Basic concept to secure the traceability of medical devices in healthcare settings using barcodes based on the GS1 standards

1. Introduction

With the promulgation of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, and Other Acts of 2019 (Law No. 63 of 2019; hereinafter referred to as the “Amended Law”), it has become mandatory to computerize precautions for use and other information on medical devices (former package inserts) and to label containers with the codes to identify medical devices, effective in August 2021 and December 2022, respectively.

These infrastructure developments for the digital transformation (DX) of medical devices have made it possible to secure the traceability of medical devices using identical codes throughout the course from distribution to use in healthcare settings. This is expected to further enhance the efficiency in distribution management of medical devices, streamlined goods management within medical institutions, and medical safety including prevention of accidental misuse of medical devices.

In securing traceability, barcodes based on the GS1 standards (hereinafter referred to as “GS1 codes”) are used as identifiers. A survey conducted as part of the “FY2018 Project Commissioned by the Ministry of Health, Labour and Welfare (MHLW): Utilization of Unique Device Identification (UDI) in Healthcare Settings” prior to the promulgation of the Amended Law revealed that awareness of the UDI system in medical institutions remained at 50% and the introduction of the system at 20%. This highlighted the need for a new approach to further secure the traceability of medical devices in medical institutions using the UDI system, such as GS1 codes, in light of the enforcement of regulations related to DX in healthcare for medical devices.

Against this background, the “Research Group on Patient-Centered Medical Innovation through Information Sharing on Medical Devices” has been established in the FY2022 Research on Regulatory Harmonization and Evaluation of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics of the Japan Agency for Medical Research and Development to conduct a survey on the current status and challenges in the utilization of GS1 codes for medical devices in medical institutions from FY2022 through FY2024 and to discuss the issues to be considered to promote their utilization based on the survey results.

This document summarizes the basic concept of securing the traceability of medical

devices at medical institutions using GS1 codes based on the results of discussions by the research group.

2. Definition of terms and abbreviations

(1) GS1

An international non-profit standards organization comprising more than 100 member countries and regions worldwide (https://www.gs1.org/).

(2) Specially designated medical devices requiring maintenance

Medical devices designated by the Minister of Health, Labour and Welfare, after seeking the opinion of the Pharmaceutical Affairs Council, as those requiring special knowledge and skills for their maintenance, inspection, repair, and other related work because of their significant potential risk to the diagnosis, treatment, or prevention of disease in the event of failure to provide proper maintenance (Article 2, Paragraph 8 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices [hereinafter referred to as the “Pharmaceutical and Medical Device Act”]).

(3) Sterilized and repeatedly used devices

Medical devices made from materials such as stainless steel, aluminum, copper alloy, titanium, and ceramics, and reused for surgery or treatment after reprocessing including cleaning and sterilization.

(4) Implantable medical devices

Medical devices that are implanted in the human body, inserted into a natural orifice of the human body, or replace the human skin or ocular surface, with all or part intended to place for more than 30 days (Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostics; MHLW Ministerial Ordinance No. 169 of 2004).

(5) GS1 application identifiers

Numeric codes standardized by GS1 that define the types and formats of various information (ISO/IEC 15418). Constantly updated by GS1.

Examples of application identifiers:

- Identifiers related to product management
  - 10: Batch/lot number; 11: Production date
  - 17: Expiration date (the date by which the product can be used or is still usable)
- Identifiers related to clinical studies

7240: Protocol

8017: Service provider ID number (used to identify a physician/nurse providing medical/nursing service at a hospital)

8018: Service recipient ID number (used to identify a hospital patient)

8019: Service relation instance number (used to identify more details in healthcare such as treatment in connection with the service recipient number to identify a patient)

- Identifiers related to reproduction of single-use medical devices

8010: Component/part ID number; 8011: Component/part serial number

- Identifiers related to software as a medical device (SaMD)

8012: Software version

(6) Patient-use unit

Unit of packaging in use for patients at medical institutions and containers or wrappings that directly pack the contents. In many cases, patients use individual packaging.

(7) Within-institution distribution unit

Unit of packaging delivered from the administration department to each medical department within a medical institution, or unit of packaging to be sold, individual packaging, or appropriately divided quantities delivered from the administration department to each medical department within a medical institution.

(8) Individual packaging

The smallest unit of packing style, and containers or wrappings that directly pack the contents.

