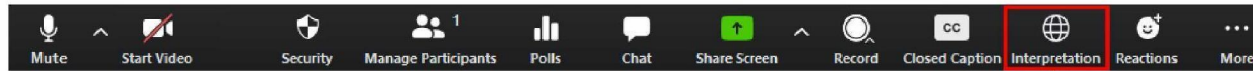




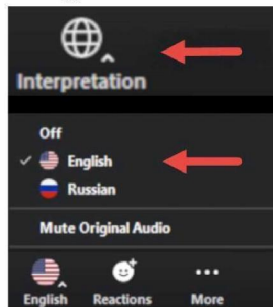
Second Joint ECDC/WHO Europe network teleconference on COVID-19 vaccine uptake and effectiveness monitoring

8 March 2021

Choose language - Выберите язык

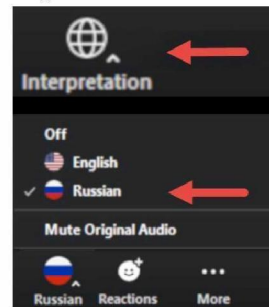


English



Click **Mute Original Audio** to hear only English.

Русский



Щелкните на **Mute Original Audio**, чтобы слышать только русскую речь.

Second Joint ECDC/WHO Europe Webinar for COVID-19 vaccine uptake and effectiveness monitoring



- Several COVID-19 vaccines now licensed for use in Europe – Astra Zeneca AZD1222, Pfizer-BioNTech, Gamaleya Sputnik V, Sinovac Coronavac, Moderna mRNA-1273
- MS prioritizing limited vaccine to reduce morbidity and mortality and protect health services:
 - Health care workers;
 - Older adults;
 - Clinical at-risk groups
- Many MS establishing uptake monitoring systems to identify (and rectify) potential gaps
- Uncertainties regarding COVID-19 real-world vaccine effectiveness (vs clinical trials):
 - By type/brand of vaccine
 - Delay for second dose to maximise available vaccine
 - By target-group e.g. elderly, at-risk-groups
 - Severity (asymptomatic infection to death)
 - Transmission/indirect effects
 - Variant strains (B1.117 (ex-UK), B1.351 (ex-South-Africa), P1 (ex-Brazil))(and thus potential need for revaccination)
 - Population impact
- **ECDC and WHO Europe established Region-wide network to support countries in monitoring COVID-19 vaccine uptake and effectiveness using standard approaches**

Agenda: Monitoring COVID-19 vaccine uptake and effectiveness in Europe



| | | | |
|----|---|---|--------|
| 1 | Opening remarks and welcome | 5.1.2e, WHO/Europe 5.1.2e, ECDC | 5 min |
| 2. | Joint WHO/ECDC overview of uptake of COVID-19 vaccine in WHO/European Region | 5.1.2e WHO/Europe | 10 min |
| | | 5.1.2e, ECDC | 10 min |
| 3. | Introduction of WHO monthly data collection on COVID-19 vaccine deployment through eJRF COVID Module | 5.1.2e WHO/Europe | 10 min |
| 4. | Discussion | 5.1.2e, ECDC | 10 min |
| 5. | Latest update on vaccine effectiveness studies from Israel | 5.1.2e | 15 min |
| 6. | First results of vaccine effectiveness studies from United Kingdom and Northern Ireland | 5.1.2e Public Health England, UK | 15 min |
| | | 5.1.2e, Public Health Scotland, UK | 15 min |
| 7. | Experiences from setting up a prospective health care worker vaccine effectiveness study, Albania | 5.1.2e, Institute of Public Health, Albania | 10 min |
| 8. | Plans, collating and pooling of early results of vaccine effectiveness studies from I-MOVE COVID-19 network and across Europe | 5.1.2e, EpiConcept | 15 min |
| 9. | Discussion | 5.1.2e, WHO Europe | 15 min |

Monitoring uptake and effectiveness of COVID-19 vaccine in the WHO European Region



Joint WHO/ECDC overview of uptake of COVID-19 vaccine in WHO/European Region

5.1.2e

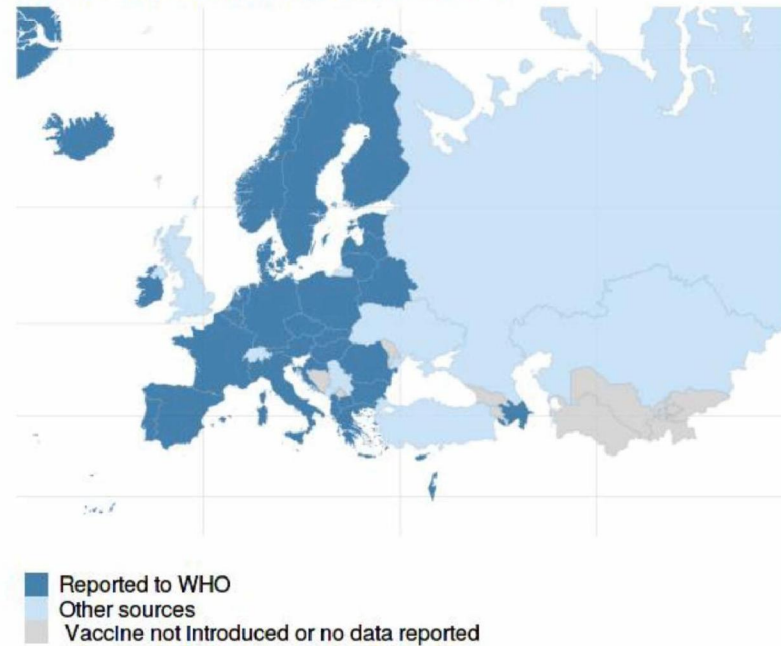
Vaccine-preventable Diseases and Immunization programme



Status of Member State reporting to TESSy as of March 3, 2021

- Weekly reporting frequency requested for non-EU/EEA countries
- 34 countries and territories reporting vaccine uptake data to TESSy
- 11 countries and territories with public reports of vaccine introduction have not yet officially reported vaccine uptake data into TESSy
- 9 countries and territories with no unofficial or official data about vaccine introduction

Availability of officially reported data



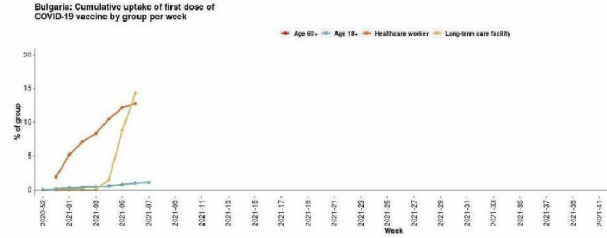
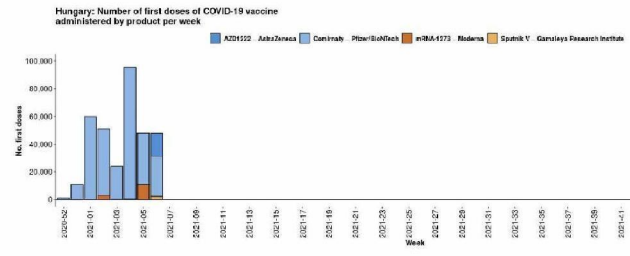
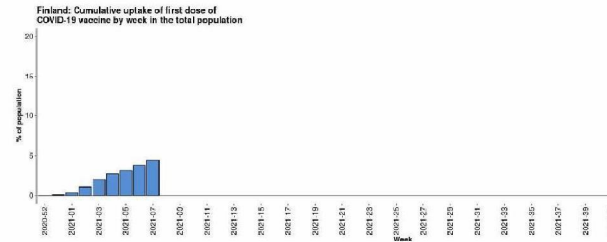
Data officially reported to WHO are current as of epidemiological week 09, 2021 as reported by Mar 03, 2021

COVID-19 vaccine uptake information products



Joint ECDC-WHO COVID-19 bulletin (coming soon)

- Visualize data on COVID-19 for all Member States, including country-specific details on:
 - Epidemiology
 - Confirmed cases and deaths
 - Syndromic surveillance for ILI
 - Testing rates
 - Hospitalizations
 - Vaccinations
- Planned enhancements to include qualitative visualization of the impact of vaccine coverage on other COVID-19 indicators



COVID-19 vaccine uptake information products



WHO/EURO COVID-19 vaccine programme monitor

- Provide regional overview of the status of vaccine introduction and uptake among all Member States
 - Cumulative vaccine doses administered and population percent uptake with first dose and complete dose series
 - Vaccine products introduced
 - Vaccine uptake by age groups and special target populations
- Blended approach to integrate available data sources to ensure completeness
 - Weekly uptake data reported through TESSy
 - Publicly reported government statements on vaccine uptake (via [OurWorldInData.org](https://www.ourworldindata.org))
 - Monthly uptake data reported through upcoming WHO eJRF COVID module

Live demonstration of WHO COVID-19 Vaccine Programme Monitor website



World Health Organization
REGIONAL OFFICE FOR Europe

45 / 54

Data from any source

34 / 54

Official WHO data

79,102,893

Total doses administered

60,412,337 (6.5%)

Total first dose uptake

18,616,281 (2.0%)

Total complete series uptake

Data availability

Availability of officially reported data

Data officially reported to WHO are current as of epidemiological week 09, 2021 as reported by Mar 09, 2021

Vaccination data officially reported to WHO

| COUNTRY | LATEST REPORT DATE | TOTAL DOSES | FIRST DOSE | SECOND DOSE | UNKNOWN DOSE | UPTAKE WITH AT LEAST ONE DOSE (%) | UPTAKE WITH COMPLETE VACCINE SERIES (%) |
|----------------|--------------------|-------------|------------|-------------|--------------|-----------------------------------|---|
| Albania | Jan 26, 2021 | 671 | 671 | 0 | 0 | 0 | 0.0 |
| Austria | Feb 23, 2021 | 653,382 | 424,602 | 228,780 | 0 | 4.8 | 2.6 |
| Azerbaijan | Feb 16, 2021 | 101,204 | 79,645 | 21,559 | 0 | 0.8 | 0.2 |
| Belarus | Feb 16, 2021 | 37,011 | 24,704 | 12,307 | 0 | 0.3 | 0.1 |
| Belgium | Feb 23, 2021 | 757,013 | 460,939 | 296,074 | 0 | 4 | 2.6 |
| Bulgaria | Feb 23, 2021 | 212,444 | 175,062 | 37,382 | 0 | 2.5 | 0.5 |
| Croatia | Mar 02, 2021 | 210,657 | 158,297 | 51,520 | 840 | 3.9 | 1.3 |
| Cyprus | Feb 23, 2021 | 77,794 | 54,014 | 22,880 | 0 | 6.2 | 2.6 |
| Czech Republic | Feb 23, 2021 | 624,244 | 391,409 | 232,635 | 0 | 3.7 | 2.2 |
| Denmark | Feb 23, 2021 | 592,452 | 408,949 | 183,503 | 0 | 7 | 3.2 |
| Estonia | Feb 23, 2021 | 103,498 | 41,194 | 31,152 | 31,152 | 5.4 | 2.3 |
| Finland | Feb 23, 2021 | 426,525 | 346,859 | 79,666 | 0 | 6.3 | 1.4 |
| France | Feb 23, 2021 | 4,111,791 | 2,712,800 | 1,396,984 | 7 | 4 | 2.1 |
| Germany | Feb 23, 2021 | 5,730,049 | 3,759,906 | 1,971,043 | 0 | 4.5 | 2.4 |
| Greece | Feb 23, 2021 | 825,798 | 539,607 | 286,191 | 0 | 5 | 2.7 |
| Hungary | Feb 16, 2021 | 658,114 | 453,896 | 204,217 | 1 | 4.6 | 2.1 |

https://aemr.healthtopics.shinyapps.io/EURO_COVID-19_vaccine_monitor/ w/ 186e4955/#shiny-tab-overview

Challenges: data quality and completeness, and way forward



- **Example data quality and completeness issues that may impact accuracy of reported results:**

- Reporting doses among specific sub-groups or sub-national areas without reporting a national total
- Not reporting target group doses (e.g. age-stratified, healthcare worker doses)
- Missing denominator for specific target groups
- High proportion of “Unknown dose”
- High proportion of “Unknown vaccine”
- Reporting more total “second dose” than “first dose”

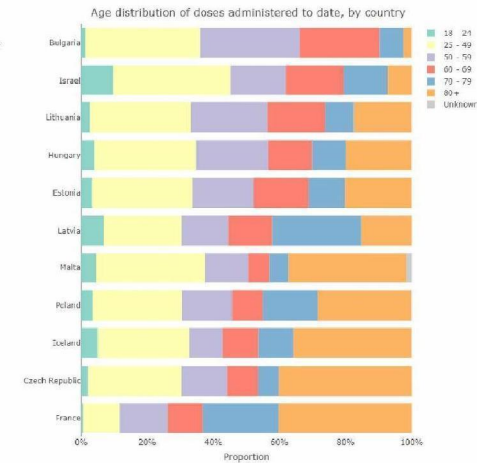
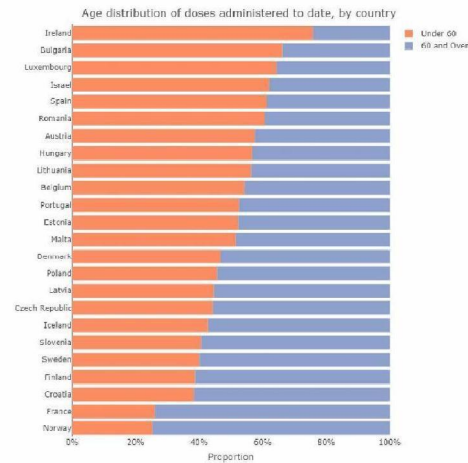
Vaccination data officially reported to WHO

| COUNTRY ↑ | LATEST REPORT DATE ↓ | TOTAL DOSES ↓ | FIRST DOSE ↓ | SECOND DOSE ↓ | UNKNOWN DOSE ↓ | UPTAKE WITH AT LEAST ONE DOSE (%) ↓ | UPTAKE WITH A COMPLETE VACCINE SERIES (%) ↓ |
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Challenges: data quality and completeness, and way forward

