Consent for Maternal and Neonatal COVID-19 Testing: A Mother's Perspective. Can we do more?

Abstract:

Background:

Research is ongoing as to the effects of Covid-19 on pregnancy and whether vertical viral transmission actually occurs.

Aims:

To determine maternal opinions regarding Covid-19 testing for pregnant women and newborns in order to increase numbers opting to participate in research related to Covid-19 and influence future clinical practice whilst advancing global knowledge of the impact of testing on patient experience.

Methods:

Service Evaluation assessing the opinions of pregnant women who were tested for Covid-19 along with their newborn babies using nasopharyngeal swabs and the SARS-CoV-2 Reverse Transcription Polymerase Chain Reaction (RT-PCR) test between 28th April and 21st May, 2020. Altogether 494 mothers and 410 babies were included and 292 (59%) of the 494 women opted to participate.

Findings:

Communication to pregnant women regarding the Covid-19 swabbing process is critical and requires improvement. Many women felt their own (60%) and their baby's (61%) swab was compulsory. A large percentage did not feel sufficiently informed about the risks and benefits of themselves (43%) or their baby (52%) being tested. Just under half of women did not understand the implications of a positive test for themselves (43%) or their baby (42%). However, ultimately, the majority would agree to themselves (97%) and their baby (86%) being tested in future pregnancies.

Conclusion:

This is the first service evaluation to explore maternal opinions regarding communication and consent of Covid-19 nasopharyngeal testing for pregnant women and their newborn babies. It has highlighted where women feel under-informed and this information can be conveyed to healthcare professionals so that these areas are covered in more detail when consenting women for Covid-19 testing in the future.

Keywords:

Covid-19; Consent; Neonates; Pregnancy; Vertical Transmission

Key points:

- Whilst coronavirus infections cause severe pregnancy complications, no definitive confirmation or mechanism of vertical transmission of Covid-19 has been identified and further research is required.
- McDevitt et al. (2020) identified nine newborns testing positive for Covid-19 within the first 24 hours of life despite eight of their mothers testing negative.

- Individual views regarding available screening tests for Covid-19 have been extremely varied and maternal opinions regarding testing are yet to be elucidated.
- To increase their participation in research, communication to pregnant women regarding all stages of the Covid-19 swabbing process is critical and requires improvement.
- We have highlighted areas where women feel under-informed and this can be conveyed to healthcare professionals to be covered when consenting women in the future.
- We have also shown that the majority of women would ultimately agree to testing for themselves and their baby in future pregnancies which is promising.

Reflective Questions:

- Do we truly obtain consent in an informed way?
- Do we consent women appropriately and provide information on what we know as well as what we do not know? (Particularly evident at the start of the Pandemic when we did not know much about Covid-19)
- How do we improve consent for neonatal swabs? Would patient information leaflets be useful?
- How do we inform and advise women if their newborn baby tests positive for Covid-19?

Introduction

Since December 2019 when the first case of the novel 2019 coronavirus (SARS-CoV-2) was identified, the associated illness (Covid-19) has become a significant international health concern. Declared a Global Pandemic by the World Health Organisation on 11th March 2020, Covid-19 remains one of the most catastrophic and unprecedented public health crises in decades (WHO, 2020). It has resulted in over 480 million reported cases worldwide and 6.1 million deaths as of 28th March 2022 (WHO, 2022), with numbers continuing to rise as new strains with potentially more harmful effects are identified.

The impact of Covid-19 on pregnant women has been the cause of much controversy and the focus of current literature regarding this cohort of the population has been two-fold; Studies have either concentrated on the effects of the coronavirus infection on mother, baby and the pregnancy or evaluated the possibility of vertical transmission from a pregnant mother to her fetus in utero, during delivery or in the post-partum period. With regards to the former, several studies have highlighted that coronavirus infections lead to more severe complications and negative outcomes in pregnancy including renal failure, disseminated intravascular coagulopathy, preterm deliveries, fetal growth restriction, a greater chance of Intensive Care admission, intubation and mechanical ventilation and spontaneous miscarriages, stillbirths or perinatal deaths (Schwartz and Graham, 2020). Normal physiological changes occurring during pregnancy are thought to underpin the rationale for pregnant women being more susceptible to developing these negative outcomes (Kourtis et al, 2014). Cardiopulmonary adaptations due to the gravid uterus predispose to hypoxaemia whilst variations in sex hormone levels and their interaction with the immune system hinder pathogen elimination and exacerbate infection severity (Kourtis et al, 2014).

