Procurement of prescriber support systems

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Abstract: Supporting the process of medication selection and electronic management of prescriptions is a high priority issue in the eHealth strategies of many countries today. Procuring such systems can be quite difficult, especially if one should encourage suppliers from different countries to participate. The new ISO Technical Report 22790 [1] provides a new approach to facilitate this process by giving an international basis for specifying the functional characteristics desired. The paper describes the content of the report and discusses the procurement process in the light of the European public procurement directive and patient safety.

Keywords: procurement, prescriber support systems, decision support, ISO, management, standards, patient safety, risk management, EU-directives

Introduction

Health care is a complex system with high quality and safety demands, hence the need to be supported by high quality information systems.

Medication is an effective means of improving health though the use of medication is costly and introduce risks to patient safety. Many countries have listed information systems to improve the processes related to prescribing as a top priority for health IT. In order to get the best products at the lowest possible cost, it is important that the procurement of such systems can work effectively on an international or at least common European market. In the case of a publicly financed entity, procurement of IT support as other things must in the EU comply with the common legislation aiming at providing equal opportunities for industrial suppliers mainly SMEs from all countries. Also, for completely private health care organizations and restricting oneself to one country, procurement of complex IT systems is not easy.

A procurer may need to spend a lot of time and costs to define and express all the requirements on the product which for international competition may need translation to usually English (at least in the small countries). The suppliers need to spend a lot of time to try to understand and respond to the differently formulated requirements from each customer. In the end many functional features are described by the suppliers in their own jargon and comparisons of the different offers is a difficult task.

In many other fields, there has been a long term effort to develop technical standards that defines various product characteristics in order to facilitate the
procurement process, for both suppliers and customers. However, in the rapidly changing eHealth field such standards are rare. The great differences between countries regarding information on medicinal products and various degrees of maturity and strategies for national eHealth systems has made it difficult to develop international standards defining agreed requirements for all the relevant aspects of prescriber support systems.

ISO, the International Organization for Standardization has developed the new Technical Report ISO/TR 22790 Health informatics - Functional characteristics of prescriber support systems. This is not an international standard with normative provisions. It takes another approach. This informative document provides an agreed description of the various functionalities and information used in a common terminology which is intended to be helpful for procurement processes. The procuring organization (and possibly national bodies) will select among the many possible requirements from the ISO/TR according to local prerequisites and priorities. The advantage is that it is much easier to choose from existing well formulated requirements and most importantly, the suppliers also international ones can be familiar with all expressed requirements which speeds up and adds quality to the process. It has also been an objective of the ISO group that some requirements that are formulated here will provide important inspiration for suppliers to develop better products and for procuring organizations to demand functionality they may not have considered.

1. Methods

This study is based on a literature study of several basic documents on public procurement legislation in the European Union: (http://ec.europa.eu/internal_market/publicprocurement/legislation_en.htm), and in particular the "Public Procurement Directive [2].

It is also based on the legislative situation as regards Medical Devices in the EU (http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html) including the basic Directive 93/42 [3].

Regarding the standards development, the author has participated in the relevant working groups of SIS and of ISO/TC 215.

The development of the standard for Functional characteristics started in Sweden in 2001 with a working group for Medication under the Health informatics committee and SIS, the Swedish Standards Institute. The results were published as SIS/TR 2 in the Swedish language in 2003.

In the ISO/TC 215 Health informatics committee, a working group 6 for medication related issues was created and it was proposed to start the work towards an international publication on the same subject. This was approved in 2005 and the Swedish document was translated and much enhanced in numerous discussions in the working group with experts from Europe, Japan, Korea, Canada, Australia and the USA and following the international formal ballot and review during 2006. The revised final version was agreed in the meeting in Montreal in March 2007 and after review and final editorial corrections published by the ISO central office in Geneva, November 2007 in both French and English languages.
2. Results

2.1. The European legislation and prescriber support systems

The general provisions of the public procurement directive [2] has been implemented in national legislations within the European Union and apply when publicly funded health care institutions procure IT systems for prescriptions. These provisions aim to ensure that there is a fair open market ensuring that suppliers from all countries should be able to offer their products. This is partly ensured by stipulating rules for the technical specifications in a call for tender that preferably refer to European standards or in their absence to international standards. The technical report from ISO is not mandatory to use yet but it is in line with the general principle to use such documents to facilitate the understanding of the requirements.

In many areas which affect safety of persons, there are also other common European legislative requirements applicable for procurement and then not restricted to public bodies. In this field of information systems for health care use, the Medical Devices directive [3] applies and depending on the class of device various provisions apply and in many cases detailed technical standards from the European Committee for Standardization CEN or CENELEC in the electrotechnical field applies. There has been an ongoing discussion between the member states and the European Commission on how to classify and control the market for information systems that have no direct or indirect contact with the patient but still are used for health care purposes. In at least the first ten years of the life of this directive, such systems were not regulated. However, in recent years there has been a change of opinion gradually and even if it is at present unclear exactly how, the interpretation in many member states is moving to include products like prescriber support systems in the controlled area. In view of this it is quite possible that the application of reference documents like the ISO/TR 22790 will become mandatory in a not so distant future. In this year of 2008, the European standard organizations are developing a new work plan in response to a formal mandate from the European Commission to develop new standards as required for eHealth. Prescriber support systems are likely to be considered in this context. However, at this point in time the ISO/TR should be considered a valuable possible help for procurers but without formal requirements to use it from a European legal point of view.

