MANAGEMENT OF MEDICATION ERRORS / OVERDOSAGE WITH PARACETAMOL (ACETAMINOPHEN) IN FRANCE

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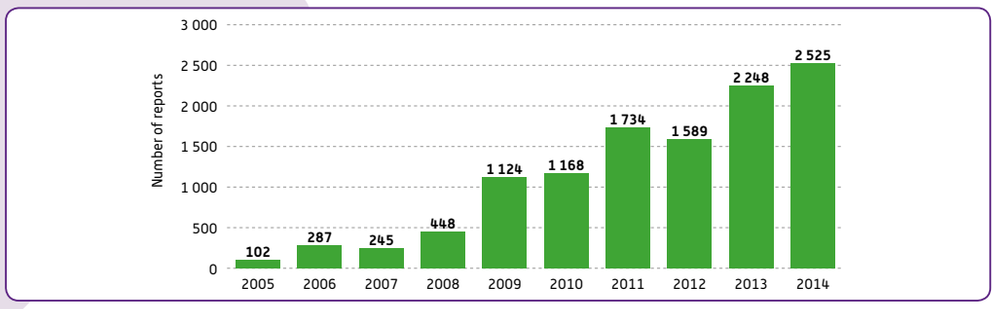
INTRODUCTION

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 analyse medication errors, non-voluntary overdosage reported to ANSM in relation with oral use of paracetamol (oral dry form containing paracetamol alone or in combination medicines) and to recommend measures to reduce these errors.

METHODS

We performed an analysis of medication errors (risk, near misses and patent) reported to the ANSM with Paracetamol (oral dry form containing paracetamol alone or in combination medicines: tablets, capsules, pellets, powder) that have resulted to an AE or not, with a request in the National Medication Error Database (from 01/01/2011 to 13/04/2015).

RESULTS

1. Medication reports received at the ANSM between January 2011 and April 2015

Since 2011, 330 reports have been identified with Paracetamol (oral dry forms containing paracetamol alone or in combination medicines), including 21 risk of medication error, 19 near misses and 290 patent errors.

Of the 290 patent errors, 20% did not lead to an adverse effect and 80% led to an adverse effect (45 % considered as serious according to the pharmacovigilance criteria including 1 fatal case).

Figure 2: distribution of the 330 medication errors reports received at the ANSM between January 2011 and April 2015

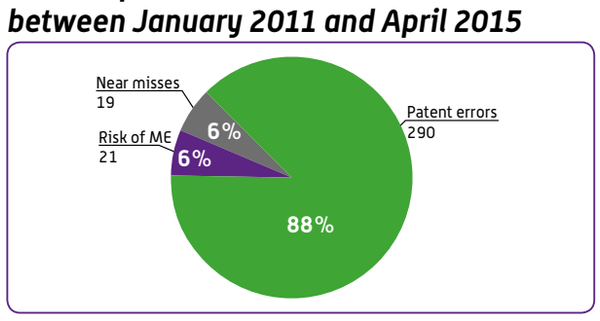
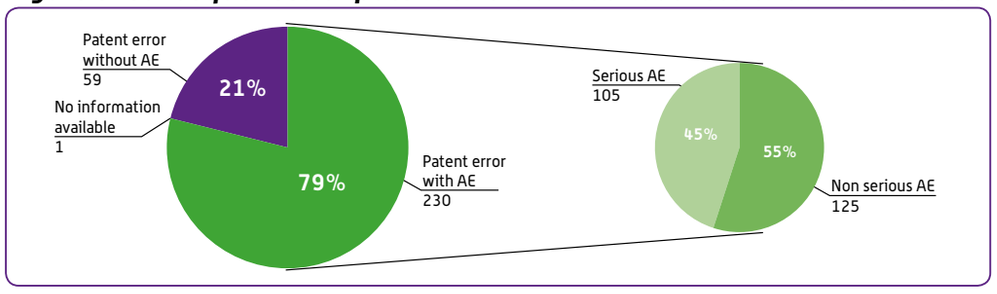


Figure 3: consequences of patent errors and seriousness of adverse effects



Review of the cases reported reveals that the majority of cases occurs at the step of administration (85%), at home (84%) and were caused by patient error (76%).

Figure 4: distribution according to the stage of occurrence of medication errors (n=309)

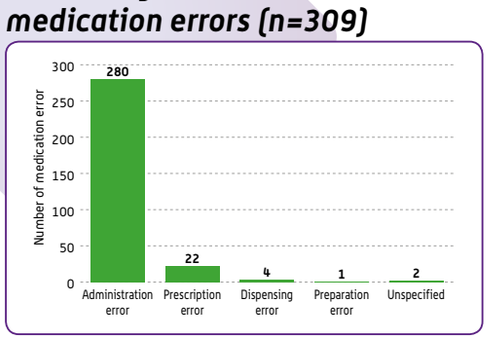
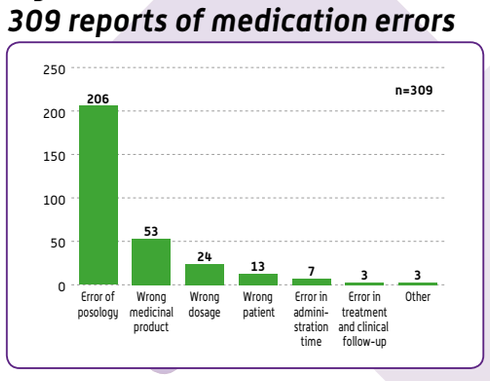
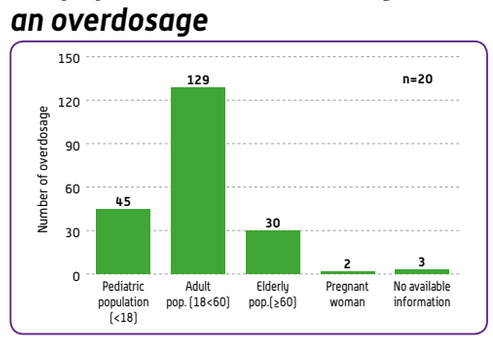


