

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 information technology/information system (IT/IS (systems¹)) interoperability have emerged as a broad, reoccurring and major challenge, or 'pain point', for providers during GS1 standards implementation projects. The issues include:

- Lack of field(s) in systems for bar code attribute data (e.g. lot/batch number, serial number and/or additional [medical] content related to the product)
- Field length in systems

A key reason these issues occur is because the systems are not GS1 standards compliant and therefore they present various challenges and could pose a barrier to widespread adoption and implementation in the provider environment. Thus, the proven benefits to patient safety could be severely limited or, at worse, not be realised.

Lack of field(s)

During an implementation project in a Canadian hospital they experienced the issue where their scanner could read the GS1 bar codes on pharmaceutical packaging, which contained Global Trade Item Number (GTIN) and additional attributes: Lot/batch number, serial number and Expiry date, but their pharmacy inventory management system only had a field to hold the GTIN; it lacked the fields for the additional attributes. They engaged a contractor to modify the scanner software to ignore the attribute information and only read the GTIN, but ideally they would require their pharmaceutical system to include the fields for the additional attributes. Having the additional attribute data in their system would enable more efficient inventory management processes, e.g. visibility of expiring product or more efficient recalls using, for example, the lot/batch number or serial number.

Providers request all the systems developed and sold by IT/IS System solution providers to be GS1 Standards compliant, e.g. in this example to have the necessary fields in their systems to capture GTIN and other attributes (e.g. Lot/batch number, serial number, Expiry date), and that compliant data flows seamlessly between the disparate systems used in and between provider organisations. In addition, in the future, systems should be designed with a degree of flexibility to allow for continuous compliance to evolving GS1 standards.



Field length

GS1 Standards define the character lengths of all specific data elements encoded in bar codes and/or held in databases. However, there are systems in use in hospitals that do have some of these fields but they do not follow the character length definitions in the standards, i.e. the length is either too short or too long. When bar codes on items are scanned the data contained in the bar code cannot be uploaded into the system, or worse, the data is concatenated, and therefore incomplete/incorrect data is held. This could impact subsequent processes, for example in the case of the recall, the scanned product would not be retrieved because the data held is incomplete/incorrect, potentially having patient safety consequences.

Providers request all the systems developed and sold by IT/IS System solution providers to be GS1 Standards compliant, e.g. in this example that the standardised data fields are of the minimum character length defined, and that compliant data flows seamlessly between the disparate systems used in and between provider organisations.

II. Historical context

Providers understand the numerous reasons that solution providers have developed systems and software solutions / applications independent of global standards. 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
- Social: increasing demands on health systems, e.g. related to aging populations
- Economic: budgets are constrained or falling, which may be related and/or driving the above, and they are likely to be under significant pressure for the foreseeable future^{4,5}

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)⁶. BUT, the systems are not GS1 standards compliant and therefore they present various challenges and 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 be realised; consequently solution provider sales could be impacted.



III. Conclusion

Non-compliance of systems to GS1 Standards and lack of interoperability between the disparate systems used in and between provider organisations can hinder the successful implementation of GS1 standards in the care-giving environment and could pose a barrier to widespread adoption and implementation in the provider environment. If a system cannot capture and share the data scanned from a bar code then the implementation benefits cannot be realised preventing improvement in follow on processes, such as procurement, inventory management, internal deliveries, dispensing, tracking, tracing, recalls and, of course Patient Safety. Thus preventing the ultimate achievement of the 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"

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 solution providers around the world to:

- Ensure their systems comply with the ONE global standard: The GS1 System of Standards
- Immediately address the issues covered above: Lack of field(s) for bar code attribute data (e.g. lot/batch number, serial number, expiry date) and Field length, in systems currently under development as well as future system developments.

NOTE: A number of GS1 Member Organisations (MOs) around the world offer solution provider testing and accreditation programmes. To find your local MO visit: http://www.gs1.org/contact



V. References

- 1. 'Systems' refers to all types of provider administration and clinical systems and software solutions / applications and includes, but is not limited to: scanners (handheld or fixed), procurement systems, finance systems, Enterprise Resource Planning (ERP) systems, analysers, patient record systems, prescribing systems, pharmacy robot systems, materials management systems, clinical information systems, spare parts systems, warehouse management systems, eCommerce systems, master data/catalogue management systems, order management systems, requisition systems, Asset management systems, bedside scanning systems, imaging systems, clinical data systems, contract management systems, pricing/billing systems.
- 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
- Budget Crisis, Entitlement Crisis, Health Care Financing Problem—Which Is It? http://www.brookings.edu/research/papers/2007/11/fall-healthcare-aaron
- ^{5.} Can Europe still afford its healthcare model? http://www.debatingeurope.eu/2012/07/26/can-europe-afford-its-healthcare-model/
- 6. http://www.gs1.org/healthcare/library#publications
- 7. http://www.gs1.org/healthcare/library#traceability

Brazil:



Sweden:



Germany:



France:



Ireland:



Netherlands:





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.

¹ The information and views set out in this discussion paper are those of the GS1 Healthcare members and do not necessarily reflect the sole opinion of GS1 AISBL. Neither GS1 nor any person acting on its behalf may be held responsible for the use which may be made of the information contained therein. GS1 Healthcare members include over 60 leading healthcare organisations worldwide. For more information please visit: www.gs1.org/healthcare