髙本 真弥	国立国際医療研究センター 医療安全管理部門 部門長
武田 理宏	大阪大学 医療情報部 准教授
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渡邉 勝	宮城県立こども病院 診療情報室 兼 医療安全推進室 主任 診療情報管理士

管轄省庁

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島井 健一郎	厚生労働省医政局研究開発振興課 医療情報技術推進室 室長補佐
小川 槙一	厚生労働省医政局研究開発振興課 医療情報技術推進室 情報推進官

【オブザーバ】（敬称・役職名略、団体名五十音順）

中部先端医療開発円滑コンソーシアム	石川 廣
日本医療機器産業連合会（医機連）	大畑 卓也
日本医療機器テクノロジー協会（MTJAPAN）	原山 秀一
日本医療機器ネットワーク協会（@MD-Net）	田村 雄一郎
日本医療機器販売業協会（JAHID）	冨木 隆夫
日本医療製品物流管理協議会（日本 SPD 協議会）	菊地 公明
	武内 昌平
	大橋 太
日本自動認識システム協会（JAISA）	白石 裕雄
米国医療機器・IVD 工業会（AMDD）	河合 誠雄
	鈴木 志都子
保健医療福祉情報システム工業会（JAHIS）	井上 貴宏
	新垣 淑仁
	友澤 洋史
	後藤 孝周

January25, 2022

The Global Language of Business

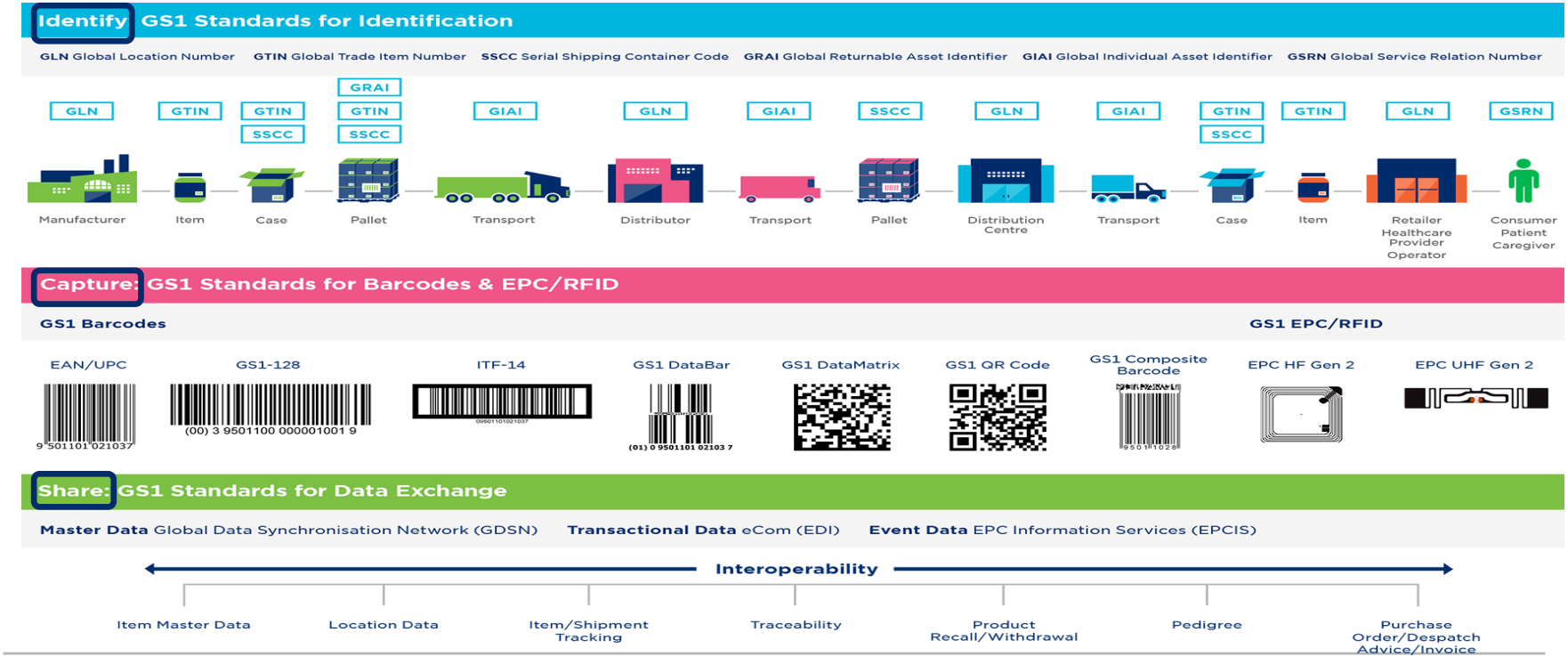
Overview of Electronic Patient Record's and GS1 standards use

