

1 **Abstract** (146/150 words)

2 **Background:** COVID-19 vaccines are protective against disease. Pregnant women benefit from
3 vaccination as they are at higher risk of poor maternal and neonatal outcomes following infection.

4 **Methods:** Following regulatory approval of two COVID-19 vaccines in the United Kingdom, a rapid
5 national study of vaccination in pregnancy was instituted using three existing safety surveillance
6 platforms: UKOSS, UKTIS and VIP. This preliminary report describes the data collected up to the 15th
7 June 2021.

8 **Results:** There were 971 reports of COVID-19 vaccination in the UKOSS/UKTIS (n=493) and VIP
9 (n=478) monitoring systems describing 908 individual pregnancies. Pfizer-BioNTech mRNA
10 vaccination was most common (n=501, 55.2%), most women were vaccinated in their second or
11 third trimester (n=566, 62.3%), and were mainly vaccinated due to occupational infection risk
12 (n=577, 63.5%).

13 **Conclusion:** Obstetric outcome data will be obtained by December 2021. However, women should
14 not delay vaccination whilst awaiting further safety data to emerge.

15 Background

16 Pregnant women, particularly those in their third trimester, are known to be at risk of severe
17 adverse outcomes following SARS-CoV-2 infection^[1,2]. Around 1% of pregnant women admitted to
18 hospital with symptomatic SARS-CoV-2 infection (COVID-19) in the UK will die, 10% require critical
19 care, and 20% have a preterm birth^[2]. Women from Black, Asian and other ethnic minority
20 backgrounds, older women, women who are overweight or obese, and women who have medical
21 co-morbidities such as hypertension or diabetes are at increased risk of hospital admission with
22 COVID-19 during pregnancy^[2]. Similar findings have been reported from pregnancy cohorts
23 worldwide^[3] and on this basis, vaccination of pregnant women against COVID-19 has been widely
24 recommended^[4–6]. However, despite these risks of COVID-19 infection in pregnancy being evident
25 from early in the pandemic^[7,8] pregnant women only began to be recruited into trials of COVID-19
26 vaccines in mid-2021.

27 Data from observational human studies currently consists of approximately 5,400 completed
28 pregnancies which were mainly exposed to mRNA COVID-19 vaccines (Pfizer-BioNTech and
29 Moderna)[9–12]. Although these data provide no evidence that mRNA COVID-19 vaccine exposure in
30 the third trimester increases the risk of adverse pregnancy, fetal or neonatal outcomes, the available
31 data are too limited to assess the safety of vaccine exposure in early pregnancy. However, given the
32 mechanism of action of these vaccines, which do not contain live SARS-CoV-2 virus, and that there is
33 currently no known fetal risk with using vaccines that are inactivated, replication-deficient, or
34 contain only structural components of the viral pathogen, it is unlikely that these vaccines would be
35 harmful if administered in pregnancy.

36 In December 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) approved
37 both the Pfizer/BioNTech and the Oxford University/AstraZeneca COVID-19 vaccines for use in the
38 UK, in adults aged 16 years and over. It was initially advised that the Pfizer-BioNTech or AstraZeneca
39 COVID-19 vaccines should be considered in pregnant women who were at high risk of exposure to
40 SARS-CoV-2, or where the woman had underlying conditions that put them at high risk of serious
41 complications of COVID-19[4]. Whilst electronic data systems were being established, it was
42 important to rapidly set up a study to describe the characteristics of pregnant women undergoing
43 COVID-19 vaccination in the UK and their subsequent maternal/fetal outcomes. Surveys conducted
44 by the Royal College of Obstetricians and Gynaecologists together with the Royal College of
45 Midwives in February 2021 indicated widespread concerns amongst pregnant women considering
46 vaccination about the lack of such evidence[13].

47 Therefore, a rapid national study of vaccination in pregnancy in the UK was instituted using three
48 existing platforms for medicine safety or vaccine surveillance: the UK Obstetric Surveillance System
49 (UKOSS) combined with the UK Teratology Information Service (UKTIS), and the UK Vaccination In
50 Pregnancy (VIP) surveillance system. This analysis describes the initial findings from this study.

