

Figure 10: Women giving birth prematurely January to October 2021

The proportion of women giving birth between January and October without adverse outcomes having received one or more doses in pregnancy (91.9% 95%Cl 91.6 to 92.1) is similar to the proportion in women who did not receive any doses in pregnancy (91.6% 95%Cl 91.5 to 91.6) (Figure 4). These positive outcomes were similar across all age groups in vaccinated and unvaccinated women (Figure 5). For the more recent period (women vaccinated from 16 April and delivering from 17 April 2021), when all pregnant women were routinely offered vaccination on the basis of age, women who had received at least one dose of COVID-19 vaccine during their pregnancy were more likely to give birth without any of the reported adverse outcomes than women who had not been vaccinated in pregnancy (92.9% 95%Cl 92.7 to 93.1 compared with 91.6% 95%Cl 91.5 to 91.7) (Figure 6). This difference was more apparent in those aged 30 years and older (Figure 7).

The stillbirth rate for women who gave birth having received one or more doses in pregnancy (3.60 per 1,000, 95%Cl 3.14 to 4.13) was similar to the rate for those who had not received any doses in pregnancy (3.90 per 1,000, 95%Cl 3.71 to 4.10) giving birth between January and October 2021 (Figure 8). In the same period, the proportion of women who had received one or more doses in pregnancy giving birth to babies with low birthweight (5.01%, 95%Cl 4.84 to 5.19) was comparable to those who had not received any doses in pregnancy (5.33%, 95%Cl 5.26 to 5.40) (Figure 6). Similarly, 0.87% (95%Cl 0.79 to 0.95) of women who had received one or more doses in pregnancy and 0.77% (95%Cl 0.74 to 0.80) of those who had not, gave birth to a very low birthweight baby (Figure 9).

The proportion of women who received one or more doses in pregnancy having premature births was 5.97% (95%CI 5.78 to 6.17), compared with 5.88% (95%CI 5.81 to 5.96) in those



who had not (Figure 10). The proportion of women with very premature births was 1.47% (95%CI 1.37 to 1.57) in those who received one or more dose in pregnancy and 1.72% (95%CI 1.68 to 1.77) in those who had not. The proportion of women with extremely premature births was 0.89% (95%CI 0.82 to 0.97) in those who received one or more dose in pregnancy and 1.21% (95%CI 1.18 to 1.25) in those who had not.

### Interpretation and limitations

The first women to be offered COVID-19 vaccine were those who were categorised as at risk of severe disease and women of older age who are at increased risk of the 3 adverse outcomes presented here (given the medical conditions that placed them in this category), together with healthcare professionals at higher risk of COVID-19 exposure. Women with underlying conditions that put them at very high risk of serious complications of COVID-19 will thus account for a relatively high proportion of early deliveries in women who had received one or more doses of the vaccine before 16 April 2021. It is therefore very reassuring that women who had received at least one dose of the vaccine in pregnancy were as likely to deliver live born babies at term without low birthweight and had no overall increased risk of any adverse outcome through January to October.

These findings support the conclusions on vaccine safety from COVID-19 vaccine surveillance report – week 47 (COVID-19 vaccine weekly surveillance reports (weeks 39 to 3, 2021 to 2022).

More detailed statistical analyses are planned (see <u>COVID-19 vaccination in pregnancy surveillance protocol (publishing.service.gov.uk)</u>. The adverse pregnancy outcomes considered are routinely reported as official statistics annually by ONS, however HES data were used to monitor outcomes more quickly than ONS data allow. There are recognised limitations of the datasets including the level of completeness of the relevant fields.

#### Methods

The same methods as used to establish coverage figures were used to group records of deliveries into those who had received at least one dose of the vaccine during their pregnancy and those who had not. The definition of this second group includes any women who received dose(s) only prior to pregnancy and those who received their first dose after delivery, as well as those unvaccinated as of 19 January 2022. Outcomes are also presented by age at delivery, using the woman's date of birth as recorded in NIMS.

