

SHORT COMMUNICATION

COVID-19 Vaccines Interim Analysis: Unanswered Questions

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ABSTRACT

It will be one year since severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has created havoc and mayhem in form of coronavirus disease 2019 (COVID-19) pandemic. Many potential vaccines candidates are identified and are currently in different phases of clinical trial. The international regulatory authority has given emergency approval of two vaccines, Pfizer and BioNTech and Moderna. The Phase 3 trial of both these vaccines are still in progress and there are scattered reports of adverse effects including allergic reaction among vaccinated health care workers. The safety profile of these vaccines requires long term follow up of patients before one can assure its efficacy and clinical effectiveness.

Key Words: COVID-19, SARS-CoV-2, Vaccines.

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The world has welcomed the good news. According to published press reports, clinical trials of four vaccine candidates have shown promising results, with three exceeding 90% efficacy.¹ The prospect of preventing morbidity and mortality is a cause for optimism. Although it is right to be hopeful, many questions still remain unanswered. Firstly, how well the vaccines work in population with co-morbidities, how well it protects against severe illness, what is the duration of protection, does it require booster dose and does it prevent transmission of disease.

Table 1: Different Vaccines for COVID -19

Vaccine Developer	Type	Doses	Efficacy*	Storage
Pfizer-BioNTech ²	RNA	2	95%	-70°C
Moderna ³	RNA	2	95%	-20°C up to 6 months
Oxford Uni-AstraZeneca ⁴	Viral vector	2	62-90%	4°C Regular fridge temperature
Gamaleya (Sputnik V) ⁵	Viral vector	2	92%	Regular fridge temperature (in dry form)

*these are preliminary results and are not peer reviewed

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COVID-19 Vaccines Secondly, there are challenges in assessing the efficacy of vaccines candidates as efficacy does not always predict vaccine effectiveness.^{6,7,8,9}

Many studies have shown that severe CoV-2 infection is dependent on multiple variables including age, ethnicity and comorbidities.⁹ COVID-19 in Older People (COPE) study has shown association between frailty and short-term mortality in older adults hospitalized for COVID-19.¹⁰ A systematic review, to assess impact of ethnicity on clinical outcomes in COVID-19, had found an increased risk of infection with SARS-CoV-2 and worse clinical outcomes, including intensive care admission and mortality among Black, Asian and Minority Ethnic (BAME) individuals in United Kingdom.¹¹ Meta-analysis, to assess the prevalence of comorbidities in SARS-CoV-2 infected patients and the risk of severe COVID-19 underlying diseases in severe patients compared to non-severe patients, the pooled OR of hypertension, respiratory system disease, and cardiovascular disease were 2.36 (95% CI: 1.46–3.83), 2.46 (95% CI: 1.76–3.44) and 3.42 (95% CI: 1.88–6.22) respectively.¹² Thus, although the most important efficacy endpoint of any vaccine candidate would be its ability to prevent SARS-CoV-2 infection and protect against COVID-19 disease⁷, yet greatest effect of any such vaccine, claiming either to prevent infection, alter clinical course of disease, or block transmission can be best gauged if the vaccine is effective efficacious against susceptible

population. This is yet to be demonstrated as very limited data of these vaccine trials is currently available. Answers to such scientific ambiguities dictates how the vaccines will affect the course of the pandemic.

Then, other questions including mass scale production, equitable distribution, storage, shipping, cold chain maintenance and clearing up, need to be address by policy makers before one celebrates the end of the pandemic via inoculations. A global survey of potential acceptance of a COVID-19 vaccine conducted in 19 countries, observed high heterogeneity in responses and far-from-universal willingness to accept a COVID-19 vaccine.¹³ This is a cause for concern for COVID-19 control. Responsible leadership and careful public communications are needed to ensure compliance of non-pharmaceutical interventions as a public health safety measure.

The year 2020 has seen remarkable scientific breakthroughs, including characterization of a novel illness, sequencing of a new virus genome, development of rapid diagnostics, treatment protocols, and randomized controlled trials for establishment of efficacy of drugs and vaccines. But there is still much to learn and many barriers to overcome. In words of Alan Watts, British philosopher, “Problems that remain persistently insoluble should always be suspected as questions asked in the wrong way”.¹⁴ Together we can work to bring an end to this global health crisis, including its devastating impact on individuals, communities, and economies.

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