TECHNICAL REPORT

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Health informatics — Functional characteristics of prescriber support systems

Informatique de santé — Caractéristiques fonctionnelles des systèmes de support prescripteur

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Contents

Page

Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 22790 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Medication is an effective means of improving health though the use of medication is costly and introduces risks to patient safety. Many countries have listed information systems to improve the processes related to prescribing, as a top priority for health IT. However, the great differences between countries regarding information on medicinal products makes it difficult to develop international standards for all the relevant aspects. This informative document provides an agreed description of the various functionalities and information used in a common terminology is intended to be helpful for the development of prescriber support solutions and for the procurement processes of such systems.

Health informatics — Functional characteristics of prescriber support systems

1 Scope

This Technical Report provides a common conceptual model of information management related to the process of prescribing or ordering medication. This Technical 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. This report shall not provide any mandatory requirements but, as an informative document, give 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 prioritizing a subset of characteristics tailored to national or local needs. The complete list here is thus not intended to be a minimum set of requirements that all systems must comply with. There may also be good reasons to further specify the generic characteristics presented here and to add other characteristics.

This Technical Report contains the following sections:

a) introduction to concepts with agreed definitions and recommended terms;

b) overview of the relationships between different actors and information flows;

c) overview of the functional model taking as its starting point the objectives of the health care system;

d) overview of the different information resources needed to achieve the requirements;

e) a list of detailed characteristics to select from in a procurement process.

The last part e) in Clause 6 is the main part of this Technical Report.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
active ingredient
ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicinal product

[ENV 12610]

2.2
central prescription store
repository for electronic prescriptions in a geographical area which receives prescriptions from several prescriber locations and serves several, possibly all, pharmacies in that area

2.3
magistral medicinal product
extemporaneous medicinal product
medicinal product manufactured in a pharmacy or a pharmacy department based on a recipe and intended to be used for one and only one subject of care

NOTE A magistral medicinal product is also a pharmaceutical product.

[ENV 12610 (modified)]

2.4
medicinal appliance
device or piece of equipment that may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

NOTE In order to be prescribable a medicinal appliance should fall within the purpose of prescribing as accepted by local rules/traditions in the area. The production of a prescription may also be required for formal reimbursement, restrictions on general sale of the appliance or need for labelling the appliance with individual instructions for use.

EXAMPLE Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, nappies for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

[ENV 12610]

2.5
medicinal product
any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making medical diagnosis or to restore, correct or modify physiological functions

NOTE Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this Technical report as medicinal products.

[ENV 12610]

2.6
medicinal product package
package
delivery unit of a medicinal product in an outer container

[ENV 12610]

2.7
medication order
documented instruction on intended therapy for an individual person with a medicinal product issued by an authorized health professional

NOTE A medication order contains information on the medicinal product(s), the intended dosage instruction and the period of time during which the medication was intended to be given.

2.8
medication record
record related to an individual person, which includes information about prescribed medicinal products, the intended dosage instruction and the period of time during which the medication was intended to be given

NOTE 1 A medication record should preferably contain information not only on medicinal products prescribed for community dispensation and home care but also medication ordered for administration to in-patients in hospital care.

NOTE 2 A medication record should be updated even when no prescription is issued to reflect current dosage and possible withdrawal of prescribed medication.

NOTE 3 A medication record considered here is part of the more general concept Electronic Health Record and as such other information should be associated to the core information in the definition such as date and place of recording, responsible person, signature etc.

2.9
payment guarantor
organization responsible for the total or partial reimbursement or payment of the price of the medicinal product

2.10
pharmaceutical product
product consisting of one or more ingredients

NOTE 1 A pharmaceutical product may have a different pharmaceutical form from the final intended medicinal product.

NOTE 2 This Technical Report does not make a distinction between a bulk product, an intermediate or a final product.

EXAMPLE 1 An amount of penicillin powder and physiologic solution to be mixed together are both pharmaceutical products. They are both part of a medicinal product, e.g. Combicillin 1 g.

EXAMPLE 2 Adepal (Fr) is a medicinal product with two types of tablets containing ethinyloestradiol and progresterone in different ratio composition. Each of these tablets are pharmaceutical products. They are both part of this medicinal product.

