BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2011.04058.x

Physicians' reported needs of drug information at point of care in Sweden

Pia Bastholm Rahmner,[1] Birgit Eiermann,[2] Seher Korkmaz,[1,6] Lars L. Gustafsson,[2] Magnus Gruvén,[2] Simon Maxwell,[3] Hans-Georg Eichle[4] & Anikó Vég[1,5]

[1]Centre of Medical Knowledge, Stockholm County Council, Stockholm, [2]Division of Clinical Pharmacology, Department of Laboratory Medicine, Karolinska Institutet, Karolinska University Hospital Huddinge, Stockholm, Sweden, [3]Clinical Pharmacology Unit, University of Edinburgh, Edinburgh, [4]European Medicines Agency, London, UK, [5]Health Services Research at Dept of Public Health and Caring Sciences, Uppsala University, Uppsala and [6]Karolinska Institutet Solna, Stockholm, Sweden

Correspondence
Mr Pia Bastholm Rahmner PhD, Centre of Medical Knowledge, Stockholm County Council, Box 17533, SE-118 91 Stockholm, Sweden.
Tel.: +46 8 737 40 79
Fax: +46 8 737 40 12
E-mail: pia.bastholm-rahmner@sll.se

Keywords
decision support systems, drug information, drug labelling, focus group discussions, health services needs and demand, medical informatics

Received
28 September 2010

Accepted
10 June 2011

Accepted Article
29 June 2011

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- The computerization of health care has increased dramatically in the last decades in most European countries, but no standardization of any of the information support systems has been established on common ground.
- The Summary of Product Characteristics (SmPC) is available all over Europe in written form and in some of the countries even electronically, but the structure and the content of the information vary.
- The physicians' needs for useful and reliable information about drugs at point of care are a question of patient safety.

WHAT THIS STUDY ADDS

- A qualitative approach, in this case focus group discussions, proved advantagous compared with questionnaires.
- Knowledge gained from physicians' experiences promoted the work of restructuring and organizing the e-SmPC database.
- Most of the required information from physicians appeared to be possible to transfer from current SmPCs to clinical decisions support systems.

AIMS

Relevant and easily accessible drug information at point-of-care is essential for physicians' decision making when prescribing. However, the information available by using Clinical Decision Support Systems (CDSSs) often does not meet physicians' requirements. The Summary of Product Characteristics (SmPC) is statutory information about drugs. However, the current structure, content and format of SmPCs make it difficult to incorporate them into CDSSs and link them to relevant patient information from the Electronic Health Records. The aim of the study was to evaluate the perceived needs for drug information among physicians in Sweden.

METHODS

We recruited three focus group discussions with 18 physicians covering different specialities. The information from the groups was combined with a questionnaire administered at the beginning of the group discussions.

RESULTS

Physicians reported their needs for knowledge databases at the point of drug prescribing. This included more consistent information about existing and new drugs. They also wished to receive automatically generated alerts for severe drug–drug interactions and adverse effects, and to have functions for calculating glomerular filtration rate to enable appropriate dose adjustments to be made for elderly patients and those with impaired renal function. Additionally, features enhancing electronic communication with colleagues and making drug information more searchable were suggested.

CONCLUSIONS

The results from the current study showed the need for knowledge databases which provide consistent information about new and existing drugs. Most of the required information from physicians appeared to be possible to transfer from current SmPCs to CDSSs. However, inconsistencies in the SmPC information have to be reduced to enhance their utility.

Introduction

Drug prescribing is becoming more complex due to the increasing number of drugs available and information about their usage, effectiveness and side effects. Patient safety is a major public concern and it is considered of vital importance to prescribe the right drug to the right patient in the right dose [1]. Therefore concise information about drugs, which is available at the moment of drug prescribing, is necessary for physicians.

Today there are various information sources about drugs. These include drug information presented in computerized decision support systems (CDSSs), and linked to electronic health records (EHRs), to provide prescribers with patient specific dosing recommendations adjusted for renal impairment [2], potential drug interaction warnings [3] or other alerts for, for example, allergies or hypersensitivities or the suitability of the drug for use during pregnancy [4]. However, the effects of these integrated systems are still being discussed and under investigation, and there is a call for international standards for the systems and their content [5–9].

The Summary of Product Characteristics (SmPC) is a statutory requirement. It is approved and issued by regulatory agencies as the legal document that is required prior to drug authorization and marketing. It contains information about the registered product, for example, its indication, content, dosage and clinical particulars such as, for example, information about drug–drug interactions, adverse reactions and contraindications (Table 1) [10, 11]. The SmPC is at present a plain text document, which can be long at over 30 pages. In addition, certain information can be included in different sections, for example, information about drug interactions might be found in the section for contraindications or drug interactions, all of which potentially reduces their utility in practice. Although the SmPC holds important information that supports rational drug prescribing, the present structure, the inconsistency of the content and the absence of classification systems prevents integration into CDSSs in their current format and the generation of alerts [12].