51 **Methods**

52 Study setting and data collection

53 This national study collected data through three distinct systems; UKOSS combined with UKTIS, and
54 the VIP surveillance system. The UKOSS/UKTIS COVID-19 Vaccination in Pregnancy Monitoring
55 System collected exposure notification data via two routes. UKOSS is an established national
56 research platform which collects reports of severe pregnancy complications from nominated
57 reporting clinicians based at each of the 194 consultant-led hospital maternity units in the UK^[14]. For
58 the UKOSS/UKTIS monitoring system, UKOSS requested notifications for all pregnant women who
59 had received any dose of any COVID-19 vaccine at any stage during pregnancy, where vaccination
60 occurred up to 31st March 2021. Requests were made on monthly reporting emails during March and
61 April 2021.

62 When notified of a vaccination exposure, UKOSS generated an electronic data collection form
63 requesting maternal identifiers, basic demographic details (maternal age and ethnicity), the
64 estimated due date for the pregnancy, and vaccination exposure details (including vaccination date,
65 vaccine manufacturer, batch number, vaccination intent and indication). All notification forms were
66 sent directly from hospitals to the UK Teratology Information Service (UKTIS) via secure NHS email,
67 and processed for follow-up of maternal and pregnancy outcome. The second route into the
68 UKOSS/UKTIS monitoring system involved direct self-reporting to UKTIS by vaccinated women via
69 telephone or email (active since January 2021). Women who self-reported into UKTIS were asked the
70 same baseline details as collected via the UKOSS data collection form. All reports of COVID-19
71 vaccination exposure in pregnancy are being followed-up to collect pregnancy outcome information
72 using UKTIS standardised procedures^[15]. Details regarding additional medical and obstetric history
73 and confirmation of the original pregnancy details described via UKOSS are also collected at the time
74 of pregnancy outcome collection.

75 The Immunisation Department at Public Health England (PHE) operates the UK VIP surveillance
76 system. VIP is an established UK-wide vaccine safety initiative which follows-up pregnancies
77 inadvertently exposed to vaccination either during pregnancy, or shortly before conception.
78 Exposure notification reports are submitted directly to VIP by healthcare professional via telephone,
79 post or email, and vaccinated pregnant women can also report directly. VIP surveillance was
80 extended to include all reports of COVID-19 vaccination in pregnancy up to 15 March 2021.

81 Following exposure notification, PHE issues a VIP surveillance form to the pregnant woman's General
82 Practitioner (GP) for completion of additional medical and obstetric history and confirmation of

pregnancy details. Pregnancy and fetal/neonatal outcome information is subsequently requested from the GP approximately ten weeks after the pregnancy Estimated Date of Delivery (EDD). Infant health and development outcome data are also requested from the primary care team, twelve months after birth for all pregnancies which result in a live birth. Reports of COVID-19 vaccination in pregnancy have been received by VIP since 21 December 2020.

UKOSS/UKTIS and VIP surveillance systems were promoted on UKTIS, Royal College of Obstetricians and Gynaecologists and VIP websites. The VIP surveillance system was additionally promoted in the COVID-19 chapter of the Immunisation Against Infectious Disease handbook^[16] published jointly by the Department of Health and Social Care and PHE.

Study sample

This preliminary report consists of all (both prospective and retrospective) reports of COVID-19 vaccination in pregnancy, as submitted to the UKOSS/UKTIS (relating to vaccination up to 31 March 2021) or VIP monitoring systems up to 15 June 2021. Any reports of preconception exposure only and duplicate reports within each of the individual systems were omitted to describe the total number of reports received by the two systems. Duplicate reports received by both the UKOSS/UKTIS and VIP data collection systems were further excluded to describe vaccination exposure details and when the prospectively reported pregnancies are expected to complete.

The exposed study group included pregnancies where one or more vaccination had occurred at any time between the date of the first day of the last menstrual period (LMP) prior to conception, and the pregnancy completion date.

