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Title

Timely use of COVID-19 vaccines could have saved thousands of lives

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Correspondence

Authors

1. T Jacob John

Retired Professor, Christian Medical College, Vellore, Tamil Nadu

Residence: 439 Civil Supplies Godown Lane, Kamalakshipuram,

Vellore TN, 632002

Tel 7845338188. E mail <tjacobjohn@yahoo.co.in>

1. Dhanya Dharmapalan

Consultant in Pediatric Infectious Diseases,

Apollo Hospitals, CBD Belapur, Navi Mumbai.

Tel No. 09820274280. Email [drdhanyaroshan@gmail.com](about:blank)

1. Jagdish Ratnanni

Director, 'Foundation of The Billion Press',

Faculty member, Bhavan's S P Jain Institute of Management & Research.

Tel No. 9987023923. Email: jagdish@thebillionpress.org

Corresponding Author

Dhanya Dharmapalan

Consultant in Pediatric Infectious Diseases,

Apollo Hospitals, CBD Belapur, Navi Mumbai.

Tel No. 09820274280. Email [drdhanyaroshan@gmail.com](about:blank)

**Manuscript**

Earlier we (TJJ & DD) had written in IJME, that during the pandemic with high case-fatality in those above 65 and younger adults with chronic lung, heart or kidney diseases or diabetes, early start of vaccination must be allowed as a life-saving procedure (1). It was pointed out that *protection delayed may be protection denied* to drive home the urgency of vaccination for saving lives. At that time Phase III vaccine trials were in progress and we had adequate data on safety, but efficacy had yet to be measured. Good immunogenicity had already been documented in Phases I and II in which there were no signals of safety problems. Efficacy was ‘on promise’ when we argued for early vaccination of those at risk of death.

It has been distressing to read about countless deaths of people COVID-19, during the months of March to May 2021. The total number of deaths reported in the second wave (between 11th March and 27th May 2021) was over 160,000 (2). We believe that this number is an under-estimate because India does not practice public health surveillance and authorities do not verify cause of death diagnosis at local levels. About 2000 COVID-19 deaths in Mumbai (60% of total deaths) have occurred in the age group over 60 years (3). Till date only 31% of this age group in Mumbai has received two doses of the vaccine, majority since the first week of March (3). In Kerala state, 2716 deaths (over 70% of total deaths) occurred in age above 60 years between March and May (4).

Extrapolating from the Mumbai and Kerala data above, we attribute one lakh deaths (65% of 160,000) to COVID-19 among the over-60 population – lives that could have been saved with two doses of a vaccine given at the appropriate time. Government opened up vaccination to those above 60 years from first week of March. There was no public education on the safety and efficacy of the two vaccines, and as a result vaccine hesitancy began growing through social media. By 21 April only 47% of those age eligible to receive vaccine had actually got at least one dose (5)

From the literature we understand that all currently used COVID-19 vaccines with two-dose schedule offer near-100 per cent protection against life-threatening severity of COVID-19 – hence are life-saving if given twice four weeks apart (6,7). In order to be effective from mid-March 2021, the second dose should have been injected latest in the first week of March and first dose in the first week of February.  Our plea for using vaccination to protect lives was in October, clearly three months earlier. The situation is tragic because we had safe vaccines made in India, and approved for emergency use on 3 January, 2021 (8). Ethics and epidemiology demanded early and prioritised vaccination of those at risk of loss of life – for those who died without 2 doses of a vaccine protection was denied by avoidable delay.

There were easily tracked data on those above 65 using Unique Identification Number (UID, Aadhaar) and on people with chronic diseases since many, if not most, are under healthcare either in public or private sector clinics/hospitals. Vaccination of these groups was the ethical responsibility of the pandemic management authorities.

We believe that over 100,000 lives were lost for want of an ethics-guided national policy to vaccinate for saving lives, in spite of our alert in IJME and in spite of vaccines undergoing Phase III trials as we wrote in October 2020. Although many may believe that ethics applies only to what is done, it applies also to what was due but not done. Withholding a life-saving intervention is unethical, as in this case of having promising vaccine candidates available, but not offering them to those who were facing the risk of COVID-19-caused mortality. To be right for saving lives is greater than to be righteous by mindlessly following man-made rules and conventions, which are actually meant for the best interests of the public. What better interests are there, than saving lives?

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