

COVID-19 Vaccine AstraZeneca Real-World Evidence Summary

Summary of real-world evidence for COVID-19 Vaccine AstraZeneca

Data from clinical trials in up to 60,000 participants show COVID-19 Vaccine AstraZeneca is generally well tolerated¹ and highly effective² against COVID-19 across all disease severities, with consistent efficacy across demographics, ethnicities and all adult age groups, including individuals aged 65 and older.³ New real-world evidence, in tens of millions of vaccinated people globally, is also demonstrating the effectiveness of the vaccine against COVID-19 death, hospitalisation and transmission.

1. COVID-19 Vaccine AstraZeneca markedly reduces the likelihood of hospitalisation or death caused by the disease

- Between December 2020 and 20 August 2021, a PHE study estimated at least 105,900 deaths were prevented as a result of the COVID-19 vaccination programme in England. This includes over 9,900 deaths prevented in individuals aged 80 years and older, 1,500 in those aged 70 to 79 years and 300 in those aged 60 to 69 years.⁴
 - People aged 80 years and over who received a first dose of the AstraZeneca vaccine were 73% less likely to be hospitalised. The study included both the AstraZeneca and Pfizer-BioNTech vaccines.⁵
 - It is estimated that at least 35,000 hospitalisations were prevented in those aged 65 and older in England as a result of the COVID-19 vaccination programme.⁶ The study included both the AstraZeneca and mRNA vaccines.⁶
- Italian Institute of Public Health data from 13.7 million people vaccinated with either AstraZeneca, Pfizer-BioNTech or Moderna vaccines between December 2020 and 3 May 2021 reported a **95% reduction in mortality risk** and **90% reduction in risk of hospitalisation** across genders and age groups at 35 days after vaccination with either AstraZeneca, Pfizer-BioNTech or Moderna vaccines.⁷
- In the UK, real-world data has demonstrated:
 - A first dose of COVID-19 Vaccine AstraZeneca **reduced the likelihood of hospitalisation by 94%**. The majority of vaccine recipients were aged over 65 years and the effects were comparable across all age groups.⁸
 - A first dose of COVID-19 Vaccine AstraZeneca was **80% effective at preventing mortality in people over 70 years old** compared to unvaccinated individuals⁹
 - A first dose of COVID-19 Vaccine AstraZeneca was **80% effective at preventing hospitalisation in elderly and frail adults aged 80 years** with extensive comorbid disease.¹⁰
 - Two doses demonstrated COVID-19 Vaccine AstraZeneca was **92% and 86% effective against hospitalisation due to the Delta and Alpha variants, respectively**, and showed that there were no deaths among those vaccinated.¹¹
- Results from Canadian Immunization Research Network (CIRN) with support from Public Health Agency of Canada (PHAC) and the Canadian Institutes of Health Research (CIHR) demonstrated that a first dose of COVID-19 Vaccine AstraZeneca was **82% effective against death or hospitalisations caused by the Beta or Gamma variants** of the SARS-CoV-2 virus, and 87% and 90% effective against the Delta and Alpha variants, respectively.¹²

2. COVID-19 Vaccine AstraZeneca reduces the likelihood of symptomatic COVID-19

- In studies conducted by PHE, COVID-19 Vaccine AstraZeneca was 73% effective against symptomatic COVID-19 from day 35 onwards in adults aged 70 years and older after a first dose and **89% effective against symptomatic COVID-19 after two doses**.¹³
- Results from CIRN with support from PHAC and CIHR demonstrated, after a first dose of COVID-19 Vaccine AstraZeneca, **vaccine effectiveness against symptomatic disease was 50% against the Beta or Gamma variants, and 70% and 72% against the Delta and Alpha variants, respectively**.¹²
- A first dose of either the AstraZeneca or Pfizer-BioNTech vaccine reduced the chance of a new COVID-19 infection by 65% compared to individuals who were unvaccinated, in a large, UK community surveillance study of people aged 16 years and older.¹⁴
- A first analysis of vaccine effectiveness in South Korea, in more than 700,000 people, showed a first dose of COVID-19 Vaccine AstraZeneca reduced the risk of COVID-19 infection by 90% after 14 days.¹⁵
- Italian Institute of Public Health data noted an 80% reduced risk of COVID-19 infection across genders and age groups at 35 days after vaccination with either AstraZeneca, Pfizer-BioNTech or Moderna vaccines.⁷

3. COVID-19 Vaccine AstraZeneca reduces the likelihood of household transmission of the virus

- Both the AstraZeneca and Pfizer-BioNTech vaccines reduced the likelihood of household transmission of COVID-19 by up to a half, in a PHE study of individuals who became infected three weeks after receiving their first dose.¹⁶ In analyses with COVID-19 Vaccine AstraZeneca, vaccinated individuals were between 38% and 47% less likely to pass the virus on to their household contacts compared to those who were unvaccinated.¹⁶

4. COVID-19 Vaccine AstraZeneca has been shown to have a favourable reactogenicity and is generally well tolerated

- Incidents of an extremely rare blood disorder, thrombosis with thrombocytopenia (TTS) have been reported in a small number of people who have received the vaccine (2.3 events per million after second dose compared with 8.1 events per million after the first dose).¹⁷⁻¹⁹ NICE and UN recommendations state that TTS in these patients are treatable.^{20,21} **The likelihood of developing very rare TTS events following the second dose are comparable to those seen in an unvaccinated population** and are several-fold lower than after the first dose.¹⁹
- According to data from three large, real-world studies with over seven million individuals who received at least one dose from the UK²² and Spain^{23,24}, COVID-19 Vaccine AstraZeneca and mRNA COVID-19 vaccines showed similar safety profiles. Rates of rare blood clotting events after the first dose of the vaccine were in line with what would be expected in the general population and lower than in those diagnosed with COVID-19.^{23,24} Rates of any venous thromboembolism associated with thrombocytopenia (VTE+TCP) were 45 times higher after a diagnosis of COVID-19 compared with the expected rate²⁴ [21-day incidence of VTE+TCP was 3.8 (95% CI 3.4-4.1) per million in the background (2019) reference population and 173.1 (95% CI 123.1-243.5) per million in those diagnosed with COVID-19].