Despite this, increased efforts in the last decades have led to a limited number of CDSSs being incorporated consistently and safely into EHR systems with optimal links between drug information and patient characteristics [5]. However, in the absence of standardized and reliable drug information sources, individual countries are beginning to develop their own solutions to support the prescribers. Consequently, a unified European information system, with the approved, standardized e-SmPC information, should provide all EU countries with appropriate data and avoid duplication of effort. However, the starting point for the development of any knowledge database and CDSS should be the analysis of the perceived needs and the priorities of potential users [13]. We are aware the information available by using CDSSs often does not meet physicians' requirements [14]. As a result, the aims of this study were firstly to explore which and what type of drug information physicians need to have available to them at the moment of drug prescribing and secondly, what additional functions a CDSSs would need to meet the physicians' needs.

Table 1

Common structure of summary of product characteristics as issued by the European Medicines Agency

Section number	Section name
1.	Name of the medicinal product
2.	Qualitative and quantitative composition
3.	Pharmaceutical form
4.	Clinical particulars
4.1.	Therapeutic indications
4.2.	Posology and method of administration
4.3.	Contraindications
4.4.	Special warnings and precautions for use
4.5.	Interaction with other medicinal products and other forms of interaction
4.6.	Pregnancy and lactation
4.7.	Effects on ability to drive and use machines
4.8.	Undesirable effects
4.9.	Overdose
5.	Pharmacological properties
5.1.	Pharmacodynamic properties
5.2.	Pharmacokinetic properties
5.3.	Preclinical safety data
6.	Pharmaceutical particulars
6.1.	List of excipients
6.2	Incompatibilities
6.3.	Shelf life
6.4.	Special precautions for storage
6.5.	Nature and contents of container
6.6.	Special precautions for disposal and other handling
7.	Marketing authorization holder
8.	Marketing authorization numbers
9.	Date of first authorization/renewal of authorization
10.	Date of revision of the text

Methods

Study design

Focus group discussions (FGDs) were used to explore the drug information needs of general practitoners and hospital physicians when they prescribe. We chose this data collection method, because FGDs are valuable in examining how people think and how ideas operate within a given cultural context [15, 16]. The FGDs were intended to get ideas and suggestions from different groups of physicians, rather than making comparisons. All participants were required to have had prior experience of using EHR and e-prescribing systems. The study was performed among prescribers in Sweden, where electronic prescribing and use of electronic health record systems with integrated decision support system, e.g. Janus toolbar [17] are

Table 2

Summary of the level of computerization in the Swedish health care system

Functions	Performance
Electronic Health Record (EHR)	• High degree of computerization with EHRs in 16 of 21 counties. In the 16 regions EHR covered 100% of primary care, 92% in hospital care and 96% in psychiatric care • Over 15 different EHRs • No exchange accessibility of data between different EHRs
Drug prescribing	• E-prescribing: 80% of all prescriptions (98% in Stockholm) • Swedish Physicians' desk reference integrated in almost all EHRs • No common drug list at national level
Decision support system (DSS)	• The DSS Janus toolbar integrated in six EHRs with support functions like drug-drug interaction alerts, pregnancy- and breastfeeding alerts, side effects and direct connection to the web site with medical information http://www.janusinfo.se
Medical services	• computerized laboratories nationwide • digitalized X-ray pictures nationwide • common X-ray archives in 14 counties
Access to computer	• on average 1.14 employed per computer
Electronic services for patients/citizens	• renewal of prescriptions electronically possible in 20 counties • booking/cancelling visit to the doctor electronically possible in 18 counties • mail/messenge by mobile phone and reminders utilized by 10% of the whole population

Data based on a nationwide survey among the 21 counties and regions in 2009. (IT-support systems in the counties in Sweden, 2009).

Table 3

Contents of the questionnaire items collected at the beginning of each session of the focus group discussions

Questionnaire items	Type of question
Background variables (age, gender, workplace, specialization)	Open-ended
Which electronic health record system do you use? How often do you use them?*	Matrix with a Likert-type scale
Which electronic decision support systems do you use when prescribing?	Open-ended
How would you describe yourself as a computer user?†	One option
What is the extent of your interest in IT in general?‡	One option
Are you familiar with the SmPC (Summary of Product Characteristics) concept?	Yes/no
What type of information do you use today when prescribing a drug?	Open-ended
Do you think some type of information is lacking when you prescribe?	Yes/no
To what extent do you find the services listed below helpful in your work?§	Matrix with a Likert-type scale
Other services you would consider helpful?	Open-ended
What should a decision support system do for you?	Open-ended
Additional ideas, e.g. if you have other experiences, training, knowledge or interests you think are useful in this context?	Open-ended

*Scale options: never, a couple of times a month, a couple of times a week, daily. †Options: very inexperienced, inexperienced, rather inexperienced/experienced, experienced, very experienced. ‡Options: no interest, some small interest, some interest, quite a large interest, large interest, very large interest. §Services on the list: Drug–drug interaction alerts, drugs and pregnancy, drugs and lactation, drugs and renal function, Overview of adverse drug reactions scale options: not helpful, helpful to some extent, helpful to quite a large extent, and very helpful.

common. The e-prescribing technology currently available in the Swedish health care system is summarized in Table 2.

In order to interpret the impact of variations in the work environment and electronic systems used by individual participants, we triangulated the data from the FGDs with a questionnaire (Table 3). The questionnaire focused on data about the participants' background and their habits of using CDSS and EHRs.

