Scan4Safety and UDI forum Q&A

Questions	Answers
Do we know if there is a plan to adopt GMDN into the NHS (National Health Service) in place of NHS e-class? This is currently the go to classification for products and we all use this to control what GL codes our orders are coded against.	There has been no statement about not using NHS eClass. Current NHS / DHSC (Department of Health and Social Care) programmes (National Wound Care Programme, MDOR, PIM (Product Information Management), etc.) are not using NHS eClass, they are utilising the GMDN Database.
There should be a mapping from NHS eClass to GMDN created	NHS eClass is the primary classification system for products and services used by the NHS; its scope expands beyond the definition of a "Medical Device" by MHRA. GMDN is the Global Medical Device Nomenclature in a multi-hierarchical classification system. To discuss any mapping project, please contact admin@gmdnagency.org
I currently label our medical devices utilising a DataMatrix comprised of a GTIN (Global Trade Item Number) for each product, batch, and expiry captured onto the labelling. This has been in place for some time. Would this meet requirements for Scan4Safety?	If it is a GS1 DataMatrix and the data is structured correctly, this meets the Scan4Safety requirement to adopt GS1 standards for product identification and barcoding. Within the medical device regulations, the UDI (Unique Device Identifier) is composed of the UDI-DI to identify the product and the UDI-PI which is the production information such as expiry date/LOT etc. When using GS1 standards the UDI-DI is represented by the GTIN – Global Trade Item Number.
How does GMDN work from a UKCA (UK Conformity Assessed) point of view?	The information required when registering your devices with the MHRA includes the GMDN Code and Term to describe your device, for further information please visit https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market
Does Scan4Safety have a plan to expand to the tracking of medicines?	There is a scoping project within NHS England investigating closed loop medicines administration using S4S principles led by Jo Goulding. The results of this activity will be available soon and we will do a webinar to share this information.
Has anyone cracked the MDOR submissions for surgical implants? We are really struggling to understand the process and have not submitted anything since the Surgical Devices data flows ended.	North Tees and Hartlepool NHSFT have submitted high volumes of test data to MDOR using the bulk upload mechanism to fully meet the core data definition requirements including identification of all medical implants. We expect to move to live data submission imminently. We are in the process of confirming legal basis and valid Data Provision Notice with our hospital IG team.
Will you share the data? Point being, scanning history going back to manufacturers would improve post market surveillance. Having a scanned UDI when submitting an incident report to MHRA ensures high data quality for post market surveillance. Linking local reporting	The PIM programme is looking into how data can be shared back to manufacturers.

systems to IMS (Inventory Management System) could enable this.	
How does Scan4Safety fulfil cyber security requirements?	Scan4Safety is an umbrella term for different solutions and does not define which software solutions to use, but rather the standards they must comply with. You should check that any solution complies with your local cyber security policies.
Is there a comprehensive list of approved providers in the market that meet the Scan4Safety standards? Additionally, is there any public framework where providers are prequalified and public organisations can engage them in a competitive procurement process?	https://www.crowncommercial.gov.uk/agreements/RM1557.13
Are DCB standards linked to ISO standards?	This is in review but the DCB standards are narrowed down and specific to our environment whereas the ISO standards are more generic.
Can manufacturers get access to the Medical Device Outcome Registry?	The PIM programme is looking into how data can be shared back to manufacturers.
What is NETIS?	National Equipment Tracking and Inventory System – NHSSC led programme aimed to develop a system to store and monitor medical equipment and device asset data.
How have healthcare organisations managed in linking their medical equipment management databases into Scan4Safety?	In Scotland, the systems used to manage medical equipment (eQuip and Medusa), and the system used for IMS and PoC (point of care) scanning (Genesis) are not currently linked and there is no requirement at this point to bring these together. That may change in future as we develop our data reporting and analytics for Scan for Safety but at this time it would be considered out of scope.
