Review of *Coding for Success* implementation

Review of *Coding for Success* implementation

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	**IM & T**
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	For Information
Gateway Reference	14782
Title	Review of Coding for Success implementation
Author	Department of Health
Publication Date	21 Oct 2010
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of Nursing, Directors of HR, Directors of Finance, Allied Health Professionals, GPs
Circulation List	Chair of Health Committee
Description	Coding for Success was published in 2007 and described how bar coding and similar technologies can be used to improve patient safety, reduce costs and improve efficiency. This review aims to outline progress made since 2007, and was recommended by the Health Select Committee in its 2009 report on Patient Safety.
Cross Ref	Coding for Success - Simple technology for safer patient care (Gateway reference: 7763)
Superseded Docs	N/A
Action Required	N/A
Timing	**Ongoing**
Contact Details	Mike Yates Patient Safety, Department of Health, Wellington House 133-155 Waterloo Road, London SE1 6LH
For Recipient's Use	

Review of *Coding for Success* implementation

Contents

Executive summary

Coding for Success simple technology for safer patient care[1] was published by the Department of Health in February 2007. It described bar-coding and similar coding technologies, and the positive impact they could have on healthcare, particularly patient safety.

The application of these technologies has great potential and spans a wide range of areas in the NHS including reducing medication errors, reducing the risk of wrong-site surgery and the effective track and trace of surgical instruments, equipment and other devices.

In addition to improving patient safety, embedding coding technologies in the procurement and supply chain processes can cut costs dramatically and improve efficiency.

Coding for success was not about a one off exercise, but advocated a continuous process to adopt and embrace relevant technology, not only for the benefit of patient safety, but also in terms of improving efficiency.

The NHS and industry, working with technology suppliers, were encouraged to take up the challenge and move the agenda forwards.

This review of implementation aims to outline progress made since 2007, and was recommended by the Health Select Committee in its 2009 report on patient safety[2].

Coding for Success focused on three areas to make change happen:

- improving the use of coding in the NHS

- improving the use of coding in the medicines and healthcare products industries

- developing and improving standards.

The most significant recommendation made in *Coding for Success* was that the GS1 Standards[3] for coding 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.

Connecting for Health have played a key role, contracting with GS1 UK and initiating a range of demonstrator projects which have highlighted areas where patient safety can be improved. Over 300 trusts are now registered to receive a prefix from GS1 to underpin their coding strategy.

Connecting for Health have led the development of information standards, and the National Patient Safety Agency (NPSA) has successfully implemented a programme of work on safe patient identification covering for example, the use of wristbands with accurate patient safety identifiers. There remains an ongoing work programme in Connecting for Health of identifying areas where standards are appropriate.

In terms of improving the use of coding in industry, coding on medicines is further advanced than on medical devices. However, in the device sector there is considerable activity at

European and Global level aimed at developing harmonisation of device identification. The US Food and Drug Administration (FDA) are about to announce a regulation that will require all device manufacturers to identify their devices and the EU are likely to follow, with the Medicines and Healthcare products Regulatory Agency (MHRA) continuing to participate in this important work. This legislation will place a considerable cost burden on industry but this can be mitigated if the NHS fully embraces the technology and there is joint realisation of the benefits. Without that commitment, it will be largely a wasted exercise.

A twin approach is required to implement coding, to drive the consistent and widespread use of Global Trade Item Numbers (GTINs) by manufacturers and to encourage the NHS to implement effective supply chain technologies. This is a challenging area and the Department of Health has this as part of its ongoing work programme, to continue to drive the application of codes across the NHS and utilise the technologies in the procurement process.

Although considerable progress has been made to introduce a coding culture to the NHS across a diverse range of practices and the key partners continue to promote good practice, overall progress has been a little slower than expected.

In some respects, this is not surprising given that coding is a necessarily complex topic that requires considerable investment, effort and co-operation across a variety of sectors and partner organisations to progress application more widely across healthcare to benefit patient safety.

Going forward, those involved in this important work area will continue to make this happen, recognising the value and increasing relevancy and currency of this agenda to improving patient safety, driving efficiencies and reducing waste in the NHS.

Introduction

Coding for Success simple technology for safer patient care[1] was published by the Department of Health in February 2007. The document describes bar-coding and similar coding technologies, and the positive impact they could have on healthcare, particularly patient safety.

The Department of Health made several recommendations in the document, the most significant being that the GS1 Standards[3] for coding 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.

Although *Coding for Success* indicated that a review of progress would be undertaken by the Department of Health, this had not happened by the time the Health Select Committee produced its 2009 report on patient safety[2]. In its report, the Committee called for an immediate review. In its response in October 2009, the Department of Health[4] said it would conduct a review of progress and report to the Committee. This document is that report. As well as being sent to members of the Health Select Committee, it will be available on the Department of Health's website.

Improving the use of coding in the NHS

Coding for Success identified a key role for Connecting for Health (CfH) in supporting NHS organisations to implement coding systems. The National Programme for IT (NPfIT), which underpins this role, is a five-year programme that will continue until 2012.

