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Barcoding in traceability

Traceability has long been perceived as a task for drug manufacturers. But with an increase in counterfeit products the healthcare community has been forced to consider track-and-trace management as a shared issue

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Since the beginning of barcode usage in the early 1970s, it has expanded in numerous fields around the world to become almost ubiquitous. When major stakeholders started to develop and implement a barcode, including both a symbology and a semantic standardisation, they were establishing a worldwide standard in supply chains – what is known today as the GS1 standard. The initial purpose was to speed up processes at the point of sale, but, 10 years later, several other purposes have emerged, such as the need to standardise tools for traceability. This led to the adoption of an extended semantic, which had to be carried over from another symbology (Code 128).

From the 1980s to the turn of the century, a new need appeared, demanding a thinner granularity in traceability processes that needed objects to be serialised. The “internet of objects,” created at the Massachusetts Institute of Technology, became a new pillar in the GS1 standard.

The user community, in defining its needs in traceability by lot (from the 1980s) or by serialisation (from the early 2000s), was responding to regulatory demands. This addressed food and beverages,¹ veterinary products (because of the connection to food for human consumption), and many other market segments where the need to trace an object’s history has become a vital need.

In healthcare, traceability has long been perceived as a task for the sole manufacturer of products such as drugs or implants.^{2,3} When new risks have appeared (such as AIDS, CJD and so on), regulatory and other incentives have led the healthcare community to consider traceability as a shared issue involving the supply chain. More recently, the increase in counterfeit products has forced users and regulators to consider product serialisation and traceability at unit level.⁴ To address this, a consensus on the use of a single standard across the geographical and branch markets has been raised.⁵

Barcode or radio-frequency identification?

Traceability – being the ability to retrieve information on the origin of a product and its destination – requires increasingly sophisticated tools as the granularity

increases. By respecting an open semantic, all parties are able to participate in the traceability effort. Relevant information would include product identity, lot number and serial number – the last two being attributable to the first.

For large objects, a linear barcode and UHF RFID (ultrahigh-frequency radio-frequency identification) tags present the best option. For smaller objects, such as a drug retail pack, two-dimensional Datamatrix or HF RFID tags offer the best technical solution. When considering small items such as a vial, a prefilled syringe, a blister pack or a surgical instrument, two-dimensional Datamatrix is the only technical solution.⁶

Several studies and discussions have taken place to define which kind of data carrier presents the best solution. Table 1, by an expert group from European Federation of Pharmaceutical Industries and Associations (EFPIA),⁷ illustrates why optical solutions are currently preferred.

The choice of technology impacts the possibility to deploy certain processes: RFID, for example, because the information can be collected without direct line of sight, allows data capture at a higher speed – such as might facilitate delivery preparation in a wholesale facility. In special applications, where temperature control is important, or where the capacity to change or add information on the item itself is an asset, RFID tags offer the best solution.

The research by EFPIA demonstrates that RFID tags on retail packs are less reliable than Datamatrix, which can be damaged up to 60% and still be readable.⁸ Reliability of RFID tags is influenced by constraints imposed by the antenna. On soft materials, antenna may be damaged, which disables data capture. When built into a more rigid base, however – such as patient wristbands or when integrated into surgical instruments – users can expect RFID tags to meet reliability requirements.

The place of traceability in hospital environments

There are many benefits to expect from track-and-trace management in the healthcare sector. Among them, it is worth emphasising the following:

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Will RFID technologies
replace barcoding in
the future?

