Research & Reviews: Journal of Medical and Health Sciences ISSN: 2319-9865

Case Report: Medical Error in Paediatric Vaccination

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Case Report

Received: 21-Dec-2024, Manuscript No. JMAHS-24-156106; **Editor assigned:** 25-Dec-2024, Pre QC No. JMAHS-24-156106 (PQ); **Reviewed:** 08-Jan-2025, QC No. JMAHS-24-156106; **Revised:** 11-Mar-2025, Manuscript No. JMAHS-24-156106 (R); **Published:** 14-Mar-2025, DOI: 10.4172/2319-9865.14.1.003

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Citation: Jamil H. Case Report: Medical Error in Paediatric Vaccination. RRJ Med Health Sci. 2025;14:003.

ABSTRACT

Analysis and writing of this case study is undertaken by evidencing and observing the entire incident while working in Aga Khan Hospital, Pakistan and asking the questions from respective departments. We are discussing a medical error associated with a hospital setting in which the neonates are affected by the negligence of medical staff resulting in adverse drug reaction by routine vaccination for the prevention of TB. BCG vaccination is routinely administered to neonates in TB prevalent areas and TB endemic countries. This vaccination is not a part of routine immunization in developed countries. This case study is written when there was accidental administration of ONCO-BCG vaccine instead of neonatal vaccine which was 80 times more potent than usual neonatal vaccination. The main methodology of the study was observation of entire incident while working in inpatient pharmacy department and data was taken from article published in PubMed journal by AKUH pediatrics department doctors and students. The results showed developing of adverse effects (skin lesions, lymphadenopathy and coagulation derangement). None of the babies has actual clinical TB or disseminated disease. All are treated with ATT as a chemoprophylaxis and followed up for one year and cost was borne by hospital. The error was disclosed to the families as well. The main reason of this error was look alike vials as well as negligence of pharmacy and nursing staff to ignore the double checking of the vial before dispensing and administration. Chemoprophylaxis with ATT proved effective in this case. No mortality is observed.

Keywords: Neonatal TB; BCG vaccine; ONCO-BCG vaccine; Vaccination

INTRODUCTION

We are discussing a medical error associated with a hospital setting in which the neonates are affected by the negligence of medical staff resulting in adverse drug reaction by routine vaccination for the prevention of TB. This vaccine prevents the infants from all types of TB including *Tuberculous meningitis*, miliary TB and other disseminated TB. It has not found effective in adults above 35 years and researches are being carried out to find an effective vaccine for adults as well. Bacillus Calmette-Guerin (BCG) vaccine contain live attenuated strain of *Mycobacterium bovis*, it is a safe vaccine and there are rarely any adverse effect reported. Its side effects are mostly associated with injection site reactions including large scars, ulcers, and other hypersensitive reactions like abscesses and skin lesions which undergo a stage of formation into scars and then they slowly disappear within 6 weeks of administration. Other side effects are swollen lymph nodes, axillary lymphadenitis, osteitis and even osteomyelitis in severe cases. However, rarely it leads to *Erythema nodosum* and induration which is thickening of the skin due to fibrous scars [1].

Background

Bacillus Calmette Guerin (BCG) is an effective vaccine for the prevention of Tuberculosis, however it is not used widely in the world nowadays. Internationally, it is only used in certain high risk groups who are living in areas having per annum cases of TB above 40 out of 100,000. It is also used in the all those countries where TB is prevalent. Pakistan falls under those TB prevalent countries and hence it is recommended to vaccinate the newborn during first 7 days of life with BCG vaccine as well as Hepatitis B vaccine [2,3].