Swedish law [18] did not require approval of this study from the research ethics committee on the basis that our study posed no physical or psychological risk to the participants. However, all participants gave their informed consent prior to involvement in the study.

Participants and data collection

In a qualitative study, a purposeful sample selection refers to information-rich cases, i.e. people who have the best possible knowledge, experience or overview with respect to the study's research topic. A purposeful sample is preferred as the researchers' interest is to capture diversity in a well-structured sample [19]. Eighteen physicians working at different practices in the Stockholm metropolitan area were recruited to the FGDs. The potential respondents were selected from a register provided by the health authorities. They were contacted by the researchers (AV, PBR) via e-mail explaining the aim and procedure of the study. After receiving the initial e-mail, the physicians were

contacted by telephone. To reach a sample of 18 participants we had to contact 45 physicians. The 18 physicians were divided into three groups of four to seven participants in each group which is optimal for this kind of study. The number and the size of the FGDs are considered to be sufficient to reach the desired level of information and to support the aim of the study [15].

Two of the FGDs were carried out at the physicians' workplaces and one at the interviewers' workplace during October 2009. The FGDs lasted for 60 to 90 min and were audio-recorded and transcribed verbatim. Two researchers (AV, PBR) were present during the discussions, one as a moderator and one as observer. Both researchers were trained and well experienced in qualitative interviewing methods. Before starting the FGDs, the participants received information about the interview study and its role in the e-SmPC project, and how the results would be used. Immediately after this, participants were asked to complete the questionnaire. This contained questions about practical information on participants' experiences of using electronic tools for drug prescribing. We started each FGD broadly with questions related to the expected outcomes of the general prescribing process. We continued by asking more specific questions about the physicians' needs for drug information:

1 What type of information do you look for prior to prescribing? How/where do you find it? What do you consider as good or poor drug information?
2 To what extent do you currently use computerized decision support systems at point of care? Do you consider the present system is useful? What additional help should the support system give to you?

Data analysis

Focus group discussion From the empirical data, an inductive thematic analysis with no predetermined themes was carried out [19]. In this study, we used thematic analyses as a pragmatic research tool when searching for the answers to the research questions in the transcriptions and for structuring the data. The data were coded with the assistance of NVivo software Version 8 (http://www.qsrinternational.com) and the analysis was performed by the same researchers (AV, PBR) who undertook the FGDs. The other researchers acted as co-readers. The phases of the thematic analysis method were as follows:

1 The transcripts were read repeatedly by the researchers independently of each other to acquire a good understanding of the whole material.
2 Sections of text and key words in the transcripts, focusing on the research question, were marked and systematically coded. Marked sections with related topics were subsequently grouped into sub-themes.
3 Associations between sub-themes were identified. When opinions differed between research members, such as about meaning or origin, we returned to the transcripts and sought evidence to establish consensus. This iterative process was used throughout the whole analysis, i.e. moving from the whole transcripts to the condensed description and back again.
4 Sub-themes were merged into four themes and named from an overall perspective. Quotes were selected to illustrate each theme.
5 Each transcript was re-read once more to ensure no aspects had been overlooked.

Questionnaire

Data from the questionnaires were summarized descriptively. This included the background of the participants.

Results

Participant characteristics

As stated, we conducted three FGDs with a total of 18 physicians in Stockholm County. The first focus group consisted of clinicians in internal medicine from a university affiliated hospital, the second consisted of geriatricians from a secondary hospital and the third group consisted of general practitioners from primary care. The first FGD included four physicians. The two other groups included seven participants each. The gender distribution was eight males and 10 females with an average age of 47 years (range 27–63 years). The physicians' specialities were internal medicine, cardiology, geriatrics and general practice (Table 4). The duration of being a specialist varied between 1 to 32 years (average = 12 years). Three of the physicians were not yet accredited as specialists. Participants came from small (number of physicians = up to 10), medium (10–30 prescribers) and large size (over 30 physicians) health care units. All physicians had access to various EHRs (Melior, Medidoc, Profdoc-Journal III and Take Care), which

Table 4

Characteristics of study participants (n = 18) in focus group discussions

Characteristic	Number/average (range)
Gender	
Female	10
Male	8
Age (years)	47 (27–63)
Speciality	
Internal medicine	1
Geriatrics	5
Cardiology	1
General practice	6
General practice + neurology	1
General practice + geriatrics	1
Without specialization	3
Years of being a specialist	12 (1–32)
Number of prescribers at workplace	33 (9–150)

Table 5

Prescribers' reported needs for drug information. Overview of the results summarized as two major themes reported during the focus group discussions

