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Title: Trends and characteristics of Tdap immunization during pregnancy in Ontario, Canada: a retrospective cohort study

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Reviewer 1

General comments (author response in bold)

Comment #1: The study is well designed, and the manuscript is clear and concise. I recommend acceptance.

Thank you for this comment!

Comment #2: Introduction - There is lots of variation between immunization programs in Canada, especially for maternal vaccination. Therefore, readers from outside Ontario would benefit from more context on how maternal vaccination is offered in this province.

Thank you for this suggestion. We have included a subsection in the methods called 'Study design, population and setting' which describes the Tdap immunization program in Ontario. Please refer to comment #3 from the manuscript meeting above for an excerpt of the revised text.

Comment #3: Introduction - Which proportions of obstetricians and family doctors vaccinate?

Unfortunately, we were unable to find information on this and have, therefore, not made any change to the manuscript.

Comment #4: Introduction - Can pregnant women get the Tdap from pharmacists or public health nurses, and if yes are these vaccinations paid for by OHIP (and therefore captured in the database used by the authors)?

In Ontario, pregnant patients can receive Tdap either from their family physician or obstetrician; it is not within the scope of practice for midwives (<https://www.ontariomidwives.ca/vaccinations-pregnancy>) or pharmacists (https://www.publichealthontario.ca/-/media/Documents/P/2018/pertussis-immunization-pregnancy.pdf?sc_lang=en) to administer Tdap. We have mentioned this in both the methods (subsection 'setting') and interpretation for clarification purposes. Until April 2022, routine Tdap vaccination during pregnancy was technically not publicly funded by the province of Ontario; however, there was already public funding for this vaccine for a single adult dose. We have clarified this in the methods and interpretation. Although routine Tdap during pregnancy was not publicly funded, healthcare providers were still billing OHIP (using the billing code used in the study: G847) and would be captured in our study. Nevertheless, it is possible that we have under ascertained Tdap in pregnancy, and this is discussion in the limitations.

Comment #5: Discussion - The authors should discuss of the validity of billing data to measure vaccination coverage. An analysis conducted by ICES (in infants) showed that OHIP billing codes have a high positive predictive value, but a low negative predictive value for immunization (Schwartz et al 2015). In other words, if a billing code is there, a

patient is likely vaccinated, but in the absence of a billing code a patient may be immunized, nevertheless. If this is still true, vaccination coverage in this study may be underestimated.

Thank you for this recommendation. We have mentioned both Ontario validation studies (Schwartz et al, 2015 and Schwartz et al, 2016) in the sub-section “Limitations” and have discussed the impact of reduced sensitivity (while assuming high specificity) on our observed estimates:

Limitations

Our analyses depended on accurate fee coding; if Tdap vaccination failed to generate a billing claim in the databases, we would have underestimated the true coverage. While the sensitivity of the Tdap billing code is unknown in our study population, previous Ontario validation studies of OHIP billing claims for adult influenza and infant immunization status (general and vaccine-specific codes) have shown high specificity (81%-96%) and positive predictive values (88%-99%).^{47,48} Assuming specificity for the Tdap vaccination code is high, any non-differential misclassification due to reductions in sensitivity would have a minimal impact on our estimates.⁴⁹

Comment #6: Moreover, the accuracy of coverage based on OHIP billing may vary by type of maternal care provider, thus confounding the association between provider and vaccination.

Thank you for this suggestion. We agree with this point and have included it as a potential limitation of the study:

Further, OHIP billing for Tdap vaccination may differ by provider type, which could have potentially biased the observed association between maternity care provider and Tdap coverage.

Reviewer 2

General comments (author response in bold)

Comment #1: Introduction - Can you mention or describe exactly the difference between the prior recommendation and the change in recommendation. What was the recommendation by NACI or others prior to 2018 (review of vaccination in pregnancy and ensure has been received in prior 3-5 years) vs change being a recommendation for vaccination in every pregnancy. Worth clarifying how exactly the recommendation changed.

Author response #1: Thank you for the opportunity to clarify. We have added text within the manuscript to provide context regarding Canadian Tdap recommendations in the years preceding 2018. Please see excerpt from manuscript below:

In the years preceding the 2018 Tdap recommendation, some Canadian maternity care providers were already immunizing pregnant women against pertussis, likely due to reported outbreaks in other countries, demonstrated successes of programs in the US⁶ and UK,⁷ and advancing research on safety.^{8,9} In 2008, the SOGC released a clinical practice guideline advising that the decision to administer Tdap be made on a case-by-case basis, considering the overall risk of infection during pregnancy.²³ Those at low risk of pertussis infection, who were due for their 10-year booster, were advised to receive Tdap during the postpartum period.²³ In a 2014 statement from NACI, it was similarly recommended to offer Tdap to pregnant individuals only in special circumstances (e.g., regional

outbreaks, not previously vaccinated in adulthood).³ Up until April 2022,^{22,24} Ontario was among the few provinces lacking a publicly-funded program for routine Tdap vaccination during pregnancy; thus, participants captured in our study were limited to one publicly funded adult Tdap dose. As administering Tdap in pregnancy is outside the scope of practice for midwives and pharmacists in Ontario,²⁵⁻²⁷ pregnant patients predominately receive Tdap vaccination from either family physicians or obstetricians.

Comments #2: Otherwise, a well written manuscript with a detailed consideration of various aspects of data collection and good analysis.

Thank you for this comment—we appreciate it!