Coding for Success confirmed that Connecting for Health had contracted with GS1 UK to enable NHS organisations to become members of GS1 and have access to its services and support. The contract is for the provision of auto-identification services, including prefixes, project management and a helpdesk specifically for the NHS. Over 300 trusts are now registered to receive a prefix from GS1 to underpin their coding strategy.

Demonstrator projects

Connecting for Health initiated, with partners, a programme of demonstrator projects across the country in specific clinical areas including pharmacy, sterile services, asset and document tracking, blood products and patient identification. Coding has been applied in different clinical and operational areas. Some examples of these and other projects are provided below and additional information and more examples can be found on the GS1 UK website[5].

Examples include:

- **Mayday Healthcare NHS Trust (Electronic Blood Tracking pilot)**
  The Trust piloted bar coding and Radio Frequency Identification (RFID) technology to track blood from ordering through to sampling and transfusion to ensure the right blood went to the correct patient. Mayday implemented the GS1 coding system for passive RFID enabled patient wristbands to help ensure positive patient identification and so improve patient safety.

- **Airedale NHS Trust**
  Implementing GS1 bar codes on patient wristbands to deliver the right treatment to the right patient. Positively identifying patients and ensuring safe prescribing of medicine and safe labelling of blood samples.

- **Wythenshawe Hospital**
  Implementing GS1 bar codes to identify uniquely, track and trace surgical instrument trays. Helps reduce the risk of operations having to be rescheduled due to missing or unsatisfactory surgical instruments. Coding also allows the traceability of decontaminated instruments used on patients in the unlikely event of a recall procedure.

- **Southlands Hospital, Pharmacy Production Unit**
  Implementing GS1 bar codes and standards to identify uniquely repackaged and labelled medicines.

- **Moorfields Pharmaceuticals (an autonomous business unit of Moorfields Eye Hospital)**
  Using GS1 bar codes to identify medicines and improve the efficiency of its manufacturing operations.

- **Birmingham Children's Hospital and the NHS Numbers for Babies (NN4B) Project**
  Birmingham Children's Hospital NHS Foundation Trust and the NN4B project implements GS1 bar codes to ensure positive identification of babies during the newborn screening process.

- **Chelsea and Westminster Hospital NHS Foundation Trust, Department for Acute Medicine**
  Implementing RFID enabled patient wristbands based on GS1 coding system and piloting of cloud based integration systems for smart tags and smart devices. Currently leading the Technology Strategy Board (TSB) funded Data Capture and Auto-Identification Reference Project (DACAR)[6] that is part of the IoT (Internet of Things) Europe Knowledge Cluster[7].

- **Instrument tracking at Great Ormond Street Hospital (GOSH)**
  With accurate tracking, instruments will remain within their original sets and information regarding patients, tissues and procedures associated with specific instruments is retained. This allows higher risk instruments to be appropriately decontaminated, used only with suitable patients or in some cases discarded. GOSH provides a useful example of the success of instrument-tracking methods in practice. It has introduced an instrument tracking system based on GS1 coding, which is used to maintain a database of relevant instrument information. The HL7 standard (a medical messaging standard) is used to communicate with other theatre systems in order that instruments can be associated with procedures and indeed patients.

Benefits have tended to be broadly similar across all projects. At Mayday, key outcomes include a reduction in errors and sample rejection in blood transfusion, and increased traceability and management of blood products/components.

At Birmingham Children's Hospital they benefitted from a quicker, easier and more accurate process of identifying the babies tested at their screening laboratory. Patient safety has improved by eliminating the risks associated with illegible handwriting and transcription errors.

Some projects have also shown cost and timesavings, effort reduction and have led to services becoming more patient-centric. It has been possible in some cases to improve the supply chain and or materials management processes, and stock and asset management have improved. Overall, projects have demonstrated improvements to staff wellbeing and patient satisfaction.

The application of coding to medicines manufactured within the NHS is also progressing. A series of well-attended workshops, run in collaboration with the National Medicines Manufacturing Group[8] have been held to support trusts in identifying how to apply and manage codes. These have resulted in the majority of manufacturing units registering with GS1. The application of codes has now started to gather pace in this area, with trusts given a deadline (by the National Medicines Manufacturing Group) of the end of 2010 to ensure that key products are coded.

An ISB standard for coding

The development of an Information Standards Board for Health and Social Care (ISB) standard for coding, representing a mandatory requirement for any NHS organisation wishing to use coding, was flagged as a key requirement in *Coding for Success.*

The work of ISB continues, although the original belief that only one submission to the Board would be needed has changed. The ISB requires a submission for each clinical area targeted (eg instantiations of auto identification and data capture (AIDC), patient ID, pharmacy, etc) and in-depth documentation about each instantiation. A full account of the development of standards to date, relating to this area, is shown later in the document under *Developing and improving standards.*

Through the development of ISB standards, any new system bought by or through Connecting for Health has to be GS1 UK compliant if it incorporates any kind of coding.

