

COVID19 vaccine: Time to go the Jennerian Way

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Abstract

Currently as of May 2020, there are more than 8 potential candidate vaccines against COVID19 in clinical evaluation and another 100 in preclinical evaluation. Considering the governing rules and regulations with respect to non-clinical and clinical evaluations, it may take around 5-6 months at the earliest to have an efficacious COVID 19 vaccine. The question lies ‘DO WE HAVE THAT MUCH TIME?’ The challenges faced today not only have implications to the public health but also the masked social and economic implications as well. Hence, it is imperative to have a Blitz Krieg solution against COVID19.

Letter to Editor

COVID19 vaccine: Time to go the Jennerian Way

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Main Text

Currently as of May 2020, there are more than 8 potential candidate vaccines against COVID19 in clinical evaluation and another 100 in preclinical evaluation.[1] Considering the governing rules and regulations with respect to non-clinical and clinical evaluations, it may take around 5-6 months at the earliest to have an efficacious COVID 19 vaccine.[2] The question lies ‘DO WE HAVE THAT MUCH TIME?’ The challenges faced today not only have implications to the public health but also the masked social and economic implications as well.[3] Hence, it is imperative to have a Blitz Krieg solution against COVID19.

As mentioned earlier, few candidate vaccines have entered the trial phase to see the efficacy.[1] With the lack of immunogenicity endpoints, the clinical endpoint of occurrence of COVID19 in those vaccinated with candidate vaccine against those with placebo is being used.[4] This is a time-consuming endpoint and also has several limitations. Any COVID19 vaccine in current scenario may work only if it able to reduce the COVID19 positive test duration following a positive human challenge test with COVID19.[5] Realistically this is not ethically acceptable. The approach to a rapid vaccine still hangs in question.

Claims are being made that the COVID19 vaccine is being developed in the shortest period till now. It is important to note that this shortest period is view of the ongoing regulations of clinical trials where it is mandatory to show that the candidate vaccine is safe and efficacious. Current times are difficult, and

going through the mortality statistics of COVID19 it appears, that thousands may die in coming 4-5 months unless we have an effective vaccine or antiviral drug. The situation demands that vaccine should be available immediately.

A way to contain the COVID19 is to allow the candidate vaccines to be used in parallel to the conduct of clinical trials for efficacy. Accepting a 14-day safety data in a short number of clinical trial participants, the candidate vaccines should be allowed to be used in masses irrespective of the proven efficacy. This may be allowed as a compassionate use of the vaccine based exclusively on proven safety. If the vaccine is shown to be efficacious in clinical trials, the parallel immunization of the masses during the ongoing clinical trial may have protected a significant proportion of people from COVID19. Even if the candidate vaccine does not show efficacy in the clinical trial, it may not necessarily cause harm in view of proven safety. Either way it is worth a try. Ethically, how does one justify the deaths of those who could have been protected by the mass immunization of the candidate vaccine. It is debatable for ethical and scientific community regarding the use of unproven vaccines to be used in masses.

The current regulations of conduct of clinical trials are very scientific and ethical and have evolved rapidly in the last 70 years.[6] Ideally, these should be followed. But looking at the current scenario, it is time to give the regulations a miss and allow safe candidate vaccines directly for human use.

The important point to consider in this aspect, is ‘Edward Jenner’ never conducted a powered clinical trial.[7] He was scientifically and conceptually strong. This same approach is the need of the hour.

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