MEDICATION ERRORS RELATED TO THE ADMINISTRATION OF MEDICINAL GASES IN FRANCE: ONE OF THE 12 FRENCH NEVER EVENTS

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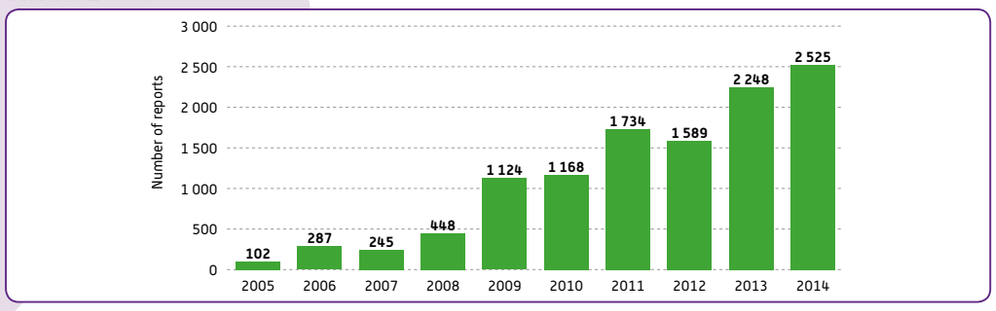
INTRODUCTION

The French National Agency for medecines and health product safety (ANSM) has set up in 2005 a department to collect and manage medication errors or potential medication errors related to medicinal products, and monitor those likely to present a Public Health risk. The "Medication errors' Guichet" enables healthcare professionals and patients to directly report to ANSM medication errors (ME) without adverse effect (AE) or near misses, in addition of reports with AE collected through the Pharmacovigilance System. In 2013 and 2014, respectively 2248 and 2525 medication errors have been collected.

Figure 1: number of medication errors reports received at the ANSM since 2005



OBJECTIVES

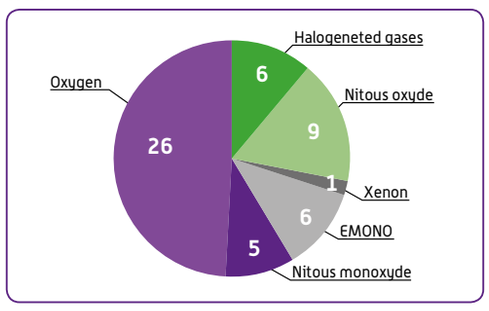
The aim of this study is to quantify and analyze medication errors reported to ANSM in relation with the administration of a medical gas and to recommend measures to reduce these errors. This type of medication error is one of the 12 French never events in hospitals.

METHODS

We performed an analysis of medication errors (risk, near misses and patent) reported to the ANSM that have resulted to an AE or not, with requests in the National Medication Error Database (from 01/01/2005 to 14/11/2014) and in the National Pharmacovigilance Database (from 01/01/1985 to 14/11/2014).

The analysis only focused on medicinal gases, which are drugs: the eight following active substances authorized and marketed in France (oxygen, nitrous monoxide, nitrous oxide, equimolar mixture of oxygen and nitrous oxide (EMONO), xenon and three halogenated gases: sevoflurane, isoflurane and desflurane), which represent 53 marketed medicinal products in France.

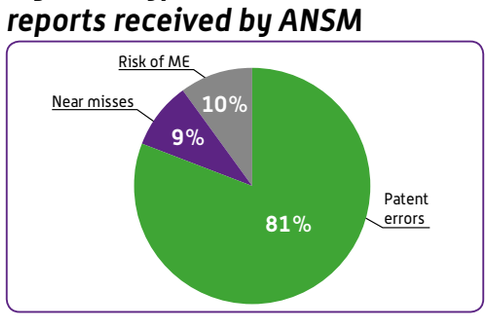
Figure 2: distribution of the 53 medicinal products with gas in France



RESULTS

Since January 1985 to November 2014, 42 reports have been identified with medicinal gas, including 4 risks of medication error, 4 near misses and 34 reports of patent errors.

Figure 3: type of medication errors reports received by ANSM



Of the 34 patent errors, 18 led to an adverse effect (which represents 53 %) and 7 were considered as serious according to pharmacovigilance criteria, including 3 fatal cases.

Figure 4: consequences of patent errors

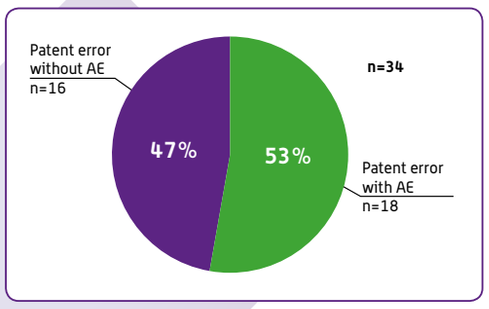
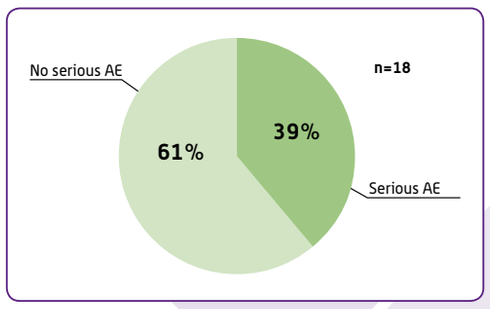


Figure 5: seriousness of patent errors that lead to adverse effect



The review of the cases reported reveals that the majority of cases occurs at hospital (78 %), at the step of administration (82%) and were caused by a confusion between two medicinal products (53 %): oxygen and EMONO cylinders due to similar packaging (80 %). Other cases were mostly in relation with practice errors and non-compliance with precautions for use.