2.2. The ISO/TR 22790 approach

The technical report ISO/TR 22790 from 2007 is intended to be used in the interaction between procurers and suppliers of systems to support the prescriber in all the different aspects. It provides a common conceptual model of information management related to the process of prescribing or ordering medication. The report provides a set of optional business requirements that could be selected by the buyer in a procurement process to be responded to by a tendering supplier. The report does not provide any mandatory requirements but as an informative document gives a common expression of various possible functions meeting different objectives for the health care system.

This document is intended to be used as a guide for a specific organization in formulating and prioritising a subset of characteristics tailored to national or local needs. The complete list of requirements of the ISO report is thus not intended to be a minimum set of requirements that all systems must comply with.
This report contains an introduction to the necessary concepts with agreed definitions and recommended terms and an overview of the relationships between different actors and information flows. The report also provides a functional model based on the objectives of the health care system:

2.2.1. Assessing the patient’s need for medication

The main method is using access to Electronic health records

2.2.2. Selecting a medication that can give an optimal result for the patient and current problem

A system can facilitate the use of Clinical guidelines for diagnosis and therapy recommendations. Systems may also provide advice on dosage and information on risks for adverse effects

2.2.3. Making cost conscious selections that can contribute to the cost containment of the insurance or publicly funded health care system as well as patient costs

This includes prices and comparisons of prices and recommendations of local drug committees. Also the consequences of the regulations for reimbursement. Examples: Positive list of allowed products, Negative list of disallowed, Reference pricing information or fixed pricing information. Also selection of packages sizes to minimize costs

2.2.4. Issuing a complete prescription in a time efficient manner

E.g. Easy renewal from medication history and using templates for complete prescriptions or dosage only

2.2.5. Transfer the information to a pharmacy

Via printed paper form

Patient data card

EDI via structured messages or other form of direct electronic communication. This can be direct to a pharmacy or via central prescription store or relaying agent

2.2.6. Communicating with the patient

Printing of patient medication list. Electronic communication

2.2.7. Communicating the medication orders to other health care professionals

Process support to medication administration and shared medication histories

2.2.8. Follow up

Functions to periodically follow up the total prescribing by the prescriber and/or unit in this system
2.2.9. Information resources needed to achieve the requirements

The TR defines a set of resources (databases) needed for the prescriber support systems to work. Many of these could be considered as part of a national information infrastructure that should be put in place to allow development and operation of such systems.

2.2.10. List of detailed characteristics to select from in a procurement process

This is the core of the ISO/TR 22790 and for each of the 90 plus requirements it is intended that the procurer indicate (in a call for tender document) how the customer is viewing each of these requirements:

- Not important = 0
- Desirable = 1
- Shall be available later at a defined time = 2
- Shall be available at delivery = 3

In the intended use of the standard the supplier indicate for each requirement the availability of the desired characteristics as:

- The function is not available = 0
- The function can be delivered at a defined time to be specified = 2
- The function is available at delivery = 3

3. Discussion

Standards from ISO and other formal standards bodies such as CEN, the European Committee for Standardization are used in many sectors to facilitate procurement including cross-border trade. In eHealth the major focus on standardization activities has been on interoperability specifications and they certainly have the potential to be of great importance although much of this potential has not yet been transferred to real implementations. This partly because many purchasing organizations have been unaware of them and also due to the fact that some interoperability standards require additional specification to be made in the form of a profile, often for national use, restricting optionalities and making the specification more concrete and hence allowing testing of compliance of products. A study performed for the European Commission during the eHealth Standardization Focus Group [4] demonstrated that many stakeholders are unaware of the fact that the current legislation in Europe actually mandates the reference to primarily European but in the absence of such, international standards in public procurement.

The new ISO/TR 22790 is one of a few international standards that address functional characteristics that are not only related to interoperability but also serving to provide optimal quality of the system used locally. The ISO/TS 18308 [5] is another example but the procurement aspect was not in the main focus of this publication as with the present standard report on prescriber support systems.

There are many advantages to provide some degree of common international framework as in this new publication even in a situation where there are strong differences between countries. It can lead to a more sound market situation and also be...
the basis for further work also on a European or International level aiming to go further in defining minimum characteristics.

The legislation on medical devices in Europe, the directive from 1996 has been considered to exclude requirements on much of the eHealth systems that are not directly connected to a device which directly influences the human body. However, this directive is currently under revision and governments are planning for a much increased control of all types of medical software in order to improve patient safety. It will be necessary to support such efforts with specific requirements in technical standards for different types of systems. We will most probably see an increased number of such standards in a near future but the whole process of improving software quality will take time. It also requires the building of appropriate certification schemes once the basic standards to test against will be present. In a first round most actors agree that a system with self declaration by the market authorization holder against an established formal standard is much better than no clear statements. This does not preclude that in some areas third party testing and certification may be needed.

It is sometimes claimed that publications from standards organizations are complicated and too technical to be possible to understand, especially by health care professionals participating in a procurement process. This is clearly not the case for the specific technical report described in this paper. This technical report is a means of facilitation and quality assurance of the procurement process. The report has been developed by a working group within ISO representing different relevant stakeholders. The procurement of IT-systems for health is often regarded as a business to be handled by the engineers. Using tools like this report, this does not need to be the case but active health professionals can easily understand and express their requirements. Other technical interoperability specifications will need to support some of the claims.

So far there is very little experience to report on actually using this new standard since it was published only a few days ago. Hopefully we will gain more experience from different countries in a near future.

4. Conclusion

A document such as the ISO/TR 22790 on Functional characteristics of prescriber support systems can be a great facilitator of procurement of such systems, contribute to the better functional of the international market and provide a basis for developing better and better solutions for enhanced patient safety in relation to medication.

References