

## JACOB PULIYEL, MD

### ***Redefining Vaccine Reactions to Erase Evidence of Harm***

#### **Speaker Introduction: BARBARA LOE FISHER**

Jacob Puliyel is a pediatrician and director of research and projects at Holy Family Hospital in Delhi, India. Dr. Puliyel received his medical qualification and his post-graduate degree certificate in pediatrics from University of Jabalpur and Membership of the Royal College of Physicians in London.

He was awarded the Sir James Flat Gold Medal of the Indian Academy of Pediatric, for outstanding research in drug abuse among adolescents. He was formerly head of pediatrics at St. Stephen's hospital in Delhi India, and a member of the government of India's National Technical Advisory Group on Immunisation.

Dr. Puliyel has published more than 140 peer reviewed articles in major medical journals, including on vaccine topics such as paralysis associated with pulse polio vaccine campaigns; rotavirus and hepatitis B vaccine effectiveness; deaths reported after pentavalent vaccine and DPT vaccines, and the World Health Organization's causality assessment of adverse events following immunization.

#### **Speaker Presentation: JACOB PULIYEL, MD**

##### **Redefining Vaccine Reactions to Erase Evidence of Harm.**

The story is told of an Indian businessman who walked into a New York city bank and asked for the loan officer. He told the loan officer that he was going to India for some business and needed to borrow \$5,000 for two weeks. The loan officer told him the bank will need some form of security for the loan, so the businessmen handed over the keys and the documents of a new Ferrari car parked on the street in front of the bank. The loan officer consulted the president of the bank. He sent the car's papers to the assessment officer. They checked out the car. Everything seemed to be in order.

The bank agreed to accept the car as security for the loan. An employee of the bank then drove the Ferrari into the bank's underground garage and parked it there. Later that evening, the bank president and the loan officer had a good laugh at the businessmen for keeping a \$750,000 Ferrari as security for a \$5,000 loan.

Two weeks later, the Indian returned and paid the \$5,000 and the interest, which was 15 dollars and 41 cents. Seeing this, the loan officer said, "We are very happy to have your business, but we are a little puzzled. While you were away, we checked you out and found out that you are a multimillionaire, the owner of an airlines company. What puzzles us is why you would bother to borrow \$5,000?" The Indian replied, "Where else in New York city, can I park my car for two weeks, for \$15 and expect to find it there when I return?"

I'll come back to the story later in the talk.

Investigations of adverse events following immunization. The investigations are the same for vaccine reactions as they are for any drugs or even an environmental agent toxin or poison, the principles are the same. The investigations are at two levels, one for the community and the other for the individuals.

Let us take smoking and cancer. Can smoking cause cancer in the community? You will have to do a cohort study or a case control study and investigate those exposed and those not exposed. If there is a statistically significant increase among smokers, then you can say that smoking causes cancer in the community. When an individual who has smoked for six months has cancer, can you say whether smoking caused cancer in him? You are looking at a probability scale.

The probability scale for adverse events following immunization is called the Brighton [Collaboration] scale. To be certain that the drug produced the reaction and it is not a coincidental event, one has to withdraw the drug and, when he's well, rechallenge him with the same drug. If the same reaction recurs, we are certain. However, if death is the adverse event, one cannot revive the person and rechallenge him to see if he will die a second time.

It would be unethical to rechallenge after serious adverse reactions, and all we can say is that the reaction was probably due to the drug. To be classified as *probably*, there must be a temporal relationship with use of the drug and there must not be any other plausible explanation for the adverse event.

If there is an alternate explanation for what happened, it is classified as *possible*, it is possibly related to the alternate explanation or it is related to the drug. If there is no temporal relationship and there are other explanations, it is classified as *unlikely* or *unrelated* to the drug. If no data is available from which we can make an evaluation, you just put [it] under the heading *unclassifiable*.

When a new drug is manufactured, it is tested in clinical trials, including Phase 3 randomized clinical trials. The drug is licensed and then given to the general public. Post-marketing Phase 4 trials are done after licensing. Less common reactions, say reactions that occur one in 10,000 recipients, will not show up in the small Phase 3 randomized trials, but will show up in Phase 4 trials. If such reactions happen repeatedly, it forms a signal and then epidemiological studies are done and case control studies can be done.

