

Patient safety and efficiency in the operating theatre

GS1 traceability business case



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1 Management summary

GS1 Netherlands is helping improve the supply chain. We are a neutral, not-for-profit organisation that proposes solutions, generates commitment among all parties involved and provides the services needed for successful implementation.

There is increasing government pressure for both higher quality □ patient safety must improve □ and lower costs in the healthcare system. This business case demonstrates that employing the GS1 Global Traceability Standard for Healthcare contributes to achieving these objectives. In the interests of clarity of the business case, the scope was restricted to medical devices (excluding capital goods) that are used in operating theatres and treatment rooms.

Current practice

Current practice leaves room for improvement. For instance, the transparency and management of inventories are far from optimum, the costs of an operation could be estimated much more accurately and completely, and the automatic registration of the products at the point of care has yet to be implemented. The lack of automatic registration leads to avoidable errors and a labour-intensive recall procedure.

The desired situation

Patient safety considerations make an automated recall procedure and 100% confidence in the registration of product-patient relationships desirable. It is also vital for inventories to be correct and transparent. Among other things, it will then be possible to avoid obsolete stock and cancel fewer operations because of out-of-stock products, bring down inventory levels and make optimum use of consignment goods. Further gains in efficiency will be achieved by digitising administrative processes. A simpler, faster ordering, delivery and billing process brings down the number of errors and clarifies the costs.

GS1 Traceability

GS1 proposes the 'GS1 Global Traceability Standard for Healthcare' (GTSH) as a means to achieve the desired situation. GTSH can be employed when a supplier and hospital both have an effective IT infrastructure to track and trace products throughout the supply chain.

GTSH ensures that each product is correctly recognised, and every movement from one location to another recorded. The key to this is a supplier-created bar code that captures the Global Trade Item Number (GTIN), expiry date and any batch or serial number. The hospital scans the bar code and stores the data in its system. Product locations are specified using a GS1 Global location number (GLN). Having this information linked to the ERP system (the software that supports business processes) means that it will be clear at all times which product can be found at which location. The data can also be linked to a specific patient, such as through a bar code on a wrist strap, and to an employee, through a bar code on their staff ID badge. These measures mean that it will always be clear which product has been used to treat which patient, and who is responsible.

Costs and benefits

Hospitals and suppliers alike must be willing to invest in hardware, software and personnel. However, there are a variety of benefits and savings in return. There will be fewer errors, with a corresponding improvement in patient safety. The clearer view of the supply chain allows better operation planning and faster (and more effective) recall procedures, which will benefit patients. Moreover, work proceeds faster and more efficiently, and inventories can be controlled with greater confidence, bringing substantial savings in costs. Hospitals are able to save a total of between € 106 and € 168 million annually.

Start now!

Increased patient safety and huge potential savings are reasons enough to start implementing traceability now. The implementation will demand commitment on all levels, not least for removing a number of obstacles. The obstacles include the absence of logistics support in some hospitals, poor integration of different IT systems within a hospital, and a lack of familiarity with GS1. Experience in other countries has shown that legislation and regulations can help accelerate implementation. GS1 Netherlands therefore favours the introduction of legislation for traceability in the Netherlands too.

100% traceability requires clear agreements between suppliers and hospitals. GS1's Traceability Focus Group is willing and able to facilitate these agreements.

2 Introduction

Patient safety currently has the highest priority in the healthcare sector. Questions such as “Which patient was given which replacement heart valve?” and “Will the right material be available at the start of the operation?” are routinely asked. Unfortunately, they are not always simple to answer, because they require a clearer view of inventories and the devices used. Patient safety and logistics are therefore intertwined.

Alongside patient safety, there is an increasing focus within hospitals on **efficiency**. Inventory levels and the high (hidden) costs involved in their management are attracting ever more attention. Logistics and administrative processes must be optimised in order to bring down costs and enable data to be exchanged simply and rapidly.

The immediate motivation for this business case was the need to improve patient safety by guaranteeing 100% traceability of products used to treat patients. This measure will also enable hospitals to improve recall procedures. 100% traceability furthermore helps increase efficiency and reduces costs substantially. This desired scenario demands soundly organised logistics processes.

GS1 Netherlands is helping improve the supply chain. We bring together organisations within the sector to jointly determine where the priorities for supply chain improvement lie. We are a neutral, not-for-profit organisation that organises and coordinates consultation and the resultant projects. We propose solutions, generate commitment among all parties involved, and provide the services needed for successful implementation.

GS1 Netherlands is part of the global GS1 organisation, which has offices in over 100 countries. GS1 has more than 30 years of experience in the development of global standards, services and solutions in many different sectors. The importance of the international component for the healthcare sector stems from the large number of multinational pharmaceutical companies. GS1 Healthcare is a global organisation that brings together all the parties involved on an international level.

2.1 What is traceability?

“Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration” – GTSH Issue 1.0.0, Feb 2009. The GS1 Global Traceability Standard for Healthcare (GTSH) makes traceability possible.

2.2 The definitive standard for healthcare

Hospital organisations including the Dutch Federation of University Medical Centres (NFU), the Dutch Hospitals Association (NVZ) and the Dutch Association of Hospital Pharmacists (NVZA) have declared the GS1 standard to be the definitive standard for healthcare. They therefore intend to use this standard in improving patient safety while lowering costs in the supply chain.

The following statement was made by the NFU, NVZ and NVZA on 27 January 2011 at the conference 'Samen zorgen voor de keten van morgen (Working together to create the supply chain of tomorrow)':

Objective

By the end of 2012 all primary and secondary packaging will carry GS1 codes (GTIN, batch and/or serial number, expiry date), preferably in a GS1 DataMatrix.

Objectives

The GS1 Global Traceability Standard for Healthcare contributes to achieving four objectives, which apply equally to medical device suppliers and buyers:

- Improved patient safety through 100% traceability as far as the point of care, with consequent improvements in recall procedures.
- More efficient logistics: institutional providers (hospital/clinic) want 100% clarity of inventories, efficient inventory management and simpler logistics processes.
- Fewer administrative steps: bar code scanning can replace numerous processes that are now still performed manually.
- Avoidance of obsolete stock: wastage can be avoided by having a clear view of expiry dates. Products that are nearing their expiry date should be used first.

2.3 Scope

This business case describes the costs and benefits of introducing traceability by means of the GS1 Global Traceability Standard for Healthcare for medical devices used in operating theatres and treatment rooms. Medical devices include many products, such as instruments, apparatus, appliances and other items used in the diagnosis and treatment of human disease and impairments. Examples include implants (prosthetic knees and hips, pacemakers), disposables, stents, incontinence material and surgical instruments.

The scope does not include X-ray equipment, MRI scanners and software.

We focus on the costs and benefits associated with the logistics process and with registering products at the point of care.

The Traceability Focus Group restricted the scope to medical devices used in operating theatres and treatment rooms, excluding capital goods, in the interest of preserving the clarity of the business case. The scope may be broadened in future to include other applications in hospitals.

Out of scope

Aspects concerned with the healthcare technical process are outside the scope of this business case. These aspects include Health Care Inspectorate (IGZ) setting-up protocols and rules for the medical process. The financial consequences of errors that affect patients are also out of scope. These costs are hard to quantify and depend strongly on how a given hospital archives information. Finally, the traceability of medicines is outside the scope of this business case.

Approach

The following activities were performed in creating this business case:

- Description of the current situation.
- Description of the ideal situation.
- Interviews with two suppliers and two hospitals.
- Discussion of interim versions and the supply of new input in GS1 Traceability Focus Group meetings.

2.4 Acknowledgements

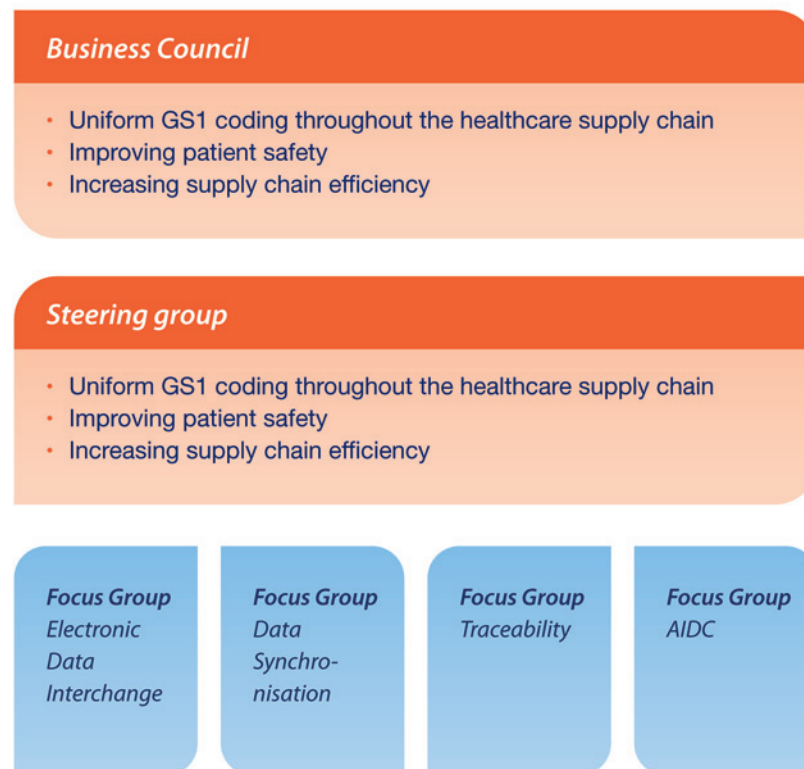
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3 Background

3.1 Organisational context

The initiative for this business case came from the Traceability in Healthcare Focus Group, which comprises representatives of suppliers, hospitals, solution providers and GS1 Netherlands. The Traceability Focus Group is one of the focus groups under the 'GS1 Healthcare Taskforce', which operates as follows.

