Department of Health

# Coding for Success

*Simple technology for safer patient care*

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# Contents

# Summary

This document describes bar-coding and similar coding technologies, and the impact they could have on healthcare. There is evidence of real improvements to patient safety when coding systems are used to match patients to their care – fewer medication errors, a reduced risk of wrong-site surgery, a more accurate track and trace of surgical instruments, equipment and other devices, and much better record keeping. Using coding to manage supplies and purchasing electronically can cut costs dramatically as well as improving efficiency.

The medicines and medical devices industries have already made significant progress on coding products to voluntary standards. Benefits for industry include effective track and trace, and supply chain efficiency; coding is also a weapon in the fight against counterfeit products.

The case for coding is compelling, but all stakeholders need to work to commonly agreed standards if the benefits are to be realised fully. The Department of Health is recommending that the GS1 System should be adopted throughout the healthcare system in England, both for manufactured products and for coding systems used within healthcare settings, such as patient identification codes on wristbands.

This policy position is backed by an action plan to support both the NHS and the medicines and devices industries in realising the benefits for patients. It will include

- membership of GS1 for all NHS organisations, with demonstrator projects and further support to help organisations implement the technology locally;
- further encouragement to the medicines and devices industries to code products supplied to the NHS using the GS1 System; and
- engagement in the GS1 Healthcare User Group, which is reviewing the GS1 System to ensure it meets the needs of healthcare providers and manufacturers worldwide.

At this stage, the Department of Health believes that coding standards should be developed and applied on a voluntary rather than a mandatory basis. The GS1 organisation develops coding standards in consultation with its members. The NHS Purchasing and Supplies Agency will work with industry to apply these standards to healthcare products. The Department of Health and its agencies, including Connecting for Health, the National Patient Safety Agency and the Information Standards Board, will provide guidance and support to the NHS to help it implement coding schemes locally. This is not just about

the technicalities of coding, but also about making sure that the essential underlying systems and processes – such as all inpatients wearing wristbands – are in place.

Membership of GS1 is available now to the NHS, and the action plan sets out when further new guidance and information will be published. It is for the NHS and industry, working with technology suppliers, to take up the challenge and move the agenda forwards. The Department of Health will review progress by the end of 2008.

# 1 Introduction

1.1 Auto-identification and data capture (AIDC) is the use of bar codes, radio frequency identification (RFID) and other machine-readable codes to identify, quickly and accurately, an item or process. The technology has been in use for decades in many sectors of industry, the most familiar of which is retail, where bar codes on products have been used to improve supply chain efficiency, driving down costs and giving retailers a rich source of information about what shoppers buy.

1.2 This document sets out the strategic case for wider adoption of AIDC technologies in healthcare. The potential applications are very wide, from verification of patient identity and recording implant serial numbers in patient records, to tracking and tracing of individual instruments through decontamination, and for stock control and supplies management.

1.3 This message needs to be heard by **clinicians** who want to improve safety and quality of care for patients. AIDC can be a vital tool in verifying patient identity through, for example, a bar code or RFID tag on a wristband. Link this to a theatre management system and the risk of wrong-site surgery due to misidentification of the patient is dramatically reduced. Link it to the blood transfusion process and it can verify that the right patient receives the right blood. AIDC can help to reduce medication errors. There is evidence that the introduction of robotic dispensing systems can reduce dispensing errors: one study in a hospital pharmacy found that dispensing errors were reduced from 2.7% to 0.9% of prescriptions.[1]

1.4 This message needs to be heard by **finance directors** and others responsible for investment decisions who want to reduce costs and improve efficiency. Using technology to verify that the right patient is receiving the right intervention can reduce the need for additional manual checks and speed up laborious processes, freeing up highly trained staff to be deployed elsewhere. At Birmingham Heartlands Hospital, improved patient identification and checking procedures using RFID tags in a day surgery unit have improved efficiency, so that an extra minor or intermediate procedure can be done on each list. This equates to savings of £270,000 per year.

1 Chelsea and Westminster Healthcare NHS Trust. Robotic dispensing system installed May 2003, K Robertson, personal communication

1.5 The NHS is also a major purchaser of all manner of goods and the scope for enhanced supply chain efficiency is significant. In Leeds Teaching Hospitals NHS Trust, the cardiac catheter laboratories have switched to an AIDC-based stock control system. The value of stock held has reduced from £1.6 million to £700,000, including 983 product lines. Orders are placed twice weekly on an electronic system instead of twice daily on a paper system, dramatically reducing both staff time and the costs of the purchasing process from up to £7.05 per line to just 39 pence.

1.6 This message needs to be heard by **managers** who want to develop high-quality services delivered by staff working in fulfilling and satisfying roles. One trust deploying a robotic dispensing system saw a reduction in time spent in the dispensary of 34% for pharmacists and 51% for technicians, enabling far more time to be spent on the wards working directly with patients and ward staff. The Oxford Radcliffe Hospitals found that using the electronic rather than the manual blood transfusion process reduced the number of staff involved from two to one, and reduced the time taken per transfusion by up to 50 minutes. At the Leeds Teaching Hospitals two grade H nurses were needed for stock management in the cardiac catheter labs; now only one nurse spends just one hour a day on the task, freeing up highly-qualified staff time.

1.7 This message needs to be heard by **industries** supplying medicines, devices and other goods to the NHS. Most medicines already have a GS1 Global Trade Item Number (GTIN) product code on the patient pack, but this needs to be on all medicines. Product codes are not used as systematically for devices, but this too needs to change. NHS Purchasing and Supplies Agency recommended in 2004[2] that all products supplied to the English NHS should have a GTIN, and manufacturers need to act on this.

1.8 This message needs to be heard by **technology suppliers** who can develop the AIDC systems to support healthcare applications. Working with clinicians through the development process will ensure that systems address the key issues in the healthcare context – maximising efficiency and safety.

1.9 The Department of Health and its associated agencies are convinced of the potential benefits of this technology. This document sets out a vision of how patients and the healthcare system could benefit if AIDC is adopted more widely, together with a set of actions to facilitate further uptake. It is for NHS organisations, industry and technology suppliers to take up the challenge and drive the agenda forwards.

2 www.pasa.nhs.uk/PASAWeb

# 2 What is the potential and where are we now?

2.1 Reducing and, where possible, eliminating errors in the matching of patients with their care is central to improving patient safety in the NHS. Auto-identification and data capture (AIDC) technology can help achieve this goal.

2.2 The National Patient Safety Agency (NPSA) in its study 'Right patient – right care'[3] described three types of mismatching error:

- a patient is given the wrong treatment as a result of a failure to match him or her correctly with samples, specimens or X-rays (e.g. Mrs Johns' blood sample is confused with Mrs Jones', leading to incorrect diagnosis and treatment of both patients);
- a patient is given the wrong treatment as a result of the failure of communication between staff, or staff not performing checking procedures correctly (e.g. wrong kidney removed); and
- a patient is given treatment intended for another patient as a result of failure to identify him or her correctly (e.g. Mr U Patel receives the medication for Mr V Patel).

2.3 There are no accurate figures on the frequency or cost of such mismatching errors, but they form a significant part of the whole range of errors in healthcare. It has been calculated that:

- in the UK about 10% of inpatient episodes result in errors of some kind, of which about half are preventable; and
- of 8 million admissions to hospital in England each year, about 850,000 result in patient safety incidents which cost the NHS about £2 billion in extra hospital days.[4]

3 www.npsa.nhs.uk/site/media/documents/781_Right%20patient%20right%20care%20final%20report.pdf

4 C Vincent, G Neale and M Woloshynowych (2001) 'Adverse Events in British Hospitals: Preliminary retrospective record review', *BMJ* 322: 517–19

2.4 AIDC technology has the potential to tackle mismatching errors in particular, as well as delivering other efficiencies and cost savings. Key applications include:

***Verification*** – a major application of AIDC is to verify the identity of an item, person or procedure and link this with the member of staff involved in patient care. A hand-held computer with a built-in scanner can be programmed with protocols for procedures such as blood transfusion: details of the treatment for each patient are downloaded from the hospital system; the hand-held computer is taken to the bedside, and prompts the clinician to follow each step of the protocol, including scanning their own name badge, the patient's wristband and the blood bag to verify the right patient is receiving the right blood.[5]

***Data capture*** – there are many situations where serial numbers or reference numbers need to be entered into electronic records. Using AIDC to enter the information eliminates the risk of manual keystroke errors.[6] Studies of two-dimensional bar-coding compared with paper-based systems record a 17.68% difference in identification errors, with bar-coding almost eliminating identification errors. It is also useful for encouraging the use of the 10-digit NHS number, as transcription errors are sometimes perceived as a major obstacle to its use.

