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Case Report

A viewpoint commentary on the success of the UK mass vaccination immunotherapy trials and european dark side history on Oxford Astrazeneca Vaccine (OAZ) deployment: is the europe's Precautionary action over OAZ vaccine is more than the science?

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ABSTRACT

The well-known by name the Oxford AstraZeneca (OAZ) vaccine manufactured at large scale for the whole world, with a novel noble idea of being almost cost free, has been validated internationally and approved by the WHO, UK- MRHA, EMA, US-FDA regulatory agencies for clinical intervention against Corona virus infection. In several observational clinical trials, using both the Pfizer and OAZ vaccines, to understand their effectiveness, on the community most at risk, it become apparent that these vaccines are capable to slow down the rate of hospitalisation and protect the recipient and save lives. Currently trials have begunwith the Pfizervaccine in assessing the safety efficacy effectiveness in Youngers age including children above the age of 12 with promising successful outcome so far. Nevertheless, surprisingly, contrary to the European Regulatory Agency approval, the OAZ vaccine, was rejected by some of the European countries, based on the fears of inducing clot on the basis a limited observational cases in some unexpected cases. Moreover voices are flagged to the unfair distribution of this vaccine, by the AstraZenika manufacturers to the European communities, despite the fact that tones of vials of this vaccine are in store in the Europe, with limited use, possibly in view of high levels of vaccine hesitancy in Europe as compared to UK. Intriguingly come the news of the unexpected export ban, by the president of the European community, poring cold water on such global collaborative efforts in developing and deploying vaccines to survive this nasty virus that continuously undergoing some fearful fast spreading mutation, requiring team working on the sprit of oneness to stop the fast transmission of this infection timely. In fact in this context the team working is the best strategy, with the concept that "No one is safe until everyone is save". Artificial and machine learning tools were extremely useful in big data and pattern analysis using newer technologies including proteomic and the flowcytometry analyses as described earlier [1-3]. Large numbers of candidate vaccines and alternative mode of innervation is developed and deployed with promising outcome [4-11]. Major studies are carried out to remove potential side effects using Coronavirus convalescent plasma derivative, including newer blood purification systems [2-12]. Some efforts are made to make these new mode of therapies available for use to countries with poorer infrastructure, in line with WHO recommendation [13].

Some very rare events of potentially vaccines-inducing thrombotic thrombocytopenia [VITTP] is reported, in some young female<30 ages (one per million cases) and for

cautionary measures the vaccination authorities recommended that recipient should be given a choice for the vaccine available to be used.

IN SHORT our current understanding of the infection dynamics of CoV-2 variants is still incomplete but based on what is happening in respect to the current UK- Alpha variant, that is currently circulating all over the world it appears that the link between the infectivity, transmissibility and hospitalisation is severely suppressed and even broken in some places with the current vaccines in use, combined with some other preventative strategies. The attention is now focussed in remedial action for the "LONG COVID" that is associated with autoantibodies against on the host cells, as described previously [10].

Several local and national clinical trials are carried, in the UK, using both national and internationally approved OAZ and Pfizer vaccines to understand better and to validate their effectiveness, on the community most at risk, and based on the interim reports delivered so far it is clear these vaccines are capable to slow down the rate of hospitalisation and save lives. OAZ vaccine proved to be highly effective in all community under investigations with no obvious sign of serious untoward outcomes or clot hence counter- indicating the Europeans takes. The interim clinical observation so far briefly summarised below:

i] Even the first jab of these vaccines appears to prevent coronavirus infection and also protect the recipient from the severe illness. Hence making the mass vaccination rollout with the first vaccine dose of these vaccines, on evidence based a reality;

ii] The hospitalisation rates, in the over 80 age, were also dropped, by these vaccines up to 85% and 94% respectively, with an 81% reduction in hospitalisation risk when the results for both vaccines were combined, by the fourth week, after receiving the initial first dose, of these vaccines;

