Bernhoven: the first Dutch hospital with a unique barcode on all medical devices

Bernhoven is the first hospital in the Netherlands that operates according to the GS1 Global Traceability Standard for Healthcare. An extensive international audit has shown that the hospital has a unique GS1 barcode on each medical device in the operating room (OR). The result is complete traceability, from the time a product enters the hospital to the point of use, thus improving patient safety and supply chain efficiency. All of this is accomplished via the support and cooperation of all stakeholders throughout the chain within the hospital, from management to purchasing, finance and IT departments.

*By Justin Bitter and Erik van Ark*

**Background**

Improving patient safety and adequate management were the motives for starting a project on traceability in Bernhoven, a 380-bed hospital located in Uden, The Netherlands. The goal was to achieve 100% visibility in the internal process flow for medical devices, including better management of product recalls, improved inventory management and reduced manual processes.

Bernhoven decided first to focus on traceability of medical devices in the operating room (OR), starting with orthopaedic implants, because 40% of medical products used at Bernhoven support this specialty. Orthopaedic implants are also characterised by a high value; showing quick results was important to lower any institutional resistance to implementing standards and provide confidence to all stakeholders of the potential benefits of traceability.

Next, Bernhoven started implementing the traceability process in the instrument sterilisation department and on high-risk medication in the OR.

As a starting point, Bernhoven used the business case “Patient Safety and Efficiency at the OR” (2012) which demonstrated that the investments had a return of investment within one year. This convinced the Board of Directors of Bernhoven as well as other management and key personnel.
involved. It is critical to have a single shared vision to ensure the entire staff is working towards the same goal. In this way the hospital will achieve the commitment that is crucial to make the implementation a success.

**Challenge**

One of the biggest challenges is persuading suppliers to assign a GS1 barcode with the right information: Global Trade Item Number (GTIN), batch number and expiration date for all medical devices. Not every supplier delivers its products with such codes. Nowadays, there is a variety of barcode types (those from GS1 and from other issuing agencies, proprietary, self-created codes, or none at all) present on the packaging of medical devices. In addition, there can be more than one barcode on the package, which makes it difficult for the OR staff to decide which one to scan and which to avoid. There is no consistent or uniform way to manage the receiving of medical products, which provides another layer of complexity.

Bernhoven must maintain 100% control of its internal supply chain. For this reason, Bernhoven secured its own GS1 company prefix, used in the assignment of unique identification numbers to the products that are lacking GS1 barcodes. Around 60% of the medical devices already do have a GS1 barcode and can be scanned right away. The other 40% need to be re-labelled by Bernhoven until the manufacturer of these products provide a uniform barcode from GS1. In the meantime, providing a hospital-generated label and barcode enables the OR staff to handle all products in the same way. Ultimately, legislation will have to be developed to require every medical device to have a GS1 barcode.

Having a more efficient process to manage the movement and inventory of medical supplies in the OR and other clinical areas empowers staff to focus on the patient, improving the quality of care and patient safety, vs. a manual-based administrative process that may take time away from the patient.

**Solution**

Currently, Bernhoven is able to track and trace all items implanted in patients by their own developed digital web-based system. The system links products’ GTIN with the unique patient number. Using GS1 standards, the hospital makes sure that each implant used in the OR can be scanned and that item number (GTIN), lot number and expiration date are recorded in the system, which benefits the whole supply chain. Scanning the related GS1 barcode in the OR completes the patient record and reduces the stock level automatically.

In case of a recall, the hospital is able to track and trace patients on the same day and remove the affected stock from the location in the OR department. Unnecessary harm to patients is avoided. By embracing GS1 standards, Bernhoven is also prepared for the Unique Device Identification (UDI) legislation to come in Europe.

**Results**

The project for traceability in Bernhoven is a success. Many benefits are achieved and costs saved.

The hospital is now able to:

- Carry out a recall efficiently without manual interference within the shortest possible time (100% complete, including internal stock position and implants in patients);
- Reduce dependency on manual-processes and the OR staff and guarantee instant and direct registration of medical devices;
- Secure digital data storage of new and removed implants (prepare the system to link data directly to a central registry of implants, supervised by the Dutch government);
- Realise accurate registration of implants in patients in their electronic health record;
- Downsize manual work in the administrative organisation of the OR department;
- Get digital visibility of stock levels in the OR department (similar to the retail and online industries);
- Reduce inventory level;
• Reduce waste by registering expiration dates (automated checks and proactive removal of expired goods);
• Obtain accurate product data from the supplier instead of maintaining that type of information by hospital staff;
• Obtain insight in costs of used products per operation, thereby improving strategic planning and resource allocation;
• Develop analyses in the yearly financial statements of the hospital.

