

COVID-19 vaccine surveillance report Week 41

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Executive summary

Rigorous clinical trials have been undertaken to understand the immune response, safety profile, and efficacy of all COVID-19 vaccines approved for use in the UK as part of the regulatory process. Ongoing monitoring of the vaccines as they are rolled out in the population is important to continually ensure that clinical and public health guidance on the vaccination programme is built upon the best available evidence.

UK Health Security Agency (UKHSA), formerly Public Health England (PHE), works closely with the Medicines and Healthcare Regulatory Agency (MHRA), NHS England, and other government, devolved administration, and academic partners to monitor the COVID-19 vaccination programme. Details of the vaccine surveillance strategy are set on the page <u>COVID-19</u>: vaccine surveillance strategy (<u>1</u>). As with all vaccines, the safety of COVID-19 vaccines is continuously <u>being monitored by the MHRA</u>. They conclude that overall, the benefits of COVID-19 vaccines outweigh any potential risks (<u>2</u>).

This report contains updates on vaccine effectiveness, vaccination in pregnancy, and vaccine impact on the proportion of the population with antibodies to COVID-19.

Vaccine effectiveness

Vaccine effectiveness is estimated by comparing rates of disease (or positivity among those tested) in vaccinated individuals to rates in unvaccinated individuals. Below we outline the latest real-world evidence on vaccine effectiveness from studies in UK populations.

Effectiveness against symptomatic disease

Vaccine effectiveness against symptomatic COVID-19 has been assessed in England based on testing data linked to vaccination data from the National Immunisation Management System (NIMS), cohort studies such as the COVID-19 Infection Survey, and GP electronic health record data.

Effectiveness against hospitalisation

Several studies have estimated vaccine effectiveness against hospitalisation, all of which indicate higher levels of protection against hospitalisation than symptomatic disease with all vaccines against the Alpha, Delta and Omicron variants ($\underline{3}$ to $\underline{8}$). Given that Omicron generally causes milder disease than previous variants ($\underline{9}$), in particular among younger individuals, an increasing proportion of individuals hospitalised with a positive COVID-19 test are likely to have COVID-19 as an incidental finding rather than the primary reason for admission ($\underline{8}$). We therefore use strict definitions to define a COVID-19 hospitalisation - at least 2 days stay in the hospital and a respiratory code in the primary diagnostic field. There are likely still some incidental admissions in our data, in particular among younger adults.

Long-term duration of protection of monovalent vaccines

All adults in the UK have been offered a primary course and a booster. The last booster offered to all adults was a dose of monovalent Moderna or Pfizer vaccine in autumn 2021. We estimated the duration of protection of the monovalent vaccines against hospitalisation in adults who have not received any further doses of bivalent boosters (<u>Table 1</u>). We found protection is long-lasting, plateauing from around 6 months after the most recent dose with a modest level of protection observed even after 15 or more months. Amongst those aged 65 years and older, protection plateaued at around 50% after a year. Effectiveness was estimated compared to the unvaccinated.

Table 1. Absolute vaccine effectiveness (VE) against hospitalisation of a second or at
least a third dose of the monovalent vaccines amongst those aged 18 to 64 and those
aged 65 years and older

Dose	Interval	VE against hospitalisation: 18 to 64 years	VE against hospitalisation: 65+ years
2	3 to 5 months	65.8 (44.1 to 79.1)	71.7 (50.5 to 83.8)
	6 to 8 months	42.0 (20.8 to 57.5)	57.6 (38.6 to 70.7)
	9 to 11 months	19.0 (-2.1 to 35.7)	51.2 (31.2 to 65.4)
	12 to 14 months	31.0 (17.3 to 42.3)	35.5 (23.3 to 45.8)
	15+ months	25.2 (9.6 to 38.2)	40.2 (31.0 to 48.1)
Booster (3+ doses)	3 to 5 months	46.4 (36.6 to 54.7)	65.3 (61.7 to 68.6)
	6 to 8 months	38.9 (30.8 to 46.0)	53.6 (48.8 to 58.0)
	9 to 11 months	28.8 (18.6 to 37.8)	51.1 (45.7 to 56.0)
	12 to 14 months	18.3 (-6.5 to 37.3)	52.3 (43.7 to 59.6)
	15+ months	Insufficient data	Insufficient data

Effectiveness of the autumn 2022 bivalent booster

Bivalent boosters with either Pfizer BioNTech (Original/Omicron BA.1 Comirnaty®) or a Moderna bivalent (Spikevax® bivalent Original/Omicron BA.1 vaccine) targeting both the ancestral strain and Omicron BA.1 were offered to those in clinical risk groups and those aged 50 years and older from September 2022. VE of the bivalent boosters was estimated against hospitalisation in the period following 5 September 2022 against all Omicron sub-lineages in circulation at the time. Only individuals who had received at least 2 COVID-19 vaccines before 5 September 2022 and with the last of these doses at least 6 months prior to the sample date were included in the analysis.

The effectiveness measured is therefore incremental effectiveness on top of at least 6 months of waned protection. The incremental protection conferred by the bivalent vaccines estimated relative to those with waned immunity was 47% for Pfizer after 2 to 4 weeks and 58% for Moderna. After 25 or more weeks after vaccination VE was 21% for the Pfizer booster and 20% for the Moderna booster (Table 2).

