NHS Supply Chain

Data Standards - Supplier Product Coding Policy

NHS Supply Chain

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1. Document control

1.1 Version control

Date	Version	Material / Non-material changes	Amended by	Approved By	Amendments
08.04.2024	1	Material	Frankie Wallace	Sara Ford	Initial document

1.2 Document information

Document	Details
Reference Number	####
Title	**Data Standards – Supplier Product Coding Policy**
Function	Strategy, Marketing & Change
Location	Navex eQMS and NHS Supply Chain public facing website
Applicability	NA
Prepared by/ Author	Frankie Wallace, Data Standards Engagement Manager
Document Owner	Frankie Wallace, Data Standards Engagement Manager
Policy Owner (Approver)	Sara Ford, Strategy Executive Director
Last Reviewed	03/04/2024
Next Review Due	03/04/2025
Review Cycle	This policy will be **reviewed annually**
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1.3 Roles and responsibilities

Role	Responsibilities
Policy Owner	The policy owner must approve any material changes to the policy and is accountable for ensuring that the requirements set out within this policy are delivered effectively.
Policy Author	The Policy Author is responsible for creating this policy in line with all current legal and regulatory requirements and maintaining it in accordance with the review cycle and change control requirements.
Compliance Manager	The Compliance Manager is responsible for coordinating the publishing and communication of the approved policy and ensuring the policy is reviewed in accordance with the review cycle and change control procedures.

2. Purpose

This document seeks to inform all our stakeholders about a policy describing GS1 as NHS Supply Chain's preferred data coding standard for product. It is part of a suite of documents that include NHS and industry facing materials. It is aligned to the NHS Supply Chain In-Hospital Services Inventory Management Systems deployment programme and should be seen in this wider context.

3. Introduction

Improving data on medical devices across the NHS system is a key contributor to improving patient safety through greater and more rapid traceability.

At present medical device data is not routinely collected in a consistent manner or standardised digital format. Current processes are often paper based and lack standardisation and validation which means that tracing medical devices is time consuming and laborious and linking devices to patient outcomes difficult.

The adoption of global standards, such as GS1, for product identification enhances the traceability of medical devices and other products used in an episode of patient care.

NHS England has a national membership licence with GS1 UK enabling all NHS organisations to adopt GS1 standards locally for identification of, for example, people, places, products and equipment.

The GS1 data standards provide a common foundation and consistent format and enables the unique identification, capture and sharing of information automatically. When data describing medical devices is captured electronically it can be easily associated with a patient and provide accurate information about which devices have been used in their care. This electronic data capture for product forms part of the NHS England Scan4Safety programme methodology to capture data for person (patient and caregiver), product, place and procedure.

Access to this data electronically in a standard format enables it to be interrogated and performance of medical devices can be monitored, patient outcomes measured, and any potential issues with devices can be identified faster and more easily allowing clinicians to intervene and if necessary, prevent harm before it happens.

4. Background

Since 2007 there have been a number of key drivers that have impacted this area and pave the way for NHS Supply Chain to implement this policy.

2007	DH publishes Coding for Success stating that GS1 Standards for coding should be adopted across the NHS in England; NHS PaSA publishes Procurement eEnablement in the NHS
2014	DH publishes NHS eProcurement Strategy, mandating GS1 Standards and includes them in the NHS Terms and Conditions of Contract
2016	DHSC launches the Scan4Safety programme in England (based on using global standards, GS1 and PEPPOL)
2017	EU Medical Device Regulations published, including requirements for implementation of Unique Device Identification (UDI) for all classes of medical devices and setting out a timescale for implementation.
2020	Cumberlege Report, First Do No Harm is published. Includes recommendation for central database* for linking patients to devices
2021	Medicines & Medical Devices Act – includes legislation for central database for linking patients to devices
2022	NHS Scotland and NHS Wales launch Scan for Safety programmes; MHRA roadmap for future Unique Device Identification requirements via UK Medical Device Regulations following public consultation, stating that GS1 will be one of 4 designated UDI issuing entities (aligned to EU regs)
2023	NHS Supply Chain launches national Inventory Management and Point of Care Solutions deployment programme in England; DHSC Medical Technology Strategy published championing the use of data standards
2024/ 2025	NHS Supply Chain deploys Inventory Management systems with point of care scanning traceability to the NHS; NHS to adopt barcode scanning of high-risk medical devices and submit data to (Medical Device) Outcome Registry* via Electronic Health Record or Inventory Management System