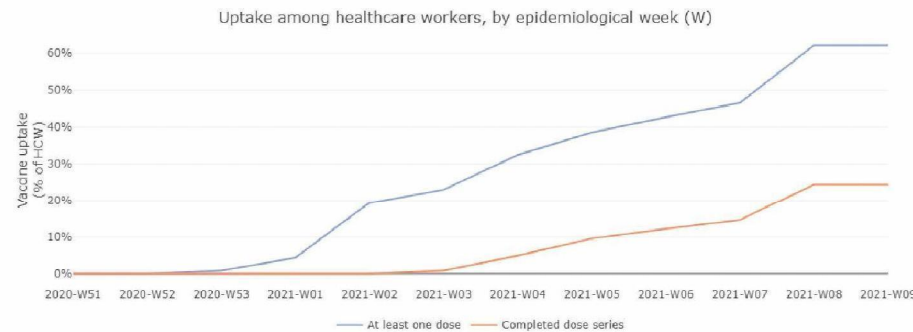
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Challenges: data quality and completeness, and way forward

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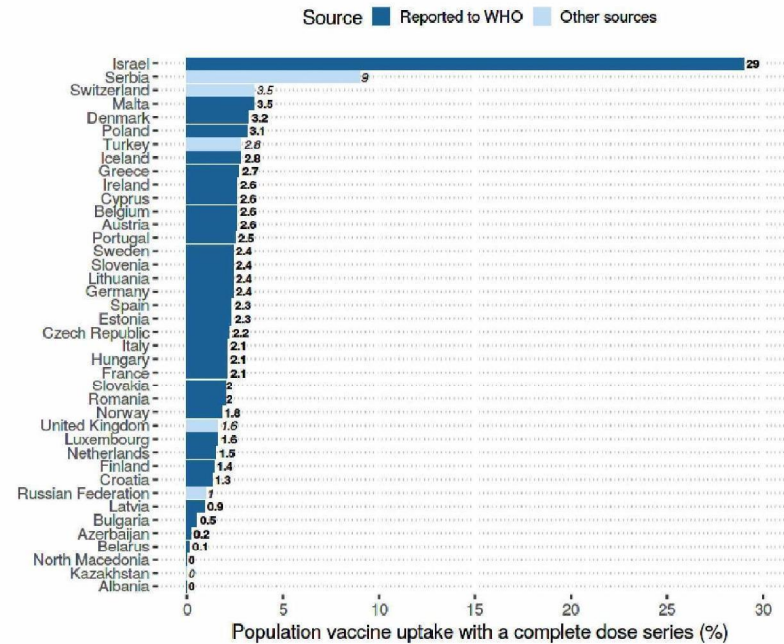


Challenges: data quality and completeness, and way forward



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Vaccines introduced
All countries and territories (N = 54)



Challenges: data quality and completeness, and way forward



- Among countries and territories already entering data through TESSy, data quality and completeness continue to improve
- ECDC and WHO will continue to provide regular feedback with questions about data quality and completeness to support Member States to correct or complete data before the next weekly update is published
- Reminder to ensure at least weekly reporting in TESSy to have latest data reflected in the weekly updates

For more information contact:

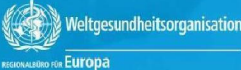
5.1.5

[https://worldhealthorg.shinyapps.io/
EURO COVID-19 vaccine monitor/](https://worldhealthorg.shinyapps.io/EURO_COVID-19_vaccine_monitor/)

WHO Regional Office for Europe

UN City
Marmorvej 51
Copenhagen Ø
Denmark

-  WHO_Europe
-  facebook.com/WHOEuro
-  instagram.com/whoeuro
-  youtube.com/user/whoeuro





Joint ECDC/WHO Europe monitoring of COVID-19 vaccine roll-out

European Centre for Disease Prevention and Control

5.1.2e

on behalf VPI/CAI Disease programmes

8 March 2021

Objectives of the ECDC/WHO joint vaccine roll-out monitoring



- The collection of data on number of distributed and administered doses aims:
 - To inform about the vaccination campaign in terms of distribution and administration of the vaccine to the target population
 - To inform about the capability of the countries to ensure timely distribution of the vaccines to the target groups
 - To identify possible shortcomings in the deployment of the vaccines and support needed accordingly

Data collection



- Proposal developed in collaboration between ECDC and WHO/Europe shared with EU/EEA Member States on Friday 8 January 2021.
- Reporting to TESSy on a **biweekly basis but countries are encouraged to report as often as possible**
 - Weekly number of doses distributed to the country by the manufacturer, total and by vaccine brand
 - Weekly number of first and second doses administered to individuals :
 - Total numbers
 - By vaccine brand
 - By target groups
 - Age groups (18-24, 25-49, 50-59, 60-69, 70-79, 80+)
 - Healthcare workers
 - Long-term care facilities
 - At national and subnational level (NUTS2/GAUL1) where available
 - The population denominators for each target group (except age groups obtained from Eurostat)
 - The number of persons who refuse the first dose vaccine
- First data call on 15 January 2021

The ECDC Vaccine Tracker

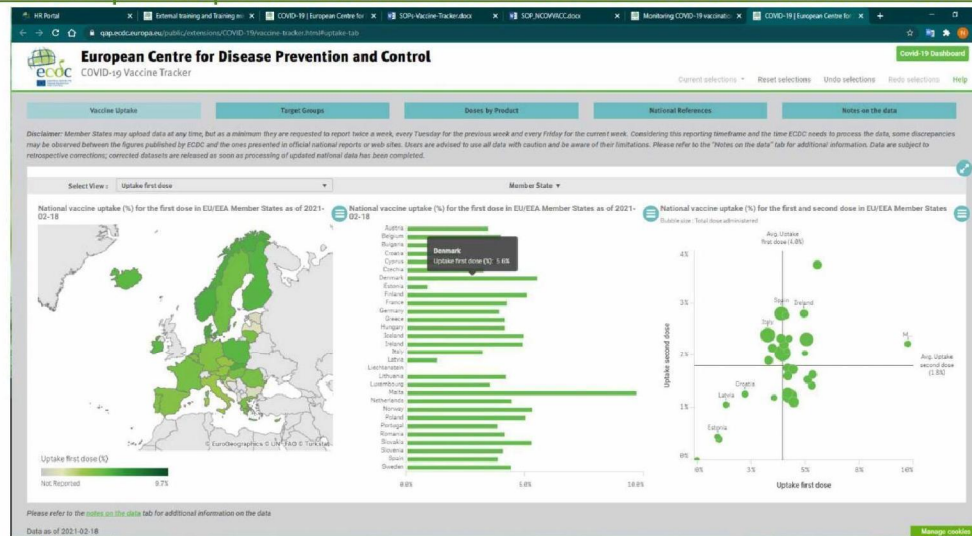


Interactive Vaccine Tracker

Live since 1 February, 2021; second version released on 17 February 2021; third version to be released next week

Data in the tracker are refreshed every day at 11.00

<https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab>



The ECDC Weekly vaccine roll-out overview report



The weekly report

Published online once a week every Thursday

Analysis of the data as of the previous week

<https://covid19-vaccine-report.ecdc.europa.eu/>

European Centre for Disease Prevention and Control
An agency of the European Union

Topics: A to Z News & events Publications & data Tools About us Q

11 topics: A to Z > Coronavirus > Threats and outbreaks > COVID-19 > Situation updates on COVID-19 > Vaccine roll-out overview

D-19 Vaccine roll-out overview

This report provides an overview of the progress in the roll-out of COVID-19 vaccines in adults (aged 18 years and above) across EU/EEA Member States. It presents the number of vaccine doses distributed by manufacturers to each Member State for the different approved vaccines and the number of first, second or unspecified doses administered to adult individuals overall, by age group and other selected target groups including healthcare workers (HCW) and residents in long-term care facilities (LTCF).

[See the report on full screen](#)

rollout summary

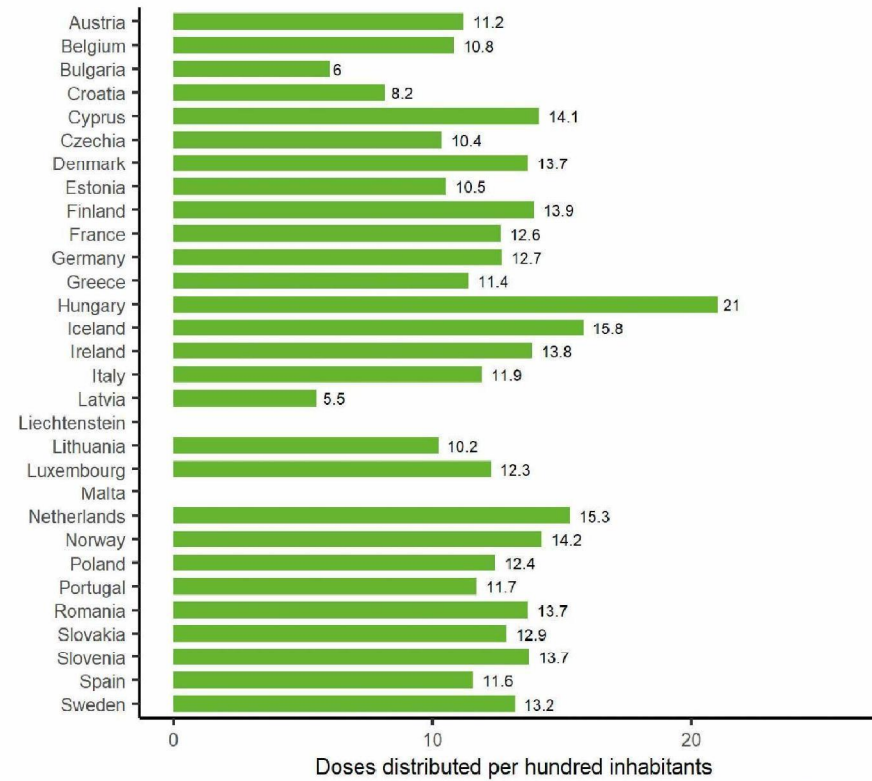
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COVID-19 Vaccine rollout overview

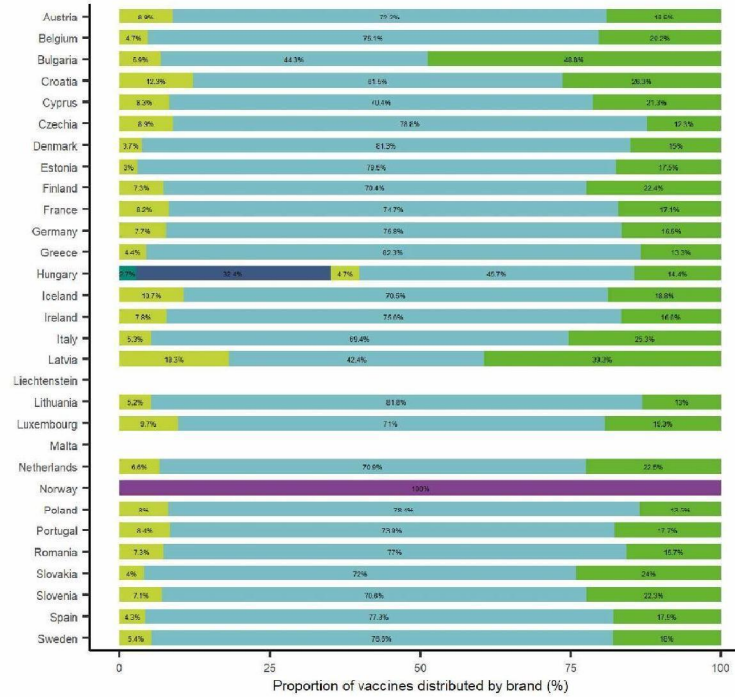
Week 8, 2021

21

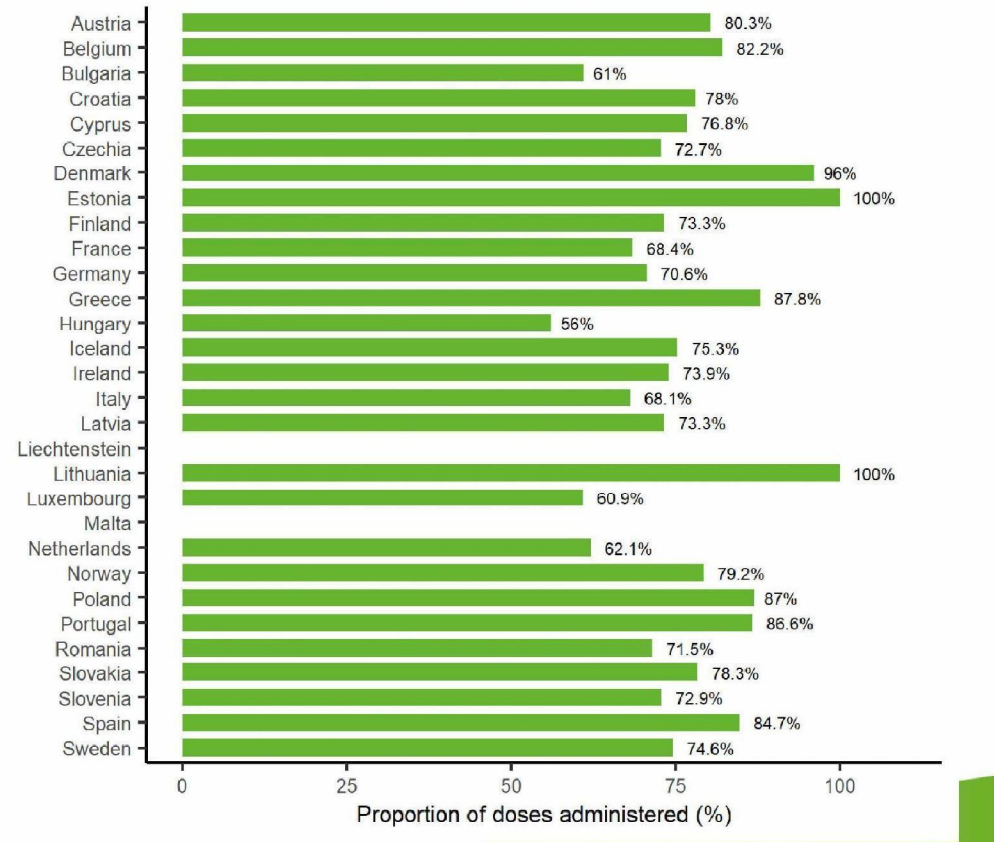
Number of vaccine doses distributed by manufacturers to EU/EEA countries per hundred inhabitants, as of Week 8, 2021