Table 2. Vaccine effectiveness of the bivalent booster vaccines against hospitalisation in
those aged 50 years and older (VE = vaccine effectiveness, CI = confidence intervals)

Vaccine manufacturer	Interval after booster dose	Controls	Cases	VE (95% CI)
Pfizer	2 to 4 weeks	1,849	315	47.4 (40.1 to 53.7)
	5 to 9 weeks	5,395	884	44.9 (40 to 49.4)
	10 to 14 weeks	4,925	1128	34.5 (29 to 39.5)
	15 to 19 weeks	2,636	1008	28 (21.1 to 34.4)
	20 to 24 weeks	1,297	605	25.2 (15.6 to 33.6)
	25+ weeks	41	18	20.8 (-41.6 to 55.7)
Moderna	2 to 4 weeks	1,130	313	58.1 (51.9 to 63.5)
	5 to 9 weeks	3,807	672	48.1 (42.8 to 53)
	10 to 14 weeks	8,597	1649	36.9 (32.2 to 41.3)
	15 to 19 weeks	4,899	1273	31.1 (25.3 to 36.4)
	20 to 24 weeks	3,385	1580	23.6 (16.9 to 29.8)
	25+ weeks	1,158	594	19.6 (8.7 to 29.2)

Effectiveness of the spring 2023 bivalent booster

Booster vaccines with either the Sanofi/GSK AS03-adjuvanted monovalent beta variant (VidPrevtyn Beta) booster vaccine, the Pfizer-BioNTech mRNA (Comirnaty Original/Omicron BA.4-5) bivalent vaccine and the Moderna mRNA (Spikevax bivalent Original/Omicron BA.4-5) bivalent vaccine were offered to all adults aged 75 years and older, and immunosuppressed individuals as part of the spring booster vaccination programme in England. The programme commenced from 3 April 2023, with care home residents being prioritised for vaccination initially. The Sanofi/GSK booster was rolled out first, followed by Pfizer BA.4-5 and Moderna BA.4-5. Very few doses of Moderna BA.4-5 were administered, and we were unable to estimate vaccine effectiveness.

VE of the Sanofi/GSK and Pfizer BA.4-5 boosters was estimated against hospitalisation amongst those aged 75 years and older from 3 April against all Omicron sub-lineages in circulation at the time (<u>Table 3</u>). Only individuals who had received at least 2 doses before their spring booster and whose last dose was a bivalent BA.1 booster given at least 3 months prior were included. The effectiveness measured is therefore incremental effectiveness on top of at least 3 months of waned protection. Effectiveness against hospitalisation was highest in the

period 9 to 13 days post vaccination for both manufacturers at about 50%; 43.6% and 56.4% for Sanofi/GSK and Pfizer BA.4-5, respectively. Confidence intervals overlapped so the difference in the VE point estimates was not statistically significant. There was some evidence of waning with a reduction to about 30% for both manufacturers 5 to 9 weeks post vaccination.

Spring booster [note 1]	Interval	Controls	Cases	Odds ratio	VE (95% C.I.)
None	-	6,334	2,150	Baseline	Baseline
Sanofi	9 to 13 days	212	41	0.56 (0.4 to 0.8)	43.6 (20.1 to 60.2)
	2 to 4 weeks	808	156	0.67 (0.55 to 0.81)	33.2 (18.9 to 45.0)
	5 to 9 weeks	1,015	131	0.67 (0.54 to 0.83)	33.3 (17.0 to 46.4)
	10+ weeks	855	203	0.82 (0.65 to 1.03)	17.7 (-3.5 to 34.6)
Pfizer BA.4-5	9 to 13 days	136	16	0.44 (0.26 to 0.74)	56.4 (25.8 to 74.4)
	2 to 4 weeks	483	52	0.47 (0.35 to 0.64)	52.9 (36.2 to 65.2)
	5 to 9 weeks	567	86	0.71 (0.54 to 0.92)	29.5 (7.9 to 46.0)
	10+ weeks	269	63	0.62 (0.44 to 0.87)	37.8 (13.1 to 55.5)

Table 3. Vaccine effectiveness (VE) against hospitalisation amongst those aged 75 yearsand older in England, stratified by spring booster manufacturer

Note 1. All individuals had received a bivalent BA.1 booster vaccine as part of the autumn 2022 booster programme, and their last dose was at least 3 months prior to their test.

Effectiveness against mortality (vaccines given prior to the autumn 2022 bivalent boosters)

Vaccine effectiveness against mortality with the Omicron variant (all sub-lineages using tests taken until 5 September 2022) has been estimated for those aged 65 years and older using a test-negative case control study design (all vaccines combined) (<u>Table 4</u>). At 40-plus weeks following the second dose, vaccine effectiveness was around 50%. At 2 or more weeks following the third and fourth dose vaccination, effectiveness was boosted to 85.0% and 80.9%, respectively. At 40 or more weeks after a third dose VE waned to 56.9% while at 20 or more weeks after a fourth dose (spring 2022 booster) VE waned to 68.2%. This analysis is also likely to include some incidental deaths of individuals who died with COVID-19 as opposed to from COVID-19, and we suspect the true VE against mortality is likely higher than the estimates presented here.

Table 4. Vaccine effectiveness against mortality in those aged 65 years and older (al
vaccine brands combined) (VE = vaccine effectiveness, CI = confidence intervals)

Dose	Interval after dose (weeks)	VE (95% CI)
2	40+	49.7 (41.5 to 56.7)
3	2 to 4	85.0 (80.8 to 88.2)
	5 to 9	83.1 (80.3 to 85.5)
	10 to 14	79.5 (76.6 to 82.0)
	15 to 19	75.6 (72.3 to 78.6)
	20 to 24	68.8 (64.3 to 72.7)
	25 to 39	62.6 (57.4 to 67.2)
	40+	56.9 (43.1 to 67.4)
4	2 to 4	80.9 (76.8 to 84.3)
	5 to 9	79.5 (75.8 to 82.7)
	10 to 14	71.2 (66.2 to 75.5)
	15 to 19	68.2 (61.2 to 73.9)
	20+	68.2 (58.4 to 75.7)

Consensus vaccine effectiveness estimates

 Table 5. Consensus estimates of incremental vaccine effectiveness of the autumn 2022 booster programme and earlier monovalent booster doses

 These results relate to a period when BA.4, BA.5, BQ.1 and CH1.1 Omicron circulated and are relative to 6+ months since the last dose (at least 2 doses).

