

Investigation of a Suspected Case of Adverse Events Post Immunization (AEFI) In the Health District of Commune VI, Bamako (Mali), June 2021

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Abstract

Introduction: A post-immunization adverse event (AEFI) is any adverse medical event following vaccination that is not necessarily causally related to vaccine use. Reporting and investigating AEFIs is useful to identify and avoid reactions related to vaccination error and to distinguish between an inconsistent concomitant event and a vaccine reaction or other vaccine-related event. Our objective was to investigate a case of AEFI in Commune VI of Bamako, June 2021.

Methods: This was a descriptive case study that took place in June 2021 following the notification of a case of severe AEFI with necrosis of the left arm in Commune 6 of Bamako.

Results: This is the case of Ms. YD, 44 years old, with no known history of having received a dose of Astra Zeneca's Covishild vaccine administered by the mobile vaccination team at a community health center in Bamako. The onset of symptomatology dates back to 2 hours after vaccination, marked by pain and redness at the injection site. The addition of swelling of the left arm on Day 1 post-vaccination followed by self-medication based on anti-inflammatory which leads to an accentuation of symptoms with the appearance of fluctuances and fistulization complicated by necrosis.

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Conclusion: This investigation allowed us to report a case of severe AEFI whose most likely hypothesis would be ERYSIPELE in a lady whose course was marked by a total recovery with preservation of the sensory and motor function of the arm.

Keywords: Investigation; Post immunization event; Necrosis; Bamako; 2021.

1. Introduction (use bold for main headings like this one. do not use italic)

Coronavirus 2019 (COVID-19) is an infectious disease originally reported in China and currently dispersed around the world. It is caused by a novel coronavirus (SARS-CoV-2 or 2019-nCoV) affecting more than seven million people worldwide [1]. The disease quickly spread throughout the country, with scientists and doctors having no answer or solution about its transmission or pathology [2]. As of January 31, 2022, this pandemic has caused 5681084 deaths in 375029904 people infected worldwide, 907080 deaths in 75,553,489 in America, 1,614,034 deaths in 124,664,941 infected people in Europe, 239,299 deaths in 10,995,496 infected in Africa [1]. In Mali, 743 deaths have been recorded out of 33,062 infected people as of 9 March 2023 [3]. More than a year after the pandemic, very few therapeutic weapons have proven capable of fighting COVID-19, the most relevant including steroids and antibody-based therapies[4]. Indeed, the virus quickly went around the world and, in March 2020, the World Health Organization (WHO) declared the disease a pandemic. Unprecedented measures have been taken to curb the spread through lockdowns, restrictions on travel and gatherings, business and school closures [2]. The hope for controlling the COVID-19 pandemic rests largely on vaccination. It uses a variety of vaccines developed with speed and ingenuity rarely equalled. These vaccines aim to elicit an immune response, mainly against the Spike (S) protein [5]. As part of the COVAX initiative (the vaccine work axis of the device to accelerate access to COVID-19 tools), Mali received in March 2021, 396,000 doses of vaccine from the AstraZeneca laboratory to vaccinate health workers and people at risk for severe forms of infection. This initiative aims to improve access to vaccines in the poorest countries for the benefit of medical personnel and populations most at risk of severe forms of this viral infection [1]. Data from pharmacovigilance studies indicate a high frequency of minor adverse reactions following administration of each of the three WHO-licensed vaccines (Pfizer, Moderna and AstraZeneca) [1]. This frequency is estimated for the AstraZeneca vaccine to be approximately 1 case per 100,000 vaccinated population [6]. Like any vaccine, COVID-19 vaccines can cause adverse events called adverse events following immunization (AEFI) or adverse events following vaccination. An AEFI represents any adverse medical event following vaccination that is not necessarily causally related to the use of the vaccine. The adverse event may be any adverse or unintended sign, abnormal laboratory test finding, symptom or disease. Reported adverse events may be true adverse events (i.e., resulting from the vaccine or vaccination process) or be concomitant events that are not due to the vaccine or vaccination process but are temporally associated with vaccination [7]. On 10 March 2021, the number of thromboembolic events reported amounted to 30 cases among approximately 5 million people vaccinated with the vaccine in the European Union (EU) or 0.0006 cases per 100 individuals, which is no higher than the number observed in the general population (in the absence of the vaccine) [8]. In Mali, 69,933 people had received their first dose as of 13 May 2021 with 9 cases of severe AEFI [8]. It is in this context that on 08 June 2021, a case of severe AEFI with necrosis of the left arm was reported in Commune VI of Bamako. Reporting and investigating AEFIs was useful to identify and avoid reactions related to vaccination error and to distinguish between an inconsistent

