

## Category: Clinical Guidance Statement (Signposting) Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44)

This statement has been developed by the C-Obs 44 Pre-pregnancy and pregnancy-related vaccinations Statement Development Panel and approved by the Women's Health Committee and associated working groups, RANZCOG Council and Board.

A list of the Statement Development Panel membership can be found in <u>Appendix A</u>, and the Women's Health Committee membership can be found in <u>Appendix B</u>.

This statement has merged C-Obs 44 Pre-pregnancy and pregnancy-related vaccinations with Clinical Guidance Statement C-Obs 45 Influenza vaccination during pregnancy (and in women planning pregnancy). A brief history of both statements can be found in <u>Appendix C</u>.

Disclosure statements have been received from all members of this committee (Appendix C).

**Disclaimer:** This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances (Appendix D).

First developed by RANZCOG: November 2011 Current version: March 2017 Review due: March 2020

Objectives:	To provide immunisation advice to registered Australian and Aotearoa New Zealand health professionals providing maternity care, to minimise the incidence of vaccine preventable disease affecting women planning pregnancy, women who are pregnant and breastfeeding, and their infants up to six months of age.
Target audience:	This statement was developed for use by registered health professionals providing maternity care in Australia and Aotearoa New Zealand and consumers.



Background:	This statement has merged with Influenza vaccination during pregnancy (and in women planning pregnancy) (C-Obs 45). Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44) was first developed by the RANZCOG Women's Health Committee in March 2011. The statement was most recently updated by the Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44) Statement Development Panel, a working group of the Women's Health Committee in July 2019. Influenza vaccination during pregnancy (and in women planning pregnancy) (C-Obs 45) was first developed by the RANZCOG Women's Health Committee in November 2011. The statement was most recently updated in March 2017.
Funding:	The development and review of this statement was funded by RANZCOG.

**RANZCOG Interim Statement on Gendered Language:** RANZCOG has a very clear path ahead in our efforts to achieving diversity, equity, and inclusion. The College has a firm commitment to be inclusive for all individuals needing obstetric and gynaecological healthcare as well as all its members providing care, regardless of their gender identity. RANZCOG currently uses the term 'woman' in its documents to include all individuals needing O&G care, regardless of their gender identity.



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### 1. Purpose and scope

The purpose of this statement update is to provide registered health professionals who care for women planning pregnancy, women who are pregnant or breastfeeding and their infants (up to six months of age) with a quick reference guide, signposting to seven pre-existing national guidelines and resources on vaccination before, during and after pregnancy. RANZCOG has performed an assessment of the quality and rigour of each signposted guideline using the Appraisal of Guidelines for Research & Evaluation Instrument (<u>AGREE Next Steps Consortium, 2017</u>).



The scope of this signposting update was determined by the Statement Development Panel. The statement aims to provide guidance in relation to:

- Vaccinations recommended for women planning pregnancy, women who are pregnant and women who are breastfeeding
- Vaccinations recommended for infants up to six months of age
- Information regarding the timing of vaccinations administered during pregnancy (preferred or recommended trimester)
- Vaccination recommendations for women and infants who identify as Aboriginal and/or Torres Strait Islander
- Vaccination recommendations for infants who are born pre-term (<28 weeks gestation)
- Vaccination recommendations for infants born to mothers who have received immunosuppressive therapy and medications, including biological disease-modifying anti-rheumatic drugs (bDMARDs)
- The safety of vaccinations, including vaccinations where pregnancy is a contraindication (should be avoided)

### 2. Plain language summary

Vaccinations are recommended in Australia and Aotearoa New Zealand to prevent the spread and/or severity of vaccine-preventable diseases in pregnant women and to promote increased protection to newborns. Pregnant women and their infants have an increased risk of severe disease and death from these infections. As such, research supports the recommendation of both routine vaccinations and additional vaccinations where indicated for women who are planning pregnancy, who are pregnant, women who are breastfeeding and their infants up to six months of age.

RANZCOG acknowledge vaccine hesitancy among women who are planning pregnancy and this signposting statement provides links to reliable and accurate information for both Australia and Aotearoa New Zealand.

RANZCOG has provided information gathered from seven guidelines and online resources and developed summary tables to show which vaccinations are recommended and when they should be given to the identified groups. The information provided in this statement has undergone a quality review to ensure the resource is of a high standard.

### 3. Executive summary

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists strongly endorses vaccination of women planning pregnancy, women who are pregnant and women who are breastfeeding.