Regarding the possibility of vertical viral transmission there has been no definitive confirmation of intra-uterine transmission of any coronavirus species to date (Schwartz and Graham, 2020; Diriba et

al, 2020). However, several published case reports make this a controversial subject for Covid-19. Whilst one study identified a positive neonatal pharyngeal swab three days after an emergency caesarean section, placental and cord blood samples tested negative (Wang et al, 2020). Furthermore in a review of 128 newborns, five tested positive for Covid-19 viral genetic material whilst six others tested negative but had elevated antibodies against the virus instead. However, alternative samples including vaginal secretions, breast milk, amniotic fluid, cord blood and placental tissues were all negative, thus refuting the concept of vertical viral transmission (Chi et al, 2021).

Following the introduction of universal Covid-19 screening for all inpatients at our NHS Trust to identify asymptomatic positive patients and reduce the spread of Covid-19, newborn babies were also included. Between 28th April and 21st May 2020, 410 babies born at two maternity units within our NHS Trust were screened using nasopharyngeal swabs and RT-PCR. Interestingly, nine newborns tested positive within 24 hours of delivery whilst eight of their mothers tested negative (McDevitt et al, 2020).

In such an unprecedented time, during a global pandemic, opinions regarding the accuracy and reliability of Covid-19 screening tests have been extremely varied. Furthermore, the effects of Covid-19 on pregnancy, mothers and newborn babies are still under investigation. More research is needed to enable definitive conclusions to be attained and fundamentally, greater numbers of mothers opting to participate in this research are required. In order to facilitate this and influence future clinical practice their opinions regarding neonatal and maternal testing for Covid-19 were considered and the consenting process for these investigations was reviewed.

Method

Prior to starting advice was sought from the Trust's Research and Development Department and Information Governance Department. The fundamental aim of assessing the existing service

provided to women was reiterated. By evaluating opinions regarding neonatal and maternal Covid-19 testing and the current consenting process for these investigations future clinical practice within the Maternity and Neonatal Services could be reviewed and beneficial changes made. It was therefore confirmed that the project did not require any formal ethical approval and should be completed as a service evaluation.

The inclusion criteria were firstly, pregnant women who had been admitted to the Trust and screened for Covid-19 by trained midwives using nasopharyngeal swabs and the SARS-CoV-2 RT-PCR test between 28th April, 2020 and 21st May, 2020; secondly, all neonates born within the Trust whose mother consented to them being screened for Covid-19 in the same way. The exclusion criteria were women who had suffered miscarriages, stillbirths or terminations of pregnancy during the time frame. Altogether 494 mothers and 410 babies were included whilst 13 were excluded.

All 494 women were initially sent an invitation to participate in the service evaluation. This provided details regarding the rationale for the project, an explanation of how it would be conducted, clarification that participation was voluntary, not compulsory and confirmation that all information gathered would be anonymised and kept confidential. It also highlighted the possibility of findings being published in a medical journal in order to increase numbers of women consenting to participate in research relating to Covid-19 and influence future clinical practice whilst advancing global knowledge of the impact of Covid-19 testing on patient experience. The invitation also provided information on who to contact if they declined to participate. The women were then given four weeks to make a decision before being telephoned. Details of the initial invitation were reiterated and any questions the women had were answered before they were asked to verbally consent to participating.

A questionnaire with mostly closed questions and pre-determined answers (Yes, No, Unsure, Cannot Remember, Vaguely, Undecided or N/A) was designed to cover all possible responses and assess the following: whether mothers and their newborn babies were offered a nasopharyngeal Covid-19 test; whether they felt this was optional or compulsory; whether they worried about the results whilst awaiting the outcome; whether they felt sufficiently informed about the risks and benefits of being tested; whether they understood the implications of a positive result and whether they would consent to testing in future pregnancies.

