

Integrated traceability in the hospital and home care settings

Summary

The purpose of this article is to illustrate the need in interoperability for traceability tasks, in the complex environment of healthcare.

Traceability usually focuses on objects or items, and their special and sequential movement. Here we want to embrace traceability as concerning at the end of the day, the patient himself (1). Therefore, the requirements to the traceability objectives include, in addition to the items and their sequential locations, the patient identified by the “hospital stay” or “patient episode”, that is the relationship between the patient and the healthcare provider.

Patient episodes are already well identified, each healthcare provider using a proprietary key or reference, which may (or may not) be carried in a barcode or a RFID Tag. The multiplication of the proprietary references, when healthcare evolves in integration, collaboration or networks, requires an appropriate answer to avoid a single hospital stay to be identified in several keys, each possibly bridged to one or more others. Adopting a same standard to identify patient episodes enables different IT systems to collect and group clinical information about a patient episode, because the uniqueness of the key and its standardised structure reduces links, administrative work and enhances efficiency and patient safety (2).

Purpose

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Glossary

GTIN: Global Trade Item Number, a 14 – 4 – numeric digit number identifying any object that can be traded, ordered, invoiced, etc.

GLN: Global Location Number, a 13 – 3 – numeric digit number identifying any location or function

GSRN: Global Service Relationship Number, an 18 – 8 – numeric digit number identifying any relation between the user and a third party; this can be the patient in his relation with the Healthcare System, the episode, the hospital staff, etc.

SSCC: Serial Shipping Container Code, an 18 – 8 – numeric digit number identifying a logistic unit during its journey.

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Following the patient in his care journey

The need to identify the patient episode in an un-ambiguous way emerged in a new approach at the Emergency Hospital Utrecht in the early

¹ We refer to the *EAN.UCC System*, developed by its 1,200,000 users through the world and managed by GSI, formerly EAN International. In this article, when we use the acronym “EAN”, we refer to the standardised system and when we use “GSI”, we refer to the organisation and one of its 103 subsidiaries. GSI publishes regularly updated *Global Specifications*; here we refer to the version 6.0, January 2005.

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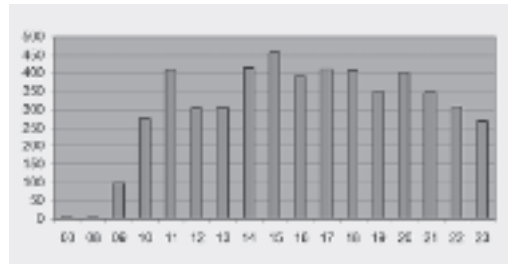


Figure 1. CHU Dijon: hourly cumulated patient movement during the pilot.

1990s. A multidisciplinary group worked on the definition of the needs to enhance processes in the case of massive patient admissions; the working group expected the solution not only to identify the patient uniquely, but also to enable real-time location of the patient, and a link on his administrative and clinical data, which will be completed along his journey by the healthcare provider [2]. The use of the newly adopted international standard identification (the Global Service Relationship Number (GSRN) has been adopted by EAN International in 1995) as a key to track and trace the patient episode, enhanced the Emergency Hospital Utrecht possibilities in its triage functions, as the patient episode ID's uniqueness was secured regardless of the possible destination of the patient for his treatment [3].

The Pilot at the CHU Dijon

Background

The patient transport department at the CHU Dijon, a 1600 beds teaching hospital in 3 main locations, has run a pilot to measure the movement of patients in the Emergency Department, over an eight-week period. Currently, the transport department manages patient transport between the 3 main sites with a web-application ("Ptah", conceived by the CHU Dijon and Géo-Soft Aquitaine; this software is now used by a growing number of French Hospitals). A detailed study about the consequences, in terms of human resources, of the transformation of the CHU in a single site Hospital has been made by the Head of the transport department in 2004 [4].

Objective

The objective of this pilot is to collect additional information about the workload and work-peaks,

to analyse and project the workforce needs in the Emergency Department (there are only two departments with obviously permanent need of staff dedicated to patient transport; the second is the Radiology Department).

Tools and methodology

The tools used for the pilot involved 2 portable laser scanners (Barman Laser, Axiome Alpha SA), programmed using proprietary machine software², a MySQL database to host the collected information and an MS-Access application for the easy data management and search functions.

The transport staff delegated to the Emergency Department captured during the working day each movement of a patient with one scan at the collecting point (location ID, patient ID, date and time), followed with a second data capture at the delivery point (location ID, patient ID, date and time).

The IDs used are structured according to EAN; we used the Global Service Relation Number (GSRN) to identify the hospital staff; and the Global Location number (GLN) to identify the locations. They were carried on an EAN-128 barcode produced by a simple standard software [5]. The Patient episode ID was allocated by the patient management system in a proprietary way and carried in a Code 128 symbology. The migration to the GSRN is in validation process.

