

REPORTS OF SUBSTANDARD MEDICINES: AN ANALYSIS OF THE BRAZILIAN HEALTH SURVEILLANCE NOTIFICATION SYSTEM

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OBJECTIVES

Substandard medicines (SM) can lead to healthcare failures, additional illness and deaths, with a significant impact on worldwide clinical and economic burden. We aimed to evaluate the profile of SM reported to the Brazilian Health Surveillance Notification System (Notivisa) in the past 11 years.

METHODS

We extracted all notifications of SM available in Notivisa during 01/01/2007 to 12/31/2017. Descriptive statistics were performed. The reasons described for the SM (i.e. open field in the system form) were gathered into a single text corpus (TC). Data correction and standardization were made by using OpenRefine and Microsoft Excel. The following analyses were performed on the TC (Iramuteq 0.7 alpha2): lexicographic analysis to obtain the number, frequency and distribution of active words; descending hierarchical classification (DHC) to categorize the active words into similar lexical classes; factorial correspondence analyses (FCA) to obtain bi- and tri-dimensional graphs of the classes.

RESULTS

A total of 61775 notifications were analyzed, most of them reported by hospitals/medical centers (46%) with a significant increase in the number of notifications after 2011 ($p < 0.05$). The TC comprised 22553 active words. The DHC of the reasons of SM produced 4 classes visualized in the FCA: (i) packing problems (16%) represented mainly by leakages and opening issues; (ii) inadequate drug identification (22%), such as labels' illegible information; (iii) stability and contamination issues (11%) such as presence of particles; and damaged tablets/blisters (23%) mainly represented by broken tablets. Most of SM (52%) were solutions of parenteral use, with sodium chloride being most frequently reported as active drug (9%), followed by glucose and dipyrone (3% each).

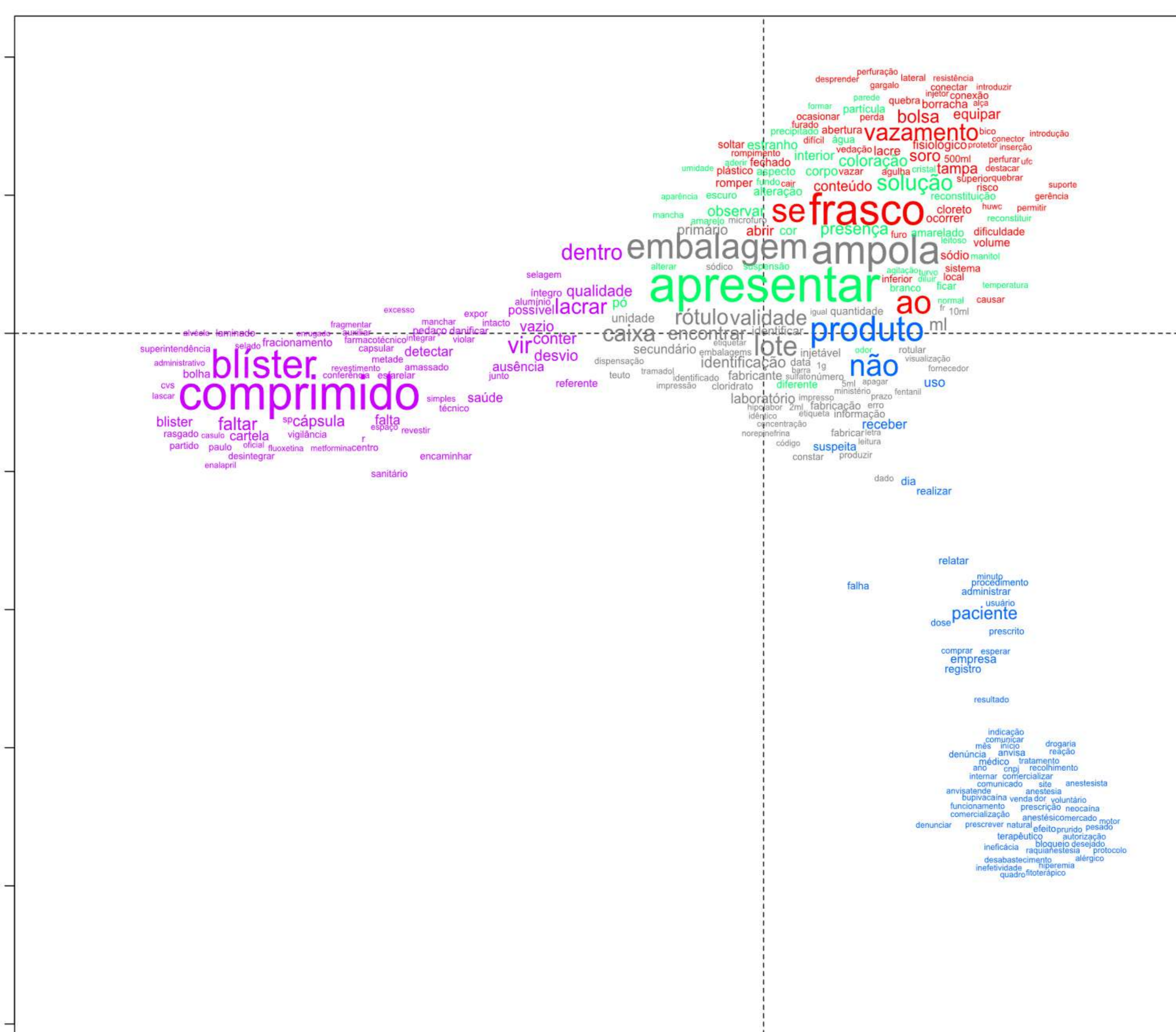


Figure 1. Correspondence analyses plot of the most frequent active words in each of the lexical groups. Sizes of active words are proportional to their frequency in the text. Colors correspond to the lexical classes (Class 5: purple; Class 2: grey; Class 3: green; Class 1: red; Class 3: green; Class 5: blue).

