IN THE SUPREME COURT OF PAKISTAN

CIVIL MISC. APPLICATION 203-K/2018

(In the matter of death of minor children due to Measal Vaccination)

COMPLIANCE OF ORDER DATED: 31.03.2018

REPORT BY

THE AGA KHAN UNIVERSITY HOSPITAL

Contents

Summary:

On March 3rd, 2018, six children in the Shaheed Benazirabad district of Sindh developed a disease called Toxic Shock Syndrome (TSS) after they were given measles vaccines which were not prepared and administered per the standard operating procedures (SOPs). Four of these children died, while two recovered after being hospitalized.

Measles vaccine is the best and only available intervention to protect children from the deadly disease of measles, which kills thousands of children in Pakistan every year. The Expanded Program for Immunization (EPI) is tasked to ensure that all children in Pakistan receive this and other lifesaving vaccines. However, the vaccines have to be administered in a safe manner, following the SOPs. Each vial of measles vaccine contains enough vaccine for up to ten doses. Measles vaccine is transported in a dried powder form, and is prepared for use by mixing it with a solvent at the time of administration. All doses must be administered within six hours of this final preparation, and any unused vaccine must be discarded. Needles and syringes must not be reused while preparing or administering the vaccine. If these steps are not followed, then very rarely, complications like the TSS can occur.

In the current event, the ground level staff (team of Vaccinators and Lady Health Workers) did not follow the SOPs with regards to always discarding the vaccine after six hours of its preparation, and not reusing the needles. The monitoring system to check the practices of the field level staff was weak. There was paper-level checking but very little on-the-ground audits by the district vaccination program leadership to monitor the practices of the field level staff. This lack of monitoring encouraged the irresponsible behavior of the field level staff.

When the babies got sick and some of them were taken to the Government hospital of Peoples Medical College (PMC), the serious nature of their condition was not picked up till very late and the babies did not promptly receive the advanced care that was needed. This was partly a misjudgment by the doctors, who are overburdened with patients and were operating with limited resources. The PMC Hospital, being one of the final hope and referral center for around one million catchment population, critically needs an up gradation in terms of human resources and life-saving facilities. The current infrastructure of the Government Hospital is not adequate to deal with sick conditions like TSS and there is no reliable system to quickly transfer sicker children to higher-level facilities in bigger cities.

While the deadly complication of TSS s rare, the practices that led to this incident are more common. The negligence that led to this complication needs to be appropriately addressed. Systems need to be revised by the Health Leadership (Health minister, Secretary Health and DG Health) to make sure that 1) all children receive measles and other lifesaving vaccines, and 2) that vaccines be administered in a safe manner according to the SOPs. The system must be redesigned with clear and independent authority of assigned leaders, along with explicitly defined strict accountability and monitoring parameters for results. Provincial leadership must ensure that district leadership is monitoring vaccination practices on the ground. Hospitals such as the PMC in Shaheed Benazirabad need an up gradation of facilities and staff. Refresher trainings of doctors are needed so they may identify the very sick children quickly. Referral mechanisms from these District hospitals to the higher level facilities in bigger cities need to be better developed, until the time that the District hospitals are upgraded to a more advanced level.

Preamble:

On 3rd March 2018, six Adverse Events Following Immunization (AEFI) were reported from District Shaheed Benazirabad, province of Sindh. These AEFI cases were specifically associated with Measles vaccination in the neighborhood of Mariam Road UC -8 of Taluka Nawabshah in District Shaheed Benazirabad in Sindh Province.

Secretary Health immediately constituted an inquiry committee that included Sindh government and EPI - WHO officials to investigate the incident within the period of 24 hours. Aga Khan University received three AEFI cases who were admitted on March 4, 2018. This Report is being submitted in compliance of the Order of the Honourable Supreme Court of Pakistan dated 31st March 2018, wherein the Honourable Court sought a report answering the question whether the death of the infants has taken place on account of the causes mentioned in the report of the Sindh Government or otherwise. A multidisciplinary team of experts was constituted and conducted an independent inquiry. The team includes:

Investigation team:

	Name	Designation	Specialty
1.	Dr. Asad Ali (chair)	Associate professor and Associate dean research, AKU	Pediatric Infectious Diseases
2.	Dr. Rehana Siddiqui	Associate professor, AKU	Epidemiologist
3.	Dr. Mairaj Shah	Director Operations, Secondary Hospitals, AKUH	Quality Assurance expert
4.	Dr. Ali Faisal Saleem	Assistant professor, AKU	Pediatric Infectious Diseases
5.	Dr. Sobiya Sawani	Instructor, AKU	Epidemiologist
6.	Mr. Atif Riaz	Manager research, AKU	Health system's research
7.	Mr. Mohammed Amir	Specialist, Pharmacy, AKU	Pharmacist
8.	Ms. Mehreen Raza	Supervisor Pharmacy-Outpatient Dispensary, AKU	Pharmacist

