

Date: 25th November 2014

To

The Prime Minister
Prime Minister's Office
South Block
Raisina Hill
New Delhi-110011

Sir

Subject: Concerns about deaths of young children following Pentavalent Vaccine

Every few days one more child dies after receiving the Pentavalent vaccine.

The Deccan Herald of 22 August 2014 reported 2 more deaths from Haryana with the Pentavalent vaccine (<http://www.deccanherald.com/content/427027/2-kids-die-vaccination-haryana.html>).

Last week it was a death in Ujjain. (<http://www.dnaindia.com/india/report-madhya-pradesh-45-day-old-baby-dies-after-taking-pentavalent-vaccine-2035748>).

Today's news paper (Nai Dunia, Indore) reports a death in Shivpuri (MP) (http://naiduniaepaper.jagran.com/Article_detail.aspx?id=17115&boxid=62815&ed_date=2014-11-24&ed_code=74&ed_page=12).

Yet as these deaths mount, it has been announced that Pentavalent vaccine is to be introduced in 3 more states.

Vaccines are a public health measure to prevent serious disease and deaths. That is how a common man perceives the role of a vaccine. Therefore, deaths in healthy children from vaccines are not acceptable. These deaths have become so frequent that in Tamil Nadu, in spite of official denials, people have stopped going for vaccination and the immunization uptake has fallen by 25% in the last 4 years. According to the *District Level Household Survey – DLHS 4: 2012-13* (<https://nrhm-mis.nic.in/SitePages/DLHS-4.aspx>) immunization coverage across districts in Tamil Nadu, with over 85% full immunization (*DLHS-3:2007-08*) has fallen to 56%.

At the same time, a study on Hepatitis B vaccine (now included in the Pentavalent vaccine) published in the latest issue of the journal of the Indian Academy of Pediatrics – Indian Pediatrics shows the vaccine does not protect babies from infection.

The study conducted by the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and the National Institute of Nutrition, Hyderabad and two editorials in the journal raised several questions regarding the universal immunization programme (UIP) itself. Dr T Jacob John in his editorial noted that "the frequency of chronic infection (carrier state with HBsAg) was similar in both the unvaccinated and the vaccinated – about 0.15%. The Hepatitis B was thus completely useless in this population. Professor Jacob John further observed that the immunological and epidemiological outcomes of rolling out Hib (Hemophilus influenza B) are not being monitored as UIP has no capacity for that function. (<http://www.indianpediatrics.net/nov2014/869.pdf>)

<http://timesofindia.indiatimes.com/home/science/Hepatitis-B-vaccines-efficacy-in-doubt/articleshow/45064258.cms>)

In short, expensive vaccines that have little utility are being rolled out without monitoring benefits or harms and which are causing deaths and serious adverse effects. As a result, in spite of official attempts at denial, the public are losing trust in the entire immunization programme.

We, a group of academicians, practitioners and teachers of pediatrics and public health would like to draw your attention to the pattern of adverse events and deaths from the newly introduced Pentavalent Vaccine (DPT+ Hib + Hep B vaccine) which is proposed to be rolled out nationwide as a government policy.

We are aware that there is global pressure from international organisations and donors. These very international organizations have ensured that even the protocol used to investigate the deaths have now been changed so the deaths can be ignored.

International Agencies Alter Protocol of Investigating Adverse Events Following Immunization (AEFI) to Deny Deaths

The deaths immediately following immunization with the Pentavalent Vaccine have piled up. There is no alternate explanation for these deaths following vaccination that they had to be classified as 'possibly due to vaccination' by the standard WHO Brighton system of classification. A new protocol has been devised to over-ride the WHO Brighton classification so that there is no acknowledgement that the deaths are possibly related to vaccine. Now only reactions that are 'known to occur with the vaccine' can be classified as adverse event following immunization (AEFI). 'Known reactions' in this context are reactions that were noted/recorded in the small clinical trials performed prior to licensing of the drug. Rarer reactions are detected only when the vaccine is administered to a large number of persons. Post marketing surveillance (PSM) is done for 4 years to pick up the more rare adverse events. The new system simply refuses to take cognizance of the rarer adverse events noted on PSM.

