St. Antonius Hospital:
The traceability of implants

ABSTRACT

The St. Antonius Hospital (STZ) in Nieuwegein, the Netherlands, implemented a standards-based solution to improve the efficiency of the electronic tracking and ordering of Implantable Medical Devices (IMD). STZ and other hospitals around the world are looking for ways to track IMDs at every step along the entire supply chain simply, accurately, reliably, and efficiently.

By **Menno Manschot,**
St. Antonius Hospital

Introduction

Group Purchasing Organisations (GPOs) in the United States are ahead in this field. This is due partly to the U.S. Food and Drug Administration's public support for standardisation of the Healthcare supply chain and its close involvement with making logistical improvements to that chain. The Netherlands is lagging slightly behind, but there are certain developments, such as bundled purchasing, that are clearly on the rise.

At present IMDs are largely tracked by hand in a variety of systems used for different purposes: Electronic Health Records (EHR), Diagnosis Related Groups (DRGs), purchasing, R&D, etc. The supply chain for IMDs is inefficient, there is limited traceability of IMDs along the chain, and different systems and standards are in use.

Bar code scanning enables traceability

With this project, St. Antonius applied bar code scanning to automatically register IMDs and link them to patient records. This reduces the number of transactions, both manual and automatic. The improved knowledge about 'which items are in use with which patient' can benefit patient safety. In addition, the registration of devices is intended to enable item re-ordering the moment that it is used, thus reducing inventories. A pre-condition for this project is that the IMD is scanned at each point of transfer within the supply chain.

The hospital's Board of Directors approved the project plan. The project sponsor is the hospital's medical staff.

About St. Antonius Hospital

The St. Antonius Hospital is the largest non-academic teaching hospital and provides clinical care in the Netherlands. St. Antonius is a modern 880-bed hospital, where almost all specialties are represented. Nationally, the hospital is known for treating patients with cardiac, vascular and lung diseases.

St. Antonius has six locations, including Nieuwegein, Utrecht Overvecht, Utrecht Oudenrijn, Utrecht Meern, Vleuten and Houten. A new hospital is being built in Leidsche Rijn with an innovative care concept.

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> "To a cardiothoracic surgeon an automated bar code system means the following: Safety, traceability, inventory control and order processing, database support and cost savings by reducing invoicing errors: all crucial to be able to perform your work efficiently and safely."
>
> **Drs. Wim Jan van Boven**, Cardiothoracic surgeon, St. Antonius Hospital, Nieuwegein, The Netherlands
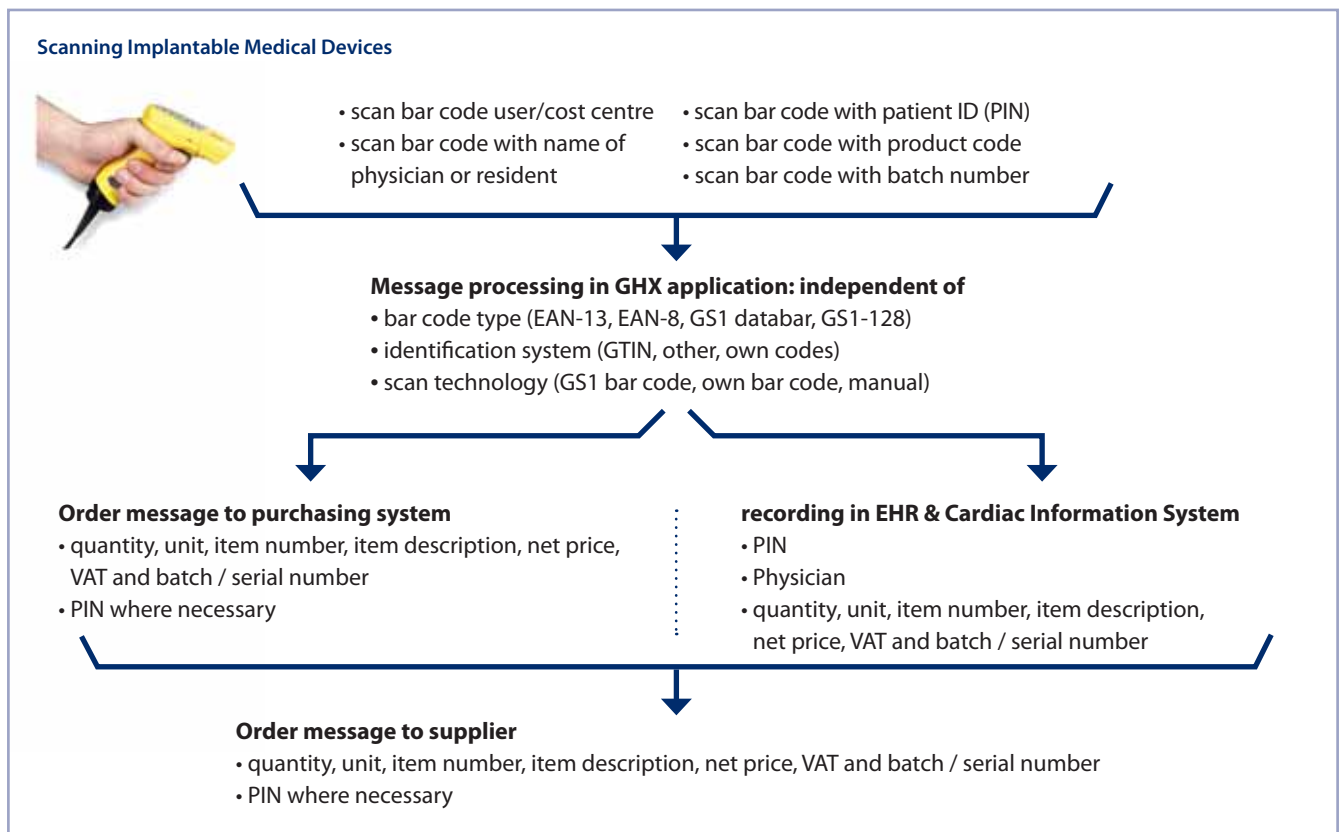
Project participants