(9) Packaging to be sold

Normally, wholesalers sell the smallest packaging units to medical institutions (the minimum unit of sale). Individual packaging is treated as packaging to be sold if it was the minimum unit of sales.

(10) Original packaging

Normally, packaging containing multiple packaging items to be sold is packed by marketing authorization holders. In principle, original packaging refers to shipped unopened packaging that does not contain the specified quantity of packaging to be sold or that contains two or more types of packaging to be sold together.

(11) Product code (GTIN [Global Trade Item Number])

General terms of product identification codes standardized by GS1. These include GTIN-13 (13 digits, Japanese Article Number [JAN] codes [standard form], Japan), GTIN-8 (8 digits, JAN codes [abbreviated form], Japan), GTIN-12 (12 digits, Universal Product Code [UPC], US), and GTIN-14 (14 digits, product codes for collective packaging). European Article Number (EAN) is used.

(12) Manufacturing identifiers

Variable information specific to the manufacturer, such as validity/expiration date, lot number, or serial number (or version number in the medical device program).

(13) GS1-128 symbols

Set of data expressed in the international standard “Code 128” linear symbols (ISO/IEC 15417) encoding GS1 application identifiers. Attribute information such as expiration date, lot number, and serial number can be included in addition to GTIN. The GS1 application identifiers for the protocol, responsible physician/nurse, patient, components/parts, software version, among others, are in place as highly scalable symbols that can be used for clinical trials, single-use medical device reproduction, and application to interoperable medical device systems.

(14) GS1 DataMatrix

Set of data encoding GS1 application identifiers represented as a two-dimensional symbol called “DataMatrix.”

(15) Designated medical devices

Medical devices were designated by the Minister of Health, Labor, and Welfare in accordance with the specifications in Article 68, Paragraph 5-1 of the Pharmaceutical and Medical Device Act (MHLW Notification No. 448 of 2014). Authorization holders are obligated to record the following information on users:

- Name, address, date of birth, and sex of designated medical device users
- Name and product number/serial number or an alternative to a designated medical device
- Date the designated medical device was implanted
- Name and address of the medical institution where the designated medical device was implanted
- Other matters required to prevent public health hazards related to designated medical devices.

3. Subjects of the basic concept

From the viewpoint of patient safety in healthcare settings (medical institutions, homes, etc.), the primary subjects of the basic concept should be specially designated medical devices requiring maintenance, sterilization, and repeated use, and implantable medical devices, which require information sharing to secure traceability and proper use in healthcare settings, owing to their significant potential risk to the diagnosis, treatment, or prevention of disease in the event of improper management and use in healthcare settings.

4. Positioning of the basic concept

The medical DX field is experiencing rapid technological innovation, and the situation surrounding the traceability of medical devices using GS1 codes and information sharing is constantly changing. This basic concept provides general information regarding the utilization of GS1 codes for medical devices in medical institutions, which are currently considered important for patient safety. It will be updated in line with future technological innovations and knowledge accumulation and will not bind to regulatory affairs such as applications for approval and post-marketing safety measures conducted by marketing authorization holders based on the Pharmaceutical and Medical Device Act. The utilization of GS1 codes for medical devices requires flexible support with scientific rationality from the viewpoint of patient safety, based on a sufficient understanding of the characteristics and clinical positioning of medical devices. This should also be taken into consideration when referring to related standards and guidelines, both inside and outside Japan.

5. Basic matters in securing traceability of medical devices in healthcare settings using GS1 codes

(1) GS1 code to be labeled

From the viewpoint of patient safety, appropriate GS1 application identifiers should be selected to set the GS1 codes to be labeled according to the characteristics and clinical positioning of medical devices.

(2) Subject labeling

The subjects for labeling of GS1 codes shall be determined after comprehensive

assessment of the administrator and user of the medical device; risks to the administrator, user, and patient in case of malfunction; presence or absence of reprocessing before use; necessity of special knowledge and skills for maintenance, inspection, repair, or other management; and referring to the following items:

- Patient-use unit and within-institution distribution unit in healthcare settings
- Individual packaging, packaging to be sold, and original packaging for distribution
- The range that will not affect the quality of medical devices imported from abroad.
- Other necessary matters

(3) Data to be labeled

From the viewpoint of patient safety in healthcare settings, proper data shall be labeled after a comprehensive assessment of the objective of management and information on proper use in healthcare settings, referring to the following items:

- Product code
- Manufacturing Identifiers
- Data related to GS1 application identifiers were selected according to the characteristics and clinical positioning of the medical devices.
- Other necessary matters

(4) Expected users

Expected users are clarified referring to the following:

- Healthcare professionals including physicians, nurses, clinical engineers, pharmacists, and healthcare information technologists
- Patients, caregivers, and family members.
- Clerical staff
- Medical supplies logistics professionals.