With Pentavalent vaccine, deaths following immunization are not a 'known reaction' as there were no deaths in the small clinical trials. Each death is investigated and as the reaction is not a 'known reaction' with the vaccine it is classified as 'Not an AEFI'. Even after over 100 deaths following the vaccine, each death is classified as "Not and AEFI" and a WHO report states that 'death as AEFI has *never* been reported' following the Pentavalent vaccine ('Global Advisory Committee on Vaccine Safety review of Pentavalent safety concerns in four Asian countries' http://www.who.int/vaccine_safety/committee/topics/hpv/GACVSstatement_pentavalent_June2013.pdf)

The above circular reasoning has led to a "Catch 22" situation!! No 'new' adverse event can be attributed to a newly introduced vaccine. According to the freshly minted protocol, all adverse events (which are not very common and so did not appear in the small clinical trials) can be deemed to be "not an AEFI," and mass vaccination can continue in spite of serious adverse events and deaths in its wake. It is obvious that the new scheme is both illogical and unscientific.

Deaths continue unrelentingly

According to the Government of India data, published by the Center for Science and Environment, in states like Kerala and Goa, there are 8 to 26 deaths respectively for every 1 lakh children vaccinated. <http://www.downtoearth.org.in/content/are-some-states-underreporting-%20pentavalent-vaccine-deaths> These are states with good health systems and consequently relatively good surveillance to reliably report adverse events following immunization and can be used to project the deaths nationwide.

More deaths from vaccine than lives saved.

If we consider the more conservative figure of 8 deaths per 100,000 children vaccinated in Kerala for our projections nationwide, this will mean, over 2000 healthy babies will die immediately after receiving the vaccine. This is six times the deaths from Hib infection that the vaccine is supposed to prevent (Please see box below).

Deaths among those with co-morbidity

In Kerala the deaths were 'investigated'. Where no alternate explanation was found to adequately explain the deaths the "experts" pointed out that co-morbidities were identified in some which 'could also have contributed to the deaths' when they were vaccinated. This is available in the draft minutes of causality assessment meeting held at Lady Harding Medical College on 15 Feb, 2013 presented to AEFI Meeting April 22, 2013 and Minutes of **Meeting of Sub Committee** set up by **NTAGI** to look at AEFI deaths following Pentavalent Vaccine in India 22.4.13. It has been uploaded here for easy reference <http://jacob.puliyel.com/paper.php?id=300> <http://jacob.puliyel.com/download.php?id=335>).

The finding of deaths in babies with co-morbid conditions who were given Pentavalent vaccine, puts the onus on the Government to identify the children at risk of death (due to the co-morbid conditions) and ensure they are NOT given the vaccine.

Death from Hib disease from best-evidence studies in India

Minz study incidence of Hib meningitis is 7/100,000 children under 5. (<http://icmr.nic.in/ijmr/2008/july/0711.pdf>). With a 10% mortality rate from Hib meningitis only 175 children would die of Hib meningitis in the year's birth cohort of 25 million.

- The rapid evaluation method of WHO of Hib pneumonia (http://whqlibdoc.who.int/hq/2001/WHO_V&B_01.27.pdf) suggests that the incidence of Hib pneumonia is 5 times the meningitis rate but the mortality is only one fifth the mortality of meningitis.
- **The total deaths from Hib meningitis and Hib pneumonia will be about 350 in the birth cohort in the first five years of their lives.**

Death from Adverse Event following Immunization

- There are 8 deaths to 26 deaths per 1 lakh immunized in Kerala and Goa respectively
- If we project Kerala death rate, when 25 million birth cohort are immunized 2000 AEFI death will happen

The trade off between lives lost and lives saved by Hib in Pentavalent Vaccine

- 2000 vaccine deaths to prevent 350 deaths from the Hib disease seems unreasonable.
- The pattern of death with Pentavalent matches that in other countries as well.