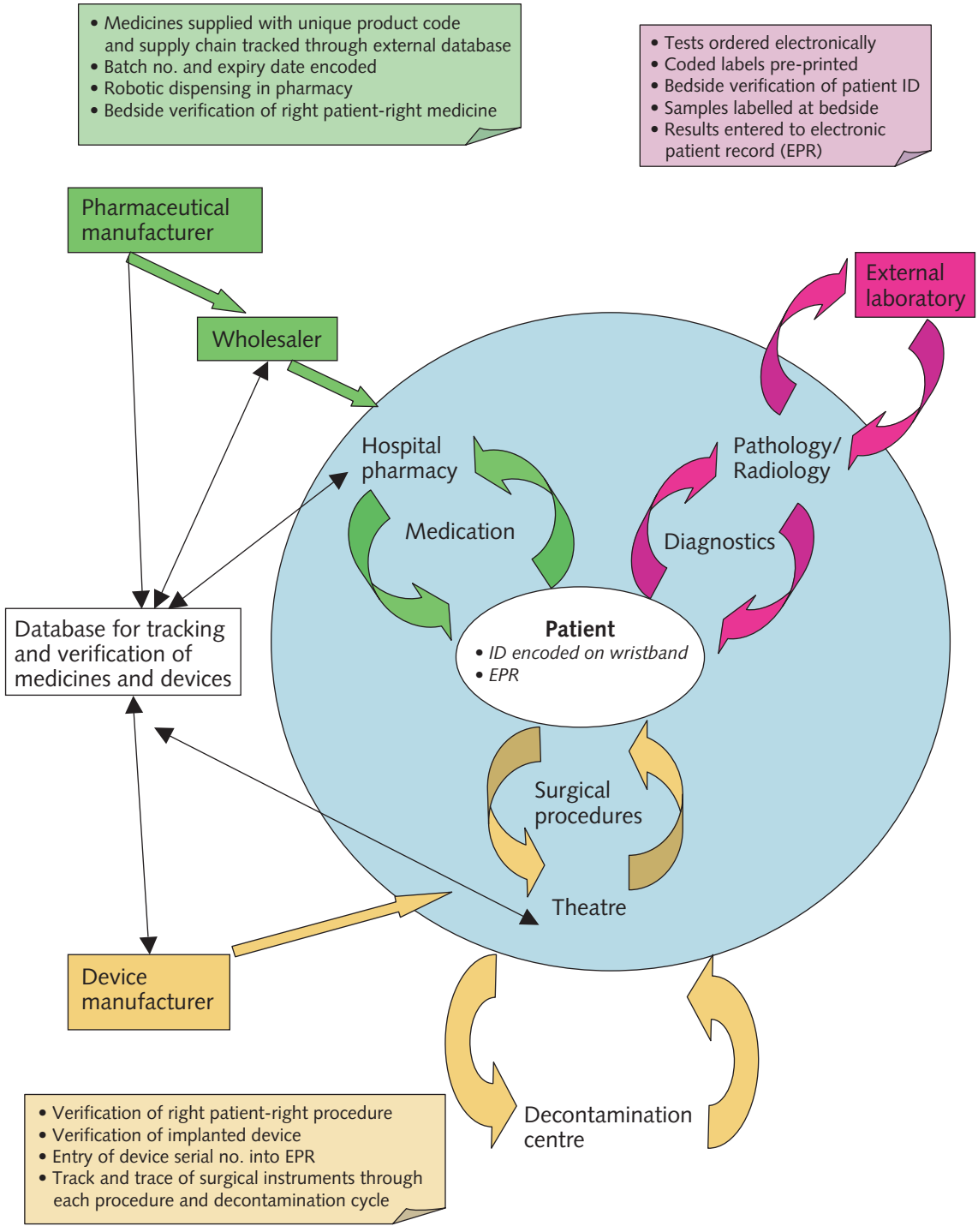
***Supply chain issues*** – effective track and trace of goods improves stock control so the right supplies are available in the right place at the right time. Unique product codes can be used on individual high-value items as an anti-counterfeit measure. Linking patients to the supply chain – by recording product information on patient records – can help to identify batches where a patient or patients have had an adverse reaction.

2.5 Figure 1 shows schematically some of the key areas in healthcare where AIDC may be of particular benefit. In the following sections, we set out a vision of how AIDC might be used in the future, followed by the current situation and the issues that need to be addressed to make further progress.

5 CL Turner, A Casbard, MF Murphy (2003) 'Barcode technology: its role in increasing the safety of transfusion', *Transfusion* 43: 1200–9

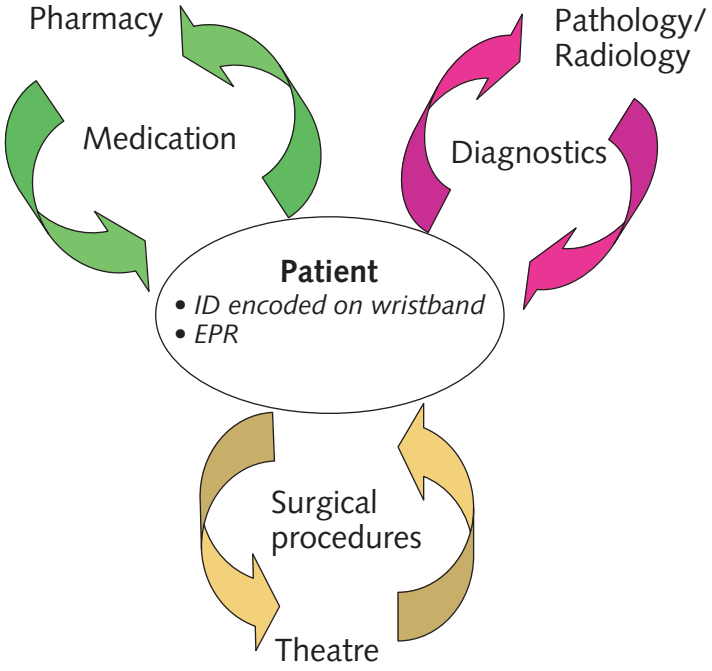
6 A Billittier IV, P Lupiani, G Masterson, T Masterson and C Zak (2003) 'Electronic patient registration and tracking at mass vaccination clinics: a clinical study', *J Pub Health Manag Pract* 9(5): 401–10

**Figure 1. AIDC and healthcare systems and processes**



## 2.6 The patient

**Figure 2. AIDC and the patient**




**The vision: how AIDC might be used working directly with patients in the future**

2.6.1 *Inpatients will be given wristbands with programmable RFID tags. These can be programmed initially with the patient's NHS number and other identification information, details of their treatment and other key information such as allergies and special blood requirements. These can be updated through the course of the hospital stay. Alternatively, some tags have minimal information stored in them, but act as a link to the patient record in the hospital information system. This is more secure for patients as their details are not contained within the tag.*

2.6.2 *The tag will be used as an additional verification check that the right patient is being given the right care, whether that is medication, diagnostics or a surgical procedure. A clinician will be able to access the patient's electronic patient record (EPR) for more detailed information by scanning the tag into the hospital or other healthcare provider's IT system.*

2.6.3 *AIDC will be used to enter details of treatment such as implant serial numbers or batch numbers for medicines or vaccines into the EPR, facilitating patient recall in the event of a problem being identified, as well as accurate stock management.*

2.6.4 *For outpatients or primary care applications, patients can have their NHS number in a linear bar code on the appointment letter or prescription, which the doctor or pharmacist can use to check that the right patient is receiving the right care.*

## Current status

2.6.5 For inpatients, the patient wristband is an ideal vehicle for carrying a machine-readable code for patient identification. Systems may be based on simple linear bar codes (which usually encode the patient's hospital number), or on RFID tags that can hold more detailed information and can also be read out of line of sight – e.g. under blankets and theatre drapes. Pilot projects looking at use of AIDC in particular areas have used both technologies successfully, but they are not widely used within the hospital system as a whole.

2.6.6 In some places, outpatient appointment letters already include bar codes to identify the patient, bringing up the correct electronic record when they attend their clinic, thus ensuring that the clinician consults the right notes and offers the right treatment options.

**Case study: RFID tags for patient identification – Birmingham Heartlands Hospital**

An RFID tagging system has been implemented at the day-case unit at the Birmingham Heartlands Hospital, to improve safety and efficiency as patients go through surgery.

Patients have a digital photograph taken when they are admitted to the unit, and this is embedded in their EPR. They are given a wristband with an RFID tag containing their identification details.

Clinicians on the unit have hand-held computers containing details of the day's operating list. These are connected through wireless (WiFi) technology to the hospital computer system. Whenever a patient's record is accessed, the patient's photograph is displayed to aid identification.

The hand-held computer prompts the clinician to carry out the pre-op checks, and the WiFi technology allows patient records to be updated in real time. A 'traffic light' system is used so that anyone can see at a glance which patients are ready for theatre.

When the patient is taken to theatre, the RFID tag in their wristband is detected by a sensor on the door, which triggers the relevant patient record to be displayed on the theatre computer screen. The surgeon completes final checks before proceeding with the operation.

If a biopsy is taken during surgery, the system can generate a pre-printed label with the patient's unique identifier encoded.

The system has saved time and enabled more patients to be treated on each list. As a result, cost savings are estimated at £270,000 per year. Patient satisfaction is high, and they are happy to be photographed and tagged as a means of ensuring they receive the right treatment. The Trust has now decided to invest in the system throughout all its theatres.

## Issues

2.6.7 Patient identification and matching patient to intervention is a much broader issue than AIDC, and goes to the heart of the issue of patient safety within the NHS. It is the subject of a major programme of work by the NPSA. *Right patient – right care*, published in 2004, summarises research on manual checking and the use of technologies for patient identification. This has been followed up with more specific work on matching the right patient to the right blood, and the use of wristbands, including development of a draft mandatory standard for the NHS Information Standards Board (see Chapter 4 for full details).

2.6.8 Patient wristbands are a vital part of verifying patient identity, but compliance is essential if they are to be used effectively. The NPSA received 236 reports of patient safety incidents relating to missing wristbands and incorrect information between November 2003 and July 2005. A Safer Practice Notice was issued in November 2005, recommending specific measures to ensure that all hospital inpatients wear a wristband. A check of the Safety Alert Broadcast System one year later shows that compliance is now at 90%.

2.6.9 Once all patients have wristbands, a code as simple as a linear bar code of the patient's NHS number can be used to verify the patient's identity at any stage of their care or treatment. Standardising the use of the NHS number to be encoded in a standard form (such as the GS1 EAN.UCC format) would still enable the patient to be identified if they were transferred to a different hospital.

2.6.10 This technology provides a valuable verification tool, but a core principle is that scanning the bar code or tag should not replace communication between clinician and patient. Patients should always be asked to state their identity (they should be asked, 'Please tell me your name', not, 'Are you Mrs Jones?'); or, if they are unable to communicate, confirmation should be sought from the nurse in charge of the ward. The bar code or tag can be used to verify this, and then scanning the medication or sample label ensures that the patient will receive the right treatment.

**Case study: 'Right patient, right blood' – Oxford Radcliffe Hospitals**

The Serious Hazards of Transfusion (SHOT) annual report, published in 2002, recommended the evaluation of computerised transfusion aids and bar code technology for confirmation that the correct blood is administered. In the period 1996 to 2005, SHOT reported 22 deaths and 94 cases of major morbidity due to incorrect blood component transfusion.

The haematology department at the Oxford Radcliffe Hospitals developed, tested and is in the process of implementing a Trust-wide electronic clinical blood transfusion management system involving bar code patient identification. Hand-held computers are used to prompt clinical staff through each step of the transfusion process, including blood sample collection, removal of blood units from blood fridges and blood administration, and to check that the right patient receives the right blood.

Each patient's first name, surname, date of birth, gender and hospital number are included in a two-dimensional bar code on their wristband. The hand-held computer is attached to a bedside portable printer to generate a label containing these details for the blood sample. The laboratory scans the bar code on the blood sample to enter the patient's details into the laboratory IT system. After laboratory testing, labels are printed and attached to the blood units for the patient; each label contains a bar code incorporating the patient's identification details and the unique identification number for the blood unit. Blood collection from blood fridges is electronically controlled; the staff collecting blood are required to bring a 'pick-up slip' with the patient's bar coded identification details generated from their wristband.