Claire Clarke , Director of Healthcare Engagement, GS1 Global Office
25th January 2022

GS1 – used across the world

2 million	150 countries	6 billion	115 MOs
Approx. 2 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 6 billion times per day globally	115 Member Organisations around the world

Global system of standards that support visibility



GS1 – global standards benefits and value in healthcare

Trust

Interoperability

Transparency & Visibility

GS1 Healthcare is a **neutral** and **open community** bringing together all related **healthcare stakeholders** to lead the successful development and implementation of global **GS1 standards** enhancing **patient safety**, **operation** and **supply chain efficiencies**.

GS1 Healthcare envisions a future in which the healthcare sector achieves **harmonised implementation of global standards** in **business** and **clinical** processes enabling **interoperability**, **optimal quality** and **efficiency** of **healthcare delivery** to benefit **patients.**

Our vision

GS1 Healthcare envisions a future in which the healthcare sector achieves **harmonised implementation** of **global standards** in **business and clinical processes** enabling **interoperability**, optimal **quality** and **efficiency** of healthcare delivery to **benefit patients.**

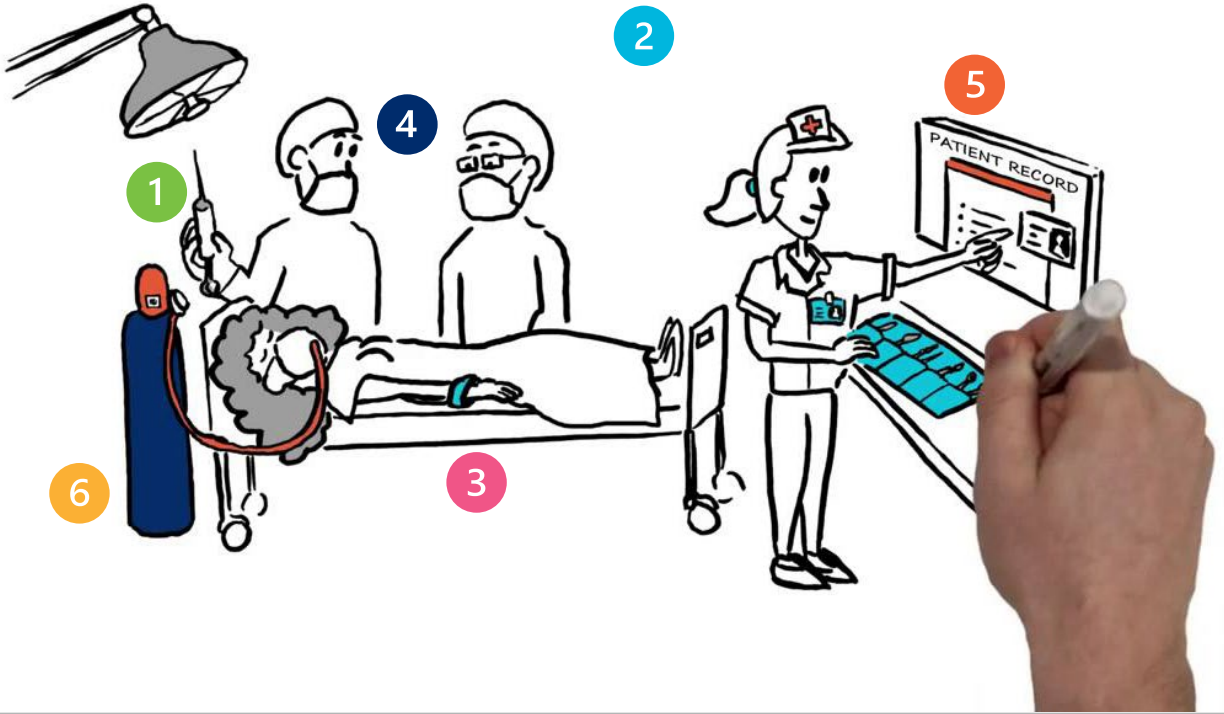
patient safety

supply chain security & efficiency

traceability

product data

Identification keys in the Operating Room



1. Global Trade Item Number (GTIN)
2. Global Location Number (GLN)
3. Global Service Relation Number (GSRN)
4. Global Service Relation Number (GSRN)
5. Service Relation Instance Number (SRIN)
6. Global Individual Asset Identification Number (GIAI)

