A high level meeting on reducing medication error in hospitals:

Making bedside scanning a systematic reality across Europe.

Monday 14th October 2013
UZ Leuven, Belgium

A REPORT OF PROCEEDINGS & CONCLUSIONS

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Acknowledgements

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Introduction

A medical error is a non-intentional deviation from ordinary standards of care, whether or not it is evident or harmful to the patient, and preventable by definition. This might include an inaccurate or incomplete diagnosis or treatment of a disease, injury, syndrome, behavior, infection, or other ailment. Medication errors are the most common single preventable cause of adverse events[1],[2],[3].

In hospitals the use of higher risk medicines, personalised medicines, and the acute condition of patients can all increase the risk and consequences of medication errors. Meanwhile the managed environment can also provide opportunities for robust systems to be put in place to prevent medication error from happening.

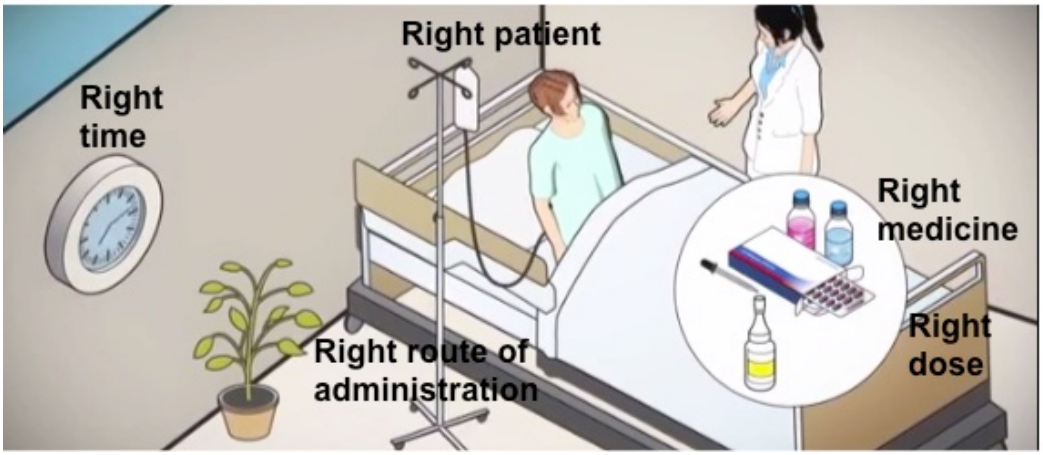
[1] Am J Health-Syst Pharm 1995;52:379-82

[2] BMJ 2000;320:774-7

[3] http://www.coe.int/t/e/social_cohesion/soc-sp/Medication%20safety%20culture%20report%20E.pdf

Whilst the problems, sources and methods of avoiding medication errors are multifactorial and multidisciplinary, the hospital pharmacist's remit as the principal of the medicines supply chain in the secondary care setting, best places them to oversee the quality of the entire drug distribution chain: from prescribing, drug choice, dispensing and preparation to the administration of drugs. Hospital pharmacists therefore have an important leadership position in improving medication safety within the hospital setting.

Technology, as in so many fields of life, can offer innovative and efficient solutions to old problems, and in the area of medication safety this is no different. From the 1980s the opportunity to make use of bar code technology to improve medication procedures and prevent error was quickly identified. Bedside scanning is the ability to conduct a final check that the medicine about to be administered to a patient is indeed about to be given to the right patient, at the right time, in the right dose, via the right route of administration.



However, in European hospitals, the full potential of barcode technology to prevent medication error has not yet been realised. This is a source of concern to the organisations associated with this document, and the October 2013 meeting at UZ Leuven on which it reports.