**Key Performing Indicators**

- Total number of medical devices registered in Bernhoven’s web-based application: 9,245
- Total number of medical devices currently active: 3,477
- Total number of medical devices associated with patients: 4,761
- Total number of patients associated with used medical devices: 1,771
- Total value of current stock/inventory of medical devices in the hospital’s financial statement at the start of the project: € 807,000 (non-sterile products included, value sterile stock: € 677,000)

**Cost reductions**

The following cost reductions were obtained:

- Reduction of stock by 31%
- Reduction in stock value by 23.6%
- Reduction of waste by 72% (representing a total value of € 25,200)
- Decrease of interest based on the reduced stock value (€ 173,575* * 1.45% = € 2,517)

**Conclusion and next steps**

The next step of the hospital is to extend GS1 standards to other products and departments. Instrument trays will be labelled using the success of St. James’s Hospital in Dublin* and its use of GS1 standards to manage its internal supply chain. To achieve closed-loop medication in the OR, high-risk medication will also be labelled. In addition, Bernhoven wants to start bedside scanning at the wards, focusing on high-risk medication first. In the radiology and cardiology departments, the Global Traceability Standard for Healthcare (GTSH)** will be applied to medical devices. As a pilot, GS1 barcodes will be introduced for assets in the OR as a proof of concept. If the project is successful, they will be applied for assets throughout the whole hospital.

Bernhoven is member of the Dutch focus group for traceability, under leadership of GS1 Netherlands. This group is now discussing with the Dutch government what can be done before the implementation of the EU-regulation on standardised barcodes. Berhoven hospital has also become a strategic partner regarding the launch of a national registry for implants. The hospital is involved in the process of preparation, providing the best vision and ideas and turning them into long-term solutions for all hospitals in the Netherlands. In the frame of this national registry, GS1 is the recommended standard for implant identification.

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* Using an Electronic Patient Record and unique medication barcoding to deliver integrated comprehensive patient care for patients with Haemophilia.

** Global Traceability Standard for Healthcare Business Process and System Requirements for Supply Chain Traceability: This standard is the definition for GS1 healthcare members of what the process standard for traceability in healthcare encompasses and it shows the corresponding GS1 numbering, automatic identification data capture (AIDC) or data communication standards that must be in place for best practice applications.
About the authors

Justin Bitter is a trained OR nurse, and manager of the OR and sterilisation departments at Bernhoven Hospital, Uden, The Netherlands. He serves as the chairman of the GS1 Dutch focus group on traceability in healthcare. In this role, Bitter is involved in improving patient safety and cost efficiency in the supply chain of hospitals by using uniform barcodes both on a national and international level. He is currently working on his PhD studies.

Erik van Ark (MD) is an Anesthesiologist at Bernhoven Hospital, and a member of its executive staff. He has been involved in implementation of pre-operative screening of patients, patients’ logistics and re-organisation of patient-scheduling and OR-organisation. Since 2012, van Ark has served as the chairman of the OR in a dual management system in which the doctors are in the lead. He is a supporter of GS1 standards in Healthcare.

Tips from Bernhoven if you wish to implement the process traceability of medical devices:
1. Ensure you have the correct network to help you.
2. Identify beforehand the processes that need to be improved.
3. Identify the areas that will benefit from the scanning process.
4. Involve your GS1 MO. Take advantage of their expertise and knowledge.
5. Visit a hospital that has gone through the same process.

“To support the establishment of UDI (unique device identifier), we will make agreements with manufacturers and the healthcare sector. UDI plays an important role in patient safety; it makes it easier to trace products, helps in the control of counterfeit medical products and moreover ensures that wastage is counteracted.”


About Bernhoven

Bernhoven is a 380-bed hospital located in Uden, and has its polyclinic in Oss, The Netherlands. Its mission is to provide the best care using modern technology and approaches. Both patients and employees (150 medical specialists and approximately 2,500 employees) take a centre stage. Together, with partner care organisations, the hospital provides comprehensive care to patients. In addition to basic care, the focus of Bernhoven is on senior care and total vascular care. Also, the hospital is well known for its Regional Pain Centre.