2.11
prescriber
healthcare person authorized to issue prescriptions

2.12
prescribing
process of creating a prescription

2.13
prescription
direction created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

[ENV 13607]

NOTE The term prescription alone should be avoided as it is colloquially used at random for the following terms used in prescription message standards: new prescription message, prescription set and prescription item. Further, it is also used to describe a prescription paper form. The use of the terms prescription set, prescription item and new prescription message, where appropriate, is recommended.

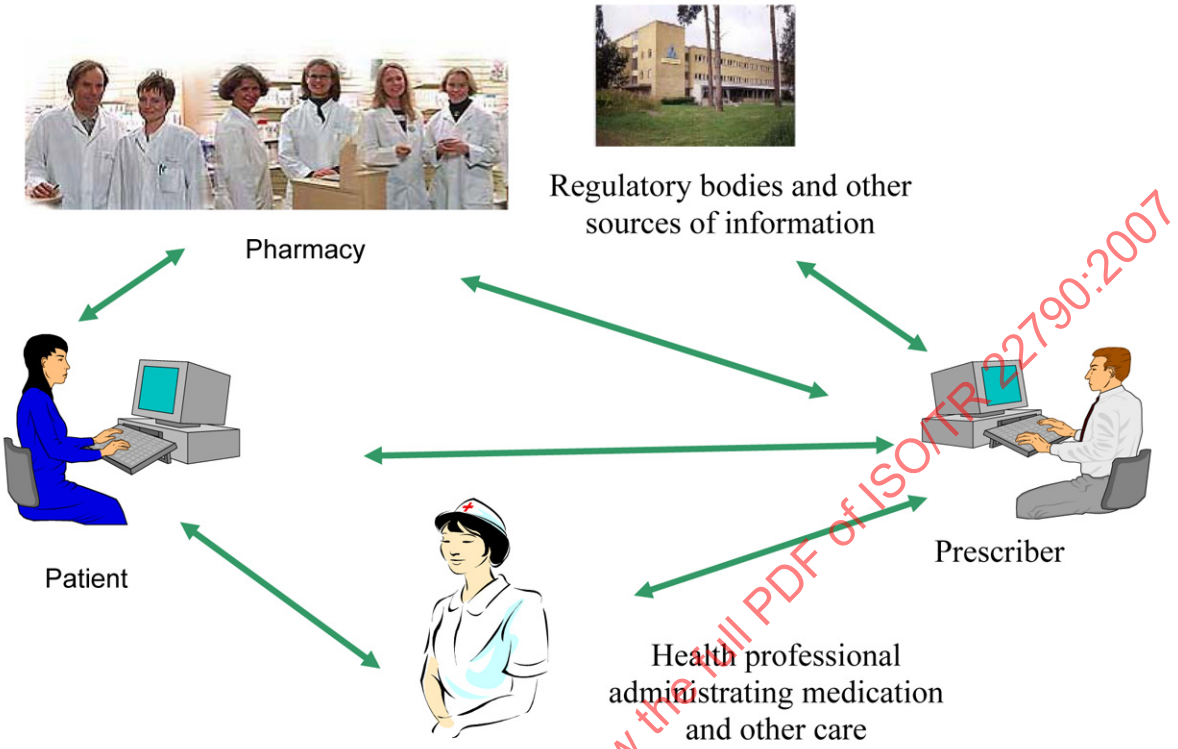
2.14
prescription item
specification created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of single medicinal product/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

NOTE A prescription item may contain administrative details needed for dispensing or derived from dispensing, but does not contain information about the prescriber or the subject of care for whom the prescription item is prescribed or to whom it has been dispensed.

2.15
prescription set
collection of one or more prescription item(s) prescribed and/or dispensed as a unit

3 Medication related communication — General model

3.1 Co-operating parties



NOTE This figure only depicts the core relationships essential for the provision of quality care. Communication with various bodies related to payment issues vary between countries and are considered outside the scope of this TR.

Figure 1 — Co-operating parties for prescription of medication

3.2 Information content

3.2.1 Prescriptions and medication orders

A prescription in this context is a direction of an authorized health professional (often a physician but in some countries also other professions have at least limited prescription rights) to a dispensing agent here called a pharmacy to dispense medicinal products to a patient.

Prescriptions have traditionally been made on paper forms or in some countries also oral prescriptions via telephone occur. Nowadays prescriptions may also be transferred electronically as structured data often referred to as messages or sometimes documents, a distinction which is not necessary for the purposes of this Technical Report.