GS1 Healthcare Taskforce



The Business Council determines policy. The steering group arranges for the focus groups to perform the actions arising, and also keeps the focus groups informed of each other's progress and developments. The steering group comprises the chairs of the focus groups and the project leaders of GS1 Netherlands.

Focus groups

- **eCom Focus Group**
Development, management and implementation of electronic business messages (EDI) for the support of logistics processes. For example, there are guidelines for commercial conditions, demand and supply signals, despatch and receipt, and financial settlement.
- **AIDC Focus Group**
Development, management and implementation of guidelines for GS1 bar codes.

- *Traceability Focus Group*
Assessment and development of guidelines for traceability. The group is also a platform for exchanging experience with traceability projects.
- *Data Synchronisation Focus Group*
Development, management and implementation of GDSN/G-Standaard Logic.

There is additional information about GS1 Netherlands, our solutions and projects on www.gs1.nl/samenzorgen.

International network

GS1 Netherlands and some members of the various focus groups participate in international GS1 Healthcare work groups. The mission of this international organisation is to improve patient safety and increase supply chain efficiency through the use of GS1 standards and solutions. Stakeholders from the care sector from around the world are involved in GS1 Healthcare. For additional information, see www.gs1.org/healthcare.

GS1 Netherlands is involved in the following work groups:

- Traceability in Healthcare II
- AIDC Healthcare Implementation Guide Work Group
- AIDC Healthcare II
- GS1 Healthcare GDSN Implementation
- GSMP Patient and Care Giver ID Work Group
- GSMP Multiple BarCodes Work Group
- GS1 Healthcare Public Policy Work Group
- GS1 Healthcare Provider Advisory Council
- GDSN Level Below the Each

3.2 Current situation

Industry

The following medical device suppliers and others have adopted GS1 standards internationally for identifying their products: Johnson & Johnson MD, B.Braun, Nutricia MD, 3M, Abbott, Alcon Laboratories, Baxter, Cook, Covidien, Medtronic and St. Jude.

Various medical device suppliers are also already using GS1 standards for product identification on the Dutch market: 3M, Abbott BV, Alcon, Baxter, Biomet, Synthes, Becton Dickinson BV, B.Braun, Boehringer Ingelheim BV, Coloplast, Covidien, EV3, J&J BV, Kimberley Clark, Koninklijke Utermöhlen NV, Medeco, Medtronic, Nutricia, Spruyt hillen and Van Straaten Medical.

An increasing number of suppliers in the Netherlands are adopting GS1 standards because:

- Dutch healthcare providers (NFU,NVZ, NVZA and KNMP) have now adopted them.
- Patient safety improvement is paramount.
- Efficiency improvement is desirable in both internal processes and the information exchange between suppliers and hospitals.
- Leading suppliers are setting the trend and others have no desire to be left behind.

Hospitals

The Dutch healthcare sector (NFU, NVZ, NVZA, KNMP, Z-index, NefeMED and ZorgDAS) supports the use of bar codes, but nonetheless little use is made of them in practice. The situation is the result, among other things, of the fragmented nature of the healthcare sector, and the need for investment in advance of any benefit being gained by the sector.

As yet only half the manufacturers bar-code their products. Many hospitals have their own packing department that applies codes, which is an extremely labour-intensive process. What is more, many hospitals and care providers perform the same process in their own way. The use of usually outdated manual systems in administering medicines and using medical devices is prone to error, inefficient, and anything but economical in costs.

Governments and political aspects

The government is imposing economies on the healthcare sector as a whole. Factors such as the ageing of the Dutch population and the increasing opportunities for treatment are pushing up government expenditure, and healthcare now costs more than in the past. Furthermore, there is a threat of severe healthcare staff shortages in the future. In order to counter the cost increases and staff shortages, the government aims to raise sector efficiency.

Simultaneously, the government wants patient safety to improve. The Nivel study 'Monitor zorggerelateerde schade 2008 (Healthcare-related harm monitor for 2008)' concluded that there is room for improvement in Dutch hospitals that will benefit patients. Almost 40% of cases of avoidable unintentional harm to a patient could probably have been prevented. This finding has prompted hospitals to develop safety management systems. Missing, unclear, or a surfeit of information during treatment may cause unintended incidents and harm to patients.

Health insurers

Under the auspices of the government, health insurers are gaining influence over the healthcare system, such as in the introduction in 2005 of the Diagnosis-Treatment Combination (DTC). A DTC is a statement of all activities and procedures performed on a patient in a hospital in a given period. There is therefore a single billable product – the DTC – that comprises all the healthcare activities performed by a hospital for a patient within the framework of a given demand for care. This approach was intended to promote efficiency: a hospital receives a fixed (average) amount for each treatment and the medical specialist also receives a fixed hourly rate. It was envisaged that hospitals and medical specialists would then work more efficiently, thereby introducing market operation into the healthcare sector.

It is essential for hospitals to have a clear view of the actual costs of treatment, to put them in a better position to negotiate with health insurers about the billable treatments.

3.3 Legal obligations

Under Dutch law a manufacturer of medical devices is obliged to report the following incidents to the Health Care Inspectorate (IGZ):

- every case of poorly functioning or impaired properties or performance of medical devices, and every inadequacy in the labelling or instructions for use, actually or potentially leading to death or a serious deterioration in the health of a patient or a user;
- every technical or medical reason related to the properties or performance of devices that led the manufacturer systematically to recall devices of the same type as a consequence of the circumstances given in the first point.

Compliance with the law implies an ability to identify medical devices and to track them throughout the supply chain.

GS1 is in favour of traceability legislation

A legal obligation to use bar codes for pharmaceuticals and medical devices throughout the healthcare sector is necessary if the objectives stated above are to be achieved. Experience in other countries has shown that legislation can help accelerate implementation. Countries such as Great Britain, France, Switzerland and Turkey have introduced legislation for this reason. Countries such as the US and Canada together with the Food and Drug Administration (FDA) are also in the process of creating a legal basis for the use of bar codes in the healthcare sector. GS1 Netherlands advocates a legal obligation for traceability in the Netherlands too.

A legal obligation will improve patient safety and also drive down the supply chain-related cost of care. This is a win-win-win situation for the patient, the healthcare provider and the national government.

3.4 International trends

As stated above, governments in several countries have already made the use of GS1 codes compulsory. The rules are often concerned with drugs, and sometimes requirements are also set on the type of bar code: the GS1 DataMatrix. There is now a conspicuous trend for governments and legislative bodies to focus more on legislation and regulations for medical devices. For instance, the Food and Drug Administration (FDA) has drafted new legislation and regulations that will come into force in 2012. The new Act will make it compulsory to give medical devices a machine-readable Unique Device Identifier (UDI), possibly in the form of a bar code. All Class 3 medical devices must have a UDI by the end of 2012, followed by Classes 2 and 1. The European Commission has also announced that it will adopt this legislation for Europe.

The figure below shows the countries in which requirements are being established for medical devices. Requirements may take the form of legal obligations, tender requirements, or other important developments.

Summary of global UDI legislation and regulations

2009	Turkey UDI code and database		
	Spain UDI code		
	Japan UDI Regulation, phase 1		
2010	Japan UDI Regulation, phase 2	Cyprus UDI Tender Guidance	
2011	Japan UDI Regulation, rest	USA Draft FDA UDI Regulation	
		Global Harmonization Task Force (GHTF), UDI Guidance	
2012	USA Final FDA UDI Regulation	EU Medical Devices Directive Recast-UDI	India UDI Guidance
		England NHS: product code	The Netherlands NFU/NVZ: GTIN
2013	USA FDA UDI Implementation Class 3		
2014	EU UDI Directive		
2015	USA FDA UDI Implementation Class 2		
2016			
2017	USA FDA UDI Implementation Class 1		
Regulated requirement		Important development	Tender requirement

Canada, China, Italy, Korea, UAE, etc: UDI regulation under development.

4 Current practice

This business case maps out the general form of the current process. The actual process may differ somewhat for some suppliers and hospitals.

Two figures show the medical devices supply chain for supplier and hospital, respectively. They show the links passed by goods in the supply chain. This information is needed because the relevant data for traceability, or at least a reference to that data, must be available in each link.

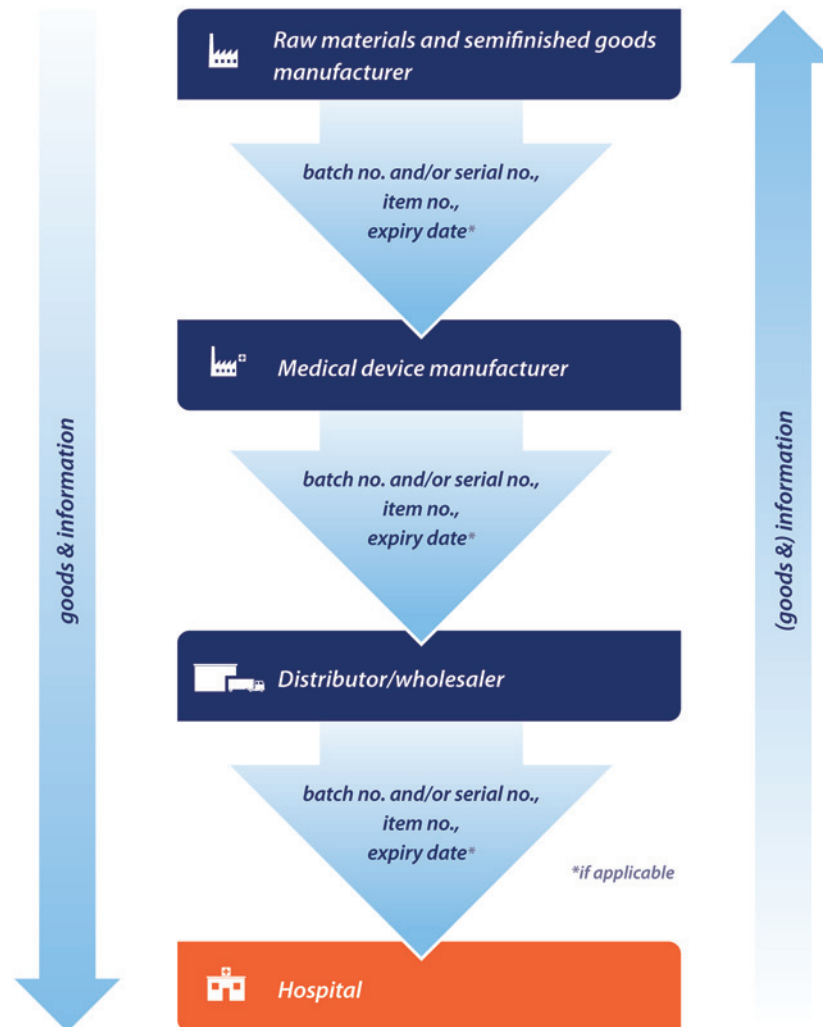
The supply chain starts with the supply of raw material or components and ends with the use of a product at the point of care.

