

Netherlands

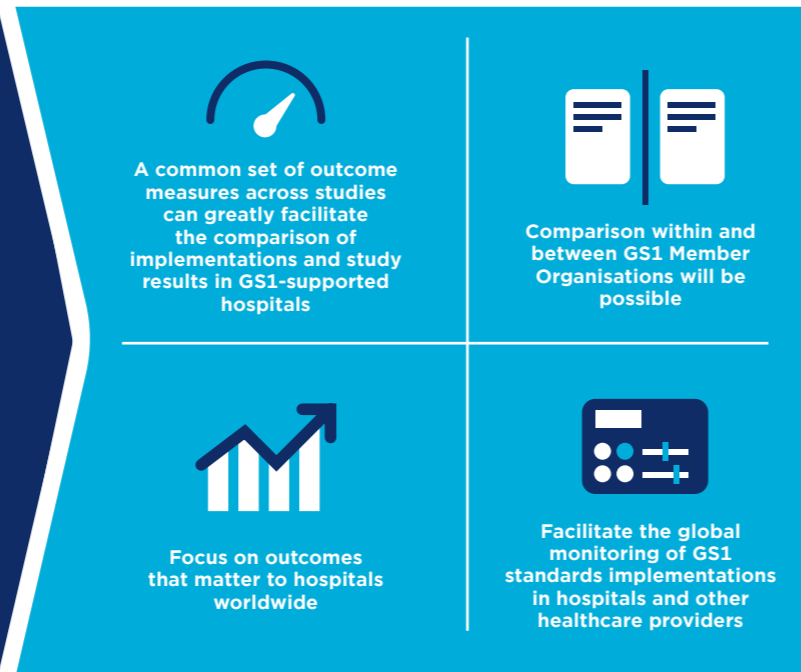
Developing the GS1 monitoring tool: a standardised set of patient safety outcome measurements

Challenge

While some studies have investigated the efficacy of barcoding, the outcomes assessed across trials are different. This inconsistency in measured outcomes poses concern when evaluating the effects of barcoding on patient safety and quality of care.

Approach

The objective of this work was to define a minimum, internationally appropriate set of patient safety outcome measurements for evaluating, generating evidence and improving the implementation of GS1 standards.



Barcode systems are designed to contribute to patient safety, improve quality of care and increase the transparency of medical processes. While barcode systems are increasingly being used in healthcare, the level of evidence for efficacy in patient safety and quality of care is

unclear due to differences in the outcomes assessed across trials.

Introduction

Since the 1970s in worldwide retail barcoding via Automatic Identification and Data Capture (AIDC) standards, using globally accepted barcodes has played a crucial role in the supply chain, ensuring that the right products are available at retail stores and significantly reducing the time for customer check-outs.

In the recent years, global healthcare regulations on pharmaceuticals and medical devices—which include implants—are aligning to global standards for product identification. Regulatory agencies and jurisdictions (e.g., in Australia, Canada, China, Europe, UAE and US) acknowledge the necessity of global barcoding standards

in healthcare for procurement and traceability reasons. In addition, there is growing evidence for the efficacy of barcode solutions in improving overall patient safety.



Maike Langelaan & Esther Peelen

Monitoring tool

Medication-related adverse events and high-risk medical device-related adverse events are important priorities for patient safety. Incidents in the medication distribution process or with medical devices, such as implants, have occurred at regular intervals in the past. These incidents have resulted in a significant number of patients harmed and great cost incurred by the healthcare system due to the necessity of additional medical treatment or corrective surgeries. Human error is an important factor in medication-related and medical device-related adverse events. Therefore, information technology solutions are often explored to mitigate the risk of human error.

The implementation of global standards in hospitals is associated with higher quality of care, greater patient safety and better supply chain management. And so, new safety programmes focus on barcode medication administration systems and medical implant traceability.