A. Reported needs of drug information	Expectations/needs for functionalities when integrating information/knowledge into the electronic health record (EHR)
A.1 Drug–drug interactions	• Integrated and automatically generated alert system • Alerts only for severe drug–drug interactions
A.2 Adverse effects	• Alerts only for severe adverse effects • Search for side effects in the patient's drug list based on PDR (Physicians desk reference) information • Information about the reversibility of adverse effects
A.3 Allergy and hypersensivity	• System should stop prescribing • Automatically generated alert system
A.4 Dose related to age	• Recommended doses for children • Should warn when the dose is too high related to weight • Calculate the approximate glomerular filtration rate or the creatinine clearance automatically
A.5 Indication, duration and treatment plan	• Indication of the prescribed drug therapy • Duration of the chosen drug therapy • Treatment plan and goals • Plan for the follow-up
A.6–A.7 Additional information about prescribed drugs	• Recommended drugs from The Wise Drug List* • Register of pictures of the drugs • Visualization of pharmacodynamics
B. User friendly features/solutions in the EHR	
B.1 Needs for smart features linked to the EHR **• better structure and disposition of information presentation** **• possibility for links/sheets for personal tips**	
B.2 Interactive functionalities **• interactive/questioning search functions** **• messenger: leaving a message for other caregivers**	

*A list of recommended drugs produced by experts from different specialities within the Stockholm County.

were not compatible with each other [20]. All participants prescribed drugs electronically by a module integrated into the EHR.

Questionnaire results

Most of the participants declared that they were fairly experienced or very experienced computer users. Only four participants reported that they were quite inexperienced. Additionally, less than half of the physicians ($n = 7$) considered that they had small or some interest in computer science and IT, whereas the majority reported that they had large or very large interest. Only 33% ($n = 6$) knew about the concept of the SmPC. Seventy-one percent of participants mentioned in the questionnaire that they were not missing any information during the drug prescribing process. To the open-ended questions, the participants described their expectations from a decision support system in terms of both functional and informational supports.

They stated that a CDSS should:

- be able to indicate whether a drug is appropriate for the patient ('right drug to right patient'), what kind of effects a drug can be expected to have and whether there are other ('better') drugs with similar effects
- present up-to-date drug recommendations and dose suggestions
- prevent prescribing mistakes (by alerts or stopping prescribing)
- warn about drug–drug interactions quickly and even linked to laboratory data and diagnoses
- provide the prescribers with pharmacological knowledge
- save time and increase patient safety
- aid the decision making
- guide but not steer

Results from the focus group discussions

In the analysis of the data, we discovered two themes (A and B) about physicians' reported needs for information when prescribing drugs (Table 5):

A. Reported needs of drug information
A.1 Drug–drug interactions
A.2 Adverse effects of drugs
A.3 Data on risks for allergy or hypersensitivity with the prescribed drug
A.4 Drug dose related to age
A.5 Indication, duration and treatment plan
A.6 Recommended drugs and guidelines
A.7 Register containing pictures of the drugs
B. User friendly features/solutions in the EHR
B.1 Need for smart features linked to the EHR
B.2 Interactive functionalities

A. Reported needs of drug information

A.1 Drug–drug interactions During the FGDs, all prescribers emphasized the essential need for information about

drug–drug interactions. In addition, this information should be embedded into EHRs and linked to the patient's drug list. At present, patient specific data are not linked to the alert system in every EHR. When the alert system is not integrated into the EHRs the prescribers do not take time to search for this information.

'The most important issue when you prescribe a drug is that you have an indication to follow. I think we are good at finding the indications. But we are not so good at finding the contraindications and the possible risk factors. I do miss drug–drug interaction warnings given quickly and easily. When you look at many drug lists of elderly patients it is not uncommon that they take 10 to 15 drugs. I think we could improve on discovering interactions if we had a better system.'

However, participants were critical about the number of drug–drug interactions alerts presented in the EHR by the current CDSS. As a result, many clinicians habitually ignore the alert information. They wish to see alerts only for severe drug–drug interactions because the excessive number of interaction warnings can lead to alert fatigue and sometimes even the severe alerts will be ignored. According to participants, when the sensitivity of alerts is too high while the specificity is too low there is always a risk that physicians judge the alert information as invalid or irrelevant.

Respondents mentioned that another weakness of alert systems was that some drugs are missing in the drug–drug interactions database and this affects confidence in their reliability. Participants wanted to be informed when important drugs were missing from the system.

A.2 Adverse effects of drugs Some participants mentioned that information about the reversibility of adverse drug effects was missing, especially for serious adverse effects. Their patients often asked about adverse effects, and lack of information made it more difficult to give patients the confidence and motivation to continue treatment. The information about the reversibility of adverse effects of drugs is not needed directly while prescribing, but is suggested to be included as a 'read more' function, or a link for deeper and further information about a specific drug. In addition, participants expressed a wish to show patients a graphic presentation of the pharmacodynamics. The prescriber could subsequently explain the multifaceted process about the drug therapy to the patient in a pedagogical way to enhance subsequent adherence.

'I do miss the page for adverse reactions, if they are reversible or not and how fast they will reverse. I will have information about if the adverse reactions occurred directly or after some days or after some weeks when the medication stopped, or never? I see it as an issue to be able to show the information to the patient in a pedagogic way because I have to inform the patient how the drug acts in the body. This information is not very often shown so I need to guess. You have to tell the patient something – real or invented.'

Furthermore, the participants requested a function that makes it possible to search for adverse effects in the patient's drug list. This function would make it much easier for the prescriber to detect whether the patient's symptom is drug related or not. One example about searching for nausea was mentioned: when searching for this symptom the list of drugs causing this side effect would appear on the display.