Before administering blood, a member of staff, using a hand-held computer, is prompted to make a series of checks and scans on the bar codes on the wristband and the blood. If the blood is not the correct match, the computer indicates 'Do Not Transfuse' and sounds an alert.

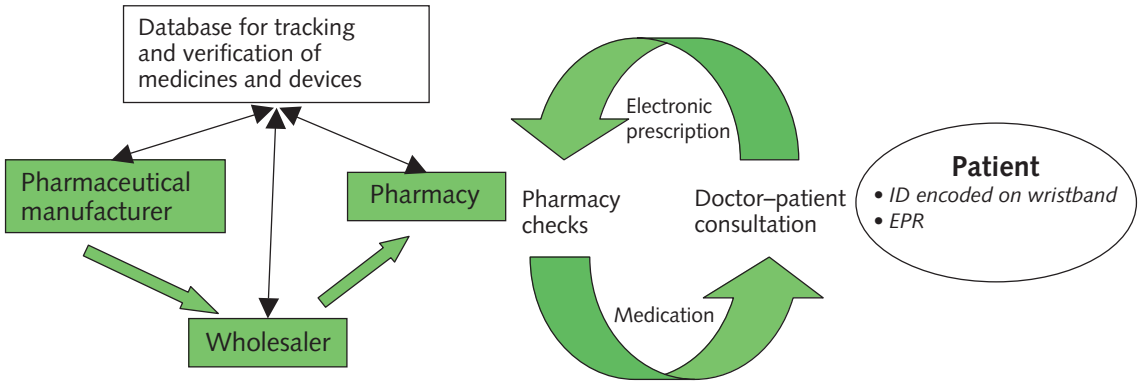
There have been multiple benefits from implementation of this technology, including a reduction in the time and number of members of staff involved in the transfusion process. Before, there were two members of staff checking two wristbands and there were 27 steps to go through. Now only one member of staff is required, checking one wristband, and there are 16 steps. This takes half the time, and staff have confidence that the process is carried out correctly every time.

New UK Blood Safety and Quality Regulations include rigorous traceability requirements for each blood unit are readily delivered by downloading data from the hand-held computers on each transfusion; the new traceability requirements are extremely difficult to achieve with paper-based systems.

As well as producing improvements in patient safety and compliance with new regulatory requirements, the costs of implementation of the electronic transfusion system throughout the Oxford Radcliffe Hospitals NHS Trust of £1.5 million over five years are anticipated to be recouped by reducing blood usage. This will be achieved by providing clinicians with a 'decision support' tool for appropriate blood use. Up-to-date blood count data are provided on the hand-held computers using a Trust-wide wireless link to the pathology IT system. This initiative has been part of 'Do Once and Share' and 'Right patient, right blood' initiatives, in collaboration with Connecting for Health and NPSA. The electronic clinical blood transfusion management system will now be piloted in other NHS hospital trusts.

## 2.7 Medicines

**Figure 3. AIDC and medication**




### The vision: how AIDC might be used to improve medicines management in the future

2.7.1 *Medicines will have a unique identifier placed on each pack by the manufacturer. The data will be held in a database accessible by all the legitimate handlers in the supply chain, to enable goods to be tracked and traced when there is a patient safety issue, such as a product recall, and their authenticity verified as they move through the chain. Lower value or less sensitive items will have a product code with the batch number and expiry date also encoded in a standard format.*

2.7.2 *Within the pharmacy, robotic systems will use the codes to store and dispense medicines. Encoding the batch number and expiry date will lead to efficient stock management and ensure that medicines are checked before being dispensed to patients, and facilitate the retrieval of medicine in the event of a recall.*

2.7.3 *At the bedside (or other point of administration), machine-readable codes in the patient's wristband and on the medicine can be used to verify that the right patient is being given the right medicine. The verification process automatically updates the EPR with medicines administered.*

### Current status

2.7.4 Over 90% of medicines used in the NHS already have a product code in the form of a linear bar code, conforming to industry standard format EAN.UCC, which is managed by the global GS1 organisation. This gives the basic product information including manufacturer, product description (e.g. paracetamol 500mg tablets) and pack size (e.g. 28 tablets) but not batch number or expiry date.

2.7.5 Within hospital pharmacies in particular, robotic systems for dispensing are becoming more and more common. Users report reduced errors in dispensing and increased job satisfaction, as pharmacists are able to devote more time to working directly with patients on wards. The system is also able to generate reordering automatically for the medicines as they are used. The Charing Cross Hospital in London has one such example and some initial results are given in the case study below.

**Case study: Automated dispensing system – Charing Cross Hospital**

The Charing Cross Hospital installed a Swisslog Pack Picker automated dispensing machine in the pharmacy in winter 2003–04. Its impact on a range of outcome measures was assessed through a before-and-after study.

- Dispensing errors were reduced from 2.7% to 0.9%.
- Time taken to pick items was significantly reduced.
- Stock control was improved, with fewer items ordered outside the regular ordering times and fewer items supplied as 'to-follow'. There was a dramatic improvement in stock discrepancies.
- There was a 23% increase in storage capacity.
- The system had no impact on time taken for labelling and assembly of prescriptions, and there was no change in turnaround time for discharge prescriptions.

Staff felt that the Pack Picker had helped the department keep pace with change and enhanced its image; it reduced dispensing errors and increased the space available for dispensing and checking.

BD Franklin and K O'Grady (2006) 'Evaluating a dispensing robot in a UK hospital'. Abstract presented at the UKCPA/GHP conference, Heathrow, 12–14 May 2006

2.7.6 To date, we are only aware of one bedside verification system for medication in the UK, also at Charing Cross Hospital, although these systems are becoming increasingly common in the US. Data from the US experience shows that the averted error rate for hospitals using safety technology has consistently averaged 2% of the doses administered. Averted errors represent the number of times a nurse or other health professional is in the process of administering medication to a patient when they receive a warning and then do not give the medication.[7]

### Issues

2.7.7 The first priority is to encourage all manufacturers to put a product code in bar-code form on all medicines. Medicines not carrying codes at present are mostly those manufactured or repackaged in hospital laboratories and manufacturing units, highly specialised medicines, and some parallel traded products.

7 JD Englebright and M Franklin (2005) 'Managing a New Medication Administration Process', *JONA* 35, 9 September

2.7.8 Industry stakeholders agree that a simple product code following the GS1 coding standard in a bar code format would be straightforward to implement for the few manufactured items that do not currently have this.

2.7.9 Many industry stakeholders are keen to see the development of more sophisticated approaches to coding, moving towards unique product codes for higher-value or more sensitive items, and using the more flexible RFID technology to carry the data. This is seen to be a key element in the ongoing fight against counterfeit medicines, and will require a database, accessible as appropriate by the different elements of the supply chain. This is being tested through a European Union initiative called BRIDGE (more details are given in paragraph 3.4.7).

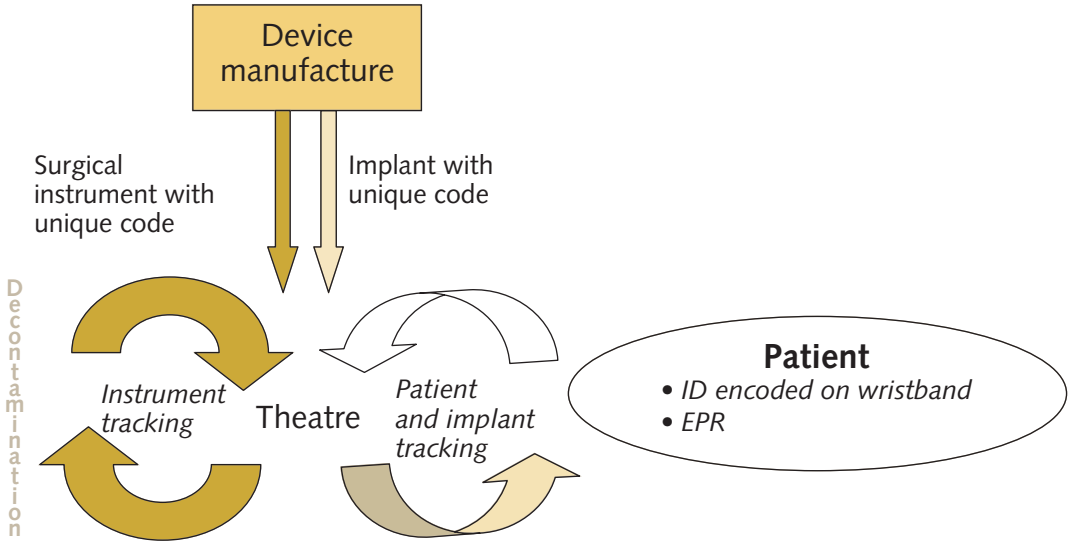
2.7.10 Other industry stakeholders are more concerned about the cost implications of more sophisticated coding, particularly for lower value items. Standardisation, potentially through regulation, is viewed by all as a way of creating a level playing field. But the pharmaceutical industry is a global enterprise and standards unique to the UK would be difficult to implement.

2.7.11 Codes need to be used by healthcare providers if they are to benefit patients. Within healthcare settings, use of the existing, relatively unsophisticated product codes is still in its infancy and there are many trusts that have yet to invest in dispensing robots to make use of them.

2.7.12 For those that have, there are still issues to address. There is no national database from which product codes can be obtained, which means that every time a new product is purchased, the details of the code and the product have to be entered manually into the pharmacy computer system. As with all manual data entry, this introduces the risk of incorrect data affecting patient safety.