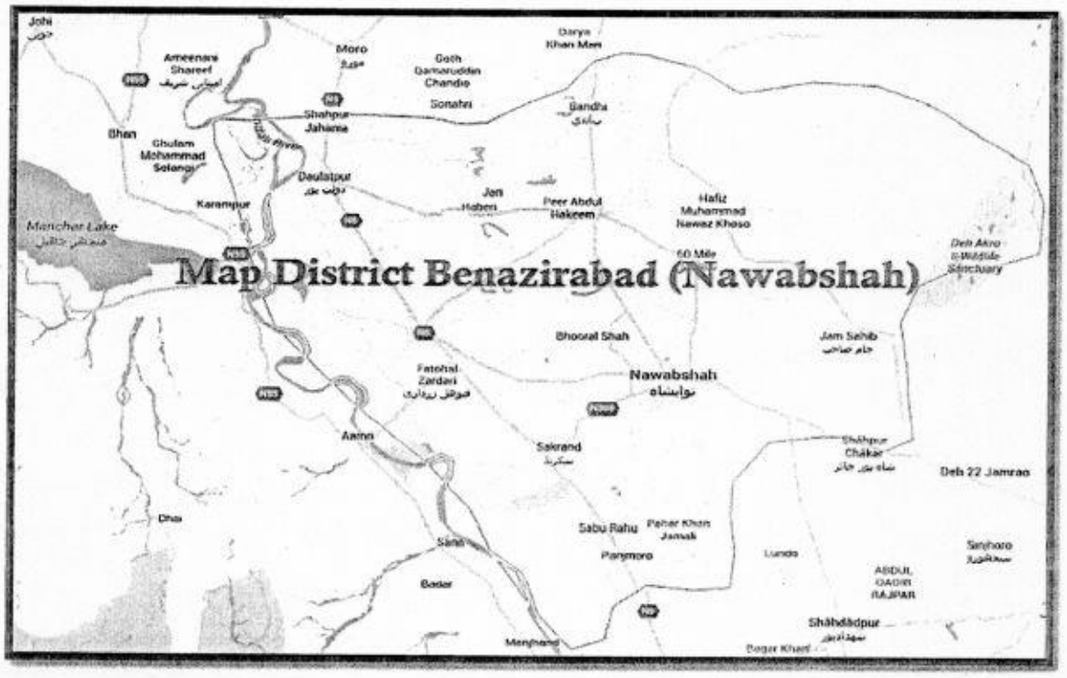
Background:

Vaccinations are one of the best public health interventions which have saved countless lives around the world, including in Pakistan. Rarely though, there can be Adverse Events Following Immunization (AEFI). An AEFI is an untoward medical occurrence following immunization. Serious AEFIs are life-threatening and may result in death, disability and hospitalization. The Expanded Programme of Immunization (EPI)

is responsible for immunization and reporting of any AEFI in Pakistan. Vaccination is done through a network of EPI centers under standard operating procedures. Trained vaccinators and Lady Health Workers (LHWs) provide outreach and center based services.

LHW program conducted maternal and child health (MCH) week activities in various parts of Sindh to complete vaccination schedules of children in their areas from 26th February to 3rd March, 2018. On 4th March 2018, six cases of AEFI were reported from Mariam road UC-8 district Shaheed Benazirabad, Sindh, after receiving measles vaccination. Following the event, vaccination campaign was immediately ceased. This report is based on AEFI investigation by AKU team, which followed the initial investigation of March 4, 2018 by Health Department in District Shaheed Benazirabad, province of Sindh.

Map of SHAHEED BENAZIRABAD DISTRICT



Methodology:

Epidemiological Investigation:

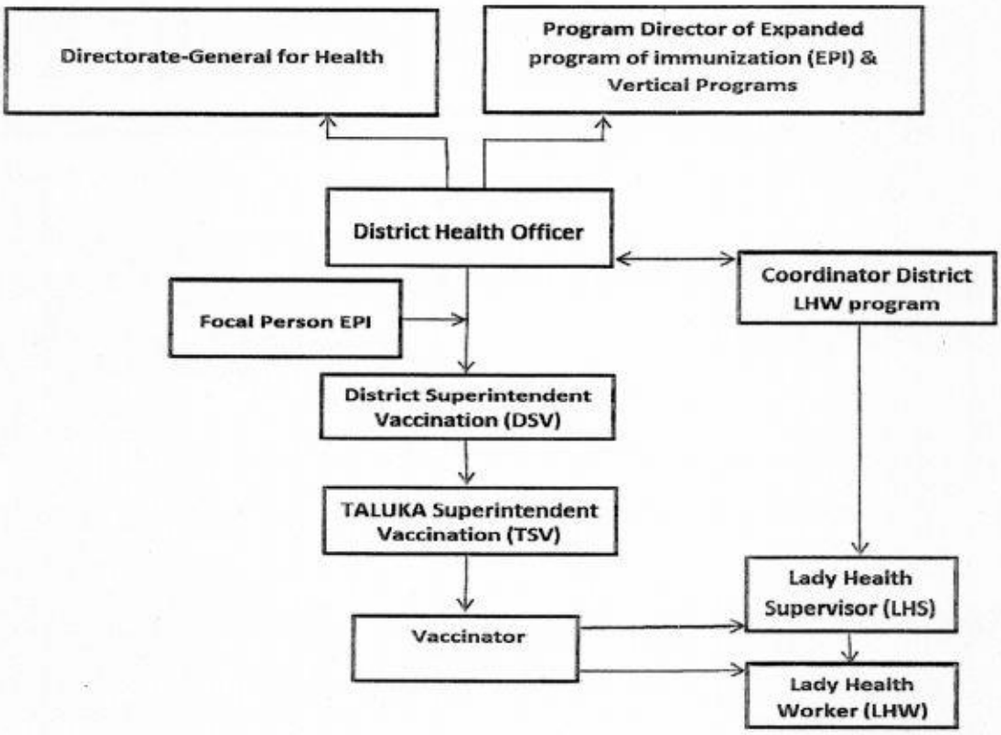
The team comprising of pediatricians, epidemiologists, public health analysts, pharmacists, and quality assurance experts met twice before visiting district Shaheed Benazirabad. During the 1st meeting the reports submitted by health department Sindh were thoroughly reviewed followed by brief discussion on root cause