There has been a confusing use of the term prescription which may be taken to mean either what is here defined as a prescription item for a single medicinal product or a set of prescription items grouped together on a form or an electronic message.

A medication order is a term that sometimes includes prescriptions as defined here but which also and preferably denotes the instruction by a physician to a nurse in a hospital to administrate medication to a specific patient. Such medication orders will in some countries be checked and be executed via a hospital pharmacy whereas medication orders in in-patient settings in other countries do not include pharmacists at all. There are certainly many similar characteristics of the requirements for IT systems supporting medication orders and for prescriptions and thus much of what is said in this document applies to both. However, there

are some requirements described herein that are not relevant (in case a pharmacy is not involved) and there are additional detailed requirements that should be made on systems, to support hospital ward medication management, that are not covered.

In many countries there are different classes of medicinal products that require special handling, e.g. for what is called narcotics or controlled substances. Since these vary considerably we do not attempt to detail such requirements in this document.

In some countries medication can be prescribed for single dose packaging performed by the dispenser where a period of treatment is specified rather than a total amount. This is a growing and important type of prescription that is included in the set of requirements even if it is by no means mandatory to support.

3.2.2 Medication Record

In this technical report Medication Record means a record kept or at least made available to the prescribers of medication that has been prescribed or ordered. It may take several different forms and have various contents. It is to be regarded as a part of an Electronic Health Record although Medication Records are in some cases kept in separate systems from the rest of the health record.

The patient is often but not always authorized to read his/her EHR including the medication record. In some cases the patient also provides information directly to a medication record e.g. on the actual dosage taken which may vary over time and/or the use of medicinal products that are not obtained via prescription.

A Medication Record must, as a minimum, contain information identifying a prescribed medicinal product, the intended dosage instruction and the period of time during which the medication was intended to be given (if known).

Additional related information such as allergies to pharmaceutical products etc is not considered part of the core medication record but rather as other relevant information from the EHR even if some separate medication systems would include such information.

NOTE With this definition, a record of medication dispensed at a pharmacy is not a Medication Record unless it is available to the prescriber.

3.2.3 Information on dispensed medicinal products

If information can be made available to the prescriber on what medicinal products have been dispensed to the subject of care, at least for the last year, this can be very valuable information. In some countries, e.g. Sweden, a national database is available which, with the consent of the patient, can be made available to any prescriber of the country. In other circumstances information on dispensing is sent to the person/institution that issued a prescription but no total picture is available. Information on dispensed products can often be made available to the patients just as medication records.

3.2.4 Request for dispensing

In some systems with electronic transfer of prescriptions, there is a possibility of separating the transfer of the prescription from the request to dispense. The electronically transferred prescription items may be stored in a central prescription store and then, upon reques,t be transferred to an individual pharmacy for dispensing. The dispensing request may also be directed to an individual pharmacy that has received an electronic prescription, particularly when one prescription may be used to request a number of separate dispensing actions at different times.

An alternative method for transfer of the prescription information to a dispensing agent/pharmacy is the use of a portable device such as a microprocessor card held by the subject of care. In this case the request for dispensing is a verbal activity when presenting a prescription holding card to the pharmacy.