As a supplier, we are facing the issue that some NHSSC locations send their orders via EDI (Electronic Data Interchange) (because they must) but do not include the serial numbers. Those are sent later separately. Are there initiatives to tackle this? With all the scanning initiatives, this does not always seem to filter down to the actual order process. Our products are in consignment, so we need the used serial number to process the billing, but that info is not always sent in the electronic order.	This may be to do with a limit for the number of characters that can be submitted via NHS Supply Chain EDI channels but would need further investigation. You can contact me directly at frankie.wallace@supplychain.nhs.uk
How important is PEPPOL within Scan4Safety and will it become mandatory eventually?	PEPPOL is preferred from an NHS Supply Chain perspective but not mandated and we do not currently have plans to make it mandatory.
Does NHS Supply Chain have a preference of which UDI carrier is used? i.e. GS1 linear barcode vs GS1 2D DataMatrix? Our pharmacy distributors prefer DataMatrix, so we need to know. As I understand it the EU regulations allow either. We will not have enough room on the actual product (garment) to print both.	NHS Supply Chain preference is for the GS1 DataMatrix. 1. It is fine to have both the EAN-13 or UPC-12 linear barcode as well as the GS1 DataMatrix for the UDI, but you need to include the ISO UDI symbol due to there being multiple barcodes on the product. 2. The type of barcode you use depends on the supply channel as well as the packaging level. So, for the single product and shelf unit (inner box) the GS1 DataMatrix is the best code to use, whereas on a transit or shipper case the GS1-128 barcode is preferrable as it is easier to read in the warehouse

	environment. This will depend upon trading partner requirements.
What is being done to ensure the NHS Supply Chain catalogue items show their GTIN online as a lot of them do not currently?	NHS Supply Chain is developing a process for our customers to notify us of problems with data e.g., barcodes, missing/incorrect GTINs (Global Trade Identification Number) etc. and when we receive feedback from customers with the specific details we will aim to rectify. You can start by submitting your queries via this form: https://www.gs1uk.org/industries/healthcare/supplier-barcode-verification. We have recently published a policy on our expectations on suppliers around the use of global data standards and we will be monitoring compliance in the future. If you want to discuss further or input to this, please contact me directly at frankie.wallace@supplychain.nhs.uk
How do your procurement categories interface with the multi-hierarchy of GMDN? Is there a place for GMDN to have an extra category to create a better join with the device governance and operational setup within healthcare organisations?	From an NHS Supply Chain perspective, I am not sure that they do currently. We are looking to include GMDN codes in our catalogue in the future, but I do not have any defined timescales I can share now. The GMDN Agency is closely collaborating with the MHRA, DHSC, and NHS Supply Chain to assist with their medical device nomenclature and categorisation needs. We strongly suggest embedding GMDN Categories and Terms, as it would help clarify the device description for all stakeholders, leading to a more efficient and effective communication process. Adding GMDN Terms would also allow the same group of devices to be traced across device databases owned and hosted by various stakeholders.
Are NHS Supply Chain looking to develop an analytic capability that sits above the IM (Inventory Management) solutions they are supporting the deployment of?	NHS Supply Chain is working with the Federated Data Platform (FDP) team in NHS England on their supply chain use case. We anticipate that NHS trusts will feed data into NHSE's platform, once built, enabling a national view and so that analytics and insights can be provided.
Are suppliers to NHS Supply Chain required to submit data for their devices? Do you foresee we will see different data requirements from different purchasers vs competent authorities?	NHS Supply Chain has set out its requirements in its recently published policy, https://www.supplychain.nhs.uk/news-article/nhs-supply-chain-launches-policy-on-data-standards-for-supplier-product-coding Yes, I think purchasers will always want different data to regulators.
Will it be possible to include additional GTIN data on the catalogue e.g. for different units of measure (UoM)? We currently need to map the inner barcodes needed at point of care (PoC) because the catalogue only contains the GTIN for the sales UoM.	From an NHS Supply Chain perspective our catalogue does not currently support GTIN hierarchy but we are aware that this causes issues for customers. We are looking at how we can improve and resolve this.