iii] In another highly informative trial, in order to identify the impact of one dose with two doses on the entire population in order to track the impacts of Pandemic and the vaccine rollout, in real time, some comparative analyses were on a set of data obtained on vaccine effects. During the period between 8 December and 15 February, covering the entire Scottish population of 5.4 million-During this period, 1.14 million vaccines were administered and 21% of the Scottish population had received a first dose based on Scottish government prioritisation and then followed by a second dose to establish on evidence based the benefit of second dose of vaccines deployment on the Scottish community on reducing the risk of admission to hospital. The two vaccines in use during this period were the Pfizer vaccine for the first jab, received by some 650,000 individuals as compared to 490,000 individuals reportedly receiving the OAZ vaccine. The obtained data were analysed on weekly basis during this period – including GP records on vaccination, hospital admissions, death registrations and laboratory test results – Both vaccines were able to protect patients from the severe effects of Covid. The observed effectiveness of one dose of the two vaccines was almost identical with a cautionary note that the study was not aimed and does not allowed head to head comparison between the two vaccines used;

iv] These highly promising results are further corroborated by another ongoing surveillance project, in Bristol, by recording the information on all adult patients admitted to hospital with symptoms, signs of acute disease in the lungs and 434 cases, who were eligible for vaccination, ten days after the UK's Covid vaccine programme began, the effectiveness of one dose was estimated by taking the acute respiratory disease cases who had a positive test for CoV-2 on hospital admission and those whose test was negative, and comparing the immunisation rates in the two groups. The observed effectiveness of one dose of the two vaccines was almost identical (Pfizer 79.3% and OZA 80.4%). These results are much in line with the above-mentioned studies from Scotland and England made public recently. It is noteworthy to emphasize that by design these clinical observational studies that were destined for a group of very elderly, frail individuals with many other illnesses and vulnerabilities was to provide on evidence base that vaccination process do protect such high-risk populations effectively and reducing pressure on hospital. While these expected successful results, in real time, on both Pfizer and OAZ vaccines, are in line with the manufacturer' validated data that were approved by the most stringent regulatory agencies in respect to safety and efficacy we still need to ensure that vaccination also stop transmission of this

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virus and its emerging mutated strains and the best way to achieve this is through following the public health guidance;

v] It is also worthy to highlight that in contrast to some of the controversial view expressed by some European members, on the basis of a small observational cases, on the efficacy of the OAZ vaccine for the over 60 age group. This is in direct contrast to previous trials on USA, Chile and Peru on the OAZ coronavirus vaccine that proved to be highly safe and effective, in all age group of 32,000 volunteers across all age groups, while the participants received either two standard doses of the OAZ vaccine or a placebo vaccine, at a four-week interval. The vaccine was well tolerated and no safety concerns related to the vaccine were identified and with 95% chance the true efficacy of the vaccine was similar to Pfizer's, with 79% effective against symptomatic COVID-19, and 100% effective against severe and critical symptomatic COVID-19. These results are also in line with the UK extensive safety data collected both in both previous and the current real-world trials with the above two vaccines rollout without a clear evidence of unexpected side effects.

Who knows in the light of having some insight on the above cumulative data on both the safety / efficacy of the OZA vaccine in all age groups, some countries in Europe might change their views, and start mass vaccination using enormous amount stored OAZ vaccine, particularly at the time that Europe undergoing the wave 3 pandemic with the UK – Kent variant spreading fast in Europe and if unwanted to pass their stored OZA vaccines to African country most in need of the good will, helping in their mass vaccination programme instead of the planned measures banning vaccine export and disturbing the international supply, that would bring about unwanted vaccine wars by reciprocity.

II. Is the Europe's precautionary ultimatum over the OAZ vaccine side effects and supply issues is more than the science?