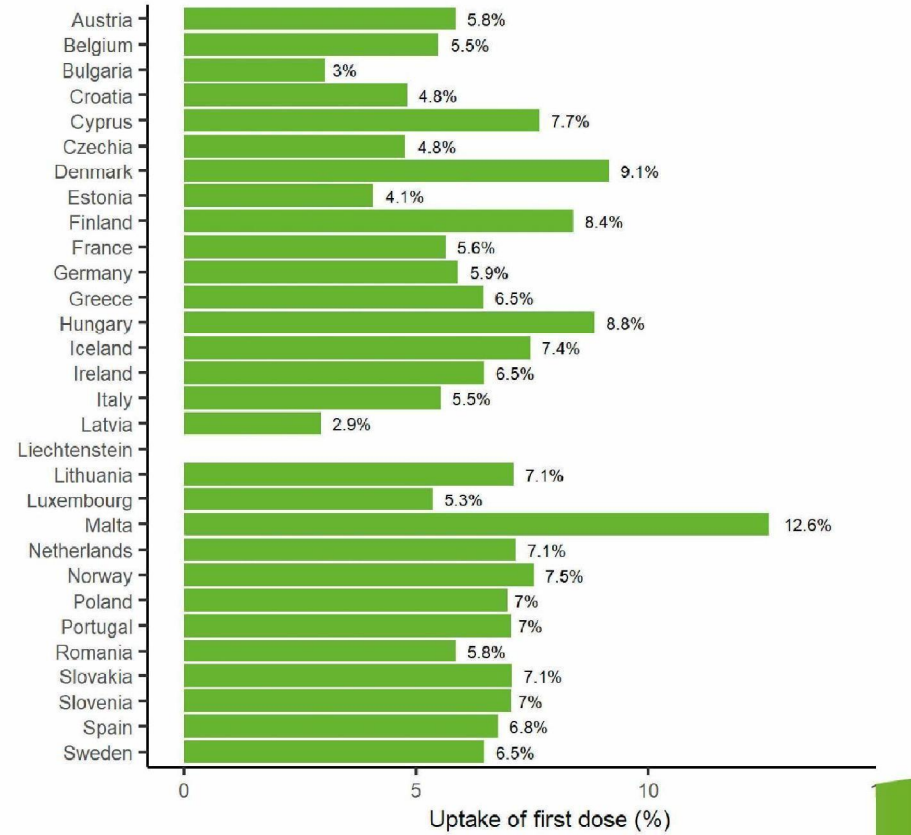
Vaccine doses distributed by the manufacturers to EU/EEA countries by product, as of week 8, 2021



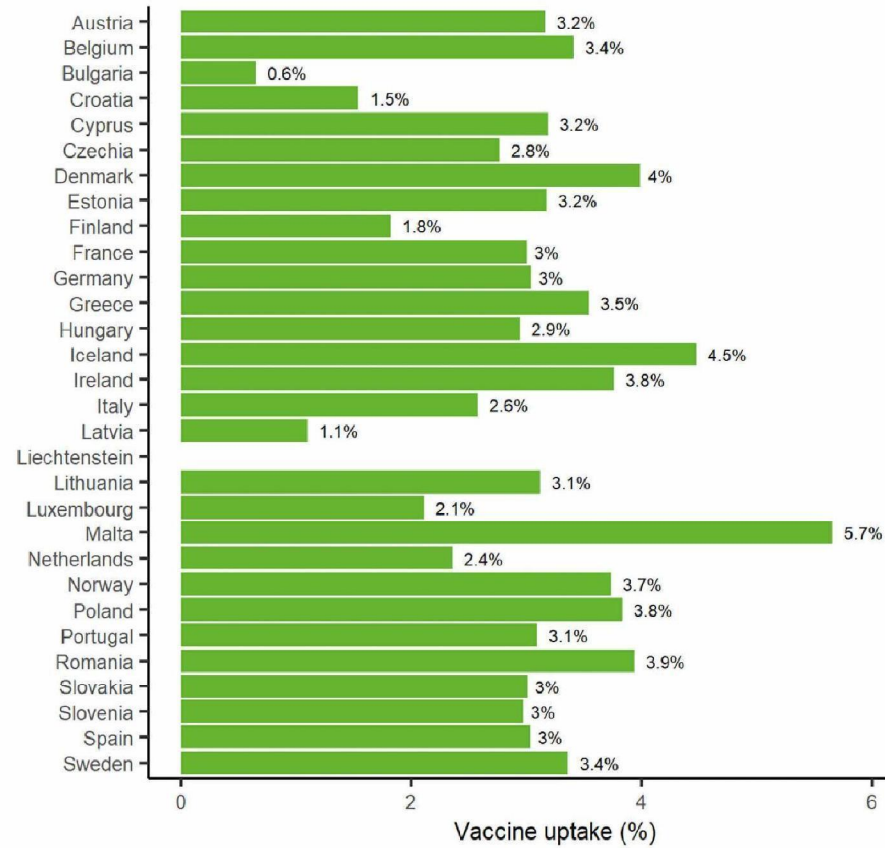
Proportion of vaccine doses distributed to the EU/EEA countries that have been administered (%), as of week 8, 2021



First dose vaccination uptake (%) in 18+ in EU/EEA countries as of Week 8, 2021



Full doses vaccination uptake (%) in 18+ in EU/EEA countries as of Week 8, 2021



First dose vaccination uptake by age groups (%) in EU/EEA countries, as of Week 08, 2021



Full doses
vaccination uptake
by age groups (%) in
EU/EEA
countries, as of
Week 8, 2021



First dose vaccination uptake in specific target groups in EU/EEA countries, as of week 08, 2021



Full doses vaccination uptake in specific target groups in EU/EEA countries, as of week 08, 2021



Main challenges/Way forward



- TESSy
 - Access to TESSy
 - Mistakes made in TESSy files
 - At country level: data identifier, double reporting, aggregated data
 - At ECDC level: impossibility to upload data of the current week
 - Unavailability of weekly data (only aggregated)
- Delay
 - Between ECDC tracker and national website
 - Stick to a minimum of biweekly reporting
- Not all the data required are documented at country level
 - Data breakdown by age groups
 - Data in specific subgroups HCW/LTCF
 - Missing denominator for some target groups (HCW, LTCF)
- Population covered by the system: Question of younger age groups is raised ? Uptake assessment ?
- Relevance of first dose when single dose vaccine on the market
- Subnational data



Thank you



Monitoring of COVID-19 vaccine deployment and vaccination

5.1.2e

WHO Europe

Webinar on Monitoring uptake and effectiveness of COVID-19 vaccine in the WHO European Region
8 March 2021



WHO European Region – Monitoring of COVID-19 vaccine introduction and implementation



- WHO/Europe Monthly Preparedness Monitoring
 - Launched on 5 November 2020
 - Continuing for countries that have not reported full completeness to identify challenges in the region by specific area, develop additional guidance, provide targeted support to countries
- Joint ECDC-WHO/Europe Weekly Uptake Monitoring
 - Launched on 15 Jan 2021 for EU/EEA countries and on 25 Jan for non-EU/EEA countries
- WHO Monthly monitoring of COVID-19 vaccination
 - To be launched on 15 March 2021

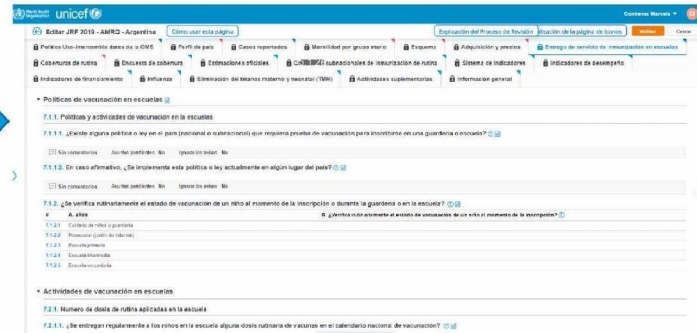
WHO Monthly monitoring of COVID-19 vaccination



Data collection process

- Data to be collected through eJRF platform
 - special COVID-19 vaccination module

WHO and UNICEF's Joint Reporting Form (JRF) Annual immunization data collection for over 20 years



eJRF platform



- Data collection for annual immunization data form and COVID-19 module will be launched at the same time, through same platform
- Identified eJRF focal points in all countries in WHO/European Region
 - Secured access; extended to additionally nominated persons
- Series of webinars organized since January to introduce eJRF platform and processes
- Ongoing trainings for eJRF users at country level
- Several training resources available (user manuals, video tutorials, walk-me function)
- Helpdesk: [redacted] 5.1.5 and [redacted] 5.1.5

WHO Monthly monitoring of COVID-19 vaccination



Data collection process

- 1st round of data collection launched on 15 March
 - data reported for the period 1-28 Feb
 - Subsequent rounds on 15th of each month to report on previous month period (ex. 15 April to report on 1-30 March period)
- One pager guidance on COVID-19 specific module will be sent together with the launch of overall eJRF data collection

WHO Monthly monitoring of COVID-19 vaccination



Indicators collected

| Programmatic areas | Details |
|---|--|
| Vaccine policy and vaccine availability | <ul style="list-style-type: none"> • Vaccine authorization and licensing • Vaccine introduction • Vaccination policy and strategy |
| Vaccine schedule, procurement and pricing | |
| Vaccine uptake | |
| System indicators | <ul style="list-style-type: none"> • Demand • Immunization information system • Safety • Cold chain • Financing |
| Post introduction studies and assessment | |

WHO Monthly monitoring of COVID-19 vaccination



Avoid duplications with other data collection mechanism

- System indicators already collected through preparedness monitoring were not included
- Uptake monitoring section included, as it can be complementary to weekly TESSy reporting

Uptake monitoring



| TESSy uptake monitoring | eJRF uptake monitoring |
|--|---|
| Weekly reporting | Monthly reporting |
| Weekly uptake | Cumulative uptake (since beginning of campaign) |
| Disaggregation by vaccine product, age, HCW, LCTF, subnational level | Disaggregation by vaccine product, age, HCW, LCTF, comorbidity, refugees, sex, other |
| General comment sections | Comment section for each reporting element |
| Denominators for HCW, LCTF, optional for other target groups | Denominators for all target groups |

If a country is already reporting through TESSy, 3 options are provided:

- Report only complementary data
- Report again all data with monthly breakdown and as cumulative figures
- Skip the section

WHO Monthly monitoring of COVID-19 vaccination



Reducing reporting burden

- Core questions to all reporting entities
- AMC specific for the 92 eligible economies
- Pre-populated data based on previous month reporting
 - ***For most indicators, monthly update only if necessary***
 - Expected regular monthly update for
 - Vaccine procurement and stock utilization
 - Vaccination uptake
 - Number of serious adverse events

Data dissemination to general public



Regional dashboards – From April

- Updated to incorporate additional key indicators in current regional dashboards

Global dashboards – From May

- COVID 19 dashboard explorer
- Immunization data portal COVID-19 vaccination module



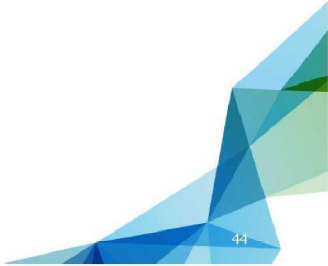
Thank you



Overview of vaccine effectiveness monitoring in the European region



Israel



PHE Vaccine effectiveness update

Official Sensitive

8th March 2021

Overview

- Routine testing - Test negative case control (TNCC)
- SIREN Health care worker cohort
- Impact

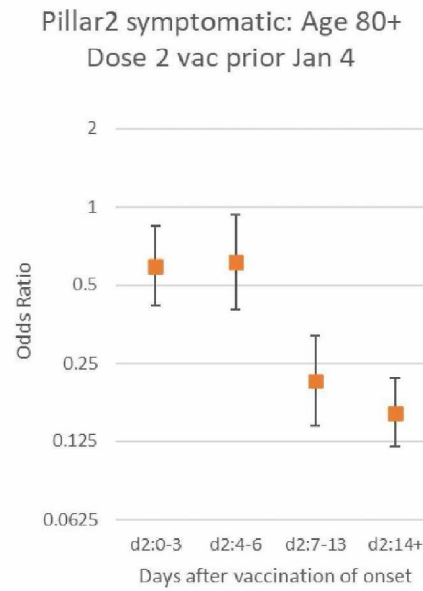
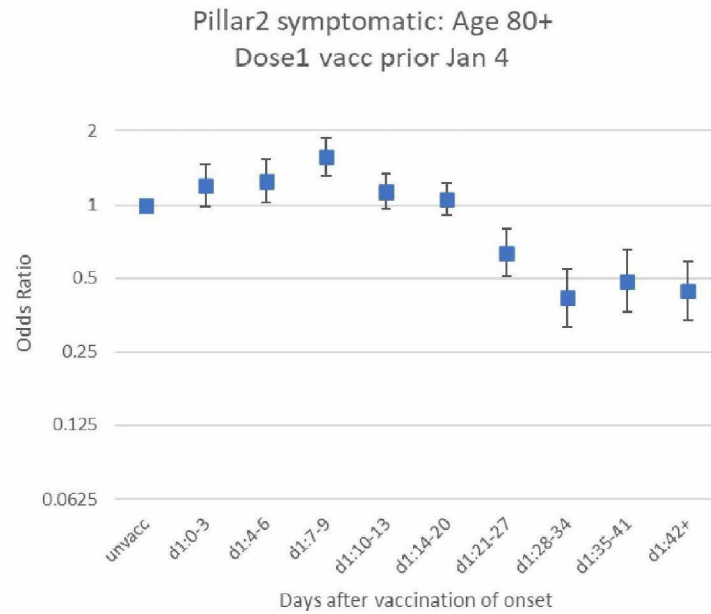
Key dates of UK vaccination programme

