PMOPG/E/2021/0588364

8.12.21

To,
The Hon'ble Prime Minister of India

Sub: Petition to improve and make functional, AEFI Reporting and it's active Monitoring in India

Dear Sir,

We, Indian Doctors for Truth are alarmed that there is practically no proper protocol to report Adverse Event Following Immunization (AEFI) in India, as mass vaccination drive for Covid vaccines is implemented.

Following the 11 deaths of health care and frontline workers that were reported from across the country after administration of Serum Institute's Covishield vaccine, the issue of AEFI reporting was raised by two-dozen scientists including Virologist, Dr Jacob T John in a letter to Health Minister Dr. Harsh Vardhan and Drugs Controller General of India (DCGI) V.G. Somani, dated 31st January 2021. Despite the warning, no action was taken, although Dr. N. K. Arora is the Working Group chairman of National Technical Advisory Group on Immunization (NTAGI) and as a member of National AEFI Committee, he himself had raised the issue about the absence of a proper mechanism in May 2021.

Briefing the press, Dr NK Arora had said, "As of now, monitoring the vaccine recipient up to 72 hours post-vaccination is the norm. It should be done in at least 28 days. There must be a proper mechanism to report AEFI on the CoWin app and all the data should be available in

the public domain," adding that severe AEFIs were reported in less than 0.5 percent of recipients out of seven crore vaccinated people assessed so far. This translates to 5 severe cases out of 1,000 vaccinations.

Dr. Shailesh Mohite, superintendent of Mumbai's civic-run BYL Nair Hospital, said, "If someone dies within a day or two of the anti-COVID vaccination, it is usually being reported. But there is no protocol available to document or report the deaths days later." No AEFI assessment is complete without knowledge of background rates of adverse effects, according to Dr. Anupam Singh from Santosh University, Ghaziabad

Most cases of serious AEFIs are not being documented or reported to authorities. "The government's silence over such incidents and non-transparency with regards to AEFI data are adding to vaccine hesitancy. Proper investigation of serious AEFIs and gene sequencing of samples of such vaccine recipients can help find whether the new variants are evading existing vaccines," experts say.

Though some advisory might exist on paper, "there is so much chaos that nobody knows who to approach in the system and how," says Shobhit, son of a victim.
https://thedialogue.co.in/article/kxmSPNKRrW2UjCjY6Lqk/post-vaccination-deaths-raise-concerns-in-india-government-and-vaccine-makers-silent-?s=08

However, *in the absence of proper reporting mechanism and proactive approach of authorities to trace vaccinated people after they leave the vaccination site, such a claim may not be reflecting the true picture and full magnitude of AEFI and it is possible several cases of AEFI may be going unreported or undetected,* says Vineeta Pandey, while writing about her first hand struggle to get her 21 yr old son's AEFI.
Reporting of vaccination adverse effects made hugely difficult, going unreported (asianage.com)

Dr Arora keeps reassuring but does not implement what the experts in our country recommend. For example, in February in response to the concerns raised by experts he had

said, *"The causality assessment by the National AEFI Committee will be on a rolling basis. This is because we want everyone to know if the vaccine caused the deaths."*

The importance of a robust AEFI reporting system was summed up by Dr. Jacob John, Virologist, when he said, "The sequence (death following vaccination) is not an evidence of consequence. Causality association is through exclusion. The time relationship of the deaths with vaccination should be explained, for which alternative cause of death should be established through investigation in each case. Only then can the vaccine be exonerated. *If you can't find any cause of death in a young person, then you have to attribute the cause of death to the vaccine."*
Vaccine death reports will be published, says adverse events panel expert - The Hindu

On 16 March 2021, a group of doctors, lawyers and journalists wrote to the central government asking for an *"urgent investigation of deaths and serious adverse events following administration of COVID-19 vaccine."*
Covid-19 vaccines: Investigate adverse events and make reports public, say health experts - The Hindu Business Line

Karnataka has scored poorly in investigating deaths following Covid-19 immunisation. The Centre's data shows that more than 30 percent of severe adverse events following immunisation (AEFI) cases in the state resulted in deaths. However, post-mortems were done only in seven of the 40 deaths reported till 20 July 2021.

The absence of proper protocols, strict guidelines and awareness about AEFI, has resulted in loss of AEFI data critical to current third phase efficacy trials. Sources confirmed that the health ministry attributed the trend to *delays in verification by district officers, incomplete investigations and causality assessment reports including a low percentage of post-mortems or delay in sending reports. Infrequent meetings of AEFI committees, inadequate capacity at the district level and lack of awareness about Thrombosis Thrombocytopenia Syndrome (TTS) are also affecting reportage.*
https://www.deccanherald.com/state/top-karnataka-stories/karnataka-lax-in-probing-deaths-following-covid-19-vaccinations-1052248.html

And whereas after the analysis by EMA, many countries have either completely stopped using Astrazeneca vaccine or restricted its use below a certain age, no such analysis could be done for AstraZeneca (Covishield) in India.