The questionnaire also included a couple of optional, supplementary, free-text questions to enable the women to explain their responses. These included reasons why they did or did not worry about the results of their Covid swab, did or did not understand the implications of a positive test and would or would not endorse testing in future pregnancies. When reviewing the answers to these questions it was clear that the same set of responses were repeated thus allowing them to be grouped for ease of interpretation.

Results

Analysis for Maternal Swabs

Of the 494 women, 292 (59%) responded and consented to participating in the service evaluation. Of these, 289 (99%) confirmed they were offered a nasopharyngeal swab whilst 3 (1%) denied this. A total of 285 (98%) consented to having the Covid-19 swab whilst 4 (2%) declined.

Figure 1 shows maternal opinion as to whether they felt their swab was optional or compulsory.

Whilst awaiting the swab outcome, 224 (79%) reported that they did not worry about their result because they assumed it would be negative after isolating for the duration of their pregnancy. The other 58 (20%) did worry, mainly due to increasing reports of asymptomatic carriers and the

possibility of contracting Covid-19 despite strictly adhering to government guidelines. Only 3 (1%) could not remember whether they were worried at the time or not.

Of the 285 women who were swabbed, 101 (35%) felt they were sufficiently informed about the risks and benefits of being tested, 121 (43%) did not and 63 (22%) could not remember (**Figure 2**). When asked whether they understood the implications of a positive test result for themselves, their new baby and the rest of their family 155 (54%) felt they understood, 121 (43%) did not and 9 (3%) only vaguely understood (**Figure 3**). Those who reported they vaguely understood advised that they knew what was expected with regards to isolating but wanted more clarification on specifics such as whether they would still be able to breastfeed or not. Of the 285 women who were swabbed, 5 (2%) tested positive for Covid-19 and of these, 4 (80%) felt satisfied that they were informed about how to manage this whilst 1 (20%) did not.

When asked whether they would consent to testing in future pregnancies 284 (97%) women agreed. Interestingly this included the 4 who declined the swab on this admission. However, 6 (2%) others declined whilst 2 (1%) were undecided, the reasons for which have been illustrated in **Figure 4**.

Analysis for Neonatal Swabs

Of the 292 mothers who responded and consented to participating in the service evaluation, 248 (85%) confirmed that their newborn baby was offered a Covid-19 swab and of these, 241 (97%) went on to have this taken whilst 7 (3%) declined. Of the 292 women, 43 (15%) denied or could not recollect being offered a test for their baby. In fact, whilst 12 (28%) of these 43 women were admitted during the dates included within the study (28th April, 2020 and 21st May, 2020) and were tested for Covid-19 themselves, they delivered after 22nd May when newborn testing had been discontinued as per revised local Trust policy.

Maternal opinion regarding whether their baby's swab was optional or compulsory is depicted in **Figure 5**, with very similar percentages to those in **Figure 1**.

Whilst awaiting the swab outcome, 174 (72%) of the 241 women reported that they did not worry about their baby's result. Reasons given included the fact that they themselves were asymptomatic, their own swab had been negative, they had strictly isolated during the pregnancy, their baby was tested within a few hours of birth and all staff in contact with their baby were wearing appropriate personal protective equipment. For some women however, they simply stated they had other things on their mind having just given birth.

The remaining 67 (28%) women conveyed that they did worry about their baby's result. Several who delivered at the very start of the Pandemic recounted how the doubt and ambiguity of the impact of Covid-19 on pregnant women and potential for vertical transmission caused a great deal of anxiety. Many women reported uncertainty regarding the implications to baby's care if they were found to be positive, particularly relating to the possibility of being separated whilst in hospital. Others reported concerns about increasing evidence of asymptomatic carriers of the virus.

Of the 241 mothers whose baby was swabbed, 81 (34%) felt they were sufficiently informed about the risks and benefits of being tested, 126 (52%) did not and 34 (14%) could not remember (**Figure 6**). Regarding whether they understood the implications of baby testing positive, 137 (57%) felt they did, 101 (42%) did not and 3 (1%) only vaguely understood (**Figure 7**). Of the 241 newborn babies who were swabbed, 6 (2%) tested positive for Covid-19 and of these, 3 (50%) mothers felt satisfied that they were informed about how to manage this and look after their baby safely whilst the other 3 (50%) did not.

