Fatal outcome due to Rocuronium

Centre Anti Poison et de Pharmacovigilance du Maroc

WHO Collaborating Centre for strenghthening Pharmacovigilance Practices

RABAT COLLABORATING CENTER

Medication Errors Workshop - October 13th, 2019

Background

On 17 December 2018

- The CAPM received a call
  - from a **maternity university hospital** in **Rabat** **(the second main hospital in Rabat)**
  - a cluster of **6 newborns**
  - **serious adverse events:** cyanosis, bradycardia and apnea a **few minutes** following the administration of the **hepatitis B vaccine (HBV)** as part of the National Immunization Program

- Preliminary investigation by the medical team

The nurse administered

Rocuronium® (Neuromuscular Blocking Agent) 10 mg/ml (dose=0.5 ml)

intramuscularly in the left thigh

instead of the

Euvax® B (HBV) issued by the National Immunization Program

Investigation – Team and objectives

On 18 December 2018

An investigation was initiated by the Ministry of Health

- The Inspection Division of the MoH
- The National Immunisation Programme
- The Centre Anti Poison et de Pharmacovigilance du Maroc
- The Hospital and Ambulatory Care Department

Objectives: to identify the underlying causes and contributing factors in order to put in place risk minimization actions

Investigation - Methods

- AEFI Investigation Form
- Root Cause Analysis
- Ishkawa diagram

Investigation findings – Patient and ADR characteristics

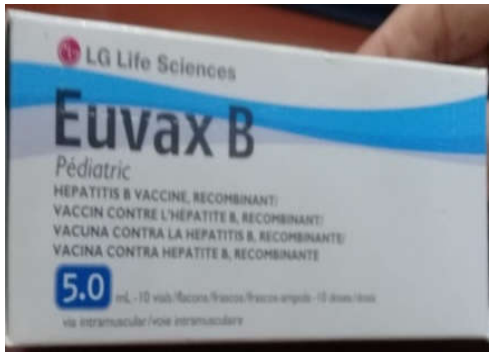
Patients	**Number: 6** newborns **Age: 1 to 3** days years olds **Gender:** 4 females and 2 males (One twin birth) **Weight :** 2.500 kg to 3.600 kg
ADR	**Bradycardia:** 6 newborns **Cyanosis and apnea:** 3 newborns **Convulsions:** 2 out of the 3 ones
Management	Resuscitation by maternity anesthetists (Adult) Administration of **Sugammadex**: NBA antidote Transfer to neonatal care unit in another hospital
Outcome	**1 death** 1 recovered with sequel 4 recovered

Investigation findings - RCA

Proximal causes

- Administration of Rocuronium instead of HBV

- Look-alike packaging Rocuronium and HBV

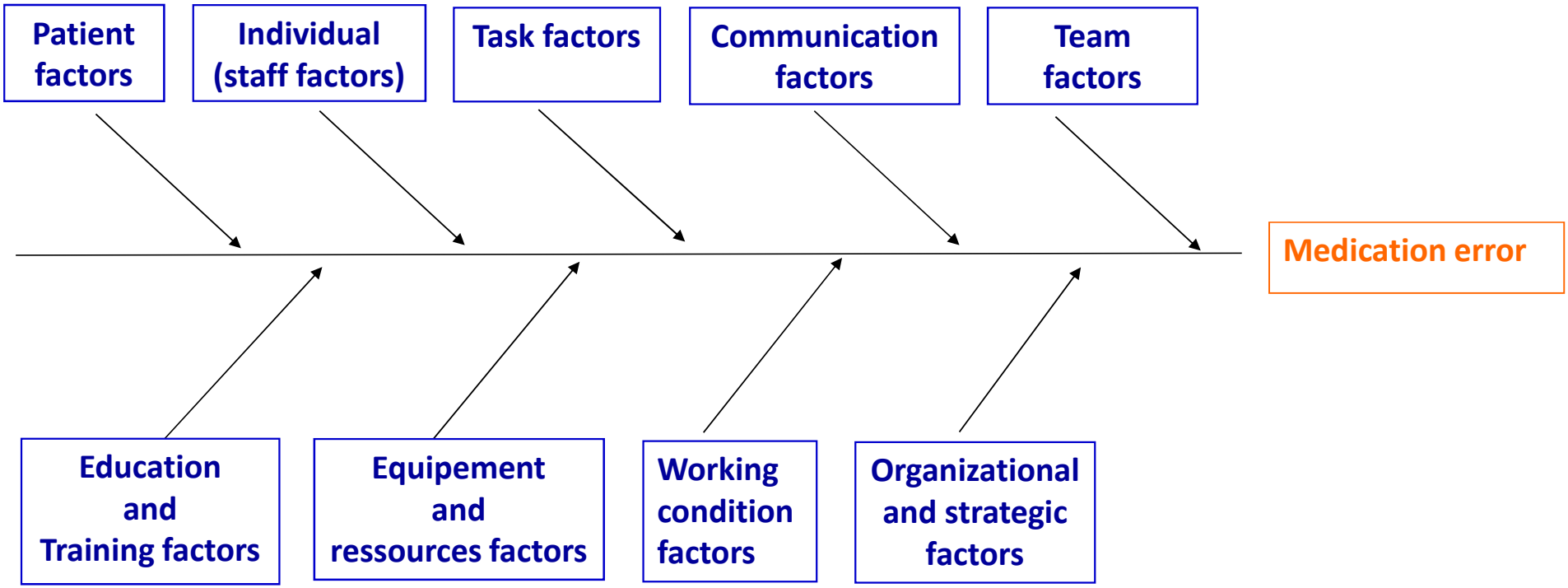


Investigation findings - ME classification

Level of achievement	**ME with harm** reached the patient and led to harm
Stage in the medication use system	**Storage error** **Dispensing error** **Administration error**
Type of error	**Wrong drug**
Seriousness	**Category F** (4 cases) An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation **Category G** (1 case : convulsion as sequelae) An error occurred that may have contributed to or resulted in permanent patient harm **Category I** (1 case) An error occurred may have contributed to or resulted in patient's death

