Journal of Medicine and Healthcare

Review Article



Feedback from an Adverse Event Associated with Medication Error Type Care. Case of the Saint Padre Pio Hospital Centre in Lubumbashi in the Democratic Republic of Congo

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Received: February 21, 2023; Accepted: March 01, 2023; Published: March 06, 2023

Introduction

During a recent routine vaccination session for children aged 0 to 11 months at the Padre Pio hospital center in Lubumbashi, a midwife administered twice the dose of the same injectable poliomyelitis vaccine (IPV) to an infant while only one dose was indicated. The child subsequently presented with some digestive disorders such as vomiting and diarrhea that required 24-hour observation in the emergency reception unit. The occurrence of this incident required the holding of a meeting with the various stakeholders. The aim was to examine the possible cause(s) of this incident, to be able to determine whether it was a fault attributable to the vaccinator or whether it was a systemic problem, the aim being to improve the safety of the practice of vaccination by preventing the occurrence of similar situations.

Development

Health care environments are known to be very complex and therefore prone to errors of all kinds. The harm caused to patients by adverse events associated with care (AAE) is one of the 10 main factors underlying death and disability worldwide. Some 134 million SAEs occur each year in healthcare establishments in low- and middle-income countries, contributing to 2.6 million deaths [1,2]. And among these many SAEs, medication errors (ME) would be one of the major causes of preventable injuries and harms causing a global cost of 42 billions US dollars [1].

According to the definition given by the National Agency for the Safety of Medicines and Health Products (ANSM), a medication error (ME) is an unintentional omission or commission of an act and which involves a medicine in the course of a care process [3]. An ME is confirmed when it is the consequence of an incorrect medication, an incorrect dose, an incorrect route of administration or even a therapeutic regimen not appropriate, potential, when identified before the drug is administered to the patient, and latent, when it is an observation that indicates a potential risk to the patient.

Any SAE related to a drug constitutes a drug iatrogeny. However, this may result from adverse effects inherent in the drug itself

or may be attributable to medication errors. The latter occur, in particular, when in administering medication, the provider does not respect the principle of the right patient, the right medication, the right dose, the right time and the right method of administration [4].

What we know about routine vaccination of children aged 0-11 months and the occurrence of ME. Vaccines are known to save lives. And every year in the world, two to three million children's lives are saved thanks to their action [5]. On the recommendations of the World Health Organization (WHO) and its partners, in particular Unicef, many countries around the world have implemented expanded immunization programs (EPI) within their health systems. Which have vaccination schedules to help providers and parents follow the different vaccines offered. This is particularly the case of vaccines that the child must receive before his first birthday. These routinely administered vaccines ensure healthy growth for children, hence the importance of respecting the 5 appointments provided for in the vaccination schedule [6]:

- At birth: vaccines against tuberculosis (BCG) and poliomyelitis (OPV)
- At 1 month and a half: the child is given four vaccines to protect against pneumococcal infections (Pneumo), poliomyelitis (OPV), diphtheria, tetanus, whooping cough, viral hepatitis B and meningitis (Pentavalent, DTC-HepB-Hib) and diarrhea (Rotasiil)
- At 2.5 months: during this vaccination appointment, the child receives the same vaccines as the previous month (1.5 months)
- At 3.5 months four vaccines will be administered to the child, the same as before, plus the injectable poliomyelitis vaccine (IPV)
- During the 5th and last vaccination appointment of 9 months, the child receives vaccines to protect them against yellow fever (VAA) and measles (VAR