Vaccine product of booster dose [note 1]	Outcome	0 to 1 months	2 to 3 months	4 to 6 months	6+ months	Consensus narrative
Monovalent	All Infection [Note 2]	30% (20 to 40%)	20% (10 to 30%)	10% (0 to 20%)	0% (0 to 5%)	Post fourth dose estimates appear similar to po period, restoring VE to similar levels provided b estimates may differ depending on whether indi studies suggest VE estimates may be slightly hi to Omicron BA.4/BA.5.
Monovalent	Symptomatic [Note 2]	40% (30 to 50%)	40% (30 to 50%)	10% (0 to 20%)	Insufficient data	Post fourth dose estimates appear similar to poperiod, restoring VE to similar levels provided by estimates may differ depending on whether indi
Monovalent	Hospitalisation	55% (40 to 65%)	45% (30 to 55%)	20% (15 to 25%)	0% (0 to 5%)	These estimates are based on UKHSA test neg hospitalisations in age 75+ with 2+ days stay ar studies covering autumn 2023. Note: As absolu months post dose 3, a relative VE of 50% would 85% compared to unvaccinated. Some studies are similar for BA.2 versus BA.4/BA.5.
Monovalent	Mortality	Insufficient data	Insufficient data	Insufficient data	Insufficient data	
Bivalent	All Infection [note 2]	30% (20 to 40%)	20% (10 to 30%)	10% (0 to 20%)	0% (0 to 5%)	Estimates for the BA.1/BA.2 bivalent booster are with BA.4/BA.5 bivalent boosters.
Bivalent	Symptomatic [note 2]	40% (30 to 50%)	40% (30 to 50%)	10% (0 to 20%)	Insufficient data	
Bivalent	Hospitalisation	55% (40 to 65%)	45% (30 to 55%)	30% (20 to 60%)	Insufficient data	Estimates for the BA.1/BA.2 bivalent booster are with BA.4/BA.5 bivalent boosters. There is some slightly lower against CH1.1 compared to BA.4/
Bivalent	Mortality	60% (20 to 80%)	55% (20 to 75%)	35% (10 to 75%)	Insufficient data	

The table presents estimates of VE compared to 6+ months since the last dose (at least 2 doses) (estimates agreed by the vaccine expert panel).

Note 1. Refers to either Pfizer or Moderna.

Note 2. Estimates were not stratified according to monovalent or bivalent.

High confidence	Evidence from multiple studies which is consistent and comprehensive.
Medium confidence	Evidence is emerging from a limited number of studies or with a moderate level of uncertainty.
Low confidence	Little evidence is available, and results are inconclusive.

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e not too different from what is being seen e evidence that VE against hospitalisation is /BA.5.

Table 6. Consensus estimates of incremental vaccine effectiveness of the spring 2023 booster programme

These results relate to a period when XBB Omicron sublineages were circulating and are relative to 3+ months since the autumn 2022 booster.

Vaccine product of booster dose	Outcome	0 to 1 months	2 to 3 months	4 to 6 months	6+ months	Consensus narrative
SP-Monovalent	Hospitalisation	45% (30 to 65%)	30% (10 to 45%)	Insufficient data	Insufficient data	
Moderna BA4/5 Bivalent	Hospitalisation	45% (30 to 65%)	30% (10 to 45%)	Insufficient data	Insufficient data	

The table presents estimates of VE compared to 6+ months since the last dose (at least 2 doses) (estimates agreed by the vaccine expert panel).

Note 1. Refers to either Pfizer or Moderna.

Note 2. Estimates were not stratified according to monovalent or bivalent.

High confidence	Evidence from multiple studies which is consistent and comprehensive.
Medium confidence	Evidence is emerging from a limited number of studies or with a moderate level of uncertainty.
Low confidence	Little evidence is available, and results are inconclusive.

Effectiveness against XBB.1.5, CH.1.1 and BQ.1

Sub-lineages CH.1.1 and XBB.1.5 increased in prevalence in England in December 2022 and January 2023, respectively. VE against hospitalisation for XBB.1.5, CH.1.1. and BQ.1 was estimated during a period of co-circulation between 5 December 2022 and 19 February 2023 (Table 7). During this period, BA.5 was not a prominent sub-lineage. Cases were classified based on sequencing information. Cases were classified as XBB.1.5 (V-23JAN-01), CH.1.1 (V-22DEC-01) or BQ.1 (V-22OCT-01) based on sequencing information, and VE was estimated as described above. VE of the bivalent BA.1 boosters given as part of the autumn 2022 booster programme was measured in addition to at least 6 months of waned protection. We did not find a significant difference in VE and these results provide reassuring evidence that the bivalent BA.1 booster vaccines provide similar protection against hospitalisation with BQ.1, CH.1.1 and XBB.1.5.

Variant	Bivalent booster	Controls	Cases	VE (%)
XBB.1.5	None	48,099	338	Baseline
	2 to 4 weeks	3,374	6	Insufficient data
	5 to 9 weeks	20,700	20	52.7 (24.6 to 70.4)
	10 to 14 weeks	45,087	109	35.0 (18.1 to 48.4)
	15+ weeks	69,263	883	21.1 (9.6 to 31.1)
CH.1.1.	None	48,099	211	Baseline
	2 to 4 weeks	3,374	11	36 (-18.3 to 65.4)
	5 to 9 weeks	20,700	80	29.7 (7.5 to 46.6)
	10 to 14 weeks	45,087	214	28.3 (12.2 to 41.5)
	15+ weeks	69,263	348	24.5 (8.6 to 37.7)
BQ.1	None	48,099	509	Baseline
	2 to 4 weeks	3,374	22	66.7 (48.7 to 78.4)
	5 to 9 weeks	20,700	218	48.0 (38.5 to 56.0)
	10 to 14 weeks	45,087	495	41.1 (32.8 to 48.3)
	15+ weeks	69,263	394	30.5 (18.7 to 40.6)

Table 7. VE estimates against hospitalisation with XBB.1.5, CH.1.1 and BQ.1 for the bivalent boosters in those aged 50 years and older

Vaccine effectiveness publications

UKHSA and collaborators have published a significant amount of <u>research into vaccine</u> <u>effectiveness</u>, which is summarised on pages 4 to 13. The publications listed in <u>Table 8</u> provide further results and details on the methods used.

