

Conceptual bases for the standardization of calculation approaches for assigning exposure duration to single drug utilization records in multi-database studies

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Background

In observational multi-database studies, prescribing, dispensing or administrations records, are usually leveraged for exposure assessment. The number of days of treatment (DOT) associated with each drug utilization record of interest can be calculated in several ways. Therefore, standardization of calculation approaches is paramount to document study methods and facilitate comparison of results between data sources.

Objectives

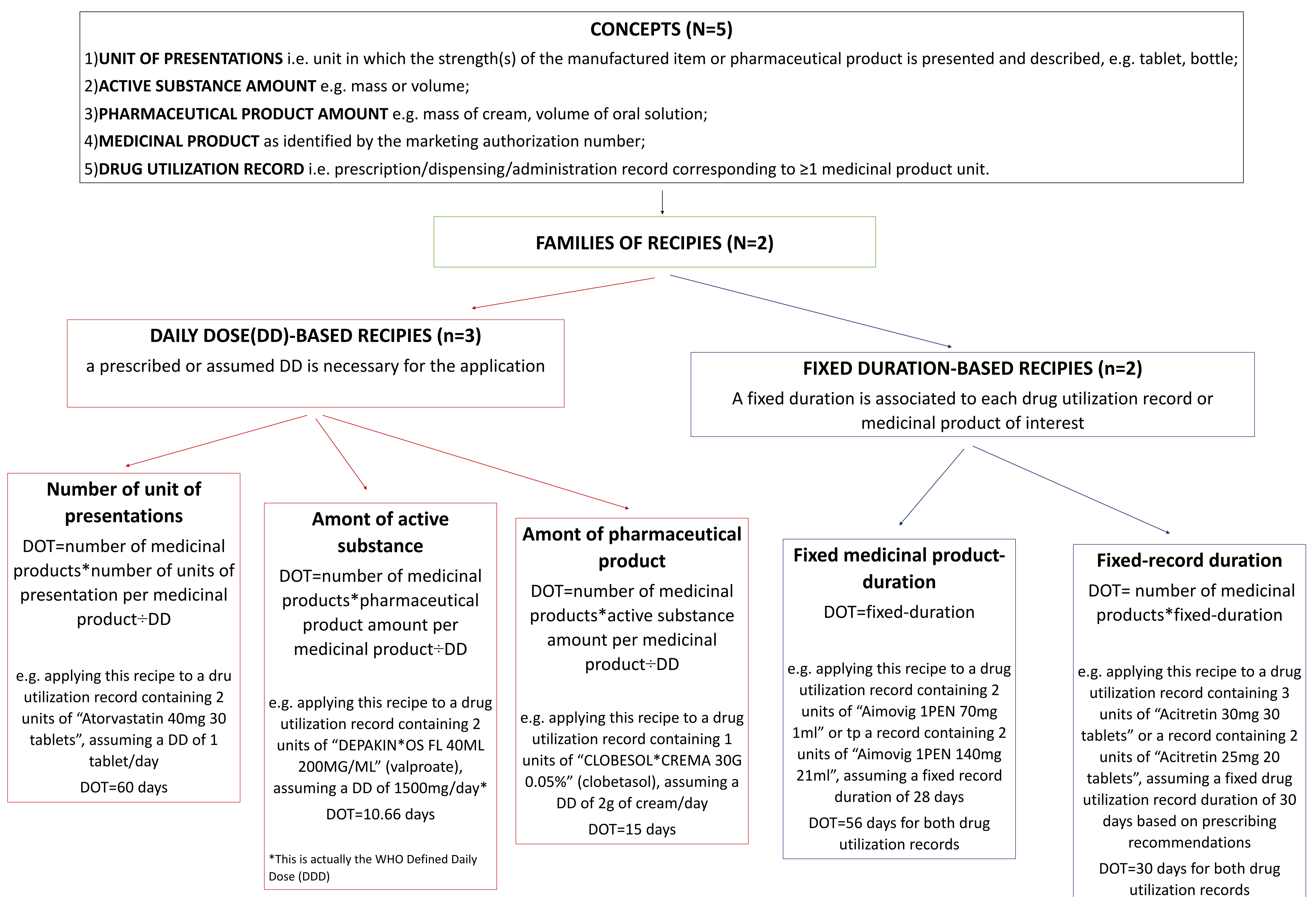
To define a set of calculation choices (recipes), for standardizing DOT calculation of single DURs from any observational healthcare datasource.

Methods

A list of recipes to calculate DOT from electronic DUR was created based on literature search and researchers' experience. Concepts needed to implement the recipes were defined using the standard terms of the European Directorate for the Quality of Medicine.

Results

Five concepts corresponding to parameters possibly recorded in the data source of interest and useful to calculate DOT were identified. A total of five recipes were created and classified in two main families according to calculation approach chosen by the investigator: Daily Dose(DD)-based (n=3) recipes and Fixed duration-based (n=2) recipes.



Conclusions

We provided comprehensive conceptual bases to standardize calculation approaches to assign exposure duration to drug utilization records. Within this framework, investigators can choose a daily dose-based recipe whenever the true daily dose is considered reasonably predictable, according to the available data. Otherwise, when the true daily dose is difficult to predict, a fixed duration recipe might be preferred if it is considered a more reliable assumption based on the expected utilization pattern.