A pilot was carried out in 2007 in the hospital's Oral Surgery Department (outpatient). It was relatively simple to implement electronic tracking and replenishment. There was a single supplier and only one product type. This new way of working has since been made fully operational within Oral Surgery.

In 2008 the electronic registration, tracking, and ordering of IMDs was implemented and has since also become operational in the Intervention rooms. Implementation here was much more complex. There is sometimes more than one bar code on a single item, and the bar codes are not all the same type (GS1, other).

In 2011, the activities will be expanded to the following departments:

*   Cardiothoracic surgery – 1st Quarter
*   Vascular surgery – 2nd Quarter
*   Orthopaedics and trauma – 3rd Quarter
*   Pain control and perfusion – 4th Quarter
*   ENT and ophthalmology – 4th Quarter
*   Cardiac Rhythm Management (CRM) – 1st Quarter

The project participants have all received an explanation and instructions in the use of the scanners, item bar codes and the software.

Scanning Implantable Medical Devices

• scan bar code user/cost centre
• scan bar code with name of physician or resident

• scan bar code with patient ID (PIN)
• scan bar code with product code
• scan bar code with batch number

Message processing in GHX application: independent of
• bar code type (EAN-13, EAN-8, GS1 databar, GS1-128)
• identification system (GTIN, other, own codes)
• scan technology (GS1 bar code, own bar code, manual)

Order message to purchasing system
• quantity, unit, item number, item description, net price, VAT and batch / serial number
• PIN where necessary

recording in EHR & Cardiac Information System
• PIN
• Physician
• quantity, unit, item number, item description, net price, VAT and batch / serial number

Order message to supplier
• quantity, unit, item number, item description, net price, VAT and batch / serial number
• PIN where necessary

Automation systems already in place

- Secure Medical Registration by GHX. In collaboration with St. Antonius Hospital, GHX has developed a bar code scan-solution in which the items used are linked to patient records in the different systems.
- Catalogue management
- Electronic messaging. At present only the order module is implemented. In the future, St. Antonius would also like to use other messaging modules: trade item data, order response, despatch advice, and invoice. Internally: such as for item information (item number, batch number) in the EHR.
- iSoft hospital information system. There is a link between iSoft and GHX for ordering.