GS1 Healthcare: an expanding, committed community of globally engaged stakeholders…

…and there are many more companies working with GS1 at a local level

Leading hospitals implement GS1

Working with global organisations…

Clinical Data Interchange Standards Consortium

European Committee for Standardization

Digital Imaging and Communications in Medicine

Health Level 7 International

Integrating the Healthcare Enterprise

International Organisation for Standardisation

Alliance to advance personal connected health

Leading healthcare terminology, worldwide

Joint Initiative Council

World Health Organization

International Hospital Federation

International Society for Quality in Healthcare

International Council for Commonality in Blood Banking Automation

European Association of Hospital Pharmacists

European Federation of Pharmaceutical Industries and Associations

European Association of Medical device and diagnostics industry

Medicines for Europe

Logical Observation Identifiers Names and Codes

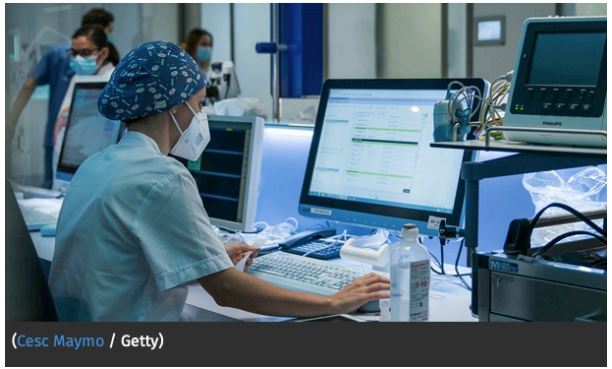
Electronic Records?

Electronic Patient Record

- A digital version of a patient's chart. It contains the patient's medical and treatment history from one practice.

Electronic Health Record

- An EHR contains the patient's records from multiple doctors and provides a more holistic, long-term view of a patient's health.



Some European Solution Providers of Electronic Records

The situation of GS1 barcodes usage on Electronic Healthcare Records

Country level Implementation

Hospital Implementation

When the nursing staff become bar code fans

ABSTRACT

Heidelberg University Hospital records its materials by scanning them: a fitness programme for DRG billing, the ordering system and budget management.

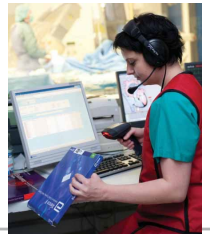
By Tobias Schneider, Heidelberg University Hospital

About Heidelberg University Hospital

Heidelberg University Hospital with its more than 40 specialised clinical departments is one of the leading medical centers in Europe.

7,300 employees, including 1,200 professors and doctors, treat hundreds of thousands of patients every year from all over Germany and many other countries, coming here to make use of our modern treatment facilities.

Scanning at Heidelberg University Hospital (Source: Heidelberg University Hospital)



The impact of Diagnosis Related Groups (DRGs) billing

"How much material do we consume for each individual patient or, in technical terms, for each individual case?" An important question for the controlling department of Heidelberg University Hospital and the other German hospitals. Since the introduction of the Diagnosis Related Groups (DRGs), health insurance companies are billed on a patient-related basis, so it is important to carefully track the individual materials consumed at the hospital. Transparency is also important in the hospital for planning and controlling internal processes. The overview of which ward consumes what volume of materials facilitates the processes for procurement and inventory control, as well as those for budget management and planning.

2011/2012 GS1 Healthcare Reference Book

Hospital Implementation

UK

Interoperability and GS1 standards – a roadmap to success in pathology and medicines administration

Challenge

Their pathology system was extremely labour intensive, and relied heavily on manual data entry. Royal Papworth Hospital NHS Foundation Trust's pathology system increasing numbers of patients needing treatment, this process became progressively harder to manage, creating as much as 24-hour delays within the pathology department.

Approach

They began work on a larger-scale, complex project to integrate five separate systems, including one for electronic prescribing and medicines administration (EPMA), with their existing electronic patient record (EPR), leveraging GS1 standards. The results enabled them to share vital patient information, improve patient safety and increase traceability across two trusts.