Table 8. UKHSA	publications of	on the effectiv	veness of COVID-	19 vaccination
	publicationo (

Publication	Subject
Direct and indirect impact of the vaccination programme on COVID-19 infections and mortality	This study estimates the direct and indirect impact of the COVID-19 vaccination using a real-time model developed by PHE and Cambridge.
Impact of COVID-19 vaccines on mortality in England: December 2020 to March 2021	This study estimates the number of deaths prevented by vaccination in England between the start of the vaccination programme and the end of March 2021.
Impact of COVID-19 vaccines on mortality in England: December 2020 to February 2021	This study estimates the number of deaths prevented by vaccination in England between the start of the vaccination programme and the end of February 2021.
PHE monitoring of the early impact and effectiveness of COVID-19 vaccination in England, March 2021	This report presents COVID-19 vaccine effectiveness against symptomatic disease, infection, and severe disease, including data up to March 2021.
PHE monitoring of the early impact and effectiveness of COVID-19 vaccination in England, February 2021	This report presents COVID-19 vaccine effectiveness against symptomatic disease, infection, and severe disease, including data up to February 2021.

Population impact

Vaccines typically have both direct effects on those who are vaccinated and indirect effects on the wider population due to a reduced probability that people will come into contact with an infected individual. The overall impact of the vaccination programme may therefore extend beyond that estimated through vaccine effectiveness analysis.

Estimating the impact of a vaccination programme is challenging as there is no completely unaffected control group. Furthermore, the effects of the vaccination programme need to be differentiated from that of other interventions (for example, lockdowns or outbreak control measures), changes in behaviour and any seasonal variation in COVID-19 activity.

UKHSA and other government and academic partners monitor the impact of the vaccination programme on levels of COVID-19 antibodies in the population and different disease indicators, including hospitalisations and mortality. This is done through population-based testing and through modelling which combines vaccine coverage rates in different populations, estimates of vaccine effectiveness and disease surveillance indicators.

Vaccination in pregnancy

Pregnant women have been included in the groups of people at greatest risk of severe COVID-19 illness who have been advised by the Joint Committee on Vaccination and Immunisation (JCVI) to have a dose of <u>COVID-19 vaccine in autumn 2023</u>. Vaccination of pregnant women is strongly recommended by the <u>Royal College of Obstetricians and Gynaecologists and the Royal</u> <u>College of Midwives</u>.

Increased severity of COVID-19 disease in pregnant and recently pregnant women was reported after the first SARS-CoV-2 wave in England (<u>10</u>, <u>11</u>) and Scotland (<u>12</u>,<u>13</u>) when Alpha and Delta variants were dominant. The disease is generally reported to be milder during the Omicron era with reduced risk of complications in pregnant women when compared to the Delta period (<u>14</u>,<u>15</u>). Omicron has, however, also been associated with higher rates of infection in pregnant women when compared to Delta (<u>15</u>) and led to intensive care admission, particularly in those who remain unvaccinated (<u>16</u>). Pregnant women who develop severe disease have been found to have increased rates of maternal admission to critical care or death, venous thromboembolism, pre-term delivery and very pre-term delivery due to medical intervention (<u>17</u>).

Data from the US Centers for Disease Control and Prevention (CDC) found that pregnant women were around 3 times more likely to be admitted to ICU and nearly 3 times more likely to require invasive ventilation compared to non-pregnant women with COVID-19 disease and 25% more likely to die (<u>18</u>).

From 16 April 2021, the JCVI advised that pregnant women be offered COVID-19 vaccines at the same time as people of the same age or risk group (<u>19</u>). Therefore, any pregnant women not in a high-risk group would likely have received their first dose in mid-April 2021 as part of the general adult population programme in those aged under 50 years which was offered by decreasing age group (<u>19</u>). As part of the ongoing review of the programme, the JCVI met on 2 December 2021 and considered further data on the severity of SARS-CoV-2 infection in pregnant women and their pregnancies together with data on vaccine safety. As a result, pregnant women were added to the UK's priority COVID-19 vaccine list (<u>20</u>). The booster dose made available to all individuals with severe immunosuppression from September 2021 and then extended to all eligible adults in England from 30 November 2021, was important to confer high levels of protection against Omicron strains (see report section vaccine effectiveness).

Pregnant women were included as one of the priority groups to be offered the autumn 2022 COVID-19 booster dose using the Pfizer-BioNTech and Moderna bivalent vaccines. This section of the COVID-19 vaccine surveillance report summarises the autumn 2022 vaccine coverage based on women who gave birth between 1 September 2022 and 30 June 2023. Over this period most of those who were pregnant during the offer of the 2022 autumn dose would have given birth. This updates the coverage data on COVID-19 vaccination in pregnant women published in the <u>COVID-19 vaccine surveillance report</u> - weeks 47 of 2021, 4, 8, 12, 16, 19 and 35 of 2022, weeks 5, 9, 14 and 23 of 2023. Pregnancy outcome data relating to vaccination in pregnancy during this period is being compiled for peer-reviewed publication.

There is evidence of high levels of protection against SARS-CoV-2 infection in pregnant women after COVID-19 vaccination (21 to 24) and evidence that vaccination induces higher antibody levels than after disease (24). There is also evidence from recent studies in England and the USA that 2-doses of mRNA COVID-19 vaccination during pregnancy might help prevent COVID-19 hospitalisations in young infants under 6 months of age (25) with increased protection observed after a booster dose (26). Between February and September 2021, 0.4% of 1,714 pregnant women with COVID-19 symptoms who required hospital treatment in the UK had received 2 doses of COVID-19 vaccine and, of 235 pregnant women who were admitted to intensive care with COVID-19 disease in that period, none had received 2 doses of vaccine (27). Similar findings have been reported from Scotland with the report that 90.9% (748 out of 823; 95% CI 88.7 to 92.7) of SARS-CoV-2 associated with hospital admissions, 98% (102 out of 104; 95% CI 92.5 to 99.7) of SARS-CoV-2 associated with critical care admission and all baby deaths, occurred in pregnant women who were unvaccinated at the time of their COVID-19 diagnosis (13,28). The researchers also found a higher extended perinatal mortality rate for women who gave birth within 28 days of a COVID-19 diagnosis compared to rates across the pandemic period and in women vaccinated and going on to give birth within 28 days.

