Developing Policy On Machine Readable Codes On Medicines In England

RFID

Professor David Cousins
Head of Safe Medication Practice
David.cousins@npsa.nhs.uk
National Patient Safety Agency

• Is a special Health Authority in the NHS for England and Wales.
• Established in 2002 with the following objectives:
  – collect and analyse information on adverse events in the NHS.
  – assimilate other safety related information from within the UK and worldwide.
  – learn lessons and ensure that they are fed back into practice.
  – where risks are identified - produce solutions to prevent harm, specify national goals, establish mechanisms to track progress.
• www.npsa.nhs.uk
Patient Safety

Patient safety is the freedom from accidental injury in health care.

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare.

*This is also referred to as an adverse event/incident, mistake or clinical error, and includes near misses.*
Patient Safety Incidents in the NHS

- Patient safety incidents are likely to be associated with around 11% of admissions, or at a rate of 850,000 per year.
- Patient safety incidents may cost around £1 billion/year in hospital stay alone - average 8.5 extra bed days attributable to incidents.
- 400 people/year die or are seriously injured in adverse events involving medical devices.
- >£400 million clinical negligence settlements/year.
- Hospital acquired infections cost £1 billion/year.
- Incidents involving medicines may account for 25% of incidents.

An Organisation with a Memory (2000)
HUMAN BEINGS make MISTAKES because the SYSTEMS, TASKS and PROCESSES they work in are poorly designed.

PROF. LUCIAN LEAPE, Harvard School of Public Health
The NHS Position on Patient Safety

• An Organisation with a Memory (2000)
  – www.dh.gov.uk
• Building a safer NHS for patients (2001)
• A spoonful of sugar. Medicines Management in NHS hospitals (2001)
  – www.audit-commission.gov.uk
• Best practice guidelines on labelling and packaging medicines. GN25
  – www.mhra.gov.uk
• Design for patient safety (2003)
  – www.edc.eng.cam.ac.uk/medical
• Improving medication safety (2004)
• NPSA/IHI/BMJ Publishing
  – www.saferhealthcare.org.uk
Seven steps to patient safety

- Step 1: Build a safety culture
- Step 2: Lead and support your staff
- Step 3: Integrate your risk management activity
- Step 4: Promote reporting
- Step 5: Involve and communicate with patients and the public
- Step 6: Learn and share safety lessons
- Step 7: Implement solutions to prevent harm

*The Seven Steps to Patient Safety. NPSA (2003).*
Patient died after drugs went to man with the same name

Wrong patient
Mis-selection errors
wrong product
Mis-selection errors
Wrong product and dose
Mis-selection wrong dose
The report indicates that the NPSA is promoting the development and implementation of modern systems and equipment in the NHS to:

- Accurately and reliably identify patients;
- Accurately and reliably match all elements of care, including samples, specimens, medicines and surgical treatment to patients.
- The responsibility for specifying what is needed lies with the NHS. The first aim is to ensure safety of patients but might potentially offer other improvements in efficiency and effectiveness.
Counterfeit Medicines
Objectives of machine readable codes

1. Improving patient safety by providing an additional safeguard to ensure patients are matched with the intended medicine products.

2. Improving patient safety by providing a method to validate the authenticity of medicine products, to minimise the risk of counterfeit medicines being supplied for use.

3. Improving patient safety by enhancing the system for product recalls.

4. Improving the efficiency and safety of the medicines dispensing process by enabling the use of automated systems.

5. Improving supply chain efficiency and accuracy and tracking.
History Of NPSA Involvement

• Role of NPSA to improve design of system and products used in the NHS for patient safety.
• 2002-2003 determine what policy/direction
• 2004 FDA decision to require linear bar codes
• 2004 draft consultation / RIA requirement
• 2005 draft RIA – DH/CfH/MHRA policy leads
• 2006 DH RIA and Consultation/DH Policy
NHS Connecting for Health
www.connectingforhealth.nhs.uk

• Over the next ten years, the National Programme for IT 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.

• National Application Service Providers are responsible for purchasing and integrating IT systems common to all users nationally. Local Service Providers will deliver IT systems and services on a local level for five regional clusters of strategic health authorities. They will supply and integrate systems to perform functions in the local setting and to interface with the national system.
Connecting for Health Issues
What is the unit of issue?

- **Unit Dose**
- **Dispensing from bulk**
- **Patient Pack**
Many UK medicines already have linear bar codes.
Medicines Legislation

- Labelling on medicines products must contain all elements required by EU Directive. The directive does not require the use of machine readable codes on medicines products.
- However, the inclusion of machine readable codes is not prohibited.
- A high percentage (80+) of licensed medicine products used in the UK already have a machine readable codes on the label.
- Current licensing review processes do not include confirming the accuracy of the information contained in the bar code.
- Reports of reuse of EAN codes by manufacturers
Use of current bar codes by the Supply Chain/NHS

- ‘A’ frame automation in pharmacy wholesalers do not use bar codes as confirmation of selection process.
- Little use has been made of these code at the point of dispensing or administration to improve patient safety.
- Recent introduction of automated dispensing systems in some hospital pharmacies.
- Unlicensed medicine products manufactured by commercial suppliers or the NHS hospital pharmacy service do not include machine readable codes.
Parallel Import Licences
GTIN information in NHS Databases

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Hospital Pharmacy System Model A

1. Prescription
2. Prescription transcription sent to pharmacy
3. Clinical pharmacy check
4. Computerised medication profile
5. Dispense unit dose medicine from central or satellite pharmacy
6. Administer medicine to patient
7. Dispense unit dose medicine from automated cabinet in clinical area
Unit Dose Medicine Products
Automated Cabinets
Hospital Pharmacy Model B