To identify deliveries where adverse outcomes were experienced; the following criteria were applied. The outcomes are related: for example babies born prematurely are more likely to be born with low birthweight, and therefore a delivery may have more than one adverse outcome. Stillbirths were identified as records where any one or more of the first 12 diagnoses was the following: Z37.1: Single stillbirth; Z37.3 Twins, one liveborn and one stillborn; Z37.4 Twins, both stillborn; Z37.6: Other multiple births, some liveborn; Z37.7: Other multiple births, all stillborn.

Low birthweight and very low birthweight deliveries were identified as records where any of the first 4 babies born had a known birthweight between 500g and 2,499g (1,499g or lower for very low birthweight).

Premature deliveries were identified as records where the gestational length was less than 37 weeks (less than 32 weeks for very premature, and less than 28 weeks for extremely premature).

Low birthweight is by convention presented as a percentage of all deliveries with known birthweights, and prematurity usually presented as a percentage of all deliveries with known gestational length. However here they are presented as percentages of all deliveries, to reduce the chance of significant findings arising from a change in the overall success of recording these fields during the pandemic. Figures will therefore differ from official statistics and should be considered for surveillance purposes only.

Confidence intervals were calculated using the Wilson Score method (38). A confidence interval is a range of values that is used to quantify the imprecision in the estimate of a particular indicator. Specifically it quantifies the imprecision that results from random variation in the measurement of the indicator. A wider confidence interval shows that the indicator value presented is likely to be a less precise estimate of the true underlying value.

# Main findings

COVID-19 vaccination is the safest and most effective way for women to protect themselves and their babies against severe COVID-19 disease.

COVID-19 vaccine coverage in pregnant women at delivery has increased as more women have become eligible for vaccination reaching 41.3% for women who gave birth in October 2021 having had one or more dose before their baby was born. This is in line with coverage reported across the UK with 42.8% of women in Scotland and 41.0% in Wales delivering in October 2021 who had received any dose and their first dose of COVID-19 vaccine respectively prior to delivery.

As in the previous report, coverage increased with decreasing levels of deprivation and women of black ethnicity had the lowest vaccine coverage. Coverage increased with increasing age group to 35 to 39 years.

Whilst coverage has improved since the August coverage presented in the 25 November report (week 47 COVID-19 vaccine weekly surveillance reports (weeks 39 to 3, 2021 to 2022)) across all groups it continues to highlight inequalities consistent with those seen across the entire

<u>COVID-19 vaccination programme</u>. The percentage point differences between the groups with highest and lowest coverage were greater than those in the November report.

It is very reassuring that women who had received at least one dose of the vaccine in pregnancy were as likely to deliver live born babies at term without low birthweight as women who were not vaccinated in pregnancy.

The group of women who were most likely to be immunised on the basis of their age group alone (vaccinated from 16 April 2021 and giving birth from 17 April 2021) were significantly more likely to deliver live born babies at term without low birthweight than women giving birth in the same period who were not vaccinated in pregnancy.

The specific outcomes that were considered (stillbirth, low birthweight and premature delivery) were similar in women who were and were not vaccinated whilst pregnant.

# Vaccination status in cases, deaths and hospitalisations

Vaccination status of COVID-19 cases, deaths and hospitalisations by week of specimen date over the past 4 weeks up to week 2 (up to 16 January 2022) are shown in tables 10 to 12.

These data are published to help understand the implications of the pandemic to the NHS, for example understanding workloads in hospitals, and to help understand where to prioritise vaccination delivery. **These raw data should not be used to estimate vaccine effectiveness.** We have published a <u>blog post</u> to accompany this section of the vaccine surveillance report.

#### Methods

COVID-19 cases and deaths identified through routine collection from the Second Generation Surveillance System (SGSS) and from UKHSA EpiCell's deaths data, as described in the technical summary, were linked to the National Immunisation Management System (NIMS) to derive vaccination status, using an individual's NHS number as the unique identifier.

Attendance to emergency care at NHS trusts was derived from the Emergency Care DataSet (ECDS) managed by NHS Digital. The same data source was used to identify COVID-19 cases where the attendance to emergency care resulted in admission to an NHS trust.