So, you can see that a signal is made up of repeated reactions seen in Phase 4 trials. When the reaction is seen repeatedly in individuals, it prompts the initiation of epidemiological trials.

I will discuss two vaccines in particular.

The pentavalent vaccine combines the five antigens diphtheria, whooping cough, tetanus, H influenzae type B and the hepatitis B vaccines. If a sixth antigen is added, namely injectable polio, it is called the hexavalent or Infanrix hexa.

In 2008, there were three deaths with pentavalent vaccine in Sri Lanka. The WHO [World Health Organization] experts went to investigate. They found clear temporal association and there was no alternate explanation found. Using the standard Brighton classification, this would have [been] classified as death probably related to [the] vaccine.

So what did the WHO report? The WHO reported in its conclusion, that the deaths were unlikely to be related to vaccination. The full report was not published online, only the conclusion was published. The full report was provided to the Delhi High Court two years later in a vaccine case. The full report explains the methodology of the experts. They wrote in their report that they were deleting *probable* and *possible* from the Brighton classification. Although there was no alternate explanation for the deaths, they were declaring it as unlikely to be related to immunization.

When we learned of this innovative and creative methodology, it was exposed in the *British Medical Journal* (1), much to the embarrassment of the WHO. So what did the WHO do in response to the BMJ article? They set up another committee called the CIOMS WHO committee to relook at the AEFI (Adverse Events Following Immunization) classification. It was made up of 40 people, 19 were

representatives of vaccine manufacturers with clear conflicts of interest (2). They developed the new algorithm for AEFI or Adverse Events Following Immunization. They decreed that in the future, an adverse event following immunization will be considered an AEFI only if there [has been] prior epidemiological evidence that such reactions can be caused by the vaccine.

I had shown that repeated reactions seen in Phase 4 trials are considered a signal to conduct epidemiological studies. Under the new scheme, such reactions noticed for the first time in Phase 4 trials are all deleted as not an AEFI, and so they can never be investigated as a signal. The CIOMS WHO book on definitions on page 188 states, "If an event is not a known reaction, not proven in epidemiological studies, it should be reported as not a case of a AEFI."

This is a strange assertion, and Adverse Events Following immunization [AEFI] only records a temporal association, it does not imply causation. The CIOMS WHO want to falsify the record and report events which follow immunization as events that did not follow immunization . Unless we note these temporal associations, we will not pick up the signals that prompt us to do community-based epidemiological studies.

This is a schematic representation of the new CIOMS WHO algorithm. **[Insert Figure 1 here** Slide 14 On the right side is the old and new classifications. The new classification is shown in red font, the old classification is in black.

The first question is, did the reaction occur after vaccination? If there is no temporal association with vaccination, it classified in the old scheme as *unrelated*. In the new scheme it is not an AEFI, which is perfectly all right.

The next question is, whether the case has been investigated sufficiently and all the data required is available? In the old scheme, if the data was unavailable, it was *unclassifiable*. In the new scheme, too, it is unclassifiable.

If there is a temporal relationship and there is sufficient data available, the next question is whether there are alternate explanations for what happened? In the old scheme, even if there is an alternate explanation, the reaction through vaccination is still possible. Here in the new system, it is inconsistent with causal association.

If there is no alternate explanation, this would automatically be classified in the old scheme as probably related to vaccination. In the new scheme, you have another question to ask. The next question is whether it is a known reaction, known in epidemiological studies to occur after this vaccination? Otherwise, what is probably related in the new classification is not a case of AEFI.

The next question is whether it fulfills the CIOMS case definitions for known reactions to vaccines. And then, and only then, is it classified as consistent with causal association. You can see that the CIOMS WHO did exactly what the Sri Lankan team did, they have deleted *probable* and *possible* from the classification.

This is the new algorithm, I've added two thick blue arrows. **[Insert Figure 2 here** Slide 15] I want you to look at the top arrow, is there a known causal association with vaccine? Are there epidemiological studies linking the vaccine to the reaction? If the answer is yes and only if the answer is yes, can the reaction be classified as *consistent with causal association*.