Latest real-world data released

Two doses of the AstraZeneca vaccine is

92% effective

against severe disease or hospitalisation due to the Delta variant¹¹ and

86% effective

due to the Alpha variant¹¹

First dose of the AstraZeneca vaccine is

82% effective

against death or hospitalisation due to the Beta/Gamma variant¹²

Vaccine effectiveness against symptomatic disease is

70%

against the Delta variant and,

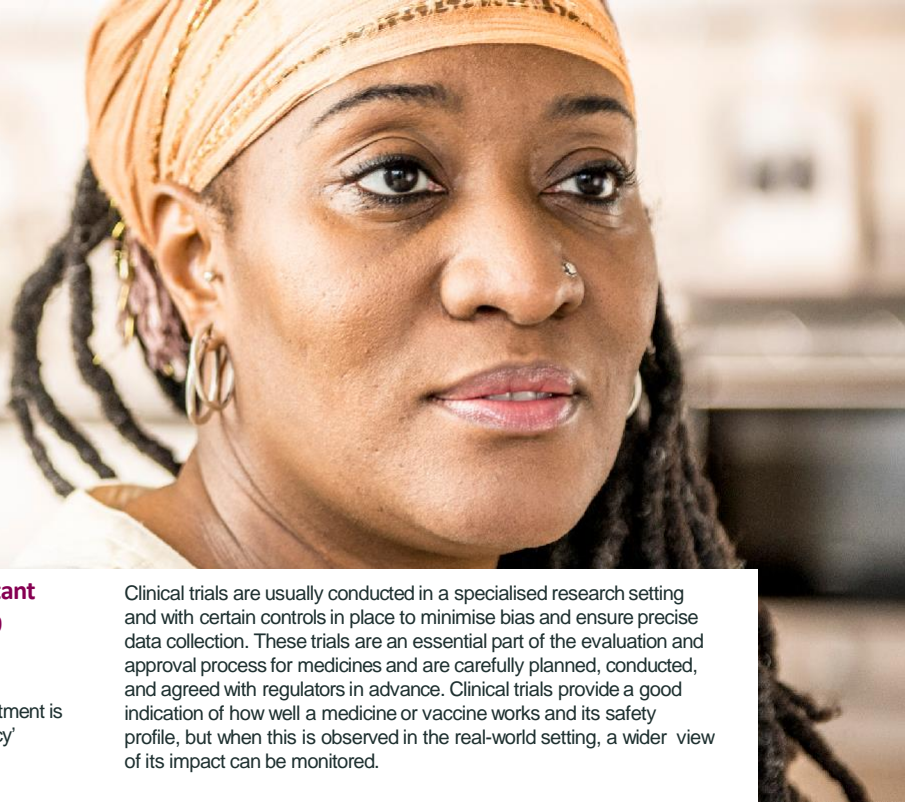
50%

against Beta/Gamma variants 21 days after first dose¹²

Incidents of TTS have been reported in a small number of people who have received the vaccine:

2.3 events per million

after the second dose and in line with expected rates in a general population¹⁹



What is real-world evidence and why is it important for learning about the effectiveness of COVID-19 vaccines?

Real-world evidence helps people better understand if a treatment is effective in day-to-day clinical practice, as opposed to 'efficacy' which is determined in controlled clinical trials.

By using this evidence, scientists, regulators and governments are able to monitor the important contribution a treatment is making to society. In the case of COVID-19, this evidence helps to demonstrate the real-world contribution vaccines are making to help manage the pandemic. It is vital in helping governments, health providers and communities understand how effective vaccines are at reducing the burden of, and protecting against, COVID-19. Specifically, understanding its effectiveness:

- Against different disease severities - from reducing deaths and hospital admissions to preventing milder forms of the disease
- To reduce rates of infection across the population
- To prevent transmission and spread of the virus
- In different populations, including age, race, ethnicity and those living with underlying health conditions, such as asthma, diabetes and HIV

How is real-world evidence different from clinical trial evidence?

A clinical trial is a carefully controlled research study that is designed to establish the effect of a medical treatment and how well it "works" (its 'efficacy'), by assigning people to different treatment groups.

Clinical trials are usually conducted in a specialised research setting and with certain controls in place to minimise bias and ensure precise data collection. These trials are an essential part of the evaluation and approval process for medicines and are carefully planned, conducted, and agreed with regulators in advance. Clinical trials provide a good indication of how well a medicine or vaccine works and its safety profile, but when this is observed in the real-world setting, a wider view of its impact can be monitored.

In combination with clinical trial data, real-world evidence helps to inform the "bigger picture" – how effective a medicine is in a larger, more varied patient population, in various healthcare settings, over an extended period of time.

Why can't you compare real-world evidence for different vaccines?

Comparing vaccines data is complex and must take many factors into account, including effectiveness, supply, storage and distribution logistics. So, while real-world evidence is helpful, not all real-world evidence is the same and it is difficult to compare.

It is captured at different times, in different populations, in different places that may have different levels of COVID-19 infection and with different variants of the virus in circulation.

To overcome the disease, many different vaccines are needed to support long-term immunity and for protection against new variants as they arise. Real-world evidence can help to improve our knowledge and understanding, and support strategies that increase vaccine uptake to protect lives and reduce hospitalisations.

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