Background

Attempts to create and use machine-readable patient identification systems in healthcare to improve safety began as early as the late 1970s in the field of blood transfusion[4]. Then throughout the 1980s modernising hospitals, especially in the USA, began implementing machine-readable identification systems to improve patient care and identification across the

[4] Sherer P, Chambers R, Taswell H, Altshuler C, Aster R, Covino K, et al. Automated donor-recipient identification systems as a means of reducing human error in blood transfusion. Transfusion 1977;17:586-597

board. However, by the early 1990s it was becoming apparent that widespread uptake of the benefits of bar code technology in hospitals was being stymied by lack of industry standards and failed cooperation among all stakeholders[5]. Quite simply, without an identifying code printed on the individual unit of medicine, internal re-labelling of the medicine in the hospital has proven an insurmountable cost obstacle for too many hospitals.

In the USA at least, the landmark 1999 report by the Institute of Medicine '*To Err is Human*'[6], provided a much-needed fillip to efforts to overcome the hurdles to new system introduction. The report revealed that at least 44,000 people, and perhaps as many as 98,000 people, were dying in USA hospitals each year as a result of medical errors and about 7,000 people were dying from medication errors. The new insights on the nature and prevalence of medication error in hospitals provided the context for galvanised action.

As nearly 40% of medication errors happen at the level of administration[7], from 2001, hospital purchasing groups in the USA began to demand the provision of medicines to hospitals with machine readable codes printed on the individual unit of medicine in order to facilitate implementation of bedside scanning[8]. By 2003 the USA Food and Drug Administration (FDA) had taken the lead in publishing a proposal for a regulation to standardise this as a federal requirement[9] (passed in 2004).

Meanwhile in Europe, whilst in the late 1980s the national member associations of the European Association of Hospital Pharmacists (EAHP) had passed policy to promote the need for bedside scanning, and systematic bar coding of medicines to the single unit package to facilitate it, uptake of the patient safety practice has not moved beyond more than a few health systems, including UZ Leuven, the University Hospital of Geneva and a number of hospitals in the Netherlands. Meanwhile, in more recent years health systems in many other parts of the world have begun to make advances in this area, including in countries such as Brazil, Taiwan and Canada.

This situation, in which Europe is failing to make advances in bedside scanning, has caused EAHP to ask itself the question: is a European level regulation required to mandate that medicines for hospitals be bar coded to the single unit package?

This was the origin of the 14 October 2013 high-level meeting on bedside scanning.

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[5] Weilert M, Tilzer LL. Putting bar codes to work for improved patient care. Clin Lab Med 1991;11:227-238

[6] Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system . Washington, DC: National Academy Press, Institute of Medicine; 1999.

[7] Bates DW, et al. Incidence of adverse drug events and potential adverse drug events. JAMA 1995; 274: 29-34

[8] https://www.premierinc.com/safety/topics/bar_coding/press_release_12-20-01.jsp

[9] http://www.eahp.eu/sites/default/files/files/USA%202003%20-%20FDA%20unit%20dose%20barcoding%20proposal.pdf

Objectives of meeting

- To invite the principal stakeholders in relation to medication safety in hospitals to learn more about the benefits of bedside scanning, and also the obstacles preventing its wider realisation.
- To learn from experts in the area the current status of developments and the latest technological possibilities, including the new GS1 Level-Below-the-Each bar code standard.
- To explore through dialogue between industry, health professionals, patients and others the best way forward for Europe in this area, and make recommendations.

Presentations

Thomas De Rijdt, Assistant Director at UZ Leuven's Department of Pharmacy

The day began with an opening presentation by Thomas De Rijdt, Assistant Director at UZ Leuven's Department of Pharmacy and the President of the Belgian Association of Hospital Pharmacists. He welcomed attendees to the meeting and outlined the purpose of the meeting, and the history of bedside scanning.

Key points of the presentation:

- The meeting should not be thought of as 'a bar coding meeting' but as a patient safety meeting – because that is the ultimate purpose of the issue.

- The 1999 '*To Err is Human'* report was a game-changer in terms of thinking about patient safety in hospitals. If one extrapolated the figures from the USA, it could be estimated that perhaps 1,000 people a year are dying in Belgian hospitals as a result of avoidable medical error.