Dictionary of Medicines and Devices (dm+d)

Coding for Success mentioned the development of a system that would populate the NHS Dictionary of Medicines and Devices (dm+d) with product code information for medicines and devices, leading to more efficient automated dispensing systems, and resulting in more efficient medicines management through the reduction of human engagement with the process. *Coding for Success* indicated that this work would be completed during 2007.

The dm+d Programme Board, chaired by the Department of Health with the responsibility of overseeing the joint development responsibilities shared by Connecting for Health and the NHS Business Services Authority (NHSBSA), approved this work.

The Global Trade Item Number (GTIN) for approximately 14,000 product packs has now been successfully mapped onto the dm+d. This represents 21.9% of Actual Medicinal Product Packs (AMPPs).

NHS Prescription Services have a process (In Demand) where suppliers provide an electronic update of product information for inclusion in dm+d, including providing GTINs. Most suppliers of medicinal products are signed up to using In Demand for electronic data update but it is not mandatory that they provide GTINs. Suppliers of medical devices cannot use In Demand unless they also supply medicinal products.

Coding for Success mentioned that information systems procured centrally for the NHS would facilitate, as far as possible, auto identification and data capture. Existing solution providers, local service providers and national providers have all been asked to incorporate GS1 standards into their systems as appropriate.

The role of the National Patient Safety Agency (NPSA)

The NPSA is responsible for providing information and guidance to improve patient safety. The organisation has played, and continues to play, a key role in the development and promotion of technologies that can lead to safer services. In its programme of work on safe patient

identification, the NPSA has developed a range of tools and guidance, working in collaboration with other organisations as appropriate (particularly Connecting for Health, and the ISB). These include:

- SPN (Safer Practice Notice) on ensuring that all acute hospital inpatients wear wristbands with accurate patient safety identifiers – *Wristbands for hospital inpatients improve safety*: November 2005

- SPN on safer blood sampling and transfusion – *Right patient, right blood*: November 2006

- SPN to standardise wristbands across the NHS, with deadlines for printing all wristbands and complying with a design specification; the core patient identifiers; use of colour coding; and the processes for producing, applying and checking wristbands – *Standardising wristbands improves patient safety:* July 2007

- SPN on avoiding patient misidentification – *Risk to patient safety of not using the NHS Number as the national identifier for all patients*: September 2008

- Information Standards Board standard to make mandatory in the NHS in England the patient identifiers on wristbands specified in the SPN of July 2007 – *Patient identifiers for identity bands*: March 2009

- Design for Patient Safety – bar coding is a central theme within a series of design guides that apply human factors principles to combat error prone situations.

More detail on these and other initiatives is set out below:

Right patient, right care
This was a 2004 NPSA study summarising research on manual checking and the use of technologies for patient identification. It represented the framework for action from which the programme of SPNs and ISB standards was developed.

Wristbands
The deadline for compliance with the recommendations set out in the November 2005 SPN was May 2006. Central Alerting System (CAS) compliance data indicate that at June 2010, 98% of acute trusts said they were compliant or action was not required.

A full ISB mandatory standard for patient identifiers to be used on wristbands was issued in March 2009, with a conformance date for IT suppliers of 31 December 2010. The standard specifies the four identifiers that must be included on NHS patient identity bands (for example, wristbands) and the format for presenting these so that identity information is clear and unambiguous. The standard supports the safe identification of patients, in line with guidance from the NPSA.

The SPN on *Standardising wristbands improves patient safety,* issued in July 2007 with a deadline for implementation of 18 July 2008, included recommendations on the design specification, patient identifiers, use of colour coding and the processes for producing, applying and checking wristbands. Central Alerting System (CAS) compliance data, at June 2010, show that 87% of trusts were compliant or action was not required, and 12% had action ongoing.

The NPSA has recently completed a follow-up evaluation of a sample of trusts in order to obtain more detailed information about compliance with the SPN – this is the second part of a 'before and after' SPN issue survey. The data are currently being analysed.

The report, *An exploration of bedside checking processes for inpatients in the acute care setting*[9] was published in 2008. Its findings on the use of wristbands and processes at the bedside support the recommendations made by the NPSA in the SPN on standardising wristbands.

Right patient, right blood
The National Blood Transfusion Committee Better Blood Transfusion survey undertaken in December 2008 found that around 59% of trusts had appraised the use of barcode patient identification and blood tracking (the 2006 SPN had a compliance deadline of May 2007). We are aware that there is general enthusiasm in the NHS for the use of barcode identification and blood tracking, but costs are high.

To provide the NHS with more information about the issues associated with adopting electronic blood tracking and transfusion systems, Connecting for Health funded a pilot of the Electrical Clinical Transfusion Management System (ECTMS) in the Mayday Healthcare NHS Trust in South London. The ECTMS is a 'high-tech' IT solution for safer blood tracking, developed as a national standard and issued as a product of the NPSA SPN *Right patient, right blood*. Trusts are able to follow progress of the pilot and learn from it on the Connecting for Health website[10].

