

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, heterogeneous electronic drug utilization records (i.e. 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 across data sources and distinct multi-database studies.

Objectives

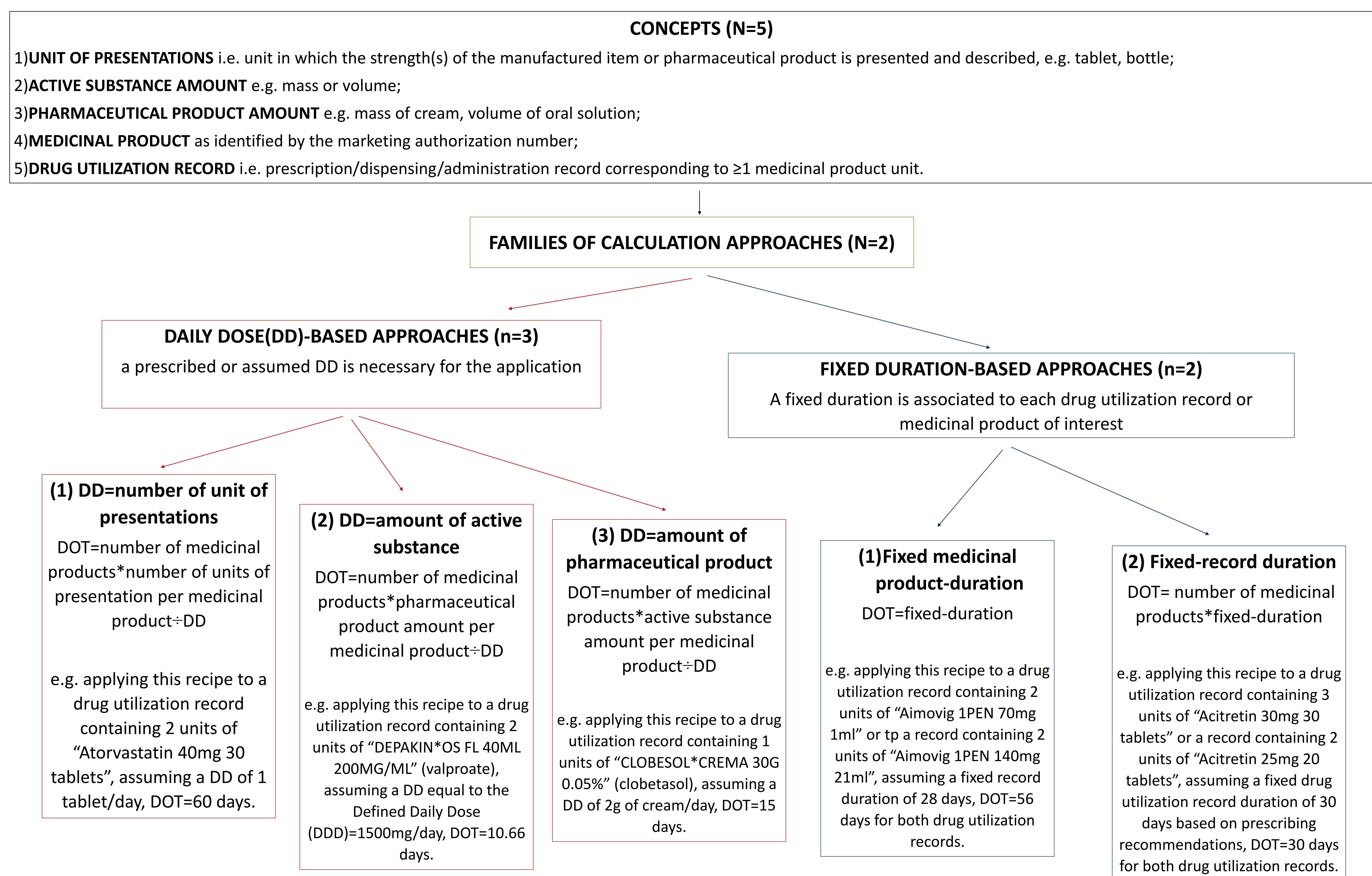
To define a set of calculation choices for standardizing DOT calculation of single drug utilization records from any observational healthcare datasource.

Methods

A list of calculation approaches useful to assign DOT to any electronic drug utilization records was created based on literature search and researchers' experience. Parameters needed to implement the recipes were defined using concept from 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 calculation approaches were created and classified in two main families according to the 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 for the standardization of calculation approaches useful to assign exposure duration to any type of single drug utilization record. Within this framework, investigators can choose a daily dose-based recipe whenever the true daily dose is considered reasonably predictable. Otherwise, a fixed duration recipe might be preferred when the true daily dose is difficult to predict and a fixed duration of the drug utilization record/medicinal product of interest represent a more reliable assumption based on the expected utilization pattern.