TECHNICAL SPECIFICATION

ISO/TS 19293

First edition
2018-04

Health informatics — Requirements for a record of a dispense of a medicinal product

Informatique de santé — Exigences relatives à un enregistrement de la délivrance d'un médicament

Reference number
ISO/TS 19293:2018(E)

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

The record of dispensed medicinal product(s) plays an important role in the patient safety domain. When a medicinal product has been prescribed, it then has to be dispensed before being administered to the subject of care. The dispensed product may correspond exactly to what was prescribed, but it may equally be different for various reasons, such as substitution, unavailability of medicinal product in the prescribed dosage or route of administration, etc.

There are further situations, when medicinal products are dispensed or supplied without any prescription. This should also be captured since a non-prescribed medicinal product may have interactions or other influences with prescribed medicinal products.

When creating a list of a patient's medication history, prescriptions can provide valuable information, but the dispensation is sometimes considered a better indicator of the medication taken by a patient than a prescription, i.e. although neither is information about compliance or administration, the dispense record is many times considered a more reliable indicator of actual medication use than a prescription (even if it also not an unequivocal indication of administration). Therefore, there is a need to capture the dispensation, as the dispensation either completes the logical chain from prescription to administration, or provides information for later prescriptions or dispensation, for instance, if interactions can be anticipated and avoided.

The dispense record should provide information in such a way that it is accurate and reusable; for example, statistics and other information can be collected across the dispensers for public health purposes, or for regulatory needs (e.g. controlled substances control).

Additionally, the dispense record is a traceability element. For clinical purposes, it supports recording the process from prescribing to administration. For supply chain, it allows reconstruction of the supply chain, for example, in the contexts of recalls or supply chain integrity.

This document defines the information that may be contained in a dispense record, and the applicability and constraints of such information. It defines a set of conditions that should be verified on detailed interoperability implementations.

This document also defines requirements for when the dispense record should be issued in the cases where it is needed. This is not required as a specific moment in a process — which would depend on a variety of processes and factors — but by providing a common set of activities that are included in a dispense.

This document addresses the requirements which are to be fulfilled by the systems that record medicinal product dispensation. It is based on use cases which are chosen from the daily life within the same jurisdiction, and when the prescription and dispensation have occurred in different jurisdictions. This document relies on the assumption that prescription and dispensation are supported by medicinal product dictionaries that ensure interoperability.

One key aspect in this document is that the notion of dispense can vary according to context (hospital versus community), jurisdiction, and other factors. The uses of the dispense record can also vary. These variations can have a strong impact on the definition of dispense.

For example, the process of dispensing a medication varies considerably between hospital and community settings, and even inside a hospital. Another example is if the dispense record is used mostly for operational concerns (reimbursement), the relevant dispense information is obtained when the medication is retrieved for that patient. But if the dispense record is supposed to support clinical systems, it may be better to capture information until the medication is delivered to the patient or handed to a next of kin and thus presumed to be delivered to the patient. It is important that the medication dispense record contains sufficient information to support these different and variable uses.

Another example of process variability is how a dispense record can be a consequence of an electronic prescription. However, in some cases, there are dispenses without a prescription. The scope of this document considers dispensing with or without the existence of a prescription.