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Table 1. European Federation of Pharmaceutical Industries and Associations

	DataMatrix	RFID
• Ability to read at distance/No direct line of sight required?	X	✓
• Difficulty to modify/alter/copy the code content?	X	✓
• Readability robustness? (Interferences with metals/liquids)	✓	X
Efficiency of reading rates? (100% required)		
• Business processes changes?	✓	X
High speed/High volumes?		
• Compatibility with biologics (vaccines, biotech products)?	✓	X
• Volume of data to manage? Network complexity (EPC Global) –	✓	X
Harmonised standards available (EU/USA/Asia)?		
• Privacy issues/Objections/Public concerns?	✓	X
• RFID tag cost ~20–40 cents €	✓	X
Datamatrix cost ~0.1–0.3 cents €		

Improved supply chain efficiency

Care providers, patients and healthcare facilities are at the crossroads of many supply industries: pharmaceutical, medical devices, disposable products, implantable devices, to name the most obvious. But there are also numerous other suppliers, such as food and groceries, beds, clothes, computers, office equipment and so on. Many hospitals are comparable to small cities, with distributed stocks management and internal markets embedded in the global market in a global world. Improving this management through greater visibility, accuracy and velocity is expected to produce the same improvement in economic efficiency as measured in other industries. Traceability is a crucial component of logistics, which is the optimal management of flows and resources. Logistics includes: physical flows, such as buildings, materials, objects and people; logical flows, such as information or processes descriptions; and financial flows.

Prevention of errors

Errors in patient or drug identification are far from rare. Unique patient information can be encoded in data carriers, as can information on care providers, drug dosage and package units of use. This enables automated verification, which enforces a last-minute check to prevent error.

Public health

Public health has important needs related to the ability to track and trace population-based events to their causal roots. A complete track-and-trace mechanism, from the manufacturer to the patient, would be very helpful, especially when faulty products are detected. Patients who have received a specific drug or prosthesis could be traced, as could the affected lots. Unfortunately, for some types of items, such as pacemakers, very good

traceability is available; for others, such as drugs, it is almost non-existent. In addition, the legal framework enforcing traceability is very dependent on national or state-level policies. A global approach – as is already proposed for food – would be of the highest value.

Medico-legal investigations

The use of an interoperable framework of identification schemes, allowing the identification of actors, objects, locations and actions in a temporal net of events, is priceless for medico-legal investigations. Such facility enables the “reverse engineering” of the cascade of events leading to unwanted or unexpected incidents, or allowing clarification on the use of patient records when privacy breaches are suspected.

Clinical research and epidemiological surveillance

The high cost of clinical research – for example, in the surveillance of side-effects – would benefit hugely by moving from the current situation, with surveys limited in time and populations, towards continuous monitoring. A robust track-and-trace management system would be of great help, leveraging the power of secondary usage of clinical data.

Flows and processes management

One of the biggest challenges faced by healthcare systems is improving global care management. This includes clinical pathways in hospitals, community networks, continuity of care between inpatients and outpatients, and care throughout the life of the patient. However, this challenge is tightly linked to the ability to build interoperability between all systems.

Billing

This is certainly the most developed domain of healthcare in terms of the use of information technologies.



However, a lot of work is still done by hand. Availability of a robust actors and assets identification and management system is mandatory in this field.

Counterfeit measures

Counterfeit drugs are increasingly available globally. While such drugs were previously only available in specific market segments, they are now extending rapidly into most markets, in part due to the use of the internet. Counterfeit drugs result in financial losses to pharmaceutical companies and are a direct cause of increased morbidity and mortality in the world. One of the best weapons against this illegal trade is a complete track-and-trace management system able to authenticate drugs and their provenance. Several initiatives are ongoing to help reduce counterfeit drugs, such as the use of ePedigree and serialisation.⁹

Five-year forecast

- Bridges between healthcare standards and supply chain standards, such as GS1 and HL7; in 2007, the two global standards organisations signed a memorandum of understanding to work together on this issue.
- Move towards serialisation of coding to identify unique items; in the USA, this is a prerequisite for the fulfilment of regulatory requirements regarding pedigree; in Europe, EFPIA is preparing a large-scale pilot to investigate and understand processes linked to serialisation. In Switzerland, during the first quarter of 2008, a pilot was run with a small number of products and parties.¹⁰
- Increased usage of high-density coding, such as Datamatrix and RFID; the French registration authority, AFSSAPS, is to migrate to GS1 DataMatrix from January 2009.
- Increased availability of multimodality readers.
- Decreased costs of RFID tagging.

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