



Position Paper (II) Healthcare Provider Advisory Council *Implementation in hospitals hindered by bar code symbol issues*

I. Introduction

Towards the end of 2011, GS1 Healthcare established the Healthcare Provider Advisory Council (HPAC) to be the forum for sharing and discussing the practical realities of implementation of GS1 Standards in the care giving environment in regards to the impact on clinical care and patient interaction. The membership of HPAC consists of thought leaders and early adopters (clinical and non-clinical) of GS1 Healthcare Standards from the global clinical provider environment (e.g. hospitals, retail and hospital pharmacies, clinics, care homes etc.) and staff from GS1 Member Organisations (MOs). Through regular monthly conference calls and occasional face-to-face meetings (e.g. at GS1 Healthcare Global Conferences) HPAC members have been exploring the opportunities and challenges of implementing GS1 standards to improve various care-giving processes and, ultimately, patient safety.

Issues with bar code symbols have emerged as a broad, reoccurring and major challenge, or 'pain point', during implementation projects. On both pharmaceuticals and medical device products (products), the issues include:

- No bar code symbol present
- Poor quality bar code symbols
- Placement of the bar code symbol
- More than one bar code symbol
- Non-standard bar code symbols

Bar code symbology

All of the above present various challenges and definitely pose a barrier to widespread adoption and implementation in the provider environment. Thus, the proven benefits – enhancement of patient safety and support of clinical processes – could be severely limited or, at worse, not be realised.

No bar code symbol present

Lack of a bar code symbol (Figure 1) on products means that the provider has to have a minimum of two separate processes: one manual, for the products without a bar code symbol, and one automatic, for those products with a bar code symbol. This scenario is counterproductive, particularly as it is likely, for example, that it is the manual process, with its inherent errors, that they are aiming to replace by implementation of GS1 standards. Indeed, it adds unnecessary complexity. Alternatively, whilst this situation persists, providers who want to progress the implementation of GS1 standards may, and are, employing the necessary resources and equipment and implementing new processes to generate and place bar codes on products. In the view of most, however, this is not a viable alternative, due to the complexity and cost of the task and the risk of errors that might endanger patients.



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Example of a suppository with no bar code.

The provider has to create and place a 'flag' bar code label on each item.

Figure 1

Providers request that all products received to carry a GS1 Data Carrier in the form of a bar code symbol, either on the package containing the product (primary package) or, for some medical devices (e.g. surgical instruments), directly marked on the item itself (Direct Part Marking (DPM)).

Poor quality bar code symbols

This is a known issue with bar code symbols in a number of industries in which they are used and can occur for numerous reasons, e.g. the type of material the bar code symbol is printed upon (substrate) or the type of printing used (e.g. thermal transfer, ink jet etc.). But, for whatever reason, if the bar code symbol is of poor quality this can result in problems in reading it when it is scanned.

Providers request bar code symbols that, at least, meet the published minimum quality criteria found in the GS1 General Specifications and associated ISO standards, whether they are printed on the primary package or, for some medical devices (e.g. surgical instruments), in DPM.

NOTE: Many GS1 Member Organisations (MOs) offer bar code symbol print quality verification services.

Placement of bar code symbols

There are products used in the provider environment that can pose particular challenges when a bar code symbol is applied (e.g. vials, syringes, ampoules, nebulas etc.), (Figure 2), but sub-optimal placement and orientation of the symbol can present particular scanning problems. For example: a) placing a label containing a linear bar code symbol horizontally around a vial renders the bar code symbol unreadable due to the curvature of the vial; in this case by placing the bar code label vertically along the vial the curvature would be minimised thus significantly improving its readability; b) a bar code symbol is usually placed at the bottom of the primary package that contains a tube, and in some cases a bar code symbol is also placed on the tube itself. In the care-giving environment the outer, primary packaging is discarded and



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the tube itself is what is dispensed. As the contents of the tube are administered at regular intervals over a period of time by the caregiver/nurse, the end of the tube is rolled up to force the contents to the top, which then hides the bar code. Placing the bar code at the top of the tube would overcome this issue.