'It would be interesting with the possibility to search for adverse effects. If the patient has this or that symptom a suggestion on what drug on the patients list could possibly cause that symptom should be presented. For example if the patient feels nauseous the information should show (with suggestions) which of the patient's drugs might cause nausea. You are just supposed to search on the patient's symptom and then the system should point out one of the drugs the patient is taking. If this drug was recently prescribed then there might be a connection. The patient might have many unexpected reactions and we have to make sure they are not caused by any drugs.'

A.3 Data on risks for allergy or hypersensitivity with the prescribed drug When the patient has an allergy or hypersensitivity to a drug, for instance penicillin, the participants requested that the system should alert automatically and stop the prescribing process. This was the only case when some of the participants raised the demands for a support system, which forced them to act according to the alert. In other cases, for example, for drug–drug interactions, the physicians want to make an active medical decision and do not want to be steered by the system.

'I started thinking about something strange that's not in this system. I continue to think about where to place the information about drugs the patient shows overreactions for. It should be so easy if you prescribe a drug and they show allergy against it. A message should show this. I've several times asked why they haven't put this information into the system.'

A.4 Drug dose related to age Some participants pointed out the difficulties with drug prescribing in children. One of the problems is the narrow arsenal of drugs which reflects currently the minimal research focused on children and drugs. However, prescribing for children, as well as for elderly people, has its own specific challenges because physicians often do not find information on recommended doses. The worries concern mostly prescribing too high doses to children. To minimize failures, the participants

suggested an automatic link between patients' weight and drug dose, i.e. the system should warn when the dose is too high related to the weight.

'More research on children. You have only very few choices of drugs to be used for them. This is frustrating. We need to get a wider range of drugs for children, because they have symptoms and today we only dispatch instead of treating. Sometimes we prescribe too high doses to children because there is no research about the drugs. If you always were forced to enter the weight of a child into the system, it should be able to calculate when the dose is too high. One suggestion is that the system displays the correct recommended dose directly. Or when the dose is too high in relation to the weight would it be possible to show a warning?'

Dosage is also a key issue when treating elderly patients where kidney function is reduced due to their age. One substantial improvement in the treatment of this patient group would be a function making the prescribers aware of the patient's renal function. The most optimal would be, if the system could calculate the approximate glomerular filtration rate (GFR) or the creatinine clearance automatically, as the participants said.

'It would be great if there was a link between the lab list and the patient's weight and creatinine so you can get an idea about the renal function. We have understood that there is room for improvements in the area of the renal function for our patients. It should be possible to calculate the clearance or GFR (if this information was passed to the system). This would make things easier for us.'

Participants had another suggestion for how to make GFR calculation technically possible. There should be a field in the health record system that makes it possible to enter parameters such as weight and age. Subsequently, the system calculates the desired medical information automatically. In this way doctors could compute for example the GFR value according to a patient's age and thereby prescribe right doses of drugs.

A.5 Indication, duration and treatment plan In cases when the drugs are prescribed by different specialists the prescribers desire to receive information about the indication, the treatment duration and the treatment plan for the chosen drug therapy. The participants mentioned that they often have to guess for what indication a certain drug was prescribed by a colleague, and how long the treatment should continue.

'And so many drugs prescribed for blood pressure too. What is the goal of the treatment? If you take Waran (warfarin) as an example, you ask the system to show the guidelines for dosage for this drug and then it would be shown so you could easily follow this specific drug. It would be nice to have it so.'

A.6 Recommended drugs and guidelines The participants pointed out that they wanted access to producer- independent and evidence-based drug information. In Stockholm County an essential drug list called the Wise List' for recommended drugs based on the best medical evidence and knowledge is published yearly [1]. These recommendations of essential drugs, as well as national guidelines, should be incorporated into the EHR directly according to the FGD participants.

'The technical solutions must be smart and the EHR and guidelines should be linked so they can communicate with each other. If we were able to transfer information between them then we have done something wise.'

A.7 Register containing pictures of the drugs The participants reported that they sometimes need a register where they can see a picture of the drug they are going to prescribe. Many patients have difficulties in swallowing and therefore it is important to give them additional information, e.g. the size of the tablet or whether it can be split.

'It would make things much easier if there was a register of pictures of the drugs. Nowadays there are many pills you are not allowed to chew or crush.'

The physicians even desired a searchable register for pictures of drugs. Sometimes they had to identify the patient's medicine because many times the patients know what the tablet they take looks like but they do not remember why they take it.

'The patient says –'yes, I am taking that pink tablet'; but they don't have any idea about the reason or the name of the pills.'

B. User friendly features/solutions in the EHR

B.1 Need for smart features linked to the HER All participants emphasized that any system needed to be easy to use. Different kinds of applications and smart features should be integrated into the EHR so the information can be found easily and quickly without any difficulties. The participants believed that ease of use was a prerequisite for the success of any technical development within health care. Clearly structured and logical layout of the information is also a crucial factor in the developmental process.

'I think everybody asks for a system that is user friendly. We are all interested in getting help in the decision-making process, but it must be safe and time saving. If the system is too complicated you will go back to paper.'