We know from the experiences of the Mayday project that in addition to the financial costs, implementation requires good leadership, efficient project management and effective staff training. While this may seem daunting to trusts, the lessons that the Mayday project is sharing through the Connecting for Health website are proving to be a valuable resource for other trusts implementing similar systems. Connecting for Health has also promoted this resource in publications (for example, in *Blood Matters*, issue 25, Summer 2008).

Connecting for Health is considering a number of options for promoting further the lessons from the Mayday pilot and intends to pursue those actions that are most likely to lead to the most effective outcomes.

There is a memorandum of understanding (MOU) in place between the International Council for Commonality in Blood Banking Automation (ICCBBA) and GS1 Global, and a Global Work Group has been established to develop a global standard for Blood Derivatives to complement ISBT 128 (a standard used for the coding of human blood, cellular therapy and tissue products).

Use of the NHS Number
Since the publication of *Coding for Success,* the NPSA has worked with Connecting for Health and Informing Healthcare (the National Information Technology Programme in Wales) to produce the NHS Number SPN with recommendations that support the use of the NHS Number as the national identifier for all patients.

The SPN *Risk to patient safety of not using the NHS Number as the national identifier for all patients* was issued in September 2008 with a deadline for implementation of September 2009.

This SPN was reissued in June 2009 with slightly amended recommendations. Compliance can be summarised as follows:

- Original SPN: at June 2010, 91% of trusts said they were compliant or action was not required
- Updated SPN: at June 2010, 84% of trusts were compliant or had no action to take.

The apparent discrepancy between the figures above is probably explained by some confusion within trusts about different alerts on the same topic - possibly leading to some thinking they had already implemented earlier advice and were not required to 'sign off' a further SPN. The NPSA have recently carried out an evaluation of the implementation of some SPNs and once complete the analysis may provide further explanation.

Design for Patient Safety guides
The NPSA has produced a series of Design for Patient Safety guides. These set out a common-sense approach to labelling of dispensed medicines where attention is drawn to avoid obscuring the bar code with the patient's label, as the bar code is intended to be used in the future for identification and safety checks.

Similarly, for packaging of injectable medicines the unique potential of the bar code to carry data for use in dispensing and administration is highlighted. The use of bar code technology to reduce dispensing errors is specifically advocated as part of the dispensing process.

The role of the Department of Health

The Department of Health's role in this area is to set policy and coordinate activity between the various partner organisations.

In 2009, the Department of Health convened the Auto-ID and Patient Safety National Oversight Group (APSNOG) to discuss progress with the key partner organisations in this field. Three meetings of the group have taken place. Consideration will be given to whether the group should meet on a regular basis, or whether the group remains in 'virtual form' for sharing ideas and progress.

The Department has considered carefully whether resources should be made available to publish more detailed information about the case studies highlighted in *Coding for Success* and others that have since come to light. This issue was discussed at the APSNOG meetings.

There is now a lot of information available relating to a significant number of local projects. The group felt that bringing this information together on a database would not in itself take things further forward. Also using resources to establish and populate the database, and then ensuring that the database is kept up to date and accessible, might not represent best value for money.

The group would consider further whether a number of case studies might be focused on further to draw out some key common themes and principles that will be of interest to those introducing auto-identification technologies to the environment in which they work (eg extent to which safety is improved, cost-effectiveness, improvements to patient-centredness, etc).

Connecting for Health has taken on the task of undertaking work to determine the current use of auto-identification technologies in the NHS, particularly evaluating the benefits. Work has just started and will form part of Connecting for Health's business continuity work.

The Department of Health promised to review progress on implementing the recommendations in *Coding for Success* and how partner organisations might be engaged to determine what further action is appropriate. The oversight group mentioned above is proving a useful mechanism for engaging the key partner organisations and discussing future priorities.

A brief internal review of *Coding for Success* took place at the end of November 2008. At that time, it was felt that significant progress was being made (albeit after a slow start), including some significant developments not envisaged when *Coding for Success* was produced. Including, for example, the development of the NHS Procurement eEnablement Programme (NPEP) (which was established to drive the effective adoption of procurement eEnablement technologies across all organisations in the NHS supply network).

Other organisations, such as Connecting for Health, were also beginning to build momentum through their individual work programmes.

When the Health Select Committee produced its report on patient safety in 2009, they suggested a review of implementation should take place. We agreed and this paper represents that review.

Summary of progress and further work

We believe considerable progress has been made to introduce a coding culture to the NHS and ensuring that technologies are used to improve patient safety. Many local projects have demonstrated that benefits can be realised if the technology is used appropriately.

The Department of Health and other organisations, including Connecting for Health, GS1 UK and NPSA, continue to promote good practice and initiate projects that build on the best aspects of local schemes already underway. There will always be more to do in this respect, but we continue to accord this subject high importance.

Further consideration needs to be given to the collection of information on local schemes and how the lessons learned are shared with a wider audience, and supports new schemes. But rather than just listing local projects, we believe a subject-based analysis covering areas such as benefits to safety and cost-effectiveness is the right way forward, particularly if benefits can be measured.