CLASSES

SUBCLASSES

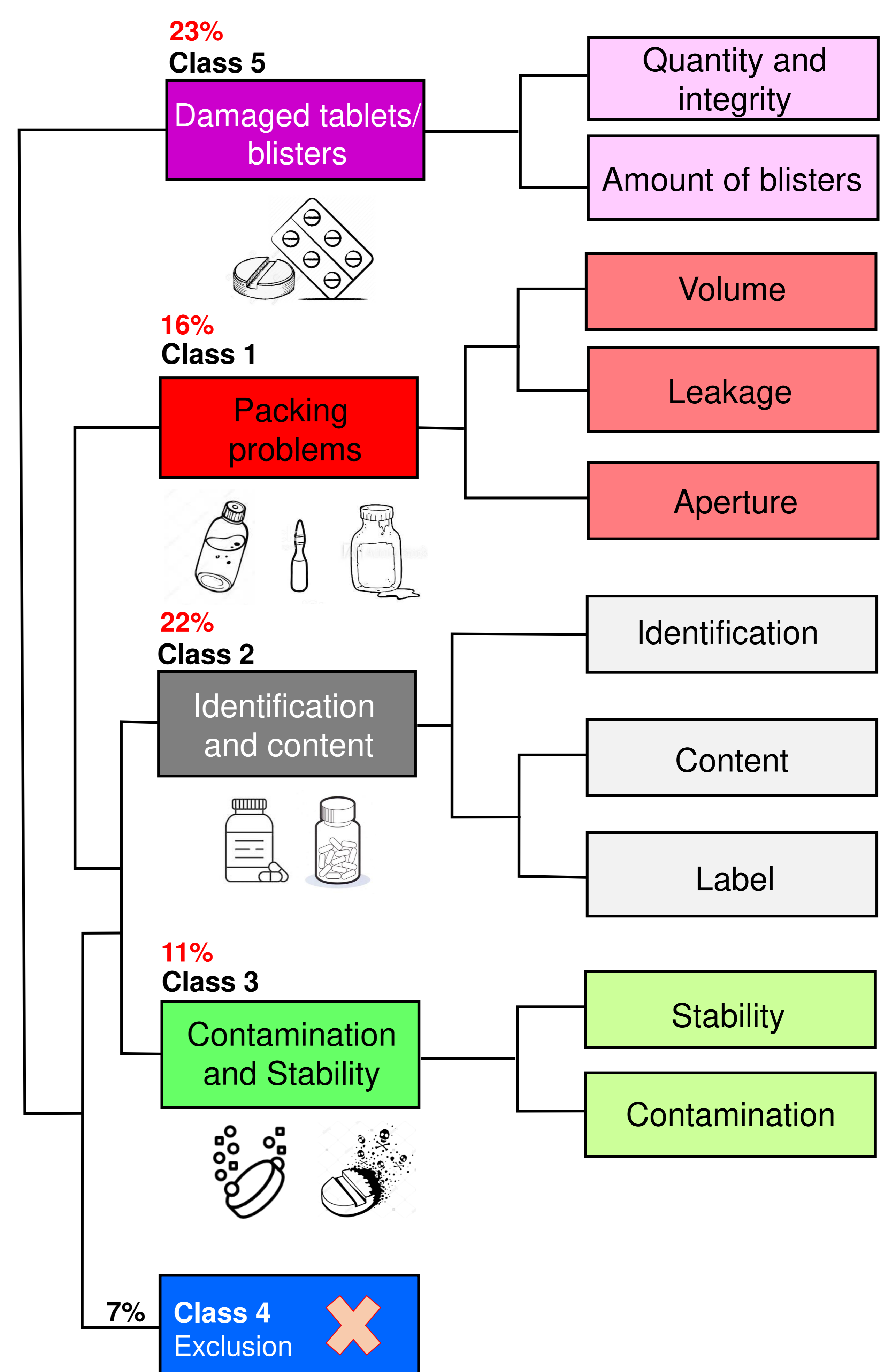


Figure 2 Schematic dendrograms of classes and subclasses.

The colors of the classes and subclasses were chosen by IRAMuTeQ and correspond to the same ones used in the correspondence analysis. Only generated correspondence analysis plots for three or more lexical classes, therefore 'Damaged tablets/blisters' and 'Contamination and stability' subclasses are represented without colors.

CONCLUSIONS

The reasons of SM could be objectively classified into four main classes that represent the main problems reported to Notivisa. This classification can guide the standardization of reports of SM and contribute to improve the surveillance notification system.

REFERENCES

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