## 2.8 Devices and surgical procedures

**Figure 4. AIDC and medical devices**




### The vision: how AIDC might be used in the context of medical devices in the future

2.8.1 *'Medical devices' encompasses a very wide range of products, from simple sticking plasters bought over the counter through to surgical instruments and implanted items such as joint replacements and cardiac pacemakers. In the future, the use of AIDC will be tailored to the type of device. Some (e.g. dressings) will require only a simple product identification code on the outer packaging to facilitate stock management, while others might need the code to be placed directly on the device.*

2.8.2 *Surgical instruments will have miniature RFID chips embedded into them with a unique serial number. RFID will be used to trace each individual surgical instrument through the cycle of use from the theatre through the sterilisation process (which might take place off-site in a dedicated facility) and back to the next patient. A link can be made between the instrument record and patient records to enable patients to be identified if a problem arises at a later date. This is particularly important in the context of variant Creutzfeldt-Jakob disease (vCJD) and other diseases where the sterilisation process cannot guarantee the elimination of infection.*

2.8.3 *Devices such as wheelchairs and other equipment are often owned by loan stores and loaned to patients when required. The equipment may be refurbished (e.g. by giving a wheelchair new wheels) before being loaned again to the next patient. Coding of such equipment will need to follow agreed standards so that the main part of the equipment (such as a wheelchair frame) is identified by a master code, with other parts having codes that link in to the main one. Coding in this way will facilitate more efficient track and trace of loan items, and make maintenance programmes more straightforward to administer.*

## Current status

2.8.4 With such a wide range of products, and a similarly wide range of manufacturers, there is far less consistency with product coding when compared with the medicines sector. Initial discussions with industry bodies suggest a willingness to make progress but the range and complexity of products make the task more difficult.

2.8.5 Coding is being used in some specific applications – we describe here how the National Joint Registry (NJR) has implemented bar code technology to facilitate data entry into the system.

**Case study: The National Joint Registry and bar-coding**

The NJR records all hip and knee replacements. There is a minimum data set required, consisting of the patient's operation details. There is a further subset of data that can be collected which includes: surname, forenames, date of birth, home postcode and NHS number.

Several data-entry tools have been developed to help staff enter data more easily, with the benefits of relieving hospital resource effort and promoting good quality data capture. This includes a bar code reader and bulk upload facilities.

The bar code reader facility allows hospitals to enter implant details automatically into the NJR by scanning the bar codes on component packaging. Scanning implant bar codes avoids having to input data manually and aids component identification, saving data-entry time.

Once the hospital's system has been made compatible, data is transferred to the NJR via a new user account on the NJR data-entry system. A bulk upload facility allows hospitals that are already collecting NJR data in their own IT systems to transfer it to the NJR database as blocks of multiple data records at regular intervals. Bulk upload avoids having to enter the data twice and hence helps to preserve data quality while saving time.

Each NJR-registered hospital is eligible to receive a bar code scanner. The NJR data-entry system recognises the majority of bar codes from leading component suppliers; however, some bar codes may not be recognised.

The NJR is working closely with all UK suppliers to incorporate as many component bar codes as possible.

2.8.6 There are examples of coding on products being used to manage stocks of devices, and to link to the patient record. The case study below describes how this is happening at the Leeds Teaching Hospitals NHS Trust.

**Case study: Cardiac catheter labs – Leeds Teaching Hospitals NHS Trust**

There are five theatres, called cardiac catheter laboratories, dealing with speciality heart treatments using catheter technology located within the Leeds Teaching Hospitals NHS Trust, and based at the Leeds General Infirmary site. These five catheter labs are supported and supplied by a theatre central store and the supplies team.

The new system, incorporating bar code scanning, and new service arrangements between supplies and the catheter lab clinicians were implemented in the catheter labs at end of 2000/beginning of 2001.

The catheter labs are now operating with a stock level of approximately £700,000 (where previously it was £1.6 million), consisting of 983 product lines. The average spend per day is £30,000, which amounts to approximately 4.5 weeks worth of supplies. Previously, two grade H nurses, who were responsible for the stock management within the catheter labs, raised orders twice daily on a paper-based system. Now orders are placed twice weekly on an electronic system, dramatically reducing both staff time and the costs of the purchasing process from up to £7.05 per line to 39 pence.

During the implementation stage, the supplies team carried out a full stock check. This enabled the team to assess whether the levels of stock were accurate and still required; £200,000 of stock was identified as 'no longer in use' and written off.

Within the new arrangement, the supplies team now manage the stock in the theatre's central store. The clinicians take the products as required for the planned operations into the catheter labs, using carousel trolleys for high-usage products. The free movement of catheters and stents within the lab environment enables the consultants to have immediate access to the product range at the patient's side. These products are still in stock in the inventory system until they are used during an operation, at which point they are immediately bar code scanned by the clinical staff to provide a 'real-time' picture of stock levels.

The new systems allow information to be scanned not only into the stock inventory system but also into the EPR and the finance database. This ensures that every piece of equipment can be traced to every patient and an accurate costing of all procedures can be established.

The supplies team are now planning to implement a similar system in an elective orthopaedic surgery centre (Chapel Allerton). Here the scanning process will not only update patient records, the inventory and financial systems, but will also link to the NJR where appropriate.

2.8.7 Instruments requiring decontamination are an area of particular interest. AIDC is already being used by a number of trusts to track surgical instruments through the decontamination process, but only at the level of instrument trays. Although this is an important first step, recent advice from the National Institute for Health and Clinical Excellence (NICE) recommends that instruments are kept in their allocated trays. Instruments can and do move between trays, and individual instrument marking is widely thought to be the most effective way to counter this. It is particularly important for instruments used in procedures with a high risk of vCJD and other prion infections.

2.8.8 The Royal Free Hospital in London is one organisation that has implemented this approach.

**Case study: Decontamination – Royal Free Hospital NHS Trust**

The Royal Free Hospital NHS Trust implemented track and trace of surgical instruments using auto-identification four years ago, working with Scantrak Ltd.

All instrument trays are marked with bar codes, and the staff also have their ID in bar code format. At each stage of the process, the staff member scans both their own ID code and the tray code so a complete record is kept of who dealt with each set at all times. These are linked automatically with records of the wash cycles, so if a problem arises with a machine then the affected instruments can be identified.

After the wash process, the instruments are checked and packed ready for autoclaving. For most instruments this is a manual check only. But neurosurgery instruments have all been laser etched with a unique bar code. After washing, these instruments are scanned individually, and matched against a database that records which instruments should be in each tray. The system will also identify any missing instruments.

Once packed, the instrument sets are autoclaved. After autoclaving the system generates sticky labels with the set number in bar code form. When a set is used in surgery, the label is added to the patient notes so a complete record is kept of which patients are treated with which sets.

As well as full track and trace, other benefits include much more efficient management of surgical instrument stocks. Clear records of when instruments are used means that obsolete equipment can be identified and removed, and if there is an increase in surgical capacity it is easy to assess how much extra equipment is needed.

### Issues

2.8.9 Devices manufacturers tend to use AIDC to manage distribution rather than as a product identification mechanism for the end user. This means that if codes are on devices, they may not be in a format that gives a straightforward product identification (unlike the coding used for medicines). Printing a simple product identification code on each item would be a major step forwards.

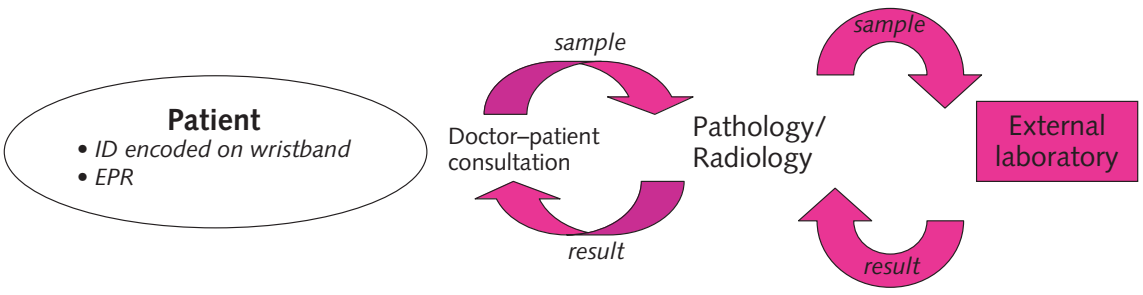
2.8.10 As with medicines, there is no nationally available database of product code information, which again means that manual data entry is required for each item the first time it is ordered.

2.8.11 For devices that require decontamination, etching or other permanent marking of individual instruments with bar codes or two-dimensional codes is possible. However, each instrument needs to be picked up and scanned individually with a hand-held scanner, adding a considerable amount of time to the current checking procedures. RFID tagging offers a more practical alternative in the long term, as the tags can be read from a distance and the whole process of checking that the right instruments are on the right trays can be automated. This is an area that is developing rapidly, with technology companies working with trusts and decontamination centres to improve RFID technology. Key issues include miniaturisation of the tags so they can be embedded safely without damaging the integrity of the instrument; ensuring the tags can withstand repeated decontamination cycles; and improving detection so instruments on a tray can be identified as the tray moves past the detector.

2.8.12 For any reusable medical devices, there will be issues about items already in use. A systematic approach will be needed to code these devices. New devices are likely to have manufacturers' codes, but may need to have additional codes or serial numbers applied to make sure that each individual device can be uniquely identified.

## 2.9 Diagnostics

**Figure 5. AIDC and diagnostics**



### The vision: how AIDC might be used in the diagnostic process in the future

2.9.1 *The doctor in primary or secondary care can order the necessary tests through an electronic link to the phlebotomy or pathology service. A laboratory number is generated and printed out in a standard bar code format and attached directly to the sample by the phlebotomist or other technician. On receipt at the laboratory, the sample is loaded into the sample analyser and the bar code used to identify the sample and the tests required. Results of those that can be carried out automatically are downloaded into the patient's record. Technicians carrying out manual tests can use the bar code to recall the patient record for entry of further results. The clinician who requested the tests can be prompted by email that results are available, and view these through an electronic link to the patient record.*

2.9.2 *Radiology services can be similarly automated, with electronic requests for scans or other imaging services generating a code that can be used to match the patient to the scan. Results will be stored electronically through Picture Archiving and Communications Systems and linked through to the EPR.*

#### Current status

2.9.3 Within the laboratory, use of AIDC technology is routine with most, if not all, sample analysers making use of bar coded laboratory numbers to automatically identify samples, carry out the correct tests and assign the results to the right patient.

2.9.4 There are some examples of extending the use of AIDC to the bedside, in areas such as phlebotomy. At the beginning of the session, the phlebotomist prints out the list of tests required, and for each patient there is a pre-printed set of coded labels. At the bedside the labels are matched to the patient, first by asking the patient to confirm their identity, then by scanning a bar code on the patient's wristband and on the first sample label to verify the match of patient to test. The sample(s) is taken, then labelled and sent for analysis. Guy's and St Thomas' NHS Foundation Trust (GSTT) is one institution that has developed this type of system.

**Case study: Phlebotomy service – Guy's and St Thomas' NHS Foundation Trust**

The phlebotomy service at GSTT has developed a system based on hand-held bar code readers with the sole objective of reducing the chance of misidentification of patients during the treatment process.