COVID-19 vaccines used in the UK programme do not contain live SARS-CoV-2 virus and therefore cannot infect a pregnant woman or her unborn child with the virus. Whilst as is commonly the case in trials of medicinal products, pregnant women were excluded from the original COVID-19 vaccine trials, there is accumulating experience and evidence of the safe and effective use of mRNA vaccines (such as the Pfizer-BioNTech or Moderna) in pregnant women.

In Scotland, the COVID-19 vaccine had been administered to more than 30,000 pregnant women by the end of March 2022 (29). In the USA data collected by the US Centre for Disease Control indicated that around 71% of pregnant people were fully vaccinated before or during pregnancy in the week ending 20 August 2022 (30).

No safety concerns relating to COVID-19 vaccination of pregnant women have been found in published studies to date (<u>17</u>, <u>30</u> to <u>35</u>). The rate of vaccine side effects appears to be similar in pregnant and non-pregnant populations (<u>30</u>). Studies from Norway, the USA and Scotland have found no association between COVID-19 vaccination and the risk of miscarriage (<u>32</u> to <u>35</u>).

Findings continue to be provisional and are not directly comparable between reports as data is updated through the complete period under consideration. All previous reports to week 9 2023 additionally included pregnancy outcomes (stillbirth, low birth weight and preterm deliveries) but women delivering in the most recent months with maternity data available have overwhelmingly been vaccinated with doses 1 to 3 before the pregnancy for which they are giving birth (Figure 1). These pregnancy outcomes would therefore not be expected to substantively alter previously published data.

This report will be the final to include data on coverage of the 2022 autumn boost that was recommended to those at higher risk of severe COVID-19 disease in the population who had not been boosted for at least 3 months, including pregnant women. It includes women who had previously given birth in the period from January 2021 when COVID-19 vaccines were first being used in women at high risk of exposure or in a clinical risk group. Autumn boost vaccination began in September 2022.

Vaccine coverage

COVID-19 vaccine coverage in women at any point before they gave birth increased as more women became eligible for vaccination. In November 2021, 48.2% of women giving birth had received at least one dose of vaccine before they delivered. This increased from 53.4% of women who gave birth in December 2021, to 72.9% of women delivering by June 2022 when it stabilised, peaking in October 2022 at 75.3%. (COVID-19 vaccine quarterly surveillance reports September 2021 to June 2023). Of women who gave birth in December 2021, 42.9% had received 2 doses of the vaccine before they gave birth increasing to 67.1% of women giving birth in June 2022 and peaking at 70.3% of women who gave birth in October 2022. By October 2022 most first, second and third doses of vaccine given to women who gave birth were administered before the start of their pregnancy (COVID-19 vaccine quarterly surveillance reports September 2021 to June 2023).

In the 10 months between September 2022 and June 2023, a total of 413,800 women gave birth with linked records on prior vaccination status for 411,520 (99.4%). Of women with linked records who gave birth over this period, 305,774 (74.3%) were known to have received at least one dose of COVID-19 vaccine prior to giving birth, 285,820 (69.5%) received at least 2 doses, 182,530 (44.4%) women had received at least 3 doses. Through September 2022 to June 2023,

25.7% of women had not received any doses of the COVID-19 vaccine before they gave birth. In that 10-month period, 302,488 women who gave birth (73.5% of all those who gave birth during that time) had received their first dose prior to conception.

A small proportion of women who gave birth in September (0.5%) 2022 had received an autumn booster dose prior to delivery, rising to 18.1% in January 2023 and peaking at 19.0% in February 2023 (Figure 1). Only 13.1% of women had received the autumn 2022 dose before giving birth between September 2022 and June 2023. A very small proportion of women (1.3% in the 10-month period) received the autumn boost after they gave birth, falling from 6.5% of women who gave birth in September 2022 to 0.1% of women who delivered in January and February 2023. Thirty-one percent of women who received a bivalent booster during pregnancy had the Moderna vaccine and 69% received the Pfizer vaccine. Thirteen percent were vaccinated in the first trimester, 35% in the second, 25% in the third trimester and in 27% of those who received the bivalent dose in pregnancy the trimester of vaccination was not known.

Differences in coverage by age group, ethnicity and quintile of multiple deprivation persist (<u>Table 9</u>).





Table 9. Vaccine coverage in women giving birth between September 2022 (when the Autumn boost was first offered) and June 2023 by age group, ethnicity and quintile of deprivation (where 1 is most deprived and 5 is most affluent) [note 1] [note 2]

Age group	% receiving autumn dose before giving birth	Ethnicity	% receiving autumn dose before giving birth	Quintile of multiple deprivation	% receiving autumn dose before giving birth
Under 20	2.2%	Asian	6.8%	1	5.1%
20 to 24	3.7%	Black	3.5%	2	9.7%
25 to 29	7.0%	Mixed	9.5%	3	14.7%
30 to 34	15.4%	Other	9.5%	4	18.7%
35 to 39	20.5%	White	15.6%	5	23.9%
40 and above	19.9%	Unknown	12.0%	Unknown	9.1%

Note 1. In this period 4,039 women could not be matched with a NIMS record. Their vaccine status is therefore unknown and they are excluded from these coverage figures. Note 2. Unlike previous reports, women giving birth in this period includes women who have previously given birth in the period of the HES maternity data extracts used from January 2021.

Methods

Data on COVID-19 vaccination status, together with details of each vaccine administered, is recorded in a central data set called the NIMS¹. In addition, NHS Digital manages the Hospital Episode Statistics (HES) data sets, containing information about hospital activity in England.