Recent unwarranted ultimatum by president of European community about the planned bans on the vaccines export internationally, in view of disparity in supply of vaccine delivered to Europe, as compared to UK become of matters concerns to many at global levels, as no country including European countries, will benefit from such a drastic action that may lead to vaccine nationalism and vaccine war. Moreover in recent time some others unwarranted views have been propagated through media from Europe that do not fit the planned team working concept, with absolute scientific openness and transparency as a true sign of quality that we are used too. While the cause for concerns still unclear but the source of these inappropriate precautionary items appear to be related to more to political gesturing than scientific evidence, as briefly highlighted below:

i] In respect to limited cases the of blood clot with OAZ vaccine it is noteworthy to highlight that the reported risk with Pfizer vaccine marginally higher [38% vs. 30%] and much lower than the risk in the general population due to genetic and acquired hypercoagulability combined. Moreover while it is correct that all vaccines do work on the inflammatory processes and do enhance activation of the contact phase of the coagulation pathways, as often observed by measuring the activation complements pathway, but infection itself can induce a higher levels of complements activation, cytokine storms, leading to organ injury and vaccination by reducing and dumping infection more likely would have a beneficial effect [9-12];

ii] Moreover while any precautionary report, on side-effects, in particular if related to a topic being relatively scant still deserve full attention nevertheless in this limited coincidental cases conceptually there is more chance that the presence of clot in these limited cases, are not vaccine- related and in fact occurring with both the Pfizer and OAZ vaccine equally that has not being mentioned by the European communities. Clearly the European leader that act for almost for numerous governments should be performing some in depth analysis on this limited uncorroborated few cases or withdraw this highly damaging statement that might contribute further lead further to vaccine hesitancy that we are noticing in Europe as compared to UK;

iii] In regard to banning the vaccine export, as highlighted in the media by the president of European community, while it is correct that AstraZeneca world wise distributed 70 million doses of vaccines and 20 million gone to UK, but failing to honor its commitment to Europe, apart from the delayed in ordering by the European is possibly the reality of life as all vaccines are in short supply in pandemic, requiring some regulatory arrangement possibly on most needed in

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geographically hot spot , through WHO export control .

iv] There might be nevertheless potentially some other factors that, unlike scientific bodies, might contributed to such a drastic European governments decision making in banning the export of vaccines unless AstraZeneca honored its commitment to Europe. The true reason for such a drastic decision making while remains unclear but one might speculate that European decision makers are probably worried about public confidence in the vaccine as during this period France for instance has struggling in implementing the intended vaccination programme and there is a long history of public suspicion of drug companies; Germany meanwhile, was the first country to refuse to allow people over the age of 65 to have the AstraZeneca vaccine in the absence of the appropriate experimental evidence of how well it worked in older people; there was also an evidence based suspicion that the supply in the UK, was plentiful stocks as compared to Europe and in addition AstraZeneca was cutting its proposed deliveries to EU, down to 30m doses in the first quarter, which is about a third of what was originally promised, without any signed contractual liability issues. Therefore, without any reflection on the outcome opted for just some political gesturing, as suspending this vaccine was much easier in Europe if such vaccine would not be available in great quantities anyway in view of the proposed cut by the manufacturer.

v] While in view of shortage vaccine and the fear of having export ban some European countries covering their needs from Russian and China manufacturing sources and the unique solidarity in Europe acting as one entity is falling apart and making unexpectedly pandemic to becoming endemic, in contrast no harm is going to happen to the UK on going road map in mass vaccination as Moderna and Johnson Johnson in addition to Novavax that appears to be effective on Kent major variant, with more that 86% efficacy going through emergency rollout at the end of April. This new vaccine will be produced in Durham and the UK has already in place an order of 60 million doses covering the planned road map.

In short, clearly in today world of interconnectedness in both peoples and vaccines the national priority does not work [Europe considering the slogan of me first as a rebel without cause, as they have plenty of supply in store unable to use; so does India but with a noble cause as experiencing the rapid arrival of the more fearful second wave; president Biden pushing through his own promises to US citizen chasing all the avenue for the new supply including one shot vaccines and those that are more targeted to all variants that are emerging; the UK chasing more vaccines for the planned booster shot in September as vaccine protection is short lived possibly 4-6 months; the WHO are chasing all government to donate vaccines to countries with poorer economical infrastructures as 550 million doses are planned so far, etc]. Clearly we all need to be cautious rather than aggressive in our decision making as third wave of some newly emerging variants are here in Europe and we will be soon requiring newer booster vaccines or alternatives.