Of the 292 women, 250 (86%) agreed to neonatal testing in future pregnancies whilst 21 (7%) declined and 21 (7%) were undecided. **Figure 8** shows the reasons given by those who agreed whilst **Figure 9** shows the reasons given by those who declined. In both groups, many women provided more than one reason.

Discussion

Main Findings and Interpretation

The principal finding of this service evaluation is that communication to women and the information provided regarding maternal and neonatal nasopharyngeal Covid-19 testing (the swabbing process, risks and benefits of being tested and implications of a positive result) is critical to obtaining valid, informed consent and requires improvement. This is emphasised by the fact that the majority of women felt their own and their baby's Covid swab was compulsory rather than optional whilst a large percentage did not feel sufficiently informed about the risks and benefits of themselves or their baby being tested. Furthermore, just under half of women did not feel they understood the implications of a positive test result on the rest of their family and only half of those whose baby actually tested positive felt satisfied with the information provided regarding how to manage this.

From the above it is now clear to see where women feel under-informed and require further clarification. This information can therefore be conveyed to healthcare professionals taking swabs so that these aspects are emphasised and covered in more detail. If this is addressed, this should lead to an increase in the number of women giving valid, informed consent for testing in the future.

However, whilst it is important to acknowledge and act on these findings to increase the number of women who consent to themselves and their baby being tested, it is also important to contextualise these results. At the time of testing, the Pandemic was still a novel concept and as such it is possible to understand the uncertainty and lack of information for both healthcare professionals and patients

alike regarding the Covid swabbing process at this early stage of the outbreak. Now that more information is known about Covid-19 and patients and healthcare professionals are more accustomed to the protocols in place if they or a close contact test positive it should be easier to ensure informed consent is attained appropriately although this remains to be seen for certain.

Another important finding of this service evaluation is the identification of two fundamental reasons why women declined testing (for themselves or their newborn baby) during this admission and would continue to do so in future pregnancies. The first reason is due to the anticipated physical pain caused by the swab itself combined with the emotional trauma to the mother upon seeing her baby distressed after the test. The latter appeared to have a greater influence on women's decision to decline testing as 22 of 40 responses (55%) provided this reason to justify why babies should not be tested in future pregnancies (**Figure 9**) whilst only 2 of 8 responses (25%) provided this reason as to why the women themselves would decline future testing (**Figure 4**). Perhaps these findings are due to the fact that women have been found to be more anxious about the pain induced by nasopharyngeal probing and experience slightly more discomfort compared to men (Marra et al, 2021; Moisset et al, 2021).

The second reason why women declined testing is due to ongoing uncertainties over the necessity of the test when appropriate precautions have been taken during the pregnancy. This is reiterated by the observation that the majority of women did not worry about their own or their baby's result whilst awaiting the outcome, for the reasons detailed in the results section of this paper. Given the retrospective nature of this service evaluation it is likely that these reasons preceded the now more acknowledged contributory role of asymptomatic carriage in Covid-19 transmission.

Asymptomatic carriage and transmission of Covid-19 has become increasingly publicised over the past year (Lee et al, 2020) with some studies calculating that over half of all transmissions occur

before an infected individual develops symptoms (Johansson et al, 2021). In a study of over 1000 healthcare workers, 3% tested positive despite being asymptomatic for Covid-19 (Rivett et al, 2020). It is therefore evident that the detection of asymptomatic carriers is fundamental to controlling the spread of the disease (Johansson et al, 2021) and this should encourage more women to have themselves and their baby tested in the future.

The final key finding identified within this service evaluation is that fundamentally, the majority of women would consent to themselves (97%) and their newborn baby (86%) being tested for Covid-19 in future pregnancies. The primary reason for doing so is to ensure the well-being and safety of everyone from themselves and their newborn baby to the hospital staff, other patients, family and friends. The second main reason for opting in is for the peace of mind and reassurance of knowing that their baby is safe (if the swab is negative) or how to treat and manage it (if the swab is positive).