- UZ Leuven now makes use of computerized physician order entry (CPOE) which has numerous benefits including decision support in the prescribing process for scenarios such as formulary switches, responsiveness to known patient allergies, alerting of potential drug-drug interactions and reflection of the needs of special patient groups.

- However the final check is at the patient bedside, which is why UZ Leuven has taken the extra step of introducing bedside scanning – to ensure it's the right medicine at the right time, for the right patient, in the right dose, via the right route of administration. Evidence to date has demonstrated particular benefits in detection of potential errors such as the wrong sequence of treatment in cytotoxics, or double dosing.

- Providing care via this system, with more than 14 million doses administered every year in the hospital, can be a challenge however. Having to conduct repackaging of medicines so that each single unit package is bar coded is a particular burden. For example, repackaging must adhere to Good Manufacturing Practice guidelines as it is legally considered as production and compounding.

- For these reasons concrete timelines for industry delivering on a commitment to achieve bar coding of medicines to the single unit package is very much required in order for bedside scanning to make further advances and he hoped the event could play a positive role in that respect.

During questions and answers, an attendee asked if the process also included a scan of the health professional administering the dose. This might be useful in respect of issues such as accountability. Mr De Rijdt replied that the health professional is logged in to the hospital information system with a personal login and password and that every action is logged, an extra scanning step has no advantage.

Attendees were then taken in groups to the hospital wards to view the technology being used in practice.

The slides presented by Thomas De Rijdt are available **here.** Film footage of the presentation is available **here.**

Chris Dierickx, Manager Business Development at Pfizer Global Supply

Following the tour, Chris Dierickx, Manager Business Development at Pfizer Global Supply, gave an industry perspective on the issue of bar coding medicines to the single unit package.

Key points of the presentation:

- In all industries and markets suppliers should understand and respond to the needs of their customers, and UZ Leuven, EAHP and others had made clear they had particular needs in respect of the single unit package bar code.
- Pfizer had therefore made investigation into facilitating this request. The process of bar coding to the single unit package at the point of manufacture is not necessarily simple as it is imperative that the information on the code is accurate and reliably printed.
- Different types of bar code exist and choosing the right one matters in terms of delivering the benefits of bedside scanning. Use of GS1 standard bar codes is important for successful application of interoperable relevant technologies.
- From a manufacturing point of view, producing bar codes containing static information (e.g. product name, manufacturer etc) to the single unit package is quite possible. The challenge mounts whenever variable information is introduced (e.g. batch number and expiry date).
- Another issue for consideration is physical space on the packaging including human readable codes.

The presentation of Chris Dierickx is available **here.**

Ulrike Kreysa, Vice President GS1 Global Office

Completing the morning session, Ulrike Kreysa, Vice President GS1 Global Office, outlined the international picture and the role of the new GS1 Level-Below-the-Each standard.

Key points of the presentation:

- Bar code technology in the hospital setting can save lives, something GS1 seeks to promote through its global healthcare user group, and its work on **the Level-Below-the-Each standard.**

- Re-bar coding by a hospital or outside contractor is not the ideal or long-term solution to the question. It would be better and safer if this process was conducted at the point of manufacture.

- The importance of including the Global Trade Item Number (GTIN) within a bar code must be understood and should ideally be available to the single unit package of medicine. In a second step then expiry date and lot/batch number could be included.

- A report by McKinsey '***Strength in Unity***' (October 2012) has revealed significant cost savings available to health systems by moving towards greater global standardisation in key areas such as the medicines supply chain, particularly in areas such as counterfeit product detection and opportunities for preventing medication error.

- Through its global practice, GS1 is aware of recent developments towards improved use of bar code technologies in the hospital setting in countries such as the Netherlands, France,

Taiwan, Brazil, Argentina and the USA. In Denmark, hospital supply company Amgros now requires primary packaging level identification for certain medicinal products.