4.1 Supplier

The supplier receives raw materials for producing the end product or intermediate product. With these raw materials the supplier receives data about a.o. the type of material, the batch number and the expiry date. The supplier order number is also stated. These data are retained until delivery of the product to the hospital.

The figure on the following page shows the supply chain of goods from the supplier. An indication is given of the relevant data for product tracking and tracing. These data must be communicated to the next link in the chain.

Supply chain – supplier

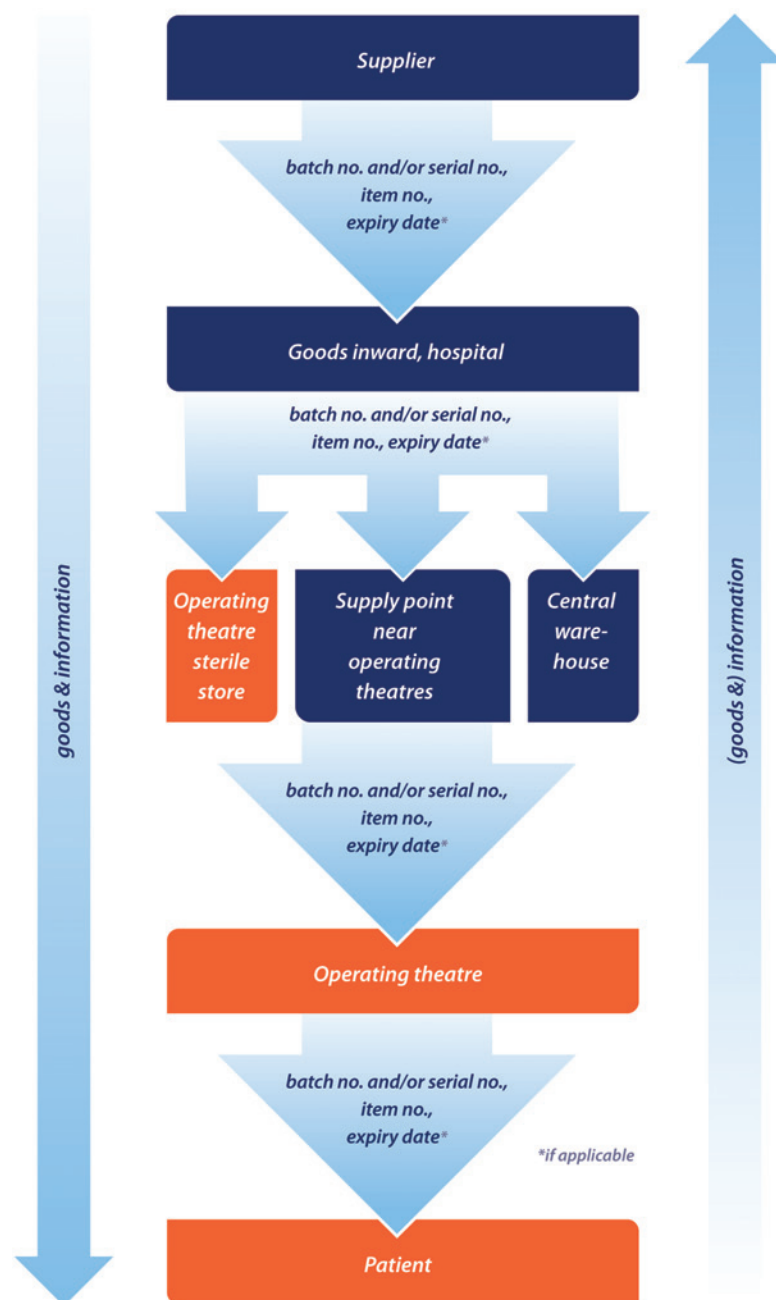


4.2 Hospital

A hospital receives medical devices from a supplier. The associated information is delivered in the accompanying packing list (in electronic or paper form), or the bar code on the package. After receipt, the products are distributed within the hospital, to the locations where they are needed.

The figure below shows the medical devices supply chain within a hospital. Here too, an indication is given of the relevant data □ item, batch and/or serial numbers and expiry date □ for traceability. These data must be available at every step of the logistics chain.

Supply chain – hospital



Bar codes

Approximately 80% of all medical devices (within the scope of this business case) that a hospital receives bear one or more bar codes. In other words, most products can be scanned and registered electronically. The rest must be registered manually.

A current difficulty is the lack of standardisation in bar codes. There are multiple types of bar code on the various packages, including GS1 and HIBC. Neither is there a standard for where on a package the bar code should be positioned, nor for the data it should contain. For instance, it is possible to have more than one bar code on a package to accommodate the various kinds of data (article number, batch number, serial number and expiry date).

Currently some 10% of Dutch hospitals use the bar codes on packages for registering medical devices. However, this number is growing.

Distribution within the hospital

On receipt of the products the order is checked and the goods are subsequently distributed within the hospital. The distribution method differs between hospitals. Some bring the received delivery quantities in the original package directly to the next point. Others divide the delivered units and combine them with other goods before bringing them to the next point.

Sterile goods flow

Sterile products demand specific logistics handling and have to be stored and used under special conditions in order to maintain sterility. Most hospitals therefore have a separate, temperature-controlled storage facility near the operating theatres. Some hospitals send sterile products directly to the operating theatre supply points, while others send them first to a central sterile store.

No stock recording

Most hospitals do not record in an inventory system the arrival of medical devices at one of the operating theatre locations (operating theatre sterile store, sterile supply room near the operating theatres, or the operating theatre itself). The operating theatre department does not then know the exact nature and location of the medical devices, nor how many are at the various supply points.

There are generally two ways of recording the use of a medical device to treat a patient:

- 1 By transferring a product information sticker (article number, batch number, expiry date) to the paper file.
- 2 By reading the information from the package and typing it manually into the Electronic Patient Record (EPR).

In some cases the bar code on the product package will be scanned.

There is no feedback to Enterprise Resource Planning (ERP, see also the Glossary) software, such as Oracle or SAP. Products are then not booked out of the inventory as they are used, which precludes automatic ordering to replenish stocks. It is necessary instead to resort to manual methods, such as counting the remaining products, and placing orders for replacements on the supplier's website, or by fax or telephone.

Out-of-stock situations are undesirable and can even be life threatening in operating theatres, which leads operating theatre staff to err on the side of overstocking. As a result, inventory levels are often unnecessarily high, which drives inventory costs upwards. Furthermore, stocktaking then becomes a time-consuming process, which is only exacerbated by its still often manual nature.

The purchasing department will generally know exactly which products have been ordered and delivered, but the hospital then has no clear view of consumption and inventory levels.

Obsolete stock

It is not always possible to rely on the currency of stock in the current situation, because it is established by visual and manual means. An employee will check expiry dates on the packing at regular intervals and move packs with the earliest expiry dates to the front, in accordance with the First Expired First Out (FEFO) system. It is unusual for expiry dates to be recorded in an inventory system.

Cost estimating

The absence of automatic feedback of used products to the Hospital Information System (HIS) or ERP system hampers accurate estimates of operation costs, since no one can know exactly which products are used in a procedure. Cost estimating is based on subjective judgment. Consequently most hospitals are not in a position to properly compare what a treatment costs with what they are paid by the insurance companies.

Recall

In most cases a supplier will be able to tell from the registered information about product, batch and serial numbers and the expiry date, which product batch has been delivered to which hospital. However, there is no record within the hospital of the supply points to which the received products are sent. In the event of a recall, a targeted search is therefore out of the question. Instead, all potential supply points must be checked physically for the possible presence of the product concerned. Ascertaining whether a product has been used to treat a patient requires working through the, usually paper, patient files. This is a time-consuming activity, which can sometimes take days, and often involves more than one person.

There are also patient-safety implications: a hospital will usually be unable to be absolutely certain which patient received which product (e.g. an implant). Where there are product quality issues, this uncertainty may have unpleasant consequences for patients.

Consignment goods

A supplier may place a consignment stock (see Glossary) with a hospital as a service. The hospital may then save costs, since inventory control of the consignment goods is effectively outsourced to the supplier. However, the unsatisfactory registration of products within hospitals currently prevents the optimum use of consignment stocks. Effective consumption recording must be in place before a hospital can determine which products in which quantity could profitably be held as consignment stock.

Available inventory

Hospitals have insufficient information about the available inventory. For instance, it is currently unclear for each product whether it can still be used for an operation, or that use is no longer possible, perhaps because the type is outdated. Moreover, consumption analyses are not available to management when selecting a new range of products, and they also have insufficient insight into the status of the existing range of products.

4.3 Points for improvement in the current situation

Various points for improvement are evident in the current situation.