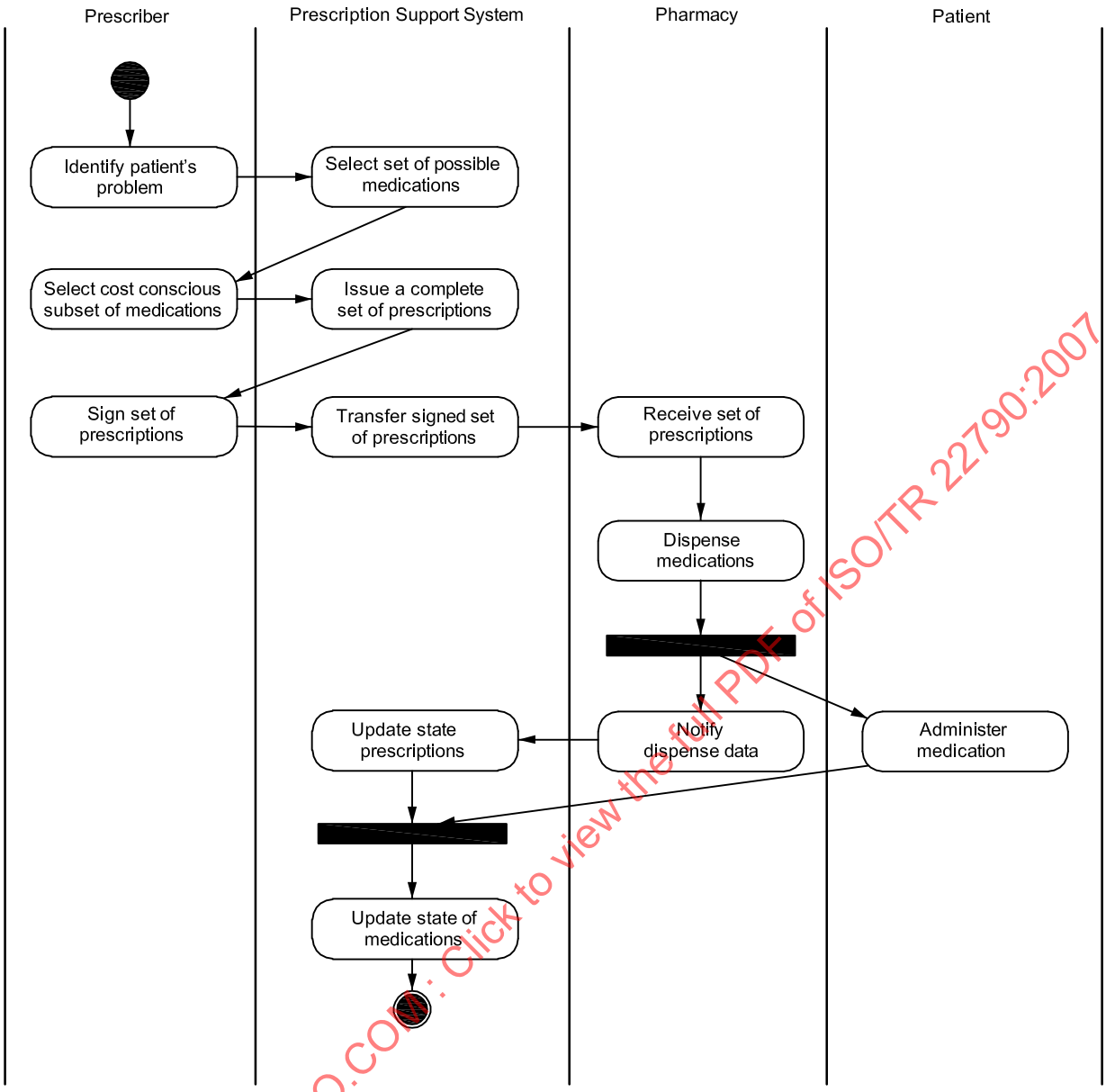


Figure 2 — State transitions of the prescription process

3.2.5 Knowledge information

This includes various types of information that is needed for the prescriber support system that is not related to the individual patient. It includes relatively static lists of information on available products and "on demand" request for specific prescription situations. Also included in this category are clinical guidelines although generally clinical guideline documents may contain lots of advice on issues other than medication and may need separate software to be managed. However, functional advice on medication to be prescribed should be possible to directly interact with a prescription support system.

3.2.6 Report on medicines taken

In order to obtain a complete picture of medication history it can be beneficial to also have in the outpatient situation a system of reporting the medication actually taken. This is still quite rare but implemented in some areas, particularly for patients with certain chronic diseases that are well educated on their treatment and instructed to vary dosage or use as required by current (sometimes daily) measures of objective or subjective symptoms. Various methods are applied from special devices to on-line reporting via web applications.

Another but only related issue is the reporting of compliance to physician's order which is known to be quite low. This can take the form of asking patients what medication they have actually taken over a certain period of time, irrespective of any known prescription. An alternative approach sometimes employed is to have home care teams checking the presence of packages of medicinal products (sometimes scanning bar code labels for easy entry) to be able to capture the actual medication history, of course respecting patient privacy and in dialogue with the patient or next of kin in the home.

3.3 Scenarios for electronic communication

3.3.1 Communication of a prescription to an identified pharmacy

The simplest sequence is the *prescriber* sending a *new prescription message* directly to the *dispensing agent,* possibly followed by a *prescription cancellation message* (these diagrams are adopted from ENV 13607).

— A new prescription message sent from prescriber to dispensing agent initiates the sequence.

— A new prescription message may be sent simultaneously to one or more alternate message receiver(s).

