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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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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.

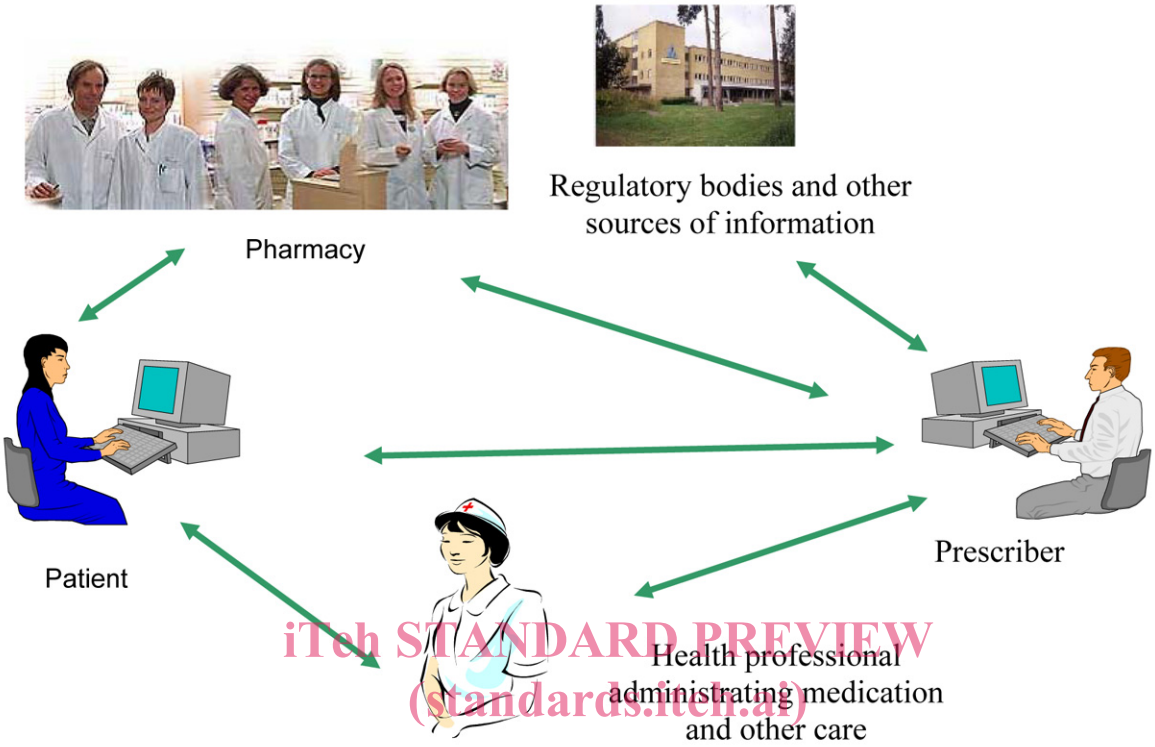
2.14
prescription item
specification created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of single medicinal product/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal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