GS1 Standards Product

Contents

1. Introduction

This standards definition guide and the implementation plan relating to ‘Product’ have been produced to set out and bring together all aspects of policy, development and implementation with regards the approach to unique identification and traceability of medical devices and clinical consumables in NHS Scotland. This workstream forms part of the national Scan for Safety programme.

In October 2021 the Health and Social Care Management Board gave approval for a programme to be established in partnership with SG, NHS Boards and National Services Scotland (NSS) to implement point of care scanning alongside the adoption of GS1 global data standards.

The purpose of the resulting NHS Scotland Scan for Safety Programme is to improve patient safety by improving the traceability of medical devices and equipment, through point of care scanning and digital data capture, utilising GS1 global standards. This will improve our ability to monitor devices and medical equipment and in the longer term improve the linkage of medical devices to patient outcomes.

2. Overview of GS1 Standards

GS1 is an independent body which provides globally recognised open standards, and related products and services, to support business communications globally and locally. GS1 has 115 not-for-profit Member Organisations operating across 150 countries supporting more than two million members worldwide. Developed and maintained collaboratively by industry users, GS1 standards enable a common language to be shared between and within organisations, helping them improve performance and safety. GS1 UK supports more than 55,000 members across many sectors, including retail and healthcare.

GS1 has established a common foundation for business by uniquely identifying, accurately capturing, and enabling sharing of standardised information about products, locations, assets and more. GS1 standards consist of three groups of standards: 1) "GS1 coding standards" (otherwise known as the GS1 identification keys) 2) “GS1 implementation standards” (otherwise known as standards to produce GS1 barcodes and Radio-Frequency identification [RFID] tags), and 3) Standards for data exchange.

The NHS Scotland Scan for Safety Programme intends to use GS1 standards to facilitate the Automatic Identification and Data Capture (AIDC) of core enablers, including product (medical devices and consumables), places (locations in health boards across NHS Scotland), patients, clinicians and staff, as well as procedures.

3. Overview of Global Trade Item Number (GS1 ID key for products)

For 'Product' identification, Scan for Safety proposes the use of the GS1 Global Trade Item Numbers (GTINs). The following provides information relating to the standard ID key and its applications. Further resources related to GTINs can be found at the end of this document (section 8.0).

- What is a GTIN?

A GTIN is a globally unique GS1 identification number that is used to identify any trade item in the supply chain. A trade item is any item (goods or services), including individual items as well as their different configurations in different levels of packaging. The GTIN acts as a key to access pre-defined information and attributes held in a database about the item.

GTINs are used to identify items that are traded between organisations so, for the NHS, the use of GTINs will primarily apply to goods and services purchased from external suppliers. Suppliers are required by some international regulatory authorities to allocate Unique Device Identifiers (UDI) to their products, of which the GS1 GTIN is the most commonly used, and to label their products with compliant barcodes. It is anticipated that a timeline for supplier compliance with the NHS Scotland Scan for Safety programme will be published following consultation with trade associations and selected suppliers.

Where NHS organisations sell goods and services to other NHS organisations, they can allocate GTINs to those traded items. NHS organisations can also apply GTINs to goods and services that are produced and consumed internally within the organisation. Guidance for the implementation of the GTIN key will be produced when further use cases are created that require trusts to allocate GTINs.

The information below about GTINs is provided to enable health boards to have an understanding of the requirements that are placed on suppliers in the creation and application of GTINs. Health boards can refer suppliers to the GS1 service desk (support@gs1uk.org) for advice and guidance on the creation and application of GTINs to products and services.

Although GTINs have an administrative structure to ensure that they are unique, they should be recorded and processed in their entirety; no part of the number relates to any classification or conveys any information.

In terms of data structure, GTINs are most commonly thirteen-digit numbers (GTIN-13) comprised of three basic segments:

GS1 Company Prefix

- Item Reference: A number assigned by the organisation to which the GS1 Company Prefix has been prepended to uniquely identify an item;
- Check Digit: A calculated one-digit number used to ensure data integrity.

It is also acceptable to have a fourteen-digit (GTIN-14) code where the first character is an indicator applied by the organisation to denote a packaging level. The indicators have no meaning and do not have to be applied in a sequential order.

- How are GTINs used?

The GTIN provides a common language for all entities and trading partners worldwide to uniquely identify and communicate information about an item.

GTINs can be used to unambiguously identify trade items online, for example in catalogues, for product traceability and recall, in electronic messages such as purchase orders and invoices, and embedded in web pages to optimise use by search.