Touching on the GTINs for product identification, as a result of the Windsor Framework where MA holders will no longer be allowed to upload pack data to EMVS for packs released to UK (United Kingdom) after 01-Jan-2025, it seems that MHRA may require them to remove the unique identifier from the packs too as such they may not even be allowed to have the unique identifier on UK packs released after 01-Jan-2025. Assuming the identifier will be	There is no requirement for product identifiers such as GTINs to be removed from the packs.

the GTIN what does this means on the Scan4Safety procurement requirement and what is GS1 UK position if it is the GTIN?	
Which level of packaging is most likely to be scanned? We intend on having unique UDI-DIs on all levels but would just like to know for reference.	At PoC it is most likely to be the inner most packaging which will be scanned but outer packaging could be scanned by materials management staff. We scan the box GTIN at point of receipt, the inner GTIN would be scanned at PoC, so it is important that catalogue data contains all applicable GTINs.
Adoption timeline - in the product coding policy there is a requirement to include all UDI data in all submissions to NHS Supply Chain and product UDI labelling before Sept 2024/March 2025. Is this date still relevant?	Yes.
What is the approach to items and versions that are currently on the shelf in organisations but may not be the information submitted by the supplier - i.e., the GTIN on the product on the shelf is a much earlier version? Will this be synchronised at some point? Also to limit this impact, can more be done to encourage suppliers not to change the GTIN when there is fundamentally no change to the product?	The ambition is to have historic data as well as current data and links between them. GS1 has set up a working group to revise the GS1 Healthcare GTIN allocation rules. Invitations to join the group will be shared via social media channels and the GS1 UK newsletters. Sign up to the GS1 UK healthcare newsletter here, or email healthcare@gs1uk.org for further information.
How can we access the public beta?	We need to procure a partner to help us build this beta and is likely to kick off in around November. There will be a six-month program of developing, which is what we call private beta, which is where we develop our minimum viable product, build it, and test it for real. But this will only be tested with a limited user cohort. And then we will go through to Public Beta, when we open it up to all users. But then, as we open this to more people, there is obviously going to be more bugs and things that we must fix. It will be a continuous process of iterating and fixing problems.
Will access to the data be free?	Access to the data will be free.
Is there a plan to mandate to suppliers of medical devices set data attributes that must be provided to the PIM for their product to be used in the UK? Like the GUDID (Global UDI Database) in the US.	The regulatory minimum data set will form part of the MHRA UDI system requirements. As we worked through the Alpha phase it is evident that NHS organisations want extra data for some types of devices and will be able to request this directly via the PIM.
Will this system have any integration/overlap with the Device Registration & CFS ordering platform?	The PIM should collate medical device data from multiple sources (including the MHRA medical devices registry), but also collect data itself.
How can manufacturers join the beta and provide testing support?	If you are interested in joining the PIM Stakeholder Group and/or participating in beta, please contact Jasleen.Rehal@dhsc.gov.uk
It is interesting that you put a lot of effort into designing the right physical barcode label. Do you think this is specific to your product, or should this be a wider adopted practice (for medical devices/products etc)?	For SageTech working across highly regulated sectors, we had to ensure we had the right solution that was as effective as possible. During our journey working with GS1 we became aware of the flexibility in terms of the options available to us. We were open to learning how the GTIN could most effectively be deployed. SageTech would recommend putting significant

	effort into establishing the most effective traceability coding system – it is worth the investment. Note that your investment cost with GS1 UK is in resource and time. We do not charge a fee for the support and the label verification service to help our members get it right. Please submit your barcode label samples for verification to GS1 UK at https://www.gs1uk.org/industries/healthcare/supplier-barcode-verification, or contact the healthcare team directly at healthcare@gs1uk.org
Do you allocate NHS numbers for patients who do not have them (e.g. Scottish patients)?	Scottish patients have an NHS number that sits behind their CHI number.