Strengths and Limitations

This is the first service evaluation to explore maternal opinions regarding information giving and consent for maternal and neonatal nasopharyngeal Covid-19 testing. A large proportion of women (nearly 300 mothers) responded and opted to participate; a significant percentage which adds strength to the findings. However given that only service users from a single Trust were included, the results cannot be generalised to the entire population. Future research should therefore aim to include larger populations to enable more definitive conclusions to be obtained.

One limitation of the service evaluation was that it was undertaken in the format of a questionnaire which is not always the most reliable form of data collection. Many women may have felt pressured to answer a certain way knowing that they were speaking to healthcare professionals from their local hospital, even though it was reiterated that the information they provided would be kept anonymous and confidential. Secondly, the project was performed retrospectively with the swabs

collected between April and May 2020 and the women contacted to participate a few months later. Between these two time periods significant advancements in Covid-19 research were made and extensively publicised and as such, maternal opinions may have changed since the time when the swabs were taken in the early stages of the Pandemic.

Conclusion

In meeting the initial aims established for this service evaluation, maternal opinions regarding nasopharyngeal Covid-19 swab testing for pregnant women and their newborn babies have been explored and a detailed account of these has been provided for the first time within the current literature to date. Important and novel information has been identified and overall the majority of women favour continuing with this testing. However, it is evident that the information given to women in order to obtain informed consent requires improvement and needs to include the swabbing process, the risks and benefits of being tested or not and implications of a positive test result. In doing so, this should increase the number of women who give informed consent for themselves and their baby to be tested in the future and subsequently contribute to ongoing research related to Covid-19. As the Covid-19 Pandemic continues to evolve, it is important that additional service evaluations are undertaken to provide further insight into opinions regarding maternal and neonatal testing regimes to facilitate future research related to this cohort of the population and influence future clinical practice.

Figures: Analysis for Maternal Swabs

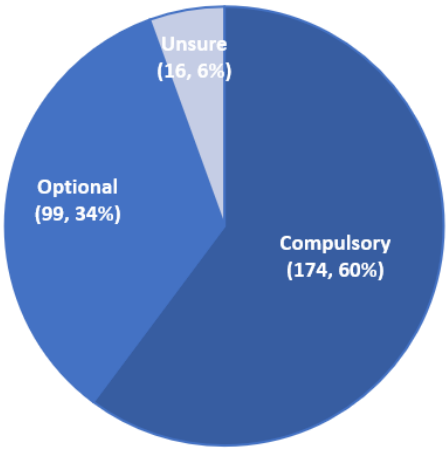


Figure 1. Proportion of women who felt their Covid swab was optional or compulsory

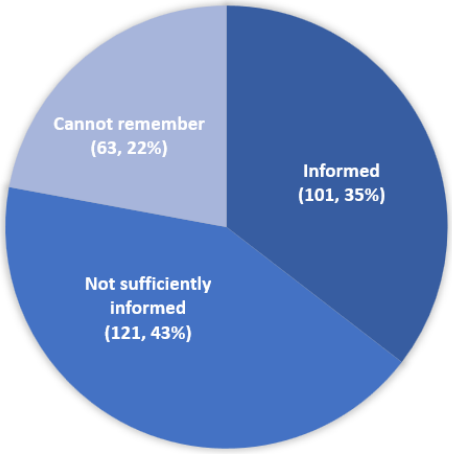


Figure 2. Proportion of women who felt sufficiently informed about the risks and benefits of being tested for Covid-19 compared to those who did not and those who could not remember

