

*Research & Reviews in*  
**BioSciences**  
*Regular Paper*

RRBS, 10(7), 2015 [244-249]

## Retrospective study of asymptomatic immunization errors

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### ABSTRACT

The objective of this study is to describe the epidemiological profile d'immunization errors asymptomatic in order to implement preventive measures to avoid their recurrence. This is a retrospective study, during the period 2009 to 2013. In our study were included all errors that occurred following immunization. During the study period, 46 cases of asymptomatic immunization errors were collected in the female was the most represented with a frequency of 59% ( $\chi^2 = 1.34$ , P > 0.05). The distribution of errors according to age groups has shown that infants are hardest hit with 53 % of cases. The incriminated in these immunization errors were: anti-Rubella Measles vaccine in 46% of cases, *Haemophilus influenzae de type B.*, Vaccins *Antipneumococcique* 9% each. The majority of these events are due to errors of redundancy (35%), posological errors (28%).

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### KEYWORDS

Error;  
Immunization;  
Asymptomatic.

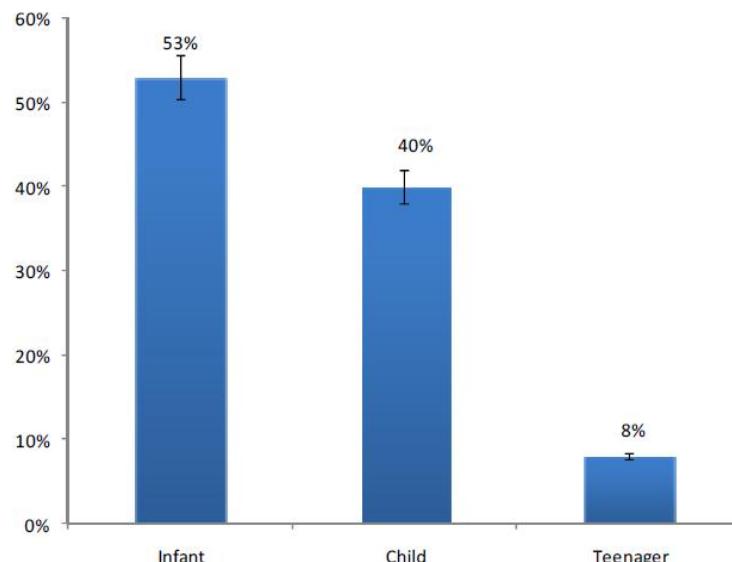
### INTRODUCTION

The medication error is a preventable iatrogenic event drug. The origin of these errors is multifactorial<sup>[1]</sup>. It occurs at all stages of the drug circuit. It implies a direct or indirect healthcare professionals and patients<sup>[2]</sup>. In the United States, drug errors were the 4th cause of<sup>[3]</sup> serious side effects, and are responsible for about 7,000 deaths annually<sup>[4]</sup>.

In France, they provoke serious adverse effects every 2000 days of hospitalization<sup>[5]</sup>, about 70 000 serious adverse effects per year.<sup>[3]</sup> However, failure and / or the unintentional execution of an act relating to a drug may be the cause of a risk or of an adverse event for the patient<sup>[6]</sup>. Furthermore, vaccines are more than 3.5% of the pharmaceutical market and vaccination occupies 5 to 10% of injections per year.

Thus, the events related to immunization errors are defined by the Who as a medical incident caused by an error in the transportation, storage, handling, prescription or administration of the vaccine. These reactions when they occur hinder the benefit of the vaccination program. They can be proven if the error results in administering to the patient a wrong drug, wrong dose or the wrong way, if the potential error is caught before administering the product to the patient, unrealized s there is a potential danger to the patient<sup>[7]</sup>.

Medication errors are classified as errors of omission; dosages; posology or concentrations; of galenic form, administration techniques, preparation techniques, route, debit and time of administration, patient; therapeutic or clinical follow-up or use an expired or or spoiled medicine<sup>[8]</sup>. These errors are,



Infant : [1mois à 4 ans] ; Child : [4 ans à 11 ans] [Teenager : [4 ans à 11 ans] [11 ans à 16 ans].