analysis and action plan related to the event. In the 2nd meeting team members focused on to their specific domains and came up with further information collection plan to be used for the visit. Assessment of root cause analysis templates were reviewed and modified according to the incident and related events. The logistic arrangement for the visit and plan was communicated to District Commissioner Benazirabad Sindh.

The AKU team visited district Shaheed Benazirabad on 9th and 10th April, 2018 and met all relevant stakeholders of district health management team. The preliminary meeting with Dr. Mujtaba Memon, acting District Health Officer (DHO) followed meetings with EPI focal person, vaccinator, lady health supervisor (LHS), lady health workers (LHWs) to gather all basic information about the cases. The team interviewed and closely observed the vaccinators, Lady Health Workers (LHWs) and Lady Health Supervisor (LHS) of UC-8 regarding their practices and record keeping. The team members met District Supervisor Vaccination (DSV), Taluka Supervisor Vaccination (TSV), District coordinator LHW program and in-charge physician of section of Pediatrics in Civil Hospital Shaheed Benazirabad. Deputy Commissioner provided logistic support to visit the Maryam Colony neighborhood and to meet parents and close relatives of children who suffered AEFI. List of interviewees is attached in annexure 1. All relevant records were reviewed and thoroughly analyzed for their fidelity and possible prompts, which could lead to logical conclusions related to event under investigation. List of all documents reviewed is attached in annexure 2. All the parents of the affected children mentioned in the report by health department Sindh were contacted to affirm any possible linkages of their illness due to measles vaccination.

Health system operating mechanism: Linkage between LHW Program and the Vaccination Program

EPI program operates through vaccinators who are responsible for vaccination procurement, storage, supplies, disposal, maintenance of cold chain, record keeping and administration of vaccines. The link between EPI and LHW program gives flexibility that LHWs can also vaccinate in community and in Health center, obtaining vaccine from the Vaccinator. LHWs are trained for vaccine reconstitution, vaccination, and disposal after obtaining vaccine vials from the Vaccinator. Lady Health Supervisor (LHS) supervises LHWs in their practices. Interview of LHS ascertained that LHS are not necessarily trained in vaccination, but they supervise LHWs in all practices including vaccination. Majority of vaccinations are performed by LHWs, and the rest are done by vaccinator in community or in the fixed center. LHWs fill the vaccination cards of those vaccinated in community and bring them back to vaccinator to log in the records and electronic system.



Findings:

UC 8 health facility based vaccination on March 3, 2018:

On 3rd March, 2018, two children Janat D/O Mohammad Amin and Qamar S/O Rafique panhwar became ill after 4-6 hours of receiving measles vaccination at municipal health facility named Nadir Shah-Dispensary located in Union council 8 of Taluka Nawabshah. As per the history of Janat's parents, her 14 month old daughter was brought to the EPI center at around 9:30 am by her father where she received measles vaccine. It could not be ascertained who injected her vaccine since all of the appointed staff at the center are denying this and no record of vaccination of Janat was found in the center. However, it was affirmed that the vaccine was administered by on duty LHW Ms. Salma Iqbal as testified by the vaccinator Muhammad Ramzan, Ms. Salma Iqbal though continued to deny this. After Janat started exhibiting symptoms of vomiting and fever, she was taken to pediatric emergency of People's Medical College (PMC) hospital Shaheed Benazirabad where she received intravenous fluids and was discharged. Janat's parents were not fully satisfied with her treatment of PMC hospital and as her condition was deteriorating with time, they took her to Jinnah Medical Centre (JMC) of Shaheed Benazirabad at around 5:00 pm. She was admitted to neonatal intensive care unit (NICU) of JMC where her fever subsided and she regained consciousness, but started having diarrhea around 11:30 pm. After her treatment at JMC, she started improving and was taken back to home around 2:00 am. Her diarrhea started worsening after *Fajr* (5:30 am) and she was taken to Dr. Mubasher (private practitioner) who examined her around 9:00 am, kept her on oxygen and cleared her airway through suctioning. She was later referred to PMC. Parents of Janat took

her to PMC at 11:00 am on 4th March, where there were children already under treatment for AEFI as the news had already spread for post immunization deaths/illness.