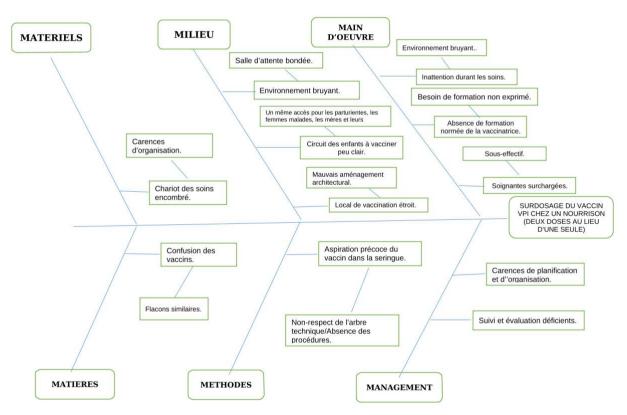
It was during his 4th vaccination appointment that a 3 and a half month old infant received at St Padre Pio hospital centre where he was to receive the vaccines provided for in his vaccination schedule. suffered a medication error due to overdose. . Indeed, the vaccinator administered twice the dose of IPV and did not realize it until the end when the mother, quite surprised, asked her why this umpteenth injection of the same vaccine. The mother received assurances of the harmlessness of the clumsiness and returned home. But towards the evening, the child presented digestive disorders (diarrhea and vomiting accompanied by a little fever) and had to be transported to the emergency room where he will spend 24 hours before continuing downstream (Pediatrics) care for 3 additional days Although the infant's reactions were considered extremely rare by the treating Pediatrician and the laboratory analyzes revealed an associated bout of malaria, the family's lawyer threatened to file a complaint against the hospital centre and the vaccinator was violently taken partly by the mother of the child.

This medication error (ME) type incident that occurred during routine vaccination required a response, as similar incidents were feared in the future with unfortunate consequences such as sequelae or even death. We must also fear the decline in the use by mothers of the routine vaccination service for the benefit of their children, which could expose them to serious diseases against which effective solutions are nevertheless available. The harmlessness or safety of care is an essential dimension of its quality. In other words, quality care cannot be considered when it is not safe for the users for whom it is intended. Moreover, the consumer of care is the main yardstick for measuring quality insofar as the determination and evaluation of the latter depend on the point of view of the final recipient of care that he is Moreover, it is established that the evaluation of users of health services relates both to the results and to the process of delivery [7].

The Approach we have Taken

We have set up a work team to, with regard to the effect, look for possible causes before considering an improvement plan. This team brought together 4 categories of members: technical expertise (two vaccinators, including the one involved in the incident), system leadership (the nursing care coordinator and the responsible midwife) and project management (the quality and safety manager). Thanks to Brainstorming, we were able to generate ideas on the possible causes of this incident and then integrated them into the fishbone diagram.

Chart 1 : The Ishikawa diagram of the causes of medication error when administering routine vaccines to children from 0 to 11 months



The fishbone diagram revealed several issues, considered to be the gaps between what is what should be:

- In terms of management, we noted poor planning and organization of the vaccination unit, deficiencies in monitoring and supervision on the part of the management of the unit with the root cause of managerial weaknesses in the latter;
- Health human resources (HRS) also had weaknesses: overwork, staff being understaffed, the vaccinator involved in the incident had not received standard training in this area like the others, and he appeared to lack mindfulness (inattention).
- On the plan of the environment, it was noted that the room reserved for the vaccination was narrow not allowing easy circulation and the circuit of the children to be vaccinated was unclear because the contingent waiting room was small, cluttered and the access used was the same for parturients admitted in labour, women coming for gynecological problems and children to be vaccinated accompanied by their mothers!
- In terms of materials, participants in the brainstorming revealed the confusion of vaccines due to the similarity of the vials, but also the misalignment of the vials on the care

trolley;

- From the point of view of the machines, the trolley used was very cluttered and as a root cause, we noted organizational deficiencies on the part of the vaccinator;
- In terms of methods, the main cause identified is the early aspiration of the vaccines into the syringes before the arrival of the children to be vaccinated (in an attempt to be able to go faster in the face of the influx of children). Non-compliance with the technical care tree for the administration of medications and the absence of guidelines in this area are root causes.

Since the problems identified (causes of the medication error) were numerous and of varying importance, we had to resort to prioritization, using Donabédian's decision tree as adapted by [8]. This tool allowed us to determine the problems presenting priorities for intervention and those for which etiological research was still essential.