Participants gave suggestions about how to improve the existing EHRs by additional functionalities. The suggestions were: add different links and/or sheets to scientific articles and news about certain drugs, and provide a place for writing personal tips/comments. The participants also thought that the length of the text in the physicians desk reference was already too long and could be reduced by creating an overview of the headlines so they do not need to scroll through the whole document. Only a short description of the most important information on drugs would be considered helpful on the main page, with an overview following a link 'read more' to preserve the possibility to receive further information.

The participants also desired an incorporated calculator into the electronic prescribing system to calculate, for example, how long/how many days a prescribed package for a certain drug will last.

One of the doctors considered that a possible solution for development of additional features would be the development of an open source solution.

'It has been shown that open source or free software is in most cases safer because everyone can have access to it, can read and change the code and things like that. If many people are working in a system it can help to improve it. This also makes it safer, standardized and easier to communicate and stop; we have had that problem during all the years of having different systems, which are not able to communicate with each other at any places in Stockholm.'

B.2 Interactive functionalities The prescribers also wished to find sufficient information in more interactive ways. Participants' examples for interactive systems/functions were solutions where questions guided them forward in their information seeking process. For example, link diagnoses to treatment options in the following way: Hypertension? What to do? Would you like to choose this dose?

Additionally, many of the physicians desired to have a function for leaving messages to other caregivers regarding a specific patient.

'It is quite old fashioned but communicating should not be more complicated than some kind of mail box with email or similar. It is once again the issue of integration that can (solve) give the answer to this. The health record systems and electronic order entry systems should be able to communicate with each other everywhere in Sweden all the time – if the patients will allow it.'

Discussion

The important findings of this study were that physicians described specific and rich information about their needs for certain drug information and in addition, how this information could be presented within the decision support and electronic health record system (Table 5). It does not seem sufficient to give prescribers reliable drug information (theme A) without linking this information to EHRs, and making them useful and usable by smart features (theme B). Some physicians stated current SmPCs were too long. They could be reduced by creating an overview of the headlines so that one does not need to scroll through the whole document. The big challenge for the future will be to see which required information from physicians is possible to transfer from the e-SmPC to CDSS.

Warnings of hypersensitivity of patients to certain drugs should force prescribers to take action. This feature seems to be easily generated using existing information in the SmPC regarding the drug content and by restructuring the SmPC and linking it to patient specific hypersensitivities in the EHR. Drug–drug interaction alerts though are currently difficult to extract from SmPC texts since information about interactions is typically not classified regarding their clinical relevance. Alongside this, often the current text contains unspecific information with no clinical recommendation about how to handle the interaction [12]. Additionally, drug–drug interaction information has to be extracted from two different SmPCs (the two interacting drugs) which often are currently not consistent [21]. Another desired drug information component of any CDSS was dosage information linked to renal function and body weight. Within existing SmPCs, dosage information is generally available under the dosage section as well as in the pharmacokinetic section of the SmPC. Alongside this, sometimes it is hidden in other sections like those for special warnings and precautions. A restructuring of the SmPC information would allow the better usage, linkage and implementation of dosage information into the CDSS. Another point raised by the participants was that the lengthy text parts of the SmPC makes it difficult to present undesirable effects in an optimal way and make them searchable. A restructuring of this information would also help fulfil physicians' needs.

In this study, few prescribers had knowledge of the information in the SmPC. This might tell us that the physicians rarely are interested in the source of information, they just want to know that the information is documented by experts, up-dated, structured and short in order to be used. The main focus of the e-SmPC project is the reorganization of the SmPC, so that it guarantees a quick overview over the most important and necessary information parts. All support systems, like CDSS and CPOEs, must follow the prescribers' needs and be applicable in the hectic clinical practices [22]. It is well known that the systems used in health care are built by technicians without input of the actual users [22–24]. This is suboptimal as technical and medical worlds vary in a distinct way. The physicians' way of thinking and their working environment and processes should determine what information a

CDSS should contain. The technical world is objective, normative and rational, compared with the health care system, especially the clinics which are among other things more interpretive, multi-faceted and collaborative [22]. These differences often result in systems and/or technical solutions which are not user-friendly and do not make daily work easier [23]. Another difficulty, which has to be kept in mind, is that physicians' attitudes towards drug prescribing and their responsibilities for patient current drug lists vary within different medical specialities [6, 25, 26]. These various ways of physicians' understanding of drug prescribing, combined with today's lack of usability in some technical solutions, underline how comprehensive the issue on information sharing is in health care and the need to address this urgently through innovative solutions such as workable eSPCs [27, 28].

Nowadays all information is expected to be available and computerized. Therefore using technology and receiving enormous amounts of information electronically are increasing within the health care sphere. However, reliable information that underpins everyday prescribing decisions is hard to find [29]. In most countries there are thousands of drugs in the national registry. It is therefore a challenge for the physician to remain focused on prescribing a limited number of essential drugs, thereby simplifying drug selection and dosage, both of which are prerequisites for personalised and safe drug therapy [30]. Moreover, the usage of standard terms for different information parts would facilitate the development of a common IT infrastructure using the same key elements for information retrieval and presentation. In this case, computerized information systems in drug prescribing might be useful to help the physicians filter and find the most appropriate information [31–33]. In this way, the e-SmPC project could improve the situation by providing standardized, restructured and optimized information and deliver it to all countries within Europe.