Three children including Janat were referred to Aga Khan University Hospital (AKUH), Karachi, by PMC physicians due to lack of local resources for the management of such condition. Janat was diagnosed as having Toxic Shock Syndrome (TSS) and was treated at AKUH where she was admitted for 10 days and ultimately recovered. The other child Qamar s/o Rafique Panhwar, was 9 months old and brought to the centre by his mother around 12:30 pm (3/3/2018) for measles vaccine. According to the statement of mother of Qamar, LHW Ms. Salma Iqbal injected the vaccine to her child using a prefilled syringe, taken out from a box. Ms. Salma Iqbal denies administering this vaccine as well. After couple of hours of receiving injection, the child Qamar developed fever, started having diarrhea and vomiting. Qamar's mother took him to Dr. Shafi Muhammad (private practitioner) at around 5.00 pm same day who gave him Disprol syrup, but Qamar's condition worsened and kept worsening during the night. Next day Qamar was brought to PMC about 2.00 pm where doctors announced that the child was dead. Qamar expired on 4th March around 02:45 pm.

Community based outreach vaccinations on March 3, 2018.

Of the six reported cases of AEFI, four children (with age range of 9 to 23 month old) Najeeullah s/o Iftikhar (9 months), Husnain s/o Imdad (23 months), Zubair s/o Mohammad Yousaf (9 months) and Hania d/o Imran received measles vaccine at home from LHW Ms. Tehseen. Mothers of these children reported that Ms. Tehseen brought a vial of already constituted vaccine in her purse to their homes. Based on parents' interview it appeared that Ms. Tehseen first went to Najeeullah's house and injected Najeeullah, then went to other homes of Husnain, Zubair & Hania. As Husnain and Zubair were cousins and lived in the same house, they received the injection in same house, reportedly with the same syringe, filling it one after the other according to the family members. The other two children who also lived in the same lane (neighborhood) Najeeullah and Hania received the measles vaccine separately in their respective houses. All aforementioned children fell ill and developed symptoms of fever, diarrhea, vomiting and skin rash after 2 to 3 hours of vaccination. According to Husnain and Zubair's mothers' they went to (LHW) Tahseen's place to know why this is happening to their children but Tahseen was not home and her sister informed the parents that this is a usual condition after vaccination and the children will be fine soon. Both children Husnain and Zubair were then taken to PMC hospital in the evening around 7:00 pm on same day (March 3) where they were given symptomatic treatment without hospital admission. Around 10:00 pm same day condition of both children got worse and they were taken to a private clinic of Dr. Akbar Sayal where symptomatic treatment was given for diarrhea. Later Husnain was taken to PMC 2-3 times around 4:00 am and 7:00 am (March 4) but didn't get hospital admission until late morning when his condition had worsened. In morning around 8:00 am Husnain died on his way to PMC hospital. At the same time Zubair got admission to PMC hospital but by that time, his condition had considerably deteriorated. He was transferred to Aga Khan University Hospital (AKUH) at 3:00 pm on March 4th, 2018, Karachi where he expired on March 10, 2018, after being admitted for seven days. According to Hania's grandmother she was taken to PMC hospital around 7:00 pm (March 3, 2018) and was discharged after symptomatic treatment. Hania was unwell the whole night and was taken to PMC hospital again in the morning at 10:00 am and expired at around 11:00 am. According to the statement of Najeeullah's mother, he was taken directly to a private clinician Dr. Umer Shahzad at 6:30 pm (March 3). He was given treatment and the child was doing better but then was brought to PMC hospital at 9:00 am (March 4) for follow-up where again child was sent home. Later at 10:30 am (March 4) parents went back to PMC at 10:30 am as news spread of post measles vaccination illness /death. They got admission to PMC but later were referred to Aga Khan University Hospital (AKUH), Karachi for further observation where they reached at around 7:00 pm March 4, 2018. Child remained admitted till March 7, 2018 until recovery.

AEFI Detail Report:

Details	1	2	3	4	5	6
Name	Janat D/O Mohammad Amin	Najeeullah S/O Iftikhar	Husnain S/O Imdad	Zubair S/O Mohammad Yousaf	Hania D/O Imran	Qamar S/O Rafique panhwar
Age	14 month	9 months	23 months	9 months	20 months	9 months
Sex	F	M	M	M	F	M
Address	Mariam Road UC -8	Mariam Road UC -8	Mariam Road UC -8	Mariam Road UC -8	Mariam Road UC -8	Mariam Road UC -8
Vaccines name and company	Measles (Bio Farma)	Measles (Bio Farma)	Measles (Bio Farma)	Measles (Bio Farma)	Measles (Bio Farma)	Measles (Bio Farma)
Vaccination Day, Date & approximate time	Saturday, 3/3/18; 9:30 am	Saturday, 3/3/18; 11:00 am	Saturday, 3/3/18; 11:15 am	Saturday, 3/3/18; 11:20 am	Saturday, 3/3/18; 11:30 am	Saturday, 3/3/18; 12:30 am
..or Vaccine received	In centre	At Home (by Tahseen)	In centre	At Home (By Ramzan)	In centre	In centre near-by
Current Vaccination received at	Nadir Shah-dispensary	In Community	In Community	In Community	In Community	Nadir Shah-dispensary
Vaccination Site reported by mother	Upper Arm	Upper Arm	Left upper arm	Left upper arm	Upper Arm	Upper Arm
Size of Syringe reported by family members	Don't Know	Already filled & diluted, don't remember the size of Syringe	A new 5 ml Syringe	5 ml (Same syringe used for Husnain	Already filled & diluted 5 ml Syringe	Already filled/diluted 0.5 ml Syringe
Vaccination given by	LHW Ms. Salma Iqbal	LHW Ms. Tahseen	LHW Ms. Tahseen	LHW Ms. Tahseen	LHW Ms. Tahseen	LHW Ms. Salma Iqbal in the presence of Ramzan
Vaccine stored/kept by ..W	Standard Vaccine Carrier	In Bag/Purse & small polio vaccine carrier inside	In Bag/Purse	In Bag/Purse	In Bag/Purse	small polio Vaccine Carrier
Approx. Time of onset for symptoms	1:30 pm	1:00 pm	2:00 pm	2:00 pm	1:30 pm	2:00 pm
Past Medical Hx	Not significant	Not significant	Not significant	Not significant	Not significant	Not significant
Clinical presentation	Fever, Diarrhea, Vomiting & Lethargic	Fever, Diarrhea, Vomiting, Lethargic & skin rash	Discomfort fever, vomiting, watery diarrhea (White color), Blue discoloration, Lethargic	Redness immediately at the site of injection, fever, vomiting, watery diarrhea (White color),, Blue	vomiting, watery diarrhea, Lethargy	Fever, vomiting, watery diarrhea. Discomfort, Blue discoloration, Lethargic