- 8th December rollout of Pfizer-BioNTech vaccine to 80+ years and health and social care workers
- 30th December – policy change to extend dosing interval to 12 weeks
- 4th January rollout of Oxford-Astrazeneca vaccine
- 18th January rollout to over 70s and clinically extremely vulnerable
- Feb-March gradual drop in age groups to 56+ and younger age groups with underlying health conditions

Routine testing VE

- Linkage of community testing data to NIMS (nation immunisation database)
- Excludes previous PCR positive
- Just those symptomatic with date of sample \leq 10 days from onset
- Pfizer-BioNTech and Oxford-Astrazeneca vaccines
- Data 8th December to 28th Feb
- Stratified according to vaccination period:
 - 80+ prior to 4th Jan
 - 70+ since 4th Jan (date of AZ rollout)
- TNCC with first PCR positive in the period and up to 3 random symptomatic negatives (which must be at least 3 weeks before any positive test in that patient)
 - Logistic regression adjusted for 5 yr age band, NHS region, week, gender, ethnicity, care home
- Survival analysis for hospitalisations and deaths among cases by vaccination status
 - Adjusting for age, care home, gender , period

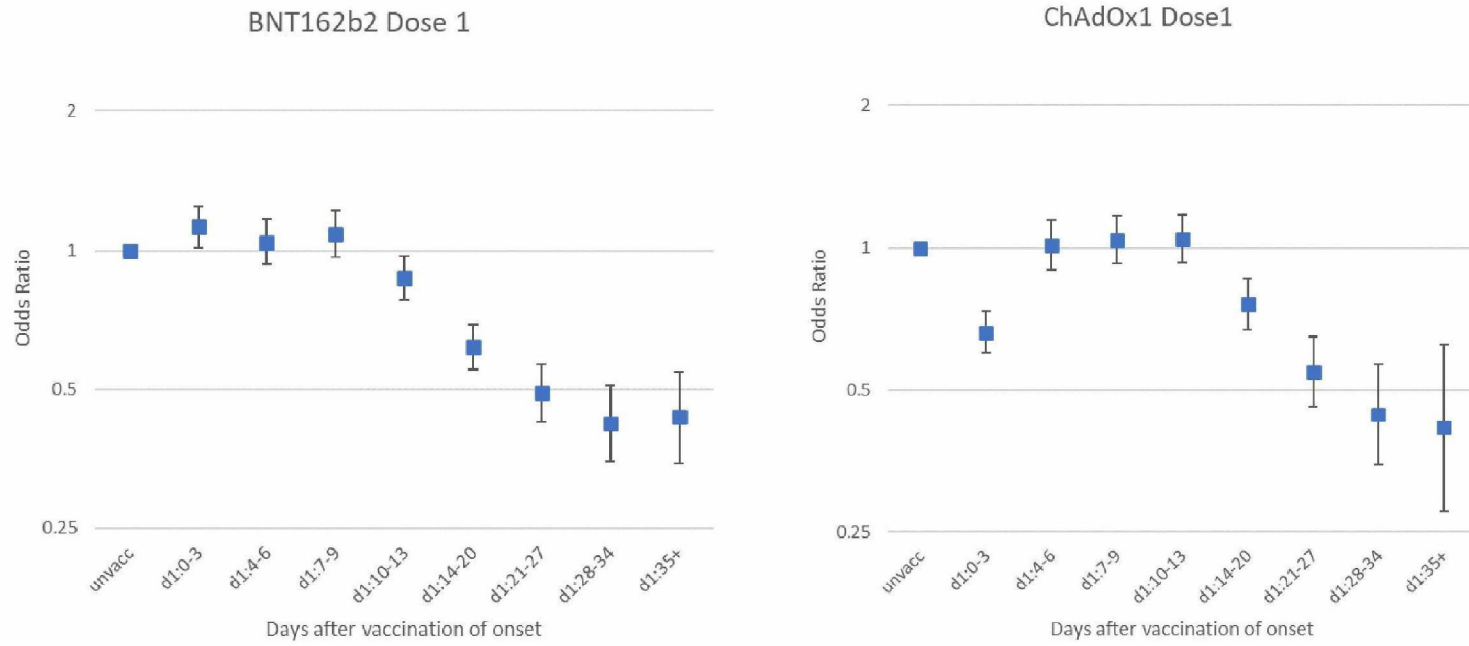
Pfizer – 80+ vaccinated prior to 4th Jan



Pfizer – 80+ vaccinated prior to 4th Jan

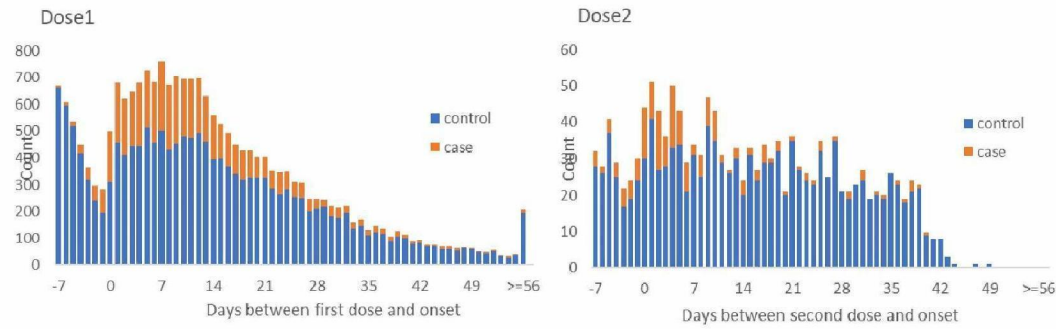
| Interval after dose (days) | | Vaccinated prior to 4th Jan | | | | |
|----------------------------|--------------|-----------------------------|-------|------------------|------------------|------------------|
| | | controls | cases | OR (95% CI) | aOR (95% CI) | OR vs day 4-9 |
| | unvaccinated | 15,781 | 9,019 | base | base | |
| dose 1 | d1:0-3 | 277 | 167 | 1.16 (0.95-1.41) | 1.2 (0.99-1.47) | |
| | d1:4-6 | 240 | 179 | 1.23 (1.01-1.5) | 1.25 (1.03-1.53) | |
| | d1:7-9 | 252 | 257 | 1.56 (1.31-1.86) | 1.57 (1.31-1.88) | |
| | d1:10-13 | 361 | 284 | 1.12 (0.95-1.31) | 1.14 (0.97-1.34) | 0.8 (0.65-0.98) |
| | d1:14-20 | 462 | 337 | 1.02 (0.88-1.18) | 1.06 (0.91-1.22) | 0.74 (0.61-0.9) |
| | d1:21-27 | 287 | 118 | 0.6 (0.48-0.75) | 0.63 (0.51-0.79) | 0.45 (0.34-0.58) |
| | d1:28-34 | 290 | 72 | 0.4 (0.31-0.52) | 0.42 (0.32-0.55) | 0.29 (0.22-0.4) |
| | d1:35-41 | 274 | 65 | 0.44 (0.33-0.59) | 0.49 (0.36-0.65) | 0.34 (0.25-0.47) |
| | d1:42+ | 604 | 94 | 0.38 (0.29-0.51) | 0.44 (0.34-0.59) | 0.31 (0.23-0.43) |
| dose 2 | d2:0-3 | 117 | 46 | 0.55 (0.39-0.78) | 0.59 (0.42-0.84) | 0.42 (0.29-0.6) |
| | d2:4-6 | 81 | 32 | 0.56 (0.37-0.85) | 0.61 (0.4-0.93) | 0.43 (0.28-0.67) |
| | d2:7-13 | 204 | 28 | 0.2 (0.13-0.29) | 0.21 (0.14-0.32) | 0.15 (0.1-0.23) |
| | d2:14+ | 785 | 52 | 0.14 (0.1-0.19) | 0.16 (0.12-0.22) | 0.11 (0.08-0.16) |

Pfizer and AZ – 70+ vaccinated since 4th Jan

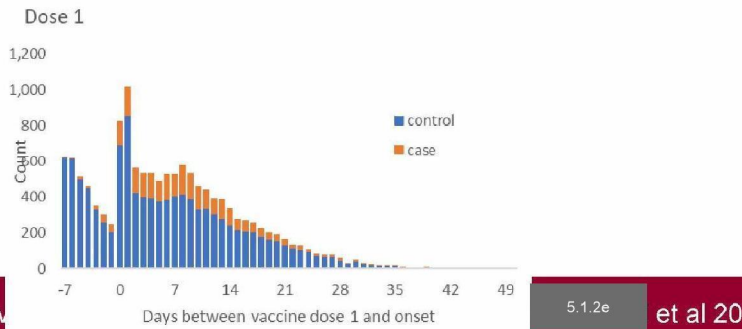


Testing by interval after vaccination

a) BNT162b2



b) ChAdOx1

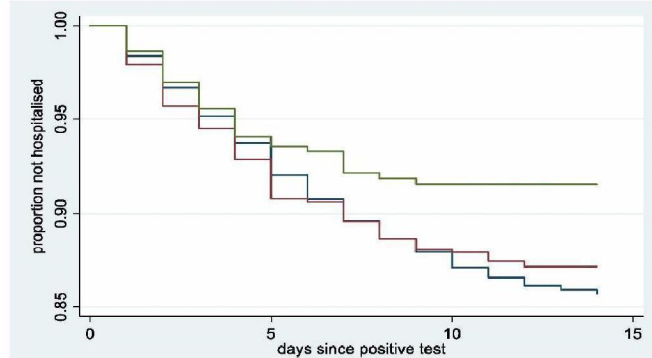
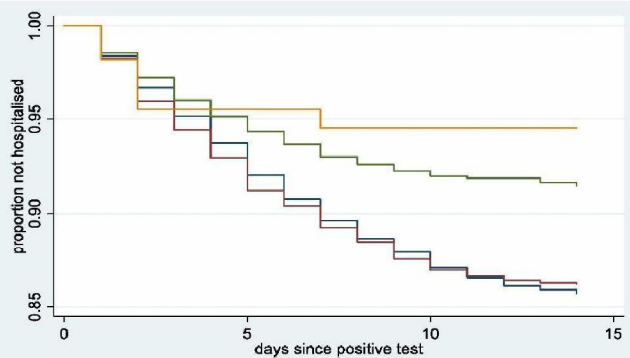


Pfizer and AZ – 70+ vaccinated since 4th Jan

| Interval (days) | BNT162b2 | | | | ChAdOx1 | | | |
|--------------------|----------|--------|------------------|------------------|----------|--------|------------------|------------------|
| | controls | cases | OR (95% CI) | aOR (95% CI) | controls | cases | OR (95% CI) | aOR (95% CI) |
| unvacc | 36,997 | 15,382 | base | base | 36,997 | 15,382 | base | base |
| d1:0-3 | 1318 | 625 | 1.27 (1.15-1.4) | 1.12 (1.02-1.24) | 2405 | 581 | 0.79 (0.71-0.87) | 0.66 (0.6-0.73) |
| d1:4-6 | 1162 | 476 | 1.2 (1.08-1.34) | 1.04 (0.93-1.17) | 1214 | 433 | 1.28 (1.14-1.44) | 1.02 (0.9-1.15) |
| d1:7-9 | 1125 | 468 | 1.26 (1.13-1.41) | 1.09 (0.97-1.22) | 1367 | 482 | 1.38 (1.23-1.54) | 1.04 (0.92-1.17) |
| d1:10-13 | 1594 | 511 | 1.09 (0.98-1.21) | 0.87 (0.78-0.97) | 1620 | 531 | 1.43 (1.28-1.6) | 1.04 (0.93-1.17) |
| d1:14-20 | 2402 | 492 | 0.78 (0.7-0.87) | 0.62 (0.55-0.69) | 2123 | 509 | 1.16 (1.03-1.3) | 0.76 (0.67-0.86) |
| d1:21-27 | 1789 | 282 | 0.67 (0.58-0.77) | 0.49 (0.43-0.57) | 1270 | 227 | 0.96 (0.82-1.14) | 0.55 (0.46-0.65) |
| d1:28-34 | 1235 | 157 | 0.61 (0.51-0.74) | 0.42 (0.35-0.51) | 636 | 97 | 0.92 (0.73-1.17) | 0.44 (0.35-0.57) |
| d1:35+ | 898 | 114 | 0.7 (0.56-0.88) | 0.43 (0.35-0.55) | 179 | 33 | 1.2 (0.81-1.78) | 0.42 (0.28-0.62) |