ECDS is updated weekly, and cases are linked to these data twice weekly. Data from ECDS are subject to reporting delays as, although NHS trusts may update data daily, the mandatory deadline for submission is by the 21st of every month. This means that for weeks immediately following the 21st of a month, numbers may be artificially low and are likely to be higher in later versions of the report.

Data from ECDS also only report on cases who have been presented to emergency care and had a related overnight patient admission and do not show those who are currently in hospital with COVID-19. As such, it is not appropriate for use for surveillance of those currently hospitalised with COVID-19. In addition, these data will not show cases who were directly admitted as inpatients without presenting to emergency care.

The outcome of overnight inpatient admission following presentation to emergency care, was limited to those occurring within 28 days of the earliest specimen date for a COVID-19 case. Deaths include those who died (a) within 28 days of the earliest specimen date or (b) within 60 days of the first specimen date or more than 60 days after the first specimen date with COVID-19 mentioned on the death certificate.

The rate of COVID-19 cases, hospitalisation, and deaths in fully vaccinated and unvaccinated groups was calculated using vaccine coverage data for each age group extracted at the midpoint of the reporting period from the National Immunisation Management Service.



#### Results

The rate of a positive COVID-19 test varies by age and vaccination status. The rate of a positive COVID-19 test is substantially lower in vaccinated individuals compared to unvaccinated individuals up to the age of 29. In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated (Table 13). This is likely to be due to a variety of reasons, including differences in the population of vaccinated and unvaccinated people as well as differences in testing patterns.

The rate of hospitalisation within 28 days of a positive COVID-19 test increases with age, and is substantially greater in unvaccinated individuals compared to vaccinated individuals.

The rate of death within 28 days or within 60 days of a positive COVID-19 test increases with age, and again is substantially greater in unvaccinated individuals compared to fully vaccinated individuals.

# Interpretation of data

These data should be considered in the context of the vaccination status of the population groups shown in the rest of this report. In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than from COVID-19.

The vaccination status of cases, inpatients and deaths should not be used to assess vaccine effectiveness because of differences in risk, behaviour and testing in the vaccinated and unvaccinated populations. The case rates in the vaccinated and unvaccinated populations are crude rates that do not take into account underlying statistical biases in the data. There are likely to be systematic differences between vaccinated and unvaccinated populations, for example:

- testing behaviour is likely to be different between people with different vaccination status, resulting in differences in the chances of being identified as a case
- many of those who were at the head of the queue for vaccination are those at higher risk from COVID-19 due to their age, their occupation, their family circumstances or because of underlying health issues
- people who are fully vaccinated and people who are unvaccinated may behave differently, particularly with regard to social interactions and therefore may have differing levels of exposure to COVID-19

 people who have never been vaccinated are more likely to have caught COVID-19 in the weeks or months before the period of the cases covered in the report. This gives them some natural immunity to the virus which may have contributed to a lower case rate in the past few weeks

These biases become more evident as more people are vaccinated and the differences between the vaccinated and unvaccinated population become systematically different in ways that are not accounted for without undertaken formal analysis of vaccine effectiveness. Vaccine effectiveness has been formally estimated from a number of different sources and is described on pages 4 to 15 in this report.

#### Denominator

The potential sources of denominator data are either the National Immunisation Management Service (NIMS) or the Office for National Statistics (ONS) mid-year population estimates. Each source has its strengths and limitations which have been described in detail on the <a href="https://www.NHS.website">NHS website</a> and <a href="https://www.NHS.website">GOV.Wales</a>.

NIMS may over-estimate denominators in some age groups, for example because people are registered with the NHS but may have moved abroad. However, as it is a dynamic register, such patients, once identified by the NHS, are able to be removed from the denominator. On the other hand, ONS data uses population estimates based on the 2011 census and other sources of data. When using ONS, vaccine coverage exceeds 100% of the population in some age groups, which would in turn lead to a negative denominator when calculating the size of the unvaccinated population.