CASE PRESENTATION

A randomized clinical trial study done in pediatric and maternity wards at three Danish University Hospitals in which all pregnant women participated and the objective of this case study was to evaluate ADR of BCG vaccine in neonates. Only minor side effects were observed and the cases of disseminated disease are nill among 2,118 vaccinated child. Two cases of ADR (regional lymphadenitis) were reported. Hence it indicates there is mild morbidity and nill mortality as a consequence of vaccination. Another such incident were reported in Taiwan by Wei et al. This was the case of incorrect dilution in which the vial is reconstituted with 3 ml diluent (standard is 2 ml). After injecting this vaccine to around 20 neonates, 15% of them developed skin abscess which takes 6 weeks to heal. They were all followed up for 18 weeks. In Central Manchester Healthcare and the Mancunian trusts, BCG vaccine was injected percutaneous instead of intradermal route in 857 neonates with a median age of 10 days between Jul-Nov 1994. ADR was observed in 11% of cases however one child who was born with immunodeficiency syndrome doesn't get recovered although there were no signs of disseminated disease from her pulmonary biopsy report. O'Brien et al. suggested look alike vials are also responsible for this incident in addition to consider as human error. Study published in journal of pharmaceutical care in 2014 conducted by MF Rafatai et al. in which there was a medication error caused poor handwriting of doctor where a 13-year-old boy who was prescribed HCG (hormone for treatment of his sexual maturation) was written as βHCG by physician which was a lab test to confirm pregnancy and this was misread as BCG vaccine. He received 6 IM doses of intravesical BCG vaccine (recommended for non-invasive bladder cancer) before this medication error was finally diagnosed. He was lucky enough to get recovered from routine anti-TB medicines. Akbulat Z et al. presents a case report published in New Zealand medical journal (Nov 2010) in which there was wrong route administration of intravesical BCG vaccine (IV instead of IM) causing serious adverse events (sepsis) but successfully treated with anti-TB medicines. Another wrong route administration error reported by Yarmohammadi A et al. when four BCG doses were administered IM instead of intravesical route causing headache, sweating and fever. No other signs n symptoms observed yet prophylactic anti TB medication therapy started [4-6].

Incident

In Aga Khan Hospital, normally the routine vaccination practice is the dispensing of one vial of BCG vaccine which contain 20 neonatal doses. The dose for vaccine is 0.05 ml of the reconstituted vaccine through intradermal route. This one vial is dispensed from the satellite pharmacy dealing with gynae wards (C2 pharmacy) once or twice weekly depending on the number of deliveries. Each vial is of 1 ml, contains ready to use reconstituted vaccine and it contains 2 to 8 million units of live strains of *Mycobacterium bovis* BCG. Sound Alike and Look alike vial of ONCO-BCG contains 81 mg (TheraCys) or 50 mg (Tice BCG). This is used solely for intravesical instillation in patients with bladder cell carcinoma and its vial clearly mentions

not for immunisation. In the present case between the period of 14th April 2016 to 16th April 2016 at Aga Khan University Hospital Karachi, routine vaccination of 26 neonates were done of which 13 were male and 13 were female, in place of neonatal BCG vaccine, ONCO-BCG vaccine was dispensed from the pharmacy, didn't caught at nursing end as well and administered to the babies aged 2-4 days. This dose was 80 times more potent than normal vaccination for neonates (Figure 1) [7,8].

Figure 1. BCG vaccine.

RESULTS AND DISCUSSION

Underlying triggering factors behind the event

Primary reasons:

- Dispensing error from the store pharmacy to satellite pharmacy and then to wards due to look alike vials. Had it not dispensed in the first place, it won't be administered.
- Cross checking at nursing counter is not performed vigilantly. It passes all the checks resulting in administration.

Secondary reasons:

- Over burden of staff due to engagement in multitasking.
- Rotation of the pharmacists are done on routine basis amid different satellite pharmacies for instance ER pharmacists are rotated to inpatient pharmacy; inpatient pharmacist are replaced by outpatient pharmacist, who are further interchanged with compounding or sterile area pharmacy preparation area. This is done to continuously train already experienced staff to enhance their competencies as well as to avert monotony from routine work. Similarly, the nursing staff are shuffled throughout the hospital. This incident happened when staff are recently moved on from their comfort zone department to new area. This lead to the consensus that management shouldn't take the training of experienced staff for granted because every department/satellite pharmacy has its own uniqueness & exclusivity.
- Product packaging is another contributive factor of this incidence. Look alike vials are major reasons for dispensing errors.

Consequences

The most common ADR of high dose BCG vaccination is skin lesions. Out of 26 babies, 16 of them established skin lesions of which 15 were turned into papule; 3 into pustule; 3 into skin indurations and 2 into skin erythema. Axillary lymphadenopathy was seen in 1 baby. 3 developed coagulation derangement. Intracranial bleeding was seen in 1 baby. However, none of them developed actual clinical/disseminated TB. Most of these lesions returned to normal after few weeks. One newborn developed a persistent weeping skin lesion at the left big toe and experienced skin biopsy at the age of 3 months that revealed inflammatory changes with eosinophilia. This lesion resolved after management with anti-allergy, topical steroids and antibiotics and it took 3 months to completely settle down. Coagulation was also deranged in 3 babies. Out of three babies who developed coagulation, 2 of them exhibited post circumcision bleed. Only 1 baby demonstrates intracranial bleeding with symptoms of fever, cough and irritability. This leads to focal seizures later on. Upon investigation, laboratory findings revealed hypocalcaemia (serum calcium: 6.5 mg/dl), sudden drop in hemoglobin (Hb 6.3 g/dl), normal