(5) Labeling location

GS1 codes should be labeled at appropriate places, considering the status of medical device use in healthcare settings (medical institutions, homes, etc.) by the expected users.

(6) Barcode symbology

Barcodes or two-dimensional codes (hereinafter referred to as the “codes”) shall

be GS1-128 symbols or GS1 DataMatrix.

(7) Database registration

Securing the traceability of medical devices in medical institutions using GS1 codes requires centralized management of the information presented in the codes, and the marketing authorization holders of medical devices shall register data related to the product with the Medical Information System Development Center (MEDIS-DC), referring to the following matters:

- The data required by expected users shall be registered in an appropriate manner, considering the work duties of the users.
- Update: The registered data shall be updated promptly in case of any changes in the registered content.
- The latest version of the “Overview and Method for Use of the Standard Master” provided by MEDIS-DC shall be referred.

6. Concept of securing traceability of medical devices in healthcare settings using GS1 codes

1) Specially designated medical devices requiring maintenance

Specially designated medical devices requiring maintenance require special knowledge and skills for their maintenance, inspection, repair, and other management. This ensures the performance and safety of medical devices that are repeatedly used for a long period because of their significant potential risk to the diagnosis, treatment, or prevention of disease in the event of failure to provide proper management.

It is difficult for medical institutions, where many different medical devices are placed together, to check the time of inspection of each medical device and communicate with the medical device management department or marketing authorization holders. For instance, artificial respirators, defibrillators (excluding automated external defibrillators), infusion pumps, and syringe pumps, used at medical institutions, include those of different manufacturers and old and new devices, and ;many types of devices are often used in combination. It is difficult to secure the traceability of portable, specially designated medical devices that require maintenance, such as infusion and syringe pumps, which are frequently moved for use within medical institutions. In healthcare settings, the confirmation of manufacturing identifiers using GS1 codes on devices at each use allows for direct or indirect confirmation of maintenance, inspection, and other

management, which may further promote the optimization of medical device management. In hospital function evaluations performed by the Japan Council for Quality Health Care, it is recommended to label the date of inspection and the next timing of inspection on the body of the device.

For medical devices such as homecare respirators used by patients or their family members at home under the direction of a physician, patients and their family members implement initial measures in case of malfunction and maintain the performance of the medical device to ensure safety. If the required information can be extracted from the measures for malfunction of these medical devices used at home by using GS1 codes on the body of the devices and referring to the package inserts (precautions and other information), latest operating instructions, and safety information, it will improve the security and safety of patients and other people concerned.

However, GS1 codes are not sufficiently utilized in healthcare settings (medical institutions, homes, etc.) because of inconsistent GS1 code labels for devices in patient-use units.

Therefore, the labeling of manufacturing identifiers should be further promoted for specially designated medical devices that require maintenance in patient-use units. Assuming the use of medical devices by healthcare professionals such as clinical engineers and nurses at medical institutions, and by patients and their family members at home, GS1 codes should be labeled where they can be scanned during device use.

2) Sterilized and repeatedly used medical devices

In Western countries, legislation for direct UDI marking is being promoted for medical devices made from materials such as stainless steel, aluminum, copper alloy, titanium, and ceramics, and reused for surgery or treatment after reprocessing, including cleaning and sterilization, to ensure safe use and traceability.

Given these circumstances, the labeling of GS1 codes on the body of sterilized and repeatedly used medical devices has already been specified as mandatory in the voluntary guidelines of the industry (UDI Operation Manual for Medical Devices 2023, The Japan Federation of Medical Devices Associations).

Direct marking of the body of medical devices should be performed taking into consideration the impact on the safety and performance of the devices, the impact on the labeling of reprocessing, including sterilization, and the responsibility of those who perform direct marking (marketing authorization holders, medical institutions, etc.).

3) Implantable medical devices

Implantable medical devices include those implanted in the human body, inserted into natural orifice of the human body, or replacing the human skin or ocular surface, and are placed for various periods. Therefore, the subject for labeling, unit of labeling, among others, should be selected in an appropriate manner, and the product information should be shared to secure patient safety and traceability according to the characteristics and clinical positioning of the implantable medical devices, taking into account the impact on the safety or performance of the devices or the level of technical difficulty.