Figure 5: natures of the 309 reports of medication errors



Analysis of overdosage :
Most of medication error led to an overdosage (72%, n=209) that could in some cases be associated with liver injury or death. Most of cases that led to an overdosage were reported at home (97%), in adults (62%), in a context of severe pain (55%) (especially dental pain and headache due to a non-pain relief), or were in relation with a lack of adaptation dosage (18%) (based on low weight, renal insufficiency or alcoholism). In cases of overdosage, the mean ingested daily dose was 9,4 g and the range of dose was 5 g to 20 g.

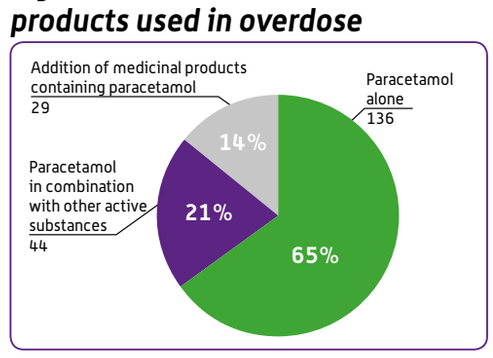
Figure 6: distribution of the population concerned by an overdosage



For oral dry forms of paracetamol, most overdoses in the pediatric population are linked to the use of adult dosage instead of a pediatric presentation (oral solutions and suppository have been excluded from the analysis).

Among the 209 cases of overdosage, 65% were due the use of medicinal products containing Paracetamol alone, 21% with medicinal products containing Paracetamol in combination with other active substances, 14% by addition of medicinal products containing paracetamol alone or in combination.

Figure 7: distribution medicinal products used in overdose

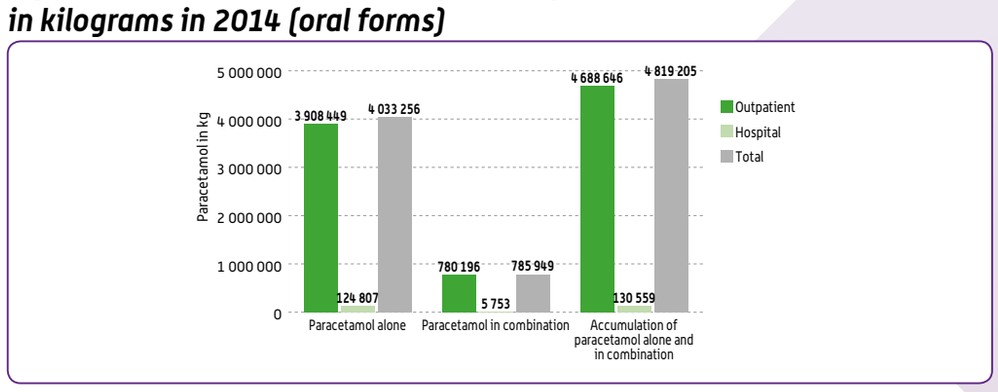


2. Analysis of medicinal products with Paracetamol marketed in France (excepted injectable) and the French average consumption

195 medicinal products with Paracetamol are marketed in France and are mostly available over the counter (81 %):

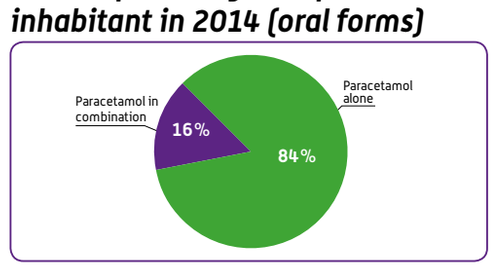
- 116 medicinal products containing paracetamol alone;
- 79 medicinal products containing paracetamol in combination with other subtances mostly codeine or tramadol.

Figure 8: distribution of consumption of paracetamol in France in kilograms in 2014 (oral forms)



In France, in 2014, an annual mean quantity of 73.7 g of Paracetamol (61.7g from medicines containing only Paracetamol and 12 g of Paracetamol in combination with other substances) **has been consumed by a patient** (principally at home).

Figure 9: distribution of annual consumption in grams per inhabitant in 2014 (oral forms)



CONCLUSION

This analysis highlights that given the consumption of paracetamol in France and the number of reports and the potential consequences associated, implementing general measures to minimize this kind of medication errors is essential, **especially due to the non-perception of risk associated with an overdosage of paracetamol to patients.**

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

- an harmonised labelling for all oral dry forms of paracetamol;
- **communication to patient and/or HCP to remind the key messages of a good use of paracetamol (recommended daily dose, interval, contraindication, dose adjustment…).**

To increase awareness among patients, information and education on the risks associated with the use of higher dose than recommended of paracetamol, are essential.

Conflict of interest statement

D. Durand, J. Taransaud, 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).