Issue	Importance of the problem		Intervention capacity		Prioritization	
	Bigger	Smaller	High	Weak	Priority 1 for intervention	
Lack of standardized training	Х		Х		Priority 1 for intervention	
Absence of work guidelines on vaccination	Х		Х		Priority 1 for intervention	
Lack of supervision and monitoring by managers	Х		Х		Priority 1 for intervention	
Early aspiration of vaccines by the vaccinator	Х		Х		Priority 1 for intervention	
Organizational shortcomings of the vaccinator	Х		Х		Priority 1 for intervention	
Cluttered care cart	Х		Х		Priority 1 for intervention	
Unclear circuit of people to be vaccinated	Х			Х	Priority 1 for RESEARCH	
Vaccine confusion	Х		Х		Priority 1 for intervention	
Vials of similar vaccines	Х		Х		Priority 1 for intervention	
Inattention of the vaccinator	Х		Х		Priority 1 for intervention	
Narrow treatment room	Х			X	Priority 1 for RESEARCH	
Lack of vaccinator planning	Х		Х		Priority 1 for intervention	
Crowded waiting room with people	Х			Х	Priority 1 for RESEARCH	
Understaffed	Х		Х		Priority 1 for intervention	

Table 1: Prioritization of Interventions and Etiological Research for Identified Problems

All the identified causes (problems) were of greater importance and the majority of them required priority 1 intervention because the hospital center's ability to intervene was obvious. A few issues, although of greater importance, were priority 1 for research because response capacity was weak.

Selected interventions have been cast in the form of operational objectives through strategic plans:

- Operational objective 1: within two weeks, provide standardized training for five midwives involved in routine vaccination.
- Operational objective 2: within two weeks, develop, popularize and implement guidelines on the stages of routine vaccination of children.
- Operational objective 3: within a month, organize a training session in management and leadership for the supervisory staff of the vaccination unit.
- Operational objective 4: strengthen the team of vaccinators with an additional caregiver within 03 weeks.
- Operational objective 5: within 12 months, fit out a new vaccination room that meets architectural and organizational standards.

Table 2 : Operational Objective 1: Within Two Weeks, Provide Standardized Training for Five Midwives Involved in Routine Vaccination

NO	ACTIVITIES	INDICATORS	RESPONSIBLE	CHRONOGRAM	CHRONOGRAM	MONITORING AND EVALUATION
1	Select 5 caregivers to benefit from standardized training on routine vaccination .	The list of 5 caregivers who should benefit from standardized training on routine vaccination is made available.	Registered nurse	26-mars-22	\$0,00	QHSE Director
2	Send the training request letter to the central office of the health zone (BCZS) in Lubumbashi	The letter requesting standardized training is sent to the BCZS in Lubumbashi with acknowledgment of receipt.	Registered nurse	31-mars-22	\$0,00	QHSE Director
3	Organize standard training on routine vaccination	the standardized training of vaccinating nurses is ensured.	BCZS Lubumbashi Expert	10-avr-22	\$450,00	Head doctor of Lubumbashi health zone
4	Evaluate the training activity	The training activity is evaluated.	Head of medical staff	12-avr-22	\$50,00	QHSE Director
	SUBTOTAL BUDGET 1					

Table 3: Operational Objective 2: Within Two Weeks, Develop, Popularize and Implement Guidelines on the Stages of Routine Childhood Vaccination

NO	ACTIVITIES	INDICATORS	RESPONSIBLE	CHRONOGRAM	BUDGET/USD	MONITORING AND EVALUATION
1	Develop a draft of procedures on the routine vaccination of children	The draft of the procedures on vaccination is elaborated	BCZS Lubumbashi Expert	01-avr-22	\$50,00	QHSE Director
2	Review, amend and adopt the text of the draft	amended text is adopted in plenary	Quality team	03-avr-22	\$20,00	Medical Director
3	Validate the document of procedures on the routine vaccination of children	the vaccination procedures document is validated.	General director	08-avr-22	\$0,00	Quality team
4	Disseminate procedures for routine childhood vaccination.	The procedures relating to the routine vaccination of children are popularized among users.	BCZS Lubumbashi Expert and QHSE Director	10-avr-22	\$50,00	Quality team
	SUBTOTAL BUDGET 2					