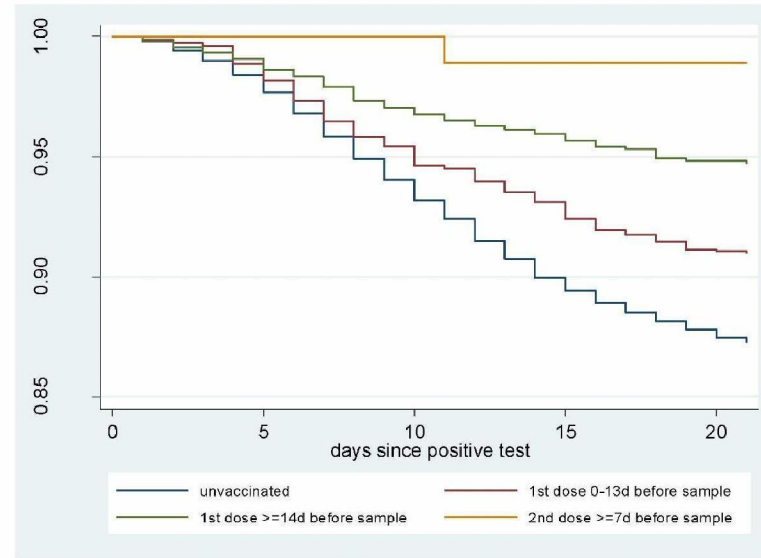
Case hospitalisation/fatality rates

| Vaccination status | BNT162b2 | | | | ChAdOx1 | | | |
|--|-------------|------------------|--------|------------------|-------------|------------------|--------|------------------|
| | Total cases | Hospitalisations | | Hazard ratio | Total cases | Hospitalisations | | Hazard ratio |
| | | n | % | | | n | % | |
| Unvaccinated | 9013 | 1361 | 15.10% | 1.00 | 9013 | 1361 | 15.10% | 1.00 |
| Test date less than 14 days after first dose | 2173 | 311 | 14.31% | 1.00 (0.88-1.13) | 634 | 78 | 12.30% | 1.03 (0.82-1.29) |
| Test date 14 days or more after first dose | 1689 | 152 | 9.00% | 0.58 (0.49-0.68) | 252 | 20 | 7.94% | 0.65 (0.44-0.96) |
| Test date 7 days or more after first dose | 97 | 7 | 7.22% | 0.36 (0.16-0.81) | | | | |
| Total | 12972 | 1831 | 14.12% | | 9899 | 1459 | 14.74% | |



Pfizer: case fatality rates

| Vaccination status | Total cases | Deaths within 21 days | | Hazard ratio |
|--|-------------|-----------------------|--------|------------------|
| | | Deaths | | |
| | | n | % | |
| Unvaccinated | 8625 | 1115 | 12.93% | 1.00 |
| Test date less than 14 days after first dose | 1367 | 131 | 9.58% | 0.74 (0.62-0.88) |
| Test date 14 days or more after first dose | 854 | 60 | 7.03% | 0.46 (0.36-0.59) |
| Test date 7 days or more after first dose | 72 | 0 | 0.00% | 0.09 (0.01-0.66) |
| Total | 10918 | 1306 | 11.96% | |



SIREN

- Multicentre prospective cohort study ~35,000 participants
- Healthcare workers, support staff and admin staff at hospital trusts
- Questionnaires at enrolment and every 2 weeks
- PCR testing every 2 weeks
- Monthly antibody testing
- ~30% previously positive at enrolment
- Cohort analysis – proportional hazards model adjusted for period, age, ethnicity, comorbidities, region, job role, frequency of COVID-19 patient contact, patient facing role, workplace setting

Vaccine coverage within SIREN

08 December 2020 – 05 February 2021

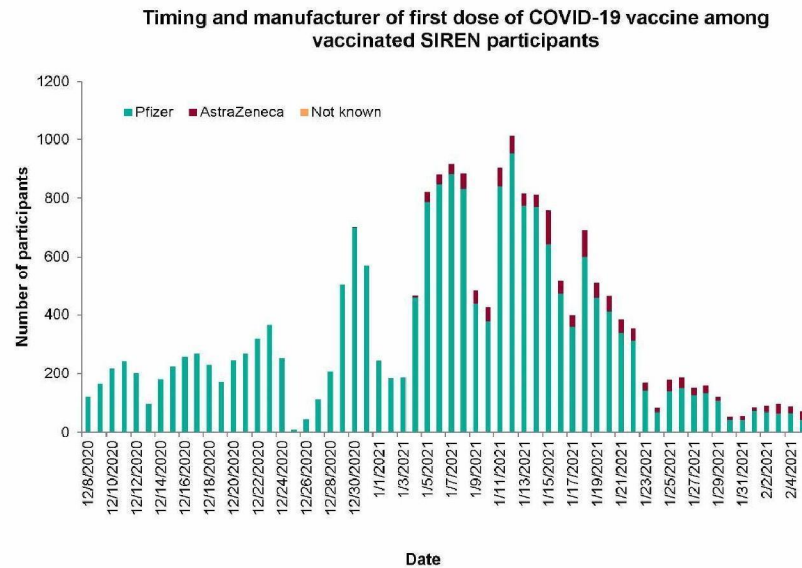
Total participants: 23,324
 Positive cohort: 8,203 (35%)
 Negative cohort: 15,121 (65%)

Total received at least one dose: 20,641
(89%)

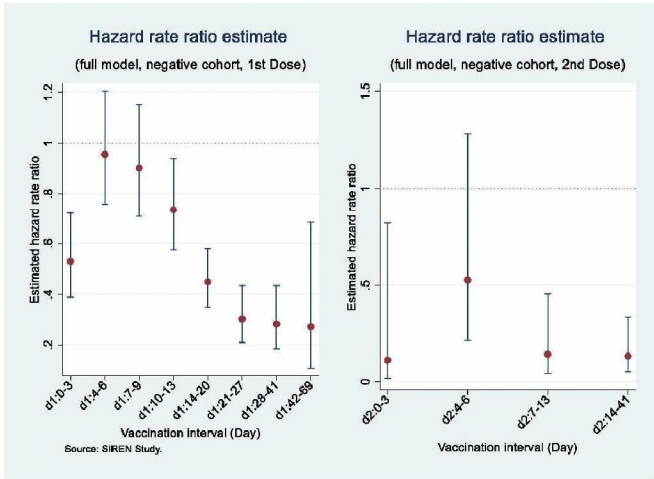
Total received 2nd dose: 1,607 (8%)

At least one dose:
 Pfizer: 94%
 AstraZeneca: 6%

Two doses:
 Pfizer: 99.9%
 AstraZeneca: 0.1%



Hall et al 2021 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3790399



Negative cohort n= 15,121

| Vaccine group | Total person time (days) | Number PCR+ | Incidence Density per 10,000 person days | Adjusted Hazard Ratio (Mixed effect model) | LCI | UCI |
|---------------|--------------------------|-------------|--|--|------|------|
| Unvaccinated | 442605 | 902 | 20 | Reference | - | - |
| d1:0-3 | 33654 | 44 | 13 | 0.53 | 0.39 | 0.72 |
| d1:4-6 | 32557 | 86 | 26 | 0.96 | 0.76 | 1.20 |
| d1:7-9 | 30787 | 79 | 26 | 0.90 | 0.71 | 1.15 |
| d1:10-13 | 37892 | 81 | 21 | 0.73 | 0.57 | 0.94 |
| d1:14-20 | 53577 | 77 | 14 | 0.45 | 0.35 | 0.58 |
| d1:21-27 | 32511 | 35 | 11 | 0.30 | 0.21 | 0.44 |
| d1:28-41 | 23408 | 26 | 11 | 0.28 | 0.18 | 0.43 |
| d1:42-69 | 3829 | 5 | 13 | 0.27 | 0.11 | 0.69 |
| d2:0-3 | 2843 | 1 | 4 | 0.12 | 0.02 | 0.82 |
| d2:4-6 | 2726 | 5 | 18 | 0.53 | 0.22 | 1.28 |
| d2:7-13 | 5829 | 3 | 5 | 0.15 | 0.05 | 0.46 |
| d2:14-41 | 8917 | 5 | 6 | 0.14 | 0.06 | 0.33 |

New PCR+ during follow-up

- 902 unvaccinated
- 433 vaccinated 1st dose
- 14 vaccinated 2nd dose

VE d1>21 days:

72% (95% CI 56-82%)

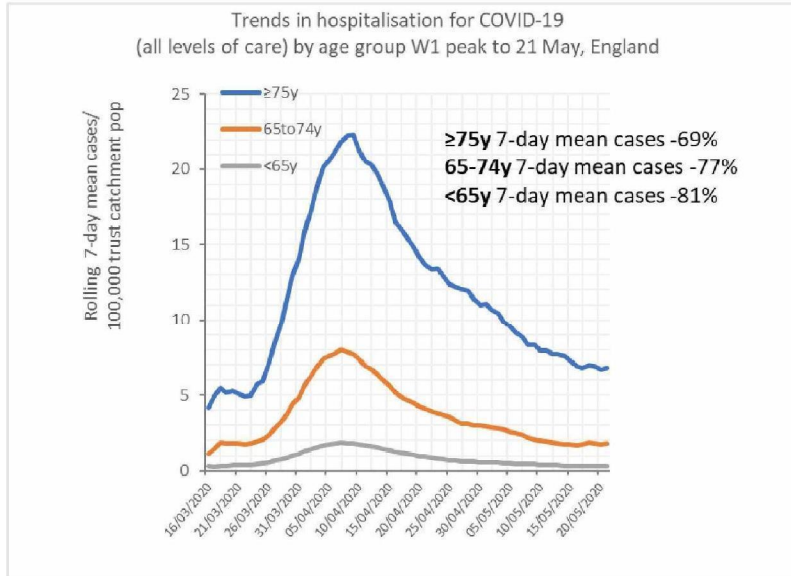
VE d2>7days:

86% (95% CI 76-97%)

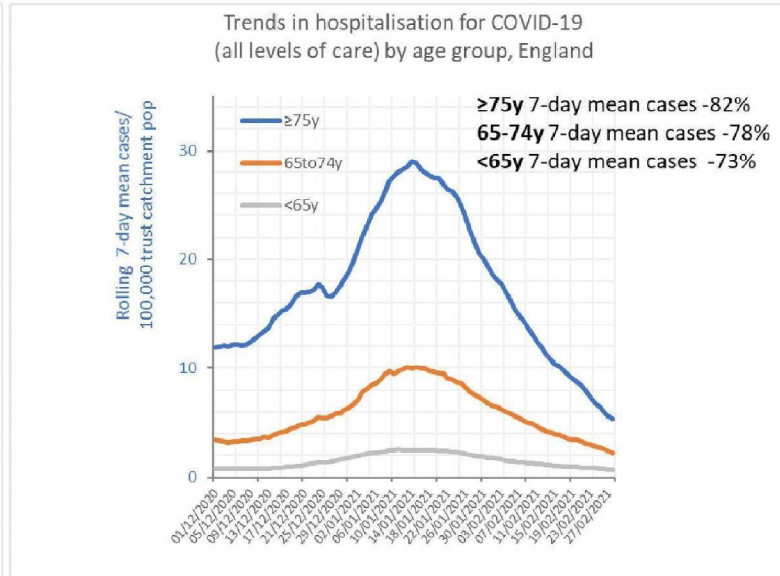
Hall et al 2021 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3790399

Impact on hospitalisations

Wave 1

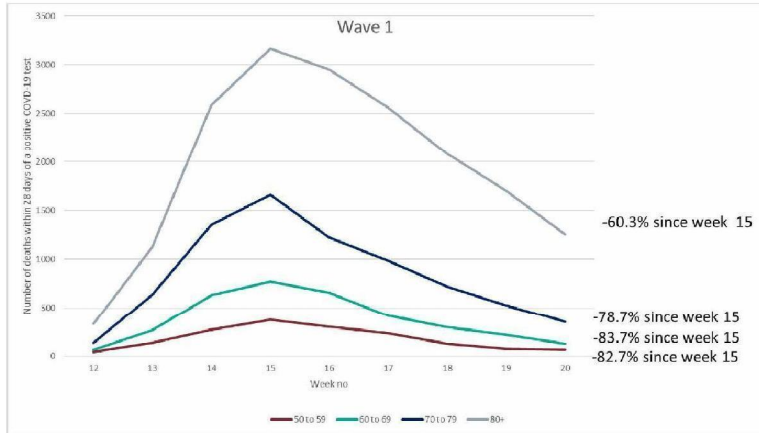


Wave 2

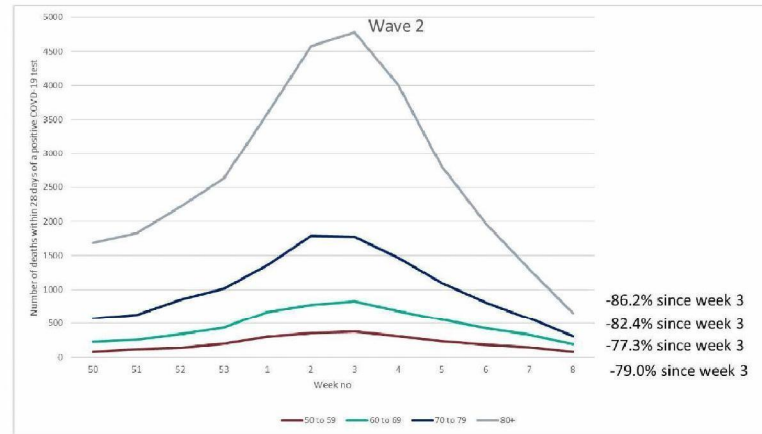


Impact on mortality

Wave 1



Wave 2



Summary

- Pillar testing VE analysis suggests VE of 60-70% in older after single dose of either vaccine from day 28+
- VE of 2 doses of Pfizer-BioNTech vaccine against symptomatic disease 85-90%
- Greater protection against hospitalisation (~80% single dose of either vaccine) and death (~85% single dose of Pfizer-BioNTech)
- Evidence that Pfizer-BioNTech vaccine effective at preventing infection in HCW (~70% after 1 dose, ~85% after 2 doses)
- Early evidence of population level impact of the vaccination programme on hospitalisations and deaths



Effectiveness of first dose of COVID-19 vaccines against hospital admissions in Scotland: national prospective cohort study of 5.4 million people

B

5.1.2e, 5.1.2e, 5.1.2e
and 5.1.2e, on behalf of the EAVE II Collaborators



Potential conflict of interests



- 5.1.2e Research grants from UKRI (MRC) and HDRUK; Member of Scottish Government's COVID-19 Advisory Group, NERVTAG Risk Stratification Subgroup and other government and professional COVID-19 advisory bodies
- 5.1.2e None
- 5.1.2e : Research grants from UKRI (MRC), Public Health Scotland and HDRUK; Member of: Scottish Government Chief Medical Officer's COVID-19 Advisory Group; - COVID-19 Nosocomial Review Group, Scotland (CNRG); SPI-M; - MHRA Expert Working Group Vaccine Benefit and Risk; NERVTAG COVID-19 Risk Stratification Subgroup
- 5.1.2e My NHS organisation has changed names in the recent past – from April 2020 from Health Protection Scotland to become Public Health Scotland. Across this time my organisation will have been in receipt of funding from NIHR/MRC and Scottish Government which is non-personal and specific to this area of applied health service research on COVID-19. My organisation has a similar return for work undertaken with our EU colleagues through the IMOVE-COVID-19 project led by Epiconcept funded by ECDC and WHO. I am also a Consultant in Public Health and Clinical Lead for Health Protection for NHS Fife, and a Trustee of Queen's Nurse Institute Scotland
- 5.1.2e : I was involved in the original creation of the precursors to EAVE-II & have remained involved in the design of EAVE-II. My NHS organisation has changed names in the recent past – from April 2020 from Health Protection Scotland to become Public Health Scotland. Across this time my organisation will have been in receipt of funding from NIHR/MRC and Scottish Government which is non-personal & specific to this area of applied health service research on COVID-19. My organisation has a similar return for work undertaken with our EU colleagues through the IMOVE-COVID-19 project led by Epiconcept funded by ECDC and WHO.

