

Refereed paper

Quality assessment of information about medications in primary care electronic patient record (EPR) systems

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ABSTRACT

Background Many different brands of primary care electronic patient record (EPR) software are available to general practitioners (GPs). Their ability to support GPs in improving prescribing varies greatly.

Objective To assess, using a ten-item tool, the quality of drug information provided by EPR software to support the appropriateness of prescriptions and to propose a list of quality standards for this type of application.

Methods The eight EPR programmes most used in general practice in Italy were assessed by a

multidisciplinary team using the ten-item tool. The tool evaluated information on single drugs and drug safety and information on prescription rules in force.

Results Out of eight EPR programmes assessed, none scored more than 55% of the maximum possible score. Two achieved scores higher than 50%, one scored 48%, four ranged from 32% to 39% and one obtained 22%. Information on drug safety, such as the ability to detect interactions, to monitor laboratory parameters or to get updated information on drug safety was particularly limited.

None of the eight EPR programmes contained drug information for patients, but two of them contained drug advertising.

Conclusions This project highlighted the poor quality of drug information provided by these EPR programmes. The ten-item tool seems suitable for assessing their quality. Based on this analysis, we have

proposed a set of ten quality standards for prescribing software.

Keywords: computerised medical records systems, electronic prescribing, medical informatics, MeSH, quality healthcare indicators, software validation

What this paper adds

- The role of electronic patient record (EPR) systems in improving patients' outcomes has not been definitely established; however, no other studies have addressed to what extent this correlates with the quality of the information contained in such tools.
- The information about medications available in EPR systems has many limitations, in particular regarding drug safety.
- A set of quality standards for EPR systems are proposed in order to strengthen the ability of these tools to support GPs in treatment decisions.

Introduction

Primary healthcare electronic patient records (EPR) were introduced years ago with the potential to improve the quality of care and the appropriateness of prescriptions, through reducing untoward side effects related to medications, decreasing testing and duplication of care, improving the management of particular conditions (such as multiple chronic diseases) and decreasing medical errors.

Many studies have addressed the role of EPR systems in health care but much less is known about the accuracy of these programmes in supporting prescribing decisions.^{1,2}

In Italy, a large range of EPR programmes is available to GPs. Their content and ability to support GPs in improving drug prescription is not well known, and decisions can be influenced by the quality of information sources upon which they rely.

In the absence of quality standards for EPR software in Italy, a study was set up with the aim of assessing the quality of drug information needed for appropriate prescription (e.g. information on adverse events, ability to generate drug alerts for drug interactions or for monitoring clinical parameters and availability of generic drugs, among others) using a ten-item tool. Another aim was to define, according to the results of the study and by consensus among the members of the Scientific Committee, a list of quality standards that EPR software should implement in order to facilitate the improvement of prescription decisions in primary health care.

Methods

The study, funded by the Regione Veneto, was conducted between July 2008 and March 2009, and involved a multidisciplinary team (MDT) composed of three GPs experienced in clinical audit and medical informatics, seven pharmacists and one clinical pharmacologist.

Before starting the assessment, the MDT stated the criterion for selecting the EPR software and defined the quality indicators and the topics to be critically evaluated.

In order to select EPR systems, use rate by GPs was set as the criterion. The eight most used EPR systems in Italy were identified and selected, having a user rate of between 1000 and 11 000 users. Suppliers were then asked to provide a copy of or access to each system.

The issues to be critically assessed by the committee addressed three main areas:

- 1 General information on individual drugs – three items.
- 2 Information on drug safety – three items.
- 3 Information on prescription rules in Italy – four items.

For each of the above areas a list of indicators was prepared in order to perform a quantitative and qualitative assessment. The three areas include a total of ten items (see Table 1).

Each item was used to assess information available on a variable number of drugs (from 1 to 12).

Drugs were selected to include some of the most prescribed drugs in primary health care including