Definitions

Prospective reports of vaccine exposure included pregnancies where the woman was still pregnant at the time of exposure notification, while retrospective reports were received after the pregnancy had completed. The reported Estimated Date of Delivery (EDD) was either projected from ultrasound dating scan results, or calculated as 280 days after the Last Menstrual Period (LMP) date. The LMP was back calculated as 280 days prior to the reported EDD to define exposure periods. The periconception period was defined as being from the LMP date to 1 week and six days post-LMP, first trimester from 2 weeks and 0 days to 12 weeks and 6 days, second trimester from 13 weeks and 0 days to 27 weeks and 6 days, and the third trimester as 28 weeks onwards. Exposure indications were defined according to the Joint Committee on Vaccination and Immunisation (JCVI) recommendations in the initial stages of the UK vaccine delivery programme, with women qualifying

for vaccination based on either their clinical (based on the JCVI Shielded Patient List^[17]) or occupational^[4] risk status (i.e. frontline health or social care workers). Details of the clinical conditions which necessitated vaccination for the clinically vulnerable group were collected. The clinical conditions on the data collection form were not always mutually exclusive, and multiple conditions could be reported. Where multiple conditions were described, a hierarchical assessment was made (by one of the clinical study authors - KKH) as to the most severe condition described and the main disease category that the study participant should be categorised into. Finally, we use the term 'women' throughout this manuscript to refer to those who are pregnant and give birth. We acknowledge that not all people who are pregnant and give birth identify as women, and it is important that evidence-based care for maternity, perinatal and postnatal health is inclusive.

Vaccine intent (inadvertent or active choice) was categorised for at least the first vaccine exposure occurring during pregnancy. Intent was only categorised as inadvertent when administration occurred prior to maternal recognition of pregnancy.

Statistical analysis

Continuous variables are described using the median (with interquartile range). Categorical variables are expressed as counts and percentages. Data visualisations were produced using Microsoft Excel.

Case review

Outcome follow-up data from completed pregnancies were individually reviewed after collection. Gestational age at vaccination, concomitant risk factors for adverse pregnancy/fetal/neonatal outcomes, obstetric history, gestational age at delivery and mode of delivery were all carefully considered when assessing any potential aetiological role of vaccination for all adverse outcomes described. Due to the limited data currently available, outcomes are not described in this manuscript, but will be published separately once data are available.

Ethical considerations

In order to rapidly implement data collection existing medicine safety/teratogen surveillance systems in the UK were utilised as the required infrastructure and ethical/information governance approvals were already in place. UKOSS case notification to the vaccine monitoring system was approved by the North London REC1 (Ref. Number: 10/H0717/20). UKTIS national surveillance is provided by section 251 of the NHS Act 2006 and regulation 3 of The Health Service (Control of Patient Information) Regulations 2002 (PHE Caldicott Advisory Panel Approval Number: 13091). VIP surveillance is also conducted under section 251 of the NHS Act 2006 of The Health Service

145 Regulation 2002. The analysis of surveillance data collected by UKTIS and VIP does not require
146 separate approval by a UK Research Ethics Committee.

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148 Results

149 There were 971 reports of COVID-19 vaccination in the UKOSS/UKTIS (n=493) and PHE VIP (n=478)
150 monitoring systems, with exposure notification ongoing. The demographic characteristics for these
151 women are described in Table 1. The majority of the reports described prospective cases of
152 vaccinated women (n=928, 95.6%), living in England (n=909, 93.6%), of white ethnicity (n=583,
153 60.0%), and with a median age of 33 years (IQR: 30 to 36). The demographics of the vaccinated
154 women were similar between the UKOSS/UKTIS and VIP monitoring systems, with the exception of
155 missing data on ethnicity in the VIP cohort, which will be collected at later follow up.

156 [Suggested location for table 1]

157 After excluding pregnancies that had been reported to both systems (n=63) there were 908 unique
158 pregnancies across the total dataset. Table 2 describes the vaccination exposure details stratified by
159 vaccine type for these non-duplicate reports. Exposure to the Pfizer-BioNTech mRNA vaccine was
160 most commonly described (n=501, 55.2%), whilst 356 women (39.2%) received the Oxford
161 University/AstraZeneca COVID-19 viral vector vaccine. Most women received at least one dose of
162 the vaccine in either the second or third trimester (n=566, 62.3%), with 405 receiving at least one
163 dose in the first trimester (44.6%); the majority of these were exposed in the critical period of
164 organogenesis (2 weeks and 0 days to 10 weeks and 6 days post-LMP, n=357). This was similar for
165 both the mRNA and viral vector vaccines, with higher proportions receiving at least one dose of the
166 vaccine in the second or third trimester (59.9% and 67.4% respectively) than in the first trimester
167 (51.3% and 36.8%).