coagulation profile (INR of 1.2), a normal platelet count (427 × 10^9/L) and also received vitamin k at birth. Neuroimaging had done which was suggestive of left subdural hematoma and minimal subarachnoid hemorrhage. His Factor XIII was found to be 102%; normal range is 70-100%; CBC was normal; coagulation parameters are normal and hence deficiency of factor XIII was ruled out. He was managed conventionally with calcium supplementation, vitamin K, antiepileptic, antibiotics and packed cell transfusion. He was discharged in stable condition and remained well on antiepileptic with no focal neurologic deficit. Hemorrhage was resolved after managing it for a period of one year. Follow-up showed he developed normal functioning at a later stage of his life [9].

1 out of 26 developed factor X deficiency and 1/26 had factor VII, IX and X deficiency all of which are vitamin K dependent factors. These babies responded to vitamin K therapy. Rifampicin, an ATT medicine, is associated with coagulopathy in vitamin K deficient patients. This complication may be associated with rifampicin usage. None of the patients developed osteomyelitis.

Management

Following the reporting of incident, the hospital took several actions to compensate this error.

- All parents were informed before starting treatment.
- The cost of the treatment was borne by the hospital for a period of one year.
- Paeds specialist and gynecologists dealing with those babies were informed about it.
- One nursing manager was assigned 24/7 in case of any emergency situation.
- Families of those who was discharged were informed and they were immediately called for follow up.
- Panel including paeds ID specialist, nursing supervisor, pharmacist, departmental chair and hospital ethics committee were created to find the appropriate management.
- As such incidence is very rare and there was no previous information regarding the management of such adverse event, therefore, an agreement was taken to initiate post-exposure prophylaxis with isoniazid at a dose of 10 mg/kg/day of and 15 mg/kg/day of rifampicin for the period of at least 3 months. For the entire course of therapy of three months, all the babies were followed up with a team of ID specialist to ensure conformity to the therapy.

Alternative courses of action

Some other actions which can be taken to avoid future occurrences.

- Identify LASA products while including them in the formulary.
- Store LASA products appropriately with auxiliary or caution labels.
- Maintain a near miss log in every satellite pharmacy and wards; review it on monthly basis to identify which types of errors are occurring occasionally and what can be done to avoid them.
- In case of fresh stock coming into the pharmacy or refunds coming from wards, there are chances of product mix-ups while placing them on shelves. This could be avoided by the use of data collected form near miss logs, identify most common errors and label the bins with red flag and checked them physically.
- Daily counting of physical stock of critical medicines in the satellite pharmacy against system quantity (stock taking) should be mandatory. These critical medicine list mostly includes those medicines in which there are more chances of errors due to their look alike/sound alike nature, their product packaging designs, logos and patterns are similar in nature (lanoxin tablet *vs.* thyroxine tablet), different dosage forms of same generic (Lasix tablet *vs.* Lasix injection), same brands and different strengths (ruling 40 mg capsule *vs.* ruling 20 mg capsule) or difference in formulations of same drugs (film coated deltacortil tablets *vs.* enteric coated deltacortil tablets).

CONCLUSION

Medical errors are inevitable; it is scary fact. It is a complex and multi task process from prescribing till administration of any medicine. It includes entire team, not a single department. We can relate it to a Swiss Cheese model which links harm/accident with the multiple layers of cheese (representative of management protocol), all layers aligned in a single line & the holes in each layer of cheese represents the loop holes or hazards (of the plan, environment, or individual parts of the system) which results in causing a serious and potential hazard.

- Reporting of medical errors should be encouraged. This is very crucial as it helps in root cause analysis and eliminate error in the first place. BCG vaccination overdoses cases are under-reported in Pakistan and worldwide as

well. Out of 1 million doses, only 2.2 cases are reported which is a minute fraction of the total cases actually happened. Harmful errors must be disclosed to patients/ attendants as well to ensure transparency.

- In case of such incidence, it is important to take compensatory actions and manage it with the help of previous data available, if any, or develop a new protocol accordingly.

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