Records of women giving birth ('delivery records') in the months between 1 September 2022 and 30 June 2023 were identified in HES. De-duplication of delivery records resulted in a data set of women who had given birth with one record per woman, identified by her NHS Number, and the latest 'delivery episode' associated with her. An 'earliest' and 'latest' likely pregnancy start date were assigned to each woman's record, using the known delivery date and further information from her record, where available:

 Where a valid gestational age was recorded (GESTAT_1 between 24 and 42), the woman's earliest pregnancy start date was calculated by taking the number of weeks away from the delivery date and then calculating an additional earlier week, to account for GESTAT_1 recording completed weeks of pregnancy. In a similar way, the latest pregnancy start date was calculated by taking the number of weeks of GESTAT_1 away from the delivery date.

¹ NIMS Data controllers are NHSEI and NHSD. The NIMS IT software is commissioned by NHSEI via South Central West CSU and is provided by the System C and Graphnet Care Alliance.

- 2. Where no valid GESTAT_1 was available, the first 12 diagnostic codes were examined to identify any with a code suggesting delivery at term (O60.2). In this case, the gestational age at delivery was assumed to be between 37 and 42 completed weeks of pregnancy, and a similar method was used to establish the earliest and latest pregnancy start dates.
- 3. Where no valid GESTAT_1 was available and there were no codes suggesting term delivery, the first 12 diagnosis codes were examined to identify any suggesting preterm delivery (O60.1 or O60.3). In this case, the gestational age at delivery was assumed to be between 24 and 36 completed weeks of pregnancy, and these values were used to establish the earliest and latest pregnancy start dates.
- 4. In the absence of any additional information in the woman's record (or in conflicting cases where diagnostic codes suggesting both term and pre-term delivery appeared in the same record), the gestational age at delivery was assumed to be between 24 and 42 completed weeks of pregnancy, and these values were used to establish earliest and latest pregnancy start dates.

Each woman's delivery record was linked to her records in the NIMS using the NHS Number, establishing her vaccine status as either having had one or more doses before delivery (including any prior to becoming pregnant) or not having had any doses of the vaccine prior to giving birth, using the NIMS vaccine records. For a woman to be identified as having had the autumn booster dose bivalent vaccine was recorded in NIMS on or after 1 September 2022 to 28 February 2023 when the spring programme was announced and the targeted risk groups did not include all risk categories, including pregnancy.

Dose administered pre-pregnancy	Dose administered before the earliest pregnancy start date
Dose administered in pregnancy	Dose administered after the latest pregnancy start date and before the delivery date
Dose administered post- pregnancy	Dose administered on or after the delivery date based on NIMS records extracted on 20 September 2023
Dose in pregnancy: unknown	Dose administered around the start of pregnancy: after the earliest pregnancy start date and before the latest pregnancy start date
Unvaccinated	No vaccine records exist for the woman, based on the NHS number

For each vaccine dose in the 2022 autumn boost period the woman was known to have received, the following information was ascertained:

The ethnicity, residence and age information when used was taken from the NIMS record. The analysis within this section was carried out on 20 September 2023. The latest HES data available was for June 2023, and all HES data since April 2023 is considered provisional.

Interpretation and limitations

Previously published findings have supported vaccine safety in pregnancy from COVID-19 vaccine surveillance reports from week 47 2021 onwards <u>COVID-19 vaccine weekly</u> <u>surveillance reports (weeks 39 to 40, 2021 to 2022)</u> and from <u>analyses published by Public Health Scotland</u>.

More detailed statistical analyses are planned (see <u>COVID-19 vaccination in pregnancy</u> <u>surveillance protocol</u>). There are recognised limitations of the data sets including the level of completeness of the relevant fields. Adverse pregnancy outcomes considered in earlier reports are routinely reported as official statistics annually by ONS, (see <u>COVID-19 hospital admissions</u> <u>by vaccination and pregnancy status, England</u>), however, HES data was used to monitor outcomes more quickly than ONS data allows.

Main findings

COVID-19 vaccination is the safest and most effective way for women to protect themselves and their pregnancies against severe COVID-19 disease. The JCVI has advised that women who are pregnant are in a clinical risk group within the COVID-19 autumn vaccine programme. Unvaccinated women who became pregnant were strongly encouraged to come forward for vaccination during the autumn 2022 booster programme. Women who were pregnant and had previously been vaccinated were offered a booster dose (<u>Joint Committee on Vaccination and Immunisation (JCVI) updated statement on the COVID-19 vaccination programme for autumn 2022</u>). Pregnancy is a risk category that has been included by the JCVI for the autumn 2023 COVID-19 vaccine dose.

This is the fourth and final report that includes coverage data for women who received the COVID-19 2022 autumn boost vaccination before giving birth in England between September and June 2023. Coverage peaked with 19.0% of those who gave birth in February 2023 receiving this vaccine and was 13.1% overall during the 10-month period. Those in the youngest age groups, of non-white ethnicity and living in the most deprived areas in England were least likely to receive the autumn 2022 boost before they gave birth. Prior to the autumn 2022 dose, Asian women had the second highest rates of coverage for COVID-19 vaccine doses administered in pregnancy whereas during this 10-month period only women of black ethnicity had lower coverage.

Estimation of hospitalisations averted from the autumn 2022 bivalent booster programme

The autumn 2022 vaccination programme was offered to all adults aged 50 years and older as well as those aged 5 to 49 years in clinical risk groups and frontline health and social care workers (see the <u>JCVI statement on the COVID-19 booster vaccination programme for autumn 2022: update 3 September 2022</u>).

The main vaccines used during this programme were bivalent ancestral/Omicron BA.1 mRNA vaccines. The number of hospitalisations averted in those aged 50 years and over during the autumn 2022 COVID-19 vaccine booster campaign was estimated by considering: (a) vaccine effectiveness against hospitalisation of the booster doses from this period and how it wanes (<u>1</u>), (b) vaccine coverage, and (c) observed hospitalisations. Hospitalisations were defined as admissions with a respiratory code in the primary diagnosis field which were associated with a positive COVID-19 test or as admissions where COVID-19 was the primary diagnosis using hospital admission data from the secondary uses service (SUS).