Data recorded and tracked

In order to meet the project's two goals, St. Antonius Hospital records at least the following data:

- Item number
- Batch number
- Serial number
- Patient number (internal number)
- Employee number: physician or assistant (internal number)
- Cost centre (internal number)
- Quantity
- Item unit
- Price

It is also important to track expiration dates for both logistical and commercial purposes. At present, these are seldom applied as a bar code to the packaging. St. Antonius does however need this information in order to know when items will pass their expiration dates. The hospital will be able to minimise loss and thus realise savings.

Lessons learned

St. Antonius' project implementation was held back by the following points:

- There is no standardised bar code and identification system for IMDs. This leads to delays in scanning. The user must first see whether there is a bar code on the item. The bar codes are not always in the same place on the packaging and look different. Sometimes a single bar code will contain varied information and at other times each information item has its own separate bar code.
- Supplier cooperation. Suppliers' knowledge of GS1 standards is not optimal.
- Different bar code(s) on the packaging. The order in which bar codes are scanned from the packaging is important and can lead to erroneous information in the system. The user must check carefully which bar code should be scanned first (for example, first the item number and then the batch number).
- Management and updating of revised codes and systems. Data quality is not optimal.

- Verification of scanning accuracy. At present this is done after the operation rather than at the moment of use since it would otherwise take too much time. The result is that not all items used during the operation can be identified and tracked. Verification shows, for example, that the batch number from a bar code ended up in the item number field in the system.

Solutions have been found for most of the problematic bar codes. 1% of the bar codes still lead to various problems (the information embedded in the code is incorrect or ends up in the wrong place in the system). This requires manual verification, resulting in more time being needed for data processing.

Improving logistics and patient safety

The project has two goals: improving logistics and patient safety.

1. Logistics
The simple and clear electronic tracking of IMDs so they can be automatically re-ordered. The order process will become faster and more accurate as a result.

Because 1% of the bar codes create problems, the optimum benefit has not yet been obtained. While the re-ordering process is faster, inventories have not yet been reduced. The time savings in the ordering process is as expected, but since data quality is still not at its optimum and 1% of scans still create problems, people lose more time on post-control and data management than expected.

St. Antonius has found savings in its consignment inventories. Costs have been reduced now there is improved stock insight. Item and batch numbers are 99% recorded in the system.

2. Patient safety
The simple and clear electronic tracking of IMDs so that the data on the IMD can be automatically linked to the patient's record. This will guarantee traceability down to the patient and thus improve patient safety.

Traceability down to the patient is now entirely automated and is 98% complete. 1% is corrected manually due to scanning problems, and another 1% needs to have the patient number entered after the fact due to emergency procedures.

This was an entirely manual process in the past. The labels with bar codes and numbers were pasted into the paper patient file and as such this data was not centrally available. Since this data (item, batch, and patient number) have become digitally available, there is now much more control over the data and the process. Mistakes are detected earlier, making it possible to rectify the situation faster. This has certainly benefited patient safety.

Positive side effects

The far greater amount of information available in the system from bar code scanning has yielded a number of positive side effects. St. Antonius Hospital uses this information for:

- Research (which implants have what effect on the patient)
- Financial statistics (cost calculations for Diagnosis Treatment Combination, reimbursements)
- Automated catalogue management (adding new items to the catalogue, updating product information)

Conclusion

Scanning provides faster IMD tracking, but as the bar codes and the information they contain is not standardised the scanning process is not yet optimal. Hospitals should join forces to speak as a single voice with suppliers to apply GS1 bar codes to their packaging. We need guidelines for the standardisation of bar codes. The pertinent data, item number, batch number and expiration date, must be contained in a single bar code to preclude this data ending up in the wrong place in the system. Information on the importance of the scanning sequence in staff training should be included; first check which bar code contains the item number, then which has the batch number, and which bar code has the expiration date. Last, but not least, information on traceability projects should be shared with colleagues from other hospitals so that we can learn from each other; to further improve and facilitate implementation.

ABOUT THE AUTHOR

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Menno Manschot joined the St. Antonius Hospital in 1996 and is responsible for the management of the procurement and logistics system in the hospital. He leads or participates in several strategic projects, including the implementation of a system for traceability and ordering via bar code scanning. Menno Manschot also actively participates in GS1 and GHX user groups.