**Figure 1: Error distribution by age groups.**

without notable consequences, some can be dramatic causing sometimes the death of the individual or leave the heavy sequelae<sup>[2]</sup>.

The objective of this study is to describe the epidemiological profile of immunization errors to detect the factors that are involved, based on data from the Center Antipoison and Pharmacovigilance of Morocco.

## DATA AND METHODS

This is a retrospective descriptive study of the asymptomatic immunizations errors reported to the Center Antipoison and Pharmacovigilance of Morocco (CAPM) reporting form by the health professional or the pharmaceutical industry or from the telephone information center by the public. This study, including all asymptomatic errors that occurred following vaccination over a period of five years between 2009 and 2013. Statistical analysis was based on the calculation of frequencies or averages of each variable of which allowed us to describe the cases related to vaccinations errors. The variables studied on the epidemiological characteristics of patients (age, sex, severity, type of vigilance). Age was classified according to the WHO classification, and we analyzed the types of errors produced and the most reported vaccines. Chi-square test was applied for some of the parameters to prove

their statistical significance.  $P < 0.05$  was considered as significant.

## RESULTS

Immunization errors represent 12% of adverse events related to vaccination which 16% are due to errors during asymptomatic période2009 and 2011. 46 cases of asymptomatic immunization at CAPM error are collected during the period study, an average of  $9 \pm 2$  cases per year. The mean age of patients was  $4 \pm 0.8$  years with a minimum of one month and a maximum of 11 years. The female is the most represented with 59% of cases, however, the difference between the sexes is not significant ( $\chi^2 = 1.39$ ,  $P > 0.05$ ). 60% of these errors are reported during the vaccination companions, and the rest during routine immunization.

The distribution of errors according to age groups has shown that infants are the most affected with 53% of cases (Figure 1).

The error distribution by type of most incriminated vaccine showed that 46% of cases are due primarily to anti-Rubella Measles vaccines, 9% in the Haemophilus influenzae type B and 9% in the Pneumococcal vaccines (Figure 2).

The different types of errors as incriminated vaccines are shown in TABLE 1.

The majority of these events are due to errors of

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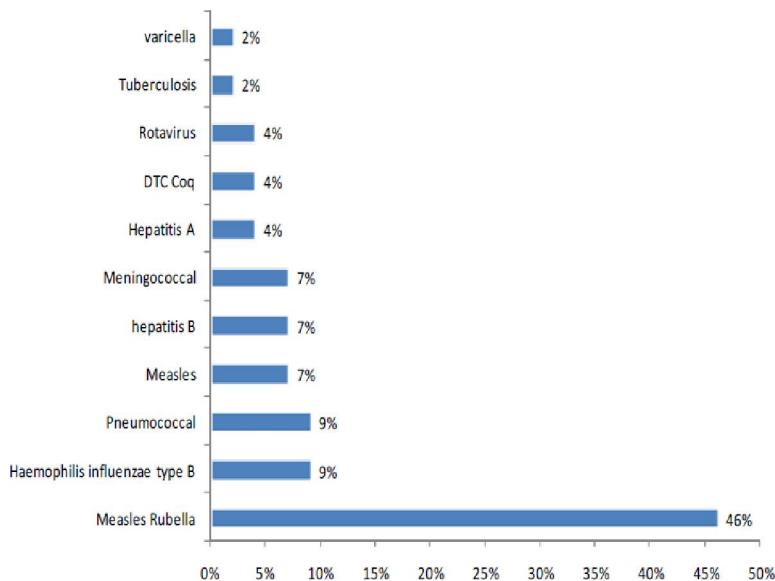