The answer is no, you can still proceed down the algorithm, but it's a waste of time. Look at the second thick blue arrow at this level you are asked is the event classifiable? Do you know enough about the case to make classification possible? This is a question that should have been asked right at the beginning, not at the end of the algorithm.

If all the data is available, below this question is a box IV A, *consistent with causal association* with immunization. To put a reaction in this box, you must ask the question, is there a known causal association with vaccine? This is the same question that we saw at level two. If the answer was no at level two, the answer cannot be different here.

So, box IV A consistent with causal association is completely redundant. Can it be classified as IV B, *indeterminate*? The CIOMS WHO definition decrees that, "Such reactions must be reported as not a case of AEFI." In India, I have yet to see a reaction classified as *indeterminate* and no reaction has been evaluated as a new signal using this algorithm.

Now I draw your attention to stage three of the algorithm. Is there strong evidence against a causal association? If so, classify the reaction as *inconsistent with causal association*.

Scientifically it is impossible to prove a negative. All the crows that I have seen in my life are black. On the basis of this, can I say that there is no such thing as a white crow? How can I test the hypothesis? I can count a thousand crows and all of them can be black, but I cannot say that there is no such thing as a white crow. Crow number 1,001 may turn out to be white.

Why did they insert this unscientific stipulation in the algorithm? An example of what they mean is provided in the text. It says, "Is there a strong evidence against causal association, for example, as between autism and the MMR vaccine." This [sentence] has been inserted primarily to deny children with autism from claiming that their autism was caused by the MMR [measles-mumps-rubella] vaccine.

Dr. William Thompson, who originally published a study saying that there was no relationship between MMR and autism, has confessed 10 years later after the publication that what they reported was not the truth. African-American children [who were] vaccinated with MMR below the age of three had a 340 percent increase in the incidence of autism compared to those who were vaccinated after the age of three (3). So there is an association between MMR and autism. The algorithm wants to cover up this inconvenient evidence.

Five years after the Sri Lankan deaths in 2008, there were 12 deaths in Vietnam with the same vaccine that was used in Sri Lanka. In the intervening five years, the CIOMS classification had been put in place and the Sri Lankan deaths could be reclassified from AEFI to not a case of AEFI. Memory of those deaths were erased. The WHO reported after the Vietnamese deaths five years later that, "No fatal reaction has ever been associated with this vaccine."(4)

The new AFI classification wants us to disregard any new reaction, not proven in epidemiological studies. It so happens with regard the deaths following pentavalent vaccine, that there are epidemiological studies.

The Token Study was conducted by the Robert Koch Institute with funding from the German government (5). **Insert Figure 3 here** Slide 17 This is table 41, it shows that children above the age of one year had an eight fold increase in the risk of death in the first three days after vaccination. The deaths after pentavalent vaccine are ignored, not for want of epidemiological studies, they choose to ignore it in spite of the epidemiological evidence.

We spoke of three deaths in Sri Lanka and 12 in Vietnam. In India, there have been 237 deaths within 72 hours of pentavalent vaccine reported to the government of India up to August 2016. Every time there is a pentavalent death, it is labeled as coincidental sudden infant death, unrelated to [the] vaccine.

We, under the Right to Information Act, got information about deaths within 72 hours of getting pentavalent vaccine. 25 million children had been given this vaccine. We compared this with deaths

among the 45 million children who had received DPT instead. The death rate among those receiving pentavalent vaccine was double that among babies receiving DPT (6).

If we assume that DPT does not cause deaths and the deaths reported after DPT are coincidental sudden infant deaths, any increase in the death rate with pentavalent vaccine must be attributed to pentavalent vaccine and not coincidental sudden infant deaths. They have a 4.7 excess deaths per million vaccinated with pentavalent vaccine. If we make our projections with data from states in India with good reporting, we anticipate that there will be 7,000 to 8,000 extra children who die in the country when the switch from DPT to pentavalent vaccine is complete.