				discoloration, lethargic,		
Hospital Visit timeline (approx.)	At 2:00 pm to PMC, at 5:00 pm to JMC on 3rd March, 2018, at 9:00 am to Dr. Mubasher, at 11:00 am to PMC, at 3:00 pm to AKU on 4thMarch, 2018	To Dr Umer Shahzad Rathor (Family Doctor) at 6:30 pm on 3rd March, 2018, At 9:00 am to PMC, at 10:30 am to PMC, at 7:00 pm to AKU on 4thMarch, 2018 till 7thMarch 2018	At 5:00 pm met Tasheen's sister, at 7:00 pm to PMC, at 10:00 pm to Akber Sayal on 3rdMarch 2018. 4:00 am to PMC, at 7:00 am to PMC, at 7:30 am to PMC, at 8:30 am to PMC (On the way died) on 4thMarch, 2018	At 5:00 pm met Tasheen's sister, at 7:00 pm to PMC & at 10:00 pm to Akber Sayal on 3rdMarch 2018, at 7:30 am to PMC & at 3:00 pm to AKU on 4thMarch,2018 till 10thMarch, 2018	At 7:00 pm to PMC on 3rdMarch 2018, at 7:00 am to PMC on 4thMarch, 2018	At 5:00 pm at Dr. Shafi (Maryum Road) on 3rdMarch, 2018, at 2:00 pm to PMC on 4th March, 2018
Labs		CBC, Blood sugar	IgM IgG, I.C.T Malaria, H.C.T,M.C.V, M.C.H, M.C.H.C, Neutrophils, eosinophils, lymphocytes, monocytes.	RBS, Urea, Na, Potassium, Calcium, WBC, HB, PLT	No Lab Test Done	No Lab Test Done
Medication from Hospital	Hospital Management: Oxygen, Dopamine, , Ceftriaxone, Avil, Deza, Nsaine, Dobutamine	Cannula, Pedicure every half an hour, Hospital Management: O2, Dexa, Adrenaline, Ceftriaxone,	ORS, Syp Calpol, Inj.Grasil, Enflor Sachet, Syp Entramizole, Syp Zicor, Inj Ceftriaxone	Syp Dormal, Syp Calpol	Syp.Calpol, Syp.Domel, Syp. Novidate, ORS	Syp after every 2 hour.
.atus	Alive	Alive	Expired	Expired	Expired	Expired
Death (Day, Date & approx.Time)	—	—	Sunday, 4/3/2018, 8:30 am	Sunday, 4/3/2018, 10:00 am	Saturday, 10/3/2018 11:00 am	Sunday, 4/3/2018, 2:45 pm
Cause of Symptoms & Death	Toxic Shock Syndrome	Toxic Shock Syndrome	Toxic Shock Syndrome	Toxic Shock Syndrome	Toxic Shock Syndrome	Toxic Shock Syndrome

Other children reported in Health Department Report

According to the report by Sindh health department, there were four more children listed in addition to the above six mentioned. The remaining four children Tania d/o Nazim, Mansab Ali s/o Salim, Abdul Samad s/o Abdul Hakim Sial and Allah Dito s/o Abdul Rehman were also followed up. Tania is 5 month old and she received a different vaccine (PCV) vaccine on that same day on 3rd March by LHW Tahseen. The other

two children Mansab and Abdul Samad were found not to be related to this incident as their date of vaccination was different from other children. Another child Allah Dito was from UC-7 was also not related to this incident since he received BCG vaccine in February (28th) and was coincidentally admitted to the same hospital and expired on 3rd March. At present the other three children Tania, Mansab and Abdul Samad are doing well.

Breach in health system: Flaws and responsibilities:

Assessment of incident showed weaknesses in practice at different level:

1. At grass root level where vaccines are stored, constituted, prepared and administered which comes under responsibility of LHW, LHS and vaccinator (UC 8 center)
2. At system level where monitoring takes place
3. At hospital level where appropriate management and prompt referrals could save lives

1. At grass root level:

The observations at this level are as under:

a. Practice flaws:

Number of practice issues were identified and confirmed which include:

1. Vaccine reconstitution timelines and place of vaccine preparation were often not according to the SOPs. Preparation of vaccine by mixing diluent and vaccine powder was often performed away from the place of administration, which is against the protocol.
2. Documentation of vial opening time/date on the vials were missing.
3. Reusing the needles for reconstitution and vaccination by LHW was reported by the parents.
4. Necessary records including temperature logs, issuing of vaccines, disposal of used vials, inventory management, vaccination records were not appropriately maintained.