An example of a linear bar code placed on a curve of a small bottle – this medication is packaged in 15 and 30ml quantity which is equivalent to the patient's dose. Care givers have difficulty scanning due to the placement of the bar code on the curve of the

Figure 2

Providers request upstream stakeholders (e.g. Brand Owners, manufacturers, suppliers, repackagers etc.) to consider the scanning constraints of downstream stakeholders, particularly in regards to the practical application in the provider environment, and that bar code symbols are placed so their readability is increased or assured.

More than one bar code symbol

Many countries have been developing regulations for identification of products using bar code standards; and, although there has been good progress towards ONE global standard being regulated and adopted (i.e. the GS1 System of Standards), there are still countries with local requirements and/or proprietary bar code systems. Providers appreciate the compliance challenges faced by upstream stakeholders whose products are sold in multiple markets that may result in more than one bar code symbol being applied to packaging (e.g. see Figure 3 (Pedea)), but having more than one symbol on a product creates challenges in the care-giving environment, for example: the time taken to identify which symbol to scan, the impact of the wrong symbol being scanned, the ability of the scanner to scan and decode only one symbol when in close proximity to another etc., these have potential to impact patient safety!



Figure 3



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The ideal situation would be for all regulators from around the world to coalesce around ONE global standard, thus negating the need to apply more than one bar code symbol to product packaging. Until that situation is achieved, **Providers request** upstream stakeholders to consider the scanning constraints of downstream stakeholders (hospitals, hospital pharmacies, care homes, clinics etc.) and that only ONE bar code symbol is placed on product packaging (see 'Bar code symbology' below). In the case where this is not possible due to extenuating circumstances, multiple bar code symbol guidance, such as that in the GS1 General Specification, should be followed.

Non-standard bar code symbol

Similar to the situation outlined in the previous issue ('More than one bar code symbol') the ideal situation of ONE global standard being regulated and adopted is yet to be achieved and therefore, there are countries using proprietary or category (e.g. medical device) specific bar code systems (Figure 4). This can result in similar issues to those previously stated, e.g. delays in scanning, but may also create problems of data capture into the provider's information systems that have been developed to comply with a global standard (See Position Paper: "Implementation of GS1 Standards based processes in hospitals is hindered by lack of interoperability of information technology systems").



Example of a nebulizer with a linear bar code that is non-standard. It's placed on a clear background, causing potential issues with scanning.

The image also shows a flag label added by the provider to overcome these issues.

Figure 4

Providers request upstream stakeholders to consider the scanning constraints of downstream stakeholders, particularly in the provider environment, and that only GS1 compliant bar code symbols are printed either on the primary package or, for some medical devices (e.g. surgical instruments), in DPM.



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Bar Code Symbology

The familiar symbology (format) of bar codes, particularly in the retail environment, is that of the '1D' or 'linear' type, vertical black lines and white spaces (Figure 5), but over recent years another generation of bar code symbology is being increasingly used, the "two-dimensional (2D) or "matrix" type symbology, e.g. GS1 DataMatrix (Figure 3).



Figure 5



Figure 6

These two symbologies
contain the same data.

A position statement¹ issued by GS1 Healthcare in October 2009, relating to Camera-Based bar code scanners, states "Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- A large amount of data (product ID, batch/lot number, expiry date, serial number, ...) to be stored in a small space
- Variable information (such as unique identification number at unit dose level) to be marked at high production rates
- Direct part marking (e.g. surgical instruments and implants)
- Bar code [symbols] that cannot be scanned not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar code symbols, but a solution is available: GS1 DataMatrix"

Today, current GS1 standard implementation projects or those in planning will include provision for purchasing camera-based scanners, which scan both types of symbologies; negating the need for both symbologies being placed on product packaging (see "More than one bar code symbol" above). Therefore, providers are or will be able to accept and scan GS1 DataMatrix symbologies.



