National Statistician's Data Ethics Advisory Committee

Correspondence Minute

Papers reviewed via correspondence, March 2022.

1. Addendum (4) to previous paper: To determine the population-level relative risk of hospitalisation or death that COVID-19 presents to people with different socio-demographic characteristics and co-morbidities. NSDEC (20)12.

1.1 Jonny Tinsley and Hannah McConnell provided a paper on the Coronavirus risk factor research previously reviewed in June 2020, December 2020, February 2021 and September 2021. The addendum set out a request for ethical consideration of the linkage of new additional data sources to the existing linked dataset in use for this work that correlate with new research questions for investigation, as well as further questions as part of the work already scrutinised by the NSDEC.

1.2 The addendum primarily outlined the proposal to add the following datasets to the project to support and improve the work to study the impact of COVID-19 on pregnancy outcomes, for both mother and baby, as well as risk factors of severe COVID-19 outcomes for pregnant women according to different socio-demographic characteristics and vaccination status. The datasets requested include:

i. Birth registrations;
ii. Birth notifications; and,
iii. Maternity Service Dataset (MSDS).

1.3 The addition of this data will allow the following immediate research questions to be explored:

i. Is pregnancy associated with severe COVID-19 outcomes (such as death, hospitalisation and ICU admission) in women of childbearing age, and to what extent can any associations be explained by vaccination take-up?
ii. Is SARS-CoV-2 infection during pregnancy related to birth outcomes (such as live birth, still birth, preterm birth, miscarriage, complication) and, if so, is this relationship dependent on gestational age when infected?
iii. Are COVID-19 vaccines safe in pregnancy, in terms of outcomes of both the mother (such as death, hospitalisation, specific cardiovascular events) and their babies (such as birth outcome, birth weight, APGAR score[1], physical exam results)?
iv. Do any of the relationships identified in questions i-iii vary according to socio-demographic characteristics (such as age of mother, area deprivation, ethnicity) or health-related factors (such as pre-existing and gestational conditions, BMI, lifestyle factors)?

1.4 Further to the work on pregnancy and births, the addendum outlined additional questions around COVID-19 risk factors to look more specifically at questions using COVID-19 testing data (which was considered in a previous addendum). Questions include:

[1] The Apgar score is a test given to newborns soon after birth. This test checks a baby's heart rate, muscle tone, and other signs to see if extra medical care or emergency care is needed.

i. Are there differences in testing behaviour by socio-demographic groups or geographical location, as evidenced by differences in the time between booking an appointment (following onset of symptoms), and then getting a test or receiving the results?
ii. Does the time taken to book a test following symptoms, or the time to receiving test results, affect one's COVID-19 outcomes? Does this vary by the individual's location, socio-demographic and medical characteristics?

1.5 The addendum also noted the future addition of COVID-19 testing data for Wales. ONS is looking at the possibility of acquiring these data which would be used in the same way as the current testing data but to extend any analyses to Wales as discussed in Addendum 3.

1.6 The Committee acknowledged the clear public good of this work and therefore supported the developments outlined in the addendum. The Committee raised the following points for further consideration by the research team:

i. The Committee noted the potential impact of the changes in testing, test and trace activities, and reporting and behavioural guidance on the validity of the overall research. In terms of the research questions regarding COVID-19 and vaccination for pregnant women, the research team assured the NSDEC that the data being used is from the past 12-15 months, when the testing efforts were high. The research team also assured the Committee that work has started to evaluate coverage and bias within the testing data to ensure validity.
ii. The Committee noted that the research question relating to whether vaccines are safe in pregnancy could seem like an operational, rather than statistical, purpose. The NSDEC were assured that the final outputs of all the COVID analyses are still strictly aggregate statistics to inform the Government's response to the COVID-19 pandemic as well as inform public debate relating to the relative risks that COVID-19 presents.
iii. The NSDEC also queried whether there would be sufficient data to provide statistical insight into the issue of vaccine safety during pregnancy. The research team assured the NSDEC that while it could be argued that vaccine effectiveness is beyond the role of a traditional national statistical institute (NSI), the ONS are the only organisation with access to the appropriate data with coverage of the whole of England.
iv. The NSDEC were provided with an update on results from outputs to date to demonstrate the impact of this work to assure the NSDEC that the results of the research were being fully utilised to achieve the public good.

1.7 The NSDEC acknowledged the addendum and confirmed their contentment with the addition and use of data for the purposes set out in the paper. It was also agreed that the NSDEC should be consulted as major amendments to this work develop in the future, while less significant updates to the project can be supported internally from an ethics perspective by the UK Statistics Authority's Centre for Applied Data Ethics.

1.8 **Action - The NSDEC requested that the Secretariat should assume that addenda of this kind are normally seen by the whole Committee but have the discretion not to circulate minor addenda which don't appear to raise any ethical questions.**