In addition, as patients using implantable medical devices may visit multiple medical institutions, sharing information on GS1 codes with patients according to the characteristics of the implantable medical devices should also be considered.

Moreover, implantable medical devices are designated medical devices for which marketing authorization holders are obligated to manage the information on users; thus, the utilization of GS1 codes by legal administrators of designated medical devices should also be considered.

4) Others

4-1) Consumable materials used repeatedly for medical care exclusively at medical institutions

In healthcare settings, many items such as sterilization bags, sterilization indicators, dedicated detergents, masks, isolation gowns, hospital gowns, and urinalysis cups are used as consumable materials that are necessary for medical devices or essential for medical practice (testing, diagnosis, and treatment). As these items are consumable materials used repeatedly for medical care exclusively at medical institutions (so-called “miscellaneous goods”), they are not subject to the obligation of labeling identification codes, and GS1 codes are labeled at the discretion of each manufacturer; therefore, many products without GS1 codes are used in healthcare settings.

Items with and without GS1 codes are mixed with miscellaneous goods commonly used in medical devices at medical institutions, which has become a bottleneck in the use of GS1 codes in healthcare settings.

For medical DX using GS1 codes, it is essential to label GS1 codes on all medical devices and miscellaneous goods used in healthcare settings according to their characteristics and clinical positioning; thus, the importance of GS1 codes in medical care should be continuously emphasized to manufacturers of miscellaneous goods.

4-2) Needs for utilization of GS1 codes

It has become apparent from an interview survey of regional medical care support

hospitals, special functioning hospitals, and SPD (Supply Processing and Distribution) vendors that there are differences in logistics management at the distribution stage and within medical institutions.

For instance, logistics management at the distribution stage is standardized using GS1 codes and is kept almost consistent, even if different marketing authorization holders and wholesalers use their unique in-house codes. In a medical institution, which is a collective entity consisting of multiple occupations and departments, diverse logistics management is performed according to the workflow and other characteristics of each occupation and department. In addition, the logistics management method differs depending on the scale or functional characteristics of the medical institution, and there are institutions where an internal department, such as a medical device management office, is responsible for logistics management, or where logistics management is outsourced to SPD vendors.

Therefore, it was determined to conduct a survey on the utilization of GS1 codes based on the differences such as utilization at the distribution stage and within medical institutions, and a questionnaire survey on the utilization of GS1 codes at medical institutions was implemented for clinical engineers and SPD vendors responsible for management of medical devices at medical institutions to summarize the current status and challenges in the utilization of GS1 codes.

(1) Outline of survey results

(1-1) Clinical engineers

- Implementation status

Target institutions: 2000 institutions to which members of the Japan Association for Clinical Engineers belong

Respondents: Clinical engineers at each institution

Survey style: Web answer

Response rate: Approximately 30%

Survey results (excerpt).

a) Purpose of using the medical device management system at 290 institutions for asset management ledgers, delivery logs, or repair and inspection logs

[1] Management of periodical inspection records (approximately 95%)

[2] Management of repair records (approximately 92%)

[3] Delivery of devices (86%)

[4] Management of the records of post-use inspection (82%)

[5] Management of the records of pre-use inspection (approximately 78%)

[6] Management of the records of in-use inspection (59%)

[7] Asset management (47%)

[8] Response to recalls, etc. (approximately 40%)

b) Types of barcodes used for the registration of medical devices with the medical device management system at 290 institutions using the system for the asset management ledger, delivery log, or repair and inspection log.

[1] In-house codes (approx. 76%)

[2] Barcodes are not used and in-house control numbers are manually input (approximately 16%).

[3] GS1 identification barcodes (approximately 9%)

c) Reasons for not using GS1 codes when registering medical devices with the medical device management system or using GS1 codes for parts of the devices at 290 institutions using the system for the asset management ledger, delivery log, or repair and inspection log (target institutions: 231 institutions for no use and 35 institutions for partial use)

[1] In-house codes have been used for the system (approximately 80%)

[2] It is necessary to manage devices to which the GS1 identification barcodes are not attached (approximately 21％)

[3] GS1 identification barcodes are labeled where they are difficult to use during operation, depending on the device (approximately 15%).

[4] Sometimes, codes are not registered in the database installed in the management system (12%).

[5] The GS1 identification barcodes cannot be used in the current management system (12%).