Robust evidence from well-designed prospective studies is required in order to further consolidate the implementation of GS1 standards as an accepted intervention applicable to hospitals. To date, there has been no formal investigation of the impact of implementing GS1 standards on the quality of care—the disease-specific process of care

indicators, hospital costs and resources related to actual budgetary expenditures.

The development of a core monitoring set of evidence-based, standardised, outcome measures would help researchers, policy makers, healthcare managers and caregivers come together with a uniform approach. This would make comparing implementations within and between GS1 Member Organisations (MOs) possible.

The purpose of the project is to develop a set of core outcome measures for the evaluation of global standards-based barcoding in hospitals worldwide—measures that are considered relevant for researchers, policy makers and hospitals. A core set of outcome measures is the *minimum* set of outcomes that should be consistently measured and reported in all studies. However, this does not restrict researchers from adding additional outcomes. A minimum set of outcomes will provide greater uniformity of reporting in clinical trials and more data to impact meta-analyses. It will reduce study heterogeneity and the risk of reporting bias by consistently measuring and reporting these outcomes. A core set of outcomes would not only result in a standardised set of *which* outcomes to measure and *how*, it could also improve the coordination, communication and knowledge transfer between research groups, policy makers and healthcare professionals.

“Our literature review revealed heterogeneity in outcomes.”



Maike Langelaan
Business Consultant
PinkRoccade Healthcare

The literature review revealed significant differences in outcomes. Yet, there was also an overlap in outcomes collected by trials, registries and those reported by GS1 experts.

Identification of potential outcomes

To identify potential patient safety outcomes related to the implementation of GS1 standards, a systematic review of relevant publications was the first phase of the project.

This search retrieved 288 articles. After screening titles and abstracts, 46 PubMed-indexed articles published as of 1 January 2010 were included for review. An additional literature review was performed to identify studies in the five most recent *GS1 Healthcare Reference Books*.

Each article was scanned for patient safety outcomes. This resulted in a lengthy list of 69 patient safety outcomes.



The outcomes from the review were categorised into six major groups:

- General outcomes (8 outcomes)
- Medication-related outcomes (34 outcomes)
- Medical device and implant-related outcomes (11 outcomes)
- System or procedure outcomes (5 outcomes)
- Specimen-related outcomes (11 outcomes)

Delphi study

The next step of the project, performed by a global working group, was an initial Delphi study that resulted in a short list of outcomes. The working group consisted of GS1 experts from six GS1 local offices in Australia, Denmark, France, the Netherlands, Poland and UK, and a healthcare expert from GS1 Global Office.

This first step involved a series of two online rounds of data collection and analysis to condense the opinions of the working group members on what outcomes should be measured.

The team used an online survey tool to create and administer the questionnaires. For each major group of outcomes, experts were given the option to provide free-text comments to support their decision, or to suggest changes or additions to the outcomes.

During the second round, experts were given the mean scores of each outcome in round 1 and the answer provided by the expert. Three outcomes that were suggested by the experts during the first round were then added.

To be included in the short-list standard set required that at least 80% of the experts voted an item as “essential,” which meant it had a mean score of 7 or higher on a 0-10 point Likert scale. This resulted in a short list of 43 outcomes.

The long list of potential outcomes and statistical scores were presented to the global GS1 Healthcare Interest Group (experts from all GS1 MOs working in healthcare) for discussion during a teleconference meeting.

“The methodology allowed for worldwide participation of GS1 MO experts, policy makers and healthcare workers.”

Maaïke Langelaan
Business Consultant
PinkRocccade Healthcare

Considerations

This methodology allowed for creation of a core set of outcomes that is relevant to measure the effectiveness of GS1 standards implementations worldwide.

Specifically, the methodology allowed for worldwide participation of GS1 MO experts, policy makers and healthcare workers. Discussion at the consensus meetings provided additional, in-depth consideration of important aspects such as the definition of outcomes, practicality of the measures and their global relevance—all which will enhance the potential use of the core metrics for quality improvements among specific risk groups.

