

# Bar coding on pharmaceutical packaging cuts costs and improves patient safety

## ABSTRACT

The bar code has been in use in the retail industry for decades, in fact the first bar code was scanned in 1974 from a packet of Wrigleys chewing gum. It is now hard to find any retail outlet that does not scan products at the point of sale. The benefits of bar code scanning extend across the supply chain, from manufacture right through to the customer (stock tracking, inventory management, billing, consumer consumption trends).

The push for bar coding on medication rose substantially with the publication of the Institute of Medicine's landmark report, *To Err is Human: Building a Safer Health System*. The IOM's findings delivered shocking estimates regarding the occurrence and effect of medical errors. What is required to ensure end to end traceability is standardised marking (bar coding) on all medication, so that all parties in the supply chain can capture, understand and share the data. The global standards organisation, GS1, provide a platform for the development and implementation of such standards.

Unlike any other time in history we now have mobile technology that can be leveraged to provide the tools required to implement initiatives that can improve patient safety and support a rapid real time recall.

The advent of the smartphone incorporating an auto focus camera has provided the unlikely platform for an innovative solution that tracks medication, gathers clinical information, increases recording compliance as well as alerting the patient to potential hazards with respect to their medication.



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## Bar codes in industry and Healthcare

Bar coding technology has had a significant impact on the retail supply chain. The ability to automatically capture, store and analyse product identification from the bar code, and to organise logistics functions and streamline the flow of information has had a significant positive benefit.

The Healthcare industry has to date been slow to fully embrace bar coding for a number of reasons. Firstly, from a hospital point of view, bar coding was viewed as a purely logistics tool for better supply chain management and cost containment. Secondly, hospitals have been traditionally slow to commit funding to implement technology infrastructure unless there is a guaranteed ROI. Finally, the lack of standards, particularly in medication marking, has hindered widespread adoption.

In the retail industry standards for bar coding have been in existence for decades. The slowness of the pharmaceutical industry to develop standards for medication marking at unit level is baffling. Standardised medication bar coding would enhance the pharmaceutical industry internal and external supply chain with associated benefits for stock management and anti counterfeiting. But looking beyond the supply chain in particular, we find benefits that extend to the care giving functions – the core business of Healthcare.

## Bar code Case Study – Hospital and home use from Ireland

Interestingly, when the entire Healthcare system works with patients to deliver and track the supply chain of services for wellness, Healthcare savings and improved patient outcomes can be achieved. More than a just a vision of the future, this is being achieved with suppliers, hospital and patients in Ireland.

The National Centre for Hereditary Coagulation Disorders (NCHCD) located at St James's Hospital, Dublin, manages patients with inherited and acquired bleeding disorders. In Ireland, there are approximately 2000 patients with such a condition, of which there

are approximately 200 patients with severe haemophilia that require intensive care/treatment. Essential to this care involves taking a medication on a regular basis, which replaces the missing factor that causes excessive bleeding. Over 75% patients with the severe form of the condition are required to self medicate at home.

This expensive medication requires specific cold chain handling that extends from suppliers all the way to the patients home and medication use.

Although the patient safety issue that has been brought to prominence is the high frequency of medical errors and the impact on patient safety of administering wrong medication, just as important is the issue of safety of the blood and blood products themselves being used to treat patients. This latter issue was brought sharply into focus in the 1980s when patients suffering from the blood disease Haemophilia became infected with HIV/Hepatitis due to blood product contamination. The situation was compounded by the fact that infected medication (plasma product) remained in the supply chain even after a recall was initiated, leading to further infections. In Ireland this led to a national Tribunal of enquiry (The Lindsey Tribunal), which acted as a catalyst for this unique initiative.

The plan was to apply the retail supply chain model, incorporating a serialised GTIN, to all haemophilia medication packaging. This would allow electronic track and trace of the product as it moved from manufacturer to the patient (particularly important as the majority of severely affected patients self medicate in the home).

However, the absence of standardised bar codes on medication packaging coming from the main haemophilia medication manufacturers (in fact some of the medication had no bar code) meant that a unique standardised bar code could only be applied once the products reached the Cold Chain supply company (TCP Ltd.) who were contacted by the hospital to deliver the medication to the patient home.

## Unique Identifiers

The key objectives of the NCHCD initiative were to implement real time identification of CFCs to ensure immediate product recall, optimize stock management and save on wastage. The unique GS1 code allocated to each patient, drug product and location facilitates the automatic linking and capture of data during the supply process, validating each step of the cold chain storage and delivery process in real-time, ensuring that the correct drug is prescribed to the right patient as well as automatically updating the stock management system so that patient consumption trends can be analyzed.

## How the Haemophilia medication Tracking system works

The key to the success of this project involves harnessing the power of bar codes. Each patient is allocated a unique identifier,

as is each unit of medication and each location in the supply chain.

