Validity of the Shake Test to Identify the Frozen Damaged Vaccine Vials

The alum-adsorbed vaccines such as DPT, DT and TT must never be frozen, as this irreversibly alters them and markedly reduces their immunogenicity. When an alum-based vaccine is frozen, the lattice gets broken, and the alum content tends to agglomerate and gets heavier and sediments faster. This faster rate of sedimentation forms the basis of positive Shake test, which attempts to compare the flake formation and rate of sedimentation in the 'test' and 'control' vials of same manufacturer(1). If the control vial (known to be previously frozen) shows much faster sedimentation than in the vial being tested, the vaccine in question is probably potent and may be used. If, however, the sedimentation rate is similar and the test vial contains flakes, it should not be used.

During a training course at Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, the trainee doctors were asked to conduct the Shake test with a set of two vials - one unfrozen and one frozen as per the following steps given in modules(2).

1. Take two DPT/DT/TT/Hepatitis-B/Typhoid vaccine vials, one test vial and another from the same manufacturer (never frozen).
2. Shake both vials to mix sediments.
3. After 15 minutes, look at the vaccine inside the two vials.
4. If the vaccine is not uniformly mixed or the sediments/flocculation are still found settled at the bottom, the test vial was frozen at some or other time.

Only 37% and 60% participants could correctly identify frozen and unfrozen vaccine vials respectively. This raises serious doubts about the validity and utility of the Shake test (as given in the module). In addition, the Shake test protocol is not correctly given in the module. Non-frozen sample cannot be used as a control vial. Besides this, the module does not mention about the comparison of the rate of sedimentation in the two vials that is the crux of the test (1).

In fact, we located five versions of Shake test in the literature(1-4). Their steps are different. The WHO test uses a waiting period of 5-10 minutes while others quote 15, 30 minutes or even 24-72 hrs. Some use frozen vials as control whereas others use unfrozen ones. Some use 'sediments/ floccules' settled at the bottom of the vial as the evidence of previous freezing, whereas others, including WHO insist on rate of sedimentation in comparison to control vial. Thus, the steps of Shake test as described in the module were different from those described in the WHO modules. This issue needs to be discussed and settled to remove unnecessary confusion.

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Massive Lipoblastoma Foot

A 6-year-old female child presented with a huge mass in her left foot for the last 5 years. The parents first noticed a pea sized mass at 1 year of age on the under aspect of left foot. The onset of this mass was not associated with fever and or trauma. The mass painlessly and steadily progressed since then to the present size, when she presented with a large swelling of the size of pumpkin on the plantar aspect of the left foot, which caused undue discomfort and difficulty in walking. Physical examination revealed an 8 × 10 cm firm, lobulated mass on the plantar aspect of left foot encroaching more on the medial aspect. The mass was nontender, noncompressible and nonpulsatile. Skin over the mass was glossy and shiny with prominent veins over it. Neurological examination and pulses in the left foot were normal. Right foot was essentially normal.

Plain radiograph of the left foot showed a lobulated rounded soft tissue swelling on the plantar aspect with no evidence of any calcification, bony destruction or hypertrophy of the underlying bones. Contrast enhanced CT scan revealed a circumscribed, lobulated, subcutaneous, hypodense lesion of fat attenuation, seen extending from inferomedial aspect of medial malleolus to the plantar aspect of the foot just proximal to the origin of toes with enhancing internal septations (*Fig. 1*). Scalloping of the inferomedial aspect of the calcaneum and first metatarsal was seen and rest of the bones were normal. FNAC of the mass revealed only fibrofatty tissue.

Wide excision of the tumor superficial to the plantar fascia was performed without any complication. Gross examination of the resected tumor showed a 7 × 9 cm sized encapsulated, firm, lobulated mass, which on cut section showed lobulations with internal septations. On microscopic examination, the tumor consisted of some immature fat cells divided into lobules by fibrous septa with minimal myxoid areas. There was no evidence of any nuclear pleomorphism, giant cells, or atypical mitoses. The mass was diagnosed as lipoblastoma of the foot.

Lipoblastoma is a rare soft tissue tumor arising from embryonic fat and is usually found in areas of abundant adipose tissue. Seventy percent of lipoblastomas occur in extremities, more so in lower limbs(1-3). However, there are reports(4,3) describing the predilection of lipoblastoma at sites with primitive adipose tissue like axilla, neck, chest, retroperitoneum and prevertebral soft tissue. Plantar aspect of foot, as seen in the present case, is an extremely unusual site due to the scarcity of the adipose tissue in this area. It is histologically, benign and lacks metastatic potential. Differential diagnoses include lipomas, fibromyxolipomas or spindle cell limpomas and soft tissue sarcoma. However the demonstration of fatty mass on CT/MRI limits the number of differentials. In the absence of any atypical lipoblasts, mitoses, hyperchromatic nuclei the possibility of ma-