Now to the six-valent hexavalent vaccine, which has recently been licensed in the United States. From the beginning, there was epidemiological evidence that deaths [were being] caused by the vaccine. One piece published in the European *Journal of Pediatrics* that there was a significant increase in deaths in the first three days after vaccination in children over the age of one year (7). The European Medicines Agency, the equivalent of the U.S. FDA (Food and Drug Administration), required the manufacturers to provide yearly its Periodic Safety Update Reports (PSUR) of data of all the doses of the vaccine manufactured and all the reports of deaths (8).

Let us examine PSUR15. [\[Insert Figure 4 here\]](#) Slide 21] 60 million doses [of hexavalent vaccine] had been used by then. The manufacturers estimate that 9.4 percent of all those doses were used in children over the age of one year. 55.5 million [children were] said to use it under the age of one year and 5.5 million in the second year.(9)

The SIDS rate in children under one year is considered to be 0.4 per 1000 per year. If you divide this by 365, you can get the deaths per day. If 55 million children are observed, 54 children would die of SIDS on any given day. This is the expected death rate per day, unrelated to immunization. If observed for two days, double that number - 108 - would have died on those two days. This is tabulated as the expected deaths.

Here you see the table of expected deaths in children under the age of one year in column three of the 15th PSUR. The deaths in children older than one year is shown in column six. The SIDS rate is lower in children over the age of one year and fewer children received the vaccine at this age. The expected number of deaths is lower.

Now look at column two, the observed deaths. You will notice that the actual deaths reported after hexavalent vaccine are all less than expected. Look at the yellow highlighted area. This is the first day, 54 deaths were expected, only 10 were observed. In the first two days, 109 were expected, but only 20 were observed. The observed deaths were less than expected. The manufacturers were implying that the vaccine was not causing deaths and all the deaths were merely coincidental sudden infant deaths.

Now I want you to ignore the expected deaths. You will see that there are 49 deaths up to day four and only five deaths in the next four days. This is a five fold clustering of deaths soon after vaccination, suggesting that it may be related to the vaccination event. But I won't quibble about that.

Let us look at PSUR 16. [\[Insert Figure 5 here\]](#) Slide 23 ]By the time of the 16th report, the number of doses of the vaccine distributed had increased from 60 million to 72 million doses. So the expected deaths would increase correspondingly. In all the PSUR up to the 15th PSUR, it was estimated not 9.4 percent of all doses were used in the second year. In PSUR 16, they say that 20 percent of all doses from the time the vaccine was licensed, were used in the second year. Suddenly the rate was doubled to 20 percent. You can see why in the next table.

This is the death in children above the age of one year. The third column has been inserted by me. It is the expected death if we assume that 9.4 percent of doses were used in the second year. This

was the percentage of doses that were used in the second year, which was noted in all the PSUR up to PSUR 15.

The observed death is nearly double the expected death. So they doubled the expectations of death.

See column four, by saying 20 percent of the doses were used in the second year, even after that, the observed deaths were more than expected on days one and two after vaccination. When they observed that the deaths were higher, they simply increased expected deaths to match the observed deaths. By the time of the 19th PSUR, it was realized that the sudden unexpected deaths in children over the age of one year was only 0.01 and not 0.06, as they had been using to calculate expected deaths.

They corrected this in PSUR 19. [\[Insert Figure 6 here\]](#)[\[Insert Figure 5 here\]](#) Slide 24 The expected deaths were lowered. The observed deaths were now higher than expected. On day two, only 1.6 [deaths] were expected, but three deaths were observed. In PSUR 19, they provide the Poisson distribution of observed deaths. It is a statistical device giving the 95 percent confidence interval within which the observed figure would lie. The expected deaths lay within the 95 percent confidence limits. So it was not significantly higher.

I have added a column with the number of deaths after PSUR 16 [\[Insert Figure 6 here\]](#) Slide 25. There were five deaths one day after vaccination in PSUR 16, but in PSUR 19 only two deaths are mentioned. Three deaths are missing from PSUR 19.

As the PSUR reports cumulative deaths. The 19th report cannot have fewer deaths than that would already reported in the 16th report. It is as if three dead babies were dug up from the graves and made alive again.