Methodological considerations

The idea behind the focus group method was that group processes can help participants to explore and clarify their shared views in ways that would be less easily accessible in a one-to-one interview [15]. This method uses the group interactions explicitly. The group dynamics, on the other hand, raise ethical issues that should be considered. In this study, the respondents discussed freely and the questions cannot be seen as discriminating or sensitive. Consequently, we do not see any ethical implications in this study.

By using two different data collection methods we can conclude that FGDs combined with a questionnaire gave ample feedback from the respondents to meet our objectives. The questionnaire was collected before the group discussions with the purpose to explore the individual's experiences of and self-reported skills in computer use at the point of care. Otherwise, discussions in groups with others from the same profession might influence the ways an individual answers the questionnaire. The questionnaire provided us with further ideas what to ask the physicians in the FGDs. Interestingly, 71% of the participants ($n = 13$) mentioned in the questionnaire that they were not lacking any information while drug prescribing, whereas the FGDs revealed that the majority of the respondents wanted more information. This is not surprising since a written question is easy to answer and therefore not necessarily related to deeper reflection about the persons' perceived needs. In contrast, the FGDs provide more time for reflection and discussions with colleagues. Consequently, it is not surprising this method helped identify more needs of drug information at point of care. Thus, we saw that the group discussions enriched the results with more and deeper thoughts, and understanding of the physicians, which would not have been possible if we had only used questionnaires. As a result, we believed our dual approach was very suitable for exploring the requirements and needs on electronic prescribing tools. This contrasts with the study by Robertson *et al*. [34], who explored established general practitioners' (GPs) and trainees' experiences of using clinical decision supports for prescribing and subsequent needs using face-to-face interviews combined with a short survey completed at the end of each interview. This study did show differences in GPs' and trainee physicians' experiences with CDSSs [34].

The participants did treat different patient types; therefore, the act of prescribing can differ from one caregiver to another. This indicates they might need different support tools/systems when prescribing. In the analysis of the data, we were interested in commonalities and the collective thinking while prescribing, rather then comparing needs between the different groups of respondents.

In conclusion, it is a big challenge to take the computerization of health care to the next level and find standards and a model to support drug prescribing at the European level. The results from the current study showed the need for knowledge databases to provide more consistent information about new and existing drugs including dosing recommendations especially where concerns such as patients with renal impairment as well as potential drug–drug interactions. The next step of research is to investigate further physicians' needs in terms of content and the restructuring of eSPCs to enhance their utility among practising physicians to improve subsequent patient care as well as enhance compatibility with decision support system functionalities in other European countries.

Funding support

The study was in part supported by development resources from the Stockholm County Council, EMA (European Medicines Agency) and by grants from Karolinska Institutet in Stockholm.

Competing Interests

There are no competing interests to declare.

The views expressed in this article are the personal views of the author(s) and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

We are most grateful to the participating physicians who shared their time and experiences during the focus group discussions.

REFERENCES

1 Gustafsson LL, Wettermark B, Godman B, Andersén-Karlsson E, Bergman U, Hasselström J, Hensjö L-O, Hjemdahl P, Jägre I, Julander M, Ringertz B, Schmidt D, Sjöberg S, Sjöqvist F, Stiller C-O, Törnqvist E, Tryselius R, Vitols S, von Bahr C, for the Regional Drug Expert C. The 'wise list'– a comprehensive concept to select, communicate and achieve adherence to recommendations of essential drugs in ambulatory care in Stockholm. Basic Clin Pharmacol Toxicol 2011; 108: 224–33.

2 Seidling H, Al Barmawi A, Kaltschmidt J, Bertsche T, Pruszydlo M, Haefeli W. Detection and prevention of prescriptions with excessive doses in electronic prescribing systems. Eur J Clin Pharmacol 2007; 63: 1185–92.

3 Böttiger Y, Laine K, Andersson ML, Korhonen T, Molin B, Ovesjö ML, Tirkkonen T, Rane A, Gustafsson LL, Eiermann B. SFINX –a drug-drug-interaction database designed for clinical decision support systems. Eur J Clin Pharmacol 2009; 65: 627–33.

4 Kuperman GJ, Bobb A, Payne TH, Avery AJ, Gandhi TK, Burns G, Classen DC, Bates DW. Medication-related clinical decision support in computerized provider order entry systems: a review. J Am Med Inform Assoc 2007; 14: 29–40.

5 Eiermann B, Bastholm Rahmner P, Korkmaz S, Lilja B, Veg A, Wettermark B, Gustafsson L-L. Knowledge databases for clinical decision support in drug prescribing- development, quality assurance, management, integration, implementation and evaluation of clinical value. 2010. Chapter in Clinical Decision Support. In. published online Vienna 2010.

6 Rahmner Bastholm P, Gustafsson LL, Holmstrom I, Rosenqvist U, Tomson G. Whose job is it anyway? Swedish general practitioners' perception of their responsibility for the patient's drug list. Ann Fam Med 2010; 8: 40–6.

7 Seidling HM, Schmitt SP, Bruckner T, Kaltschmidt J, Pruszydlo MG, Senger C, Bertsche T, Walter-Sack I, Haefeli WE. Patient-specific electronic decision support reduces prescription of excessive doses. Qual Saf Health Care 2010 (in press).