The relative vaccine effectiveness (rVE) of receiving a bivalent BA.1 booster vaccine in addition to at least 2 doses of a prior monovalent vaccine was used in the calculation. This was taken to be 40%, 50%, 40%, 30%, 20%, 20%, 10% in months 1 to 7 after vaccination, respectively, to allow for waning following a peak in the second month, which has been seen following booster doses (<u>36</u>). Coverage by the end of the 2022 varied from 45% for those aged 50 to 54 to 82% for those aged 70 to 74.

In each week the impact of vaccination was calculated as the cumulative coverage in that week multiplied by the estimated effectiveness for that week. For example, 70% uptake and 30% effectiveness gives an estimated 21% reduction. The expected number of hospitalisations in the absence of vaccination is then calculated as observed divided by 1 minus the reduction (for example 1 - 0.28) and the averted as expected minus observed. This was done across 5-year age bands and across weeks 36 of 2022 to 12 of 2023 and then summed to get an overall estimate.

Figure 2 shows the observed and estimated averted hospitalisations by week. In total an estimated 14,400 hospitalisations were averted in adults aged 50 years and older in England as a result of the vaccination in the autumn 2022 COVID-19 vaccine booster programme. Note that this calculation is a direct calculation and does not include any additional cases prevented from herd immunity. It also does not include cases averted where COVID-19 exacerbated a non-respiratory condition that led to hospitalisation.



Figure 2. Observed COVID-19 hospitalisation and the estimated number averted from vaccination by week autumn to winter 2022 to 2023, aged 50 and over

Date

Vaccine impact on proportion of population with antibodies to COVID-19

Seroprevalence

The results from testing samples provided by healthy adult blood donors aged 17 years and older, supplied by the NHS Blood and Transplant (NHS BT collection) between weeks 35 2020 and week 35 2023 are summarised. As of week 44 2020, approximately 250 samples from each geographic NHS region are tested each week.

The COVID-19 vaccination campaign began on 8 December 2020 (week 50) with a phased rollout by age and risk group. Booster doses have been offered from the beginning of September 2021. Booster doses are typically offered in spring and autumn to populations in risk groups. A spring 2023 booster was introduced from 3 April 2023 for adults aged 75 years and older, older adults in care homes and immunosuppressed individuals aged 5 years and older. The offer of the spring 2023 booster was available until the end of June 2023 and was offered at least 3 months after the last dose. The 2023 autumn booster programme began in September 2023 for adults aged 65 and older, people in clinical risk groups, older adults in care homes, health and social care workers and individuals who live closely with or are carers for clinically vulnerable people. We intend to monitor the programme and its impact on seroprevalence in the coming months.

Seroprevalence in blood donors aged 17 years and older

The results presented here are based on testing samples with Roche nucleoprotein (N) and Roche spike (S) antibody assays.

Nucleoprotein (Roche N) assays only detect post-infection antibodies, whereas spike (Roche S) assays will detect both post-infection antibodies and vaccine-induced antibodies. Thus, changes in seropositivity for the Roche N assay reflect the effect of natural infection. Increases in seropositivity as measured by S antibody reflect both infection and vaccination. Antibody responses to both targets reflect infection or vaccination occurring at least 2 to 3 weeks previously given the time taken to generate a COVID-19 antibody response. Currently, donors are asked to defer donations for at least 48 hours post vaccination (previously 7 days), and for at least 10 full days after a positive COVID-19 test as well as 7 days following resolution of any symptoms (previously 28 days, changes were implemented during January 2022).

This report presents Roche N and Roche S seropositivity estimates on the same set of samples, using a 12-week rolling prevalence for national, age group and regional estimates. Seropositivity estimates are plotted using the mid-point of a 12-weekly rolling period that reduces to 8 weeks in the most recent weeks to allow for a more representative current estimate of seropositivity. However, this also means the data will reflect seroprevalence several

weeks previously. Seroprevalence estimates reported are based on seropositivity which are unadjusted for the sensitivity and specificity of the assays used.

National prevalence

Overall population weighted (by age group, sex and NHS region) antibody prevalence among blood donors aged 17 years and older in England was 87.2 % (95% CI 86.5% to 87.8%) using the Roche N assay and 99.9% (95% CI 99.8% to 100.0%) using the Roche S assay for the period 12 July to 3 September 2023 (week 28 to week 35 2023). 12,218 out of 14,035 were Roche N positive and 14,024 out of 14,035 samples were Roche S positive. This compares with 87.1% (95% CI 86.6% to 87.7%) Roche N seropositivity and 99.9% (95% CI 99.8% to 99.9%) Roche S seropositivity for the period of 20 April to 9 July 2023 (week 16 to week 27 2023).

Seropositivity (weighted by region, age group and sex) varies over time. Figure 3 shows the overall 12-weekly rolling proportion seropositive over time for the Roche N and Roche S assays. Seropositivity estimates are plotted weekly using the mid-point of a rolling 12-weekly period.





Regional prevalence of infection over time

Seropositivity (weighted by age group and sex) using the Roche N assay which detects infection only, varies by region (Figure 4).





NHS region	Weeks 16 to 27 2023	Weeks 28 to 35 2023
East of England	86.1% (84.6% to 87.4%)	84.2% (82.4% to 85.9%)
London	88.8% (87.4% to 90.1%)	90.9% (89.4% to 92.2%)
Midlands	87.3% (85.9% to 88.5%)	86.0% (84.2% to 87.6%)
North East and Yorkshire	88.4% (87.1% to 89.7%)	88.9% (87.2% to 90.3%)
North West	88.9% (87.5% to 90.1%)	89.9% (88.4% to 91.3%)
South East	85.1% (83.5% to 86.5%)	84.7% (83.0% to 86.2%)
South West	84.7% (83.1% to 86.1%)	84.7% (82.8% to 86.5%)

Roche N seropositivity has remained stable in all regions compared to the previous 12-week period (<u>Table 10</u>). While seropositivity has increased in some regions and decreased in others, estimates deviate by no more than 2.1% between the 2 periods. Decreases in prevalence estimates are likely to reflect waning immunity and potential changes in the locations of sampling over time.