— A prescription cancellation message may follow, sent by the prescriber, cancelling the previously sent new prescription message. It will only have effect if received at the dispensing agent before dispensing and delivery of the medicine.

— The dispensing agent may be requested to forward the prescription cancellation message to alternate message receiver(s). This should only happen if cancellation is effective.

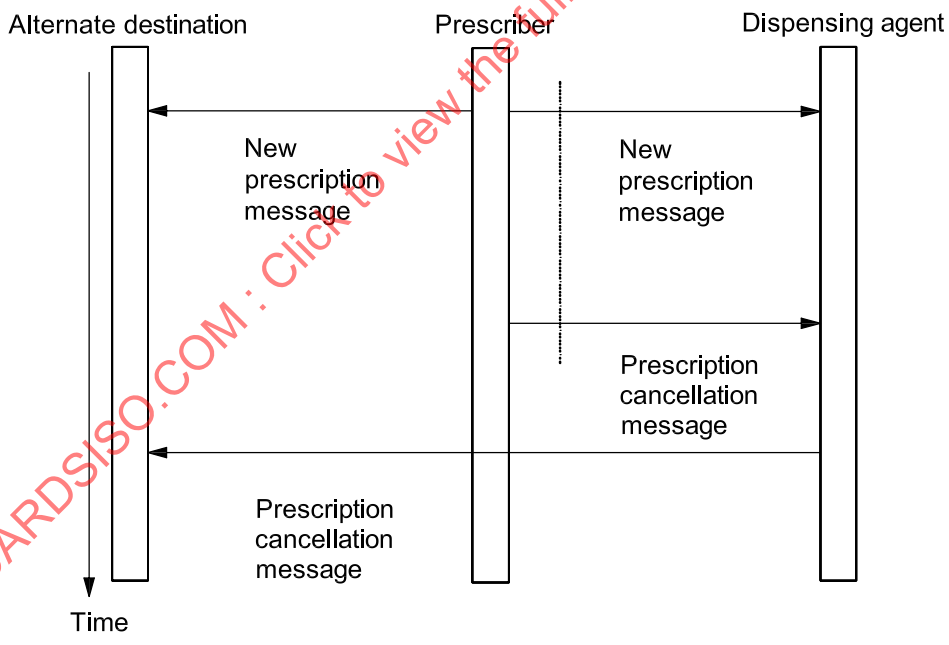


Figure 3 — Prescription message directly to dispensing agent

3.3.2 Direct communication of dispensing report messages

Another simple sequence is the *dispensing agent* sending a *prescription dispensing report message* directly to the *prescriber* and/or an *alternate destination,* informing on the medicine(s) actually dispensed, possibly followed by a prescription dispensing report cancellation message.

— The prescription dispensing report message sent from the dispensing agent to the prescriber initiates the sequence.

— A prescription dispensing report message may be sent simultaneously to one or more alternate destination(s).

— A prescription dispensing report cancellation message, sent by the dispensing agent to the same parties, may follow, cancelling the previously transmitted prescription dispensing report message.

