BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2011.03981.x

Commentary

e-SPC – delivering drug information in the 21st century: developing new approaches to deliver drug information to prescribers

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Prescribing medicines safely and effectively represents one of the greatest challenges for healthcare systems. Prescribing errors are common. A recent prospective observational study in the UK suggested that 10% of hospital prescriptions contained errors and that senior doctors were almost as frequently culpable as those who had recently graduated [1]. Avoidable adverse drug reactions are a frequent cause of consultations in primary care, admission to hospital and increased length of hospital stay [2, 3]. All healthcare providers should be striving to provide high-quality prescribing that meets the goals of being safe, effective, cost-effective and patient-centred [4].

The reasons for this failure to deliver these optimal standards of care are multiple but can be broadly divided into those that surround individuals, such as education and training and those that relate to the systems in which they work. The healthcare environment is now increasingly demanding for prescribers because of the widening choice of medicines available, expanding indications for drug treatment, greater complexity of treatment regimens and associated 'polypharmacy', and a more elderly and vulnerable patient cohort. The other major challenge is the pace of change in therapeutics. New evidence on effectiveness, emerging safety signals and altered costs means that what is considered good prescribing today may not necessarily be so in a year.

Amidst all of these pressures it is now clear that the mid-20th century model of training prescribers in medical school and providing them with books of reference information (e.g. national or local formularies) is no longer fit for purpose. The modern day prescriber will need electronic drug information that is instantly available and in a logical format that can interface with the electronic health record and decision support systems. Bringing these three developments together has the potential to help prescribers to improve selection and dosage of drugs, make better predictions of adverse effects and interactions and will also help patients to engage more fully in the process of selecting and monitoring their own treatment.

However, there is plenty of evidence to suggest that delivery of information could be improved [5, 6]. A recent

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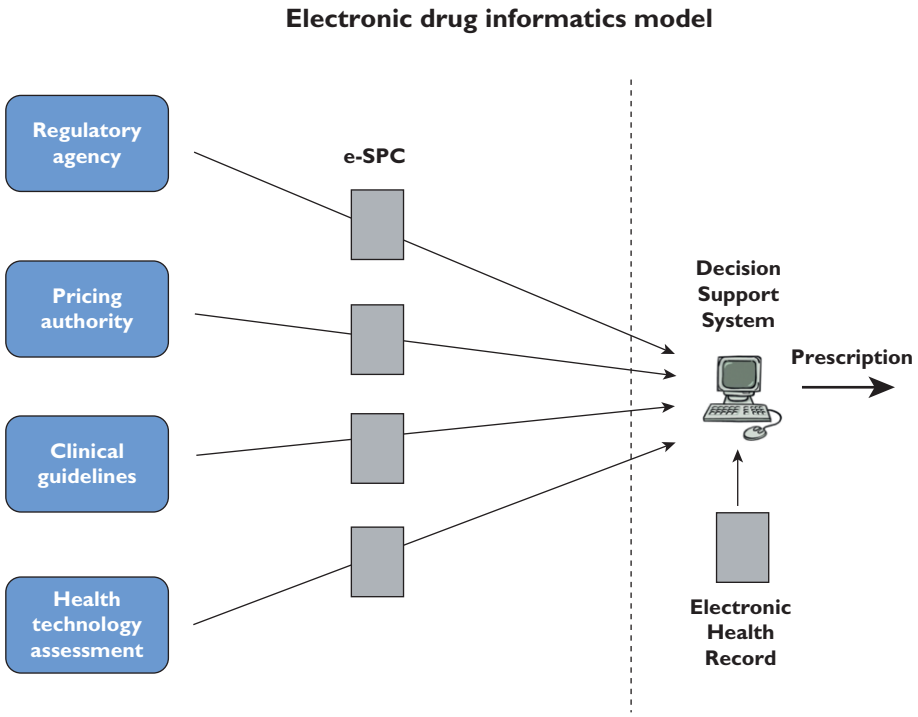

Figure 1

The e-SPC structure with data content can be co-ordinated with other data sources and knowledge databases, as well as electronic health records (EHR) and decision support systems (DSS), to implement a new model of electronically supported prescribing. Prescribing decisions may also be influenced by other national and local factors (e.g. drug pricing and re-imbursement, clinical guidelines, appraisals of cost-effectiveness and formulary decisions). Electronic data sets (▯)

report of healthcare in six European member states (Czech Republic, France, the Netherlands, Sweden, Spain and the UK) estimated that about 100 000 inpatient adverse drug events could be avoided each year in the six member states by implementing better electronic drug services [5]. This would correspond to an annual saving of €300m in bed days. The potential for improved information technology to save money and advance important political objectives such as patient safety, healthcare access and continuity of care should accelerate our efforts to develop new and user-friendly sources of drug information.