How long did it take for the staff to get on board of scanning everyone to each location? I presume this is audited for gaps/errors.	We work from patient and staff user stories and continuously audit the new processes. It typically takes a week for a ward to move from their current processes to point of care scanning. We deliver a 20-minute training to each nurse to demonstrate the benefits of patient ID band scanning.
Which IMS do you use?	SupplyX from Omnicell.
With all these new systems relying heavily on UDI, will there be any guidance on how the UDI formats implemented should be verified? Verification will need to be on-going as the full UDI will change with each manufactured batch (UDI-PI details).	Systems are in place to process the production information captured by scanning the UDI barcode on the device and this is used for expiry date management to reduce waste and for quicker product recall processing.
Does this also help with bed allocation as you will know when a patient is discharged?	Yes. We have a live bed state application that allows us to track patients arriving at and leaving the hospital.
Are there plans to record adverse incident and send the information to manufacturer faster and more accurately?	Yes, I am very keen that the organisation is tracking as many products as possible so we have a better understanding of consumption and can work more closely with manufacturers.
We have similar systems and set up but far from what you just described. I have just joined the company, but it would great to understand in more details. Can we have a contact to reach out?	Please liaise with GS1 healthcare engagement team but more than happy to meet. healthcare@gs1uk.org
Is this the same process used for newborn babies in delivery wards?	Yes, as a baby is registered, they get a wristband with the identifier on as we create their record.
Have you linked in your reusable medical devices?	We are starting to look at this as well as multi use consumables.
What is your scanning compliance for trauma theatres especially orthopaedic implants?	I cannot give a percentage. We are in the middle of a product swap over at present. However, we have had high levels of compliance as it is the quickest way of ensuring we have stock in the storeroom.
Are you able to share details of the size of your team, and the types of roles you have in there please?	There are four of us in the Scan4Safety team. 1 x Programme manager 1 x Project manager 2 x Project assistants We then have one member of staff dedicated to managing the inventory solution on a day-to-day basis. All other staff are matrix managed depending on the programme of work.

Should we be working towards a national medical equipment management system in NHS Wales as per Scotland?	I would fully support this but I am not aware of any plans at present. Like the PIM, I think the more national repositories of common data that are available, the better.
With regards to primary packaging identification a key element that has become apparent to stipulate is what not to add to product labels. Can we get the message out to manufacturers that one product one barcode does not just mean we want one barcode with all applicable data for healthcare in it but that no other barcodes exist on the product so staff at PoC are not struggling to know which barcode they should be scanning?	Thank you for your suggestion. The one product, one barcode goal within the GS1 Healthcare strategy is indeed to eliminate multiple barcodes on healthcare product packs at the PoC care and work with industry to move towards a single GS1 barcode. An important reason to focus on this is to ensure there is no confusion at PoC on which barcode to scan.
Regarding the DataMatrix, what if your hardware does not have a lot/batch number or expiry. How do you show that they are not applicable to the product? Is that part of the coding of product in GS1?	Only production information that is applied to the product label to meet the labelling requirements needs to be captured in the barcode. The statement below is from the EU MDR UDI System. "3.5 If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI."
You talked about primary package identification being part of the GS1 strategy – since this goes beyond legal requirements for single-use devices e.g. in US and EU, is this balancing the cost and effort to implement it for manufacturers? I understand users may ask for it but in the end much of the increased cost will be carried by public healthcare systems.	Our efforts in the Primary Packaging Identification strategy are currently focused on medicines and prescription drugs. This initiative is being led by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in collaboration with the European Association of Hospital Pharmacists (EAHP). GS1's role in this is to ensure that the agreements between both parties comply with GS1 standards, and that is what we are working on right now. We are not dealing with primary identification for medical devices at this stage.
It would be good to have a clear template to send to manufacturers illustrating the best practice for GS1 labelling as some overseas manufacturers do not have an understanding and need to be clearly guided.	Thank you for your suggestion. As part of the one product, one barcode goal we will work with industry and our GS1 Member Organisations to ensure we develop support material to support the move towards a single GS1 barcode on a package.