concomitant event and a vaccine reaction or other vaccine-related event. The aim was to quickly contain necrosis in order to minimise its impact on the normal continuation of the vaccination campaign. The objective was to investigate the case of MAPI in Commune VI of Bamako, June 2021.

2. Methodology

2.1. Study Framework Structure

The health district (HD) of commune VI served as a framework for our study. It is covered by a two-tier health system in accordance with the health sector policy:

- Community Health Centres (CSCoM) at the health area level are the first level;
- The Reference Health Centre (CSRéf) of the DS represents the second level.

The commune has 12 health areas in 2022 and vaccination is carried out in the 12 CSCoM by fixed and mobile teams and often with the collaboration of certain private structures under the supervision of the CSREF.

At the 1st level (health area), all CSCoMs are staffed by qualified staff, we have two doctors and 5 midwives per CSCoM at least.

Each CSCoM is managed by a Community Health Association (ASACO). ASACO's management bodies are the Board of Directors set up by the delegates and the Management Committee composed of five members from the Board of Directors and the General Assembly (body).

The CSRéf is the second level of the health district. It essentially fulfils two functions:

- A public health function with planning, monitoring and coordination tasks in the implementation of the Circle Health and Social Development Plan (PDSC).
- A clinical reference function allowing it to take care of cases beyond the technical platform of first-level structures. These include cases requiring surgery, radiological explorations, biological examinations or hospitalization.

This second level is headed by a Chief Medical Officer who coordinates a multidisciplinary or multisectoral team.

2.2. Study Type and Period

This was a descriptive case study that took place in June 2021.

2.3. Study population

These were vaccinated people, vaccination stakeholders and clinicians from Commune VI.

2.4. Data collection tools and techniques

We conducted a literature review of CScCom Expanded Programme on Immunization (EPI) registries where vaccination was performed and Cabinet and CScCom consultation records that saw the patient. As well as the observation of the cold chain of the EPI, the interview with the health workers of the Medical Practice, the CScCom, the interview with the relatives and friends of the patient.

2.5. Case definition of AEFI General guidelines for the preparation of your text

Post-vaccination adverse event or AEFI is defined as any untoward medical incident that:

- Follows vaccination,
- Does not necessarily have a causal link with the use of the vaccine,
- Perhaps an adverse symptom of which a vaccinated person complains,

Perhaps an abnormal laboratory finding, symptom or illness observed by a member of the medical staff.

2.6. Data processing and analysis

The data collected was presented in narrative form.

2.7. Ethical considerations:

Confidentiality and anonymity have been guaranteed. There was no data to identify the victim.

3. Result of the investigation

3.1. Case Description

This was the case of AEFI in Mrs. YD, aged 44, resident of the Yirimadio district in commune VI of Bamako. On May twenty-four (24) 2021, at ten (10) a.m., Mrs. YD presented herself to the COVID-19 mobile vaccination team at a community health center in Bamako to receive her first dose of the Astra Zeneca vaccine. After questioning, it was noted that our candidate had no comorbidities and a history of allergies. The usual formalities have been completed, including the registration of all information in the information tools as recommended by the procedures relating to vaccination against COVID-19. The vaccine administered was from lot 4121Z006 named Covishild. The cold chain had been respected. It was injected with a 0.5 ml dose of Astra Zeneca's Covishild vaccine into the left deltoid and no blood was returned during the injection. After fifteen (15) minutes of observation, no particular reaction was observed. A vaccination card has been issued with all the information and the date of the next appointment. On June eight (8) 2021 at fifteen (3 p.m.), Mr. DT of the Directorate General of Health and Public Hygiene (DGSHP) called the pharmacovigilance focal point of Commune VI to inform him of the state of health of Mrs. YD. She was invited to make a consultation at the CSRéf of Commune VI and an interview around her state of health. According to her, the onset of the symptomatology dates back to two (2) hours after vaccination, marked by pain and redness at the injection site.