So what might a new electronic system look like? It will involve several important elements including an electronic health record (EHR), a computerized physician order entry system (CPOE) and a highly developed decision support system (DSS). Each of these elements will have to be underpinned by access to an authoritative, standardized, validated and regularly updated repository of information about prescribed drugs (dosages, packages and mode of administration; Figure 1). Although many parts of the electronic prescribing vision are already in place there is still a lack of standardized electronic drug information (EDI) that can be integrated easily into DSS and EHRs. The need for standardized formats of structure, storage, visualization and communication of drug information has been highlighted in various reports [6, 7].

How can EDI be developed? The European Medicine Agency (or the national regulatory bodies) currently require the manufacturers of all medicines to provide a summary of product characteristics (SPC) prior to the granting of a market authorization. The SPC contains detailed information about the medicinal product accumulated during the development process and regularly updated after approval and can help health professionals to use the medicinal product safely and effectively. The current SPC is a chapter-based document available only as plain free text. Each is available as a single document file and is published in portable document format running typically to between 10 and 30 pages. Its length and the fragmentation of information make them time-consuming to read and data hard to retrieve. Prescribers simply do not have the time to consult them as they make rapid 'point of care' decisions in clinical practice [8, 9]. Although this information provides support for health professionals as they initiate and supervise treatment safely and effectively, it falls short of the standardization and detail required to make accurate predictions on outcome. For example, adverse effects of medicines need to be described in standard terms and grouped according to frequency and body

system that they affect. Dosing decisions require detailed information about pharmacokinetics in different groups of patients and drug indications should be described with specific diagnostic codes for easy linkage to patient data in EHRs. These problems emphasize the need for a detailed and carefully structured SPC that is available in a logical electronic format (e-SPC) that can complement the increasingly detailed information available in EHRs (e.g. past diseases and care episodes, current and past medicines, physiological and biochemical data).

A major challenge is that a new e-SPC that offers relevant data to support complex decisions regarding, e.g. dose selection, will require information about parameters that are currently not available (or only incompletely) at the time of marketing. For example, the current SPC gives insufficient details to allow prescribers to make common dose adjustments necessitated by factors such as renal impairment or drug interactions [10, 11] and variations in pharmacokinetics are not well supported [12, 13]. Providing these details will involve not only pre-licensing studies but also careful accumulation of relevant data in the post-marketing phase. This will have to focus more clearly on parameters that will be of importance to patients who will be exposed to the drug, doctors who prescribe it and those who administer the drugs.

The primary focus of future efforts with improved drug information should be to support prescribers and patients but the new e-SPC could also help other groups. These might include: (i) drug companies or clinical researchers during pre- and post-registration clinical drug development; (ii) clinical researchers who wish to combine existing EHRs with the results of prospective clinical trials to understand better how drugs produce their beneficial and adverse effects; and (iii) pharmacoepidemiologists who wish to understand safety signals derived from observational studies in large linked data sets. All of these groups would have access to carefully structured and predictable information that could be integrated into their own data sets.

There will be many hurdles to overcome before rolling out the new era of EDI. The new e-SPC format needs to be specified and this will require agreement between stakeholders in the pharmaceutical industry, the regulators and healthcare providers. Another important stakeholder will be those who develop CPOE and DSS systems with which e-SPC would have to integrate. There will need to be an effective education package created, together with guidelines for use in other software systems across European healthcare institutions. It will be a major task to convert all, or even a subset of, the existing SPCs to the new format.

While we strongly support the utilization of new technology to deliver extra layers of safety to the complex task of prescribing, we also readily acknowledge that such systems offer the potential to introduce new kinds of hazards [14, 15]. The introduction of CPOE and DSS systems requires close monitoring to identify potential flaws [16] and unanticipated clinical risk situations [15]. Nevertheless, prescribing-related errors and harm are so common that we should address these new challenges and not lose sight of the potential gains that the new electronic prescribing era will offer [17].