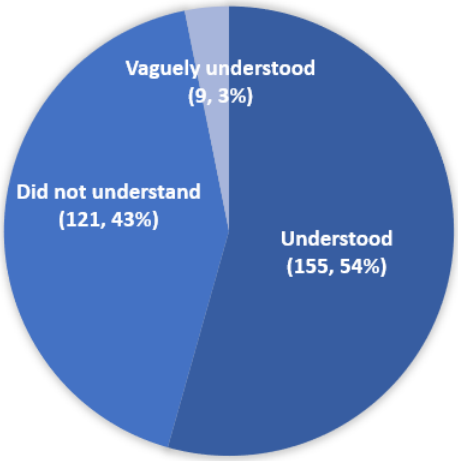
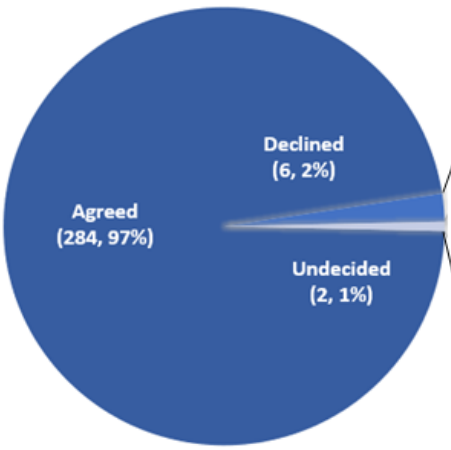


Figure 3. Proportion of women who felt they understood the implications of a positive test result for themselves, their newborn baby and the rest of their family



Reasons given for not having the Covid-19 Nasopharyngeal Test on future hospital admissions	*Total Number of Women (%)*
Declined	**6 (2%)**
No reason given	1
Too painful/unpleasant	1
Asymptomatic therefore unnecessary	2
Strictly self-isolating therefore unnecessary	1
Worried about testing positive and being separated from her baby	1
Undecided	**2 (1%)**
No reason given	1
Too painful/unpleasant but understands need for testing	1

Figure 4. Proportion of women who agreed to being tested for Covid-19 on future hospital admissions compared to those who declined or were undecided. The adjoining table demonstrates the reasons given by those who declined or were undecided

Figures: Analysis for Neonatal Swabs

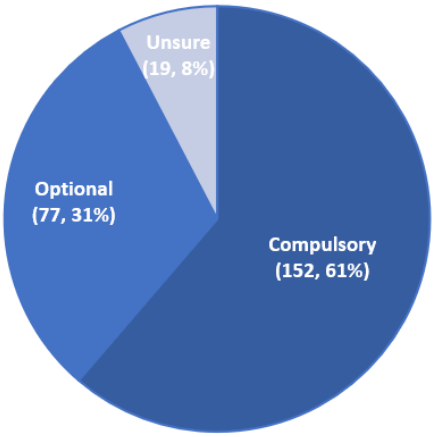


Figure 5. Proportion of women who felt their baby's Covid swab was optional or compulsory

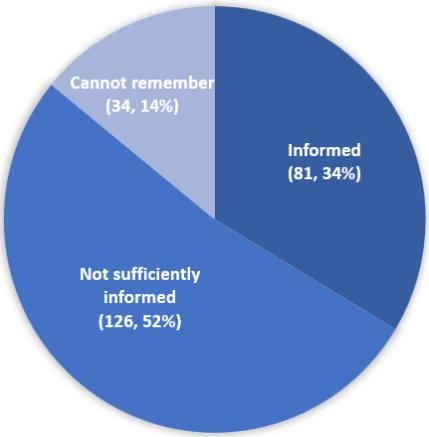


Figure 6. Proportion of women who felt sufficiently informed about the risks and benefits of baby being tested compared to those who did not and those who could not remember

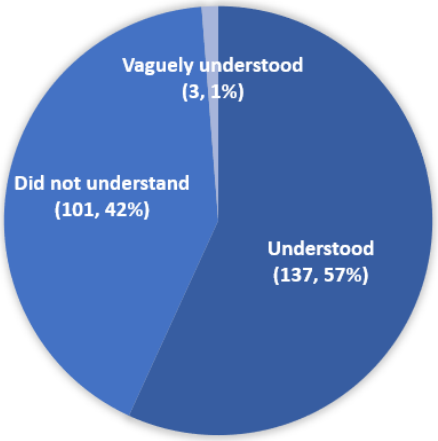


Figure 7. Proportion of women who felt they understood the implications of baby testing positive