- Insufficient agreements have been made within the supply chain about the use of unique identification and electronic communication for logistics and administrative processes.
- There is insufficient insight into where a product is within a hospital.
- The recording of products at the point of care is often still a manual process, which hampers the identification of which products have been implanted or used. Manual registration is also prone to error. Both factors are detrimental to patients and hospitals alike.
- The processes □ from ordering a medical device through to receipt at the operating theatre □ are insufficiently compatible, because the various IT systems are not interconnected.
- Stock replenishment is inefficient. Ordering involves many manual steps.
- The view of inventories is not optimum, with the following effects.
 - Too many products are held in stock, leading to excessive cost.
 - Planning uncertainties. A planned procedure may have to be cancelled if products that are needed are not in stock at the scheduled time of the operation.
 - Dependence on staff. Staff are aware of what products are available, but the information is not recorded in an IT system.
- There is no clarity surrounding the expiry dates of products, leading to unnecessary obsolete inventory.
- Cost estimating of used products is too inaccurate, leading to difference between the cost of a treatment and the amount paid out by health insurers (in accordance with DTC and DOT).
- Recalls cannot be 100% effective and are currently still extremely labour intensive manual procedures.

5 The desired situation

This chapter presents the desired situation, which would yield great benefits for both hospitals and suppliers, and how this situation can be realised. We are convinced that using the GS1 Global Traceability Standard for Healthcare (GTSH) can achieve substantial benefits, in terms of both patient safety and efficient logistics.

5.1 Objectives

Patient safety objectives

The following patient safety objectives are achieved in the desired situation.

- Automated recall procedure. Information about which patient has received which implant is available at the press of a button.
- 100% secure product-patient registration. The products used in an operation can be fully identified through the EPR and HIS systems.
- Operations always go ahead as planned. Product availability is matched to the planning.

Logistics efficiency objectives

The following logistics objectives are achieved in the desired situation.

- 100% insight into hospital inventories, thereby achieving:
 - An approximately 80% reduction in obsolete inventory.
 - Optimum use of consignment stock.
 - Complete control of inventory (FEFO, planning).
 - Complete clarity of where a product is within the hospital.
 - Fewer last-minute orders.
 - Lower inventory levels.
- Digitisation of administrative processes, thereby achieving:
 - A faster product ordering process with fewer errors.
 - Automatic ordering of replenishment products □ the system places an order as soon as the quantity drops below a defined limit.
 - Less time spent by supplier and hospital on product range and item management.
 - Faster booking of incoming goods.
 - More complete cost estimating with fewer errors (for reimbursement reasons).

5.2 GS1 Traceability: how it works

The GS1 Global Traceability Standard for Healthcare (GTSH) is used in implementing traceability. Exactly how it works, from the processes involved to registration at the point of care, is described in detail in Appendix I. This section briefly describes the use of GTSH.

Constraints

This business case assumes the following constraints.

- It is essential for both the supplier and the customer (hospital) to have a sound IT infrastructure. The minimum infrastructure includes:
 - an ERP system;
 - a Hospital Information System (HIS);
 - Electronic Patient Record (EPR), which does not refer to a national Electronic Healthcare Record (EHR);
 - hardware, such as PCs, printers and scanners;
- Traceability extends from the supplier up to and including the point of care, which is to say throughout the medical devices supply chain;
- Traceability is based on the GS1 Global Traceability Standard for Healthcare (GTSH).

The **hard** measurement points in this business case are concerned mainly with efficiency. The **soft** measurement points are concerned with patient safety.

Multiple levels of traceability

An outer carton, a case, a surgical kit, an individual product (e.g. a surgical screw, plate, or instrument) are all **forms** that have to be tracked. We refer to each of these forms as a traceable item. The following levels are relevant for the items used in operating theatres.

Item	Description
Logistic unit	A package containing multiple products. E.g. a carton, crate, or a surgical kit on a tray.
Batch	All the products made in the same batch. E.g. 1,000 surgical screws with the same batch number.
Individual product	All products of a given type. E.g. sutures or scissors.
Unique specific instance of an individual product	E.g. a prosthetic knee joint.

Most recalls are on batch level: the supplier recalls from the market all products made in one production run. The batch number of the product determines what is included.

Risk-based traceability

Hospitals and suppliers jointly determine which products are to be traceable. One determinant is whether a product entails risk for the patient (e.g. implants), and another is whether the product is relevant for financial administration (DTC and DOT registration).

GS1 identification

The ability to track and trace products throughout the logistics chain relies on the ability to identify the products. It is also necessary to record the movements of the products from one location to another in the supply chain, to create clarity about where the products are in the chain. Finally, the use of the products at the point of care requires patients to be identified, and likewise the staff who use or implant the medical device in treating the patient.

GS1 has the following solutions for identification.

Item to be identified	International	Dutch
Logistic unit	Serial Shipping Container Code* (SSCC)	GS1-verzendcode
Medical device	Global Trade Item Number* (GTIN)	GS1-artikelcode
Party/location	Global Location Number* (GLN)	GS1-adrescode
Hospital employee	Global Service Relation Number* (GSRN)	GS1-relatienummer
Patient	Global Service Relation Number* (GSRN)	GS1-relatienummer

* These ID numbers are also referred to as 'GS1 keys'.

Exchange of master data

Hospitals and suppliers exchange item and location data, which are also referred to as master data. GS1 Netherlands has various solutions based on the GS1 keys to make this exchange as efficient as possible. The key is exchanged between various parties while the associated data are located in the system, which greatly reduces the quantity of data to be exchanged.

A hospital is able to obtain the product data about a medical device through a bilateral database, or a data pool, where the supplier enters the data and gives the hospital access.

The GS1 Global Data Synchronisation Network (GDSN) is available for the exchange of item data. The Dutch GS1 GLN registry (GS1-adrescodeboek) is available for the exchange of location data.

Electronic business messaging (GS1 eCom)

The following GS1 eCom implementation guides can be used to support logistics and administrative processes:

- Demand and supply signals.
- Despatch and receipt.
- Financial settlement.

The most relevant guide for the traceability of medical devices is that for despatch and receipt. Because this business case also covers the logistics-related benefits of electronic ordering and billing, we also mention the other guides.

There is additional information about our solutions on www.gs1.nl/samenzorgen.

5.3 New method in hospitals

When a supplier has delivered a logistic unit to a hospital, one of two working methods is possible:

- The logistic unit remains intact and is transported to the operating theatre department.
- The logistic unit is opened after delivery and the products destined for each department are combined.

In achieving traceability, the following hospital locations are relevant for registering the traceable products in the ERP system (see also the figure in Chapter 3: hospital supply chain).

- Arrival and booking in at central warehouse
- Arrival and booking in at operating theatre sterile store
- Arrival and booking in at operating theatre supply points
- Arrival and booking in at operating theatre
- Use at the point of care

At logistic unit level

Where the logistic unit remains intact as far as the operating theatre, the method is as follows. The Serial Shipping Container Code (SSCC) is registered on each movement within the hospital by scanning the bar code on a carton, case or surgical kit. The locations are identified with a GS1 Global Location Number (GLN). The bar code is scanned and recorded at the GLN for every movement of the unit, from which it can be seen that the logistic unit has been distributed from GLN1 to GLN2.



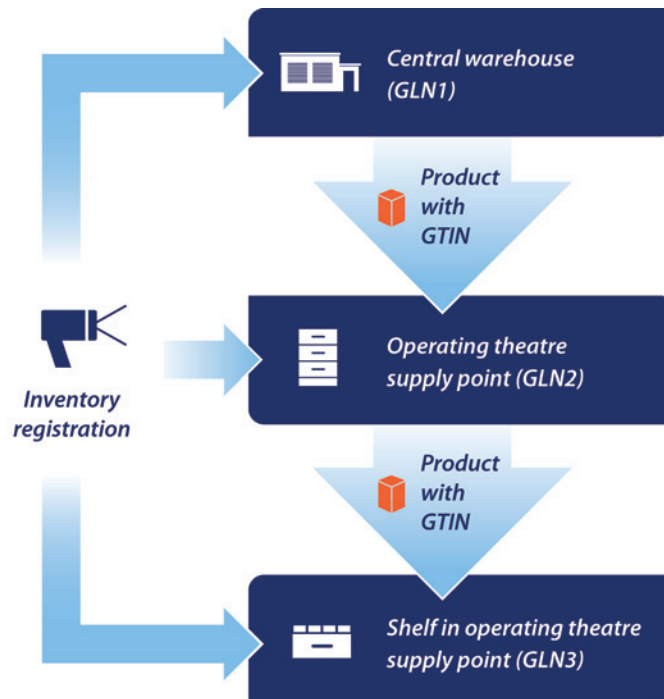
The location of a logistic unit within the hospital is then clear at all times. The unit is unpacked and placed on the shelves at the various supply points near the operating theatres. The logistic unit ceases to exist at this point, and from here on it is the individual products that are registered, possibly as unique products.

On product level

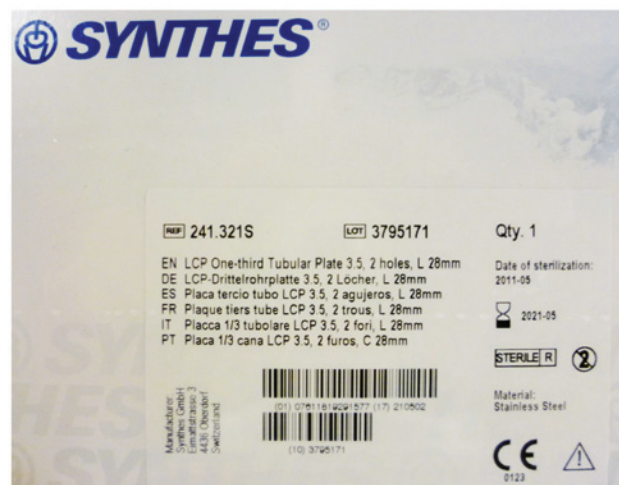
Traceability on product level is concerned with individual products, regardless of whether they form part of a larger logistic unit, or occur separately in the supply chain. The important point is whether or not a unique instance of a product is involved.

The item number, expiry date and batch and/or serial number of the products are recorded in the system by scanning the bar code or codes on the product. A First Expired First Out (FEFO) system can then be applied to avoid obsolete stock. By also recording a serial number, it is possible at all times to ascertain where the specific product is in the supply chain.