Table 1 Software assessment grid

Item	Contents assessed	Maximum score	Drugs assessed (number)
1 Summary of product characteristics (SPC)	Presence of the following SPC sections: 1 Name of the medicinal product 2 Qualitative and quantitative composition 3 Pharmaceutical form (1 point) 4.1 Therapeutic indications (1 point) 4.2 Posology and method of administration (1 point) 4.3 Contraindications (1 point) 4.4 Special warnings and precautions for use (1 point) 4.5 Interactions with other medicinal products and other forms of interaction (1 point) 4.6 Pregnancy and lactation (1 point) 4.7 Effects on ability to drive and use machines (1 point) 4.8 Undesirable effects (1 point) 4.9 Overdose (1 point) 6.1 List of excipients 6.2 Incompatibilities 6.4 Special precautions for storage 6.6 Special precautions for disposal and other handling (1 point)	132	aripiprazole; digoxin; enoxaparin; etoricoxib; isotretinoin; lithium; nimesulide; piroxicam; pregabalin; rosiglitazone; rosuvastatin; warfarin (12)
2 Other information for GPs	Presence and quality of information other than SPC (1 point)	12	same as item 1
3 Information for patients	Presence of drug leaflet (1 point) Presence of other information sources for the patient for each individual drug (1 point)	16	amiodarone; chlorthalidone; digoxin; enoxaparin; isotretinoin; lithium; simvastatin; ticlopidine (8)
4 Drug interactions	Detection of interaction (1 point) Description (1 point) Severity (1 point) Suggestion to physicians (1 point) Book references (1 point) Date of last updating (1 point)	60	amiodarone + warfarin; carbamazepine + clarithromycin; clarithromycin + simvastatin; digoxin + hypericum; digoxin + furosemide; enalapril + NSAIDs; methotrexate + NSAIDs; sildenafil + nitroglycerin; simvastatin + fenofibrate; warfarin + NSAIDs (10 couples)

Table 1 Continued

Item	Contents assessed	Maximum score	Drugs assessed (number)
5 'Dear doctor' letters (DDLs)/ national safety advice letters	Availability of product safety announcements (PSAs) most recently published by EMA (and/or the Italian Drug Agency AIFA) (1 point) The DDL is made available at prescription (1 point) The SPC is updated, including DDL information (1 point for 5 drugs)	17	ceftriaxone; ketorolac; moxifloxacin; piroxicam; strontium ranelate; salbutamol (6)
6 Reminder and follow-up of clinical data	At first prescription a reminder appears suggesting the prescription of laboratory testing as indicated in the SPC (1 point) At subsequent prescription a reminder appears regarding monitoring of laboratory testing, as indicated in the SPC (1 point)	18	amiodarone; chlorthalidone; digoxin; enoxaparin; isotretinoin; lithium; rosuvastatin; ticlopidine; warfarin (9)
7 List of available generic drugs	Presence (1 point) and completeness (1 point) with regard to the list published by AIFA on equivalent drugs for each drug Presence of a banner in the software (1 point)	24	amlodipine; enalapril; gabapentin; lansoprazole; nimesulide; omeprazole; ramipril; simvastatin (8)
8 Generic prescription using INN	Prescription of drugs by their international non-proprietary name (INN) (1 point)	12	same as item 1
9 Prescribing rules in force	Presence of limits to drug prescription, drug reimbursability, conditions of delivery etc.	14	alendronate; aripiprazole; clopidogrel; enoxaparin; epoetin alfa; gabapentin; omeprazole; rosiglitazone (8)
10 CV risk card	Presence (1 point) and linking (1 point) at the time of prescription of simvastatin to cardiovascular risk charts published by ISS	2	simvastatin (1)
TOTAL SCORE		307	

some drugs having a narrow therapeutic index (items 1, 2, 3, 6 and 8). Ten pairs of drugs were selected for item 4, for which risk of interaction is recognised as 'relevant' in the scientific literature. For item 5, drugs were selected which have been the subject of recent product safety announcements (PSA), through 'dear doctor' letters (DDLs), produced by the European Medicines Agency (EMA) or by the Italian Drug Agency (AIFA). For item 6, selected drugs corresponded to drugs frequently used in primary health care for which some laboratory parameters should be monitored.

For item 7 we chose eight of the most used generic drugs. Item 9 concerns drugs whose prescription and/or dispensation are limited in Italy, and item 10

considered the drug most prescribed to control hypercholesterolemia and cardiovascular risk, linked to a limited prescription (i.e. AIFA 13).

To obtain a quantitative assessment for each item, a scoring ranging from 0 – 'no information available' to 1 – 'information available' was used for each drug considered within each specific item.

The total score for each item is the sum of the scores of its individual sub-items, multiplied by the number of drugs considered in that specific item. For example, item 3 (Information for patients) has two sub-items and eight drugs assessed. The total score is $2 \times 8 = 16$ and can oscillate between 0 and 16.

As the different items have different scores, a weighted score was calculated to make the contribution of every item equivalent. To do so, we have applied the following formulae:

Weighted score per item = (score obtained in the item/maximum score obtainable for that item) × total maximum score.

Weighted total score per software = Σ score per each item/number of item.

EPR software analysis

To test the indicator system and the procedure for scoring the different items and sub-items, two researchers (raters) performed a pilot assessment on a system. During follow-up meetings between the working group and the two raters, assessment and scoring procedures were standardised.