Next steps

The 43-item short list will be sent to GS1 MOs and care workers in hospitals. They will be asked to rate their confidence regarding several elements of the set on a 10-point Likert scale, with an open field for comments.

Outcomes with a mean score of 7 or higher will be included in the final set of outcomes (the monitoring set). This set will be worked into a monitoring tool, an IT-based tool to be shared with the GS1 MOs. The next step will be to conduct a pilot study to validate the core set of outcomes in a daily hospital practice.

The final stage of this project will be to promote the implementation of the set of outcomes, using the monitoring tool.



Major hurdles to be overcome include:

- 1 **Gaining agreement of local research teams willing to use the set**
- 2 **Ongoing evaluation of what is and is not being measured**
- 3 **Ensuring efficient and user-friendly means of collecting and storing clinical data**
- 4 **Confirming systematic and consistent collection of data**
- 5 **Budgeting**

“A common monitoring set of outcome measures across studies would greatly facilitate the comparison of implementations and study results within and between GS1 Member Organisations.”

Maaïke Langelaan
Business Consultant
PinkRocccade Healthcare



Benefits and conclusion

In the end, a common monitoring set of outcome measures across studies will greatly facilitate the comparison of implementations and study results. This could also improve the coordination, communication and knowledge transfer between research groups and professionals and, thus, facilitate implementation of GS1 standards in hospitals.

The cross-MO team will develop a consensus recommendation for a standardised set of outcomes that is deemed most important to healthcare providers using GS1 standards. This recommendation is targeted for integration into implementation research and publication of evaluation studies. Use of the standard set may enable researchers, policy makers, healthcare managers and caregivers to monitor, compare and improve the implementation of GS1 standards worldwide.

About the authors



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Maaïke Langelaan works as a business consultant of patient safety and quality of care. She is the project leader of the implementation of patient safety indicators based on routine data in hospitals. She carried out several (systematic) reviews for the development of evidence-based medicine and several guidelines. Her fields of interests are quality in healthcare organisations, patient safety, and the development and validation of methods for measuring patient safety and adverse events.



Esther Peelen
Manager, Healthcare Providers
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Esther Peelen is Sector Manager, Healthcare Providers at GS1 Netherlands. Ms. Peelen supports providers in implementing GS1 standards in the operating room, pharmacy and other departments. She uses the experience and insights from the providers to create tools and to facilitate knowledge exchange between providers. Ms. Peelen works closely with other standards organisations in healthcare and with provider associations to spread this knowledge and, thus, take implementation a step further.

About the organisation

PinkRocccade Healthcare is a provider of software solutions in the Netherlands. The business unit, Hospitals BI, ensures that hospitals have the necessary data management at their disposal. Hospitals BI has an extensive data warehouse as well as ample knowledge of quality and patient safety. Its solutions include:

- Performance monitor: current total overview of the quality indicators in a hospital
- Datadash: anonymize data to support the GDPR legislation
- Geniq: complete data warehouse for the most critical flows in the hospital