It is also possible to assign GLNs to the shelves or racks in the various operating theatre supply points, which would make the precise location of each product known to the system. The figure below shows how a product is recorded at the various locations.



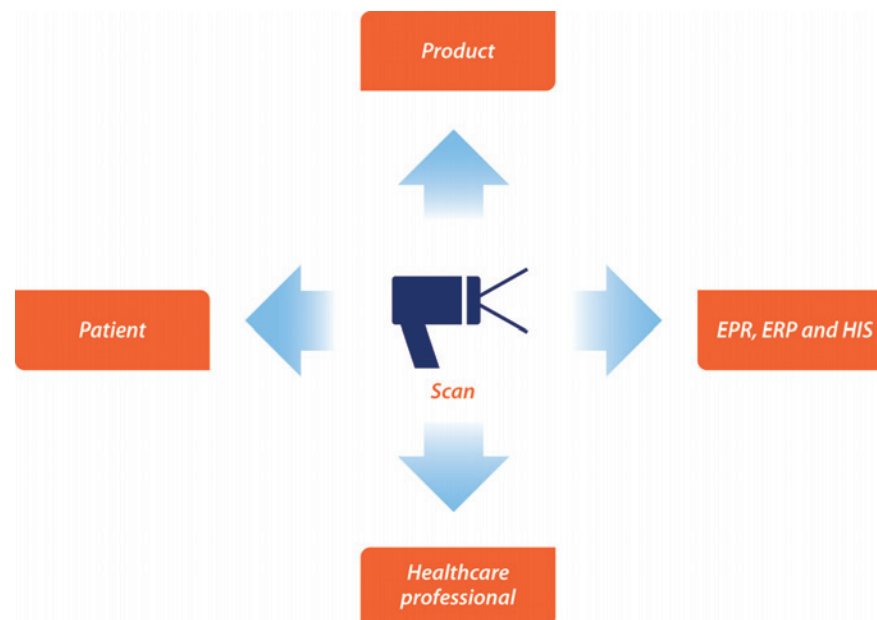
This business case assumes that all secondary packaging (see Glossary), as in the example below, bears one or more bar codes containing an item number, batch and/or serial number and expiry date.



The used product is scanned and the item number, batch and/or serial number and expiry date are recorded in the EPR. These data can be linked to the patient by reading the ID given on the patient's wrist strap. The data of the member of staff involved is also recorded by scanning the bar code on the staff ID badge.

Scanning the product once at the time of use in treating the patient captures the GS1 Trade Item Number (GTIN), expiry date and batch and/or serial number in the EPR, HIS and ERP systems.

The figure below shows how product data are linked to a patient and the member of staff who implants or applies a product.



The EPR records which product has been used to treat a patient, and by which member of staff. The information from the bar code is also recorded in the HIS and ERP systems, allowing the costs of the products used to be calculated and the products to be booked out of stock immediately. The products used are then automatically reordered from the supplier.

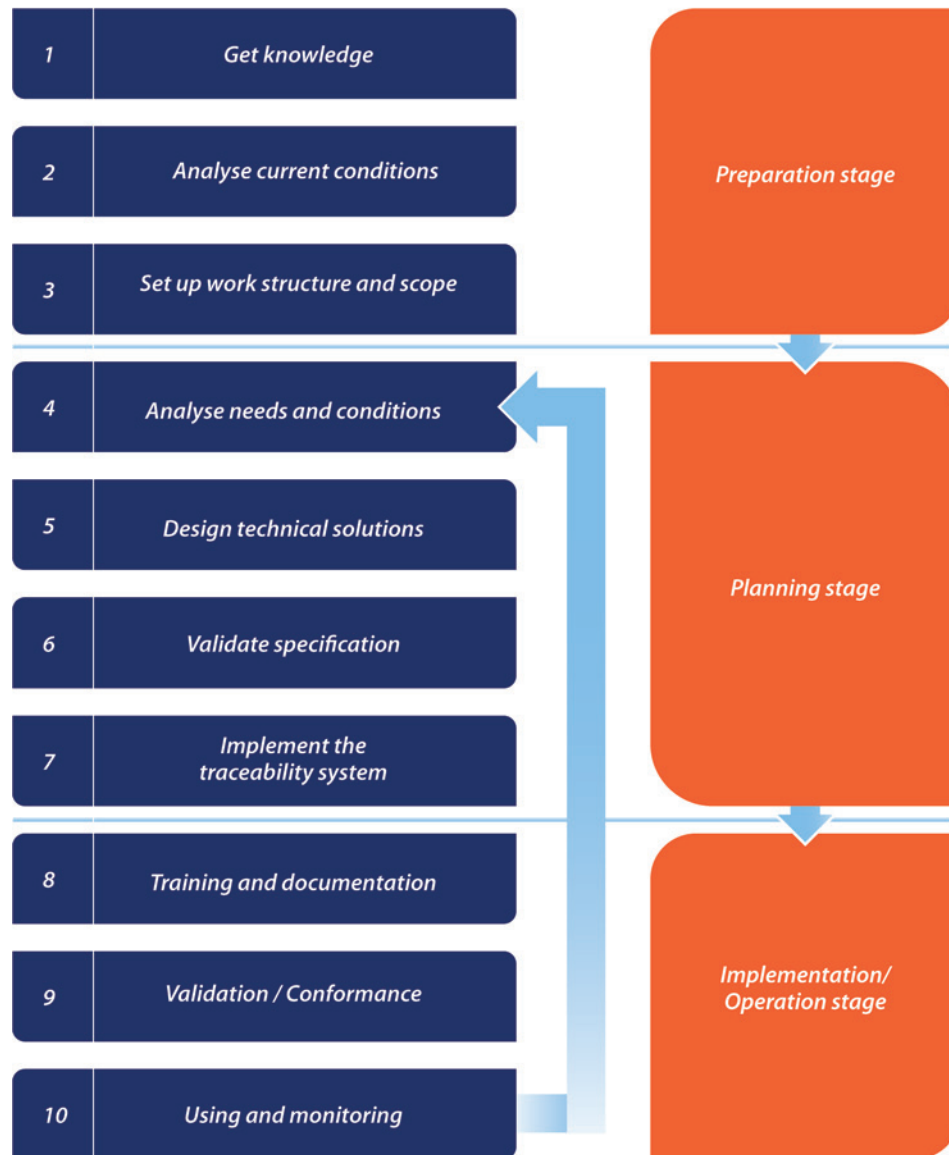
Electronic ordering, receipt and billing

The hospital ERP system automatically raises an order when the product quantity in stock reaches a predetermined minimum. The order is sent to the supplier, who then gathers the requested goods and sends them, along with a despatch advice, to the hospital. The hospital receives and checks the goods. The supplier then sends an electronic invoice to the hospital for the ordered, and now delivered, products.

The use in the communication between hospital and supplier of the same GS1 keys (GTIN, GLN, SSCC) for identifying products and locations simplifies the integration of the logistics and administrative processes. The efficiency of the entire process of ordering, delivery, use and billing is greatly enhanced in this way.

5.4 Traceability implementation

A number of steps must be taken when introducing traceability by means of GS1 standards, as shown in the figure below.



There is additional information and an explanation of the "Ten Steps to Traceability Implementation" plan in the Traceability section of the GS1 Global website.

5.5 Checklist

The following conditions must be satisfied in the desired situation.

- The main processes are handled automatically in the HIS and ERP systems.
- Patient information is captured in the Electronic Patient Record (EPR).
- Each distinct product has a GS1 trade item number (GTIN), expiry date and batch and/or serial number, in the form of a GS1 bar code*.
- All relevant locations are identified with a GS1 Global Location Number (GLN).
- Each logistic unit has an ID, which may be a GS1 shipping code (SSCC).
- Each patient has a unique identification (GSRN or an alternative code, e.g. citizen service number (BSN)), possibly in the form of a GS1 bar code* on a wrist band.
- Each member of hospital staff has a unique identification (GSRN or an alternative code), possibly in the form of a GS1 bar code* on a staff ID badge.
- Registration at the supplier and hospital of the item number, expiry date, batch number and, if necessary, also the product serial number, is achieved electronically, by scanning the bar code. Assumption: these data are contained in a single GS1 bar code*.
- Product information (product name, dimensions, supplier, etc.) are exchanged electronically between supplier and hospital, either bilaterally or through a GS1-certified GDSN data pool.
- Electronic registration of a product at the point of care by scanning the product identification (GTIN) in the bar code on the package, the patient ID in a bar code and the staff ID in a bar code.
- The products used in an operating theatre are registered in the patient's EPR.
- The products used are registered in the ERP system in order to book them out of stock, thereby facilitating automatic reordering.
- The products used in the operating theatre are registered in the ERP and HIS systems for the purpose of costing (DTC or DOT).
- The hospital sends an electronic GS1 order to the supplier.
- The supplier sends a GS1 despatch advice (electronic packing list) to the hospital.
- For consignment goods, the hospital sends an electronic consumption report to the supplier.
- The supplier sends an electronic GS1 invoice to the hospital.

** Alternatively, the data could be recorded in an RFID tag. This business case considers only the bar code application, in order to avoid introducing too many different aspects with a possible impact on the outcome.*

5.6 Agreements in the sector

Effective implementation of GS1 Traceability requires the parties involved, suppliers and hospitals, to make clear agreements. Only then can both parties obtain optimum benefits.

Information in the data carrier

It is important to make sound agreements about the data in the data carrier (bar code or RFID tag). It is common in the current situation for the information to be distributed over multiple bar codes. Hospitals need clarity about what has to be scanned. NFU, NVZ and NVZA have expressed a desire to have the item number, batch and/or serial number and expiry date included in a single bar code, and specifically in the form of the GS1 DataMatrix. The above applies to what are known as consumer units, but not to the logistic units, for which the recommendation is still to capture the data in a GS1-128 symbol.