[6] GS1 identification barcodes may affect communication with other occupations at an institution (approximately 8%).

[7] The GS1 identification barcodes cannot be read by healthcare professionals (e.g., nurses) working in wards and outpatient departments (approximately 6%).

[8] Information not included in the GS1 identification barcodes (ward where the device is used, date of purchase, etc.) must be included in the codes (approximately 6%).

[9] Information provided to the GS1 identification barcodes (e.g., expiration date) must be labeled directly on the medical device (approximately 4%).

d) Functions that are not currently used in medical device management systems but are considered most beneficial if installed in the system.

[1] Function to inform the real-time operating conditions of the medical device

(approximately 33%)

[2] Function referring to the latest operating instructions of the medical device (approximately 27%).

[3] Function to refer to the latest package insert of a medical device (approximately 23%)

[4] Function to refer to the latest information on malfunctions of medical devices (approximately 11%).

e) Awareness of the MEDIS medical device database

[1] Aware (80%)

[2] Not aware (20%)

f) Use of the MEDIS medical device database at 123 institutions where the database is known.

[1] No (78%)

[2] Yes (22%)

g) Opinions and requests for improvement of the MEDIS medical device database at 27 institutions where the database is known and used.

[1] N/A (7 institutions)

[2] Difficult to see

[3] Accuracy and consistency of the registered information

(Data items include the product name, product name abbreviation, and model number; however, the generic device name is listed in different items depending on the registered device. There are also inconsistent uppercase/lowercase notations in some cases, and many devices remain unregistered in the database.)

[4] The software used to process the data downloaded from the database is very useful. However, as there is a large amount of information, software that enables more targeted processing in the field would be easier to use. For work optimization, the downloaded files should be combined into a file.

[5] Medical devices are not registered in this database.

[6] Therefore, it is easier to search for applicable devices. The classification and applicability of the special maintenance of devices should be presented.

[7] The update frequency is unclear. However, some devices could not be searched for.

[8] All devices must be covered.

[9] It should be possible to view operating instructions, package inserts, and inspection records.

[10] A function to notify users of any updates should be added.

h) Reason for not using the MEDIS medical device database despite knowing the database (target: 93 institutions).

[1] Necessity not recognized (33 institutions)

[2] Convenience not understood (11 institutions)

[3] Issues related to interoperability with the existing system (11 institutions)

[4] Issues related to the convenience of use (10 institutions)

[5] Issues on the in-house network (8 institutions)

[6] Cost (5 institutions)

(1-2) SPD vendors

- Implementation status

Target institutions: 24 corporate members of the Japan SPD Association

Respondents: Each vendor

Survey style: Web answer

Response rate: 50%

Survey results (excerpt).

a) Use of barcodes in registration at the time of purchase from marketing authorization holders.

[1] GS1 barcodes were partially used (4 vendors)

[2] Use of GS1 barcodes (4 vendors)

b) Use of barcodes in the registration of medical devices at delivery to medical institutions.

[1] Partial use of GS1 barcodes (5 vendors)

[2] Use of GS1 barcodes (2 vendors)

c) Use of in-house codes for the partial delivery of medical materials to medical institutions.

[1] Use of in-house and other codes (5 vendors)

[2] Use in-house codes only (4 vendors)

[3] Ungiven in-house codes not given (3 vendors)

d) Barcode label given to partial delivery of medical materials to medical institutions

[1] In-house codes (unique to SPD vendors) (8 vendors)

[2] GS1 identification barcodes used by the device manufacturer during distribution (3 vendors)

[3] Codes designated by medical institutions (3 vendors)

e) Linking GS1 codes to in-house codes in the system master used primarily by SPD vendors.

[1] Linked to all in-house codes (5 vendors)

[2] Linked to part of in-house codes (5 vendors)

[3] Not linked (2 vendors)

f) Reason for use of in-house codes

[1] The GS1 identification barcodes are not attached to the devices for in-house distribution, the devices need to be divided into small units, and in-house distribution codes are given to each unit (10 vendors).

[2] It is necessary to manage the materials to which GS1 identification barcodes are not attached (including daily necessities and miscellaneous goods) (9 vendors)

[3] Information not provided by the GS1 identification barcodes (ward where the device is used, date of purchase, etc.) must be provided to the codes (4 vendors)

[4] Sometimes, codes are not registered in the database installed in the management system (3 vendors)

[5] The GS1 identification barcodes could not be read by healthcare professionals (nurses, etc.) working in wards and outpatient departments (2 vendors)

[6] The GS1 identification barcodes are labeled when they are difficult to use during operation, depending on the device (2 vendors)

g) Information linked to GS1 identification barcodes used to link the in-house codes.