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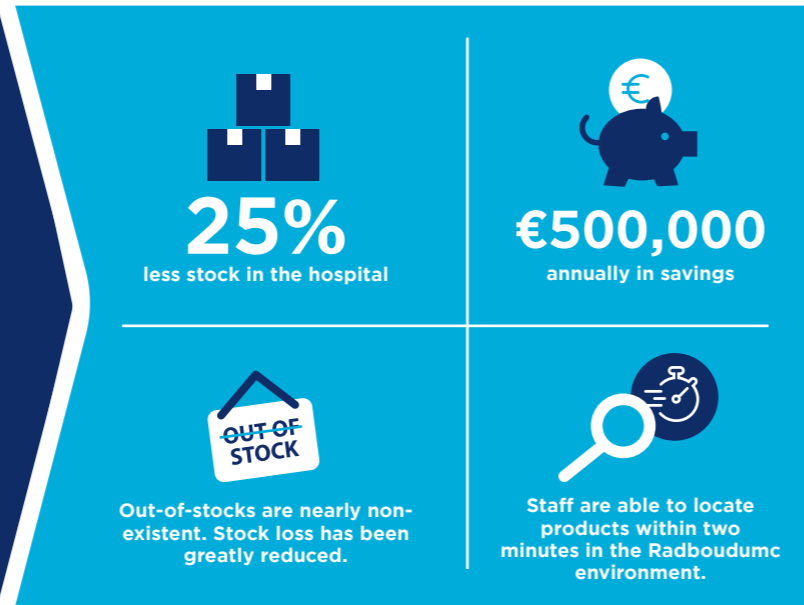
Fewer bricks and more clicks result in optimal medical device inventory at Radboudumc

Challenge

Radboud University Medical Centre (Radboudumc) wanted to eliminate out-of-stock situations for its operating theatres to ensure better patient care and outcomes. The hospital recognised that human behaviour would be a major challenge when implementing GS1 standards and the necessary change processes.

Approach

Radboudumc designed optimal processes, secured systems and connected people, using GS1 standards to uniquely identify medical devices and share valuable data throughout its hospital—from receiving goods to patient use.



Radboudumc

A situation of “being out-of-stock” is not an option in a hospital. If a crucial medical device is not available at the right time, this can make the difference between life and death. For the best care, more control over stock was needed at Radboud University Medical Centre. Today,

enabled by GS1 standards, the medical centre’s processes are optimally running, systems are correctly connected and people are working differently and better.

“Fewer bricks and less walls” means that people no longer work for just their own departments, but together. Everyone focuses on the goals of increasing efficiency in processes and safety of care, all while reducing costs.

Processes conforming to standards

In 2015, Radboudumc did not yet have complete control when managing its stock levels. The various stock locations throughout the hospital were managed in different ways by healthcare professionals with no logistics background. Everyone managed the inventory as well as they could, often using manual processes and with systems that were not interconnected. The chance of an out-of-stock situation was highly probable.

Alex van der Putten, Head of Procurement & Supply Chain at Radboudumc, wanted to

improve inventory management for better patient care. He understood that the inventory management processes would need to be redesigned and supported by GS1 standards and integrated systems.

“At the beginning of the project, various barcode formats were in use,” says Mr. van der Putten. “This led to problems with scanning; sometimes, we had to enter item numbers manually. It was crucial to have a record about which implant was used in which patient.”

Alex van der Putten

Now, Radboudumc only accepts and uses GS1 barcodes—the GS1-128 barcode and two-dimensional (2D) GS1 DataMatrix. By using GS1 standards to uniquely identify medical devices, they can be easily scanned in the operating room, capturing valuable information for use throughout the hospital. Stock management

processes have also been revised to include scanning as an efficient way to safeguard medical supplies with GS1 standards. The information collected when scanning barcodes is also linked with the various systems and databases at Radboudumc.

Fewer bricks, less walls

“There is no doubt that standards are needed in the future. There are three factors that shape the future in hospitals,” says Mr. van der Putten. “The first factor is ‘fewer bricks.’ Due to several factors, including reduced length of in-patient-stay, we see our hospitals literally shrink. We are working on a new construction in

Nijmegen, where we will ‘hand in’ 100,000 square meters. That means that the hospital will soon have a quarter less space—less space also for inventory.”

The “virtual walls” between departments have also been removed at Radboudumc. “Previously, each department had its own processes and methods,” continues Mr. van der Putten. “Now, we have one logistics organisation responsible for inventory management in the entire hospital. Before implementing GS1 standards, if an employee (responsible for stock in a specific department) went on holiday, additional inventory was sometimes stocked in that department in advance. This would lead to extra stock that would eventually expire. Now, there is uniformity in inventory management processes that are more efficient, resulting in less waste and fewer risks.”