Setting up the Auto-ID and Patient Safety National Oversight Group has provided an opportunity to bring together all those involved in the development of these services. We need to consider further how we make best use of this resource.

A significant amount has also been done to embed consistent coding into NHS procurement processes, particularly the integration of GTIN numbers with the dm+d. Again, there is still more work to do but good progress has been made.

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

Coding for Success recognised that the medicines industry had made significant progress in ensuring that 90% of medicines had a product code (Global Trade Item Number or GTIN) following the introduction of the GS1 coding standard (and in time, it was hoped that the codes would incorporate batch number and expiry date information).

However, the medical devices industry had only embarked on a programme for adopting coding after the Healthcare Industries Task Force (HITF) project was completed in 2005 and was therefore lagging behind the pharmaceutical industry in this respect. In addition, the challenges presented by the need to identify uniquely devices were greater than with medicines due to the diversity of both products and of packaging formats.

Application of common standards across all healthcare products

Since the publication of *Coding for Success* in 2007 there have been global developments in the use of product codes for medical devices, particularly the US Food and Drug Administration's announcement that it would introduce legislation in 2010 requiring all devices to carry a unique identifier.

The work done so far in promoting the message of *Coding for Success* means that in the UK we now have the basis for a common standard to identify uniquely medical devices that will enable products to be effectively traced through the NHS supply chain. This capability has the potential to make services safer and will also bring supply chain efficiencies.

Although we now have the basis for introducing a common standard, manufacturers currently use a range of coding systems, which means that devices cannot be identified uniquely. The NHS does not yet have mature adoption and use of the technologies that facilitate the more effective identification, use and control of devices. This lack of widespread implementation of eEnablement[11] means that even if unique identifiers were available, NHS trusts would not always be able to use them in their systems and maintain traceability.

Since 2004, the NHS Purchasing and Supply Agency (NHS PASA) promoted the standard European Article Numbering Uniform Code Council (EAN.UCC), now the GS1 standard, as the one global coding standard. Following the decommissioning of NHS PASA, DH Procurement, Investment and Commercial Division (PICD) has assumed responsibility for promoting the adoption of the GS1 standard, together with DH Commercial Medicines Unit (CMU).

Effective use of coding within the NHS supply chain is a major contributor to delivering the savings that can be realised from more effective use of product data in the NHS supply chain data as a whole.

DH PICD advocates that this standard should be adopted, controlled and maintained by all suppliers in the NHS supply chain, for all products supplied to the NHS regardless of the supply chain entry level. The only exclusion should be for products already using Health Industry Bar Codes (HIBC). HIBC is a competing standard to GS1, however its use is declining and it will eventually be replaced by GS1 standards and codes.

A twin approach is required to drive the consistent and widespread use of GTINs by manufacturers and to encourage the NHS to implement effective eEnablement supply chain technologies. DH PICD is leading the eEnablement programme and will be progressing this as part of its programme of work from 2010 onwards.

Although the adoption of GTINs continues to be a challenge, a number of approaches aimed at driving-up the use of GS1 GTINs by manufacturers, and encouraging the NHS to implement effective eEnablement supply chain technologies, have been taken. As well as developments in the wider market, hospital manufactured and pre-packed medicines that do not go through the commercial environment are also gradually adopting a bar code for use with their products.

GTIN adoption and contracting requirements introduced since *Coding for Success*

NHS Supply Chain (provides healthcare products and logistics services to the NHS) has been encouraged to ensure that standard contract terms include the requirement for the adoption of GS1 GTINs by suppliers. NHS Supply Chain are currently working closely with elements of their supply base to ensure that GS1 product information is an integral part of their service and incorporated into the product catalogue produced for the NHS.

The requirement for suppliers on national pharmacy contracts to have GTINs on their products is already included in the existing NHS standard terms and conditions. However, NHS PASA contracting systems (Pharmacy Contracting Tender and Evaluation Resource – PHACTER) at present do not have the capability, nor is a manual resource available to check all products tendered have a valid GTIN. However, once dm+d is effectively populated this could be utilised. The DH Commercial Medicines Unit, who are committed to developing this functionality, hope it will be in place in 2011, subject to resource availability.

A draft clause for inclusion in the NHS Supply Chain contracts to ensure that suppliers utilise national data standards, was prepared. However, its application has not yet been effected. The majority of equipment is purchased by trusts and through regional NHS purchasing and supply networks. The requirements to use GTINs have not yet been included in all the terms used by these organisations. The intention is that this would be done through the NHS Procurement eEnablement Programme (NPEP) in partnership with DH PICD.

The requirement for the provision of GTIN codes will be taken forward by DH PICD in collaboration with the NHS acting with procurement agents of the NHS, including NHS Supply Chain and regional Commercial Support Units (CSUs) where appropriate.

The EU and global perspectives on the use of coding and technologies

The MHRA has been negotiating on EU legislative proposals for anti-counterfeit measures, produced as part of the Pharmaceutical Package in December 2008.

This draft Directive sets out requirements for safety features to be applied to certain categories of medicines (at present, those subject to medical prescription, although we believe this scope is likely to change).

