Scan for Safety

NHS SCOTLAND

Scan for Safety: Information for Medical Device Suppliers to NHS Scotland

November 2022

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1. Purpose

This document aims to provide information about the Scan for Safety programme to medical device suppliers to the NHS in Scotland. For more detailed implementation guidance and actions that suppliers need to take please see *Scan for Safety: Implementation Guide for Medical Device Suppliers to NHS Scotland.*

2. Introduction

Scan for Safety is a pioneering patient safety programme established in Scotland in January 2022. It is sponsored by the Chief Medical Officer in Scottish Government and delivered through a partnership between Scottish Government, NHS National Services Scotland and NHS Health Boards. It is envisaged that the programme will be delivered over a period of five years through a phased rollout model.

Scan for Safety is a methodology which utilises Automatic Identification and Data Capture (AIDC) technologies at the point of care, primarily using barcode scanning, capturing the Unique Device Identifier (UDI) and linking it to patient and key procedure details using global standards. This will ensure that data is captured in a consistent and digital format at the point of use. It will improve patient safety and facilitate better clinical outcome data.

Similar to other health administrations in the UK, NHS Scotland has a national membership licence with GS1 UK and these standards will be used wherever most appropriate to do so to deliver the programme's objectives. The GS1 standard for device identification is the preferred standard for use within NHS Scotland. Appendix A illustrates how we will use the standards. The programme teams in the UK working on traceability of medical devices to patient records, Scan for Safety in England, Scotland and Wales, and Encompass in Northern Ireland are in regular contact and are working to ensure that requirements on suppliers are aligned wherever possible.

3. Background

At present medical device data is not collected in a consistent manner or standardised digital format in NHS Scotland. 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. Improving system wide data on medical devices will improve patient safety through greater and more rapid traceability, the monitoring of device performance outcomes and identification of issues more quickly than is currently possible. This would better enable clinicians to intervene and, if necessary, prevent harm before it happens.

UK legislation, through the new Medical Device Regulations, is due to come into effect by 1 July 2024 and will including 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 NHS Boards to store the UDI codes of implantable medical devices.
The Scan for Safety programme was established to address the issues outlined above; improving patient safety through better traceability of medical devices and supporting compliance with the new regulatory requirements.

4. Benefits to Suppliers and NHS Scotland

Scan for Safety is a programme designed to improve patient safety that will bring benefits to multiple stakeholders, those of significant value to suppliers to NHS Scotland include:

- **Data relating to product safety** will be captured and will be used to inform better patient outcomes
- **Reduced transaction** costs due to fewer price-based invoice queries and reduced supply chain disputes by provision of accurate and timely order, delivery and invoice information, as the whole of the supply chain will be using the same product identifiers;
- **Greater efficiency** and visibility of product throughout the supply chain reducing wastage, lowering the costs of product recall and enabling compliance with forthcoming UK and existing traceability legislation, eg in the EU and USA;
- **Standardised data** enabling increased automation in the flow of product data between NHS Scotland and its trading partners.

The application of GS1 standards in healthcare offers benefits. In July 2020 GS1 UK published A Scan of the Benefits: the Scan4Safety Evidence Report that looked at implementation across a small number of NHS trusts in England and that identified 140,000 hours of clinical time released to care, almost £5M of recurrent inventory savings and £9M of non-recurrent inventory reductions.

Suppliers to NHS Scotland will be able to gain the following benefits:

- reduction in inventory levels through more accurate and timely information leading to improved demand forecasting and inventory planning;
- improved visibility and reporting of consignment stock
- reduction in wastage due to improved expiry date management;
- saving in time and increased efficiency and reliability in production, storage, picking, shipping and reporting using barcode scanning;
- improved insight into product performance through better data management and inventory systems being deployed
- increased protection against counterfeit products and the associated loss of sales and damage to brand integrity;
- reduced cost and time associated with supply chain partner disputes by provision of accurate and timely information about orders, deliveries and invoices;

- improved product traceability delivering faster, and lower cost, product recall processes through more accurate and timely information about product locations within the supply chain;
- more effective monitoring of customer contractual requirements through accurate and comprehensive information relating to orders, deliveries and invoices;
- provides the basis for compliance with the upcoming UK and existing European traceability regulations for medical devices.

For those suppliers already utilising the standards, and with NHS Scotland also beginning their implementation, there will further opportunity to realise the above benefits from a larger customer base.

We acknowledge that the implementation of Scan for Safety will also bring some challenges to some of the supplier community, recognising it has implementation costs at a time when industry is under pressure to reduce its costs to the NHS; with this in mind we are keen to hear from suppliers who think they will find this particularly challenging to see where we can help and perhaps extend timelines for adoption accordingly.

Please use the following contact details if you wish to discuss this or other aspects of the Scan for Safety programme: NSS.ScanForSafetyProgramme@nhs.scot.

5. Implementation

NHS Scotland's Scan for Safety programme is a national initiative covering all Health Boards. Our Implementation Roadmap is included in Appendix B.

Implementation of the national Inventory Management System for stock management is currently underway and is due to be completed in the early part of 2023. This programme of activity has been included in the wider Scan for Safety programme and has provided useful insight, from a Health Board perspective, on the practicalities of implementing large-scale change within a pressurised operational environment.

