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COVID-19 vaccines and the possibilities and the challenges into the future.

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Editor Note

The development of a replacement vaccine usually consists of a linear sequence of several steps and lasts a few years. The sudden outbreak of the SARS-CoV-2/COVID-19 pandemic urged for a fast response and led to an unprecedented effort to supply a vaccine against this virus during a very 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 various technologies, a number of which haven't been utilized in a licensed vaccine before. There's a robust need for vaccines against SARS-CoV-2 as they potentially represent a robust tool to counteract the spread of the virus together with non-pharmaceutical interventions that, although essential, aren't ready to control it sustainably, and within the absence of an efficient therapeutic protocol against COVID-19. Supported disease and immune reaction knowledge acquired over the course of the pandemic, vaccines should induce high affinity virus-neutralizing antibodies specific for SARS-CoV-2 to optimally prevent infection and unfavorable events like severe disease and death. Namely, these neutralizing antibodies should be directed against a specific domain (the so-called receptor binding domain—RBD) within the spike (S) protein, which interacts with target cell ACE2 receptors. The first immune mechanism of avoiding infection is through blocking viral attachment to focus on cells. Of note, S protein vaccination may induce un-wanted antibodies additionally to the neutralizing ones directed against the RBD. Therefore, it's important to construct a vaccine displaying the RBD—or even only the RIS (Receptor Interaction Site) conformation rather than the entire S protein—as other antibodies might sustain the danger of disease enhancement as demonstrated within the past for a few inactivated coronavirus vaccines in animal models. The herd immunity threshold for SARS-CoV-2 has been calculated to range between 50% and 67%, with the idea of no population immunity, within the absence of any interventions and considering all individuals are equally susceptible and infectious. Certainly, the sturdiness of immune memory is vital 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 people are still vulnerable to the infection. The different sorts of vaccines under development include inactivated or weakened virus (virus vaccines), protein subunit or virus-like particles (protein-based vaccines) and replicating or non-replicating viral vector vaccines. However, the important novelty is represented by macromolecule vaccines (DNA- or RNA-based) that are designed to insert genetic instructions, mainly for virus spike's pieces production, into the human cell; thus far this type of technology has not been utilized in approved vaccines. This method shows great potential because no culture or fermentation is required, allowing a quick production. As of 23 December 2020, after quite eleven months since the isolation of the strain of the new coronavirus, there are 287 vaccines 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 the present , the ecu Medicines Agency (EMA) 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 authorisation. 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, BNT162b2 and mRNA-1273 vaccines are approved in several countries. On 2 December 2020, the UK granted emergency authorization to the BNT162b2 vaccine, thus being the primary Western country to offer 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 authorised 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 therefore the European context, the assessment by the EMA of the marketing authorization application is on going and at the start of January 2021 a gathering will happen to possibly conclude it.

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