I worked out the Poisson distribution for observed deaths in the 16th PSUR. You can see that the points on distribution on days one, two and three, the actual deaths were significantly higher than what was expected. So they deleted observed deaths from the PSUR 19. They fudged the data (10).

After pentavalent deaths, AEFI classification was changed: *probable* and *possible* were deleted from the classification. In the case of deaths after hexavalent vaccine, the data itself was forged. All the papers that I've quoted, are referenced in this open access journal article. You can take a screenshot of the slide, or you can contact me on email if you want the references.

This is the CIOMS WHO algorithm for AEF.I In case you live in the first world, the industrialized capitalistic countries of Western Europe, North America, Japan, Australia or New Zealand, you need not be upset by this irrational and unscientific CIOMS WHO algorithm. Chandlers, a scientist in the Brighton group, has published in the *British Medical Journal*, that the CIOMS WHO algorithm is for use only in poor developing countries. Rich countries continue to use the Brighton classification for pharmacovigilance (11). Bellavite from Italy has published this paper showing that, although the Brighton classification may be use for pharmacovigilance in Europe to deny compensation to vaccine victims, Italy uses the CIOMS WHO classification (12).

*1986 The Act* is a brilliant movie produced by Andrew Wakefield. It refers to the 1986 Act [National Childhood Vaccine Injury Act], which gives vaccine manufacturers indemnity from product liability [in the U.S.]. No matter what the adverse reaction, manufacturers cannot be held liable. But the public need not be upset by this. There is a Vaccine Injury Table and for all the injuries in the Table, compensation is made automatically by the State. There is no need to prove that the injury was caused by the vaccine. Only one small point needs to be remembered: that after receiving compensation, the vaccine injury victim is prohibited from discussing his injury.

Here are some examples from the Vaccine [Injury] Table. For vaccines containing the tetanus toxoid, if you have anaphylaxis in less than four hours, the [Table] excludes delayed anaphylaxis. If you have brachial neuritis, that is, that the nurse wrongly injects the nerve and you have a paralysis reaction not less than two days and not more than 28 days later, or if the nurse injects the shoulder joint instead of injecting it into the muscle and the joint becomes stiff in less than 48 hours, or if there is fainting - how much compensation can you get for fainting?

For vaccines containing the whole-cell pertussis or the antigens of pertussis, if you develop anaphylaxis within four hours; encephalopathy or encephalitis in less than 72 hours; the nurse injects the shoulder joint and you react within 48 hours, or if you faint. The human papillomavirus vaccine HPV vaccine, if you develop anaphylaxis in less than four hours; a shoulder injury because of injection of the shoulder joint within 48 hours, or for fainting within less than one hour. Any new vaccine recommended by the CDC for routine administration to children after publication by the Secretary of a notice of coverage, they will be compensated if they develop a shoulder injury related to vaccine administration or fainting.

You can see that the vaccine table compensates minor injuries like fainting and [administration] process-related injuries like wrongly injecting the shoulder joint, not vaccine product related adverse effects. Vaccine product related injuries can appeal the decision [to] the special masters of the vaccine court, but they find it difficult to get compensation because their injuries are not listed on the Vaccine Injury Table.

The businessmen told the bank that he was looking for a loan. The bank officer did due diligence. He got permission from the president of the bank. He had the car and the documents checked out. The businessmen did not say that all he was looking for was a place to safely park his car without paying the New York standard parking charges. This is the distraction technique of conjurors.

With the Vaccine Injury Table, the effort is to concentrate on minor issues like fainting and process errors. It is to distract from serious vaccine induced injuries and deaths.

The WHO AEFI classification, redefines vaccine reactions to erase evidence of harm. If it is not a normal reaction, it is not an AEFI [and] *probable* and *possible* reactions are deleted. If AEFI is not recorded, it will never be investigated as a signal, no matter how frequently the reactions occur.

All deaths after vaccination are recorded as coincidental, normally occurring sudden infant death syndrome deaths. If there is an excess of SIDS after vaccination, these are simply deleted. They say that the WHO AEFI classification applies only to poor developing countries, but it is used in Europe to deny compensation for vaccine injuries.

Thank you.

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