Positioning of the data carrier

It is important for hospitals and suppliers to make agreements about positioning the data carrier. The current lack of agreement on this point means that some bar code symbols are on the underside of a package, and others on the top or side, leading to delays in the scanning process as the end-user hunts for the bar code. In order to avoid these delays, the information carrier, whether it is a GS1-128 bar code, a GS1 DataMatrix, or an RFID tag, must always be in the same position on a package or actual product. Users will then know immediately where to look for the data carrier, which will benefit the product registration process.

Use of serial numbers

The Focus Group recommends assigning a serial number to all critical products applied in treating a patient. Critical products include fe prosthetic knee and hip joints, laparoscopic disposables, stents and spinal implants. Suppliers apply the serial number to the primary packaging or the higher packaging layers, and hospitals record this serial number with the patient data. This procedure records exactly which patient has received which specific product.

Obstacles

We foresee several obstacles to introducing traceability into the healthcare system in accordance with the GS1 Global Traceability Standard (GTSH).

- Support for logistics within hospitals cannot be taken for granted.
- Suppliers are confronted with a fragmented demand from customers for item codes (HIBC, GS1, others).
- There is insufficient integration of the different IT systems within a hospital: HIS, EPR, ERP.
- There is a great diversity of hardware used in hospitals for the automatic registration of incoming goods (laser scanners, optical scanners, etc.).
- Not all hospitals are familiar with GS1, and so do not always consider GS1 standards as a solution.
- There are many suppliers.
- Regulations in different countries and regions are incompatible.
- Hospitals are waiting for suppliers, and vice versa, to move first, rather than making a start themselves.

6 Benefits, costs and risks

Investing in GS1 traceability yields benefits for patient safety while raising logistics efficiency. The 'hard' measurement points in this business case are concerned mainly with efficiency. The 'soft' measurement points are concerned with patient safety.

6.1 Costs and benefits for hospitals

Benefits

Chapter 5 described how traceability can be achieved. This chapter sets out the benefits and savings to be obtained from this method.

Benefits in patient safety.

- Operations can proceed as planned. There is a clear view of inventories, so that staff can be certain that the products needed are in stock.
- Improved recall procedure. Products are registered throughout the supply chain, and are then simple to locate in the system, regardless of whether they are still at the supplier, at a hospital supply point, or have already been used to treat a patient.
- Better information when replacing an implant. When implants have to be replaced, e.g. at the end of operating life, it must be known which implant has been used to treat which patient. The 100% secure product-patient registration means the patient and the product that was applied are simple to locate in the system.
- Fewer errors with automatic product-patient registration by means of bar code scanning. Manual actions are no longer needed, which reduces the number of errors. Research into the effect of bar coding in the administration of medicines has shown an approximately 40% drop in the number of errors in product-patient registration. No comparable study is yet available for medical devices, but it may be assumed that the reduction in error rate will be similar (study by Poon et al., see Sources and references section.)

Logistics benefits

Based on experience and findings of the UMC Nijmegen, UMC Utrecht, Ziekenhuisgroep Twente and the St. Antonius hospital, and on a comparison of the annual reports of various other hospitals (university medical centres and several small and large general hospitals), we have quantified a number of benefits.

The registration of traceable products at all relevant points in the logistics chain facilitates complete transparency of inventories. It is then possible to:

- Reduce inventory levels by approximately 20%.
- Bring down obsolete stock by approximately 80%.
- Save time and money through automatic reordering*.
- Save time and money through the use of electronic packing lists (despatch advice)*.
- Save time and money through electronic billing*.
- Accelerate recall procedures. Hospital staff no longer need to search physically through paper files and supply points, because the information is available in the relevant systems. The time gained can range from a couple of hours to several days;
- Make the most effective use of consignment goods.

**We are aware of no data to quantify the savings. Further research is required on this point.*

The hospitals mentioned above estimate that the rate of obsolete stock in Dutch hospitals is between 5 and 8%. They also report that obsolete stock could be reduced by approximately 80% through the automatic registration of expiry dates.

Potential savings

We have established that the total amount of inventories of medical devices in the Netherlands is approximately 200 million euros.

In accordance with NVZ figures the total turnover of medical devices, excluding capital goods, is 2.4 billion euros.

We have assumed the above amounts in calculating the potential collective savings for the hospitals. See the table below:

Indicators for the hospital sector	Conservative scenario	Optimistic scenario
Inventory value to balance sheet	€ 200 million	€ 200 million
Turnover of goods excluding pharmacy*	€ 2.4 billion	€ 2.4 billion
Reduction of balance stock	20%	30%
Waste percentage	5%	8%
Reduction of waste	80%	80%
Handling expenses for replenishing stock	25%	25%
Saving		
Potential waste reduction	€ 96 million	€ 153 million
Lower handling expenses for new inventory level	€ 10 million	€ 15 million
Total saving	€ 106 million	€ 168 million

**Source: NVZ*

In addition to the stated savings, there is also a reduction of the stock on the balance sheet in favour of the hospital's income statement. This benefit is between 40 (conservative) and 60 (optimistic) million euros.

Costs per hospital

Implementing traceability by means of GTSH depends on hospitals' willingness to invest. We present below the costs a hospital would incur. Needless to say, these costs depend on the extent to which systems and processes have already been set up.

Hospital investment	Nonrecurring	Annually recurring
Hardware and software		
Scanner procurement	€ 21,200	
- Depreciation		€ 4,500
Software procurement	€ 50,000	
- Licence fees		€ 7,500
System configuration	€ 50,000	
Item data pool		€ 2,000
GS1 Netherlands membership	€ 2,000	
- GS1 Barcodes (identification keys)		€ 2,500
- GS1 eCom		€ 2,000
Subtotal	€ 123,200	€ 18,500
Personnel costs		
Nonrecurring training	€ 50,000	
Placing bar codes		€ 100,000
IT system maintenance		€ 100,000
Subtotal	€ 50,000	€ 200,000
Total investment	€ 173,200	€ 218,500

Hardware and software

In order to scan bar codes on all products, a hospital needs optical scanners at all relevant locations. For example: each operating theatre needs a rugged scanner for reading bar codes in challenging conditions, such as poor light and much reflection from surgical instruments. The costs are € 2,000. Each supply location needs two scanners costing € 600 each. An average hospital with ten operating theatres, one central store and one operating theatre supply point would have to invest € 21,200. The depreciation period is 5 years.

Where applicable: modifying the administrative software for automatic ordering and the receipt of electronic packing lists and invoices. The estimated costs are € 50,000 per hospital. The licence fees are 15% of the purchase per year.

The estimated costs for configuring the hospital systems are € 50,000 per hospital.

Join an Item Data Pool. The costs for an average hospital would be € 2,000 per year, depending on the chosen solution.

Membership of GS1 Netherlands for GS1 identification keys to uniquely identify locations (GLN), trade items (GTIN), logistic units (SSCC) and patients and staff (GSRN). Also for the use of GS1 eCom. Rates depend on the number of beds per hospital.

The following prices are for an average hospital (400 beds □ category H):

- GS1 Netherlands membership (GS1 identification keys) one-off € 2,000 plus € 2,500 per year.
- GS1 eCom package € 2,000 per year.

Personnel costs

The nonrecurring personnel training costs for the modified procedures are € 50,000.

Any bar codes that are not already applied to the products by the supplier must be printed on receipt of the goods and attached to the items concerned. (It is assumed that it will become increasingly uncommon for hospitals themselves to need to apply bar codes, as more suppliers apply GS1 bar codes to their products.) Estimated costs 2 FTE: € 100,000 per year for 3 years.

IT system maintenance € 100,000 per year.

6.2 Costs and benefits for the supplier

The focus of this business case is the hospitals, but it goes without saying that the method described in Chapter 5 also has benefits for suppliers. We have set out the costs and benefits for suppliers in rather less detail than for hospitals.

Benefits

A reduction in the variety of identification methods and bar codes to a single uniform coding system, leading to substantial savings. The opportunity to optimise the ordering process by means of electronic order processing and improved management of trade item data.

- A centralised data pool leads to better managed and higher quality item data, resulting in fewer errors in the ordering and delivery process.

Potential savings of between 1 and 3 FTEs through automated ordering: 50,000 to 150,000 per year per supplier.

- Fewer problems with peak orders because hospitals have a clearer view of inventories.

More precise inventory control with possibly 10-20% lower inventory levels. The stock of medical devices in the Netherlands is estimated at 400 million euros, implying potential savings for the entire market of between 40 and 80 million euros.

Improved recall procedures that extend as far as the point of care give suppliers a firmer grasp of any recalls compared with the current situation. Suppliers then also have more control over possible liability.

Costs per supplier

Implementing traceability by means of GTSH depends on supplier's willingness to invest. We present below the costs a supplier would incur. In this case too, these costs depend on the extent to which systems and processes have already been set up.

Hardware and software

- Assigning all products a GS1 trade item number (GTIN) and bar code.
- For products that require a batch and/or serial number and expiry date as well as an item number, investment is needed in GS1 DataMatrix printers and verifiers for use in the production process.

Estimated investment € 50,000 to € 100,000 per production line. These costs are incurred by the production unit that, based on standard application, is able to distribute the costs over the various customer countries.

- Where applicable: modifying the administrative software for automatic ordering and generating despatch advices and invoices.

Estimated costs €€50,000.

- GS1 Netherlands membership for GS1 identification keys (GTIN, GLN, SSCC).

Membership: one-off € 1,000 plus on average € 1,000 per year.
GS1 eCom package approximately € 2,000 per year.

- Membership of an (GDSN) Item Data Pool.

On average € 2,000 per year.