Results

The study lasted 42 working days, or a total of 600.35 hours. It has involved 25 staff members who spent between 1 and 77.25 hours in patient transport at the Emergency Department between 11 May and 17 July 2005.

In average, each patient has been moved 1.84 time during his stay (the average of patient movement per day varies between 1.5 to 8.5). The workload intensity demonstrated that the average movements were stable through the working hours (10.00 to 24.00). As there was no dedicated staff for the transport of patients between 00.00 and 10.00, we can state that this was only possible because knowingly, there were only limited movements during this timeframe.

² The same equipment is widely used at the University Hospital of Geneva.

Conclusion

The study has demonstrated that the use of a barcode reader was well accepted by staff members, but presented some difficulties in the handling and the reading of the patient episode code on the wristband. As a result, the study had to be interrupted once when the barcode readers had to be repaired. No particular difference in the data management process has been noted between the wristband carrying the patient episode (code-128) and the GSRN or the GLN (UCC/EAN-128).

The workload was now objectively available to be evaluated in the specific existing environment.

The first evaluation demonstrated that the hourly relatively stable workload and the short reaction times explain why dedicated staff are necessary in the Emergency Department. Further, a centralised work allocation would be difficult because of the short reaction times; the extension of administrative work for the care givers may slow down the whole rhythm of the Emergency Department. On the other hand, the first evaluation confirmed that staff members can be allocated to the Emergency Department in a rotation without negative impact on the workflow in the Department (provided the staff knows the Department and its working methods).

The Irish Implementation

Background

A pioneering project between GS1 Ireland and local health bodies is using the latest GS1 technology to trace expensive and time-sensitive Clotting Factor Concentrate (CFC), the product used by haemophilic patients. GS1 Ireland is working with the National Centre for Hereditary Coagulant Disorders (NCHCD, opened at St James Hospital, Dublin in 2002) on the project which kicked off by using EAN-128 barcodes and later looked at Electronic Product Code (EPC) technology. It is believed that the project, which has been launched by the Health Minister in April 2004, could be destined for global application, like traceability of vaccines. To bring this about, a consultative group has been organised that includes representatives from the US Food & Drug Administration, the EU Commission and from EMEA [European Agency for the evaluation of Medicinal Products] as well as clinicians, medical informaticians and patient representative bodies – both local and global. Their role is to validate the solution during its

implementation and to specify the eventual system for application in further countries and for the extension to the full vaccine traceability.³

There are about 2000 patients suffering of Haemophilia in Ireland, 300 of them being treated at their home with Clotting Factor Concentrate and followed closely by their clinician, located in 13 treatment centres. Some years ago, arising from the treatment of haemophilic patients with infected blood products causing some fatalities, and a subsequent inquiry, the Department of Health and Children addressed haemophilia treatment as a matter of priority.

Objective

The objective of the Health authorities in Ireland is to implement real time identification of the CFCs (to make immediate product recall possible and to manage the distributed CFCs as a virtual stock), real time updated patient treatment history, permanent validation of the cold chain storage and delivery process, an accurate solution to ensure that the correct product has been prescribed and will be administered to the right patient, a permanently updated information tool to analyse patient treatment data.

Tools and methodology

The ID used are structured according GS1 standards; the Patient ID is the GSRN, the patients home and alternate delivery points are each identified with a GLN, the CFCs are identified with a GTIN with also a lot number, an expiry date and a serial number. The data is carried on an EAN-128 symbol, which will progressively be labelled directly by the manufacturer at the end of the manufacturing process.

Even if currently the tender for the data capture is still open, it is conceived that the barcodes will be read with a mobile phone (or a similar device) and sent to the NCHCD for populating the electronic patient file and other management tools. The EPF is based on OpTx, software developed by the US solution provider *Varian*; it has been adapted by *Clintech Healthcare Systems*, an Irish company, to correspond to the clinical needs and to host GS1 formatted information.

Data is captured at each product movement within the cold chain company (TCP, Tempera-

³ *The Ministry of Health of Canada has decided to implement full traceability of the vaccines by using EAN Datamatrix.*



ture Controlled Pharmaceuticals Ltd), when the products are delivered at the patient's home, and finally by the patient when the patient administers himself the CFC. This enables real time information about the product step by step from its entry in the Irish Supply Chain through its journey to the patient. Data are managed for logistical and clinical purposes in an automatic way.

Results

The first phase of the project started in the summer of 2005 with home deliveries, and the country wide roll out is planned for the first half of 2006.

The GRSN was assigned to the patient and was used as the key identified for both the Supply Chain Database and the Clinical Database, thereby establishing a globally unique reference linking the two databases. Later phases of the project will use this reference to link with the prescription, patient self administration and treatment within the hospital.