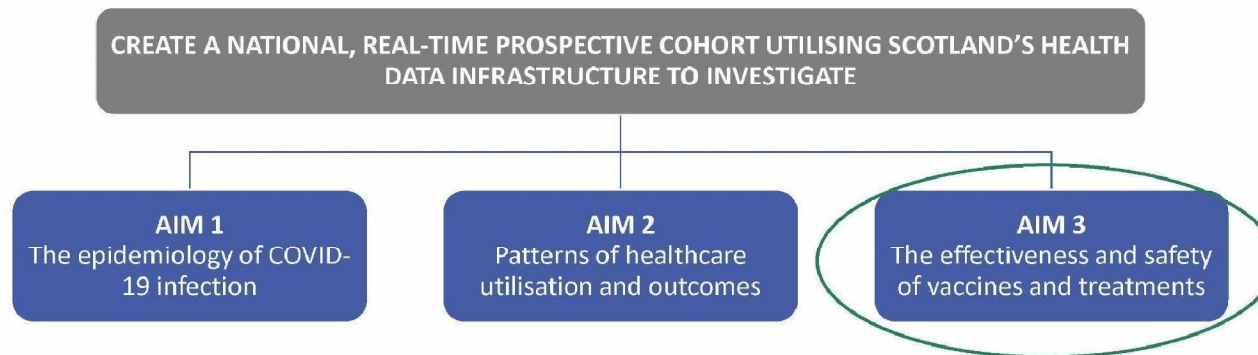
5.1.2e

5.1.2e



Background to EAVE II

- Utilising linked data is crucial to monitor, understand and mitigate the effects of COVID-19
- EAVE II aims to do this for Scotland using a 'hibernating' NIHR funded platform originally created to respond to H1N1 pandemic
- Prospective observational cohort covering 99% of Scotland's 5.4 million population



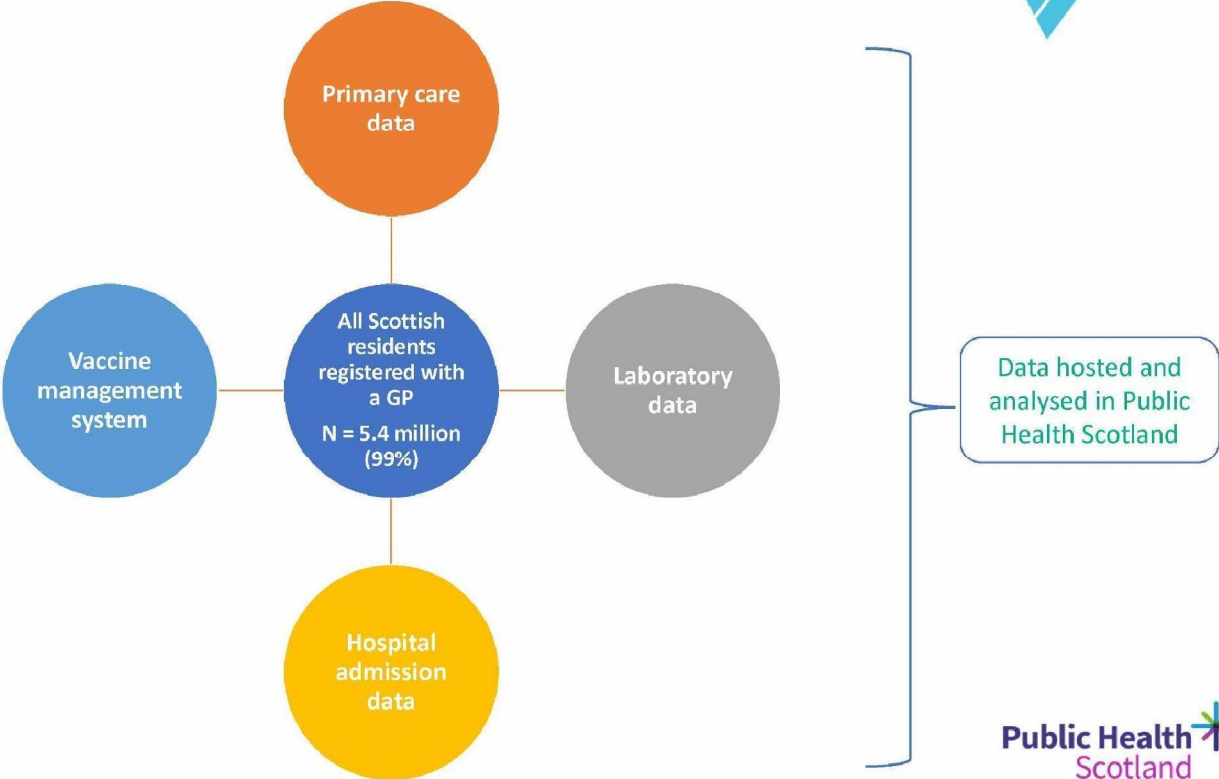


Investigating the effectiveness of COVID-19 vaccines

- Pre-print format our initial results on the effectiveness of the first doses of the Pfizer/BioNTech (PB) and Oxford/AstraZeneca (AZ) vaccines in preventing hospital admissions
- Prospective study of over 1.1 million first doses administered between 8/12/20 and 15/2/21 in Scotland
- Paper has been submitted for publication in a peer-reviewed journal

Methods

Data linkage using unique Community Health Index (CHI) Numbers

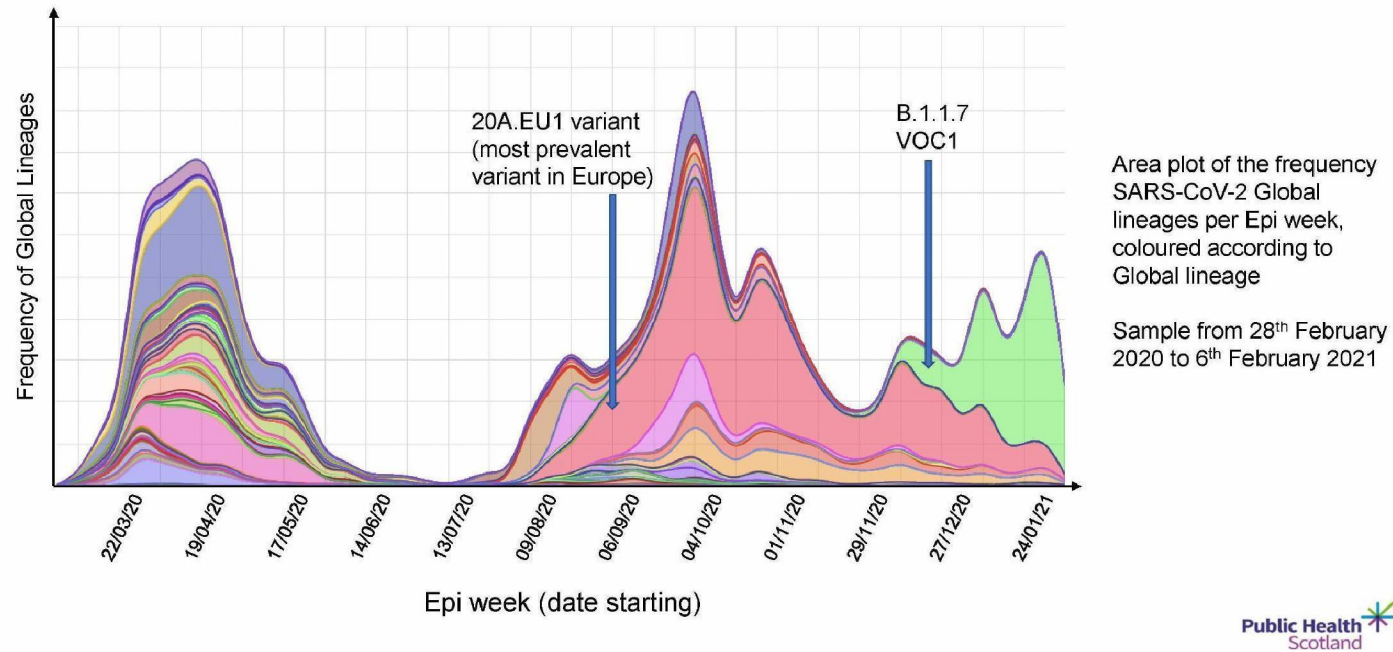




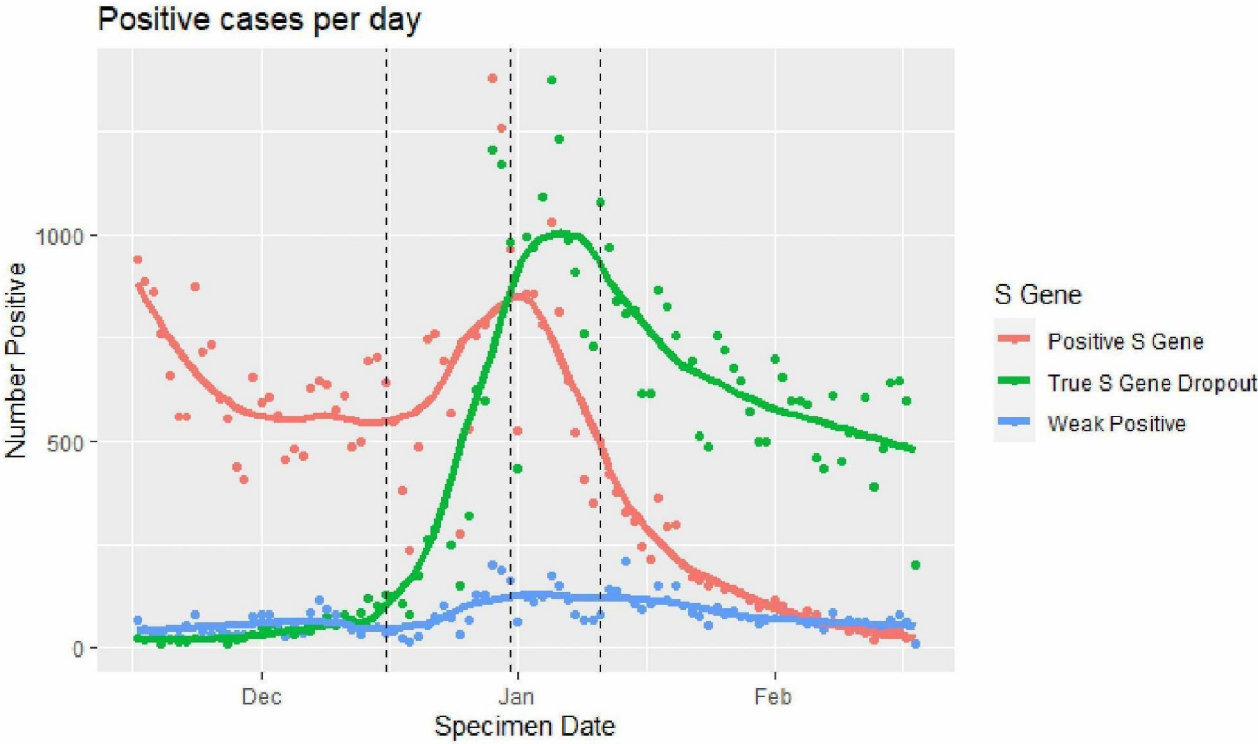
Prospective cohort study design

- Participants did not have the outcome of interest to begin with
- Two groups of people: vaccinated vs. unvaccinated
- Follow-up of both groups (vaccinated and unvaccinated individuals) over time to measure the risk of hospital admissions in each group
- Statistical approaches to adjust for confounders
- Hazard Ratios (HR) and Vaccine Effects (VE) in preventing hospital admissions estimated

