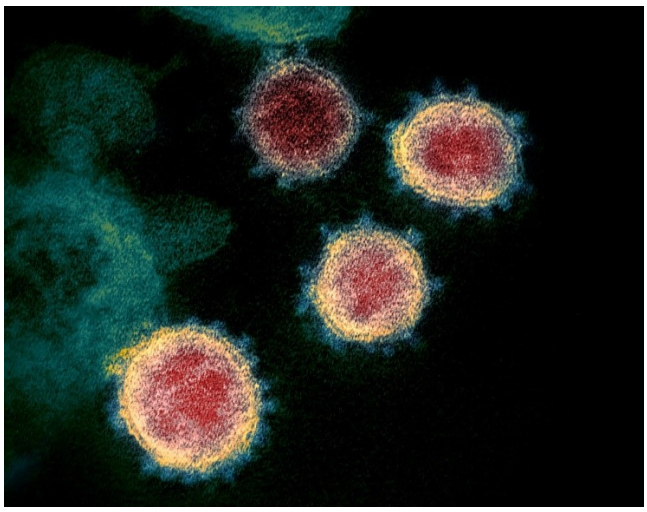
COVID-19 vaccine post-licensure effectiveness study

CASE STUDY



GIZ and P95 training

Background

For the first time, a cluster of pneumonia cases of unknown etiology was reported in Wuhan in China on 31 December 2019. On 9 January 2020, the China Center for Disease Control and Prevention reported the causative agent as being a novel coronavirus, called later severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Subsequent to China, COVID-19 underwent further geographical spread and on 11 March 2020, World Health Organization (WHO) declared COVID-19 a pandemic. Since then the COVID-19 are registered all around the world.

Most of the symptomatic cases have been reported in adult population. Older age and people with comorbidities were found to be at risk of severe disease and death due to COVID-19 infections. Thus, older adults with comorbidities and long term case facilities residents have been identified as priority groups for vaccination against SARS-CoV-2 infection. It is critical to evaluate post-introduction effectiveness of vaccines against SARS-CoV-2 among these groups.

You were asked to design observational study to:

1. Estimate post-introduction effectiveness of SARS-CoV-2 vaccines in preventing laboratory-confirmed COVID-19 hospitalizations among adults ≥ 65 years of age vaccinated with at least 1 dose.
2. Estimate post-introduction effectiveness of SARS-CoV-2 vaccines in preventing laboratory-confirmed COVID-19 hospitalizations among residents of long-term care facilities ≥ 65 years of age vaccinated with at least 1 dose.

Please discuss with you group and try to prepare a draft of study protocol to address the above mentioned objectives.

Study design *(Please propose most appropriate and effective study design that can be used in your country)*

Data sources *(What data sources are available in your country and can be used ? Indicate strengths and weaknesses of each of data sources)*

Study duration *(Please provide planned study duration)*

Study participants *(Please provide case definitions, inclusion and exclusion criteria)*

Confounders *(Please indicate the possible confounders)*

Data collection *(Please indicate how you are planning to collect the data)*

Statistical analysis *(What methods will you use? How will you calculate vaccine effectiveness?)*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