Ulrike Kreysa finished by giving a brief introduction to the issues to be covered in the afternoon workshops. Can greater use of single unit package bar codes on medicinal products be brought about by customer pressure/requirements, regulations/directives, and/or a jointly agreed timetable/roadmap between all relevant parties?

The presentation is available **here.** Film footage of the presentation is available **here.**

Workshops

In the afternoon attending participants broke into 4 workshop groups to consider in particular how best to bring about an improved situation in Europe in respect of bar coding medicines to the single unit package.

The contribution of bedside scanning to patient safety

On the question of whether bedside scanning represents a major contribution to patient safety by preventing medication administration error, workshop groups reported that the technology appeared to be tried and tested and looked very much like the future. Fuller realisation of its safety benefit would likely only be possible however if single unit package bar coding took place at the point of manufacture. It was also recognized that bedside scanning will never offer the full

solution to medication error, with mistakes at prescribing and dispensing level still possible. It was nonetheless a powerful tool at the point of care, that should be viewed contextually within a suite of other solutions for the other points of the medication use process.

The need for 'one message'

Looking at whether stakeholders in the medicines use process with ethical responsibilities should work together to see bedside scanning become a standard feature in European hospital care there was agreement amongst participants that this was the case. However it was requested that the hospital sector give one message to industry about their requirements, particularly around the level of information to be included on the bar code e.g. whether batch number and expiry date were being sought.

Bringing the relevant parties together

Investigating the form by which stakeholders might work together on achieving greater uptake of bedside scanning, and who those stakeholders were, software companies and providers were identified as an important group to be involved in the solution process, as well as health insurance companies. Universities and research institutes could have an interest in the information gathering power of bedside scanning technology. It could helpful to think of the packaging industry as conceptually separate from the manufacturing industry. All these partners, alongside hospital management, pharmacists, nurses and the pharmaceutical industry, should be brought into a joint coalition for change.

Obstacles to introducing bedside scanning

On the issue of major obstacles to bedside scanning, alongside the single unit package bar code issue, one workshop group highlighted the start-up investment costs as an obstacle, in terms of the technology, software, equipment and training, especially in a period of widespread public spending austerity. This obstacle increases in magnitude the smaller the hospital (e.g. relative to overall budget).

Another workshop group raised as an obstacle the fact that politicians have little awareness not only of bedside scanning, but also of the general issue of medical and medication error. This in itself is a reflection of low public awareness, and the situation where it may not always be seen as serving hospital or health systems purposes to widely broadcast issues of error rate, for fear of distorted media reporting which may cause public alarm or unduly undermine confidence in the health system. Taken all together this can create a more difficult environment for making the case for bedside scanning technology investment than should otherwise be the case.

Another highlighted obstacle was the heterogeneous IT systems operated across European hospitals, and even within national systems. This interoperability problem was an issue not only between hospitals, but also between manufacturing companies and packaging companies.

One perspective given was that current regulation of bar coding could be an obstacle in respect of authorities making inflexible demands that get in the way of single unit package bar coding i.e. in how available space is used, demands for human readable codes etc. The technical aspects referred to by Chris Dierckx in the morning presentation were also highlighted by the workshop groups e.g. slowing down production lines, production of more waste, and the challenge of printing codes on small and curved packaging. Workshop participants stated that these were not insurmountable however.

Regulatory uncertainty might provide another obstacle, leading to timidity in introducing new systems while no mandate is placed on manufacturers to bar code to the single unit package.

The question of regulation

Reflecting on whether national and/or European regulations were required in order to mandate bar codes be placed on the single unit package of medicine at the point of manufacture, one workshop suggested that there could be a specific role for the European Medicines Agency in requiring single unit package bar coding for approved orphan drugs.