This statement update is classified as a signposting statement. These are utilised by RANZCOG to direct the reader to available online evidence-based guidance that the College supports but has neither endorsed nor co-branded (*Manual for Developing and Updating Clinical Guidance Statements for RANZCOG, 2022*). The decision to signpost to existing resources, using a quality assessment tool (<u>AGREE Next Steps Consortium, 2017</u>), was made to ensure information available to registered health professionals and the public is clear and consistent with national guidelines and recommendations on vaccination. Furthermore, directing readers to pre-existing, evidence-based resources reduces duplication and reiterates confidence in the accuracy of information already publicly accessible.



A further description of the critical appraisal process using AGREE II can be found in <u>Appendix C</u>. A list of the seven resources and guidelines signposted by this statement can be found in <u>Appendix E</u>. The assessment and scoring information for each guideline, including the specific questions AGREE II asks of appraisers can be found <u>Appendix F</u>.

Using the appraised, evidence-based guidelines, RANZCOG has prepared a summary table which offers an overview of the advice and recommendations regarding vaccination for women planning pregnancy, who are pregnant, women who are breastfeeding and their infants up to six months of age. Recommendations are grouped into timed categories- for women: planning pregnancy; first, second and third trimester and post-partum, including breastfeeding. For infants- two months; four months and six months of age.

While the advice for Australia and Aotearoa New Zealand is largely consistent, there are several jurisdictional differences in vaccination recommendations. This is due to differences in the wording of advice in each Immunisation Handbook, in addition to the structure of respective National Immunisation Programs. This includes funding agreements (out of scope within the context of this statement update) and the status of vaccine-preventable disease prevalence in each country. Thus, the information is presented in two separate tables (Table 1: Vaccination recommendations- Australia and Table 2:Vaccination recommendations- Aotearoa New Zealand) to ensure registered health professionals and consumers obtain the correct information for their region. Table 3: Additional vaccinations recommended for higher-risk population groups- Australia and Aotearoa New Zealand summarises additional vaccinations recommended for specific population groups. Information for Aboriginal and Torres Strait Islander women and their infants is included, however the signposted guidelines in Aotearoa New Zealand did not identify any vaccines recommended specifically for Māori and/or Pacifica women who are planning pregnancy, who are pregnant, who are breastfeeding and/or their infants under the age of six months of age. Further information for other population groups, including infants up to six months of age and groups who have different vaccination requirements (i.e., occupational risk factors, severe immunocompromise), is not included in this statement update. However, Tables 1-3 contain hyperlinks to the signposted guidelines, directing readers to the relevant section and resource where detailed information and recommendations can be found.

The Statement Development Panel further determined that the treatment and management of vaccinepreventable diseases and discussion of funding agreements and policies around vaccination programs would remain out of scope for this statement.

### Additional Practical Advice

#### Consent and counselling

Women who are planning pregnancy, who are pregnant and who are breastfeeding are entitled to make an informed choice and voluntary decision about vaccination, without fear of discrimination by registered health professionals or institutions. That decision should be made with knowledge and understanding of the benefits and risks involved, informed by a registered health professional who provides clear explanations and advice on current vaccination recommendations for the identified groups in this statement. Research has consistently shown that a well-communicated recommendation by a trusted



registered health professional is a significant determinant in a patient's decision regarding vaccination.<sup>12</sup>In Aotearoa New Zealand, research with Māori Māmā about vaccination reports that mothers ( $M\bar{a}m\bar{a}$ ) want the best for their children (*tamariki*) and a trusted relationship with a registered health professional is central to engagement in care, including vaccination<sup>3</sup> Acceptance and uptake in Aboriginal and Torres Strait Islander women who are pregnant in Australia has also been associated with vaccination programs which are developed and led by First Nations people, where the voices, histories, experiences and perspectives are prioritised<sup>4</sup>. For more information regarding informed consent and provision of counselling prior to and during pregnancy, please see RANZCOG Clinical Guidance Statements <u>C-Obs 2a</u>, <u>2b</u> and <u>C-Obs 3a</u>.

# Information for women who inadvertently receive a live attenuated vaccine while pregnant (or within 4 weeks prior to conception)<sup>5</sup>

Pregnant women who are inadvertently administered a live-attenuated vaccine (including but not limited to Varicella, MMR) at any time in pregnancy should be reassured that there has been no evidence of adverse fetal effects or other adverse events from vaccination occurring in pregnancy<sup>6 7</sup>. Inadvertent vaccination involving a live-attenuated vaccine or inactivated vaccine is not a reason for abortion <sup>7</sup>. However, registered health professionals are required to report adverse events as a result of vaccination as per jurisdictional guidelines<sup>6 8</sup>.