GSTT has implemented the use of EPRs. A test is ordered through the electronic system, the patient hospital number generates the bar code for the test samples and the codes are added to the record and printed either at the lab or on the ward.

The system alerts staff to a misidentification by means of an audible alarm and a warning displayed on the screen.

In the next stage, GSTT wants to develop the system so that it is built around a central process for matching patients and their care, which can be used in different clinical situations by being programmed with a number of different protocols. Initial proof-of-concept work is being undertaken in haematology.

The current cost of purchasing a system including 50 bar code scanner units is approximately £20,000; this includes the development of the application software and staff training.

### Issues

2.9.5 Many processes within diagnostics have already been automated, with AIDC being an essential tool for the smooth running of pathology and other diagnostic services. However, errors in matching the right sample to the right patient are still common. A UK survey of 27 hospitals found that 1 in 1,501 blood transfusion samples were taken from the wrong patient or labelled with the wrong patient's identification details.[8] Using AIDC to verify the patient's identity, and to eliminate the need for handwritten labels would be a major step forwards. This takes us back to the central importance of patient identification (see paragraph 2.6.7).

2.9.6 The major issue in extending the use of AIDC throughout the diagnostic process is correct identification of the patient and the associated identification of the sample. As indicated earlier, evidence shows that wristband compliance cannot be taken for granted, and many centres will need to address this before AIDC can be implemented effectively.

8 MF Murphy, BE Stearn and WH Dzik (2004) 'Current performance of patient sample collection in the UK', *Transfusion Medicine* 14: 113–21

# 3 Evidence, conclusions and recommendations

3.1 In the previous section we set out an ambitious vision for the way in which automatic identification and data capture (AIDC) technologies can be incorporated into patient care, described how the technology is being utilised at the moment and some of the issues that need to be addressed if further progress is to be made.

3.2 This chapter draws together the currently available evidence of the benefits, and reaches some conclusions. This is an area that is developing rapidly, with good examples of innovation at local level as well as voluntary action on an international scale to improve coding standards.

## 3.3 Evidence for improving patient safety

3.3.1 Use of AIDC within healthcare is still restricted to some specific applications, and the evidence base is still limited. The evidence we do have, though, is powerful.

3.3.2 In medicines management, the use of robotic dispensing systems has been shown to reduce dispensing errors significantly (from 2.7% to 0.9% at the Charing Cross Hospital in London), and this in turn will reduce the number of medication errors.

3.3.3 The Charing Cross experience of a 'closed loop' electronic prescribing and administration system, including both the dispensing robot and the ServeRx bedside verification system, has been evaluated fully and the results will be published shortly. This will provide valuable information about how these systems can benefit healthcare in the UK. The system has also been assessed as part of an evaluation of electronic prescribing in the UK, and key results from that study are shown in the Evidence box below. These are not due to auto-identification alone, but the system could not work without this technology.

3.3.4 In the management of vaccines, inclusion of a batch number and expiry date within a bar code placed on vaccine products and linked to patient records have been shown in Canadian pilots to reduce immunisation errors significantly, increase providers' confidence in the record accuracy from 76% to 92%, and to provide a time saving of an average 11 seconds per immunisation.[9]

9 Vaccine Bar Coding Initiative in Canada, 'Automated identification of Vaccines: A Pilot Project', Canadian Health Agency

3.3.5 In blood safety, the Serious Hazards of Transfusion (SHOT) annual report published in 2002 (see case study on page 12) recommended the evaluation of computerised transfusion aids and bar code technology for confirmation that the correct blood is administered. Bar coding use in blood transfusions has now been associated with reduced transfusion errors in the UK[10] and there have been similar results elsewhere.

**Evidence: Evaluation of electronic prescribing**

- The Department of Health commissioned research into the impact of hospital electronic prescribing systems on patient safety. The ServeRx system at the Charing Cross Hospital in London was included in this study.
- The ServeRx system has three elements:
  - electronic prescribing, scheduling and administration software;
  - ward-based automated dispensing; and
  - electronic drug trolleys.
- Prescriptions are entered electronically. The majority of medicines are stored in large automated cabinets. To prepare for each drug round, the nurse selects the patient name on the computer and is presented with a list of doses due. When each dose is selected, the relevant drawer in the stock cabinet opens automatically and the dose can be taken out. A patient-specific drawer opens in the drug trolley for all the patient's doses. On the ward, scanning the bar code on the patient wristband triggers the patient's drawer in the trolley to open. Administration is confirmed using a touch-sensitive screen on the trolley.
- An evaluation of electronic prescribing describes the following key findings:
  - 4,803 prescriptions were studied and prescribing errors were reduced from 3.8% to 2% (95% CI difference: –0.9% to –2.7%);
  - 2,822 drug administrations were observed and administration errors (excluding intravenous errors) fell from 7% to 4.3% (95% CI difference: –0.9% to –4.5%);
  - checking of patient identity before administering medicines rose from 17% to 81%; and
  - staff time on medication-related activities increased significantly for all professions.

N Barber, BD Franklin, T Cornford, E Klecun and I Savage (2006) 'Safer, Faster, Better? Evaluating Electronic Prescribing', Report to the Patient Safety Research Programme (Policy Research Programme, Department of Health)

Full report at: www.pcpoh.bham.ac.uk/publichealth/psrp/Publication_PS019.htm

10 MF Murphy and JDS Kay (2004) 'Barcode identification for patient safety', *Current Opinion in Haematology* 11: 334–8

3.3.6 These results are building a consensus that this technology is worth pursuing, and the available evidence suggests that it can be an effective tool to reduce errors. Its application within healthcare needs to mature, with more evaluation studies, before the safety benefits can be fully quantified.

## Evidence of other benefits

3.3.7 Evidence to quantify other benefits is similarly limited at present, but positive where it does exist. Sites that have introduced robotic dispensing systems report increased job satisfaction and reduced staff turnover, with staff able to devote more time to working directly with patients on the wards.

3.3.8 Evidence of financial benefits is also emerging, although full cost–benefit analysis is limited as many systems have been provided by manufacturers to enable them to be tested in real environments. But savings are easier to identify. Using AIDC to manage stock control, as in Leeds (see case study on page 19), bureaucracy is reduced and the supply chain becomes much more efficient, allowing staff and other resources to be redeployed elsewhere. The system also enables accurate records to be kept of the cost of each patient episode, which facilitates more accurate financial management, including charging the Primary Care Trust for procedures that are not part of the Payment by Results tariff.

3.3.9 Working directly with patients, the radio frequency identification (RFID) tagging project at Birmingham Heartlands Hospital (see case study on page 10) has led to a more efficient method of checking patients through the process, and more patients can now be treated in each session. Efficiencies are in the region of £270,000 per year.

image supplied by GS1UK

3.3.10 Similar efficiencies have been found at the Oxford Radcliffe Hospital with implementation of the blood transfusion system. These include a reduction in the time and number of members of staff involved in the transfusion process. Before, there were two members of staff checking two wristbands and there were 27 steps to go through. Now only one member of staff is required, checking one wristband and there are 16 steps. This takes half the time, and staff have confidence that the process is carried out correctly every time.

3.3.11 More generally, the development of traceability through AIDC will enhance the fight against counterfeits. Counterfeiting of medical products, particularly medicines, is a serious issue in the UK and globally. While the UK's legitimate supply chain is tightly regulated and has a good record for being difficult to penetrate, no supply chain is impenetrable. Counterfeit products can also be obtained from other countries direct to customers in the UK by mail order, via the internet or on a personal basis.

**Conclusion 1: Evidence of patient safety and other benefits is limited at present, but promising where it does exist. Safety can be hard to quantify, but we know from studies in other industries and some within healthcare that standardisation, which is what AIDC brings, contributes greatly to safety.[11] Evidence emerging from existing projects is already showing patient safety benefits, but more needs to be done. The Department of Health recommends that all new coding schemes should be fully evaluated and the lessons shared widely to facilitate further development.**

11 DW Bates (2000) 'Using information technology to reduce rates of medication errors in hospitals', *BMJ* 320: 788–91

## 3.4 Standards

3.4.1 Standards for coding have developed over time through voluntary action across industry. There are a number of different standards and associated organisations, but the most widely used is the GS1 System, owned and managed by GS1, which is a not-for-profit membership organisation.

3.4.2 The GS1 organisation has established a Healthcare User Group which is reviewing and revising the GS1 standards for healthcare products worldwide. The work is due to be completed in 2008. In the meantime, existing GS1 standards are being used by the majority of manufacturers and many health organisations that have implemented coding systems.

3.4.3 Use of the GS1 System is very well embedded in the medicines sector, where the major manufacturers are keen to move to more sophisticated coding, but less so among medical devices. The NHS Purchasing and Supplies Agency (PASA) recommended in 2004 that all supplies to the English NHS should have a product code in accordance with the GS1 System. This forms part of the contract negotiations for supply of medicines to the NHS.

3.4.4 We have considered whether any action should be taken to require manufacturers to code products using a given standard through regulations. Medicines and medical devices are subject to European legislation. The use of coding is not currently mandatory. Under existing medicines legislation, the UK may be able to introduce national requirements for unique identifiers but this would need to be compliant with wider EU law. Mandatory requirements for medical devices would need to be negotiated at European Union (EU) level. These would be complex and lengthy processes.

3.4.5 Manufacturers, while keen to see a level playing field with the same requirements applying to all of them, also operate in European and wider global markets. Different labelling requirements in different countries would be complex and costly to administer, and an EU-wide, or even global approach would be preferable. This is also an area where technology continues to develop and regulation may restrict helpful developments.

3.4.6 However, the use of auto-identification is under active discussion in a number of EU and wider international fora. It is recognised as a useful tool for patient safety, supply chain efficiency and the fight against counterfeit products. Work is under way in the World Health Organization (WHO) the Council of Europe and several EU fora.

3.4.7 The Pharma Traceability Pilot, part of an EU initiative called BRIDGE (Building Radio Frequency Identification solutions for the Global Environment), is looking at the potential of radio frequency identification in a variety of applications. The pilot aims to demonstrate the benefits of an 'electronic pedigree' for all levels of packaging, using AIDC techniques with a mix of data carriers using linear and two-dimensional bar codes and RFID tags. The pilot is expected to be completed in autumn 2007 and the results will be widely published.