The GTIN can be encoded in a barcode or RFID tag. By scanning the barcode or RFID tag, it is possible to efficiently and accurately identify and capture product-related information. Product information relating to the device including serial, batch or lot number as well as expiry date can be captured. Once fed into clinical systems, this information is useful for product recalls, as well as minimising the occurrence of some of the common causes of incidents of avoidable patient harm. However, the level of information retrieved from a scan is dependent on the size and format of the GTINs used by the manufacturer.

Product information such as the above can be used when receiving goods into a hospital store, for example. As well as the widely used linear barcodes found in shops, some products may carry a square GS1 DataMatrix barcode, also called a two-dimensional (2D) barcode. Camera-based scanners are required to scan 2D barcodes and these scanners can also read linear barcodes.

- How are GTINs allocated?

A GTIN is used to identify any item that may be priced, ordered or invoiced at any point in any supply chain, for which there is a need to retrieve pre-defined information for the lowest level of packaging, as well as higher packaging levels.

There should be only one GTIN for each product or service. The allocation of a GTIN should take place once and, for medical devices and other clinical products, the GTIN must never be reallocated or re-used on any other product or service. For more information about the allocation of GTINs to healthcare products and services see: http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf.

A separate unique GTIN is required whenever any of the pre-defined characteristics of an item are different in any way that is relevant to the trading process. If any significant change is made that distinguishes a new trade item from an old trade item, a new GTIN should be assigned.

For more information about the allocation of GTINs on non-clinical products and services see http://www.gs1.org/1/gtinrules/.

4. Benefits

This section to include details on the associated benefit for the specific standard.

Patient Safety	The GTIN improves our ability to monitor performance of devices and their outcomes
	The GTIN facilitates the product and patient recall process
Patient Care	The GTIN provides accurate identification of products, supporting efforts to ensure that the right product is used for patient care
Clinical Productivity	GTIN and associated product data can be stored in the patient record
Operational (Supply Chain) Efficiency	The GTIN in a barcode frees up staff time by eliminating the manual checking of product codes from point of manufacture to point of care
	The GTIN ensures that product information is identical among supply chain partners, eliminating identification errors
	The GTIN supports inventory management processes by enabling reductions in requisition, order and payment processing costs through the automation of data capture and exchange
Covid Recovery	The GTIN supports better management and visibility of medical devices and consumables

Additionally, listed below are examples of why unambiguous identification of products within an organisation is needed:

- Support patient safety through enabling accurate identification of products used on individual patients, to give a single version of the truth for products across all systems that hold product data in a health board.
- Ensure accuracy of communication between the health board and its trading partners regarding product identification during the purchase to pay process.
- By enabling increased automation in the flow of product data from trading partners, manual intervention will be reduced, increasing product data accuracy and operational efficiency.
- Accurate product data will reduce queries within the purchase to pay process e.g., price mismatch; enabling resources to be focused on value-add activities.
- Design-out process inefficiencies both within the hospital and its wider supply base and to deliver a radical step-change in system interoperability.
- To enable procurement teams to manage “procurement and pricing” and not catalogues or supplier data.

Further benefits are also summarised below:

- The maintenance of master data is automated
- The information extracted from the different systems used within a health board is consistent and can be compared

- The improved accuracy and quality of the information can be leveraged to improve patient safety.
- Querying of product data in databases is improved in efficiency and accuracy.

5. System Requirements

The implementation of GTIN for product identification and traceability will involve considerations regarding systems in use in NHS Scotland. These may be different at national, regional and local level, as is set out in more detail below.

1.1 National Level System Requirements

The system requirements to support rollout of global standards through the Scan for Safety programme in NHS Scotland are largely carried at a national level. This is as a result of some of the national cornerstone systems that are either already in place (e.g., PECOS and PCCM) or are being rolled out (e.g., Genesis for inventory management system - IMS).

Therefore, the burden of systems-related activity and data enrichment will largely fall on National Services Scotland (NSS) and be done on a 'Once for Scotland' basis.

The following assumptions are made with regards to the systems required for the capture of GTIN and product information.

Assumptions and dependencies:

- All Health Boards are using Single PECOS as their main eOrdering system
- All Health Boards are using PECOS Catalogue Content Management (PCCM) system to manage catalogues at a national and local level
- All Health Boards will use Genesis IMS as their main stock management system for managing consumables
- Catalogue enrichment will be done by National Procurement for national catalogues. Local catalogue content managers will enrich Health Board catalogues

Catalogue enrichment with product GTINs – National Procurement (NP) and Inventory Management System (IMS) considerations.