These mandated safety features will include safety seals, overt and covert markings, as well as the ability to individually and uniquely identify individual packs of medicine.

The scheme will apply EU-wide, meaning that all manufacturers will have to comply if they want to market their products in the EU. It is anticipated that these proposals will be agreed in late 2010 or early 2011 with a transition period for implementation of the safety feature requirements (possibly up to ten years after publication of the initial EU Counterfeits Legislation).

As indicated above there are also developments in the medical device sector. The move by the US Food and Drug Administration (FDA) to create a regulation requiring all devices to carry a unique identifier has considerable implications for international trade in an industry which is not only global but is dominated by US multinationals. This development has led to the Global Harmonization Task Force[12] (GHTF) setting up a top-level working group to seek global harmonisation of device identification.

How a unique device identification (UDI) system should work globally is the remit of this group. In November 2009 the working group published a discussion paper for consultation[13] on a globally accepted UDI system for the medical devices sector. While the conclusions of the GHTF will not be mandatory it is nevertheless important in that it could well inform any future legislative proposals from the EU Commission to introduce UDIs within the European regulatory system for devices.

On the back of the GHTF work, the EU Commission has recently established a working group of selected Member States to consider both its response to the GHTF agenda but also to advise on possible changes to the EU regulatory system for devices in this area. One possibility is that a requirement for UDI may be incorporated in the Recast of the Medical Devices Directive. The UK, through the MHRA is participating in this work and looking to influence the developing EU Commission thinking where it can.

The BRIDGE project
Coding for Success made mention of the BRIDGE (Building Radio-frequency IDentification for the Global Environment) project, where one of the work packages (the Pharma Traceability Pilot) considered the feasibility of using RFID tags to track and trace medicines from manufacturer to patient.

The operational pilot involved the trialling of a standards based tracking and tracing system with a live, end-to-end supply chain that started with drug packaging and progressed through distribution until received in the hospital pharmacy.

The pilot successfully tracked 15 different drugs from their manufacturing origin in the Netherlands and Ireland to the pharmacy department of Barts' and the London NHS Trust. It used GS1 standards, including barcodes and a range of technologies.

The pilot successfully demonstrated how a complete supply chain traceability system (full track and trace) for pharmaceutical products could be implemented to improve patient safety and supply chain efficiency. Other benefits included the development of authentication recall, financial reconciliation and inventory management.

The deliverables from the Pharma Traceability Pilot (including the evaluation report, problem and requirements analyses) are available on the BRIDGE website[14].

EU regulation and the link to patient safety
Although the developments that have been taking place at an EU level are welcomed, we must be careful to ensure that successes achieved in the UK are not duplicated or compromised. We must also ensure that patient safety is promoted as the prime underlying reason for pursuing the use of coding and technologies in this area.

Summary of progress and further work

Although good progress on coding has been made in the area of medications and their management, there is still a considerable amount of work needed in the devices and medical products market. DH PICD is leading the eEnablement programme and will be progressing this as part of its programme of work from 2010 onwards.

MHRA will continue to monitor developments in Europe, particularly the work of the Medical Device Unit in the European Commission Directorate General for Health and Consumers (DG SANCO) and also the Global Harmonization Task Force (GHTF) and its possible impact upon European device regulation.

Developing and improving standards

As *Coding for Success* stated, there are two different types of standards associated with this area:

- standards for the codes themselves
- standards for how auto-identification systems should be implemented and used.

Connecting for Health lead this work and are responsible for the development, rollout and adoption of standards, and management of the contract with GS1.

Coding standards

GS1 standards are the coding standards that *Coding for Success* promotes. The ongoing programme of work that has arisen in recent years, led by Connecting for Health, is designed to achieve the embedding of GS1 codes into NHS purchasing and supply operations, and has been successful in doing so – the standards have been adopted by over 300 trusts. Trusts are accepting more and more that identifying and dealing with risks to patient safety is at the heart of healthcare provision; further, that good asset tracking and stock management can help.

The production of application guidelines for the NHS by Connecting for Health and the sharing of good practice case studies has shown that whilst there is a lot of work needed to get auto-identification projects up and running, the benefits can be great.

The only other standard that is prevalent in the healthcare industry is ISBT 128, which is used for the coding of human blood, cellular therapy and tissue products (and is managed by the International Council for Commonality in Blood Banking Automation, ICCBBA, a non-profit organisation connecting health care facilities throughout the world). GS1 and the ICCBBA joined forces via a memorandum of understanding in September 2007 to advance global standards to improve patient safety. A joint working group has been formed and work has commenced between ICCBBA and GS1 looking into AIDC standards in the areas of blood derivatives, vaccines and plasma.

Partner engagement and discussion, and service support
The GS1 Healthcare User Group UK (HUG UK) has been established to be a single source of knowledge, best practice and implementation support for data standards to all UK healthcare providers, trade organisations (manufacturers, wholesalers, distributors) and regulatory agencies. It also provides input and direction to the development of global standards in the healthcare industry supply chain.