The process starts at the Cold Chain Company where the medication from the suppliers is received. Information on each vial box (Product name in the form of a GTIN, expiry date, batch number) is entered into their stock management system. A GS1 standard bar coded Vial Box Serial Number (VBSN) label is generated and applied to each unit of medication. The medication is then stored in validated cold chain conditions. Once a prescription is received for a patient or hospital delivery, all picking packing and shipping is performed using bar code scanning to track and trace the product as it moves through the supply chain, to either the patient home or the hospital. Within the hospital another software system then takes over the tracking and tracing of the medication as it moves around the hospital, again based on bar code scanning.

## Measurable success

The result has been an overwhelming success on a number of fronts. St. James's Hospital now has total visibility of each unit of Haemophilia medication in the supply chain. In the event of a recall the location of 100% of any selected batch of product can be identified within 10 minutes (a key recommendation of the Tribunal). Patients are extremely happy with a Cold Chain delivery service they can rely on. Product wastage due to failure of cold chain conditions or documentation issues has been eliminated. Interestingly, possibly because patients have confidence in the delivery method, €5 million worth of medication has been removed from the supply chain. This is due, most likely, to the fact that patients no longer "over order" and the fact that patient consumption trends are now visible in real time.

## Datamatrix bar codes

### Bar code advancements

The prospects for the use of bar codes in Healthcare have advanced considerably with the introduction of 2 Dimensional (2-D) bar codes. 2-D bar codes are much smaller than linear bar codes while at the same time capable of carrying significantly more information. It is the ideal format where the size of the package or vial is small, and the space is not available for printing linear bar codes. This is particularly relevant for medication that is administered as a single dose unit within the hospital or the home. For example, the Data Matrix bar code, shown here, requires the least amount of label space than any other available bar code standard. Datamatrix bar codes also apply error correction algorithms. In simple terms this means that up to 60% of the label can be damaged without affecting the integrity of the scan.



*Datamatrix bar codes*



### Patient handheld devices and point of care

Extending the concept of traceability to drug administration at the bedside and within the patient home is providing the final piece of the jigsaw. The bar code on the packaging (and the vial) serves as an index key in clinical databases. At the point where medication is administered, bar codes can be used to identify the drug, patient and/or the person administering the drug. This will assure a match between the patient and their prescribed medication, and also identify who is administering it. The system can be linked to software that references information in the patient Electronic Patient Record (EPR) to comply with the "Five Rights" of patient medication administration ensuring the right drug is administered at the right time to the right patient in the right dose by the correct route. However, the technology used needs to be portable and easy to use.



*Smartphone with Medication Scanning App*

As part of the Irish initiative mobile devices (smartphones) such as the HTC above, are currently being rolled out. As well as having standard mobile phone features, the devices are equipped with a software application (App) to allow the patient records their medication usage by simply scanning the B/C on the Vial Box. A realtime check is then performed against the EPR to ensure that the medication is not subject to a recall. In addition, the application offers the patient the opportunity to record key clinical information relating to why they needed to take the medication. The information (medication taken and reason for treatment) can then be transmitted back to the EPR and form part of the treatment history. Other significant

benefits have also emerged as a result of this application. For example, because information is gathered in "real time", care givers can now identify the time of day that treatment is being administered. Due to the fact that it has a specific half life, it is recommended that it should be taken before the patient is most active. But information gathered to date showed that some patients were self infusing last thing at night. Changing this practice would give improved protection against "breakout bleeds" that can lead to a decrease in quality of life, as well as reducing the necessity for additional, non prophylaxis, treatment.

Initial feedback from the patients has been overwhelmingly positive. Compliance with medication recording has improved significantly, which in turn helps the caregivers manage the patient's condition more effectively. A patient focus group has been established to feed back ideas on software and service improvements.

The Irish initiative should help encourage the pharmaceutical and Healthcare industries to reach an agreement on a bar code standard for medication. Once they have achieved a standard, and medication packaging contains the bar code, vendors of medication administration applications and EPR systems will begin supporting it. This in turn will lead to wider adoption within the Healthcare industry, and hospitals in particular, leading to improved patient safety whilst simultaneously driving down the cost of Healthcare delivery.

### ABOUT THE AUTHOR

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Feargal Mc Groarty is Project Manager, IMS Department, St James's Hospital, Ireland. A Medical Laboratory Scientist (MLS) by profession Feargal has over 20 years experience in Laboratory Haematology, Coagulation and Blood Transfusion. He headed up a large routine diagnostic Haematology laboratory, and has a particular interest in Laboratory Information Systems (LIS) and laboratory automation.

In his present role he is responsible for managing the multi faceted initiative that combines a number of strands including the use of bar code technology, an Electronic Patient Record (EPR) along with a cold chain delivery service to provide integrated patient management processes which is the first of its kind.

Mr. Mc Groarty holds a Fellowship in Haematology from the Institute of Biomedical Science along with a Diploma in Management and Employee Relations from the National College of Ireland (NCI).