Universal Health Organisation (UHO) Weekly Newsletter – 16 Feb 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

HPV Vaccine manufactured by Serum Institute of India by trade name CERVAVAC

The Union Government is taking cautious steps to include the HPV vaccine to prevent cervical cancer in women and cancers of the ano-genital regions in the male in the Universal Immunization Program (UIP). Cervical cancer affects the cervix or lower part of the uterus and is the fourth commonest cancer in women after breast, lung and colorectal cancer.

In her interim budget speech for 2024-25, the Finance Minister Nirmala Sitharaman indicated that the government will *actively* promote HPV vaccine to prevent the *deadly* disease. The mainstay of reducing deaths from cervical cancer is periodic screening of women with PAP smear. The HPV vaccine is not foolproof for many reasons and will not eliminate the need for screening for cervical cancer.

Including the HPV vaccine in the UIP will incur huge investments from the public exchequer. Towards reducing the cost, the Serum Institute of India (SII) has launched an indigenous HPV vaccine Cervavac costing Rs 200-400 per dose which is about 1/10th of the existing brand Gardasil manufactured by Merck. In a phase 2/3 trial sponsored by the manufacturer comparing Cervavac with Gardasil, the indigenous vaccine showed adequate antibody response. However, the study which included both boys and girls mentions that each gender experienced 1% serious adverse events requiring hospitalization. The paper does not mention what these adverse events were, strangely. There were no deaths, fortunately.

There are many uncertainties around the HPV vaccine and therefore debate and deliberation are called for. We feels that even 1% serious adverse events is one too many, given our poor Adverse Events Following Immunization (AEFI), and overcrowded and understaffed public hospital services. We fear while 1% serious adverse events could be taken care of under trial conditions, these may be missed in actual practice if the HPV vaccine is launched in unholy haste before improving out public health services and putting an efficient AEFI in place. This is relevant as in Gujarat and Andhra Pradesh trials of HPV vaccine was conducted by Gates Foundation and ICMR among vulnerable tribal girls violating all ethics and safety precautions, and some girls died after receiving the HPV vaccine. A joint parliamentary committee indicted the Gates Foundation and ICMR of gross negligence.

UHO has serious reservations for mass immunization of children with a vaccine with 1% serious adverse events as reported during the Cervavax trials when the incidence of cervical cancer is 0.0147% and death rate from it is 0.009% in women aged over 50 years.

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Vaccinating 100% of children 9-14 years of age and exposing them to 1% chance of serious adverse events is not logical. UHO recommends the following to resolve these uncertainties before including the HPV vaccine in the UIP.

1. Establish national baseline epidemiological data on cancer incidence, mortality and HPV subtype prevalence to support evidence based decisions about whether the currently available vaccines are likely to be cost-effective and should be a priority.

2. Ensure that cancer surveillance and registries are in place before any vaccination programme is implemented so that changes in incidence of cervical cancer and its precursors can be studied.

3. Initiate national long-term efficacy and effectiveness studies that are free of industry funding, focus on clinically meaningful outcomes, and enroll and analyze the vaccine target populations. In this regard a critical appraisal of the current evidence by independent researchers has unveiled many gaps raising serious doubts about the role of HPV vaccine in preventing cervical cancer.

4. Improve our public health services with adequate access for women to undergo screening for cervical cancer particularly in less served and remote areas where it is most required.

It is also relevant to point out that the incidence and deaths of cervical cancer in India have shown drastically declining trends over the last three decades . This can be attributed to better genital hygiene, safe sexual behavior, perhaps due to the AIDS scare and screening services. There is therefore no rationale in pushing the vaccine in the UIP in a hurry with shaky evidence.

Good sense seems to have prevailed among the health policy makers. For the time being, at least, the government has stalled the inclusion of the HPV vaccine in the UIP . The reasons given were the cost and concerns around side-effects related to the vaccine.

Law panel calls for exhaustive revision of the Epidemic Act 1897 amended in 2020 to make it more stringent

Public health post covid "pandemic" seems to have become everyone's baby except of doctors. The law panel of India took up a "comprehensive review of the Epidemic Diseases Act 1897," on a suo motu basis pointing out many gaps in the provisions. It suggested that the Act should be made more stringent to control future epidemics.

Showing ignorance of the latest evidence, it suggested on a proper definition of "Physical Distancing," as an exercise of maintaining sufficient physical distance between individuals to limit the spread of infection. Even the arrogant Anthony Fauci who became the high priest of Science had to concede recently in a hearing in the US senate that the recommendation of

physical distancing was not based on any evidence! The learned judges of the law panel have been caught napping!

The Epidemic Diseases Act was enacted in 1897 during colonial times. It was harsh enough reflecting the power of the rulers over the ruled. And there were genuine pandemics like the plague which in the pre-antibiotics era wiped out whole villages.

We are living in the 21st century where such pandemics are rare. Covid-19 is definitely not in the class of plague or smallpox, or even cholera. It has an infection fatality rate of 0.05% till the age of 69 years compared to these ancient scourges which had fatality rates ranging from 10% to 40%. Even the high fatalities during the 1918 swine flu pandemic were due to secondary bacterial infections in pre-antibiotic times.

Since the Second World War and coinciding with the discovery of antibiotics and modern medicine such pandemics are confined to public health history. Even cholera does not kill much since the invention of the simple and low cost, "oral rehydration solution."

The UHO wants to put on record that stringent Epidemic Acts would not prevent pandemics. What is required is improvement in general standards of living, good water supply, sanitation, housing, healthy foods and recreational facilities. Control of obesity by imposing "acts" against fast and processed foods rather than a more stringent Epidemic Act would make a better impact in improving the health and immunity of the population compared to hastily developed vaccines and pharmaceuticals pushed through experimental use authorization among the masses. Unfortunately, the Law Panel has stressed on the latter instead of the former.

The Law Panel has exceeded its brief. The steps to be taken during any disease outbreak are the job of public health experts at the time when it happens weighing in the scenario and circumstances. Laws cannot dictate what is to be done. If this trend continues the time is not far away when lawyers will peep over the shoulders of doctors treating individual patients dictating what medicines are to be administered! To a large extent even this happened during the pandemic when doctors were bound to give drugs recommended by diktats from "experts" instead of using their individual judgments.

UHO strongly recommends that this authoritative trend which is stifling the art and killing the science of medicine should be reversed and freedom to practice the art restored to doctors treating patients in the frontlines.

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