A report from WHO suggests there are more deaths following Pentavalent vaccine in babies who have an underlying heart disease – very often asymptomatic and undetected previously. http://www.who.int/vaccine_safety/committee/topics/hpv/GACVSstatement_pentavalent_June2013.pdf The WHO report says Sri Lankan Pentavalent-death rate was reduced after screening babies for heart disease. In India we have no mechanism for screening all babies before giving them this vaccine. Postmortem studies in some of the children in India also showed heart defects.

When this is clearly stated by the WHO report, to continue to administer the vaccine without a mechanism to screen for heart disease, to avoid these deaths, cannot be justified.

Inadequate Evidence for Deaths Labeled as SIDS

Where not even a co-morbidity is found, the Kerala report calls them deaths due to Sudden Infant Death Syndrome (SIDS) following Immunization! SIDS by definition implies the baby was perfectly well and had no indication they were ill before they were found dead in their sleep. It cannot be used in children who received a vaccine, had high fever and was crying excessively before being put to bed.

The diagnosis of SIDS were made by the AEFI experts based on the following evidence: all the babies were infants (age) there were more deaths in the second half of the year (winter season in Kerala where no winter exists) and many were found dead in the morning (time of death). This is the 'scientific evidence' considered sufficient to declare that the deaths were unrelated to vaccine!

The Pressure from International Agencies

September 12th issue of Science shows how interventions are promoted.

(<http://www.sciencemag.org/content/345/6202/1260.full>). We are concerned that under pressure for international agencies like the WHO and the Bill and Melinda Gates Foundation we are continuing this programme to the detriment of our children. The linkages of international philanthropies were brought out recently by this article.

(http://articles.economictimes.indiatimes.com/2014-08-31/news/53413161_1_hpv-vaccine-cervarix-human-papilloma-virus). We now have private organisations like PHFI running the secretariat of the National Technical Advisory Body that is supposed to advise policy on immunization. Government of India who should be primarily responsible for the immunization policy has outsourced this work to a private organization who is obviously playing in the hands of private corporate sector and Bill Gates Foundation (perhaps again as suggested by the funding partners)

Parallels to Death from Anaphylaxis

That babies die repeatedly as reaction from a vaccine is unacceptable. Already as per RTI reply there have been 76 deaths in India till August 2014 from Pentavalent adverse events following immunization (AEFI).

These deaths are like the reaction that happens in adults with penicillin injection. Thousands of persons receive penicillin injections without reaction, but some react fatally. It is the responsibility of the doctor to test each person before administering this penicillin, which is known to produce this reaction occasionally. We have no such test for Pentavalent vaccine and we have no method of preventing these deaths.

We request this note from us may please be taken on record since PMO has itself been involved in pronouncements of vaccine initiatives in the past few months. We feel it is our responsibility to place these scientific facts before the PMO so that it is aware of the facts and so that urgent and appropriate action may be initiated by you to direct the Ministry of Health to act in public interest and in accordance with basic precautionary principles. We hope we will receive an action taken report in the next 2 weeks.

We would be willing to come and discuss this matter as a delegation with the PMO.

Yours faithfully,



Professor BM Hegde

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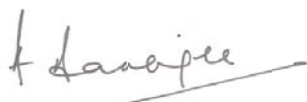
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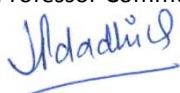
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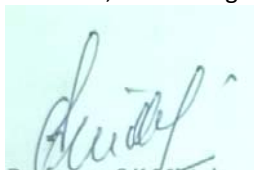
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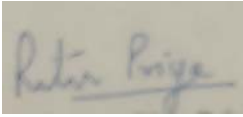
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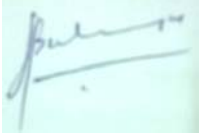
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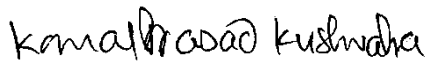
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