There are several ways to enrich the national catalogue with GTINs. One method would be to use source data from suppliers and work closely with suppliers to ensure up-to-date GTINs are included with their datasets.

Instead, catalogue enrichment will be a more organic process through which scanning of GTINs at local level are shared nationally and used to enrich the national product catalogue and also any local catalogues. An interface between national product catalogue (PCCM) to the Inventory Management System (IMS) is being established to facilitate this. PCCM is the 'single source of truth' for catalogue content data. The catalogue will be uploaded from PCCM to IMS. If a WPM does a scan and there is no GTIN in the product information, the central programme team will contact the supplier to get this information and then add to the product data in PCCM.

Effective catalogue Management should:

- enable the flow of accurate product data (including GTINs) from manufacturer
- link product data to inventory management and purchase-to-pay systems (potentially also to theatre and/or patient information systems)

1.2 Local Level System Requirements

Local level system requirements may vary from board to board; however, a standardised data set will be required to be identified, captured and shared as part of Scan for Safety. This includes the GTIN as well as wider associated product information. Details of this can be found in Annex A of this document.

The local systems impacted by this and therefore with a requirement to identify, capture and share the fields in Annex A may include:

- Inventory management system (Gensis IMS);
- Theatre management systems (TrakCare);
- Patient Administration System (PAS);
- EOrdering system (PECOS)
- Catalogue management system (PCCM);
- And any other systems in use, capturing information related to patient care episodes.

6. Roles and Responsibilities

National

The NHS Scotland Scan for Safety Programme team is responsible for determining the identifier used for products, helping to ensure that unique identifiers are being used for products, and for the overall delivery of a change programme to ensure their implementation and use across NHS Scotland. Manufacturers and suppliers of medical devices to the NHS are responsible for allocating GTINs to their products. A breakdown of the roles, responsibilities and governance of the NHS Scotland Scan for Safety Programme can be provided via the central contact mailbox: NSS.ScanForSafetyProgramme@nhs.scot.

Local

Health boards are asked to support the implementation of the standards, including GTIN as the identifier for product, as set out in the letter from the Chief Medical Officer in May 2022. At a national level, all reasonable effort has been made to minimise the effort required and potential disruption to local health board services as a result of the Scan for Safety programme.

Some resource will be required from existing health board teams for the following reasons:

- Local resources in health boards who are familiar with the processes and systems in use in a health board and therefore are required to advise and assist with implementation
- Scan for Safety is a change programme and it is vital that the change is embedded culturally into the organisation and the skills and knowledge needed to maintain the new processes exists within health boards

Suppliers

Suppliers of medical devices are asked to adopt GTINs into their product catalogues, customer service process and add GTIN barcodes to their products when supplying them to NHS Scotland. This request is aligned with UK and international regulatory requirements, which require the use of Unique Device Identifiers (UDI).

A centrally-coordinated programme of engagement with product suppliers will be led by the NHS Scotland Scan for Safety Programme team, in conjunction with NHS teams. A timeline for suppliers will be published as part of this engagement.

System Providers

System providers that are used in NHS Scotland and where the systems are required to identify, capture or share standardised product information, are asked to ensure that their systems are able to perform these functions with a GS1 GTIN.

A centrally-coordinated programme of engagement with system providers will be led by the NHS Scotland Scan for Safety Programme team.

7. Process Considerations

There are process implications for several core functions within a health board as a result of the implementation of a core identifier (GTIN) for product. This includes, but not limited to the following functions:

- Procurement – purchase-to-pay processes, including stores and top-up sites;
- Product recall (and patient recall) - where the processes should be amended to include use of the GTIN in identifying the product in the event of a recall or field safety notice;
- Clinical processes in theatres and wards – where the process for allocating, using and tracking medical devices should be amended to include scanning and thereby capture of the GTIN as the core identifier of the products used in patient care.

Further consultation with health boards is required to understand the impact on these processes in more detail. The level and type of impact may vary from board to board as well as from clinical area to clinical area.

8. Further Resources

- GS1 Introduction to the Global Trade Item Number (GTIN): GS1_GTIN_Executive_Summary.pdf

9. Annex A: Required Product Data Set Specification

TBC once confirmed.

10. Document Control Sheet

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