Of particular relevance is the UK legislation, through the new Medical Device Regulations which are due to come into effect 1 July 2024, as it will include requirements for manufacturers to:

- Assign Unique Device Identifiers (UDI) codes to medical devices before they are placed on the market
- Require reusable medical devices to bear a UDI carrier (for example, a barcode) that is permanent and readable after each process on the device itself
- Include requirements for Basic UDI device identifiers (Basic UDI-DIs) to identify medical device models

The legislation will also require healthcare professionals and/or health institutions to store the UDI codes of implantable medical devices.

Whilst there are not any regulatory obligations for clinical consumable products there are other benefits to including these products in this policy, such as patient level costing per procedure and the efficiencies in scanning all products involved and not just some (makes the process simpler for clinical staff), maximises visibility of inventory to support demand management in a hospital and enables product recall.

5. Policy

All our suppliers of all classes of medical devices and clinical consumables are to adopt globally recognised coding standards, preferably the GS1 Global Trade Item Number (GTIN), for product identification and relevant data submissions should include them.

For medical devices, Unique Device Identification (UDI) compliant barcode labels should be carried on the device packaging at all packaging levels, including unit of use level.

For clinical consumable products, barcode labels with device identifiers, preferably the GS1 GTIN, should be carried on the packaging.

6. Implementation

In order to make this part of business-as-usual we are working to build this into our existing processes to maximise efficiencies and so will update our procurement documentation and make provision within our tendering, evaluation and catalogue management processes. We will work with our NHS customers to ensure they understand the value this brings and work with NHS England and the Department of Health and Social Care on alignment with national strategies. We will monitor GTIN coverage in our catalogue and quality of labelling through the trusts that are participating in the Inventory Management System deployment programme and through our customer Inventory Management best practice group.

7. Data usage

Access to this data will support our strategy over the medium term to provide better data back to our customers and improve our catalogue content and support our warehouse management system. It will also support us in our commitment to NHS England and supporting the Federated Data Platform to enable better visibility of system-wide inventory management data.

8. Our commitment

- Provide clear guidance documentation to suppliers describing our requirements
- Align to UK wide requirements, wherever possible
- Work with NHS England, supporting its Strategic Framework for NHS Commercial and its Digital Clinical Safety Strategy with the Scan4Safety programme.
- Work collaboratively with the Department of Health and Social Care, supporting its Medical Technology Strategy
- Update relevant procurement documentation

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Supplier Adoption Timeline

		Medical Devices UK Classification				Clinical Consumables
	Requirements	**Class III**	**Class IIb**	**Class IIa**	**Class I**	
Data	Allocate GTINs/UDI-DIs at all packaging levels and at unit of use level where the item is not packaged separately[1]	30 September 2024				31 March 2025
	Include GTINs/UDI-DIs in all relevant data submissions to NHS Supply Chain[2]	30 September 2024				31 March 2025
Labelling	Include a Unique Device Identifier compliant barcode at all packaging levels including unit of use[3] [4]	30 September 2024			26 May 2025	N/A
	Include a product identifier barcode at all packaging levels including unit of use	N/A				31 March 2025
	[1] Unit of use level where the item is not packaged separately is not required for clinical consumables					
	[2] For example, catalogue templates and tender submissions					
	[3] In the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level					
	[4] For single-use devices of Class I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging, but it shall appear on a higher level of packaging e.g., a carton containing several individually packaged devices.					