Notwithstanding all of these challenges it is clear that structured and standardized electronic drug information that can be easily accessed is vital for future clinical drug development, clinical drug research and for improving the prescribing decisions that are made at the point of patient care across Europe. Such a development will also help to enhance overall efficiency in the use of healthcare resources and will establish drug information standards that will benefit development of medical guidelines and knowledge bases by medical professional organizations and universities [18]. This development will not happen without the input of considerable effort and resource at a time when budgets are tight. However, looking at the costs currently imposed by suboptimal use of medicines in Europe the question should not be 'Can we afford to do this?' but rather 'Can we afford NOT to do this?'.

Competing Interests

HGE is a full-time employee of the European Medicines Agency.

REFERENCES

1 Dornan T, Ashcroft D, Heathfield H, Lewis P, Miles J, Taylor D, Tully M, Wass V. An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education – EQUIP study. 2009. Available at http://www.gmc-uk.org/about/research/research_commissioned_4.asp (last accessed 20 April 2011).

2 Leendertse AJ, Egberts ACG, Stoker LJ, van den Bemt PMLA, for the HARM Study Group. Frequency of and risk factors for preventable medication-related hospital admissions in the Netherlands. Arch Intern Med 2008; 168: 1890–6.

3 Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR Pirmohamed P. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS ONE 2009; 4: e4439; doi:10.1371/journal.pone.000443.

4 British Pharmacological Society. Ten principles of good prescribing. Available at http://main.bps.ac.uk/Springboard WebApp/userfiles/bps/file/Guidelines/BPSPrescribing Principles.pdf (last accessed 20 April 2011).

5 Gartner. eHealth for a healthier Europe! Available at http://www.regeringen.se/content/1/c6/12/98/02/5b63bacb.pdf (last accessed 20 April 2011).

6 Jha AK, Doolan D, Grandt D, Scott T, Bates DW. The use of health information technology in seven nations. Int J Med Inform 2008; 77: 848–54.

7 Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change. Lancet 2003; 362: 1170–5.

8 Arguello B, Fernandez-Llimos F. Clinical pharmacology information in summaries of product characteristics and package inserts. Clin Pharmacol Ther 2007; 82: 566–71.

9 Bergk V, Haefeli WE, Gasse C, Brenner H, Martin-Facklam M. Information deficits in the summary of product characteristics preclude an optimal management of drug interactions: a comparison with evidence from the literature. Eur J Clin Pharmacol 2005; 61: 327–35.

10 Martin-Facklam M, Rengelshausen J, Tayrouz Y, Ketabi-Kiyanvash N, Lindenmaier H, Schneider V, Bergk V, Haefeli WE. Dose individualisation in patients with renal insufficiency: does drug labelling support optimal management? Eur J Clin Pharmacol 2005; 60: 807–11.

11 Seidling HM, Storch CH, Bertsche T, Senger C, Kaltschmidt J, Walter-Sack I, Haefeli WE. Successful strategy to improve the specificity of electronic statin-drug interaction alerts. Eur J Clin Pharmacol 2009; 65: 1149–57.

12 Quinzler R, Gasse C, Schneider A, Kaufmann-Kolle P, Szecsenyi J, Haefeli WE. The frequency of inappropriate pill splitting in primary care. Eur J Clin Pharmacol 2006; 62: 1065–73.

13 Quinzler R, Szecsenyi J, Haefeli WE. Tablet splitting: patients and physicians need better support. Eur J Clin Pharmacol 2007; 63: 1203–4.

14 Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL. Role of computerized physician order entry systems in facilitating medication errors. JAMA 2005; 293: 1197–203.

15 Strom BL, Schinnar R, Aberra F, Bilker W, Hennessy S, Leonard CE, Pifer E. Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction: a randomized controlled trial. Arch Intern Med 2010; 170: 1578–83.

16 Horsky J, Kuperman GD, Patel VL. Comprehensive analysis of a medication dosing error related to CPOE. J Am Med Inform Assoc 2005; 12: 377–82.

17 Bates DW. CPOE and clinical decision support in hospitals: getting the benefits. Arch Intern Med 2010; 170: 1583–4.

18 Eiermann B, Bastholm-Rahmner P, Korkmaz S, Lilja B, Veg A, Wettermark B, Gustafsson LL. Knowledge databases for clinical decision support in drug prescribing- development, quality assurance, management, integration, implementation and evaluation of clinical value. Chapyrt in Decision Support Systems, edited by Chiang S. Jao ISBN 978-953-7619-64-0, Vienna 2010.

RECEIVED
4 January 2011

ACCEPTED
22 March 2011

ACCEPTED ARTICLE
6 April 2011

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