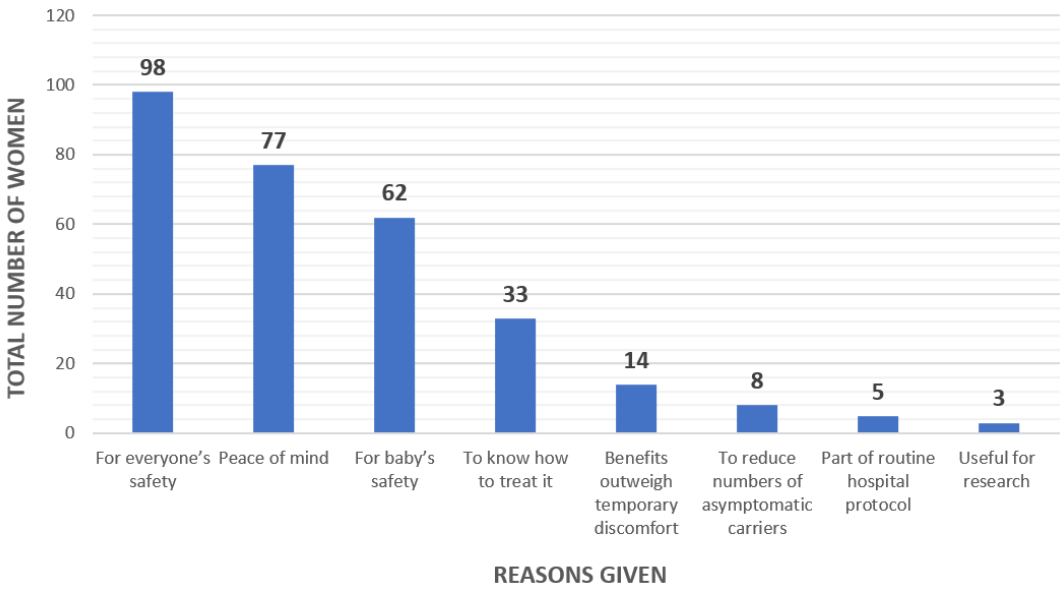


Figure 8. Reasons for babies to be tested for Covid-19

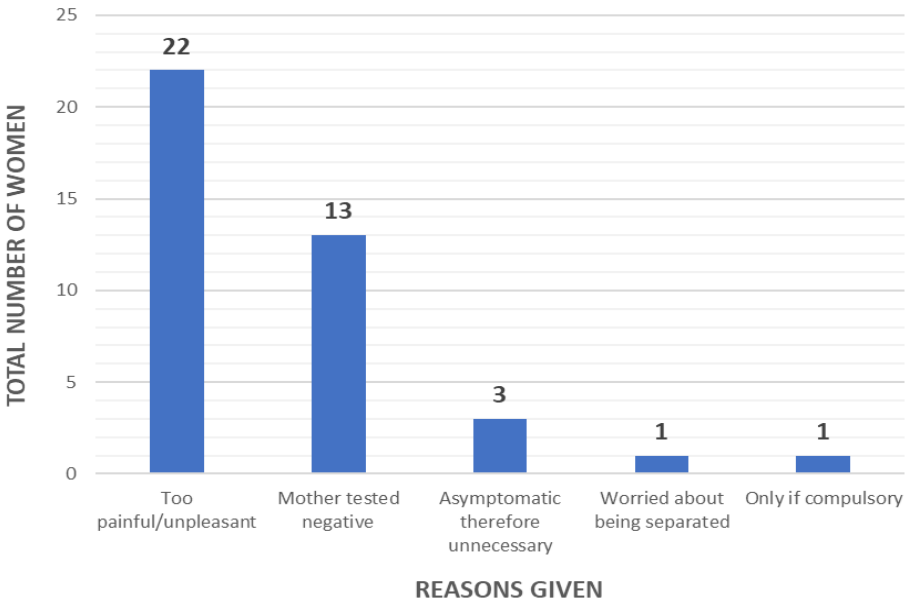


Figure 9. Reasons for babies not to be tested for Covid-19

References

Chi J., Gong W., Gao Q. Clinical characteristics and outcomes of pregnant women with COVID-19 and the risk of vertical transmission: a systematic review. *Arch Gynecol Obstet.* 2021. *303*(2), 337–345. Available from doi: 10.1007/s00404-020-05889-5. [Accessed: 11th March 2021].