UKHSA uses NIMS throughout its COVID-19 surveillance reports including in the calculation rates of COVID-19 infection, hospitalisation and deaths by vaccination status because it is a dynamic database of named individuals, where the numerator and the denominator come from the same source and there is a record of each individual's vaccination status. Additionally, NIMS contains key sociodemographic variables for those who are targeted and then receive the vaccine, providing a rich and consistently coded data source for evaluation of the vaccine programme. Large scale efforts to contact people in the register will result in the identification of people who may be overcounted, thus affording opportunities to improve accuracy in a dynamic fashion that feeds immediately into vaccine uptake statistics and informs local vaccination efforts.

## Sources of further information

UKHSA has published a blog post to accompany this section of the report.

The Office of the Statistics Regulator has published a blog post.

UKHSA has published a significant amount of  $\underline{\text{research into vaccine effectiveness}}$  which is summarised on pages 4 to 15 of this report.

The Office for National Statistics has published research into the <u>risk of testing positive for COVID-19 by vaccination status</u>, impact of Delta on viral burden and vaccine effectiveness (4), and the <u>risk of death by vaccination status</u>.



Table 10. COVID-19 cases by vaccination status between week 52 2021 and week 3 2022 Please note that corresponding rates by vaccination status can be found in Table 13.

Cases							
reported by specimen date between week 52 2021 (w/e 02/01/2022)	Total	* Z Z Z	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date¹	Third dose 214 days before specimen date1
2022 (w/e 23/01/2022)	[These date	a should be inter	These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]	. See information b	selow in footnote a	bout the correct in	terpretation of
Under 18	683,221	44,076	506,720	7,242	104.524	19 56B	4 004
18 to 29	603,773	53,619	103,692	5.764	36 145	202,000	1,000
30 to 39	568,148	42,049	82.142	3 200	20, 70	000,400	/90,101
40 to 49	443,556	28,056	39.207	1 237	10.378	250,960	167,244
50 to 59	364,486	21,104	19,212	583	10,370	100,178	208,502
60 to 69	202,664	11,997	7,258	297	1779	70,000	739,18/
70 to 79	106,103	6,379	2,526	117	693	6.010	130,432
80 or over	62,458	5,760	1,664	44	641	6,142	48,207
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<sup>\*</sup> Individuals whose NHS numbers were unavailable to link to the NIMS.

This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may 1 In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

Table 11. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 52 2021 and week 3 2022

Please note that corresponding rates by vaccination status can be found in Table 13.

				III Idule 13.			
Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between		Z Z Z Z	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date¹	Third dose 214 days before specimen date1
week 52 2021 (w/e 02/01/2022) and week 3 2022 (w/e 23/01/2022)	[These da	ata should be	interpreted will	[These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]	ormation below in e figures]	footnote about t	he correct
Under 18	1,835	85	1.597	40			The state of the s
18 to 29	1,445	32	529	5 6	1.18	21	4
30 to 39	1.395	7	110	2	140	580	161
40 to 49	1 340	76	040	סס	105	513	211
50 to 59	1.696	17	369		92	482	352
60 to 69	1 866	200	104	0	9/	530	602
70 to 79	0000	7	440	<u>ස</u>	99	480	840
	4,003		411	9	89	576	1,611
Individuals whose NHS numbers were unactional at the second	4,025	9	435	8	96	817	2 889
In the content of the	ulayallable to l	INK to the NIMS			***************************************	*	4,000

This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19. In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective.

Table 12. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 52 2021 and week 3 2022 Please note that corresponding rates by vaccination status can be found in Table 13.  $\widehat{\omega}$ 

Death within 28 days of positive COVID-19 test by date of death between week 52	Total**	Chinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date¹	Third dose ≥14 days before specimen date¹
2021 (w/e 02/01/2022) and week 3 2022 (w/e 23/01/2022)	[These data should be interpreted	should be inte	E .	with caution. See information below in footnote about the correct interpretation of these figures]	ion below in footnoteres]	e about the correct	interpretation of
Under 18	13	0	10	0	6	7	
18 to 29	28		16	0	0	- C	0
30 to 39	69	0	32		7	0 10	777
40 to 49	104		49		t a	17	9
50 to 59	291	4	112		2 0	30	0
60 to 69	609	33	192		20	5 66	45
70 to 79	993	4	224	· m	43	234	142
80 or over	2,530	13	375	4	62	803	1 258
						)	1.6.7.1

\* Individuals whose NHS numbers were unavailable to link to the NIMS.

