

CASE STUDY

Background:

Following the state-wide launch of a vaccine, there were reports of white sediments in a few vaccine vials in 3 PHCs on 17th December and 3 PHCs on 23rd December.

As per the report of the drug testing laboratory, the sample was found “not to be of standard quality and vaccines were exposed to below the recommended storage temperature of +2 to +80 C”.

Based on the report, a technical team was formed and the team investigated the situation in order to assess the vaccine damage, identify the factors leading to damage and suggest remedial measure by visiting the entire supply chain.

Observation:

A total of 3,80,010 vials containing 3.8 million doses of the vaccines were received at State Vaccine Store in refrigerated vaccine vans in two consignments (21,00,000 doses on 19th October and 17,00,100 doses on 21st December). All the vaccines comprised of 8 batches. The concerned batch (5,90,400 doses) was delivered in the first consignment. The copy of the Vaccine Release Certificate by Central Drugs Laboratory and Vaccine Arrival Report (VAR) at State Vaccine Store indicate that the quality of vaccine after manufacturing and at the time of receipt at state vaccine store were good. VAR was not available for all the batches received.

Observation:

The refrigerated van was carrying vaccines packed in 292 thermocol boxes with ice packs having freeze indicator with each box. Due to paucity of space in the State Vaccine Store, the vaccines were kept in the refrigerated van on 19th October. On 20th October vaccines were shifted from the Manufacturer's Refrigerated van to SVS's insulated van and transported to 3 RVS. Remaining vaccines were shifted to a nearby private cold store on 20th October evening at 8:30 pm. There was no documentation available for the duration the vaccines were kept in the refrigerated vaccine van and private cold store. The net storage capacity at the SVS was grossly inadequate.

Observation:

From the Private Cold Store, vaccine was transported to 3 RVS on 21st and 22nd October. Remaining vaccines were shifted to SVS on 23rd October. From SVS Vaccines were transferred to 3 RVS between 23rd to 26th October. There was no documentation of the shift of vaccines from the private cold store to the SVS and RVS.

As per the VAR submitted by the state one box was opened to check the status of the freeze marker and VVM and it indicates the vaccine at the SVS was in usable condition at the time of receipt. The Vaccine Arrival Report was found to be incomplete without batch number of opened box and freeze marker status.

What are the processes and practices that were not ideal in this case study and could have contributed to vaccine freezing?