Figure 2 : Graphical representation of responsible vaccines errors

TABLE 1 : Types of errors by incriminated vaccines

| Vaccine                           | Error type   |
|-----------------------------------|--|
| Measles and rubella vaccine       | - Posology error<br>- Omission<br>- Redundance<br>- Redondance                         |
| Antipneumococcal                  | - Vaccine error<br>- Moment of administration<br>- Therapeutic Monitoring and Clinical |
| Measles                           | - Moment of administration   |
| Antituberculosis                  | - Patient<br>- Redondance  |
| Meningococcal                     | - posology error<br>- Moment of administration   |
| Diphtheria, pertussis and tetanus | -Posology error  |
| Hepatitis A                       | - Posology error   |
| Rotavirus                         | - Technique of administration<br>- Route of administration                             |
| Hepatitis B                       | - Redondance<br>- Posology error   |
| Haemophilus influenzae type B     | - Expired or deterioration vaccine   |
| varicella                         | - Patient  |

redundancy or posology (TABLE 2), the chi-square test showed a highly significant liaison between the type of error and the vaccine ( $\chi^2 = 275.8$ ,  $p < 0.001$ ).

## DISCUSSION

Vaccination is a medical procedure that requires

compliance with certain rules, and technical precautions before, during and just after the vaccine<sup>[9]</sup>. This vaccination can contribute to errors, which can be of no clinical consequence on the vaccine as they may be symptomatic causing adverse reactions of local type, systemic allergic or that could be the result of the administration of inappropriate products

TABLE 2 : Type of immunization-related errors

| Error Type                          | n  | %  |
|-------------------------------------|----|----|
| Redondance                          | 16 | 35 |
| Posology error                      | 13 | 28 |
| Expired or deterioration vaccine    | 4  | 9  |
| Therapeutic Monitoring and Clinical | 2  | 4  |
| Moment of administration            | 2  | 4  |
| Omission                            | 2  | 4  |
| Patient                             | 2  | 4  |
| Moment of administration            | 1  | 2  |
| Route of administration             | 1  | 2  |
| Vaccine error                       | 1  | 2  |
| Technique of administration         | 1  | 2  |