The addition of a swelling of the left arm on Day 1 post-vaccination motivates a consultation in a clinic in Yirimadio where antibiotic treatment was instituted. Faced with the persistence of symptoms and the failure of treatments, the family establishes self-medication based on anti-inflammatory which leads to an accentuation of symptoms with the appearance of fluctuances and fistulization. Faced with this situation, she made a new consultation at ANIASCO (Niamakoro Community Health Center) which in front of the necrosis the doctor of the center referred her to surgery where a necrosectomy and a dressing were performed. As a result, parents decide to go to the Directorate General of Health and Public Hygiene to express their dissatisfaction. At the CSRéf CVI after the clinical examination and complementary; The following diagnostic hypotheses were retained: Necrotizing and fascist necrotizing cellulitis and the patient was put on treatment with antibiotics, analgesics, multivitamins, vaccine and tetanus serum and a daily dressing.

3.2. Active search for additional cases of death and AEFI

The review of the consultation records by the investigation team concerned the community health centre and the clinic where she was admitted for consultation. At the end of this count, no case of AEFI or death was noted.

3.3. Identification of the vaccine vial and the persons who have received the doses of that vial

We listed and identified all people who were vaccinated with the same vial used for the AEFI case under examination. A special follow-up programme has been put in place. To date, no incidents have been recorded and all these people are doing well.

3.4. Actions taken

At the end of the investigation, the following actions were carried out:

- Alerting health workers;
- Verification and dissemination of technical guidelines on AEFI cases;
- Briefing of health workers on AEFIs;
- Planning of awareness-raising activities in the patient's entourage (family);
- Active search for other cases in the community and in health facilities.

4. Discussions

In our study, the occurrence of necrosis could be explained by self-medication based on anti-inflammatory drugs, however the data from pharmacovigilance studies show a high frequency of minor adverse reactions after the administration of each of the three vaccines approved by WHO (Pfizer, Moderna and AstraZeneca). Severe life-threatening adverse events in vaccinated individuals were rare. This frequency is estimated for the AstraZeneca vaccine at approximately 1 case per 100,000 people vaccinated.

According to a study carried out in Ivory Coast in 2022, the average incidence density of AEFI was 4.8 cases per 100 person days with extremes of 1.8 and 6.5. It did not differ by vaccination site, vaccine type and dose rank. The only factor associated with the occurrence of AEFI was gender, since it was noted that women were 1.5 times more likely to have AEFI after vaccination against COVID-19 compared to men (9).

According to a study conducted in Morocco, side effects are frequent but tolerable, hence the importance of clinical monitoring of vaccinated subjects (10).

Pharmacovigilance, models mathematics, updated statistical data however, should be regularly assessed to adapt the vaccination strategy in order to guarantee a favorable benefit/risk ratio (5).

Efforts have been made by the WHO within the framework of insurance quality of there vaccination notably against COVID-19. Despite these efforts, cases of AEFI have been reported in some countries including:

- The Austrian Federal Office for safety in healthcare (basg) reported a death occurring 10 days after serious disorders of the coagulation as well as a case requiring hospitalization following a pulmonary embolism Austria on march 7, 2021
- The 11th march 2021, the danish health and welfare authority drugs reported one death from clots blood
- Norway where on march 14, 2021, the agency Norwegian medicines reported one death unexpected followind a cerebral hemorrhage and three others case of clots blood or bleeding brain in people under 50 requiring hospitalization
- The Netherlands where the 14 March 2021, the dutch center for pharmacovigilance (lareb) announced 10 potential cases having been reported in the country(11)

5. Conclusions

This investigation allowed us to report a case of severe AEFI whose most likely hypothesis would be ERYSIPELE in a lady whose evolution was marked by a total recovery with preservation of the sensory and motor function of the arm

Remind providers and the community about AEFI management mechanisms as part of the COVID-19 vaccination campaign.

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Figure 1: Image of the arm before treatment.



07/04/2023

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Figure 2: Image of the arm being processed.