168 [Suggested location for table 2]

169 At the time of reporting most women had only received one vaccination (n=644, 70.9%), and in most
170 cases this was their first vaccination of the two dose schedule (n=573, 63.1%), with a smaller
171 proportion having received both vaccinations during pregnancy (n=234, 25.8%).

172 The majority of the women actively sought to be vaccinated during pregnancy (n=545, 60.0%), with a
173 smaller proportion inadvertently vaccinated in pregnancy (n=307, 33.8%). Maternal occupational risk
174 was the indication for vaccination in a higher number of women (n=577, 63.5%) compared to clinical
175 vulnerability (n=228, 25.1%). The majority of those vaccinated due to occupational risk were
176 healthcare or social care workers (n=551, 95.5%). The various conditions reported among the
177 clinically vulnerable sub-group are described in Figure 1.

178 [Suggested location for figure 1]

179 Figures 2 and 3 describe the cumulative number of prospectively reported pregnancies reaching
180 their estimated due date by month and year, stratified by vaccine type (Figure 2) and trimester of
181 exposure (Figure 3).

182 [Suggested location for figure 2 and 3]

183 Discussion

184 Data regarding pregnancy outcome following COVID-19 vaccination in the UK are accumulating, and
185 through combination of the UKOSS/UKTIS and VIP safety monitoring systems, outcomes for a cohort
186 of approximately 900 vaccinated women is expected to be available for analysis by December 2021.
187 Currently, approximately 300 women have reached their estimated due date, and follow-up of these
188 mainly third trimester exposed pregnancies is underway. Data regarding outcomes of first trimester
189 exposed pregnancies are also beginning to accumulate. The results of this preliminary analysis
190 describe the study population which will be included in the December 2021 analysis of pregnancy
191 outcome data. As expected, given the national vaccination recommendations at the time the study
192 sample was collected, the indication for vaccination was mostly due to occupational risk or clinical
193 vulnerability. Accordingly, exposure to the Pfizer-BioNTech mRNA vaccine, which requires stringent
194 cold-storage conditions and was predominantly used to vaccinate healthcare workers at hospital
195 vaccination centres, was more common than the Oxford University/AstraZeneca viral vector vaccine.

196 Since April 2021, national databases have been modified to allow the identification of women who
197 knew they were pregnant at the point of vaccination. Data linkage studies are underway, linking
198 vaccination to obstetric outcome data obtained through routine clinical care (e.g. Hospital Episode
199 Statistics in England and COPS study in Scotland^[10]). Automating data collection in this way provides
200 an opportunity for improved data capture within the population; however, it is unlikely that these
201 studies will produce data imminently. The UKOSS/UKTIS/VIP study aims to fill the immediate need
202 for safety data, and to reassure pregnant women that the safety of these vaccines is being
203 monitored. Although a formal statistical analysis of pregnancy outcome data will not be performed
204 before the end of the year, preliminary safeguarding techniques are being undertaken. Any
205 prospective follow-up outcome reports of adverse pregnancy, fetal or neonatal events are being
206 closely reviewed by experienced clinicians and pregnancy pharmacovigilance specialists to assess
207 any potential aetiological role of vaccination. Patterns of adverse outcomes that are unexplained by
208 concomitant risk factors will be rapidly communicated to key public health and medicines regulatory
209 stakeholders. Another key strength of the UKOSS/UKTIS/VIP study is that the indication for
210 vaccination has been clarified for the majority of exposure reports. Vaccination in the UK was initially
211 limited to healthcare and social care workers and those in a 'Clinically Extremely Vulnerable' (CEV)
212 group. It is therefore anticipated that a proportion of the women initially vaccinated at the start of
213 the programme would be at increased risk of adverse pregnancy outcome due to their pre-existing
214 health conditions. Careful interpretation of outcome data from this group, which represents
215 approximately 25% of the cohort, will be necessary. Comparisons of pregnancy outcomes between

the CEV group and women vaccinated due to other indications will aid this interpretation. This will allow distinctions to be made between possible vaccine related adverse effects and any consequences of the underlying maternal medical condition.