Diriba K., Awulachew E., Getu E. The effect of coronavirus infection (SARS-CoV-2, MERS-CoV, and SARS-CoV) during pregnancy and the possibility of vertical maternal-fetal transmission: a systematic review and meta-analysis. *Eur J Med Res*. 2020. 25(1), 39. Available from doi: 10.1186/s40001-020-00439-w. [Accessed 11th March 2021].

Johansson M.A., Quandelacy T.M., Kada S., Prasad P.V., Steele M., Brooks J.T., Slayton R.B., Biggerstaff M., Butler J.C. SARS-Cov-2 transmission from people without COVID-19 symptoms. *JAMA Netw Open.* 2021. 4(1), e2035057. Available from doi: 10.1001/jamanetworkopen.2020.35057. [Accessed 7th July 2021].

Kourtis A.P., Read J.S., & Jamieson D.J. Pregnancy and infection. *N Engl J Med*. 2014. 370(23), 2211–2218. Available from doi 10.1056/NEJMra1213566. [Accessed 9th May 2021].

Lee S., Meyler P., Mozel M., Tauh T., Merchant R. Asymptomatic carriage and transmission of SARS-CoV-2: What do we know? *Canadian Journal of Anaesthesia.* 2020. 67(10), 1424–1430. Available from doi: 10.1007/s12630-020-01729-x. [Accessed 16th July 2021].

Marra P., Colacurcio V., Bisogno A., De Luca P., Calvanese M., Petrosino M., De Bonis E., Troisi D., Cassandro C., Cavaliere M., Ralli M., Cassandro E., Scarpa A. Evaluation of Discomfort in Nasopharyngeal Swab Specimen Collection for SARS-CoV-2 Diagnosis. *Clin Ter*. 2021. 172(5), 448-452. Available from doi: 10.7417/CT.2021.2357. [Accessed 28th March 2022].

McDevitt K., Ganjoo N., Mlangeni D., Pathak S. Outcome of universal screening of neonates for COVID-19 from asymptomatic mothers. *J Infect*. 2020. 81(3), 452–482. Available from doi: 10.1016/j.jinf.2020.06.037. [Accessed: 11th February 2021]

Moisset X., Gautier N., Godet T., Parabère S., Pereira B., Meunier E., Gerbaud L., Lesens O., Henquell C., Beytout J., Clavelou P. Nasopharyngeal swab-induced pain for SARS-CoV-2 screening: A randomised controlled trial of conventional and self-swabbing. *Eur J Pain.* 2021. 25(4), 924-929. Available from doi: 10.1002/ejp.1722. [Accessed 28th March 2022].

Rivett L., Sridhar S., Sparkes D., Routledge M., Jones N.K., Forrest S., Young J., Pereira-Dias J., Hamilton W.L., Ferris M., Torok M.E., Meredith L., CITIID-NIHR COVID-19 BioResource Collaboration, Curran M.D., Fuller S., Chaudhry A., Shaw A., Samworth R.J., Bradley J.R., Dougan G., Smith K.G.C., Lehner P.J., Matheson N.J., Wright G., Goodfellow I.G., Baker S., Weekes M.P. Screening of healthcare workers for SARS-CoV-2 highlights the role of asymptomatic carriage in COVID-19 transmission. *eLife*. 2020. *9*, e58728. Available from doi: 10.7554/eLife.58728. [Accessed 16th July 2021].

Schwartz D.A., Graham A.L. Potential maternal and infant outcomes from Coronavirus 2019-nCoV (SARS-CoV-2) infecting pregnant women: Lessons from SARS, MERS, and other human coronavirus infections. *Viruses*. 2020. 12(2), 194. Available from doi: 10.3390/v12020194. [Accessed 11th March 2021].

Wang S., Guo L., Chen L., Liu W., Cao Y., Zhang J., Feng L. A case report of neonatal COVID-19 infection in China. *Clin Infect Dis.* 2020. 71(15), 853–857. Available from doi: 10.1093/cid/ciaa225. [Accessed: 2nd March 2021].

World Health Organisation. *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020.* Available from: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. [Accessed 20th March 2021].

World Health Organisation. *WHO Coronavirus (COVID-19) Dashboard, 2022*. Available from: https://covid19.who.int/. [Accessed: 28th March 2022].