

Post-Introduction COVID-19 Vaccine Effectiveness Studies Among Healthcare Workers in the European Region



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Outline

- Background and Justification
- Explanation of Studies in the WHO/Europe region
 - **Health Worker (HW) Vaccine Effectiveness study**
 - Severe Acute Respiratory Infection Vaccine Effectiveness study
- Considerations for Conducting Studies
- Current HW studies underway in non-EU European countries
- Challenges
- Resources

Why do post-introduction COVID-19 vaccine effectiveness (VE) studies?

- Evaluating the real-world vaccine performance is critical for understanding the risks and benefits of Covid-19 vaccination programs
- Many factors impact real-world vaccine effectiveness
 - Vaccine transportation and storage
 - How patients are vaccinated
 - Differences in the people who get the vaccine
 - Clinical trial participants are often are young, healthy adults
 - In the real-world people are older and have underlying medical conditions
 - Vaccination of previously infected persons

Why do post-introduction COVID-19 vaccine effectiveness (VE) studies?

- Additional questions that VE studies can answer
 - Differences in VE by age group and chronic disease profile
 - Duration of protection
 - Protection against severe disease
 - Relative effectiveness of different vaccines
 - Relative effectiveness of one dose vs. two doses vs. three doses
 - Ability to evaluate VE against variants of concern

WHO/Europe has developed guidance documents for two kinds of COVID-19 VE studies

1. COVID-19 Vaccine Effectiveness in preventing infections in **healthcare workers**
 - cohort study
2. COVID-19 Vaccine Effectiveness in preventing Severe Acute Respiratory Illness (**SARI**)
 - case-control study using test-negative design (TND)

COVID-19 VE in preventing infections in health workers (I)

- HWs likely to be the first population vaccinated → opportunity to study VE during initial implementation
- Prospective Cohort study
- Healthcare workers in hospitals
 - Enrolled before the healthcare workers get vaccinated (ideally)
 - All HWs in a site can be enrolled in study
 - Regardless of intention to get vaccinated

COVID-19 Vaccine Effectiveness (VE) in preventing infections in health workers (II)

- Active surveillance
 - Swabs and follow-up for symptomatic patients
 - Swabs tested by PCR for SARS-CoV-2 in-country
 - Weekly respiratory swabs and symptom questionnaire for all participants
 - But \$\$\$\$
- Serology – baseline, and again periodically during study
 - Tested by commercial test kits for anti-Spike IgG and anti-nucleocapsid IgG
 - Understand baseline rates of infection, understand new infections
 - Limited in studies where inactivated vaccines like coronavac used

COVID-19 Vaccine Effectiveness (VE) in preventing infections in health workers (II)

- Study period at least one year
- Estimate VE against
 - Overall infection
 - Symptomatic infection
 - Asymptomatic infection
 - Difficult to estimate VE against severe illness because relatively small cohorts
 - More potential with pooling?

Considerations for Conducting Studies

- Commitment to study from hospital administration, national laboratory or approved laboratory that can conduct PCR testing
- Adequate laboratory capacity to test weekly samples by PCR
- Reliable documentation of COVID-19 vaccine
- Available staff to oversee study
- In-country ethical review committee approval
- Familiarity with WHO ethical review process (If WHO is involved, providing funding)

Considerations for Conducting Studies

- For health worker study
 - Previous experience conducting studies in HWs
 - Large number of healthcare workers in one or multiple hospitals
 - Resource-intensive (staff, budget, laboratory testing, coordination)

Current studies underway in non-EU European countries

- Israel and UK – multiple studies
- Health worker Covid Vaccine Effectiveness Studies
 - Albania (Pfizer) (started late February 2021)
 - 3 hospitals
 - Georgia (AZ, Pfizer, Coronovac) – started March 2021
 - 6 hospitals
 - Azerbaijan (Coronovac) – started April 2021
 - 7 hospitals
- Approximately 1500 HWs in each study
- All are collaborative studies between WHO and in-country public health agency
 - US CDC also supporting Albania study

Challenges (1)

- Complicated study
 - Extensive coordination
 - Weekly symptom questionnaire administration requires adequate study staff
 - Electronic data collection is easier (if possible)
- Understand staffing needs
 - Ensure adequate budget
- Database management
 - REDCap has been useful
- Ethical Review Process
 - Can be time-consuming; important to understand details of process
- HWs want timely serology results
 - Can be challenging

Challenges (2)

- Data completeness and timeliness
 - Epiconcept runs periodic checks
 - Validation of laboratory and vaccination data through national databases
- Timely analysis
 - Changing variants
 - Changing doses of vaccine
- Genomic sequencing of PCR-positive samples

Resources (1)



The screenshot displays the WHO Europe website interface. At the top left is the WHO logo and the text "World Health Organization REGIONAL OFFICE FOR Europe". On the top right, there are language options: "English", "Français", "Deutsch", and "Русский". Below the language options is a search bar with a "Search" button. A navigation menu is located below the search bar, with "Health topics" selected. The breadcrumb trail reads: "Health topics > Health emergencies > Coronavirus disease (COVID-19) outbreak > Publications and technical guidance > Cohort study to measure COVID-19 vaccine effectiveness among health workers in the WHO European Region: guidance document (2021)".