“We can implement beautiful processes, systems and standards, but it is ultimately people who have to work with them. That’s why agreements are needed.”



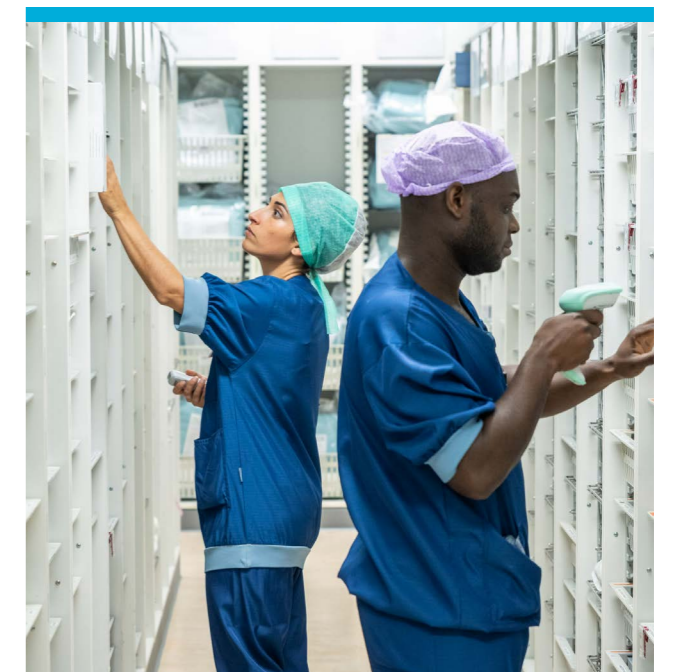
Alex van der Putten
Head of Procurement & Supply Chain
Radboudumc

Growing assortment of medical devices

Another factor driving change in hospitals is the exponential increase in the amount of data. This is partly due to the growing types of medical devices.

“We used to have a certain set of medical devices and instruments that we could use for different treatments,” explains Mr. van der Putten. “Today, a certain procedure increasingly has its own specific set of medical devices and instruments. Moreover, the medical devices become obsolete faster. In the past, the useful life was perhaps five years, now sometimes only twelve months.”

As a result, data becomes outdated faster. By using GS1 standards and GS1-approved data pools, healthcare providers like Radboudumc can more readily update and control their medical device data and guarantee the quality of the data.



Human behaviour

The third factor is the behaviour of people in hospitals. “We can implement beautiful processes, systems and standards, but it is ultimately people who have to work with them. That is why agreements are needed,” says Mr. van der Putten.

In the past, consumption of materials in Radboudumc’s operating rooms was only registered after treatment. The medical devices were prepared in advance for a planned procedure, but not yet deducted

from stock levels. Logistically, that was not efficient nor desirable since there was not a real-time view of what devices were available for procedures. Now, every physical movement of a medical device and other medical supplies is recorded in real time by barcode scanning. Barcodes are scanned in all steps of the process, on arrival in the store room, on picking for a procedure and before use in the operating room. Interoperability of the IT systems fully supports the real-time view.

Paralysing syndromes

Mr. van der Putten also knows that human behaviour has a major influence on change processes. A pattern of behaviour that many organisations are familiar with is the “not

invented here” syndrome. “If people have not invented something themselves, they consider the solution as not being good enough,” explains Mr. van der Putten. “Logistics is a unique area of discipline in itself.”

“Previously, each department had its own processes and methods. Now, there is one logistics organisation responsible for inventory management. There is uniformity in inventory management processes that are more efficient, resulting in less waste and fewer risks.”

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“The Six Sigma syndrome can also be paralysing. If a hospital strives for perfection, it will not get there. Choices must be made—what is facilitated in the process and what is not. Here at Radboudumc, we have chosen to support a realistic view of 95% process support and not feel pressured to achieve 100%.”