**Conclusion 2: Significant progress has already been made through voluntary actions, and standards for coding by manufacturers should continue to develop on a voluntary basis. The work of the GS1 Healthcare User Group to review and update GS1 standards for healthcare products is welcomed. The Department of Health endorses fully the NHS PASA recommendation that all supplies to the English NHS should have a product code following the GS1 standard bar code format, and recommends that all manufacturers of medicinal products and medical devices adopt this approach.**[12]

## 3.5 Enabling use of AIDC within the NHS

3.5.1 Use of AIDC within the NHS is patchy at present, focused on individual projects rather than used generically throughout the system. There is a need to share learning and encourage the evaluation of projects to ensure that benefits are quantified and the most beneficial approaches adopted more widely.

3.5.2 Robotic dispensing systems in hospital pharmacies are one of the most widely used applications at present. These systems suffer from the need to input data manually when a new medicine is received for the first time. The electronic Dictionary of Medicines and Devices (dm+d), which is available to all NHS organisations and which forms the backbone of e-prescribing systems, will be upgraded to include bar code information for each product. This will enable robotic systems to call down details of new products automatically, without them having to be input manually. This system will ultimately be developed to include information about devices and their related bar code information.

12 See NHS PASA website for full details

3.5.3 Application of codes within the NHS more widely could benefit from a more systematic approach – e.g. to identify medicines or other items manufactured within hospital laboratories for use within other organisations. Connecting for Health will work with the GS1 standards organisation to enable each NHS organisation to have a globally recognised organisational identifier, and to provide the support necessary to enable coding to be implemented within the organisation. Demonstrator projects will inform wider implementation.

3.5.4 Although the GS1 coding system will be the coding of choice for most new applications, there will be occasions when alternatives will be necessary. In the case of blood management, all blood units are coded using a dedicated global standard, managed by ISBT (International Society for Blood Transfusion). In other very specialised areas, such as marking surgical instruments, there may be issues about the physical size of the code that lead to an alternative code being selected.

3.5.5 More generally, the benefits of AIDC will not be fully realised unless the correct underpinning systems and processes are in place. These include both straightforward good practice – such as ensuring every patient in a hospital is wearing a wristband – as well as technological developments such as the electronic patient record.

**Conclusion 3: Much can be done to facilitate further uptake of AIDC within the NHS. Individual applications of AIDC, such as automated dispensing in pharmacies and bedside verification systems, can make significant improvements to patient safety on their own. It is also clear that wider benefits will come through as the IT infrastructure across the NHS develops in the coming years.**

**Open, global standards need to be used for coding applications as far as possible, and the GS1 (EAN.UCC) system will offer the most appropriate coding structure for most applications in the NHS.**

# 4 Action plan: making change happen

4.1 The Department of Health, its agencies, NHS organisations and industry all have a part to play in making change happen. This is not about a one-off exercise, but about embracing the relevant technology through the continuous process of upgrading systems, equipment and working practices.

4.2 Here we outline a range of actions to support both the NHS and industry to take the agenda forward. We will be reviewing progress and consider what further action is required by the end of 2008.

4.3 Auto-identification is a tool that can improve safety and efficiency in many systems and processes. It will often provide a means of implementing mandatory standards and achieving high-quality services in particular areas. Two key examples are in decontamination and in blood safety, where auto-identification systems are in development (see Action box). Alongside these applications are the many other areas where auto-identification can improve patient safety, efficiency and data management while reducing costs.

**Action: New requirements driving uptake of auto-identification**

- **Decontamination**. Health Service Circular (HSC) 2000/32 contains a clause on the traceability of surgical instruments. This requires that instrument sets, as distinct from individual instruments, be tracked through decontamination processes and traced in terms of identification of patients with whom sets of instruments have been used. Advice from both the National Institute for Health and Clinical Excellence (NICE) and the Engineering and Science Advisory Committee into the decontamination of surgical instruments including prion removal (ESAC-Pr) in 2006 recommends that instruments be retained within their allocated sets. This new recommendation is seen as a significant stimulus to individual instrument tracking, particularly where these instruments may come into contact with central nervous system/brain or posterior ophthalmic tissues which are associated with high potential risk of human prion transmission. The use of radio frequency identification (RFID) technology has been trialled in this application.
- **The Blood Safety and Quality Regulations** require the maintenance of a complete record of all blood components and products, from donor to recipient, for 30 years. The National Patient Safety Agency (NPSA) has already developed a standard specification for IT tracking systems (Electronic Clinical Transfusion Management System) based on work carried out by the 'Do Once and Share' blood transfusion project team for NHS Connecting for Health and the National Blood Transfusion Committee. The specification builds on the experience of users of the different systems currently available and addresses the patient safety risks identified in the transfusion process. NHS Connecting for Health is currently finalising arrangements for piloting the specification in a healthcare trust in South London.

Office of Public Sector Information, The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005

4.4 We are not proposing any new statutory requirements on either the NHS or industry, as this is a fast-moving area where voluntary action will be faster to implement and more responsive to change. The action plan includes direct support for both auto-identification technology and the underpinning systems and processes, such as patient identification, that must be in place before auto-identification solutions can be implemented effectively.

4.5 Uptake in the NHS will be facilitated through a new contract with the GS1 organisation. Further guidance and good practice will be available through recognised mechanisms such as NPSA Patient Safety Alerts and Safer Practice Notices (PSA/SPN). These steps will be backed by development of standards through the NHS Information Standards Board (ISB), so that those NHS organisations that choose to adopt auto-identification technology do so in a systematic way.

4.6 Industry has already made substantial progress, particularly in pharmaceuticals, but more is needed. The GS1 Healthcare User Group (HUG) will be an important forum for further development of coding standards and the Department of Health and its agencies will be engaging in those discussions. The NHS Purchasing and Supplies Agency (PASA) will work directly with manufacturers to encourage the use of product codes in appropriate formats as part of the contracting process.

4.7 Full contact details for the organisations and programmes listed below are given in Annex 1.

## 4.8 Improving the use of coding in the NHS

4.8.1 **Connecting for Health (CfH)**, with its role to implement the National Programme for IT, has a key part to play in supporting NHS organisations implementing coding systems. Actions for CfH:

- CfH has contracted with GS1 to enable NHS organisations to become members of GS1 and to use its global coding standards. This will, for example, allow surgical instruments being sent outside a particular trust for decontamination to be uniquely identified and separated from equipment belonging to other organisations.
- A series of demonstrator projects will be developed to show how coding can be implemented and used effectively. More details will be published shortly.
- An NHS ISB standard for coding in the NHS will be developed. This will be informed by the demonstrator projects and wider consultation over the coming months. When completed, this will become a mandatory requirement for any NHS organisation seeking to use coding.
- The Dictionary of Medicines and Devices (dm+d) contains unique identifiers and associated textual descriptions for medicines and medical devices. The system is being developed to allow for an interlinking file to be published, which will be updated to include product code information for all medicines and devices. When linked to automated dispensing systems, this will enable product information to be downloaded directly, rather than relying on an operator keying in information manually. This will be completed during 2007.
- Future centrally procured systems for the NHS will include the use of automatic identification and data capture (AIDC) as appropriate (ongoing).

4.8.2 The **NPSA** is responsible for providing information and guidance to improve patient safety. NHS organisations are expected to implement PSAs/SPNs and compliance is checked as part of the Healthcare Commission inspection process. Patient identification is a major programme of work for the NPSA, and includes the following:

- 'Wristbands for hospital inpatients improves safety' – an SPN recommending that all acute hospital inpatients should wear wristbands that identify them and match them to their care (November 2005);
- 'Right patient, right blood' – an SPN recommending both high- and low-tech solutions to making blood sampling and transfusions safer (November 2006);
- 'Safer patient identifiers to be used on identity bands' – a mandatory standard for the NHS in England currently being developed to draft standard by the NPSA for the ISB (spring 2007);
- PSA/SPN to be issued in early 2007 – to standardise wristbands across the NHS including: the design specification; patient identifiers; the use of colour coding, if any; the processes for producing, applying and checking wristbands; and the production of printed wristbands from the hospital demographic system (e.g. Patient Administration Systems);
- 'Right patient – right care' – an NPSA study that summarises research on manual checking and the use of technologies for patient identification (December 2004); and
- Bedside checking – research commissioned by the NPSA and currently under way to explore the processes of care at the bedside, where most patient safety errors occur or are picked up, and make recommendations for standardisation.

4.8.3 The **Department of Health**, with its role in setting policy and co-ordinating activity between stakeholders, will:

- publish more detailed information about the case studies highlighted in this document and other examples (spring 2007);
- undertake further work on the current use of AIDC in the NHS, including evaluating the benefits (spring 2007); and
- review progress by the end of 2008, and consider with stakeholders what further action might be appropriate at that time.

## 4.9 Improving the use of coding in the medicines and healthcare products industries

4.9.1 The medicines industry has already made significant progress in ensuring that over 90% of medicines have a product code (Global Trade Item Number, GTIN) following the GS1 coding standard. Manufacturers not providing product codes in this form are strongly recommended to do so. In time it is expected that these will evolve to become codes that incorporate batch number and expiry date information.

4.9.2 The wider healthcare products and medical devices industry is less consistent in the use of product codes. This needs to change if patients, the NHS and the industry itself are to benefit from improved safety and efficiency.

4.9.3 The **NHS PASA** published recommendations in 2004 stating that all products should have a product code (GTIN) in the GS1 standard format.

- Provision of GTIN codes is already required as part of the NHS PASA contracting arrangements with medicines suppliers, and this will continue.
- Provision of GTIN codes will form part of contract negotiations with suppliers of medical devices from now on.

4.9.4 The **Medicines and Healthcare products Regulatory Agency (MHRA)** is responsible for the regulation of medicinal products and medical devices. At this time the Government believes that a regulatory approach which applies only to the UK would be inappropriate. There are no proposals at present for European Union (EU) action, but this may change in the future. The MHRA will:

- monitor developments at EU level, in particular the BRIDGE programme, which is looking at the feasibility of using RFID tags to track and trace medicines from manufacturer to patient; and
- ensure that any proposals for regulation in this area take full account of the need to focus on benefits to patient safety.

## 4.10 Developing and improving standards

4.10.1 Standards in this area are of two different types: standards for the codes themselves – the numbering systems used and how numbers are allocated; and standards for how auto-identification systems should be implemented and used.