\*\* number of deaths of people who had a positive test result for COVID-19 and either died within 60 days of the first positive test or have COVID-19 mentioned on

This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19. 1 In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective.

These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures.   These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures.   These figures   These figures
eted with caution. See information below in footnote about these figures]         0       10       0       2         2       23       1       2         4       47       0       6         2       59       0       6         8       147       1       23         5       230       1       33
10     0       23     1       47     0       59     0       147     1       230     1
23     1     2       47     0     6       59     0     10       147     1     23       230     1     31
47     0     6       59     0     10       147     1     23       230     1     31
59     0     10       147     1     23       230     1     31
147     1     23       230     1     31
230 1 31

\* Individuals whose NHS numbers were unavailable to link to the NIMS.

\*\* number of deaths of people who had had a positive test result for COVID-19 and either died within 60 days of the first positive test or have COVID-19 mentioned on their death certificate.

1,420

985

8

4

392

4

2,900

80 or over

451

436

48

4

This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.



Please note that the following table should be read in conjunction with pages 39 to 42 of this report, and the footnotes provided on page 47. Table 13. Unadjusted rates of COVID-19 infection, hospitalisation and death in vaccinated and unvaccinated populations.

	Cases reported by specimen date between week 52 2021 (w/e 02/01/22) and week 03 202	ecimen date between 1/22) and week 03 2022	Cases presenting (within 28 days of a r	Cases presenting to emergency care  (within 28 days of a positive test) resulting in overnight inpatient admission, by	Death within 28 days of postest by date of death betwee
	(Wie zsiutizz)		Specimen date betwee 02/01/22) and week (	specimen date between week 52 2021 (w/e 02/01/22) and week 03 2022 (w/e 23/01/22)	(W/e 02/01/22) and week 23/01/22)
			see Information on popu	lation bases and unadjus	see information on population bases and unadjusted rates in footnotes 1 and 2 t
	Unadjusted rates among persons vaccinated with at least 3 doses (per 100,000)	Unadjusted rates among persons not vaccinated (per 100,000) <sup>1,2</sup>	Unadjusted rates among persons vaccinated with at least 3 doses (per 100,000)	Unadjusted rates among persons not vaccinated (per 100,000)²	Unadjusted rates among persons vaccinated with at least 3 doses (per 100,000)
Under 18	2,290.5		V A		CONTRACTOR OF THE PROPERTY OF
18-29	3 477 9			0.0	0.0
30-39	A 489 6	10 10 10 10 10 10 10 10 10 10 10 10 10 1	0.0	16.9	0.0
40-49	0.0012		5.7	19.9	0.2
\$ <del>\$-0\$</del>	4,499.0	2,330.5	7.6	23.7	C U
50-59	3,894.4	0.826	8.6	463	O coffee
69-09	2,971.6		To 8		TO 1
70-79	1,995.7	- Caron	35.6	0.10	7.7
>80	1,920.9		106.3		4,4
	THE PERSON NAMED AND PE	A COMMENSATION OF THE PROPERTY	A A A A	0.000	0.00

<sup>&</sup>lt;sup>1</sup>Comparing case rates among vaccinated and unvaccinated populations should not be used to estimate vaccine effectiveness against COVID-19 inf estimated from a number of different sources and is summarised on pages 4 to 15 in this report.

The case rates in the vaccinated and unvaccinated populations are unadjusted crude rates that do not take into account underlying statistical biases differences between these 2 population groups. For example:

The rates are calculated per 100,000 in people who have received either 3 doses of a COVID-19 vaccine or in people who have not received a COVI the number of unvaccinated individuals and individuals vaccinated with 3 doses in the population changes.