Other than this, many workshop participants cautioned that pursuing regulation could be a very time consuming and resource intensive business with no guarantee of success in view of the legal difficulties in securing pan-European regulation in the field of health. There may be more immediate gains to be made by all partners working in collaboration towards a step-by-step

timelines. This might, for example, include commencing systematic bar coding to the single unit package for one category of medicines (e.g. orphan drugs) first, followed by a period of time by another category (e.g. high risk medication), and so on.

Another alternative proposed was reimbursement and purchasing incentives. France had made certain requirements on packaging in return for reimbursement incentive. There were examples of purchasing groups making certain mandates from the supplier before agreeing purchase.

Thinking about realistic timeframes for achieving medicines bar coded to the single unit package in Europe one workshop group felt the first step in the timeline is to form a rigorous agreement between all parties, not just hospital pharmacists and industry associations, but others (e.g. software companies and providers, health insurers, hospital managers etc), as to exactly what the needs were. From this the timetable for realisation could then be established. Some element of caution and room for flexibility may need to be incorporated to such an agreement as one size may not fit all health systems in Europe.

Other comments expressed during the working groups included:

- There is an ongoing need to accumulate the documentation and evidence of the difference bedside scanning makes to reducing error;
- Whilst the Falsified Medicines Directive makes no explicit mention of primary packaging bar coding, there could be scope, in terms of national level interpretation of the Directive requirements, to advocate for single unit package bar coding to be a part of the implementation
- The pharmaceutical industry needs a list of high-priority-products. Market size of one of the big European countries would be enough to adapt then the production line, first for this country, second for all Europe.

Film footage of the reports back from the workshop groups is available **here.**

Key conclusions

Listening to the workshop discussions, as well as the key points from the presentations, questions asked, and conversations held during the breaks, the event facilitation team have made the below key conclusions from the day's session:

- There is a need to better coordinate efforts being made towards achieving systematic bar coding of medicines to the single unit package in Europe. This coordination should include not only hospital pharmacy and the pharmaceutical industry, but also representatives of the packaging, software, IT and equipment industries, representatives of hospital and health system management, health insurers, and the nursing profession.

- This greater coalition for medication safety and prevention of errors, should set out one detailed demand in respect of articulated requirements on single unit package bar coding, including the exact levels of information required on the bar code, taking into account reported feasibilities when the bar code contains static data as opposed to variable data.

- This coalition should also consider developing a step-by-step timetable for full realisation of the single unit package bar code needs, and give thought to constructing this according to categories of medicine, whereby orphan drugs could be viewed as step 1, followed by high risk medication.

- Remaining opportunities to utilize the national level implementation of the Falsified Medicines Directive should be explored.

Next steps

EAHP, UZ Leuven, and GS1 will seek to work with other identified partners for patient safety in hospitals (nursing, hospital management organisations, health insurers and packaging and software companies) to:

1. Clarify definitively the customer requirement for bar coding of medicines in hospitals;

2. Construct a stage-by-stage timeline for achieving bar coding of medicines to the single unit package, potentially built on a concept of realising the goal according to categories of medicine (e.g. orphan drug, high-risk medication, newly authorised, biological, generic etc)

Further to this, EAHP will share this report widely with identified stakeholders and partners, and submit an article centred on the meeting to the European Journal of Hospital Pharmacy.

More Information

Further information about the event, including the list of participants, and the workshop questions, is available here:

http://www.eahp.eu/content/report-leuven-event-medicines-bar-coding

Further information about EAHP's policy in this area is available here:

http://www.eahp.eu/practice-and-policy/bar-coding-medicines-to-the-single-unit

The background reading papers supplied to participants in advance of the meeting is available here:

http://www.eahp.eu/content/leuven-event-bedside-scanning-background-papers

Further information about the GS1 Level-Below-The-Each standard is available here:

http://www.gs1.org/1/newslib/detail.php/new-standard-to-address-missing-link-in-hospital-supply-chain-processes/?nid=1486