Investigation findings - RCA

Contributing factors: Ishikawa Diagram



Investigation findings - RCA

Contributing factors: Working conditions

- Shortage of human resources
  - Lack of a full time pharmacist in the hospital maternity
  - Cumulative tasks
- Lack of neonatology Intensive Care Unit in the Maternity University Hospital

Investigation findings - RCA

Contributing factors: Education and training

- Lack of knowledge of drugs names (INN and brand names) used in daily practice
- Hospital staff unfamiliar with vaccines and immunization session

Investigation findings - RCA

Contributing factors: Equipment and ressources

- Lack of secure and lidded container for high-risk drugs storage: NBA requires particular storage conditions as well as labeling precautions

- Lightning issue: The cold room in the hospital pharmacy was poorly lighted

Investigation findings - RCA

Contributing factors: Tasks

Same storage area of Rocuronium® with other drugs: high-alert medications should be stored separately

This shot was taken with a cellphone lamp

Investigation findings - RCA

Contributing factors: Tasks

- For the first time running HB imminization for newborns in the maternity university hospital : the immunization session should involve a medical team and not a staff person only
- Lack of double checking vaccines name before administration
- Order form and delivery note : both mentioned **Hepatitis B Vaccine** **without the brand name**

This shot was taken with a cellphone lamp

Investigation findings - RCA

Contributing factors: communication

- The nurses line manager : not aware that some nurses did not attend the practical training organized prior to the launching of the HB immunization in the hospital
- Verbal launching of the first HBV immunization session
- Verbal claim regarding the light problem in the pharmacy

Literature review

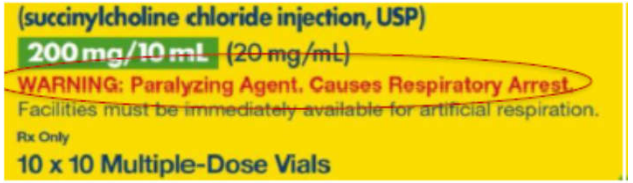
Several reports involving Neuromuscular blocking agents

Proposed Risk Minimisation Actions

- The nomination of a full time pharmacist
- The reassessment of the safety of drug storage and dispensing of medicines at the hospital pharmacy particularly for high risk medications
- Raising awareness of nurses ensuring vaccination about the importance of implementing procedures related to immunization practices
- Raising awareness of HCP about:
  - the risks due look alike sound alike medications
  - the importance of reporting ME and learning from cases

Proposed Risk Minimisation Actions

- Placing warning labels on all storage bins and final medication containers (e.g., vials, syringes, IV bags) of neuromuscular blockers that state: **“Warning: paralyzing agent—causes respiratory arrest”**



- The availability of the NBA antidote in health facilities that have neuromuscular paralyzers

The consequences of this fatal ME


الصباح
خاص

سة الكاملة لوفاة رضيع بمستشفى الليمون

تن ستة رضع بدواء مخدر بدل لقاح التهاب الكبد الفيروسي واعتقال الصيدلانية والممرضة

اعتقال وغضب في الجسم الطبي

في انتظار نتائج التشريح

اعتقال ممرضة وصيدلانية للتحقيق معهما في وفاة رضيع بالليمون

كوثر زكي - LeSiteinfo بالعربية

اعتقال ممرضة ومحضرة في الصيدلية في قضية اللقاح الذي أودى بحياة رضيع

تم اعتقال ممرضة ومحضرة في الصيدلية التابعة لمستشفى الليمون بالرباط، على خلفية فاجعة وفاة رضيع وإصابة خمسة أطفال رضع آخرين بسبب حقنهم بتلقيح ضد التهاب الكبد الفيروسي.

وما زالت الأبحاث التي تجريها وزارة الصحة مستمرة لتحديد المسؤوليات المترتبة عن هذا الحادث والأسباب التي أدت إلى وفاة رضيع، وتدهور حالة خمسة آخرين بعد حقنهم مباشرة.

كشف مصد

للمركز الا

OURRISSONS EN DANGER
LA MATERNITÉ DES ORANGERS

Dans la journée du 17 … élude également les raisons … détérioration de l'état de santé de … s, les différentes … ques apportent … ntradictoires, mais

نقابة صحية تتضامن مع ممرضة مشفى الليمون

أيوب صدور

الجمعة 21 دجنبر 2018 – 15:30

استنكر عبد القادر طرفاي، الكاتب العام للنقابة الوطنية للصحة CGT-Santé، اعتقال ممرضة ومحضرة في الصيدلة بمستشفى الليمون، التابع للمركز الاستشفائي الجامعي ابن سينا، على خلفية حادث

Consequences

- The staff involved in the ME faced legal issue
- The discontinuation of HB immunization only at Maternity University Hospitals
- Designing of a national strategy on drug risk management for hospitals by the CAPM at the request of the Ministry of Health

Nurses Association

Pediatricians association

Internal and Resident Pharmacist Association

Community Pharmacists

Hospital University, Fes and Casablanca

Conclusion

Reporting ME, particularly a serious one, leads to make patient safety a priority for health authorities and enable to raise awareness of health care professionals to their role in preventing and reporting ME to improve patient safety

Thank you for your attention

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