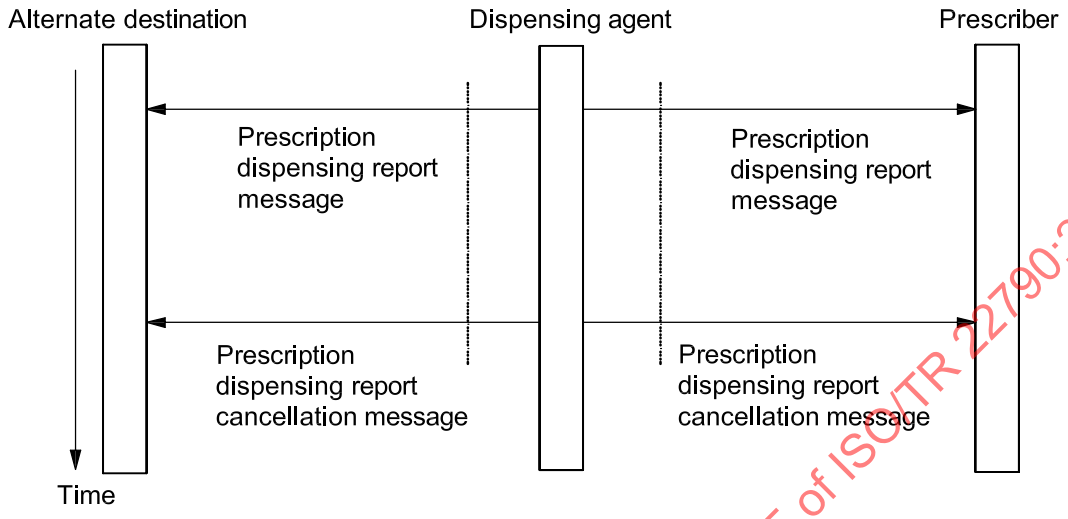


Figure 4 — Prescription dispensing report message

3.3.3 Prescription store/relaying agent

In addition to the direct communication between prescriber and pharmacy there are several possible scenarios being implemented in different countries with an intermediate.

One scenario is the following with a relaying agent that is storing prescription messages, awaiting a query from a dispensing agent to select a specific prescription message.

That there are several variants to this scenario which are not important for the purposes of this Technical Report.

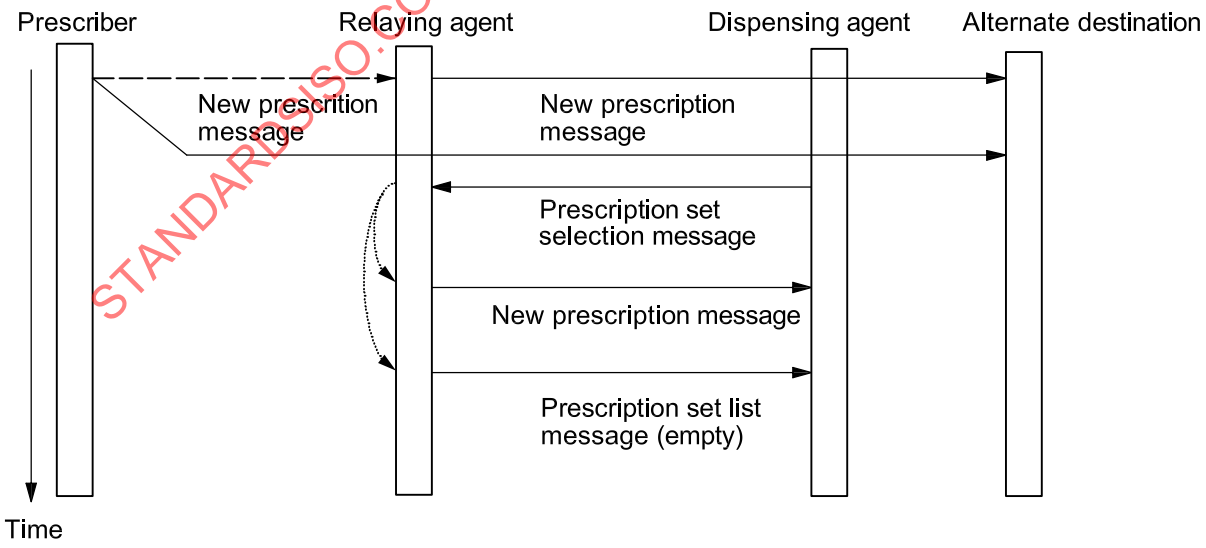


Figure 5 — Query service message communication, direct prescription set selection

3.3.4 Communication of medication record

The availability of a medication record is essential for many of the functions desired for prescription support systems. In some systems, where all prescriptions for a patient are done by essentially only one prescriber or at least organization with one record system, this is easily available. However, in many countries the real situation may be different. A patient may be given prescriptions from several different institutions during the same period. These may be different hospitals and outpatient clinics that in many circumstances will have different record systems (products and installations). In order to provide a complete medication record for the prescriber (usually with the consent of the patient required) several approaches are being pursued in different areas.

a) Prospective common record

A system may require all prescribers in an area to deliver the prescription information (and possibly medication orders, e.g. changing dosage) to a certain central repository.

b) Search and view function on the web

A system where a common web portal allows authorized prescribers and, in some jurisdictions, the patient to request information on medication record which will generate a request to all connected separate local systems which will retrieve current medication records and deliver them to the portal for view functionality.