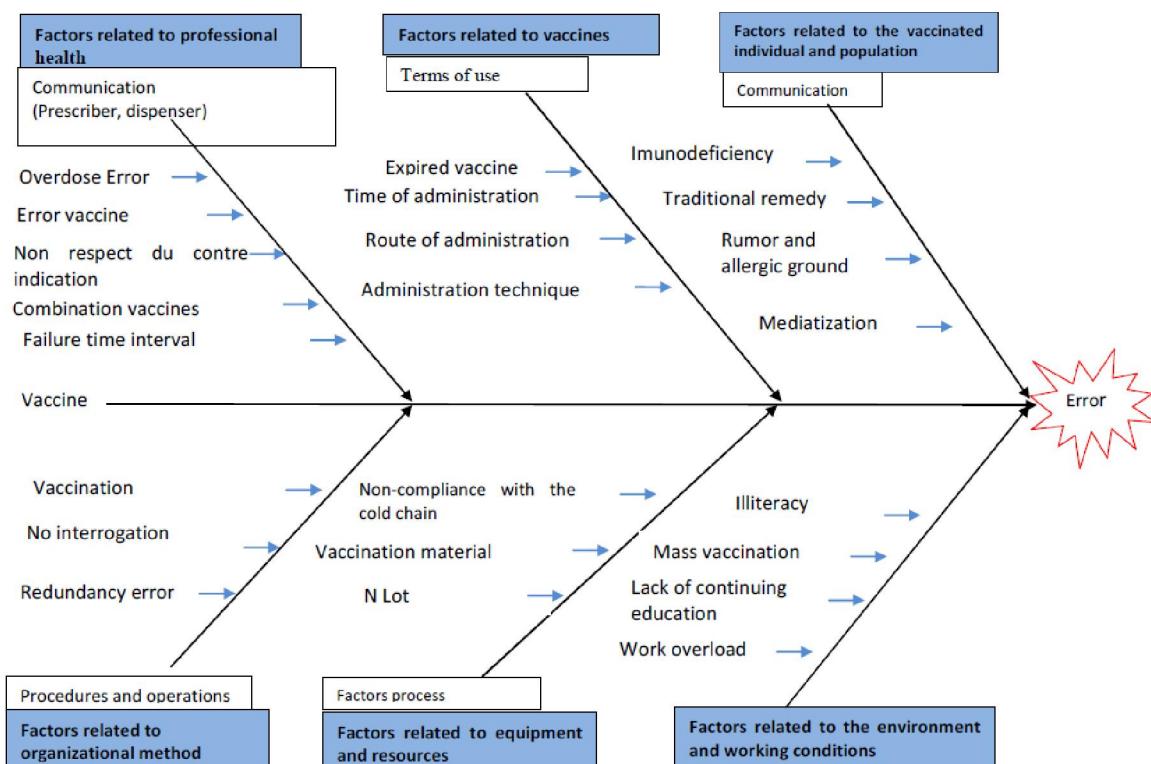


Figure 3 : Diagram of ichikawa representing causal factors related to errors due to vaccines

at age of the person, the administration made regardless precautions, against-indications, preparation, injection site, the route of administration, dosage or timing or the contamination of product from the injection point or equipment used.

The different factors related to these errors are shown schematically in Figure 3 graphically illustrates the causes leading to an error.

Throughout this study, we analyzed data related to immunization errors reported to the CAPM between 2009 and 2013, a total of 46 cases were

counted to asymptomatic immunization errors. Infants were the most affected by these errors with 53% of cases, this result is discordant with another study<sup>[10]</sup>, predominantly female.

In our series, the types of errors are many, the most frequently observed were: redundancy error (35%), dose (28%), expired vaccine or deterioration vaccine (9%), therapeutic and clinical follow-up (4%), time of administration (4%), omission (4%) and patient error (4%). In other studies, the majority of reported errors occurred at the moment of admin-

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istration (69%), injection of an incorrect dose (26%)<sup>[7]</sup> Lenclen<sup>[11]</sup> reported errors concerned in particular dosages (28%), the route of administration (18%), the retranscription (14%).

A vaccination campaign against measles and rubella was organized for the age range from 9 months to 19 years, launched during the period April-May 2013, however, during a campaign, a large number of doses over a short administered, resulting in a high number of vaccine reactions and events occurring coincidentally, and also an increase in program errors may also occur, this is similar to our study, which shows that the majority of these errors are caused by Measles Rubella vaccine (46%), followed by Haemophilus influenzae type B, pneumococcal 9% for each of them and Measles (7%). For against, in the literature, administration errors were noted, there is an injection of BCG vaccine subcutaneously rather than intradermally with an overdose corresponding to 10 times the normal dose of BCG with an average age of 25 years<sup>[12]</sup> other errors have been associated with the Rotavirus (16%), combined against the pneumococcus (11%), Varicella (11%)<sup>[13]</sup>.

Vaccines are sensitive biological products that may lose their effectiveness or deterioration if the cold chain is not observed in the literature between 17% to 37% of health professionals expose vaccines to inappropriate warehousing temperatures<sup>[14]</sup>. They should be checked as soon as they receive up to the stage storage to verify the validity, soundness and primary packaging<sup>[15]</sup> to remove expired products in appropriate security conditions, in our study, 9% errors are due to expired vaccines.

By elsewhere, any vaccination should be recorded on the child's health booklet in order to avoid errors of omission, which represent in our case 4% of these errors. One dose of vaccine should be administered properly checking the way, the technique of administration and dose intervals. A vaccinator or health center are responsible for an error cluster, this may diminish public confidence in respect of vaccines or the health care system, so scrupulous management of human resources is very important to minimize the frequency of errors that negatively impact on the health status of the population by putting in place appropriate measures.

## CONCLUSION

After this study, we can conclude that immunization errors are preventable and can harm the vaccination program. Identifying and correcting these incorrect immunization practices are of great importance. Increased vigilance monitoring of these errors, an awareness of health professionals and good communication are desirable.

The immunization error is usually related to the person rather than the vaccine, or it is related to the technical administration eg abscesses at the injection site, these errors can be simply begin by adequate training immunization team as well as the supply and correct use of equipment to perform safe injections for the vaccinated and the general population.

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