According to The Hindu, *the EMA included only six deaths from India after vaccination with Covishield because of a massive backlog in processing assessments in India, according to Malini Aisola, co-convenor of All India Drug Network (AIDN). In addition, Dr Gagandeep Kang also said in an interview with Karan Thapar for The Wire, that while the risk is low, the issue has been compounded by the Indian government's secretive deliberations on the matter.*
617 Serious Adverse Events After Vaccination Reported In India Until March 29 - The Wire Science

There have been multiple reports of people dying of blood clots following the vaccine or other injuries in the media.

"Patient Dies of Covid Vaccine-induced Blood Clot, 7 Other Cases Reported: Delhi's Sir Ganga Ram Hospital" https://www.news18.com/news/india/delhi-7-cases-one-death-of-covid-vaccine-induced-thrombotic-thrombocytopenia-reported-in-sir-ganga-ram-4336937.html

"Rare neurological disorder documented following COVID-19 vaccination,"
"Seven cases were reported from a regional medical center in Kerala,"
"The frequency of Guillain-Barré syndrome in these areas was estimated to be up to 10 times greater than expected."
https://medicalxpress.com/news/2021-06-rare-neurological-disorder-documented-covid-.html

April, 2021: "India reviewing 700 serious post-vaccine adverse events."
http://timesofindia.indiatimes.com/articleshow/81979541.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

The National AEFI Committee has assessed only 363 of severe or serious AEFIs till 18th October 2021, of which only 4 cases of death were found to be directly linked to Covid Vaccine Product Related. Though 3 out of 4 were cases of anaphylaxis, there was one case where the diagnosis given was “Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia”. We beg to ask the question, is it really possible that we have only one confirmed case Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), when 16 countries have banned or age-restricted Astrazeneca (Covishield) Covid vaccine for the same reason?!

Thus in the absence of proper protocol such reports do not generate confidence in people and doctors alike. Other moderate AEFIs like severe rashes, severe headache, are not even reported. As doctors we have seen many cases going unreported.

In the EU, anyone can report post-vaccine illness directly to the national authority or vaccine makers. The patient volunteers are followed up for at least six weeks post-vaccination and tracking of even long-term effects, says European Medicines Agency (EMA) rules for COVID vaccines. In the US there is an online system of reporting VAERS. Given the scale of vaccination in India, why isn't there a proper AEFI reporting mechanism in India?
In the US, we can see 18,853 deaths as per the official US VAERS database (a total of 894,143 Adverse Event reports till 12/11/21). In Europe, in just 27 countries, 31,014 death reports are available in the official European Union database Eudra Vigilance (a total of 2,890,600 Adverse Event reports till 20/11/21). What are the equivalent numbers in a huge country such as India? It is unbelievable that a country of our size with the largest Covid Vaccination drive on this planet has only 2116 AEFIs which also includes death. The following link itself provides media reports of over 10,600 deaths that have occurred post vaccination in India.
https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

Regretfully, almost 12 months after the frenzied rollout of the third phase of the Covid-19 vaccine, there have been no guidelines issued or protocol designed for the proper surveillance of AEFIs. Absence of information pertaining to safety makes it impossible for both doctors and patients to make informed decisions based on the risk/benefit profile of the vaccine. It

also compounds the difficulty in diagnosing and treating AEFIs. The need for an Active Surveillance System cannot be more emphasized.

Looking at the current system of AEFI reporting, we demand immediate implementation of the following steps.

1. Immediate development of AEFI Online reporting system on the lines of VAERS system in US, with retrospective effect from the beginning of the vaccination drive.
2. Wide publicity of this system for the general public, including doctors to know the existence of the system.
3. Easy and Open public access to AEFI reports with rolling weekly updates.
4. Compulsory post-mortem of all sudden deaths post covid-19 vaccination, where obvious cause of death is not found or where cause of death is blood clotting in one part of the body (to rule out clotting in other parts of the body).
5. Immediate setting up of Vaccine Courts at State level to adjudicate on compensation payable to victims of vaccine injury/death.

We urge you to kindly look into the matter and expedite the setting up of an AEFI reporting system by MoHFW, including an advisory for diagnosis, treatment and reporting of adverse events occurring post Covid-19 vaccination.

Thanking You For Your Concern,

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