There are limitations to this study. Whilst pregnancies reported through UKOSS had good ascertainment through active null reporting (i.e. obstetric units provide monthly exposure data, even if this is zero) pregnancies reported through UKTIS and VIP rely on active voluntary reporting, and as such there may be a bias towards reporting those with adverse pregnancy outcomes. This may be particularly problematic for pregnancies where the outcome was known prior to reporting (retrospective adverse outcome reporting bias). However, detailed information is being collected in both the UKOSS/UKTIS and VIP monitoring systems which will allow strict definitions of prospective and retrospective cases to be applied. Through restricting analysis to cases which meet true prospective case definition, the impact of the sampling bias in the UKTIS and VIP datasets will be limited. An additional limitation is that as time elapses and vaccination uptake increases the UKOSS/UKTIS/VIP study cohort will likely represent a small sample of the wider vaccinated pregnant population. Although ethnic diversity was represented in our sample with 7% Asian, 3% Black, 1% Chinese and 2% of mixed ethnicity, this was not quite in keeping with estimates of the national UK ethnicity demographics^[18] where approximately 12% Asian, 5% Black, 5% Chinese and 2% of mixed ethnicity would be expected. Possible reasons for the variation in ethnicity could relate to the documented vaccine hesitancy of non-white ethnicity in the general population of the UK[ONS data]. Of note, there was considerable missing data regarding maternal ethnicity (28.9%), which is mainly explained by the VIP system collecting this data on pregnancy follow-up rather than at exposure notification. Further attempts to obtain missing ethnicity data will be undertaken when collecting obstetric outcome data. Finally, although this study was national across the UK, fewer than 7% of the reports were obtained from outside England. Caution may need to be applied on interpretation of the final study results in their applicability to the wider general population of the UK.

Around the world a number of pregnancy vaccine surveillance systems have reported initial maternal and fetal outcome data^[9–12]. Most of these datasets consist of vaccinations which occurred during the second or third trimester, and outcome data have now been published on more than 10,000 completed pregnancies^[9–12]. Collectively, these data do not provide evidence indicating adverse effects in either the mother or the baby. Although the majority of these data are not currently suitable for assessing risks pertaining to early pregnancy vaccine exposure and malformation risks, four studies have provided preliminary data indicating that miscarriage is not associated with COVID-19 mRNA[Head Zauche and Kharbanda] or viral vector[Hillson and Magnus]

vaccination. The UKOSS/UKTIS/VIP cohort includes over 350 cases of Oxford/AstraZeneca viral vector vaccine exposure. In combination with the Public Health Scotland dataset which includes more than 1,000 women who have received the Oxford/AstraZeneca vaccine, these data will provide important additional information on the safety of this viral vector vaccine in pregnancy (noting that this vaccine is not yet authorised for use in US and therefore US reports have not included outcome data). Since guidelines regarding vaccine type have changed in the UK to favour mRNA COVID-19 vaccines in pregnancy^[20], substantial further UK data are unlikely to accumulate. However, vaccines based on viral vector technology are useful for other emerging pathogens of public health concern, for example Ebola virus^[21], and may be relevant for further COVID outbreaks in countries where mRNA vaccines are unavailable, and for other emerging epidemics in future.

Initial COVID-19 vaccine trials excluded pregnant women. However, COVID-19 infection is potentially harmful to both the woman and baby, and emerging variants are showing signs of increased transmissibility and pathogenicity[Vousden]. If pregnant women had been included in initial vaccine trials, then at least some safety data would be in the public domain at the time of the initial vaccination rollout. However, this did not occur and therefore it is vital that data are routinely collected on as many pregnant women as possible to provide further reassurance. Our cohort will report approximately 900 women who received the vaccine in the early stages of the UK vaccination programme. Meanwhile, the COVID-19 pandemic has reached a critical stage, and pregnant women, a largely unvaccinated population, are at significant risk. Women should be advised not to delay vaccination whilst awaiting further safety data to emerge, since doing so puts them at risk of COVID-19 at a time when they are particularly vulnerable.

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341