NOTE The view-only function does not allow the use of decision support functions looking e.g. for interactions.

c) Request and transfer of local medication record

A system that is informed that information on a medication record is available at another or several other organizations may issue a request for such information which is then transferred to the requester in a structured format that allows the import to the local medication record. This may be regarded as a special case of the general communication of EHR information such as described by the ISO/EN 13606 series but there may also be other specialized messages restricted to medication record information defined for this purpose in various areas.

d) Patient data card

Finally, patient data cards have been used in some countries to provide a medication history to all prescribers. This may or may not be combined with the function of being dispensable prescriptions. This approach may have difficulty ensuring that a card is always present when needed to be updated. On the other hand the advantage of this approach is that authorization to access may be easier to control in an international context with a card than with a database solution. This is assuming that the patient is given the access rights to his/her card and can control access for a prescriber from a foreign system (usually another country).

4 The components of a prescription support system

4.1 Functional overview

A prescriber support system can assist the prescriber with the following tasks:

4.1.1 Assessing the patient's need for medication

— Electronic health records

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

— Clinical guidelines for diagnosis and therapy recommendations

— Advice on dosage and information on risks for adverse effects

4.1.3 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

— Prices and comparisons of prices

— Recommendations of local drug commitee

— Consequences of the regulations for reimbursement

EXAMPLES positive list of allowed products; negative list of disallowed; reference pricing information or fixed pricing information.

— Selection of package sizes to minimize costs

4.1.4 Issuing a complete prescription in a time-efficient manner

— Easy renewal from medication history

— Templates for complete prescriptions or dosage only

4.1.5 Transfer the information to a pharmacy

— Via printed paper form

— Patient data card

— EDI (Electronic Data Interchange 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

4.1.6 Communicating with the patient

— Printing of patient medication list

— Electronic communication

4.1.7 Communicating the medication orders to other health care professionals

— Process support to medication administration

— Shared medication histories

4.1.8 Follow up

— Periodically follow up the total prescribing by the prescriber and/or unit in this system

4.2 Information needed for prescription support

4.2.1 Registered medicinal products

This refers to a list of all available medicinal products in a geographic area. This usually includes as a minimum, the name of the product, a unique identifier, dosage form and strength. It may include package sizes and prices.

4.2.2 Basic pharmacological information

This refers to information about each product which, in addition to specifying the information from 4.2.1, also specifies information on indications, contra-indications and dosage recommendations but usually several more items. In the European Union, the common regulation specifies a summary of product characteristics which is available in all of the EU member states for each product.

Suppliers of such information are of two types.

a) Manufacturers or associations of manufacturers provide information for which they are responsible. This is often channeled through a third party service provider (a database producer) to the end users. This may include additional information, see 4.2.3.

b) Information on the products which is officially approved by the regulatory bodies in each country. The information may be provided directly by the authority or through a third party service provider. This may include additional information, see 4.2.3.

4.2.3 Extended pharmacological information

This is information that provides the scientific evidence of the claims in the basic pharmacological information or additional claims on e.g. indications recommended dosages or adverse effects. The providers may be found on the open internet or assembled together by some national source at least for selected groups of medicinal products.

4.2.4 Recommendations from the local drug committee and other agencies on reimbursement rules

In a health care organization, a local or regional committee may issue recommendations that are subsets of what is generally available in the country. They may simply indicate if a product is recommended or not (sometimes based on price consideration) or indicate more complicated advice dependent on indication or previous results such as when there is a recommendation of the first hand selection for e.g. hypertension and then a second choice if the first does not give the desired results. This information on reimbursement rules may include a positive list of allowed products, negative list of disallowed products, reference pricing information or fixed pricing information.

4.2.5 Clinical guidelines for various problems

Clinical guidelines may be defined for a variety of purposes, many of them not structured to allow computer processing. Of interest here are clinical guidelines that provide medication advice but where the search structure take as its base a problem or diagnosis. Ideally for some of the requirements described in 4.2.6 to 4.2.8, this source should allow direct linkage from the guideline medication description that may often be in the form of a generic active ingredient name to a list of medicinal products in the prescriber support system without the need for re-entry of information. There is currently little available in a form that follows any standard.

4.2.6 Patient medication history

The patient medication history includes a current medication record as well as previously prescribed medicinal products. For the core clinical decision, only the product and dosage is relevant but for other purposes so are the availability of information on amounts prescribed at certain time points and possibly the dispensed packages.

4.2.7 Other parts of the patient health record

For adequate decisions on medication the prescriber needs access to often large parts of a health record although certain elements are more frequently relevant:

a) problem or diagnosis;

NOTE Not necessarily the same as indication, c.f. cancer and pain.

b) information on certain lab tests indicating renal and liver function;

c) body mass and length;

d) age;

e) allergies or other hypersensitivities;

f) certain genes which influence effect or metabolization.