The next stages of implementation will include some point of care scanning pilots, for which UDI compliant barcoded products will be key, and then full adoption of key enablers (e.g. Place, Patient, Practitioner, Procedure) and initial use cases will be undertaken by specialty in Health Boards, in a phased rollout. We anticipate that the scope of the rollout will increase incrementally but essentially will be as follows:

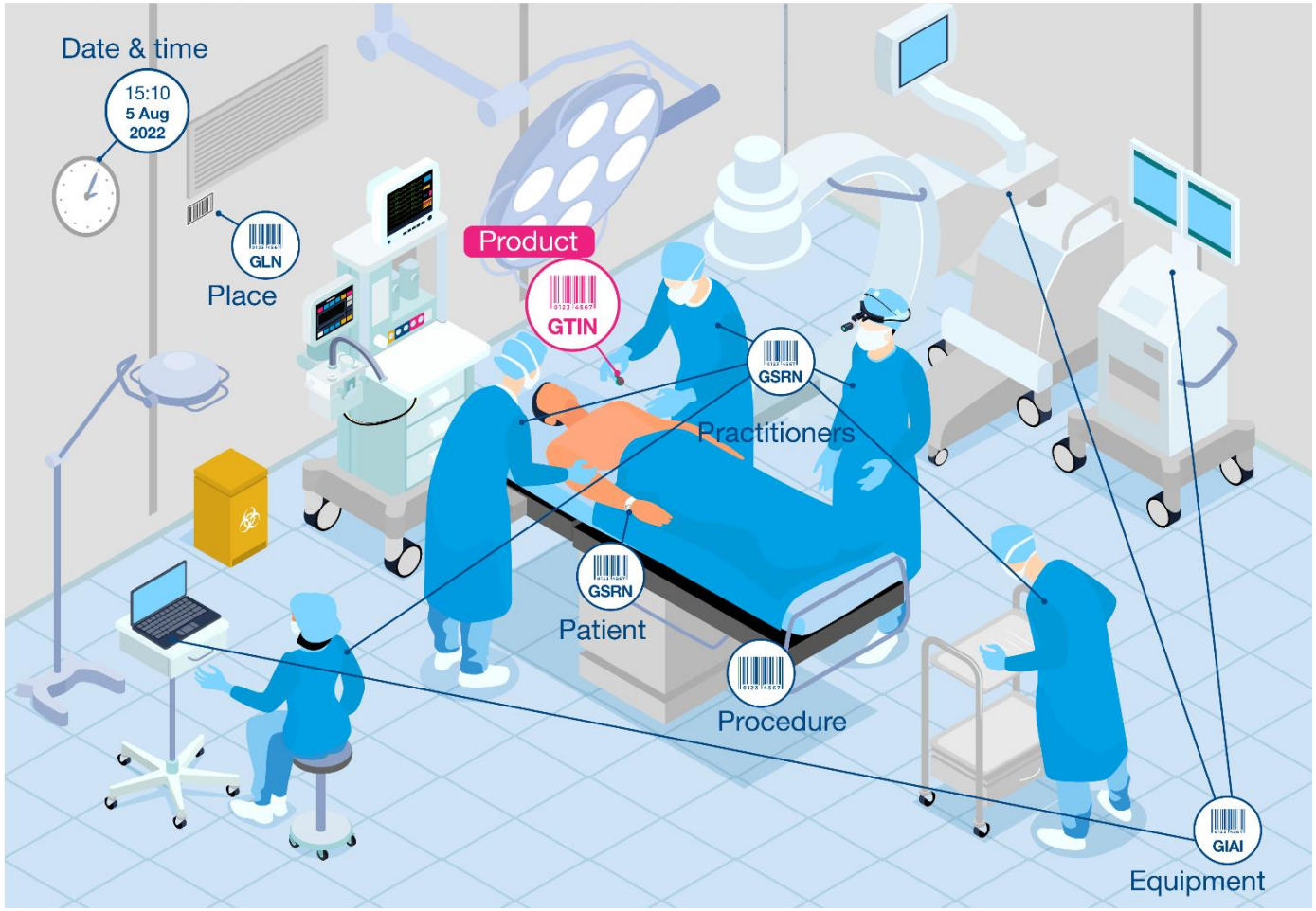
- **Phase One**: Inventory Management only
- **Phase Two**: Point of Care Scanning pilots
- **Phase Three**: Adoption of high risk devices
- **Phase Four**: Identification of further Use Cases (e.g. Pharmacy, Sterile Services)

6. National Infrastructure

Discussions are underway across the UK healthcare system exploring the potential to establish a single Product Information Management (PIM) system from which all healthcare organisations could draw down product data. As this is still at discussion stage we are unfortunately unable to provide any further detail at this time. We recognise the importance

of a PIM and the potential for a positive impact on suppliers and the broader efficiency benefits to the supply chain in healthcare this could bring and so engagement will take place with suppliers as national strategies are developed.

Appendix A: Illustration of Standards in Action



Appendix B: Implementation Roadmap