Automatic Quantification of Abbreviations in Medicine Package Leaflets and Their Comprehension Assessment

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ABSTRACT

Medication errors occur as a consequence of misunderstandings with abbreviations and symbols (A&S). According to pharmaceutical regulations, A&S should be avoided in medicine package leaflets (PLs). Using a sample of 531 Portuguese PLs, this study aims at: quantifying A&S in PLs, comparing how A&S were distributed, identifying non-recommended units of measure, checking whether the full meaning of abbreviations was presented, and determining educated peoples’ interpretation of A&S. A computational tool was used to identify A&S. Participants’ comprehension was evaluated with a questionnaire. Overall, 828 different A&S were identified. PLs of prescribing medicines contained a significantly higher proportion of A&S than PLs of over-the-counter medicines (chi-square = 13.4; p = 0.004). A&S with their meaning not fully described and units of measure with a non-recommended format were identified. Only 9.9% of the questionnaire answers were correct. Portuguese PLs may need to be revised. The software used is appropriate to checking A&S in PLs.

KEYWORDS

Abbreviations, Medicinal Products, Package Leaflets, Patient Safety, Readability

INTRODUCTION

Currently, there is an increased interest in shaping medical information, as a way of ensuring readers’ adequate use and comprehension of written health materials (Vromans et al., 2013). The use of abbreviations and symbols (A&S) may be considered a more efficient way of transmitting certain types of written information,
because their use may contribute to the simplification of certain expression in texts (e.g. abbreviations of long terms) (Brunetti et al., 2007) or to the standardization of information between countries with different languages (e.g. chemical symbols used worldwide) (Moore, 2004).

On the other hand, it is possible to identify some reports of medication errors due to the inappropriate use of A&S in the literature:

- 643,151 medication errors were reported in the program MEDMARX¹ between 2004 and 2006: 29,974 medication errors (4.7%) were attributable to the inappropriate use of A&S by health professionals with the death of some patients; the abbreviations associated to the occurrence of more medication errors were: “QD” instead of “once daily” (43.1%), “U” instead of “units” (13.1%), and “cc” instead of mL (12.6%), and the health professionals with a higher registration of medication errors were physicians (78.5%), followed by nurses (15.1%), and pharmacists (4.2%) (Brunetti et al., 2007);
- 5470 medication errors were reported by health professionals under the Madrid community program (2008 to 2009), of which 3412 occurred in ambulatory care units (56.9% associated with prescription errors, and 7% to the inadequate use of medicines by patients), with 53 of these errors also relating to the incorrect interpretation of abbreviations and units of measure (Taravilla-Cerdán, Marrubia-Muñoz, Corté-García, Cruz-Martos, & 2011).

Package leaflets (PLs) or the consumer medicine information are relevant documents for the safe use of medicines (Stahl, Brauer, Zeitler, & Gulich, 2006). There are legal requirements on the use of abbreviations in the PLs of medicinal products for human use, i.e. the consumer medicine information. In accordance with the “Guideline on the readability of the labelling and package leaflet of the medicinal products for human use” of the European Medicines Agency (EMA) (EMA, 2009a):

- In general, abbreviations should not be used in the PLs, except for the situations in which their use is considered inevitable and justified by the marketing authorization holders;
- When abbreviations are used in PLs, their meaning must be fully presented between brackets when they are first mentioned in these documents (EMA, 2009a, 2012).

Among the abbreviations that may be presented in PLs without the full description of their meaning are units of measure. In a similar way, the inappropriate presentation of dosage instructions may lead to medication errors (Fuchs & Hippius, 2007), and there are specific recommendations on how to present the strength of the medicine, as follows: x mg/ml = concentration; z mg = total active substance; y ml = total volume; z mg/y ml = total active substance per total volume (EMA, 2009b).

The recommendation to not use A&S in PLs and especially recommendations on the format of units of measure are common in the international regulations (ACSQHC,
The Implementation of Cloud-Based Telemedical Applications for External Quality Control Purposes in the Field of Cytopathology
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