Conclusion

At a mid-term stage of the implementation, we can state that the use of the EAN.UCC System had very little influence on the investment for this project; it offers the security of the uniqueness of the identifications and is in full alignment with industrial practices within the Pharma supply chain as well as with the requirements of the US FDA on product (and single dose) identification. Further, the approach made by NCHCD and GS1 Ireland is in alignment with the implementation of the Electronic Product Code, which may be carried in a RFID Tag or in a barcode – or both together.

The patient can be treated at his home or at any treatment centre in Ireland, with the assurance of the highest quality and security.

Discussion

We consider the two examples of use of the GSRN as an interesting opportunity to compare the use of proprietary solutions – as it is widely the case – with a standardised data format, providing worldwide uniqueness.

First we can state that anyway the patient episode has to be identified; this can be achieved with any solution. What is then the benefit of the GSRN?

When considering an isolated hospital (having no interaction with another hospital), the patient

episode will be generated by one of the IT components – i.e. the patient administration tool. Then all the surrounding IT components – for laboratory samples and other clinical processes – should adopt this identification as a key. The use of one single patient identification across the hospital reduces significantly the number of data capture devices, as these should be able to capture the same data format.

When items have to be linked to a patient episode, the data capture process will face sequentially the hospital episode and the item identity, which is a GTIN in at least 54% of the cases [6]. The risk of confusion cannot be excluded if we consider that a significant part (7%) of the hospital supplies arrive with proprietary identification. Then, the data capture system has to be implemented to “decode” EAN data structure (for example to distinguish a lot number from an item number).

As the hospital produces also product identification (for example at the central sterilisation), these are usually identified with another proprietary solution. A special attention to avoid any data collision with the patient episode ID will be necessary. On the data capture process, either one will use a dedicated scanner or will have to implement an additional data structure in the existing one, beside episode ID and supply ID. If another task in the hospital produces item IDs, the complexity of the process grows dramatically – or the number of dedicated scanners.

By adopting the EAN system with the target to enhance some elements of interoperability, the hospital adopts an existing standard describing the data formats and securing the uniqueness of the IDs. The episode ID is, according the EAN standard, a GSRN, whilst an item (coming from the suppliers or being produced at the central sterilisation), is identified with a GTIN (with an appropriate format for the lot number, the expiry date, the serial number, etc.). The marginal additional cost to any proprietary solution is the membership fee to the local GS1 organisation; the marginal economy is the security of uniqueness of the IDs, the capacity to integrate one single data decoding process for various IDs, regardless of their origin (external or internal supply, staff or episode identification, assets, etc.).

Unfortunately we have no indication about the economies made in Ireland by adopting the EAN system compared to any proprietary solution. We can state that the additional costs have been extremely low, and when the CFC manu-

facturers will extend the standard they already use to the CFCs, one cost reduction will be put in evidence.

The use of the EAN system in the Dijon pilot does also not demonstrate cost reduction, and did not cost more than any proprietary solution (as the Hospital in Dijon is already a member of GS1 France). It has demonstrated that the current patient ID could be integrated in a GSRN, with full discrimination with the staff GSRN.

The hospitals of Geneva and Lausanne are considering the adoption of GSRN for episode ID and staff ID, and the Dijon study has been part of the input for the decision and implementation process.

Conclusion

Whilst the EAN system is widely used in the world in more than 20 market segments, we

have very few cost/benefit evidence of its advantage to any other proprietary solution in the Healthcare environment. The two cases in Ireland and Dijon helped to understand that interoperability becomes cost effective by using this standard, as the hospital is in relation with a large number of external parties and intends to outsource or collaborate: each of these considerations requests the standardised approach.

We express our thanks to Jim and Jean-Yves for their close collaboration in the preparation of this summary.

Conflict of interest: As an independent consultant, Christian Hay and Medinorma LLC provide services and participate to implementation of identification and traceability projects in Healthcare. One of the important customers of Medinorma LLC is the GS1 Organisation in Switzerland, France and Europe.

References

- 1 "Patient died after drugs went to man with the same name", Daily Mail, 2 November 2001.
- 2 Noordergraaf GJ, et al. Development of computer-assisted patient control for use in the hospital setting during mass casualty incidents. *Am J Emerg Med* 1996;14:257.
- 3 Boumn HH, et al. Computerization of patient tracking and tracing during mass casualty incidents. *Eur J Emerg Med* 2000;7:211.
- 4 L'informatisation de la fonction transport patients au CHU de Dijon, Conséquences et perspectives d'évolution, Jean-Yves Gerbet, Mémoire de licence de logistique hospitalière, IUT Chalon sur Saône, 2004.
- 5 Seagull Scientific Inc, BarTender version 7.5.1.
- 6 La belle histoire des CHU et du code à barres, Christian Hay, Décodez No 89, Paris 2005.