Table 4: Operational Objective 3: Within one Month, Organize a Training Session in Management and Leadership for the Supervisory Staff of the Vaccination Unit

NO	ACTIVITIES	INDICATORS	RESPONSIBLE	CHRONOGRAM	BUDGET/USD	MONITORING AND EVALUATION
1	Hold a meeting with the Human Resources (HR) Officer	An update meeting is held with the HR officer	QHSE Director	17-avr-22	\$0,00	Quality team
2	Train the supervisory staff on the theme of management and leadership in health	The supervisory staff of the vaccination unit is trained in health management and leadership	QHSE Director	18-avr-22	\$120,00	Quality team
3	Evaluate the training session on health management and leadership	The training session is evaluated	Quality team	20-avr-22	\$50,00	QHSE Director

	Table 5: Operational Objective 4: Reinforce the Team of Vaccinators with an Additional Nurse Within 03 Weeks							
NO	ACTIVITIES	INDICATORS	RESPONSIBLE	CHRONOGRAM	BUDGET/USD	MONITORING AND EVALUATION		
1	Assign an additional caregiver to the routine immunization team	An additional caregiver is assigned to the vaccination team.	HR Manager	24-avr-22	\$0,00	Registered nurse		
	SUBTOTAL BUDGET 4							

Table 6 : Operational Objective 5: Within 12 Months, Fit Out a New Vaccination Room that Meets Architectural and Organizational Standards

NO	ACTIVITIES	INDICATORS	RESPONSIBLE	CHRONOGRAM	BUDGET/USD	MONITORING AND EVALUATION
1	Develop the specifications for the construction of a vaccination room + waiting room and toilets (44 m2)	The specifications for the construction of a vaccination room and its annexes have been drawn up.	QHSE Director, Medical Director, Care Director and Head of the Technical and Logistics Department.	08-May-22	\$50,00	General director
2	Launch a restricted call for tenders for the construction of a vaccination room and its annexes.	The restricted invitation to tender for the construction of a vaccination room and its annexes has been launched.	Head of technical and logistics department	15-May-22	\$500,00	Quality team
3	Select the lowest bidder.	The lowest bid is selected.	hospital management board	22-May-22	\$100,00	General director
4	Sign the service contract with the selected company.	The service contract is signed with the selected company.	General director	23-mai-22	\$0,00	Quality team
5	Pay the estimate for the construction of the vaccination room and its annexes.	The cost of the construction estimate is paid to the contractor	Chief Accountant	31-mai-22	\$17 600,00	Control Director
6	Receive the work	The finished work is handed over to the contractor.	General director	30-déc-22	\$250,00	Board of Directors
	·	·	\$18 500,00			
			\$19 290,00			
			\$964,50			
		GRAND TOTAL E	BUDGET		\$20 254,50	

Conclusion

The medication error that occurred during the administration of the IPV vaccine to a 3.5-month-old infant reveals how fragile the healthcare environment is to various incidents, the consequences of which can be disastrous both for the healthcare organization, the patient and family, and even the provider.

Routine vaccination for children from 0 to 11 months is an integrated activity in many hospital establishments and it is part of the flagship measures of health systems throughout the world to protect children against fatal and/or disabling diseases at the like poliomyelitis, and ensure their good growth. Two to three million children's lives around the world would thus be saved thanks to routine vaccination. It is not surprising that this practice is made compulsory in many countries.

The safety of care is an essential dimension of the quality of care. Thanks to multisectoral teamwork, brainstorming and the Ishikawa diagram, we were able to highlight the possible causes

of this ME. The prioritization made it possible to identify the problems susceptible to intervention and those still requiring etiological research. Finally, measures taken and cast in the form of operational objectives have been implemented with a view to continuous improvement of the quality of the routine vaccination service for the benefit of children from 0 to 11 months.

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