

Archives of Surgical Research | Invited Commentary

Coronavirus Vaccine Landscape in Pakistan: Where Do We Stand?

Maryam Riaz Tarar¹, Shehnoor Azhar²

IMPORTANCE Developing countries like Pakistan have had an opportunity to make the ongoing pandemic count. The country has already been on forefront of several natural disaster and conflicts in the past decades. In less than one year, recruitment of over 25000 volunteers nationwide shows the potential and local expertise available to undertake phase III trials for experimental vaccines. It augurs well for the local population to now be able to partake in high quality multi-country research given the health emergency created by SARS-CoV-2 since March 2020. Academic institutions have paved the way for biopharmaceutical sector to capitalize on.

KEY WORDS Clinical Trial, Covid-19 Vaccination, Corona virus Vaccine, CanSino, BIO ZF2001 Vaccine

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Invited commentary

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The year 2020 has seen a novel virus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) spreading unchecked at global level resulting in unanticipated increase in morbidity and mortality caused by the new infection termed Covid-19. The transmission of this new virus among populations has been reduced to an extent by non-pharmaceutical interventions (NPIs) like mask usage, hand hygiene and maintaining social distancing. However, it is apparent now that vaccination may be the only way to effectively control this new affliction. In Pakistan, the handling of the Coronavirus pandemic and strategic decision making from the capital has been under the domain of National Command & Operation Centre (NCOC) and Ministry of National Health Service (NHS). Initial pandemic control rested mostly on NPIs and lockdown of hot-spot areas of Coronavirus transmission in different parts of the country. However, vaccine procurement was not pursued by the government with the urgency it deserved. In Pakistan, the second unanticipated wave of infections in fall of 2020 was a stark reminder that Coronavirus situation was unpredictable and needed more than only promoting NPIs.

of a Chinese company CanSino Biologics, co-developed by the Chinese military. It was to be administered to above 18-year-old adults as a single shot intramuscular injection. Prior to enrolment at five centres nationwide during August 2020, the National Institute of Health (NIH) Islamabad, acting as the principal investigator on behalf of Government of Pakistan entered into an agreement with the parent company. This was to facilitate inclusion of private and public sector healthcare organizations into a multicentre phase 3 clinical trial, for recruiting volunteers for this vaccine candidate. The trial was approved by the Drug Regulatory Authority of Pakistan (DRAP) and National Bioethics Committee (NBC). In Lahore, University of Health Sciences (UHS) as a public sector organization took an initiative to develop a specially designed vaccine centre for this purpose to facilitate the recruitment process (Fig 1-3). It started enrolling volunteers on October 01, 2020, coincidentally the national day of Peoples Republic of China. A public health expert, directly reporting to the Vice Chancellor UHS, was nominated as a coordinator (Dr S.A) for overseeing the project from start to finish. At this facility, a total of 5000 volunteers were recruited in the trial during next couple of months, out of a total of 17,800 participants recruited on behalf of the NIH at Shifa International Islamabad, Shaikat Khanum & Hospital Research Centre, Indus Hospital and Agha Khan University². The active ingredient was administered to half of the participants whereas the other half received a placebo. Besides Pakistan, participants were also recruited from Russia, Mexico and Chile. The product was based on traditional recombinant protein technology using Adenovirus 5 vector.

COUNTRY PARTICIPATION IN VACCINE TRIALS

CanSino BIO

The participant recruitment for multi-country study of candidate vaccine "CanSino BIO" started in Pakistan sometimes during late September 2020¹. This was a product



Figure 1-3: UHS Vaccination Centre (Picture credits: Mr Kamran Faig – Autumn Pictures).

After CanSino BIO study, our public and private sector healthcare organizations also took part in another trial for Coronavirus vaccine "ZF2001" (Fig 4). This vaccine is co-developed by Institute of Microbiology in Chinese Academy of Sciences (IMCAS) and Anhui Zhifei Longcom Biopharmaceutical company². Like the CanSino BIO trial, this was also approved by DRAP and NBC. The recruitment of adults above 18 years of age started in April 2021. The vaccine is different from CanSino BIO and belongs to a class called the protein subunit vaccines, based on Chinese Hamster Ovarian (CHO) cell³. It requires three doses to be administered by intramuscular injection over a period of two month and is without a placebo arm. The partnership with sponsors of ZF2001 and UHS Lahore has resulted in a project that will lead to development of a "Silk Road Clinical

Research Centre" in the coming months, which will be a dedicated trial centre for future collaborative work.