6.3 Return on investment (ROI) model for hospitals

Conservative scenario

Costs in euros	Year 1	Year 2	Year 3
Total revenues	€106 million	€106 million	€106 million
Nonrecurring costs*			
Hardware and software procurement	€ 12.3 million	-	-
Personnel costs	€ 5 million	-	-
Total nonrecurring costs	€ 17.3 million	-	-
Structural costs*			
Hardware depreciation	€ 450,000	€ 450,000	€ 450,000
Software licences	€ 750,000	€ 750,000	€ 750,000
Connection to data pool	€ 200,000	€ 200,000	€ 200,000
GS1 Netherlands membership	€ 450,000	€ 450,000	€ 450,000
Personnel costs	€ 20 million	€ 15 million	€ 10 million
Total structural costs	€ 21.9 million	€ 16.9 million	€ 11.9 million
ROI hospitals	+ € 66.8 million	+ € 155.9 million	+ € 250 million

* 100 hospitals were assumed in estimating costs.

Optimistic scenario

Costs in euros	Year 1	Year 2	Year 3
Total revenues	€ 168 million	€ 168 million	€ 168 million
Nonrecurring costs*			
Hardware and software procurement	€ 12.3 million		
Personnel costs	€ 5 million		
Total nonrecurring costs	€ 17.3 million	-	-
Structural costs*			
Hardware depreciation	€ 450,000	€ 450,000	€ 450,000
Software licences	€ 750,000	€ 750,000	€ 750,000
Connection to data pool	€ 200,000	€ 200,000	€ 200,000
GS1 Netherlands membership	€ 450,000	€ 450,000	€ 450,000
Personnel costs	€ 20 million	€ 15 million	€ 10 million
Total structural costs	€ 21.9 million	€ 16.9 million	€ 11.9 million
ROI hospitals	+€ 128.8 million	+€ 279.9 million	+€ 436 million

* 100 hospitals were assumed in estimating costs.

6.4 Risks

At present not all products yet have GS1 identification and /or bar codes, which constitutes a risk in the introduction of the proposed method. However, approximately 60% of the products do already have the correct codes and a growing number of suppliers is adopting GS1 coding.

Another risk is the severe cost pressure on hospitals, which may impede investment in IT infrastructure. However, this investment is vital for introducing the GS1 Global Traceability Standard for Healthcare.

7 Conclusions and recommendations

7.1 Conclusions

The introduction stated that application of the GS1 Global Traceability Standard for Healthcare makes it possible at all times to answer questions such as "Which patient was given which replacement heart valve?" and "Will the right material be available at the start of the operation?".

There is increasing government pressure for both higher quality and patient safety must improve and lower costs in the healthcare system.

We have exposed a number of points for improvement in the current situation. As yet there is no optimum transparency and control of inventories, and the registration of products at the point of care is not automated. The lack of automation leads to avoidable errors and labour-intensive and time-consuming recall procedures. The costing of operations can also be more effective and complete.

This business case has demonstrated that patient safety is improved by using the GS1 Global Traceability Standard for Healthcare by making clear which patient has received which medical device, and under whose responsibility. Recall procedures are thereby simplified. The application of the GS1 standard also leads to confidence in operation planning: the right material will be available. Furthermore, the costs per operation for reimbursement (DTC and DOT) can be estimated more accurately.

The greater transparency in inventory control helps lower costs. Hospitals can make potential annual savings of between 106 and 168 million euros.

7.2 Recommendations

Start now!

In view of the enormous savings potential for hospitals, coupled with increased patient safety through the use of the GS1 Global Traceability Standard for Healthcare, the Traceability Focus Group recommends: start introducing the GS1 Global Traceability Standard for Healthcare.

The motto is: start now! However, do start with projects that are compatible with the organisation and introduce traceability step by step. Use the experience gained in other hospitals. Follow the example of hospitals such as the University Medical Centres in Utrecht and Nijmegen, and the St. Antonius hospital, by starting with one department and extending later to the others.

Set up a project team and set to work with the multistep plan given in Chapter 5.

Obtain commitment!

Commitment is essential on all organisational levels for both suppliers and hospitals. The embedding of GS1 standards throughout the healthcare sector also requires management level support for the introduction of GS1 Traceability.

Achieving compatibility between the GS1 Global Traceability Standard for Healthcare guidelines and the processes in the Dutch healthcare sector will require clear agreements between suppliers and hospitals. These agreements must cover positioning the bar code, the data required for each type of product, and the appropriate packaging layer (secondary or primary, or directly on the product).

GS1's Traceability Focus Group is willing and able to facilitate these agreements.

Appendix I

GS1 Traceability: how it works

The GS1 Global Traceability Standard for Healthcare (GTSH) is used in implementing traceability. Exactly how it works, from the processes involved to registration at the point of care, is described below.

Multiple levels of traceability

Traceability is desirable on various levels. When products are transported from a supplier to a hospital, the traceable item is usually a carton, case, or pallet containing several products, which is referred to as a logistic unit. It is necessary to track a logistic unit. Once it is delivered to a hospital and distributed internally, it may be necessary to track the individual products. For example, a prosthesis ordered for a specific patient is required to be in stock at the operating theatre before the planned date of the operation.

GS1 identification of the traceable products

The desired traceability level determines the data and the GS1 ID key to be used. The table below gives the appropriate GS1 identification key for the various levels. This guideline is based on international agreements.

Traceability Level	GS1 ID key (Dutch)	GS1 ID key (English)	Abbreviation
Logistic unit	GS1-verzendcode	Serial Shipping Container Code	SSCC
Batch	GS1-artikelcode + Batchnummer	Global Trade Item Number + Batch Number	GTIN + Batch No.
Individual product	GS1-artikelcode	Global Trade Item Number	GTIN
Unique product	GS1-artikelcode + Serienummer	Global Trade Item Number + Serial Number	GTIN + Serial No.

In accordance with GS1 specifications the supplier assigns each traceable product a GS1 number (GTIN or SSCC). This number is incorporated in a GS1 bar code (GS1 DataMatrix, EAN-13, GS1-128 or other).

As well as the GS1 trade item number, most medical devices also have an expiry date and batch number for quality control purposes. If needed, these data are also included in the GS1 bar code. This bar code may be GS1-128 or GS1 DataMatrix, depending on the process concerned, the traceability level and the product packaging.

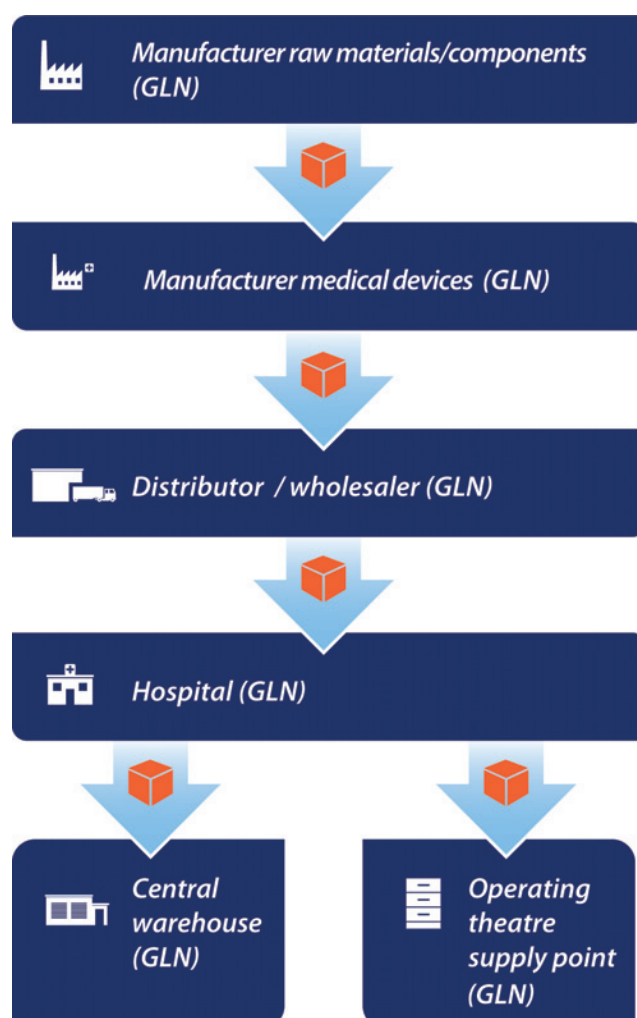
Internationally, GS1 has drafted recommendations for suppliers about the applicable GS1 coding, see Appendix II. Please contact GS1 for additional information about the recommendations and the application.

Fewer errors

The supplier appends the data, which are then used by and recorded in systems by various parties in the supply chain. For example, the GS1 bar codes are scanned by the various departments within a hospital and the data from the bar code are saved in the relevant system: HIS, ERP or EPR. In this way, each party can access the appropriate data about a product. Because each party uses the same data, there will be fewer errors in the communication about the products.

GS1 identification of the supply chain parties

Each party in the supply chain must have an identification, which may be a GS1 global location number (GLN), which is used in the electronic communication (EDI) for ordering, delivery and billing. The GLN is also the reference point for the movement of goods in the supply chain, as shown in the diagram below.



GS1 Netherlands provides a location directory for registering and referring to location codes. This tool is available free of charge to all healthcare parties.

GS1 identification of patients and staff

Each service relation in the supply chain also needs an identification, which may take the form of a GS1 global service relation number (GSRN).

A patient is identified as the party who receives the service and a member of staff as the party who provides it. It is then possible to record by electronic means which patient has received which product and from whom. A GSRN also supports the monitoring process: the right product for the right patient in the hands of the right member of staff.

Electronic business messaging (GS1 eCom)

The despatch advice is of particular importance in the traceability of medical devices. The supplier delivers the ordered items to the hospital as a logistic unit, which may be an outer carton, case, surgical kit, or other form of packaging. The supplier assigns a unique code to the logistic unit: a Serial Shipping Container Code (SSCC). Synonyms: batch number, logistics code, shipping code. The SSCC facilitates the traceability of the logistic unit.

The SSCC is incorporated in a bar code (usually a GS1-128 symbol) and the bar code is printed on a label on the logistic unit.



On arrival the hospital scans the GS1-128 bar code, which contains the SSCC, on the shipping unit.