In the event of uncertainties or disagreement between the two raters, the assessment was discussed and resolved by the Scientific Committee.

In addition, for every system assessed, a GP for reference was selected from among the users. Based on the qualitative and quantitative assessment of each system, a detailed grid divided into two parts was

designed: a quantitative part for each item and sub-item (non-weighted score) and a qualitative part with comments on the results achieved. A total score could then be obtained for each system.

The scores were reviewed and discussed by the Scientific Committee which finally approved its use, and deemed that no ethical approval was needed for this study. The final results for each system were then sent to the software suppliers for their approval or to include eventual comments.

Results

Out of eight EPR systems assessed, none scored more than 55% of the maximum score. In only two cases were scores higher than 50% (52% and 54%) obtained; one system scored 48%, four ranged from 32% to 39% and one was around 22%.

Table 2 summarises the percentage score obtained for each item by different EPR systems. Figure 1 illustrates the maximum weighted score obtained by each EPR system.

Table 2 Percentage score obtained for each item (not weighted score)

Item	Software (%)							
	A	B	C	D	E	F	G	H
1 SPC	23	24	27	77	74	75	73	76
2 Other information for GPs	100	100	0	0	100	100	100	100
3 Information for patients	0	0	0	0	0	0	0	0
4 Drug interactions	13	3	30	0	10	13	15	77
5 Dear doctor letters (DDLs)	6	0	6	29	18	29	18	24
6 Reminder and follow up of clinical data	0	0	33	0	0	0	0	0
7 List of available generic drugs	25	42	46	33	75	50	63	50
8 Prescription by INN	0	100	58	100	0	100	100	100
9 Prescribing rules in force	50	79	86	71	57	64	100	64
10 CV risk card	0	0	100	50	50	50	50	50

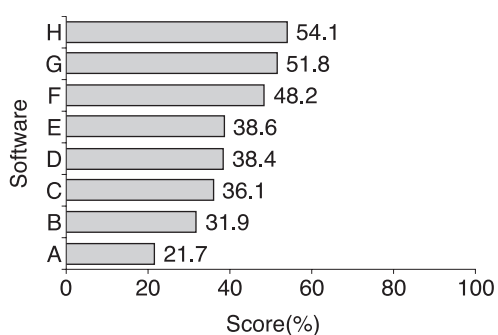


Figure 1 Software ranking (weighted score)

General information on drugs

Item 1

No software provided all the information contained in the summary of product characteristics (SPC) of each medicine. Differences in the texts were identified. In two out of the 12 drugs considered, therapeutic indications did not coincide with those of the SPC. In the case of digoxin, indications and dosages differed from the SPC in all software, and for piroxicam there were differences in five out of eight programmes assessed. Parts of the text were also found to be missing and in some cases the sections under examination did not appear at all. For example, in the different software, the contraindication sections were incomplete for between three and eight drugs. Parts of the texts in the section on adverse effects had also been deleted or changed. Some sections of the technical sheet could not be found in three EPR systems because monographs were used instead of the SPC. Figure 2 illustrates the maximum weighted score obtained on this item.

Item 2

In six software systems the only information on drugs available to GPs was for management purposes, such as price, reimbursability, dispensing rules etc. Monographs of the SPC were found in most of the software.

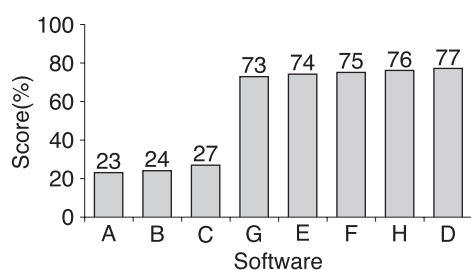


Figure 2 Final score for Item 1 – summary of product characteristics (SPC)

Item 3

None of the software provides drug information for patients.

Information on drug safety

Item 4

The type of interaction for each pair of drugs is provided in seven of the software programmes; the source of this information, however, is only indicated in three EPR systems. The clinical impact of the interaction (severity), the evidence it is based on, the course of action suggested to physicians and the date it was updated were found only in one software system (but they were not found for all ten pairs of drugs).

Figure 3 illustrates the maximum weighted score obtained on this item.

Item 5

Letters sent out to doctors updating safety information or indications were termed 'dear doctor' letters (DDLs). The DDL is a tool to update the safety profile and was not captured by any of the EPR systems. Some DDLs include an SPC update option; however, SPC was only updated in two brands of EPR, and not for all drugs.

Item 6

A prompt to perform laboratory testing (usually in a banner pop-up window) was only found in one software system, for just three out of nine drugs assessed.

