

Universal Health Organisation (UHO)

Weekly Newsletter – 20 Sep 2024



The weekly newsletters bring the updates on the science, battered and bruised during the pandemic, legal updates and impact of activism for a just society, across the world. These are small steps to promote Transparency, Empowerment and Accountability – the ethos of the UHO.

Announcement: Membership & endorsements to the UHO invited: <https://uho.org.in/member.php>

The author of Plotkin’s Vaccine considered the last word on vaccines has co-authored a perspective in the leading medical journal New England Journal of Medicine (NEJM), expressing the need for research fund allocations for long term adverse effects of vaccine.

Stanley A Plotkin, Emeritus Professor at University of Pennsylvania, and considered the final authority on Vaccines and chief editor of the standard Textbook, “Vaccine” which is the last word on the subject for decades, has co-authored a [perspective](#) published in the number one” medical journal in the world, the NEJM, titled, “Funding postauthorization Vaccine Safety Science.” The authors of this paper expressed that, “...the widespread vaccine hesitancy during the Covid-19 pandemic suggests that the public is no longer satisfied with the traditional safety goal of simply detecting and quantifying the associated risks after the vaccine has been authorized for use. The public also wants public health authorities to mitigate and prevent rare but serious adverse events – which no longer seem rare when vaccines are given to millions or billions of people.”

The authors conclude that post authorization studies are essential to give a complete profile of a vaccine’s safety. Preauthorization clinical trials have limited sample sizes, limited duration of follow up and mixed study participants, which may fail to detect some adverse events. They said it is critical to observe adverse events following immunization (AEFI) to capture adverse events not detected during preliminary trials. When they occur, the biological mechanisms should be established to identify contraindications and also for deciding compensation to the vaccine injured. The authors have pointed out an important lapse towards this end. They state that presently no separate funds are earmarked for this kind of research and they emphasized the need to allocate funds for post marketing research on vaccine adverse events.

UHO expresses happiness that the [doyen](#) on vaccines has shared this important perspective expressing concern on lack of funding for research studies on long term effects of vaccines post marketing. . We certainly need them

While leading Global Vaccine Experts are recommending more robust research on adverse events of vaccines post authorization, India seems to be taking a regressive step by suppressing uncomfortable research findings by litigation rather than proper exploration and debate around preliminary findings of Covid-19 vaccine side effects.

While leading global experts on vaccines like Professor Stanley Plotkin and his coworkers are demanding that there should be more funds for research on long term adverse effects of vaccines post marketing, India seems to be going back in research on this important issue. Both its august research body, the Indian Council of Medical Research (ICMR) and Bharat Biotech, the manufacturer of Covaxin the indigenous vaccine against Covid-19, have attacked honest researchers at the prestigious Banaras Hindu University (BHU), who attempted to do such a study with their limited resources.

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The team of researchers at BHU, followed up over 1000 participants who had taken the Covaxin against Covid-19 for more than a year from January 2022 to August 2023. The recipients of the vaccine were interviewed telephonically for any adverse effects following vaccination. A number of minor and major side effects were reported by the subjects of the study. These included respiratory infections, skin infections and some serious ones like Guillain-Barre syndrome. The study had a number of limitations which the authors had conceded in the [research paper based on the study](#) published in the peer reviewed journal Drug Safety published by the reputed publisher Springer Nature.

Soon after the study was published, the [ICMR distanced itself](#) from this pioneering study, citing the same limitations which the authors had already accepted in the paper. Not only the ICMR criticized the study on methodological grounds but also threatened administrative and legal action against the authors. How does one take this action by the ICMR in view of their serious conflicts of interest? They entered into partnership with the manufacturers of the vaccine and also [shared royalty worth over Rs 170 crore](#) from the sales of the vaccine. Perhaps emboldened by this, recently, their partners in vaccine production, [Bharat Biotech, has sued the researchers](#) and the journal alleging defamation and sought an injunction and Rs 5 crore in damages. The journal editor probably under pressure has expressed his decision to [retract the paper](#). The authors however, stand their ground and communicated to the journal to refrain from doing so until the case is disposed by the court.

We feel that these developments are highly disturbing and do not augur well for science as well as for patient safety. The Covid-19 vaccines were released in the market under “emergency use authorization” and detailed study on safety and efficacy are lacking. BHU researchers attempted to do such a study by following up a large sample of vaccine recipients. UHO concurs with the view that their study has number of limitations, as most pilot research studies do have. But in spite of these limitations, the study has provided leads for more detailed investigation. The ICMR as the apex research organization could have followed up on this study by allocating funds and resources. The study participants could have been contacted for detailed investigations and further follow up.