4.2.8 Templates to ease prescribing

Such templates may contain all information, including dosage, for a certain class of patients.

5 Detailed list of possible requirements

5.1 The intended use

The purpose of this list is to give buyers and suppliers of systems a common conceptual framework to describe different requirements.

This may need to be adapted to national available knowledge resources in order to be operational.

After each standard requirement description the potential buyer, e.g. for a call for tender, indicates how important a requirement is:

— not important = 0;

— desirable = 1;

— shall be available later at a defined time = 2;

— shall be available at delivery = 3.

In the same document the supplier can specify available functionality in his product:

— 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.

The standard list of requirements will thus not assign any minimum requirement, only a means of defining them.

5.2 Assessing the patient's need for medication

Number	Characteristic	Buyer's level	Supplier's level	Comments
5.2.1	While using the prescription support system, all information from the available EHR is available for inspection e.g. by flipping through different parts of the record without permanently exiting the prescription module with perhaps only partially filled information. This function may be solved by the use of different windows that are visible at the same time.			
5.2.2	EHR information on hypersensitivity to medication is always visible in the prescription module. The system can distinguish between different levels of severity of reactions and particularly observe the regulation to display such intolerance that may cause a serious threat to the patient's life to be display with the text WARNING.			
5.2.3	The total current medication list from the unit is displayed at the start of issuing a new prescription.			
5.2.4	The list of active medication can be supplemented by importing anamnestic information from other record systems of other units or from the patient's own telling. It may be necessary to supply less complete information in such cases with a pharmacological group (perhaps an ATC or alternative code) without giving strength, dosage or amount.			
5.2.5	The patient's total current medication can be shown with additions from other health care organizations in addition to what is prescribed in the "own" unit. NOTE the requirement here is only for a view function not that the external information is imported in a structured way to the record of the system. Summary vs. detail (dispensing vs. prescribing and information on active use).			
5.2.6	The patient medication record can be imported from records of other units.			
5.2.7	Information on length, weight and relevant lab results are available in a knowledge management system of the prescriber support system without the need for explicit reading and memorizing of these data.			

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

Number	Characteristic	Buyer's level	Supplier's level	Comments
5.3.1	The system allows searching in a knowledge base with guidelines for medication treatment, taking as an entry the patient problem (or diagnosis). Indicate if the problem/diagnosis can be taken from the electronic health record (e.g. by selecting the current problem). Indicate which knowledge sources (from whom) and what it covers in terms of diagnoses (groups).			
5.3.2	The system allows searching on the internet to find guidelines for medication treatment. Indicate if this is a free search or a short list of available sources.			
5.3.3	The system allows the local input of guidelines for medication treatment of certain problems/diagnoses.			
5.3.4	The system includes guidelines in a form adapted for distribution to the patient.			
5.3.5	The system allows a direct link from the problem- oriented knowledge sources to the selection of specific products by “clicking” into a hierarchy rather than just viewing and remembering.			
5.3.6	The system provides basic product information provided by the market authorization holder (e.g. in Sweden FASS issued by the Swedish pharmaceutical industries). Indicate in a comment the mechanism to make this updated.			
5.3.7	The system gives access to Summary of Product Characteristics which is a European Union regulated way of uniformly describing the characteristics of a medicinal product and issued in the national language by the 27 country authorities. This is information authorized by the regulatory body.			
5.3.8	The system gives access to the register of products available by a specific pharmacy (or a pharmacy group, in Sweden one national corporation which includes price information).			
5.3.9	The system can issue a warning for a known risk of interaction in a total analysis of the current medication record while selecting a new product. Also indicate if a warning can be issued without a new prescription but including new knowledge.			
5.3.10	The system can issue a warning if a dosage is prescribed which is outside the normal range (minimum and maximum). Indicate if only maximum dosages are provided. This may be given per dose or per day.			
5.3.11	The system gives advice on adequate dosage for a specific patient by the combination of information from the knowledge source and e.g. the following information from the EHR, age, sex, weight (surface area), renal function data e.g. creatinine (clearance) or GFR as well as recorded pregnancy, lactation and smoking.			
5.3.12	The system gives access to extended pharmacological information with scientific background and evidence base for any claims on the effects.			