COVID-19 سے موثر بچاؤ کیلئے تحقیقاتی کلینکل ٹرائلز ایک امید ہیں۔ پاکستان میں جاری ZF-2001 فیر 3 کلینکل ٹرائلز رضا کاروں کو اس تحقیق میں شمولیت کی دعوت دے رہا ہے تاکہ مقامی آبادی کیلئے ایک موثر COVID-19 ویکسین کی دستیابی یقینی بنائی جاسکے۔ یہ تحقیق بہترین معیار اور قومی و بین الاقوامی اداروں کی تصدیق کے ساتھ کی جا رہی ہے۔

اس تحقیق میں شمولیت سے رضا کاروں کو چار کلیدی فوائد حاصل ہوسکتے ہیں۔

- تحقیق کے 4 ماہ کے دوران مفت طبی مشاورت اور حسب ضرورت تشخیصی ٹیسٹ
- سفری کرائے کی مدد میں اخراجات کی واپسی
- مستقبل میں ڈرگ ریگولیشن اتھارٹی سے اجازت کی صورت میں پہلی ویکسین کی مفت دستیابی
- امیدوار ویکسین لگنے کے 50% امکانات۔

آئیے رضا کار بنیں۔

ZF-2001 پاکستان کے 4 شہروں کے مختلف اداروں میں جاری ہے

 0323-1403358 0324-0926304	 0308-4535342	 042-111000262	 0302-9464734	 042-11171819	 0322-4450251
 0318-5804108		 0378-5804115-6			

MOVING BEYOND CLINICAL TRIALS

The contribution of our institutions, researchers and general population who acted as participants in Coronavirus vaccine clinical trials, with international companies at the forefront of vaccine production, has put our country's name on the map of vaccine related clinical research. It is of interest to note that one out of four different type of Coronavirus vaccines named on the front page of Dawn Lahore (2 June 2021, p. 1) bore the name PakVac; others being Pfizer BioNTech, Sinovac and Sinopharm. However, PakVac is not a pure Pakistani product as the name suggests. The vaccine concentrate that has been used to make locally packed doses of this vaccine has been procured from China and is a precursor of CanSino BIO vaccine as mentioned above. The PakVac vaccine was launched in the country on the first day of June 2021 at NIH Islamabad. It is hoped that three million doses will be packed every month and will be used to

immunize our population at a fast pace in year 2021 and beyond.

Currently, we are at a slow pace in vaccinating our population, keeping in view that the drive that should have started last year began on 2nd February 2021 with a limited quantity of gifted doses of Sinopharm from our Chinese neighbours. Initially “targeted approach” concentrated on vaccinating individuals in high risk category like front line health care workers (HCWs) and those above 60 years of age. Now, with getting additional doses of different vaccines like Sinovac, Astra Zeneca and lately Pfizer BioNTech being added to the growing list (latter two vaccines through global COVAX initiative), the idea is to move towards “vaccinate all” approach. The government has now set aside one billion dollars for this purpose which is the way forward.

The procurement of Coronavirus vaccine has been difficult from international market as demand for vaccines surged with pandemic picking up momentum last year with devastating consequences for healthcare services, education sector and global economy. Who would have thought that by the end of year 2020, there would be hundreds of projects, all with one focus of producing the same vaccine? But this was all a part of pandemic control strategy which is dependent on vaccine production at fast pace. World Health Organization (WHO) has developed a landscape and tracker tool for Covid-19 that provides visual analysis of different candidate vaccine categories (Inactivated, Vector-based, mRNA, Subunit, VLP [Viral like particles] & DNA).³ It also provides overview about progress on different phases of trials being carried out in different parts of the world. Currently, there are 287 candidate vaccines with 102 in the clinical phase and 185 in the development phase³. The amount of interest in rapid development of the Covid-19 vaccines is an understatement as the amount of information being shared on daily basis as publications is difficult to keep a track of. We have seen new vaccine production technologies take the centre stage like messenger RNA

vaccines without any stumbling blocks. We have also become familiar with terms like “Emergency Use Authorization” which in the past was only reserved for select situations as far as the vaccines were concerned.

This is certainly not the last pandemic to hit the humanity. It is of utmost importance that we are prepared as a nation to combat any assault of a similar kind in future and clearly define our pandemic control strategies. The wait and see policy in pandemics may work but is a very risky approach. We should not blur our focus from becoming a vaccine producing nation due to reliance on COVAX alliance donated doses. Pakistani public and private sector institutions with their proactive approach should provide a platform to involve biopharmaceutical industry to invest in research and local vaccine production.

As vaccine roll-out gathers momentum, the immediate task should be to allay fears in the mind of public at large so that there are minimum vaccination refusals. About 300,000 people who had received the first dose have failed to turn up for their second doses (Dawn Lahore 13 June 2021, p.6). There should be a fresh awareness campaign with citizen engagement to address this reluctance issue. Coercive measures like blocking salaries or phone SIMs will be counterproductive at this crucial stage (Dawn Lahore 6 June 2021, p. 6). There will be difficult times ahead when vaccination will move into urban areas. The key is to be provide up to date information to the public about success stories in other countries who have opened their borders for renewed business and economic activities. Don't we all wish to be included in “Green list of safe countries” instead of “Red list of unsafe countries” and avoid global travel restrictions?

In the future, there may be more vaccine defying variants than the ones we have at our hands now and more “waves” of infection to tackle. The emphasis must be on timely and smart decisions to fight this pandemic.

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