The current membership list includes the Department of Health, Connecting for Health, NPSA, NHS Supply Chain, Leeds Teaching Hospitals, The Association of British Healthcare Industries (ABHI), The Association of British Pharmaceutical Industries (ABPI), Smiths Medical, Bunzl, Molnycke Healthcare, the Oxford Radcliffe hospital and GS1 UK.

Connecting for Health has produced application guidelines and use cases to assist the development of auto-identification projects. It also runs workshops, conferences and

'knowledge days' to help trusts gain an understanding of what is involved in setting up projects. Connecting for Health has worked with and within programmes of work run by other agencies, including the NPSA.

Connecting for Health also works with the collaborative procurement hubs (collaborative procurement organisations within the NHS) which aim to make the most effective procurement and supply chain decisions to provide best value within their area. The regional hubs have published buying frameworks to enable trusts to get hold of AIDC solutions more easily.

Standards for deploying auto-identification technologies in the NHS

Coding for Success mentions that the NHS Information Standards Board (ISB) publishes standards relating to information and IT systems that are mandatory for NHS organisations. Information standards describe a common way of managing information (eg specifying that medical records should be identified by a single, unique number is covered by the NHS number information standard).

Best use of this mechanism should be used to embed the right standards for using auto-identification technologies in to common practice.

Submissions, led by Connecting for Health, relating to a number of areas associated with auto-identification have been accepted by the ISB. These are as follows:

- code numbering standard for the purposes of Automatic Identification and Data Capture (AIDC) – requirement for a fundamental standard

- data carriers standard (for the purposes of AIDC) – requirement for a fundamental information standard

- bar codes standard (for the purposes of AIDC) – requirement for a fundamental information standard

- RFID (for the purposes of AIDC) – requirement for a fundamental information standard

- AIDC – Bar codes for NHS manufactured and repackaged medicines – requirement for an operational information standard.

- AIDC – Bar codes for patient identification on the wristband – requirement for an operational information standard.

Details of appraised information standards are available on the ISB website[15].

In addition, the following have been submitted to the Appraisers for review:

- AIDC – Bar coding the NHS Number – requirement for an operational information standard

- AIDC – Unique Identification Prefix standard for the purposes of Automatic Identification and Data Capture (AIDC) – Draft submission for a fundamental standard (note, this was

previously referred to as 'Code Numbering standard for the purposes of Automatic Identification and Data Capture (AIDC)').

Other submissions Connecting for Health have planned include (dates shown are best estimates only):

- AIDC for Bar Coding the Patient Wristband Draft Operational Instantiation (submission to ISB October 2010)

- AIDC – Bar Codes for NHS Manufactured and Repackaged medicines - Draft for an Operational Information Standard (submission to ISB December 2010)

- AIDC for RFID (tagging) the Patient Wristband Requirement Operational Instantiation (May Day Project) (submission to ISB December 2011)

- AIDC for Surgical Instruments - Requirement for an Operational Instantiation (submission to ISB February 2011)

- AIDC for Physical Location Identification - Requirement for an Operational Instantiation (submission to ISB April 2011)

- AIDC for Medical Records Identification – Requirement for an Operational Instantiation (submission to ISB June 2011).

Summary of progress and further work

There has been considerable progress made by Connecting for Health and others in developing and promoting standards in this complex area, and there is an ongoing work programme of identifying areas where standards are appropriate and making the appropriate cases to the Information Standards Board.

Engagement with partner organisations, such as that undertaken by Connecting for Health in the NHS, to raise awareness and encourage uptake has been successful and will continue.

Regular meetings of the GS1 Healthcare User Group UK (HUG UK) continue to ensure that partner organisations are brought together to discuss and plan progress. This has been a valuable mechanism for driving forward this policy and improving patient safety.

Conclusion

Coding, and the standards underpinning their application, is a necessarily complex topic that requires considerable investment, effort and co-operation across a variety of sectors and partner organisations to progress application more widely across healthcare to benefit patient safety.

Despite this complexity, progress has been made across a diverse range of practices and many NHS organisations are making good use of technologies that can improve patient safety, as well as drive cost-effective healthcare delivery generally.

Uptake in the NHS has been facilitated through the contract Connecting for Health established with GS1 and although a relatively high number of trusts (300) have taken advantage of this, others need to be encouraged to follow.

Mechanisms, such as the safer practice notices developed by NPSA have been made available, underpinned by the work led by Connecting for Health to develop and introduce information standards that are crucial to the usage, management and application of information in this area.

But overall, progress has been a little slower than expected. We must continue to use what mechanisms we have to share good practice in this area and promote the benefits that auto-identification technologies can bring.

There is also some work to be done to evaluate and measure better the impact and benefits of these technologies and share this information with local NHS commissioners and providers, and national policy teams considering quality, innovation and productivity.

We need to ensure that unique coding standards drive the application of codes across the NHS, and the Department of Health has this as part of its ongoing work programme to continue to push the requirement for GTINS and encourage NHS to utilise technologies in the procurement process.

