

Covid-19 vaccine along with its challenges

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Description

The development of a replacement vaccine usually consists of a linear sequence of several steps and lasts a couple of years. The sudden outbreak of the COVID-19 pandemic urged for a quick response and led to an unprecedented effort to provide a vaccine against this virus during a really short time, within the context of very limited pre-existing clinical experience with any coronavirus vaccine and with multiple steps of development administered in parallel, with the deployment of varied technologies, variety of which haven't been utilized during a licensed vaccine before. There is a robust need for vaccines against Covid-19 as they potentially represent a strong tool to counteract the spread of the virus alongside non-pharmaceutical interventions that, although essential, aren't able to control it sustainably, and within the absence of an efficient therapeutic protocol against COVID-19. Supported disease and immune response knowledge acquired over the course of the pandemic, vaccines should induce high affinity virus-neutralizing antibodies specific for Covid-19 to optimally prevent infection and unfavorable events like severe disease and death. Namely, these neutralizing antibodies should be directed against a selected domain (the so-called receptor binding domain RBD) within the spike (S) protein, which interacts with target cell ACE2 receptors. The primary immune mechanism of avoiding infection is through blocking viral attachment to specialize in cells. Of note, S protein vaccination may induce un-wanted antibodies additionally to the neutralizing ones directed against the RBD. Therefore, it is vital to construct a vaccine displaying the RBD or maybe only the RIS (Receptor Interaction Site) conformation instead of the whole S protein as other antibodies might sustain the danger of disease enhancement as demonstrated within the past for a couple of inactivated coronavirus vaccines in animal models. The herd immunity threshold for Covid-19 has been calculated to range between 50 also as 67%, with the thought of no population immunity, within the absence of any interventions and considering all individuals are equally susceptible and infectious. Certainly, the durability of immune memory is significant in sustaining herd immunity. Seroprevalence studies administered worldwide suggest that less of 10% of the included population has been infected, highlighting that the overwhelming majority of individuals are still susceptible to the infection. The various kinds of vaccines under development include inactivated or weakened virus (virus vaccines), protein subunit or virus-like particles and replicating or non-replicating viral vector vaccines. However, the important novelty is

represented by macromolecule vaccines that are designed to insert genetic instructions, mainly for virus spike's pieces production, into the human cell; so far this sort of technology has not been utilized in approved vaccines. This method shows great potential because no culture or fermentation is required, allowing a fast production. As of 23 December 2020, after quite eleven months since the isolation

of the strain of the new coronavirus, there are 287 vaccine candidates, of which 224 are at the pre-clinical stage of development, sixty-three are being tested in clinical studies on humans and fifteen reached phase three of development and are being tested for efficacy on an outsized scale. Moreover, at this, the EU Medicines Agency is considering four COVID-19 vaccines through the "rolling review" procedure, a regulatory tool to hurry up the assessment of medicines or vaccines during a public health emergency and consisting of reviewing data as they become available, before the submission of the formal application for marketing authorization. Especially, two candidate mRNA-based vaccines include BNT162b2 and mRNA-1273, and two non-replicating viral vector vaccines include ChAdOx1 nCoV-19 and Ad26.COV2.S. Currently mRNA-1273 also as BNT162b2 and vaccines are approved in several countries. On 2 December 2020, the United Kingdom (UK) granted emergency authorization to the BNT162b2 vaccine, thus being the first Western country to supply an approval to a coronavirus vaccine, followed some days later by the Food and Drug Administration (FDA) within the US. Shortly after, on 21 December 2020, the BNT162b2 vaccine was authorized across the EU following EMA's recommendation for a conditional marketing authorization. As regards the mRNA-1273 vaccine, it received emergency use authorization by the FDA on 18 December 2020. Considering this candidate and thus the EU context, the assessment by the EMA of the marketing authorization application is on-going and at the beginning of January 2021 a gathering will happen to possibly conclude it.

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