24 hrs reduction in real-time pathology information being available to clinicians

All medicines administration information was linked into the patient record, providing clinical decision support to the trust's clinical teams

Increased traceability and patient safety benefits saved over £50k in the first year

£42,000 saved by automation of medicines administration

Royal Papworth Hospital NHS Foundation Trust

Prior to 2017, pathology at Royal Papworth Hospital NHS Foundation Trust was a systematic but manual process. However, when the time came to integrate their pathology services with a neighbouring trust, they found the need to introduce an interoperable solution that could interact with both trust systems using GS1 standardised information.

During this time, Royal Papworth began work on a larger-scale, complex project to integrate five separate systems, including one for electronic prescribing and medicines administration (EPMA), with their existing electronic patient record (EPR). The results enabled them to share vital patient information, improve patient safety and increase traceability across both trusts.

Andrew Raynes

Integration and interoperability for healthcare in England

Integration has become a top priority for healthcare organisations in the UK. This first came with the introduction of 44 Sustainability and Transformation Partnership (STP) regions across England in 2015.

Now these regions are evolving into integrated care systems (ICSs) to create a foundation for integrated health and social care where providers work together, sharing patient records, operational information and systems to improve patient care.

Hospitals, GP practices, and local authorities are now collaborating to bridge the operational silos across the health and care landscape. However, enabling different systems to seamlessly interact and share information is a challenge many providers face.

Tackling the challenge

For Royal Papworth Hospital NHS Foundation Trust, this became a key priority as part of their integration plans with neighbouring trust, Cambridge University Hospitals NHS Foundation Trust (CUH), to share a pathology service.

To make this happen successfully, they needed to have a process in place where they were able to link the systems at each trust, enabling clinicians to order tests and share patient information and pathology results in a timely manner.

The situation of GS1 barcodes on products and their usage

Belgium	Germany	United Kingdom	Brazil
• Products with GS1 barcodes 76% in 2016 to 87% in 2019	• Products with GS1 barcodes 70% in 2016 to 86% in 2019	• Products with GS1 barcodes 57% in 2016 to 80% in 2019	• Products with GS1 barcodes 86% in 2016 to 87% in 2019
• No Barcode 12% in 2016 vs 7% 2019	• No Barcode 8% in 2016 vs 9% 2019	• No Barcode 8% in 2016 vs 4% 2019	• No Barcode 2.5% in 2016 vs 1.4% 2019
• Non GS1 13% products in 2016 vs 6% in 2019	• Non GS1 23% products in 2016 vs 9% in 2019	• Non GS1 5% products in 2016 vs 2% in 2019	• Non GS1 12.2% products in 2016 vs 10.5% in 2019

Capturing information from GS1 barcodes without customisation

Dependent on the following

1. Tender specification
2. Version of Health record
3. Country of implementation
4. Customer request
5. Cost

Master Data Creation

- Region/ Country level data
- Hospital Data
- GDSN

RFID Usage

Medical Devices

- Legislation states RFID allowed but not as the primary identifier

Pharmaceuticals

- Legislation allows
- Argentina legislation states RFID however it is not used
- South Korea- RFID required for narcotics medication
- USA – starting to see it for blister packaging but is very exceptional

Hospital Re Labelling

- Hospitals may re label medical devices or pharmaceuticals with RFID to enable traceability / movement of these items

United States

Fresenius Kabi: First to provide healthcare providers with GS1 EPC-enabled RFID tagging at the dosage level

Challenge

Fresenius Kabi, a global healthcare company, launched an ambitious program to support healthcare providers and become the first in its industry to tag vials of medication using Electronic Product Code-enabled radio frequency identification (EPC/RFID) technology.

The company's goals: Each container of medication would have an encoded EPC that carries the globally unique product code, unique serial number, expiration date and batch/lot number. The product code would consist of the Global Trade Item Number® (GTIN®) with an embedded National Drug Code (NDC), which identifies the manufacturer. The RFID tags would have to comport with the dielectric properties of the drugs, not impede manufacturing speed, and eventually be brought to scale across the company's extensive portfolio of pharmaceuticals.

Solution

Fresenius Kabi chose an EPC/RFID tagging system based on GS1 standards. Using no proprietary software or rules, GS1 standards enable any supply chain participant across the globe to read data with the proper RFID equipment, including hospitals and pharmacies that comprise Fresenius Kabi's primary customer base. By tagging each dose of medication, the healthcare provider and patient have an additional serialised measure of unique product identification.

Hospitals that are applying their own RFID tags to pharmaceuticals no longer need to expend that time-consuming effort (and avoid potential process-quality or security issues) when using drugs from manufacturers that supply their products with RFID tags embedded in the label of each dose.