## Coding standards

4.10.2 The coding standard referred to throughout this document is the standard owned and managed by the **GS1 organisation**. It has been recommended as the standard for all medicines and medical devices, and GS1 has now been contracted to supply coding services to NHS organisations. This will enable auto-identification solutions to be used in a consistent manner throughout the NHS, with patients, staff and equipment all readily identifiable. There will be some occasions when an alternative standard is used (e.g. blood and blood products have their own standard).

4.10.3 The GS1 organisation has established a Healthcare User Group (HUG), which is reviewing and revising the coding standards to ensure they fully meet the needs of the healthcare industry and it users. The review should be complete in 2008.

- The Department of Health recommends that the GS1 System should be adopted as the coding standard to be used throughout the medicines and devices industries and in the NHS.
- The Department of Health and its agencies will take an active part in the HUG process.
- Other stakeholders, including industry groups and trade organisations, individual companies, NHS organisations and relevant professional groups, need to become involved to get the right standards in place for the future.

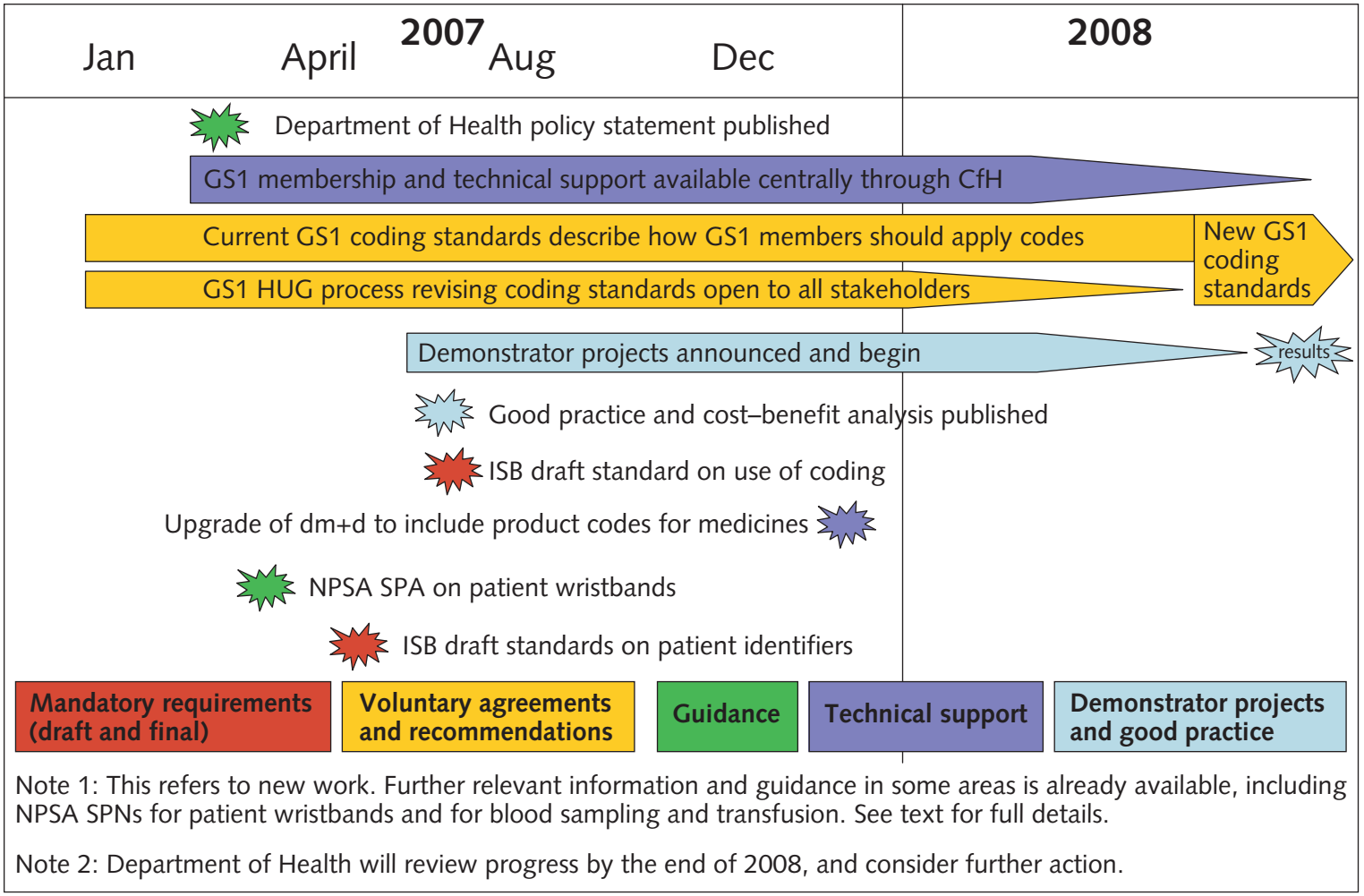
## Standards for deploying auto-identification technologies in the NHS

4.10.4 The **NHS ISB** publishes standards relating to information and IT systems that are mandatory for NHS organisations working in the area concerned. Two such standards relevant to auto-identification, currently in development, have already been highlighted in this section:

- Connecting for Health will develop an ISB standard to support implementation of the GS1 contract for organisational identifiers for the NHS. This will be informed by the demonstrator projects and wider consultation over the coming months.
- The NPSA is developing a standard on safer patient identifiers to be used on identity bands. The draft standard will be considered by the ISB in spring 2007.

4.10.5 This area will be kept under review and further standards will be developed as the need arises.

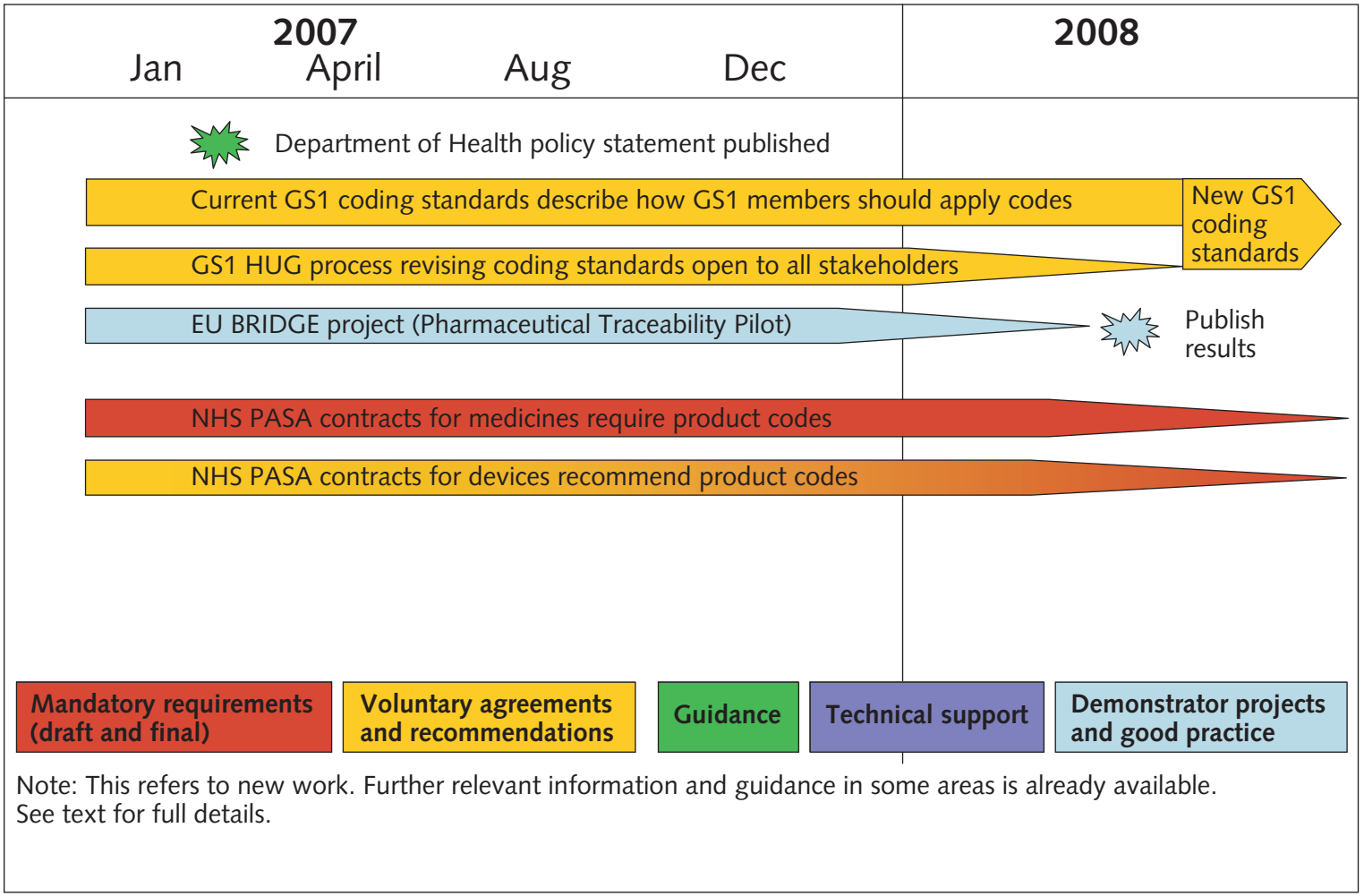
## Action plan: NHS




Note 1: This refers to new work. Further relevant information and guidance in some areas is already available, including NPSA SPNs for patient wristbands and for blood sampling and transfusion. See text for full details.

Note 2: Department of Health will review progress by the end of 2008, and consider further action.