1. Prescription

2. Ward Stock
   - Yes: Select and prepare medicine from ward stock
   - No: Send ward stock requisition to pharmacy

3. Central pharmacy dispenses manufacturers pack

4. Select and prepare new ward stock medicine

5. Administer medicine to patient
Ward Stock Cupboards
System continuity and risk management

{ Risk Management A }    { Risk B }    { Risk Management C }

Community Care  Hospital  Community Care

------------------------Risk Management D------------------------
Hospital Pharmacy Model C

Hospital Pharmacist Group RPharmSGB. One stop Dispensing. Hospital Pharmacist 2002; 9:81-86 (www.pjonline.com)
Patient Bedside Cabinets
Medicines Automation Dependent on Unit of Issue
Jumping paradigms with new technology
Jumping paradigms with new technology
Identification of evidence base
Oren, Shaffer, Guglielmo.
Impact of emerging technologies on medication errors.
AJHP. 2003; 60: 1447-1458

- Forty six studies were found on bar codes on medicines to reduce supply errors in hospitals.
- Unfortunately only seven of these publications included measured end points.
- Of these end points there were reductions in dispensing errors and supply errors.
- It should be remembered that hospitals in the USA repackage many of the manufacturers packs into unit dose packaging and it was these repackaged items that had been bar coded.
- Only eight studies had been published on the use of bar code medicines at the point of administration in hospitals.
- None of these studies had measured end points
Tuner CL, Casbard AC, Murphy MF. Barcode technology: its role in increasing the safety of blood transfusion. Transfusion 2003; 43:1200-9

- In their annual report for 2000-01, the Serious Hazards of Transfusion (SHOT)19 reported 213 incidents of the wrong blood being issued for transfusion in the NHS, compared with an annual total of 3,426,782 transfusions.
- During the last five years there have been 11 deaths either definitely or possibly related to incidents of incorrect transfusion.
- In a UK study to evaluate a barcode system for blood administration a baseline audit revealed poor practice to confirm the identity of the patient (11.8% of patients identity was confirmed).
- Following the introduction of barcode patient identification confirmation of patient identity was confirmed in 100% of patients prior to blood administration.
Aegate Study 2004

• Qualitative study to demonstrate the principle of scanning the product at the point of dispensing, and to examine how it fits with existing workflow processes,
• Some 50 scanners installed in dispensing outlets: 37 in community pharmacies, 9 in hospital pharmacies, and 4 in dispensing doctors surgeries.
• Five pharmaceutical suppliers agreed to introduce RFID tags on eight products.
• As part of the study an electronic scanner was developed that incorporated a RFID reader (13.56MHz), a linear bar code (including EAN-UCC, RSS) and a 2D datamatrix reader. The scanner was connected to by high speed internet (broadband or ISDN2e) to the Aegate server that incorporated a medicine product database based on the Chemist and Druggist database.
• During the study more than 175,000 medicine products were scanned.
Hammersmith Hospital Study 2004
Serve Rx

• Before the implementation of the bar code system, patients identity was only formally confirmed in 17% of patients before medicine doses were administered and following the implementation this increased to 81%.

• Some 8.6% of doses for administration had medication errors before the use of the bar code system and this decreased to 4.4% after the implementation of the bar code system
Options
PROCESS FOR USE OF MEDICINES WITH MACHINE READABLE CODES

Packaging design development

Capital Equipment

Line Conversion

Running costs Consumables

Code Verification

Database Management

Allocate EAN.UCC Codes

Regulatory approval of packaging

Enter product codes Into NHS databases

Publish serialisation codes on internet

Supply chain

Receipt & Storage in dispensary clinic (internet access)

Electronic prescription with Medicine code

Dispensing Process (internet Access)

Administer Medicine

Parallel Imports
Option 1
Do Nothing

- Low cost.
- Danger of un-coordinated development.
- Separate systems for blood, medicines – devices
- No safeguard to prevent wrong codes on products
Option 2
Linear Bar Code

• Over 80% have EAN13 already.

• As long as NHS have systems to use these codes – will prevent some but not all mis-selection errors.

• Too big to be applied to all unit of use medicine products.

• Does not prevent expired products being used.

• Does not prevent recalled batches being used.

• Does not prevent counterfeit medicines being used
Option 3
2 D Bar Code – Variable Data

• Small size will enable all unit of use packs to have a bar code
• Will prevent ‘all’ mis-selection errors.
• Will prevent expired products being used.
• Will prevent recalled batches being used.
• If serialised number included can prevent counterfeit medicines being used
Option 4
RFID – Variable Data

- Benefits in the supply chain.
- No line of site requirement – this may not be a benefit in the clinical area
- Same benefits as Option 4
Regulatory Impact Analysis

• In August 1998, the Prime Minister announced that no proposal for regulation which has an impact on business, charities, or the voluntary sector should be considered by ministers without a RIA being carried out.

• A RIA must be signed by the responsible Minister before progressing to any possible legislation stating “I have read the RIA and I am satisfied that the benefits justify the costs”.

Regulatory Impact Analysis

- A RIA analyses the likely impact of a range of options for implementing a policy change.
- The principle of RIA is evidenced based policy making. An RIA must set out the risk or problem to be addressed and the options available including ‘do nothing’ and ‘non regulatory options’.
- It must also set out the likely costs and benefits from each option.
- A good RIA will action the question. “Is this the best way of achieving the objective?”
Work Plan On Safe Medication Practice

1. Raising awareness and developing a patient safety culture.
2. Development of a standardized terminology and taxonomy.
3. Develop guidelines for improving the safety of drug labelling and packaging and establish a liaison with the EU/EMEA/National Regulatory Organisations.
5. Enhancing safety for drugs and devices by quality information practices. Develop guidelines on the basis of available best practices review.