The difference in seropositivity by region has narrowed over time with the lowest seropositivity observed in the East of England, South West and the South East. The highest seropositivity has consistently been observed in London, closely followed by the North West.

Overall COVID-19 case rates through Pillar 1, for week 36 2023, have increased in most regions and overall positivity through Respiratory Datamart increased compared to the previous week (Weekly national Influenza and COVID-19 surveillance report week 37 2023). Pillar 1 testing is undertaken by NHS hospitals and UKHSA labs for those with a clinical need and some health and social care workers. Testing recommendations have been updated and routine asymptomatic testing through NHS settings has been paused since the end of August 2022, which will have an impact on Pillar 1 case rates and positivity rates. Changes in testing practices are likely to influence a range of surveillance indicators highlighting the importance of maintaining the serosurveillance programme to provide consistent data on exposure to infection and vaccine impact in the population over time.

Prevalence by age group

Seropositivity estimates by age group using the Roche N assay are presented below.

Figure 5. Population weighted 12-weekly rolling SARS-CoV-2 antibody seroprevalence (% seropositive) in blood donors from the Roche N assay by age group



Based on testing samples using the Roche N assay (Figure 5) as a marker of infection, the highest seropositivity continues to be observed in those aged 17 to 29 and the lowest in those aged 70 to 84.

Age group	Weeks 16 to 27 2023	Weeks 28 to 35 2023
17 to 29	92.6% (91.3% to 93.7%)	93.2% (91.6% to 94.5%)
30 to 39	90.6% (89.5% to 91.5%)	89.6% (88.3% to 90.8%)
40 to 49	89.7% (88.7% to 90.6%)	89.0% (87.8% to 90.2%)
50 to 59	87.2% (86.2% to 88.1%)	88.0% (86.8% to 89.0%)
60 to 69	83.4% (82.2% to 84.6%)	84.0% (82.6% to 85.4%)
70 to 84	75.4% (73.0% to 77.6%)	75.2% (72.4% to 77.7%)

Table 11. Roche N seropositivity (95% CI) estimates by age group

N seropositivity has recently remained stable across age groups (<u>Table 11</u>) compared to the previous 12-week period.

In England, Pillar 1 COVID-19 case rates for week 36 2023, increased across most age groups with the highest rates currently seen in individuals aged 80 years and older (Weekly national Influenza and COVID-19 surveillance report week 37 2023). The high, static seropositivity implies that the majority of recent COVID-19 cases have experienced prior infection. Roche S seropositivity in blood donors has plateaued and is now over 99% across all age groups. Historical seropositivity estimates for S antibody in blood donors are likely to have risen more steeply than would be expected in the general population, reflecting the fact that donors are more likely to be vaccinated. Seropositivity estimates for N antibody will underestimate the proportion of the population previously infected due to (i) the waning of the N antibody response over time and (ii) observations from UKHSA surveillance data that N antibody levels are lower in individuals with breakthrough infections (post-vaccination) compared to primary infection likely reflect the shorter and milder infections in these patients. Patients with breakthrough infections do have significant increases in S antibody levels consistent with boosting of their antibody levels.

Vaccination has made an important contribution to the overall Roche S increases observed since the rollout of the vaccination programme. The impact of the booster vaccination programmes can be assessed by monitoring Roche S antibody levels across the population over time.

Roche S levels by age group and month

The Roche S assay that the UKHSA uses for serological surveillance is fully quantitative, meaning that it measures the level of antibodies in a blood sample; an antibody level above 0.8 au/ml (approximately 1 IU/ml using the WHO standard) is deemed positive. The UKHSA surveillance since autumn 2021 has found that over 99% of the population of blood donors test positive for S-antibodies, which may have resulted from either COVID-19 infection or vaccination. With such high seropositivity, it is important to look at population antibody levels in order to assess the impact of the vaccination booster programmes.

Figure 6 shows monthly categorised Roche S levels in N-antibody negative individuals by age group over the past year. An increase in the highest antibody levels can be seen in October following the autumn booster in those aged 40 to 84, with the highest increase seen in those aged 70 to 84. In November 2022 the proportion of donors aged 70 to 84 with very high antibody levels of 25,000+ au/ml remained high, and the proportion of donors aged 50 to 69 years with very high antibody levels increased. From January 2023 the proportion of donors aged 50 to 84 years with very high antibody levels of 25,000+ au/ml antibody levels of 25,000+ au/ml decreased, with the lowest levels seen in April and May. We observed a slight increase in June after the spring booster in 2023, and levels have remained stable since then.

By 2 July 2023, 71.1% of all people aged 75 years and older, living in England, had been vaccinated with a spring 2023 booster dose (<u>Weekly national Influenza and COVID-19</u> <u>surveillance report week 37 2023</u>).

Figure 7 shows categorised Roche S levels in N-antibody positive individuals, those likely to have experienced past infection. Pre-vaccination antibody levels will be influenced by time since infection, variant and severity of infection, as well as individual factors such as underlying health conditions and age. Increases in the highest antibody levels were seen across those aged 60 to 84 in October following the rollout of the autumn booster. In November 2022 increases in the proportion of donors with very high antibody levels of 25,000+ au/ml continued to be observed in donors aged 50 to 84 years. Since January 2023 decreases were seen in the proportion of donors, aged between 50 to 84 years, with very high antibody levels of 25,000+ au/ml. A slight increase in very high antibody levels of 25,000+ au/ml was observed in the 70 to 84 age group in June, following the 2023 spring booster, but this decreased in July and August 2023. Comparing Figure 6 with Figure 7, the overall higher profile of antibody levels in those who have experienced past infection is evident; both vaccination post infection and breakthrough infection following vaccination are expected to boost existing antibody levels.

Whilst it is thought that no threshold antibody level offers complete protection against infection, higher antibody levels are likely to be associated with lower probability of infection.

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Figure 6. Categorised Roche S antibody levels by age group and month in N negative samples, September 2022 to August 2023

Figure 7. Categorised Roche S antibody levels by age group and month in N positive samples, September 2022 to August 2023



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