Coronavirus disease (COVID-19) outbreak

- [News](#)
- [Latest updates](#)
- [About the virus](#)
- [Publications and technical guidance](#)**
- [Country information](#)
- [Weekly surveillance report](#)
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Cohort study to measure COVID-19 vaccine effectiveness among health workers in the WHO European Region: guidance document (2021)

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Download

English (PDF, 1.069 MB)

This guidance document outlines the methods of a prospective one-year cohort study of hospital-based healthcare workers (HWs) to evaluate the effectiveness of COVID-19 vaccine in preventing laboratory-confirmed SARS-CoV-2 infection.

This document is intended to be used as a guidance document to support countries and institutions that are interested in conducting research on COVID-19 vaccine effectiveness in health workers. It outlines an approach to post-introduction COVID-19 vaccine effectiveness evaluation in HWs that complements existing WHO Unity Studies, which focus on sero-epidemiological investigations. Research should be conducted only after site-specific protocols are developed and approved by the relevant local ethical review committee(s).

<https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/publications-and-technical-guidance/2021/cohort-study-to-measure-covid-19-vaccine-effectiveness-among-health-workers-in-the-who-european-region-guidance-document-2021>

Resources (2)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Prevention and Attenuation of Covid-19 with the BNT162b2 and mRNA-1273 Vaccines

M.G. Thompson, J.L. Burgess, A.L. Naleway, H. Tyner, S.K. Yoon, J. Meece, L.E.W. Olsho, A.J. Caban-Martinez, A.L. Fowlkes, K. Lutrick, H.C. Groom, K. Dunnigan, M.J. Odean, K. Hegmann, E. Stefanski, L.J. Edwards, N. Schaefer-Solle, L. Grant, K. Ellingson, J.L. Kuntz, T. Zunie, M.S. Thiese, L. Ivacic, M.G. Wesley, J. Mayo Lamberte, X. Sun, M.E. Smith, A.L. Phillips, K.D. Groover, Y.M. Yoo, J. Gerald, R.T. Brown, M.K. Herring, G. Joseph, S. Beitel, T.C. Morrill, J. Mak, P. Rivers, B.P. Poe, B. Lynch, Y. Zhou, J. Zhang, A. Kelleher, Y. Li, M. Dickerson, E. Hanson, K. Guenther, S. Tong, A. Bateman, E. Reisdorf, J. Barnes, E. Azziz-Baumgartner, D.R. Hunt, M.L. Arvey, P. Kutty, A.M. Fry, and M. Gaglani

COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study



Victoria Jane Hall, Sarah Foulkes, Ayoub Saei, Nick Andrews, Blanche Oguti, Andre Charlett, Edgar Wellington, Julia Stowe, Natalie Gillson, Ana Atti, Jasmin Islam, Ioannis Karagiannis, Katie Munro, Jameel Khawam, Meera A Chand, Colin S Brown, Mary Ramsay, Jamie Lopez-Bernal, Susan Hopkins, and the SIREN Study Group*

Summary

Background BNT162b2 mRNA and ChAdOx1 nCoV-19 adenoviral vector vaccines have been rapidly rolled out in the UK from December, 2020. We aimed to determine the factors associated with vaccine coverage for both vaccines

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Published Online

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Covid-19 Breakthrough Infections in Vaccinated Health Care Workers

Moriah Bergwerk, M.B., B.S., Tal Gonen, B.A., Yaniv Lustig, Ph.D., Sharon Amit, M.D., Marc Lipsitch, Ph.D., Carmit Cohen, Ph.D., Michal Mandelboim, Ph.D., Einav Gal Levin, M.D., Carmit Rubin, N.D., Victoria Indenbaum, Ph.D., Ilana Tal, R.N., Ph.D., Malka Zavitan, R.N., M.A., Neta Zuckerman, Ph.D., Adina Bar-Chaim, Ph.D., Yitshak Kreiss, M.D., and Gili Regev-Yochay, M.D.



Vaccine
Available online 10 December 2021
In Press, Corrected Proof



Early effectiveness of BNT162b2 Covid-19 vaccine in preventing SARS-CoV-2 infection in healthcare personnel in six Israeli hospitals (CoVEHPI)

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Thank you