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Providers request upstream stakeholders (when printing one bar code symbol as requested above), to select the GS1 DataMatrix symbol, the preferred symbology if there is a need to:

- Hold a large amount of data on small space (e.g. Global Trade Item Number (GTIN), Lot/Batch No., Expiry Date, Serial No., etc.)
- Note: In the Netherlands the Federation of University Hospitals, The general Hospitals and the Hospital Pharmacists) has stated that they want GS1 bar codes on their products, preferably, not necessarily, a GS1 DataMatrix, including GTIN, expiry date, batch number and/or serial number.
- Include variable information, e.g. serial number
- Direct Part Mark (DPM) an item, e.g. a medical device such as a surgical instrument

If these constraints are not present, then the traditional GS1 linear/1-dimensional bar code is acceptable.

II. Historical context

Providers understand the numerous reasons that upstream stakeholders have established and continue the approaches outlined above. A common argument is that upstream stakeholders who have implemented GS1 Standards have realised the efficiency benefits but the use of the bar code stops at the doors of the provider. But the situation is changing! Indeed, it has been changing over the last 5-7 years due to a number of drivers:

- Patient Safety: numerous reports related to medical errors and, for example, how bar code standards reduce mistakes at administration of drugs diminishes with 42% (Poon et al, 2010²)
- Regulatory: Over a number of years Regulators have been publishing regulations focussed on upstream healthcare stakeholders such as manufacturers, now there are examples of regulators or governing bodies expanding their focus to the healthcare provider community, e.g. in May 2012 in the Foreword to NHS procurement: Raising our game³, Sir David Nicholson, NHS Chief Executive demanded all trusts take action to implement GS1 in NHS Procurement
- Efficiency: as a route to improving their procurement processes and systems, some providers are now entering GS1 Standards compliance as a criteria in tenders

There is increasing evidence that the situation is changing by the number of case studies published related to the implementation of GS1 Standards and the benefits realised. Many of these have been captured and published over the last four years in the GS1 Reference Books, 2009-2010, 2010-2011, 2011-2012, 2012-2013 (New)⁴. BUT, the growth in implementation has, in parallel, increased the occurrence of the bar code symbol issues covered in this paper and these could pose a barrier to widespread adoption and implementation in the provider environment. Thus, the proven benefits to patient safety, and the other drivers mentioned above, could be severely limited or, at worse, not realised.



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III. Conclusion

Bar code symbol issues have hindered successful implementation of GS1 standards and could pose a barrier to widespread adoption and implementation in the care-giving environment. Receiving pharmaceuticals and medical devices that carry GS1 standards-based, quality bar code symbols on the packaging or in DPM are fundamental to enable their adoption and use in hospitals, hospital pharmacies, care homes, clinics with the primary objective of improving Patient Safety. They are also foundational to enabling and improving other key processes such as procurement, inventory management, internal deliveries, dispensing, tracking, tracing, recalls etc. and ultimately realising GS1 Members Vision for Traceability in Healthcare:

“Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production to Point of Use”⁵

To eventually achieve this long-term Vision, ALL stakeholders involved in healthcare globally would be required to collaborate and work together to implement GS1 Standards-based systems and processes.

IV. Call to Action

The GS1 Healthcare Provider Advisory Council (HPAC) issue this ‘Call to Action’ to all upstream stakeholders and Regulators around the world to:

- Adopt ONE global standard: The GS1 System of Standards
- Immediately address the issues covered above: no bar code symbol present, poor quality bar code symbols, placement of the bar code symbol, more than one bar code symbol, non-standard bar code symbol, bar code symbology etc.



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V. References

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2. Effect of Bar-Code Technology on the Safety of Medication Administration, The New England Journal of Medicine <http://www.nejm.org/doi/full/10.1056/NEJMsa0907115>
3. <http://www.sci-ware.com/documents/NHS%20Procurement%20raising%20our%20game.pdf>
4. GS1 Reference Books: <http://www.gs1.org/healthcare/library#publications>
5. GS1 Members Vision for Traceability in Healthcare
<http://www.gs1.org/healthcare/implementation/traceability>

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.