Nevertheless it is pleasing to note that today a joint statement is made by the European president and the UK government that that they are working together as team and going along with the concept of “win win approach” on the supply of vaccines in terms of “Reciprocity and Proportionality” and the future remains bright and spotlighting no harms might occur on the vaccine deployment in the UK as the fast runner and the European community as the slow starter that is still lingering while the third wave with fast spreading Kent variant is already establishing in Europe unfortunately. In pandemic virus does not recognize any borders so should be the vaccine supply as it was the aim of the OAZ vaccine so called the vaccine of the word that is supplied almost cost free without considering boarder and nationalism and the future still looks bright and remains in spotlight. Finaly recognising the global emergence of others CoV-2 variants, requiring a higher levels antibodies produced by vaccines efforts are directed to targeted vaccine with a higher antigen load and better efficacy and many manufacturers are working on the development the next generation of specific vaccines against the newer variants and evaluating the overall safety, reactogenicity, immunogenicity and thrombogenicity in view of the European concerns.

Meanwhile in parallel some more efficacious one dose vaccine are on the way, having a better efficacy against some variant and becoming available in large scale by the end of April.

Moreover the Russian Direct Investment Fund (RDIF) and a

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global pharmaceutical company headquartered in India have partnered to produce and supply a minimum of 200 million doses of the Russian Sputnik V vaccine against COVID-19, sufficient to vaccinate 100 million people. Sputnik V is now approved for use in over 50 countries. Sputnik V is a two-dose vaccine, which uses two different human adenoviral vectors in the course of vaccination. The vaccine demonstrates a 91.6% efficacy rate as confirmed by a peer-reviewed study published in The Lancet, which found the vaccine offers consistent and strong protective effect across all participant age groups. The supply commence from the third quarter of 2021 and will also continue to work with the RDIF to provide additional supply volumes beyond the initial agreement with Stelis Biopharma for a significant capacity of Sputnik V. The significant vaccine volumes will be produced jointly with Stelis will help to widen access to the vaccine on a global scale. These approved vaccines together with new comers in this field might partially overcome the current enormous hesitancy in vaccine, reaching about 40% in Europe, in view of their limited usage, a lesson to be learned from the UK involving all the community nationally how to go forward. No wonder, in contrast to the Europe has achieved the greatest success in mass vaccination as more than 50% of adults are received their first jabs.

Meanwhile the world is still from the shortage in supply of effective vaccine and while everyone is committed to assure their own supply first and with the elegance in attitude of working together as a team, helping the others in the sprit of oneness to survive Covid, it is rather disappointing that the current ban in export is placed by the European community president insisting AstraZeneka not to export any vaccine until secured supply to European community. Clearly we need to a better and fairer organised strategy, as team approach, for the geographically hot spot areas, where infection occurring and appropriately targeted vaccine combined with the alternative interventional approaches.

In short a pure science dictates interdisplinary exchanges and genuine sharing expertise and know how, for the purpose of connecting resources, technologies, in particular on healthcare systems. This unique virtue should remain in all medical fields including vaccine deployment to survive CoV-2 infection. The EU vaccine chaos with 17 countries in jap meltdown despite health care regulators backing OAZ jabs sending a clear message to take home to EU president either to use first what is your store already or ''loose it'' as there are plenty of theothers takers in need of this scarce commodity instead of disturbing the current progress that everyone witnessing by the UK strategies in mass vaccination with considerable success.

Helping in the better distribution of vaccine to those countries most in need , in the sprit of oneness has never being as crucial as right now, with the emergence of new strain of CoV-2 Indian variant so called Delta variant, originated in the Indian native communities, that are poorly vaccinated [< 2%] and now circulating all over the world, causing plenty of health care problems and economical chaos, at least in 92 countries so far, including the UK, where at least 65% of the adult population are vaccinated.