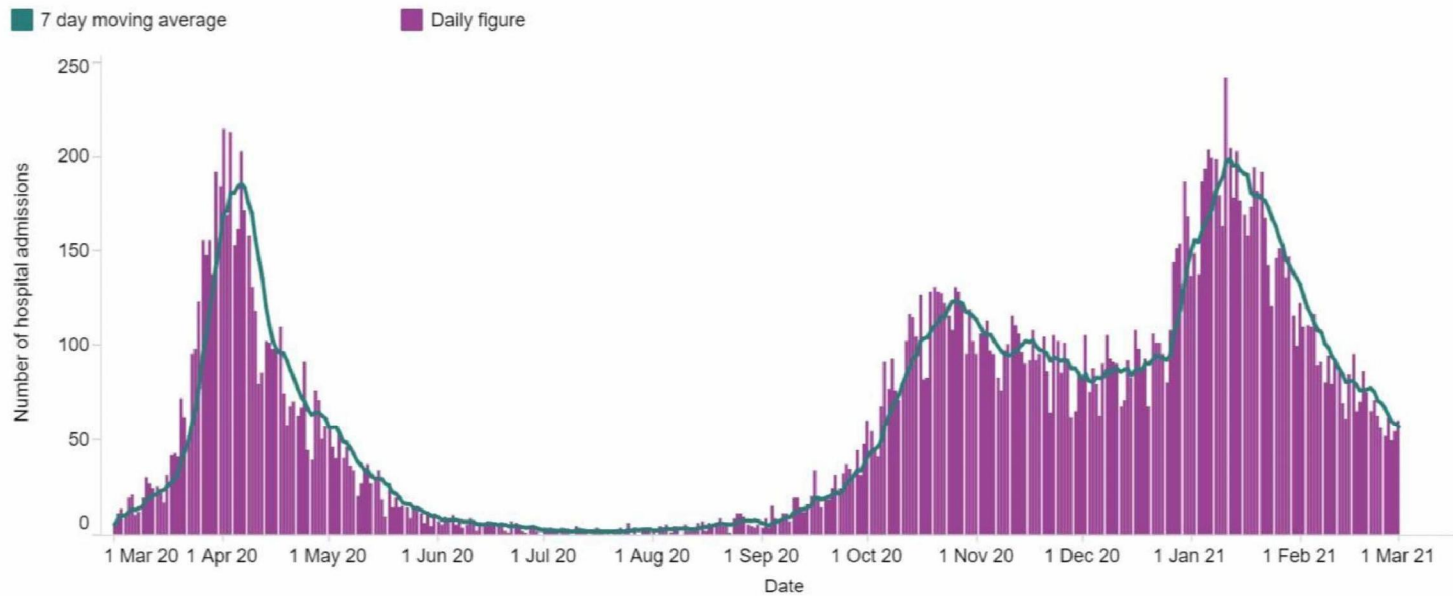
Diversity of the SARS-CoV-2 sequenced in Scotland – Increasing dominance of UK Variant of Concern during the period of vaccine offer



Utilisation of the S Gene Target Failure/ S Gene Dropout as a proxy of UK Variant of Concern B1.1.7



Hospital admissions by admission date in Scotland

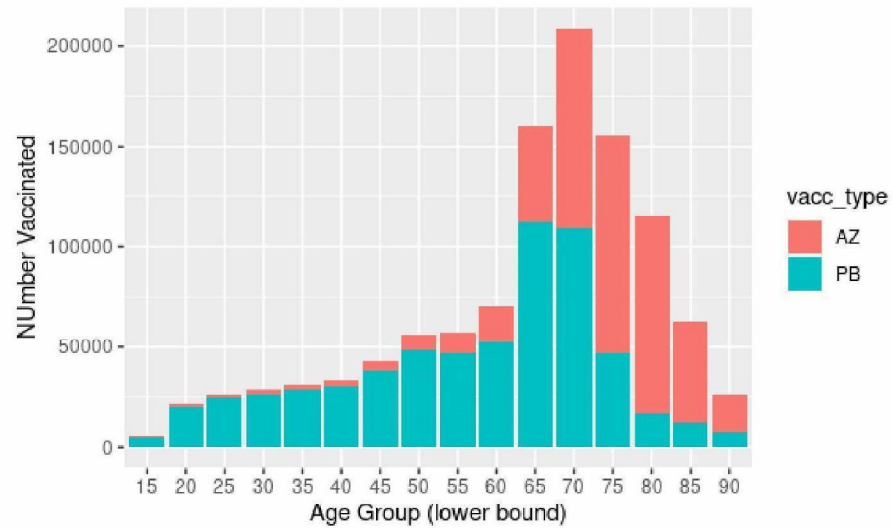


Figures for the most recent dates are likely to be incomplete due to the time required to process tests and submit records.



https://public.tableau.com/profile/phs.covid.19#!/vizhome/COVID-19DailyDashboard_15960160643010/Overview

Vaccine administration across all ages from the EAVE-II cohort
(combines both **BNT162b2 (PB)** & **ChAdOx1nCoV-19 (AZ)**
data)



PB Vaccine available from 8th December 2020 and available to all age groups but relatively low use in over 75's
AZ Vaccine available from 4th January 2020 and largely used among the over 65's

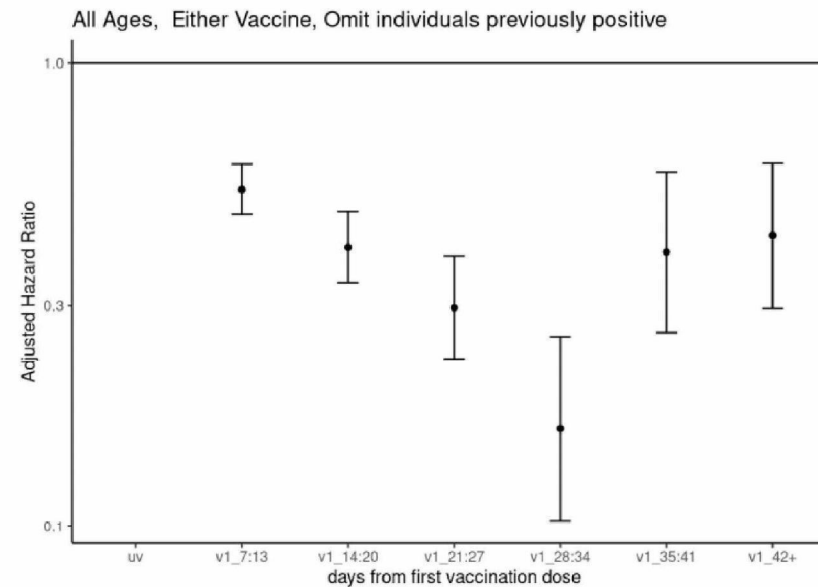
Vaccine effect across all ages from the EAVE-II cohort on risk of hospitalisation – protective effect of any vaccine (combines both PB and AZ data)



Numbers and Hazard Ratios

| Vaccine Group | Person Years | Number Events |
|---------------|--------------|---------------|
| uv | 787518 | 7472 |
| v1_7:13 | 13487 | 212 |
| v1_14:20 | 9191 | 120 |
| v1_21:27 | 6343 | 52 |
| v1_28:34 | 3867 | 20 |
| v1_35:41 | 2326 | 17 |
| v1_42+ | 3843 | 21 |

uv: Unvaccinated



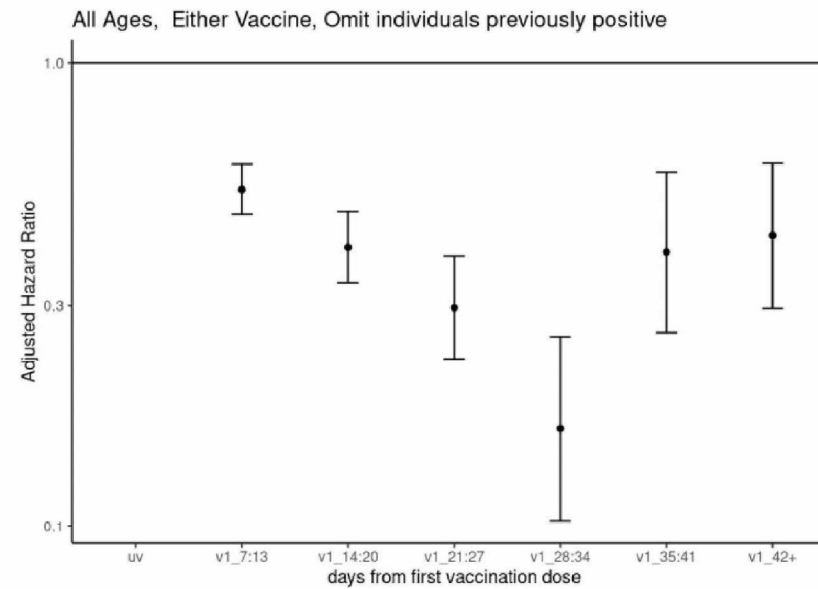
Interpretation – The hazard ratio represents the risk of hospitalisation among vaccinated individuals compared to unvaccinated. These ratios and the confidence limits are below 1 indicating that a single dose of the vaccine is associated with a reduced risk.

Vaccine effect across all ages from the EAVE-II cohort on risk of hospitalisation – **protective effect of any vaccine (combines both PB and AZ data)**



Numbers and Hazard Ratios

| Vaccine Group | Person Years | Number Events |
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| v1_42+ | 3843 | 21 |



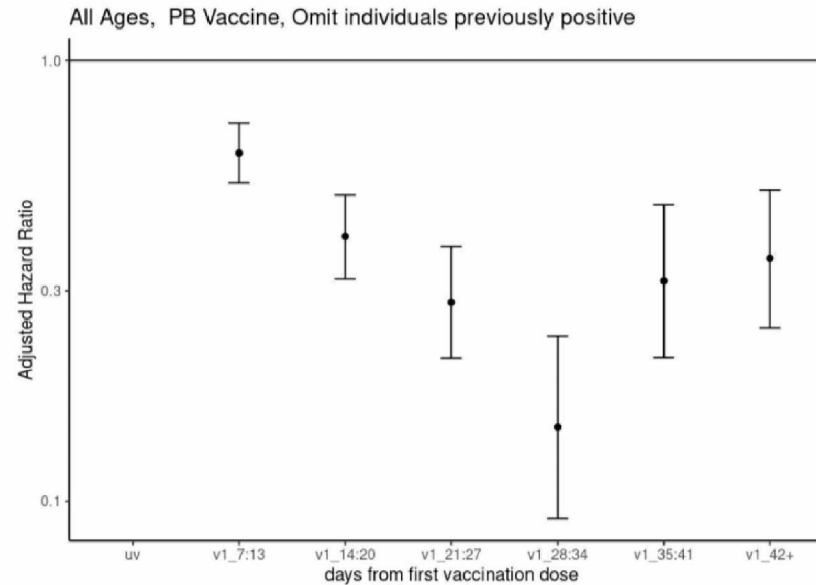
After 3 weeks the ratio is 0.30 (95% CI 0.23-0.38), 4 weeks 0.16 (0.10, 0.26), 5 weeks 0.39 (0.26, 0.58), 6 weeks 0.42 (0.30, 61) hazard ratios relative to unvaccinated

Vaccine effect across all ages from the EAVE-II cohort on risk of hospitalisation – protective effect of PB vaccine alone



Numbers and Hazard Ratios

| Vaccine Group | Person Years | Number Events |
|---------------|--------------|---------------|
| uv | 708129 | 6690 |
| v1_7:13 | 7766 | 104 |
| v1_14:20 | 5758 | 60 |
| v1_21:27 | 4688 | 34 |
| v1_28:34 | 3346 | 18 |
| v1_35:41 | 2275 | 17 |
| v1_42+ | 3842 | 21 |



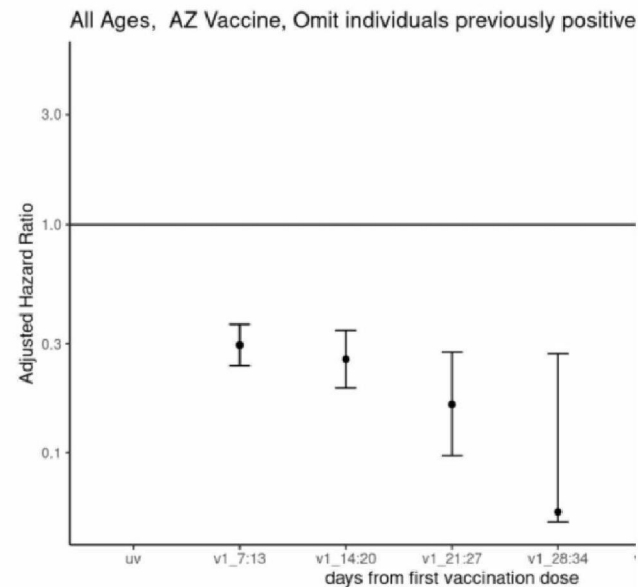
After 3 weeks the ratio is 0.28 (95% CI 0.21-0.38), 4 weeks 0.15 (0.09, 0.24), 5 weeks 0.32 (0.21, 0.47), 6 weeks 0.36 (0.25, 0.51) hazard ratios relative to unvaccinated

Vaccine effect across all ages from the EAVE-II cohort on risk of hospitalisation – protective effect of AZ vaccine alone



Numbers and Hazard Ratios

| Vaccine Group | Person Years | Number Events |
|---------------|--------------|---------------|
| uv | 700859 | 7090 |
| v1_7:13 | 5721 | 108 |
| v1_14:20 | 3433 | 60 |
| v1_21:27 | 1655 | 18 |
| v1_28:34 | 521 | 2 |
| v1_35:41 | 51 | 0 |
| v1_42+ | 1 | 0 |



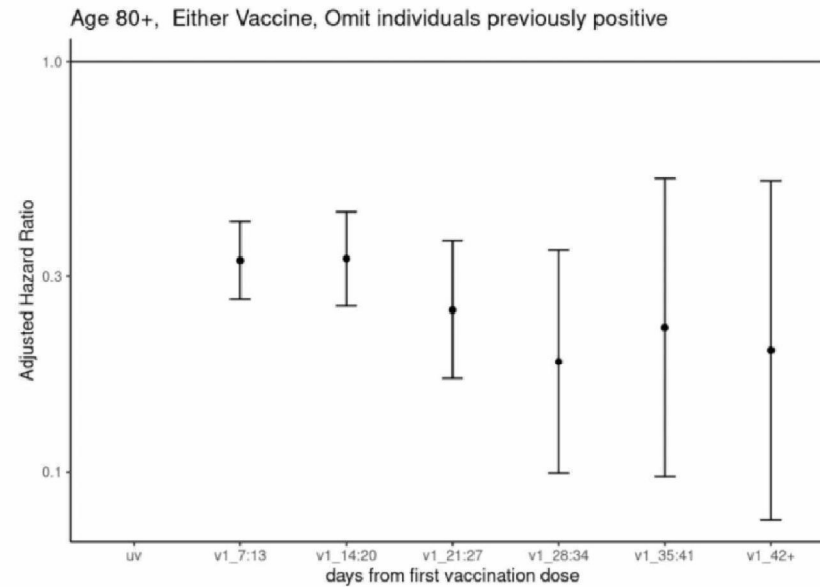
After 3 weeks the ratio is 0.16 (95% CI 0.10-0.28), 4 weeks 0.06 (0.01, 0.21), limited information from 4 weeks onward hazard ratios relative to unvaccinated

Vaccine effect aged 80+ from the EAVE-II cohort on risk of hospitalisation – **protective effect of any vaccine (combines both PB and AZ data)**



Numbers and Hazard Ratios

| Vaccine Group | Person Years | Number Events |
|---------------|--------------|---------------|
| uv | 40436 | 1861 |
| v1_7:13 | 3789 | 115 |
| v1_14:20 | 3188 | 79 |
| v1_21:27 | 1906 | 36 |
| v1_28:34 | 795 | 14 |
| v1_35:41 | 288 | 7 |
| v1_42+ | 339 | 6 |



After 3 weeks the ratio is 0.25 (95% CI 0.17-0.37), 4 weeks 0.19 (0.10, 0.35), 5 weeks 0.23 (0.10, 0.52), 6 weeks 0.20 (0.08, 51) hazard ratios relative to unvaccinated



What are the implications of these results?