UHO had expressed its criticism on this unprofessional and unscientific action of the ICMR which was [published in mainstream media](#) as well as the prestigious [British Medical Journal](#), BMJ. ICMR is functioning more like a medical dictator rather than a promoter of robust and honest research which should be its role. The ethos of science is debate, discussion and exploration and not censorship. Adding insult to injury the legal proceedings by Bharat Biotech will have far reaching negative consequences. A message will go to researchers not to undertake studies on adverse events of medical interventions. At stake will be human lives.

Critique of One Health Approach published in the BMJ recommends power to the local people rather than top down colonial approach.

A [critique in the British Medical Journal \(BMJ\)](#), has raised concerns that the models of “One Health” approach being promoted have omitted the inputs of the local people in their research. Nor is indigenous knowledge related to health and wellness are being incorporated in the strategy of One

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Health which aims for an holistic approach integrating human health, animal health and climate change under the One Health umbrella. The paper criticizes the top down approach and recommends that instead of interpreting how One Health would help the local people, it is important to consider how the indigenous people can contribute to the One Health Model, in other words a grassroots approach. The author concludes that the One Health model should shed its attitude rooted in double standards and hierarchy reminiscent of the colonial approach. For best results, the author recommends that the indigenous people should be involved in decisions involving their health and illness. UHO concurs with this approach of people's health in people's hand and draws attention to the following wisdom from an ancient Chinese philosopher which echoes the same thoughts.

“Go to the people. Live with them. Learn from them. Love them. Start with what they know. Build with what they have. But with the best leaders, when the work is done, the task accomplished, the people will say 'We have done this ourselves.’ — Lao Tzu

Selfless workers do not try to grab power and leadership but empower the people. The WHO is striving in the opposite direction. It is trying to grab power under the One Health top down approach and instead of empowering the people the WHO Treaty will make citizens lose their autonomy and become vulnerable to human rights violations on the pretext of real or imagined pandemics.

Mask Mandates and other restrictions in Kerala after one death due to Nipah virus.

After [one death due to Nipah virus](#) in Kerala's Malappuram district, authorities have enforced mask mandates, containment zones, and restrictions on public gatherings in five wards of the district. School, colleges, madrassas, tuition centres, cinema halls have been closed down and shops have been allowed to function from 10 am to 7 pm. Out of the 225 people who had come into contact with the deceased, 50 individuals were categorized as high-risk. Samples from 16 of these high-risk individuals, tested at the Manjeri Government Medical College, [confirmed no signs of infection](#).

UHO expresses concerns that ham-handed restrictive and draconian measures have become the protocol for all infections post Covid-19 pandemic. Studies have established that these crude unscientific measures caused more [collateral harm](#) with no benefit particularly in poor countries. Such measures fracture society and are uncalled for. Mask mandates are also an encroachment of human rights and an opportunity for harassment of the people with no benefit as [large studies](#) have demonstrated. More rational would be preventive measures at individual level by proper awareness among the masses. Disease specific, depending on the mode of transmission and vulnerable group specific, rational awareness is all that is required. How will limited hours shop opening will save transmission. There will be more crowding during that time, and loss of business for those food outlets which run in the evening only. This [occurred in Mumbai](#) during the Covid-19 lockdowns.

This scientifically based awareness [can be achieved in several ways](#). Social media platform and local television channels are important for proper risk communication without causing panic. Others include FM radio stations and local newspapers and posters. Farm workers may be informed to avoid direct contact with farm animals, especially during slaughter and disposal, wearing appropriate

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personal protective clothing during hazardous tasks. Villagers may be told to avoid eating date palm fruits and drinking date palm juice that may be contaminated if fruit bats live on these palm trees.

These are similar to the simple measures we teach to avoid getting killed in road traffic accidents. We educate the public to follow traffic rules. In vain it seems in our country, and the police too is casual in penalizing defaulters unlike the gusto they display in enforcing draconian measures like mask mandates and lockdowns! If media hypes each case of road traffic accident occurring on a daily basis, people can be psyched to stop using motorized transport and stepping out as well.

Daily around 422 people mostly young die due to [road traffic accidents in India](#) and many more get disabled for life. This is perhaps more than all the deaths due to Nipah virus since it was discovered in 1999 in Malaysia, almost 24 years ago!

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