Department of Health
Auto-ID and Patient Safety National Oversight Group (APSNOG)

October 2010

Annex 1: Abbreviations

AIDC   automatic identification and data capture

APSNOG   Auto-ID and Patient Safety National Oversight Group

CfH   Connecting for Health

CMU   Commercial Medicines Unit (part of PICD)

DH   Department of Health

dm+d   Dictionary of Medicines and Devices

FDA   US Food and Drug Administration

GHTF   Global Health Task Force

GTIN   Global Trade Item Number

HIBC   Health Industry Bar Codes

ISB   Information Standards Board

MHRA   Medicines and Healthcare products Regulatory Agency

NHSBSA   NHS Business Services Authority

NPSA   National Patient Safety Agency

PASA   NHS Purchasing and Supply Agency (now known as Commercial Medicines Unit CMU, part of PICD)

PICD   DH Procurement, Investment and Commercial Division

RFID   Radio frequency identification

SPN   Safer Practice Notice

Annex 2: Further information

Association of British Healthcare Industries (ABHI)
http://www.abhi.org.uk

Association of the British Pharmaceutical Industry (ABPI)
www.abpi.org.uk

Connecting for Health
http://www.connectingforhealth.nhs.uk

Department of Health
http://www.dh.gov.uk

Department of Health. Coding for Success: simple technology for safer patient care.
Department of Health. 2007
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082

Dictionary of medicines and devices (dm+d)
http://www.dmd.nhs.uk

The Government's response to the Health Select Committee Report 'Patient Safety'. Cm 7709.
The Stationery Office, 2009
http://www.official-documents.gov.uk/document/cm77/7709/7709.pdf

House of Commons Health Committee. Patient Safety. Sixth Report. Session 2008-09. HC-151. The Stationery Office, 2009
http://www.publications.parliament.uk/pa/cm200809/cmselect/cmhealth/151/151i.pdf

NHS Commercial Medicines Unit
www.cmu.nhs.uk/ebusiness

GS1 UK
http://www.gs1uk.org

European Commission's website on anti-counterfeiting measures
http://ec.europa.eu/health/human-use/quality/fake-medicines/developments/index_en.htm

Medicines and Healthcare products Regulatory Agency (MHRA)
http://www.mhra.gov.uk/index.htm

MHRA's consultation on European Commission proposals for anti-counterfeiting measures:
http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON033660

National Patient Safety Agency (NPSA)
http://www.npsa.nhs.uk

National Patient Safety Agency. Design for patient safety: A guide to the design of dispensed medicines. 2007:33
http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59829

National Patient Safety Agency. Design for patient safety: A guide to labelling and packaging of injectable medicines. 2008:36-7
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59831

National Patient Safety Agency. Design for patient safety: A guide to the design of the dispensing environment, 2007:48-9
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59830

(website links last checked 29 September 2010)

Annex 3: APSNOG member organisations

Association of British Healthcare Industries (ABHI)

Association of the British Pharmaceutical Industry (ABPI)

Connecting for Health

Department of Health – Estates & Facilities

Department of Health – Medicines & Pharmacy & Industry

Department of Health – Patient Safety Branch

Department of Health – Procurement, Investment and Commercial

GS1 UK

Imperial College (acute medicine)

Imperial College Healthcare NHS Trust (Centre for Medication Safety and Service Quality)

Medicines and Healthcare products Regulatory Agency (MHRA)

National Patient Safety Agency (NPSA)

NHS Commercial Medicines Unit

References

1. Department of Health. Coding for Success: simple technology for safer patient care. Department of Health. 2007.

2. House of Commons Health Committee. Patient Safety. Sixth Report. Session 2008-09. HC-151. The Stationery Office, 2009.

3. The GS1 Standards are owned by the GS1 organisation, a global, not-for-profit membership organisation that develops and supports information standards for the improvement of efficiency and effectiveness of members' supply chains. The UK Member Organisation of GS1 is GS1 UK. The company prefixes (prefix of the identifiers) procured by NHS Connecting for Health under the agreement with GS1 UK form the root of all the identification numbers to be used by the NHS (www.gs1uk.org).

4. The Government's response to the Health Select Committee Report 'Patient Safety'. Cm 7709. The Stationery Office, 2009.

5. http://www.gs1uk.org/news/Pages/CaseStudiesAll.aspx

6. www.dacar.org.uk

7. www.rfid-in-action.eu/cerp

8. The group is made up of leading pharmacist and medicines manufacturing unit managers from around the country.

9. An exploration of bedside checking processes for inpatients in the acute care setting http://www.haps.bham.ac.uk/publichealth/psrp/documents/NPSA001_Smith_2008_Bedside_Checking.pdf

10. http://connectingforhealth.nhs.uk/systemsandservices/bloodpilot

11. eEnablement can be defined as the application of electronic communication technologies to business transactions and communications within and between organisations.

12. http://www.ghtf.org/

13. http://www.ghtf.org/ahwg/ahwg-proposed.html

14. http://www.bridge-project.eu/index.php/public-deliverables/en/

15. http://www.isb.nhs.uk/isbsearch/isb-standards/health-and