Although Ms. Salma Iqbal was denying it, the evidence is clearly pointing that she administered the vaccine which was prepared more than six hours ago to the two children (Janat and Qamar) coming to the Nadir Shah-dispensary, instead of preparing a fresh vaccine. Then Ms. Tahseen also instead of using a fresh vaccine, took the same old vaccine for her door to door vaccination campaign which was being conducted as part of the Mother and Child Health week. All these children developed TSS.

The second flaw was the reuse of syringes for reconstitution and administration of vaccine. Improper syringes were used for the constitution and administration of vaccine which increased the risk of vaccine contamination and spread of infection from one person to another. During our home visit, the family members of the affected children reported that Ms. Tehseen had reused the same syringe in some of the cases.

The third important issue related to practice was improper handling of vaccines and records. During the visit to EPI center UC-8, it was identified that there was no record available for vaccine issuance and disposal. There was no mechanism of documenting how many vials were disbursed to LHWs for vaccination in their respective communities by incharge vaccinator and how many doses were disposed if not being used within a duration of 6 hours of reconstitution. Furthermore, safety practice of writing date and time of vaccine vial's opening was not being followed either in EPI center or in outreach.

Temperature logs were incomplete and vaccination records were not properly maintained. Inventory of vaccines was also not maintained at the EPI center. Vaccinator Muhammad Ramzan was responsible to maintain these records at the EPI center. He was recently appointed as incharge because previous incharge was on leave since 10th February.

b. Behavioral Flaws:

During our visit, LHWs, Lady Health Supervisor (LHS) and Vaccinator were separately interviewed to know each and every practice followed on 3rd March. Even though the complete scenario was presented in front of them, few of the staff including Ms. Salma iqbal, Ms. Tehseen and Ms. Samar kept consistently denying their role, even when the evidence clearly suggested that they are not telling the truth. Vaccinator Ramzan and LHS Abida cooperated better with the investigative team.

2. At System level:

An SOP is available for monitoring and accountability of frontline workers by district and provincial level management and leadership team. Yet a number of issues were identified in monitoring system including:

1. Monitoring in both EPI and LHW programs is focused more on completing documentation and filling due checklists rather than using information to identify gaps and building capacity of frontline workers to improve quality of service delivery. Monitoring reports are submitted from district to provincial level, but there is no proper validation of reports carried out at any level to assess fidelity of data submitted.

2. Monitoring checklists are not comprehensive and there is apparent gap between what is being done at ground level (the actual practice) and what is being truly monitored. For example, there is no provision of monitoring the process of vaccine constitution and administration at EPI center and community level. The focus of monitoring has been outcome of services such as coverage of vaccination, and not the quality of service delivery.
3. Data presented in review meetings at the district and provincial level are aggregates, and miss the individual level practices on the ground.
4. There are no practice audits of the ground level field staff for quality assurance by the district level management. There should be quality assurance process beyond checklists, which should cover on-the-ground practice.
5. There is a weak integration between the two vertical programs - LHW program and EPI program for routine vaccination. District health officer is apparently not directly responsible for monitoring

of District coordinator of LHW program, who monitors all functions of the LHWs including their vaccination portfolio. Furthermore, there are no written guidelines about clear demarcation for monitoring roles of EPI and LHW programs for routine vaccination.

6. There is discrepancy in policy laid out by provincial leadership and on ground practice. According to Director General (DG) health, LHWs are only responsible for bringing children to centres and vaccinators of EPI program are responsible to reconstitute vaccine and vaccinate children. LHWs can also administer the vaccines, but under the supervision of the vaccinator. On the ground however, some LHWs are even more trained than the vaccinators and many are administering vaccines without direct supervision.
7. Weak governance and lack of accountability from leadership is one of the key reasons for casual behavior of frontline workers and monitoring teams at district. The accountability system is not actualized at the district and provincial level. For example, district and provincial program managers and medical superintendents of hospitals are reluctant to exercise their authority over their subordinate staff due to numerous apprehensions. Civil service act and rules for appointment posting and transfer (APT rules) do not allow secretary health to take actions against civil servants who are not performing their duties as per their job description.

3. At Hospital level:

Peoples Medical University Hospital is the only hospital for district Shaheed Benazirabad and other two districts nearby covering the population of almost 8 to 10 lakhs. There is no single comprehensive healthcare facility in district Shaheed Benazirabad which is fully equipped to manage cases as complicated on TSS. For example, there is no single ventilator available in the hospital for children; which is usually required in the management of TSS. Case fatality rate of TSS is very high all over the world and demands prompt and aggressive management from healthcare providers. The existing PMC has been upgraded from a primary level healthcare facility but lack resources and capacity to cater to approximately one million population. The existing protocols of case management in the hospital are not of adequate quality to cater ground situations and the magnitude of disease burden that comes their way. Bed occupancy rate is high and only 50-60 pediatric in-patient beds are available resulting in bed sharing between two to three patients. Doctors at PMC were not able to correctly identify the severity of illness in these patients when they initially presented to them. This was partly because of the limited skill of first line physician and partly because of the fact that they are overburdened and operate with limited resources and infrastructure. While survival after developing TSS is not certain even in advanced hospitals, earlier identification, management and referral of these cases might have saved few more lives.