Following despatch, the supplier sends the hospital a despatch advice (electronic packing list), which specifies the shipping codes alongside the items in the logistic unit: the content of an outer carton, case, or surgical kit. E.g. SSCC1 comprises 10x GTIN1, 5x GTIN2 and 2x GTIN3.

The hospital reads the despatch advice into its ERP system and, when the SSCC is scanned on the goods themselves, there is an automatic match with the electronic information received. If the supplier also includes the expiry date and the batch and /or serial number of the products in the message, these data can also be saved directly in the ERP system.

If the logistic unit remains intact during further distribution within the hospital, the hospital may use the SSCC as a key within its ERP system. If the logistic unit is unpacked on receipt, a different working method is appropriate. The central warehouse may combine goods from multiple orders for a given delivery point. The hospital then assigns its own number (shipping code) to the new composite unit.

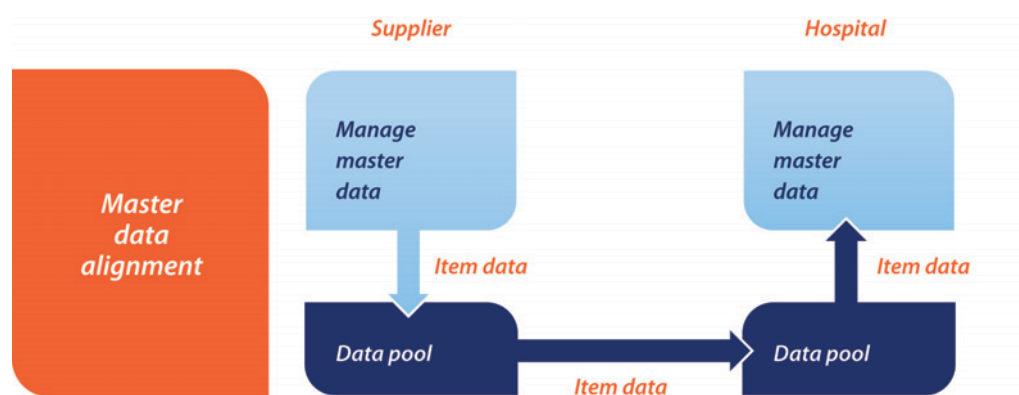
The GS1 order and order response are available for electronic ordering. A GS1 invoice and payment specification may be used for the financial settlement.

For additional information, see www.gs1.nl/samenzorgen.

The exchange of item information

Since a product bar code contains only the GS1 trade item number (GTIN) and possibly also supplementary data such as the batch number and expiry date, a database is needed for determining which item is involved, e.g. by providing the name of the product. Other item data are important: dimensions, weight, method of administration, manufacturer, specific product properties, information about dangerous goods, etc.. There are various ways of exchanging item information of this kind: bilaterally between a supplier and a hospital, or through a data pool. With a data pool, the supplier enters the data at a central registry that the hospital is able to access. In this way all parties in the supply chain have the same data, which has obvious benefits for data quality.

A diagram is given below of the exchange of item data through a data pool.



GS1 has an international standard for the exchange of trade item information: GS1 Global Data Synchronisation. Various suppliers of data pools in the market comply with this standard and are connected to the international Global Data Synchronisation Network (GDSN).

Appendix II

Internationally, GS1 has drafted recommendations for suppliers about the applicable GS1 coding. Suppliers and hospitals were involved in drafting these recommendations. The recommendations are as follows.

If a product requires only a GTIN, and there is sufficient space on the package: use an EAN-13 bar code.



Where GTIN plus supplementary information (expiry date, batch number, serial number) are required, and there is sufficient space on the package: use a GS1-128 bar code.



Where GTIN plus supplementary information are required and there is **insufficient** space on the package, use a GS1 DataMatrix.



Appendix Glossary

AIDC	Automatic Identification and Data Capture. The set of technologies and systems for identifying goods, parties, locations and people without human intervention, and for making the information captured available to systems.
Batch	A controllable group of goods produced concurrently in the same process step.
Consignment	Consignment goods are stocked in a hospital by a supplier. The hospital notifies the supplier when a product is drawn from the consignment stock. The supplier then invoices the product and replenishes the stock.
DTC	Diagnosis Treatment Combination. The DTC includes all the healthcare activities performed by a hospital and medical specialist arising from the need for care presented by the patient when consulting the hospital specialist. The DTC is the billable performance.
DOT	(DTCs Towards Transparency). A plan that introduces DTC healthcare products as a successor to the current DTCs. Healthcare products are more readily identifiable for medical purposes, more cost-homogeneous, and transcend specialisations. DOT is being defined jointly by the Ministry of Health, Welfare and Sport (VWS), the Dutch Healthcare Authority (NZa), trade associations, care providers, health insurers, IT suppliers and DBC-Onderhoud.
Electronic Data Interchange (EDI)	The exchange of standard business messages in electronic form, such as Order, Despatch Advice and Invoice.
ERP	Enterprise Resource Planning. Software for supporting business processes, such as the financial accounting system, inventory control and purchasing.
Expiry date	The latest date for consumption or use. It is a guide for safe use.
Global Data Synchronisation Network (GDSN)	The Global Data Synchronisation Network (GDSN) is an automated, standards-based, global environment that enables secure and continuous data synchronisation, allowing all partners to have consistent item data in their systems at the same time.
Global Location Number (GLN)	Dutch: GS1-adrescode. The GS1 identification key used to identify a physical location or party.

GS1 eCom	Global standards for Electronic Business Messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners. The standard formats are GS1 EANCOM and GS1 XML.
GS1 DataMatrix	A two-dimensional symbol that supports the data structure of the GS1 system. It is an extremely flexible symbol that encodes series of elements by means of Application Identifiers.
Global Trade Item Number (GTIN)	Dutch: GS1-artikelcode. is an identification number for products and services. It is normally constructed from a GS1 company prefix assigned to a company, an item reference designated by the company, and Check Digit.
GS1 Invoice	A standard invoice message that a supplier sends a customer to request payment for products and services.
GS1 Order	A standard order message with which a customer can place an order with a supplier using EDI.
GS1 Order Response	Standard EDI order confirmation message with which a supplier gives feedback to a customer about a previously placed order.
GS1 Despatch Advice	The EDI message sent by a supplier or logistics service provider to a customer about the time and details of products to be delivered. Synonym: electronic packing list.
GS1 GTSH	GS1 Global Traceability Standard for Healthcare. The GS1 standard that supports traceability.
Logistic unit	Any combination of goods that is not permanently bound to other goods and that is tracked individually through the entire supply chain from sender to receiver. Logistic units include cartons, cases, pallets and containers.
Medical device	<p>Any instrument, apparatus or appliance, software, material, or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by its manufacturer to be used for human beings for the purpose of:</p> <ul style="list-style-type: none"> - diagnosis, prevention, monitoring, treatment, or alleviation of disease; - diagnosis, prevention, monitoring, treatment, alleviation of, or compensation for an injury or handicap; - investigation, replacement or modification of the anatomy or of a physiological process; - control of conception, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. <p><i>Source: Medical Devices Directive</i></p>
Primary packaging	The first level of packaging that is in direct contact with the product and is marked with a data carrier on the package or with a label attached to the package. Primary packaging may comprise a single item, or a group of

**Secondary
packaging**

items for a single therapy, such as a surgical kit. For packaging configurations that contain a consumer item, the primary packaging level is one level below that of the consumer item.

A packaging level that is marked with an AIDC data carrier that may comprise one or more primary packages or a group of primary packages with a single item.

**Serial Shipping
Container Code
(SSCC)**

An 18-digit number that uniquely identifies a logistic unit. The SSCC consists of an Extension Digit, a GS1 Company Prefix, a Serial Reference and a Check Digit.

Any logistic unit that is stored, shipped, transported, or received, is thus readily identifiable using an SSCC.

Traceability

The ability to trace the history, application or location of an item.

Appendix Sources and references

GS1 Standards Document – GS1 Global Traceability Standard for Healthcare	GS1 Healthcare	2009
GS1 Global Traceability Standard for Healthcare (GTSH) – Implementation Guide	GS1 Healthcare	2009.
www.swissmedic.ch/rueckrufe_medizinprodukte/archiv/index.htm?lang=en	Swissmedic	2011
GLN in Healthcare Implementation Guide	GS1 Healthcare	2010
Handboek GS1-codesysteem (GS1 bar code manual)	GS1 Netherlands	2007
Business Message Implementation Guidelines for Healthcare for the following electronic messages: Order, Order Response, Despatch Advice and Invoice	GS1 Netherlands	from 1993
AIDC in Healthcare Implementation Guide	GS1 Healthcare	2010
AIDC in de gezondheidszorg Implementatierichtlijn (translation into Dutch of the above publication)	GS1 Healthcare	2011
Monitor Zorggerelateerde Schade 2008 (Healthcare-related harm monitor 2008) www.onderzoekpatientveiligheid.nl	Nivel	2010
Inventory Management for the OR at the UMCU: Are there efficiency opportunities?	Tom Pereboom	2010
Effect of Bar-code Technology on the Safety of Medication Administration. By Eric G. Poon et al.	New England Journal of Medicine	2010
Kwestie van meten – voorraadoptimalisatie door integratie en registratie (A matter of measuring – inventory optimisation through integration and registration)	UMC Nijmegen	2010
Onderzoek kwaliteit van barcodes op steriele implantaten (Study of bar code quality on sterile implants)	GS1 Netherlands with Erasmus MC	2011

Contact

If you would like to find out more after reading this business case, please visit www.gs1.nl/samenzorgen.

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GS1 Netherlands has been the driving force behind implementing improvements in the supply chain for more than 30 years. Our areas of expertise are joint efforts towards appropriate services for consumers, innovative logistics, and information sharing. With and for the industry we create agreements and translate them into specific solutions for various sectors.

*This business case describes the costs
and benefits of using GS1 standards
to introduce medical device
traceability as far as the point of care.*



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