[1] Expiration date (10 vendors)

[2] Lot number (10 vendors)

[3] Product code (9 vendors)

[4] Serial number (7 vendors)

h) Information visualized by printing labels

[1] Packaging unit (9 vendors)

[2] Expiration dates (eight vendors)

[3] Number of lots (eight vendors)

[4] Product code (seven vendors)

[5] Serial numbers (five vendors)

i) Positive examples of the use of the GS1 identification barcodes at medical institutions

[1] Management of expiration date (2 vendors)

[2] Response to recalls (2 vendors)

[3] Realization of individual device management (1 vendor)

[4] Printing of GS1 barcodes on stickers for individual devices (1 vendor)

j) Negative examples of the use of the GS1 identification barcodes at medical institutions

[1] Existing systems cannot scan two-dimensional codes. (2 vendors)

[2] The GS1 codes per packaging unit were not labeled for some products. (1 vendor)

[3] Some products have barcodes that cannot be scanned. (1 vendor)

[4] Some products do not have barcodes. (2 vendors)

[5] GS1 codes are not labeled on individual devices. (2 vendors)

k) Points that require improvement regarding GS1 codes

[1] Labeling of the codes per device use (minimum unit) (5 vendors)

[2] Completeness and prompt information update of main database

[3] Differences in GTINs depending on the unit of distribution (large box, medium box, and individual packaging)

[4] Consistency of notation with one-dimensional or two-dimensional codes

[5] Education for companies that do not understand rules.

[6] Labeling of codes for all products, including miscellaneous goods

(2) Summary of the questionnaire survey

(2-1) Clinical engineers

Many institutions use medical device management systems for periodic inspection, recording, management of pre-use/in-use/post-use inspection records, and responding to medical device recalls. Institutions using GS1 codes for the registration of medical devices with the system accounted for less than 10% and nearly 80% of the institutions used in-house codes. The reasons for using in-house codes included the conventional use of in-house codes, the need for managing devices without GS1 codes, labeling of GS1 codes where they are difficult to use during operation, and lack of interoperability with the existing system.

In addition, the functions requested to be added to the existing system included references to the latest operating instructions, latest package inserts, and information on the malfunction of medical devices.

In the survey on awareness of MEDIS-DC, only 20% of medical institutions were aware of it. Institutions did not use the MEDIS database, although close to 80% (93 institutions)

knew the database. Reasons for not using the database included lack of necessity or convenience, issues related to interoperability with the existing system, and issues on the in-house network.

Based on these results, the following measures are considered necessary to further promote the utilization of GS1 codes by clinical engineers.

[1] Development of business support applications using GS1 codes (support for various inspections, reference to the latest information on regulatory affairs)
[2] Establishment of an environment for utilization of GS1 codes (improvement of the redirect system for use with the medical device database)
[3] Secure interoperability with the medical device management system
[4] More thorough labeling of GS1 codes in medical devices
[5] Labeling of GS1 codes onto places considering the usage condition of medical devices in healthcare settings.

(2-2) SPD vendors

In the partial delivery of medical materials to medical institutions, SPD vendors using their unique in-house codes reached nearly 70% and those using GS1 codes partially exceeded 80% when creating in-house codes. GS1 codes were used by many vendors to collect information such as expiration date, lot number, product code, and serial number to create their in-house codes, and were also utilized for the management of expiration dates and responses to recalls.

The reasons for using in-house codes included no attachment of GS1 codes for distribution within medical institutions, existence of miscellaneous goods and other items without GS1 codes, the need to add information not given to GS1 codes (ward where the device is used, date of purchase, etc.), lack of interoperability with the management system, and labeling of GS1 codes at inconvenient locations in use.

Moreover, the points that require improvement regarding GS1 codes include labeling per use of the device, completeness and prompt updating of the database, consistency of notation (one-dimensional or two-dimensional), and labeling of all products, including miscellaneous goods.

Based on these results, the following measures are necessary to further promote the use of GS1 codes, including indirect use through in-house codes:

[1] Thorough labeling of GS1 codes on miscellaneous goods and medical devices
[2] Secure interoperability of management systems

[3] Achievement of consistency of notation method

[4] Labeling of GS1 codes onto the places considering the usage conditions of the devices