Supplying the combination of the GTIN, serial number and tag ID, the RFID-tagged drug is virtually impossible to counterfeit, strengthening serialisation already in place in compliance with the U.S. Food and Drug Administration (FDA) Drug Supply Chain Security Act[1] (DSCSA).

In the event of a recall, the identity of target items can be pinpointed, with the item date, batch/lot, serial number or other related manufacturing details.

Hospitals can achieve more precise inventory management, with the ability to read many RFID tags in one scan. This could lead to better drug management overall, and improved charge capture in hospital settings where barcode scanning is not conducive to the workflow.

From the customer's perspective

Fresenius Kabi specialises in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. As a leading manufacturer of sterile injectable medications in the US, Fresenius Kabi believes that the company's values of collaboration and creativity are a strategic advantage, and using GS1 standards for traceability exemplify these values.

As Angie Lindsey, Vice President of Marketing, puts it, "Our responsibility as a healthcare company does not end at the hospital's loading dock. By including RFID technology in the label of our medications, we are helping our customers manage their drug inventory with more precision and accuracy, tracking the medication all the way to the patient."

A few years ago, a senior executive from Fresenius Kabi was visiting a hospital customer in Chicago in the US when a pharmacist showed him how they were using the hospital's RFID system and manually tagging drug vials, associating the information for the medication with the tag, including its name, manufacturer and expiration date. It was clear that this very labour-intensive tagging process was something Fresenius Kabi could help with.

[1] Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).

RFID for asset management

- Cambridge University Hospitals, UK using both active and passive RFID for tracking equipment
- Aarhus Hospital , Denmark
- Leeds Teaching Hospitals, UK
- Galway Clinic , Ireland

DANISH HEALTH DATA AUTHORITY

Providing guidance in Danish healthcare

In 2015, the Danish Health Data Authority and Danish Regions agreed to extend an existing reference architecture published by the Danish Regions covering all healthcare providers throughout Denmark. The Danish Health Data Authority established a working group with representatives from municipalities, regions and the Ministry of Health, with support from GS1 Denmark, resulting in the National Reference Architecture for Object Locating and Identification. The national reference architecture was completed in October 2016, with an English version made available in April 2017.[1]

1 http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referencearkitektur-og-it-standarder/referencearkitektur/object-locating-and-identification-1_-d-,0,-d-,4,-d-,3,_en-public.pdf?la=da

The Danish Health Data Authority [2] has the task of creating coherent health data and digital solutions for patients and clinicians, research and administrative purposes within Danish healthcare. Thus the Danish Health Data Authority is authorised by law to approve standards within Danish healthcare. Reference architectures describe architecture and points to standards within areas of strategic interest.

2 *The Danish Health Data Authority can approve standards according to an executive order. Read more here: http://sundhedsdatastyrelsen.dk/da/rammer-og-retningslinjer/om-referencearkitektur-og-standarder/referencearkitekturer. A reference architecture describes a strategic area of concern and may be used to substantiate such approvals.*

Inventory management

Cambridge University Hospitals implement GS1 standards to manage medical devices

Cambridge University Hospitals NHS Foundation Trust was challenged with tracking its mobile medical devices, spending unnecessary time to manually locate them while not focusing on their primary duties or, worse yet, not caring for patients. In addition, extra costly inventory was being kept on hand to serve the needs of the hospital. The Trust implemented GS1 standards to uniquely identify each device along with EPC-enabled RFID (Radio Frequency Identification) technology for tracking devices. Now, devices can be easily and quickly located, resulting in increased utilisation, availability of devices and improved patient care. Costs savings have also been realised. For example, tagging all ECG monitors has resulted in a capital cost savings of £175,000.

By Simon Dawkins

Cambridge University Hospitals NHS
NHS Foundation Trust

Background

Cambridge University Hospitals NHS Foundation Trust (CUH) is one of the largest and best known Trusts in England. The Trust includes Addenbrooke's Hospital, which offers general and specialist care, and the Rosie Hospital, which provides maternity and women's care. As well as delivering care through the Addenbrooke's and Rosie hospitals, the Trust is also a leading national centre for specialist treatment for rare or complex conditions and is one of only five academic health science centres in the UK with a worldwide reputation.

CUH was the first hospital in the UK to introduce GS1 standards for the identification and tracking of mobile medical devices using EPC/RFID technology.

CUH was the **first hospital in the UK to introduce GS1 standards** for the identification and tracking of mobile medical devices using EPC/RFID technology.

1

Any Questions ?