Many people are so busy with the daily activities and solving issues that participation in change processes could become secondary. However, the involvement of all disciplines is crucial for sustainable change, support and, ultimately, the success of the change process.

Alex van der Putten
Head of Procurement & Supply Chain
Radboudumc

Becoming a hospital of the future... today

Radboudumc is working to achieve “hospital of the future” status. Work is underway to automatically link data with data pools, so that data from manufacturers is automatically deposited in the hospital’s enterprise resource planning (ERP) system.

In addition, work is being done to apply RFID (radio frequency identification) tags to all devices. The unique GS1 identifier is still crucial, but will now be encoded in the RFID chip, making automatic detection possible.

“And we would like to do more with the data we collect,” says Mr. van der Putten. “With our Bill of Materials—a type of ‘shopping list’ that we prepare with typically a large number of medical devices and instruments—it clearly shows some of these are ultimately not used during the procedure. By analysing the inventory data, we can provide targeted advice on the medical devices and instruments to be prepared per procedure. By having a clear view, this helps reduce potentially dangerous situations, increasing safety, decreasing waste and being much more efficient.”

“By implementing GS1 standards, our hospital staff knows exactly where specific products are, identified by serial numbers and expiration dates—but, most importantly, they know exactly which patients received them.”

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Alex van der Putten
Head of Procurement & Supply Chain
Radboudumc

Our GS1 standards-based processes have led to an estimated 25% reduction of inventory levels and a 25% reduction of waste (due to expiration).”

Since out-of-stock item situations are basically non-existent, patient safety has improved considerably. In case of a recall, Radboudumc knows exactly which implant has been used with which patient. “Scanning takes time but we save a lot of time elsewhere in the operation,” says Mr. van der Putten. “By scanning barcodes combined with the accurate recording of data in the patient’s file, for instance, retrieving data for a recall or for other purposes is very easy.”

By using the Global Data Synchronisation Network™ (GDSN®) to exchange medical device and other product data, Radboudumc readily complies with and is prepared to comply with healthcare regulations such as the Dutch Implant Registry (LIR) and the Medical Device Regulation (MDR).