For policy makers?

- The vaccination programme to date is likely to be preventing people from developing severe illness due to COVID-19
- Positive news for the vaccine delivery programme
- Positive news for protecting capacity within the NHS hospitals
- No alterations from current JCVI advice
- No effect for transmission policy

For the public?

- When offered, please take your first dose of vaccine
- When offered, please take your second dose of vaccine
- By doing so, you protect yourselves, you family and your friends, and your NHS
- Please continue to stop the spread of transmission by following [public health guidance](#)

Trial & Real World – confluence in results?



| Timing of estimate of vaccine effect relative to date of first dose | Phase III BNT162b2 i.e. Pfizer-BioNTech (PB) % & (95% CI) | Phase III ChAdOx1nCoV-19 i.e. Oxford-AstraZeneca (AZ) % & (95% CI) | Community use Israel (HCW) BNT162b2 i.e. Pfizer-BioNTech (PB) % & (95% CI) | AvonCAP – Bristol, England. Prospective cases in 70+ yrs Hospitalisation (Pre-pub) | PHE – Symptomatic disease & Hospitalisation (Pre-pub) | Scotland- Hospitalisation Both BNT162b2 i.e. Pfizer-BioNTech (PB) AND Oxford-AstraZeneca (AZ) (Pre-pub) |
|---|---|--|--|--|---|---|
| Day 14 | | 66.7% (57.4 to 66.7) | | 79.3 PB 80.4 AZO | | |
| Day 15-21 /15-28 | 89% (52-95) | | 75% (72-84) - All 85% (71-92) - Sym | | | |
| Day 22-90 | | 76% (59%, 86%) | | | | |
| Day 28-35 | | | | | Symptomatic 61% (51-69) PB 60% (41-73) AZO | |
| Day 28-35 | | | | | Hospital 80% PB | 85% (76 to 91) PB 94% (73 to 99) AZO |



Conclusions

- **Strengths**

- National near real-time dataset for virtually the entire Scottish population
- Cohort allows adjustment for many confounders

- **Limitations**

- Small number of observations particularly beyond 28 days for single dose
- Unmeasured confounders may be present that limit interpretation

- **Bottom-line**

- Population-level data demonstrating the real-world effectiveness of the first doses of the Pfizer/BioNTech and Oxford/AstraZeneca vaccines in substantially reducing risk of hospital admission
- Confluence of encouraging hospital vaccine effect estimates from different designs since pre-publication of Scotland results

- **Next steps**

- Further reports on:
 - First doses over longer time periods
 - Effectiveness of second dose
 - Mortality and safety end-points

Setting up a HWs COVID -19 efficacy study in Albania

5.1.2e

Important Steps

- **COVID -19 vaccination strategy**
- **Setting up a COVID -19 vaccination program**
- **Setting up a health care worker COVID-19 vaccination program based on vaccine availability (prioritization and gradual increase)**
- **Improving immunization information system (IIS) by adding COVID -19 vaccine**
- **Establishing a detailed vaccination form and refusal form on paper and within the IIS**
- **Establishing COVID-19 vaccine module within infectious diseases information system**
- **Monitoring vaccine efficacy (HCW, ILI and SARI)**

- **December 2020**
 - Assessment
 - Identification of hospitals
- **January 2020**
 - VE working group – IPH and representatives from hospitals and partners
 - Preparation of the protocol
 - Discussion and approval of the of protocol and presentation to ethical committee
 - Implementation plan
 - Budget preparation
- **February 2020**
 - Aproval from ethical committee
 - Implementation plan and documents
 - Training
 - **Recruitment and Enrolment**
 - Red cap
 - Monitoring
- **March 2020**
 - Enrolment
 - Monitoring

Assessment (1)

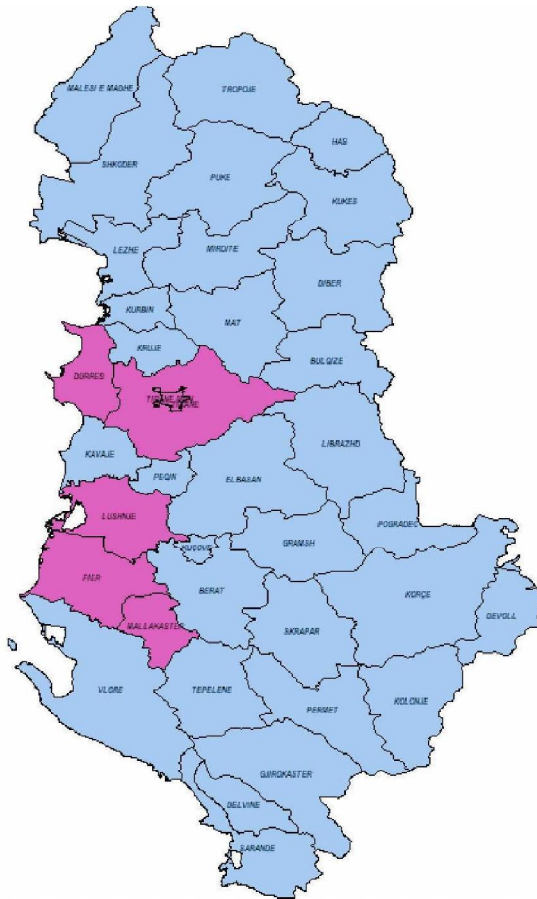
- **HW COVID-19 vaccination ongoing or planned**
- **Commitment from selected hospital administration, heads of medical wards, quality-assured laboratory to participate in studies**
- **Capacity to reliably confirm COVID-19 vaccination status (including date of vaccination and type of vaccine used)**
- **Access to list of HWs at hospital(s) to allow selection of participants according to protocol**
- **Availability of current staff or contractors dedicated to:**
 - **a) follow-up with HW (including specimen collection);**
 - **b) perform data collection, data entry, data validation;**
 - **c) coordinate and supervise the study.**
- **Capacity to directly perform PCR testing for COVID-19 or perform adequate specimen collection, packaging, transport to a reference lab**
- **Capacity to collect sera collection, including centrifuge and transport to -70C freezer**
- **Ability to ensure approval by local ethical review board**
- **Accept monitoring visits from National Public Health Institute team**
- **Number of participating HW staff, including doctors, nurses, and support staff, is at least 1000**

Assessment (2)

- **Previous experience in conducting studies among HW or research involving active surveillance and sample collection for laboratory testing**
- **Electronic medical records where HW vaccination history and comorbidities are available**
- **Experience in conducting vaccine effectiveness studies**
- **Willingness to share anonymised data with WHO for data pooling**

Identification of hospitals

- Good previous collaboration
- Research implementation capacities
- Willingness to perform the study among high burden of COVID-19
- Appreciation of benefits of the study



Identified hospitals

1. **Tirana University Hospital “Mother Theresa”:** 3200 employees;
2. **University Hospital Shefqet Ndroqi:** 470 employees;
3. **Durrës Regional hospital:** 700 employees;
4. **Fier regional hospital:** 527 employees.

VE working group

- IPH representatives - leadership, vaccination program and surveillance office, representatives from hospitals
- Discussions of possibility to implement the study
- Discussions on the protocol
- Identification of challenges and how to address them
- Weekly meetings and ad hoc meetings



Study objective

- **To measure the effectiveness of COVID-19 vaccines against laboratory-confirmed SARS-CoV-2 infection (both symptomatic and asymptomatic) amongst hospital health workers eligible for vaccination..**

Secondary objectives

- What is the effectiveness of Covid-19 vaccine in preventing symptomatic laboratory confirmed SARS-CoV-2 infection?
- What is the effectiveness of Covid-19 vaccine in preventing asymptomatic laboratory confirmed SARS-CoV-2 infection?
- How long does the COVID-19 vaccine confer protection against infection?
- What is vaccine effectiveness by age?
- What is VE by various comorbidities?
- What is the VE in people who have been previously infected with SARS-CoV-2 compared with those who are uninfected?
- Does vaccine effectiveness vary by degree of exposure to COVID-19 patients in the hospital setting and physical distancing practices outside of the hospital?
- Does vaccine effectiveness vary by new strains of SARS-CoV-2 that may emerge?
- What is the effectiveness of one dose of vaccine against infection and for how long?
- Does vaccine effectiveness vary by specific brand of COVID-19 vaccine?

Recruitment and enrolment

- **Recruitment will last for a maximum of 3 months or until the samples size is reached.**
- **Each participant will be followed up for 12 months.**

Inclusion criteria

- All HWs eligible to receive the COVID-19 vaccination according to the national guidelines of Institute of Public Health.
- HWs working at Tirana University Hospital “Mother Theresa”, University Hospital “Shefqet Ndroqi”, Durres Regional hospital and Fier Regional Hospital.
- May enrol HWs who have received their COVID vaccine no more than 4 days prior to the day of enrolment in the study

1500 HWs

Information and questionnaires

Flier for the study

Informed consent

Questionnaires

1. Enrolment questionnaire
2. Weekly symptom follow-up questionnaire
3. Questionnaire for following up ad hoc symptomatic participants
4. 30-day follow-up questionnaire for SARS-CoV-2 PCR- positive participants



- 11 January 2021 start of COVID -19
- Presentation to ethical committee
- Implementation plan
 - Preliminary organisational chart
 - Human resources
 - Laboratory capacities (equipment, kits and reagents etc)
 - Identificaton of staff in selected hospital and IPH and who is doing what
 - Preliminary budget scenarios
 - Very high budget for weekly testing and changes and adaptation of the protocol to ensure the objectives of the study



February 2021

- 2 February 2021 Approval from Ethical committee
- 4 February distribution of fliers in selected hospitals
- Organizational chart
- SoP – follow up positive cases etc
- **Descriptions and Duties of Study Staff**
- Process map
- Laboratory workflow
- Laboratory procedures
- Training agenda and materials and training including site training

February 2021

- 17 February start of the enrollment in Durres Regional Hospital
- Use of paper questionnaires
- 4 IPADs lend by SECID to study staff
- RED CAP training and accounts
- Study preparation in RED CAP
- Monitoring chart

Enrolment



| Table 1 | |
|--------------------------------------|--|
| Total number of participants | 575 |
| Sex | Male 21% Female 79% |
| Age | Range: 23-68 years Median: 44.5 years |
| Previous medical problems | Yes: 23% Hypertension: 11% Obesity: 6% Others (diabetes, chronic kidney disease, chronic liver disease, cancer, neurologic disease, autoimmune disease): 6% No 77% |
| Vaccinated (first dose) | Yes: 65% No: 35% |
| Previously Diagnosed Covid Infection | Yes: 38% No: 62% |
| Current Smoking Status | Smoker: 12.5% Non-smoker: 87.5% |
| Profession | Doctor: 30% Nurse: 59% Other (lab technician, radiology technologist, social worker): 11% |

Challenges

- Set up the study and implement the vaccination program at the same time
- Time constraint to reach the objective due to the start of vaccination program
- Budget constraints
- Revision of protocols
- Training and continuous training amidst the high numbers of cases
- Lack of IPADs and paper questionnaires
- RED CAP training for the field staff

Opportunities

- Motivated staff and willignes to perform the study
- Very good support form hospitals and IPH leadership
- Previpus experience with studies
- Good organisation and organisational chart
- Adaptation of inplementation plan
- Experienced RED CAP coordinator
- Very good support from WHO team
- Excellent support from Boston Children Hospital

Thanks to

[Redacted] 5.1.2e

[Redacted] 5.1.2e

Thanks to WHO Euro and country office and the hub especially to

[Redacted] 5.1.2e

[Redacted] 5.1.2e

Thanks to Boston's Children Hospital

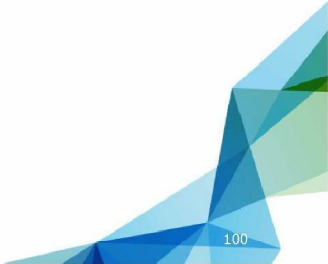
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Overview of vaccine effectiveness monitoring in the European region



Discussion





Monitoring COVID-19 vaccine uptake and effectiveness in Europe



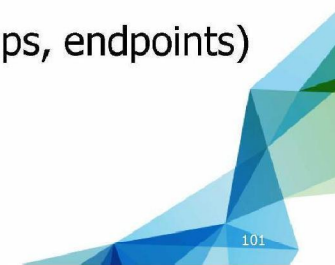
Potential topics for future Joint ECDC/WHO Europe webinars:

- **Uptake monitoring:**

- Early results (in range of settings, vulnerable populations)
- Different approaches (e.g. electronic registers)
- Risk factors for reduced uptake

- **Vaccine effectiveness:**

- In other settings
- Early results (1 vs 2 dose; variant strains; different target groups, endpoints)
- Different methods (e.g. screening method)
- Indirect effects (transmission studies)
- Pooling





Overview of vaccine effectiveness monitoring in the European region



Thank-you