In fact, our current understanding of the infection dynamics of CoV-2 variants is still incomplete but based on what is happening in respect to the current UK- Alpha variant, that is currently circulating all over the world it appears that the link between the infectivity, transmissibility and hospitalisation is severely suppressed and even broken in some places with the current vaccines in use, combined with some other preventative strategies.

Nevertheless, with the added unexpected appearance of the newly imported doubly mutated Indian Delta variant, with the highest transmissibility so far, that attributed, in a very short time to more than 40 million CoV-2 cases in Indian communities that are lacking the appropriate levels of immunity to CoV-2, there is due concerns about the third wave of pandemic infection in all over the world, even in the UK, where almost about 65% adults are vaccinated by two types of vaccines (Pfizer and AstraZeneca).However despite this enormous vaccination achievement, it appears that this doubly mutated Indian Delta variant, is still going around spreading fast exponentially, with a doubling time every 9 days with about 30 death daily in the UK.

Conceptually it appears that this variant is saying to venerable unvaccinated youngsters collectively "You are turning me on and you can't cool me down with your current vaccine, because the immunity created by your time dependent

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slow acting vaccine against my spike proteins, even in a double dose, is not the same as full immunity against my multivariate' strains. If you can't beat me to survive in this race then pass it to others and clear out of my way and get ready for long COVID. Clearly the immunity based only on the tiny spike proteins, with plenty of the individuals' variability, is not the same than immunity against the diverse CoV-2 variants that continuously undergoing shape, size, and charge alterations upon mutation to escape all the physiological defence barriers. In addition the vaccine induced generation of neutralising antibody in majority of the fully vaccinated good responders individual against the tiny spike part of CoV-2 strains is not 100% and there are plenty of non responders, even with the use of more efficacious mRNA Vaccines- a lesson to be learnt for going ahead promptly for production of the multivariants vaccines that recognises not only the spike proteins but others high affinity binding sites of CoV-2 viral mutated strains.

Meanwhileas the round up, this newly emerged Delta variant not only is edging to win the race against the speed of current vaccination for all ages, in favour of the new CoV-2 Delta variant that now is considered to be the fastest transmissible variant yet, and with its enhanced ability to prey on the vulnerable younger populations, in places with low vaccination rates and being somewhat more resistant to current vaccines in use, and is about 60% more transmissible than the UK- Alpha variant and accounting for 90% of new Covid cases, and might also become linked to a greater risk of hospitalisation, as the third wave of pandemic infection is just on the way upward and intriguingly causing thousands of deaths in predominately younger unvaccinated and in some single and even some double vaccinated individuals, though the risk appears to be 20 times lower in doubledose and 4 times less in single vaccinated individuals, respectively urging to bring down the second jab to optimally 4 weeks to optimise the protection as earlier as possible. Moreover while vaccination appears to be lowering transmission, and in the race against further spread the vaccination of persons over 18 should be intensified, to provide a better immunity. Accordingly providing the second dose without further delay and vaccinating the youngsters are crucial, though it must be remembered that no vaccine is 100% effective, and we need to reach somehow soon the targeted levels of the absolute maximum level national immunity. May be the UK vaccination authorities should seek information about combining the Astra-Zeneca vaccine with a second shot of the mRNA vaccines in case this should mount an even more efficient protection from the Delta variant, in addition to bringing forward the proposed booster alternative strategies, [7-8], even with the use of the plasmas derived from successfully vaccinated individual from the AB blood group that have a higher content of neutralising antibodies to the pool of convalescent CoV-2 plasma for the sake of comprehensiveness having neutralising antibodies against all circulating variants. Clearly it is timely to compare the influence of various vaccines on the Delta variant antibodies seroprevalance in certain specific groups of population in a like with like comparison manner as becoming the current practice in some Nordic countries.

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