8 Maxwell S. Rational prescribing: the principles of drug selection. Review. Clin Med 2009; 9: 481–5.

9 Teich JM, Osheroff JA, Pifer EA, Sittig DF, Jenders RA. CDS expert review panel. Clinical decision support in electronic prescribing: recommendations and an action plan. J Am Med Inform Assoc 2005; 12: 365–76.

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

11 EMEA Mission Statement. Guideline on core SmPC and package leaflet for radiopharmaceuticals. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/03/WC500104483.pdf (last accessed August 2011).

12 Wall A, Bateman D, Waring W. Variability in the quality of overdose advice in Summary of Product Characteristics (SPC) documents: gut decontamination recommendations for CNS drugs. Br J Clin Pharmacol 2009; 67: 83–7.

13 Revere D, Turner AM, Madhavan A, Rambo N, Bugni PF, Kimball A, Fuller SS. Understanding the information needs of public health practitioners: a literature review to inform design of an interactive digital knowledge management system. J Biomed Inform 2007; 40: 410–21.

14 Bastholm Rahmner P, Andersén-Karlsson E, Arnhjort T, Eliasson M, Gustafsson L-L, Jacobsson L, Ovesjö M-L, Rosenqvist U, Sjöviker S, Tomson G, Holmström I. Physicians' perceptions of possibilities and obstacles prior to implementing a computerised drug prescribing support system. Int J Health Care Qual Assur 2004; 17: 173–9.

15 Kitzinger J. Qualitative research: introducing focus groups. BMJ 1995; 311: 299–302.

16 Dahlgren L, Emmelin M, Winkvist A. Qualitative Methodology for International Public Health: Umeå International School of Public Health. Umeå: Umeå University, 2004.

17 Eliasson M, Bastholm P, Forsberg P, Henriksson K, Jacobson L, Nilsson A, Gustafsson LL. Janus computerised prescribing system provides pharmacological knowledge at point of care – design, development and proof of concept. Eur J Clin Pharmacol 2006; 62: 251–8.

18 SFS. Lag (2003:460) om etikprövning av forskning som avser människor (Svensk författningssamling). Available at http://www.notisum.se/rnp/SLS/LAG/20030460.HTM (last accessed February 2008). Cited February 2008 in Swedish. In; 2003:460.

19 Patton MQ. Qualitative Evaluation and Research Methods, 2nd edn. Newbury Park, CA: Sage Publications, 1990.

20 Kristianson K, Ljunggren H, Gustafsson LL. Data extraction from a semi structured electronic medical record system for outpatients: model for quality control of drug prescribing in diabetes care. Health Informatics J 2009; 15: 305–19.

21 Bergk V, Haefeli W, 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.

22 Wears RL, Berg M. Computer technology and clinical work – Still waiting for Godot. JAMA 2005; 293: 1261–63.

23 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.

24 Westelius A, Edenius M. Gaps between intended and actual use – turning problems into opportunities in health informatics. Int J Public Inf Syst 2006; Available at http://www.ijpis.net/issues/no2_2006/IJPIS_no2_2006_p3.pdf.

25 Montgomery K. How Doctors Think. Clinical Judgement and the Practice of Medicine. Oxford: Oxford University Press, 2006.

26 Groopman J. How Doctors Think. New York: Houghton Mifflin Company, 2007.

27 Howard R, Avery A, Bissell P. Causes of preventable drug-related hospital admissions: a qualitative study. Qual Saf Health Care 2008; 17: 109–16.

28 Chiang V. Commentary on electronic documentation in medication reconciliation – a challenge for health care professionals. Appl Nurs Res 2008; 21: 240–1.

29 Maxwell S. Evidence based prescribing is the goal, but prescribers still need education, experience, and common sense. BMJ 2005; 331: 247–8.

30 Sjöqvist F, Bergman U, Dahl M, Gustafsson L, Hensjö L. Drug and therapeutics committees: a Swedish experience. WHO Drug Inf 2002; 16: 207–13.

31 Teich JM, Merchia PR, Schmiz JL, Kuperman GJ, Spurr CD, Bates DW. Effects of computerized physician order entry on prescribing practices. Arc Int Med 2000; 160: 2741–7.

32 Bobb A, Gleason K, Husch M, Feinglass J, Yarnold PR, Noskin GA. The epidemiology of prescribing errors: the potential impact of computerized prescriber order entry. Arc Int Med 2004; 164: 785–92.

33 Sjöborg B, Bäckström T, Arvidsson L, Andersen-Karlsson E, Blomberg L, Eiermann B, Eliasson M, Henriksson K, Jacobsson L, Jacobsson U, Julander M, Kaiser P, Landberg C, Larsson J, Molin B, Gustafsson LL. Design and implementation of a point-of-care computerized system for drug therapy in Stockholm metropolitan health region – bridging the gap between knowledge and practice. Int J Med Inform 2007; 76: 497–506.

34 Robertson J, Moxey AJ, Newby DA, Gillies MB, Williamson M, Pearson S-A. Electronic information and clinical decision support for prescribing: state of play in Australian general practice. Fam Pract 2011; 28: 93–101.