Summary of Key findings:

- The event cannot be looked in isolation. There are issues of practice at grass root level as well as system level.
- Practice level issues include deviation from standard protocols of vaccine reconstitution, administration, handling of vaccines and records maintenance.
- There are insufficient mechanisms of monitoring service delivery at grass root level by the district management team and at provincial level to monitor district team.

- There are limited resources in terms of trained staff, and material resource including equipment, beds and space in the public sector hospital of Shaheed Benazirabad to cater to a population of up to 1 million.

Recommendations:

While the deadly complication of TSS is rare, the practices that led to this incident are more common. Following are the recommendations:

1. The negligence that led to this complication needs to be appropriately addressed. .

2. At the Health Leadership level (Health minister, Secretary Health and DG Health), systems need to be revised, strengthened and strictly implemented (including through regular audits) to make sure that 1) all children receive measles and other life-saving vaccines, and 2) that vaccines be administered in a safe manner according to the SOPs.

3. Provincial leaderships must ensure that district leadership of the vaccination program is monitoring practices on the ground.

4. Hospitals such as the one in Shaheed Benazirabad needs an up gradation of facilities including infrastructure, equipment, utilities & supplies and availability of sufficient trained staff.

5. Refresher and continuing medical education trainings for doctors and other medical staff at the hospitals are needed so they identify the very sick children quickly.

   Referral mechanisms from these District hospitals to the higher level facilities in bigger cities need to be better developed.

Annexure 1: List of interviewees

District Vaccination Team		
Name	Designation	Role in immunization services
Dr. Mujtaba Memon	Ex-DHO	Overall monitoring of EPI focal person for district, DSV, TSVs, and Vaccinators
Mr. Allah Bux Rajpar	Health Education officer/ EPI focal person	Health education and EPI service monitoring
Dr. Sikander Ali Rahu	District coordinator of LHW program	Supervision of Lady health supervisors
Mr. Tahir Mirza	DSV	Monitoring vaccination and all vaccinators of district
Mr. Ramzan	Vaccinator	Routine vaccination at centers and outreach
Ms. Zahida	Incharge vaccinator	Routine vaccination at centers and outreach, maintaining inventory of vaccines and records of vaccinations
Ms. Abida Mansab	Lady Health Supervisor	Monitoring LHWs
Ms. Salma Iqbal	Lady Health Worker	Educating and mobilizing community for vaccination
Ms. Salma Rehman	Lady Health Worker	Educating and mobilizing community for vaccination
Ms. Tehseen	Lady Health Worker	Educating and mobilizing community for vaccination
Ms. Samar	Lady Health Worker	Educating and mobilizing community for vaccination
Ms. Firdous	Lady Health Worker	Educating and mobilizing community for vaccination

Provincial Team		
Dr. Ghulam Hussain	LHW program manager	Overall management and supervision of LHW program
Dr. Sohail bin saeed	Deputy Program director EPI	Overall management and supervision of EPI program
Dr. Muhammad Akhlaque	DG health	
Mr. Fazlullah Pechuho	Secretary Health	

Parents/ caregivers interviewed

Sr. #	Name of child	Relationship of interviewee with child
1.	Janat D/O Mohammad Amin	Father and mother
2.	Najeeullah S/O Iftikhar	Grand father and mother
3.	Husnain S/O Imdad	Grand father
4.	Zubair S/O Muhammad Yousaf	Father and mother
5.	Hania D/O Imran	Grand father
6.	Qamar S/O Rafique panhwar	Father and mother

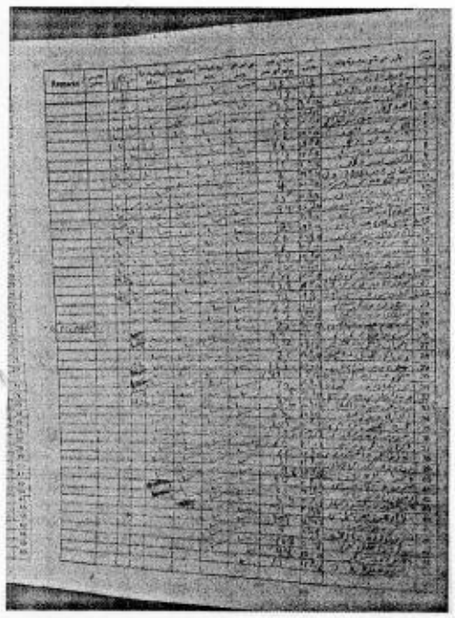
7.	Abdul Samad S/O Abdul Hakeem	Father and mother
8.	Mansab ali S/O M Salim	Father and mother
9.	Bismal D/O Shahid	Mother
10.	Ali S/O fayaz Ali	Mother
11.	Anaya D/O Muhammad Asif	Mother