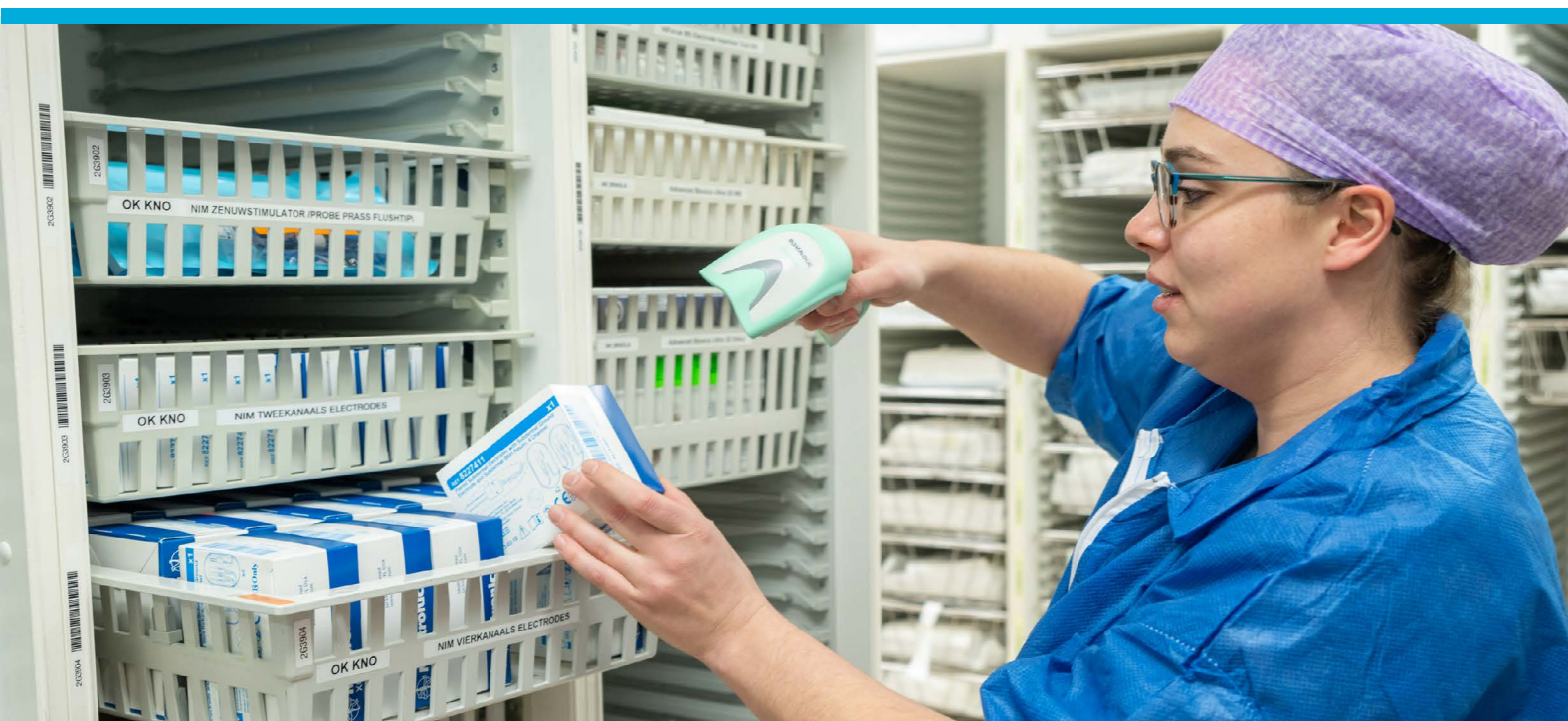
Radboudumc clinical and administrative staff are spending less time on non-clinical tasks. For example, instead of looking for the model of a medical device, the scannable label based on GS1 standards makes this information readily available. “And now, automated processes for data entry and electronic medical records releases more time for physicians and nurses to focus on patients,” confirms Mr. van der Putten.



Remarkable results

By using GS1 standards in its inventory management processes, Radboudumc has experienced remarkable results. Inventory levels have decreased over three years by more than 25% and the cost savings are significant at approximately €500,000 annually.

“Improvements in our processes have delivered tangible benefits,” says Mr. van der Putten. “We are realising lower emergency room costs since we are in total control of our inventory for emergency procedures. Costs are also lower since we are ordering the right quantities, at the right time . . . and we’re preventing waste.



About the author



Alex van der Putten
Head of Procurement & Supply Chain
Radboud University Medical Centre

Alex van der Putten is an experienced procurement and supply chain professional with a demonstrated history of working in the retail, convenience and hospital & health care industry.

He has worked since 2012 as Head of Procurement and Supply Chain for the University Medical Centre Radboudumc, in Nijmegen in the Netherlands. Radboudumc aims to be a pioneer in shaping a personalised, innovative, affordable and sustainable healthcare system for generations to come. Less “bricks”, the right use of data and different behaviour in procurement and supply chain are in his opinion crucial matters to make a significant next step.

About the organisation



Radboud University Medical Centre

(Radboudumc) in Nijmegen, the Netherlands is a university medical centre dedicated to three core activities: (tertiary) care, education and research. Care is organised in more than 50 care departments and several centres of expertise recognised by the Ministry of Health, Welfare and Sport. Radboudumc is also one of the major trauma centres in the Netherlands. The Radboudumc Health Academy coordinates, regulates and monitors all education in the Radboudumc. Scientific research is organised within three research institutes: Radboud Institute for Molecular Life Sciences, Radboud Institute for Health Sciences, and the Donders Center for Medical Neuroscience.

www.radboudumc.nl/en