## Action plan: Medicines and healthcare products industries




Note: This refers to new work. Further relevant information and guidance in some areas is already available. See text for full details.

| Organisation | Role or specific programme/project | Contact details |
|---|---|---|
| Connecting for Health (CfH) (see 4.8.1) | **General:** NHS CfH is delivering the National Programme for IT to bring modern computer systems into the NHS, which will improve patient care and services. Over the next 10 years, the national programme will connect over 30,000 GPs in England to almost 300 hospitals and give patients access to their personal health and care information, transforming the way the NHS works. | www.connectingforhealth.nhs.uk |
| | **NHS membership of GS1:** CfH has a contract with GS1 to enable NHS organisations to become members of GS1 and to use its global coding standards. Contact CfH via the dedicated mailbox for more information. For more general information about GS1 and its standards, see contact details listed under 'Standards Organisations and Technical Help'. | cfh.aidcenquiries@nhs.net |
| | **Dictionary of Medicines and Devices (dm+d):** The dm+d contains unique identifiers and associated textual descriptions for medicines and medical devices. It has been developed for use throughout the NHS (in hospitals, primary care and the community) as a means of uniquely identifying the specific medicines or devices used in the diagnosis or treatment of patients. This will be updated during 2007 to incorporate product code information. | www.dmd.nhs.uk |

| Organisation | Role or specific programme/project | Contact details |
|---|---|---|
| National Patient Safety Agency (NPSA) (see 4.8.2) | **General:** The NPSA is a Special Health Authority created to co-ordinate the efforts of all those involved in healthcare and, more importantly, to learn from patient safety incidents occurring in the NHS. | www.npsa.nhs.uk |
| | **'Right patient – right care':** Published in 2004, this summarises research on manual checking and the use of technologies for patient identification. | www.npsa.nhs.uk/site/media/documents/781_Right%20patient%20right%20care%20final%20report.pdf |
| | **Patient identification:** The NPSA has a number of projects under way on patient identification. | www.npsa.nhs.uk/display?contentId=4401 |
| Department of Health (see 4.8.3) | **General:** The Department of Health website includes current guidance and information for the NHS and social care. | www.dh.gov.uk/ |
| | **Decontamination:** Guidance on decontamination and copies of presentations given at recent conferences on decontamination can be found on the Department of Health's decontamination programme website. | www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/EstatesAndFacilitiesManagement/EngineeringEnvironmentAndTechnology/EngineeringEnvironmentArticle/fs/en?CONTENT_ID=4118225&chk=QGWbyF<br>http://deconprogramme.dh.gov.uk/default.aspx |
| NHS Purchasing and Supplies Agency (PASA) (see 4.9.3) | PASA works to ensure that the NHS in England makes the most effective use of its resources by getting the best possible value for money when purchasing goods and services. Its prime target is to release money that could be better spent on patient care by achieving purchasing savings and improving supply performance across the NHS.<br>PASA will be working with manufacturers of medicines and devices to improve the number of products supplied to the NHS that have GTIN product codes in accordance with the GS1 standards. | www.pasa.nhs.uk/PASAWeb |

| Organisation | Role or specific programme/project | Contact details |
|---|---|---|
| Medicines and Healthcare products Regulatory Agency (MHRA) (see 4.9.4) | **General:** The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. | www.mhra.gov.uk/ |
| | **Blood safety:** The MHRA is the regulator for blood safety and quality, under the terms of the Blood Safety and Quality Regulations. | www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2022523&RevisionSelectionMethod=Latest |
| GS1 Worldwide (see 4.10.2) | **General:** GS1 worldwide is a leading global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 System of standards is the most widely used supply chain standards system in the world. | www.gs1.org/ |
| | **GS1 Healthcare User Group:** GS1 has established the HUG with a mission to lead the healthcare industry to the effective utilisation and development of global standards with the primary focus on auto-identification to improve patient safety.<br>Its aim is to become the single source for regulatory agencies and trade organisations (manufacturer, wholesaler, hospital and pharmacy) that seek input and direction for global standards in the healthcare industry.<br>The HUG is currently reviewing the GS1 standards to ensure they are fully fit for healthcare applications. | www.gs1.org/hug |
| | **GS1UK:** This is the UK arm of GS1 worldwide. CfH has a contract with GS1UK for membership of all NHS organisations in England. | www.gs1uk.org/ |

| Organisation | Role or specific programme/project | Contact details |
|---|---|---|
| EU BRIDGE Programme (see 4.9.4) | The objective of the BRIDGE project is to research, develop and implement tools to enable the deployment of RFID applications in Europe. The Pharma Traceability Pilot is testing the use of RFID technology for track and trace of medicines from manufacturer to patient. | The BRIDGE Project website www.bridge-project.eu/<br>The GS1 press release www.gs1.org/docs/media_centre/gs1_pr_120706_Bridge_launch.pdf |
| Association for Automatic Identification and Mobile Data Capture (AIM) | AIM represents the automatic identification, data capture and mobility industries. As a not-for-profit industry organisation, AIM's mission is to stimulate the understanding, adoption and use of AIM technology by providing timely, unbiased and commercial-free news and information. | www.aimglobal.org/ |

# Annex 2: Glossary

## Courtesy of GS1

*(Based on GS1 General Specifications GS1 Standards Glossary of Terms January 2007 – Version 7.10)*

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| Data carrier | A means to represent data in a machine-readable form; used to enable automatic reading of data (element string) held within the carrier. |
| Data character | A letter, digit or other symbol represented in the data field(s) of an element string. |
| Data field | The smallest part of the data component of an element string that needs to be distinguished. |
| Data Matrix | A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix ISO version ECC 200 is the only version that supports GS1 System identification numbers, including Function 1 character. Data Matrix Symbols are read by two-dimensional imaging scanners or vision systems. |
| EAN/UPC symbology | A family of bar code symbols including EAN-8, EAN-13, UPC-A and UPC-E Bar Code Symbols. Although UPC-E Bar Code Symbols do not have a separate symbology identifier, they act like a separate symbology through the scanning application software. |
| Electronic Product Code™ | An identification scheme for universally identifying physical objects (e.g. trade items, assets, and locations) via RFID tags and other means. The standardised EPC data consists of an EPC (or EPC Identifier) that uniquely identifies an individual object, as well as an optional Filter Value when judged to be necessary to enable effective and efficient reading of the EPC tags. |
| EPC Manager Number | The number allocated to a company or a company entity. |

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| EPC Middleware | EPC Middleware is the component of the EPCglobal Network that manages real-time read events and information, provides alerts, and manages the basic read information for communication to EPC Information Services and a company's other existing information systems. EPCglobal is developing a software interface standard for services enabling data exchange between an EPC reader or network of readers and information systems. |
| EPCglobal Inc™ | A not-for-profit organisation entrusted by industry to establish and support the Electronic Product Code and the global adoption of the EPCglobal Network as the global standards for immediate, automatic and accurate identification of any item in the supply chain of any company, in any industry, in any country in the world. |
| EPCglobal Network™ | A set of technologies that enable immediate, automatic identification and sharing of information on items in the supply chain. |
| Global Document Type Identifier (GDTI) | The GS1 Identification Key, comprising a GS1 Company Prefix, Document Type and Check Digit, used to identify documents. |
| Global Location Number (GLN) | The GS1 Identification Key used to identify companies, organisations and locations. |
| Global Trade Item Number (GTIN)® | The GS1 Identification Key for any pre-defined product or service that may be priced, ordered or invoiced at any point in the supply chain. |
| GS1 Check Digit Calculation | A GS1 System algorithm for the calculation of a Check Digit to verify accuracy of data. |
| GS1 Company Prefix | Part of the GS1 System identification number consisting of a GS1 Prefix and a Company Number, both of which are allocated by GS1 Member Organisations. |
| GS1 General Specifications | Defines the GS1 System data and application standards related to the marking and automatic identification of trade items, locations, logistic units, assets, and more using bar codes, RFID, and GS1 Identification Keys. |

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| GS1 Global Data Dictionary | A repository tool used to record GS1 member standards agreements on business terms and definitions used by all business units. |
| GS1 Global Office | Based in Brussels, Belgium, and Princeton, USA, is an organisation of GS1 Member Organisations that manages the GS1 System. |
| GS1 Global Registry | A component of GS1 GDSN. It acts as a pointer (directory for the registration) to source data pools where catalogue item and party master data are housed. It also fulfils the role of matching subscriptions to registrations to facilitate the synchronisation process. |
| GS1 Identification Key | A numeric or alphanumeric character string managed by GS1 to ensure the global, unambiguous uniqueness of the identifier in the open demand or supply chain. |
| GS1 Member Organisation | A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in GSMP. |
| GS1 Prefix | A number with two or more digits, administered by the GS1 Global Office that is allocated to GS1 Member Organisations or for Restricted Circulation Numbers. |
| GS1 System | The specifications, standards and guidelines administered by GS1. |
| GS1–128 Bar Code Symbol | A subset of the Code 128 that is utilised exclusively for GS1 System data structures. |
| Human Readable Interpretation | Characters that can be read by persons, such as letters and numbers, as opposed to symbol characters within bar code symbols, which are read by machines. |
| Identification number | A numeric or alphanumeric field intended to enable the recognition of one entity versus another. |

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| Radio frequency | Any frequency within the electromagnetic spectrum associated with radio wave propagation. When a radio frequency current is supplied to an antenna, an electromagnetic field is created that then is able to propagate through space. Many wireless technologies are based on radio frequency field propagation. |
| Radio Frequency Identification | A data carrier technology that transmits information via signals in the radio frequency portion of the electromagnetic spectrum. A Radio Frequency Identification system consists of an antenna and a transceiver, which read the radio frequency and transfer the information to a processing device, and a transponder, or tag, which is an integrated circuit containing the radio frequency circuitry and information to be transmitted. |
| RFID reader | Also known as an Interrogator or a reader, a Radio Frequency Identification reader communicates via radio waves with RFID tags and delivers the information in a digital format to a computer system. |
| RFID tag | A microchip attached to an antenna that sends data to an RFID reader. The RFID tag contains a unique serial number, and can also contain additional data. RFID tags can be active, passive or semi-passive tags. |
| Scanner | An electronic device to read bar code symbols and convert them into electrical signals understandable by a computer device. |
| Serial Number | (1) A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.<br><br>(2) Specific instance of the Object Class being tagged. |
| Supplier | The party that produces, provides or furnishes an item or service. |
| Tag | See RFID tag. |
| U.P.C. Prefix | A special representation of the GS1 Prefixes '00 – 09' with the leading zero removed. |

## Abbreviations

| | |
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| AIDC | automatic identification and data capture |
| dm+d | Dictionary of Medicines and Devices |
| EPR | electronic patient record |
| EU | European Union |
| GTIN | Global Trade Item Number |
| HUG | Healthcare User Group |
| ISB | Information Standards Board (NHS) |
| MHRA | Medicines and Healthcare products Regulatory Agency (NHS) |
| NJR | National Joint Registry |
| NPSA | National Patient Safety Agency (NHS) |
| PASA | Purchasing and Supplies Agency (NHS) |
| PSA/SPN | Patient Safety Alert and Safer Practice Notice |
| RFID | radio frequency identification |
| SHOT | Serious Hazards of Transfusion |
| vCJD | variant Creutzfeldt-Jakob disease |
| 95% CI | 95% confidence interval |




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