Information on prescription rules and impact on drugs spending

Item 7

All software includes a list of generic drugs, but this list was not complete, and did not include the entire AIFA generic drugs list. Only in two systems was the list of generic drugs made available at prescription.

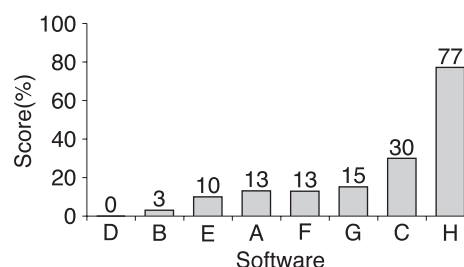


Figure 3 Final score for Item 4 – drug interactions

Item 8

In six out of the eight EPR systems assessed it was possible to prescribe drugs generically, using the international non-proprietary name (INN).

Item 9

Although limited conditions for prescribing were reported in all the software, the complete information was available in only one system. Other limitations concerning drug distribution were found in only four of the assessed software systems.

Item 10

Cardiovascular risk charts/calculators did not appear when the cholesterol lowering statin simvastatin was prescribed. In only one system did the risk chart appear during prescription issue.

Two out of the eight programmes contained drug advertising.

Discussion

The contents assessment of the most widely used EPR systems in Italy in terms of supporting correct prescription is rather disappointing. None of the systems assessed achieved 60% of the maximum score. In varying degrees, all the software under examination shared common problems and, in particular, the information contained in the technical sheet was found to be incomplete. This might be partly due to the fact that there is no official source of summaries of product characteristics available in Italy. Other shortcomings might be attributed to suppliers selecting sources in which the texts are not adequately updated and/or modified so that their content is no longer reliable. Information and updating on drug safety is also inadequate, particularly concerning the identification of severe interactions or raising the alert on the possible parameters to be monitored. To be helpful, such alerts should be selective and based on a quantitative risk assessment to avoid GPs cancelling or ignoring them.³ A large consensus on the most important safety features of EPR systems for GPs, like that proposed in the UK,⁴ is greatly needed in Italy. Besides this, information on the prescription rules currently in force in Italy is also deficient in the EPR systems assessed.

Although on the whole the international rate of EPR system use is still low⁵ the potential of these programs to improve the quality of health care seems promising.

Many studies have demonstrated the positive effect of these systems on several outcomes, including patient satisfaction,^{6–8} but other studies have reported no consistent association.^{9,10} Different methods of assessment as well as differences between EPR systems actually used in primary health care could explain such discrepancies. In Italy, there are many suppliers of EPR systems but there are no quality standards for such tools. The contribution of this study is to propose a tool to assess the quality of EPR systems, in particular for prescription related outcomes, and the development of quality standards required for EPR systems to effectively support drug prescribing.

A first limitation of the study is that the analysis was undertaken on EPR systems that do not include any patient records, hence the performance of the tools in real practice could not be verified. A second limitation is that no score was assigned to the qualitative assessment, which could have modified the final score of EPR systems.

The following quality standards are proposed for EPR systems which include prescribing:

- 1 Drug information contents
 - full text of SPC essential
 - information on drugs other than SPC, possibly from independent sources
 - patient leaflet and/or other independent and patient oriented sources of information
 - no advertising of drugs.
- 2 Drugs safety contents
 - database on severe interactions of drugs used mainly in primary health care. Such information should include: detection of interaction, description, severity, suggestion to physicians, references and date of last updating
 - communications on drug safety released by European or national safety bodies should be exhaustive and linked to the prescription of such drugs
 - there should be a reminder, at the point of prescription, of the most relevant parameters to be monitored when using new drugs and for drugs that have a narrow therapeutic index
 - include for each drug the adverse reaction reporting form making it easier for this to be completed in the case of any adverse reaction.
- 3 Prescription rules information
 - a complete and updated list of equivalent drugs marketed in the country (in our case Italy), listed by indication and dosage
 - prompts to prescribe generically, ideally using the INN
 - updated and exhaustive information on all the prescription rules in force.

Further research is needed to establish how EPR systems in Italy can improve patients' safety in clinical

practice. An international comparison with EPR systems used in other countries would also be useful in order to propose other tools and standards to upgrade EPR systems as well as providing a common assessment method to compare them.

Conclusions

This project has highlighted the low quality of information and support functions related to prescription found in the most widely used software systems in general medical practice in Italy. The assessment grid used in this study can be viewed as a suitable tool to assess the quality of information needed to support drug prescription. A set of minimum quality standards for EPR systems has also been proposed.

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CONFLICTS OF INTEREST

None.

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