Figure 6: distribution according to the stage of occurrence of medication errors (n=38)

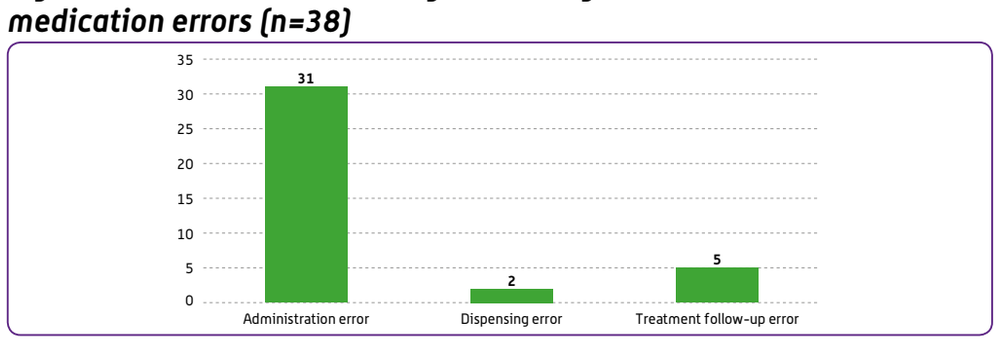
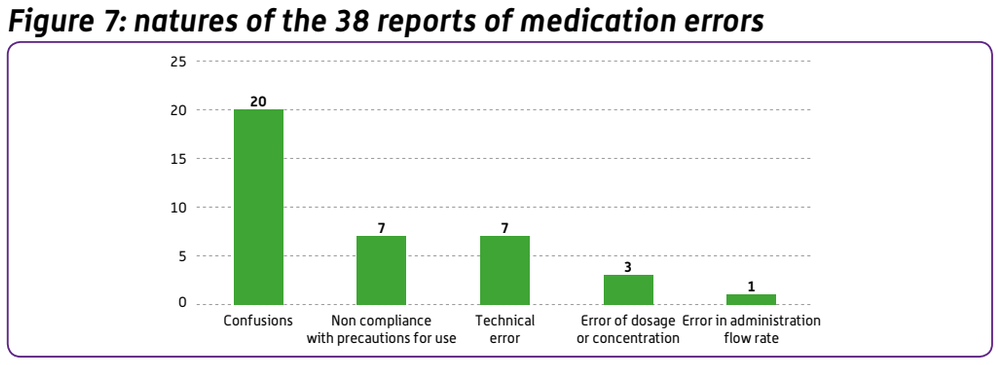


Figure 7: natures of the 38 reports of medication errors

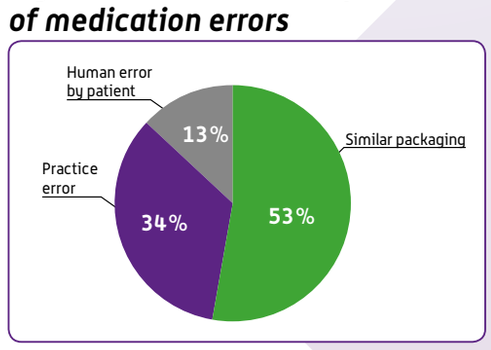


In 75% of the confusion cases it is the EMONO gas that is administered instead of oxygen, which can potentially cause a life-threatening respiratory distress.

Forgetting the opening of the cylinder valve while the flow-liter has been set is the most frequent practice error and corresponds to 34 % of cases. In 13% of cases the cause of medication error is a human error caused by the patient himself with no respect of the precautions for use (for example smoking cigarette with nasal oxygen canula during the administration which causes burns of the face).

Figure 8: packaging examples: oxygen cylinder (left side) and EMONO cylinder (right side)

Figure 9: causes of 38 reports of medication errors



CONCLUSIONS

In France, more than 109 millions of gas cylinders have been sold in 2013. Database queries revealed a probable significant under-reporting of medication errors, probably in relation with the fact that healthcare professionals don't think that gases are drugs.

This analysis highlights that medication error with gas can lead to adverse reactions considered as serious, implementing general measures to minimize this kind of risk is important.

Risk minimization measures are currently studied (in accordance with the ANSM medication errors experts group):

- a sticker is currently developed to improve clarity of the labelling of EMONO cylinders in order to limit confusions with oxygen,
- communication to healthcare professionals highlighting the risk of medication error related to the use of gas cylinders,
- an illustrated poster with short and precise texts to ensure good use of medicinal gases for a wide diffusion to healthcare professionals and patients

To increase awareness among healthcare professionals and patients, information and education on the risks associated with the use of gas are essential.

Conflict of interest statement

D. Durand, M. Hervé-Bazin, F. Cardona, P. Maison: none

Reminder : In France, physicians, dentists and dental surgeons, pharmacists and midwives are required to report any adverse reaction suspected of being due to a medicine to their local PharmacoVigilance Centre (CRPV).