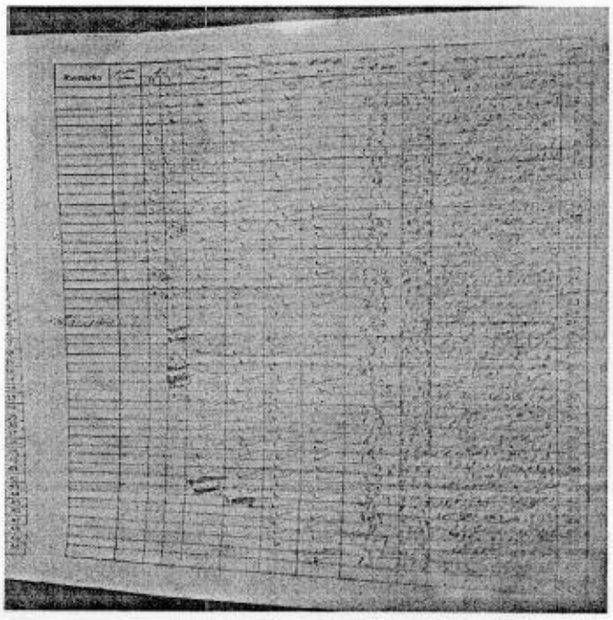
Hospital (PMC): Staff Dr. Ali Akber Sayal

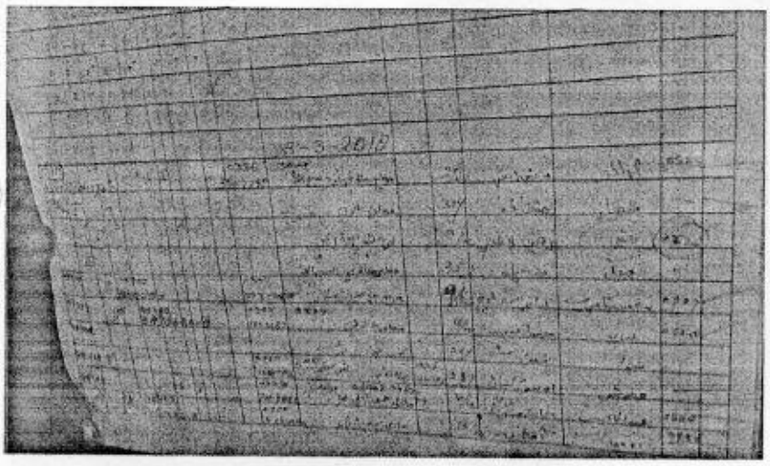
Annexure 2: List of documents reviewed

Sr. Number	Name of document
1.	AEFI report prepared by WHO team
2.	Records of Lady health supervisor and Lady Health workers
3.	Records of vaccination and inventory (Nadir Shah-Dispensary-UC 8)
4.	Monitoring checklists of Lady health supervisors
5.	Monitoring checklists of district coordinator LHW program
6.	Micro plan LHW program mother and child week district Shaheed Benazirabad
7.	District Monitoring checklists of EPI
8.	Vaccination cards of children affected due to vaccine
9.	Minutes of district EPI review meetings
10.	List of employee and duty registers of staff at PMC Nawab shah

Annexure 3: EPI Records and vaccine storage images





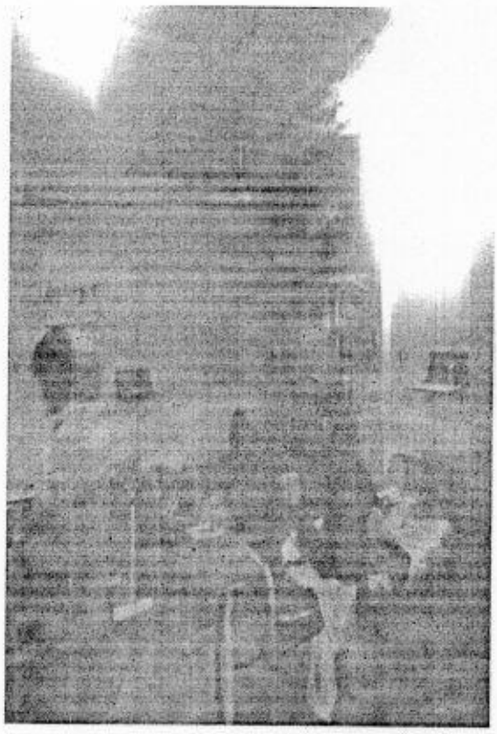


Vaccine storage at Nadir Shah Dispensary UC 8 District Nawab shah

AKU Investigation team speaking to the parents of affected children

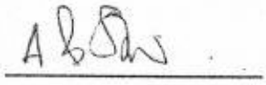
Newspaper reports of Serious AEFI cases

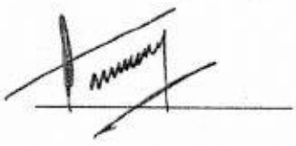
Hospital Visit by team of AKU

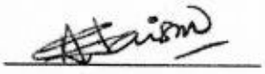


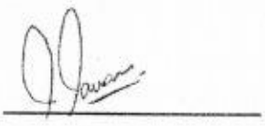
This report is prepared and submitted by:

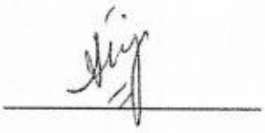
1. Dr. Asad Ali 

2. Dr. Rehana Siddiqui 

3. Dr. Mairaj Shah 

4. Dr. Ali Faisal Saleem 

5. Dr. Sobiya Sawani 

6. Dr. Atif Riaz 

7. Mr. Mohammed Amir 

8. Ms. Mehreen Raza