<sup>&</sup>lt;sup>1</sup> Gargano LM, Herbert NL, Painter JE, Sales JM, Morfaw C, Rask K, Murray D, DiClemente RJ, Hughes JM. Impact of a physician recommendation and parental immunization attitudes on receipt or intention to receive adolescent vaccines. Hum Vaccin Immunother. 2013 Dec;9(12):2627-33. doi: 10.4161/hv.25823. Epub 2013 Jul 24. Erratum in: Hum Vaccin Immunother. 2014;10(9):2631. PMID: 23883781; PMCID: PMC4162064. Impact of a physician recommendation and parental immunization attitudes on receipt or intention to receive adolescent vaccines - PubMed (nih.gov)

<sup>&</sup>lt;sup>2</sup> Shen SC, Dubey V. Addressing vaccine hesitancy: Clinical guidance for primary care physicians working with parents. Can Fam Physician. 2019 Mar;65(3):175-181. PMID: 30867173; PMCID: PMC6515949. <u>Addressing vaccine hesitancy: Clinical guidance for primary care physicians working with parents - PubMed (nih.gov)</u>

<sup>&</sup>lt;sup>3</sup> Brown, S., Toki, L. & Clark, T. C. (2021). Māori Māmā views and experiences of

vaccinating their pēpi and tamariki: A qualitative Kaupapa Māori study. WotMatters Consulting contracted by NZ Work Research Institute, Auckland NZ

<sup>&</sup>lt;sup>4</sup> McHugh L, Crooks K, Creighton A, Binks M, Andrews RM. Safety, equity and monitoring: a review of the gaps in maternal vaccination strategies for Aboriginal and Torres Strait Islander women. Hum Vaccin Immunother. 2020;16(2):371-376. doi:

<sup>10.1080/21645515.2019.1649552.</sup> Epub 2019 Sep 6. PMID: 31368832; PMCID: PMC7062431.

<sup>&</sup>lt;sup>5</sup> Laris-González A, Bernal-Serrano D, Jarde A, Kampmann B. Safety of Administering Live Vaccines During Pregnancy: A Systematic Review and Meta-Analysis of Pregnancy Outcomes. Vaccines (Basel). 2020 Mar 11;8(1):124. doi: 10.3390/vaccines8010124. PMID: 32168941; PMCID: PMC7157743. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7157743/</u>

<sup>&</sup>lt;sup>6</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccination for women who are planning pregnancy, pregnant or breastfeeding- Inadvertently giving a live attenuated viral vaccine during pregnancy or shortly before pregnancy. Canberra, 2022. <u>https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-women-who-are-planning-pregnancy-pregnant-or-breastfeeding#inadvertently-giving-a-live-attenuated-viral-vaccine-during-pregnancy-or-shortly-before-pregnancy</u>

<sup>&</sup>lt;sup>7</sup> Manatu Hauora (Ministry of Health) Aoteroa New Zealand. Immunisation Handbook- Measles. 12.6- Contraindications and precautions. Auckland, 2020. <u>https://www.health.govt.nz/our-work/immunisation-handbook-2020/12-measles#11-6-1</u>

<sup>&</sup>lt;sup>8</sup> MedSafe New Zealand Medicines and Medical Devices Safety Authority. How to report a problem. Revised 29 October 2021. Online. <u>https://www.medsafe.govt.nz/safety/report-a-problem.asp</u>



#### Key: 4. Summary tables of information This vaccination is safe to be given. It may be routinely Table 1. Vaccination recommendations- Australia recommended or given if clinically indicated This vaccination is contraindicated in pregnancy or the safety of the × vaccination in these populations has not been determined This vaccination is recommended if international travel is required Infants Postpartum (including Planning Trimester Trimester Trimester Disease/Vaccination breastfeeding) pregnancy 2 3 2 months 4 months 6 months Recommended

COVID-19	Recommended for people 5 years and older <sup>9</sup> .	Strongly recommended <sup>9</sup> (mRNA type only). Safe to give at any stage of pregnancy and postpartum for women of any age.	Not indicated <sup>9</sup> .	Not indicated <sup>9</sup> .	for infants aged 6 months with severe immunocompro mise, disability and those at greatest risk of severe outcomes from COVID-19 only <sup>10</sup> .
<u>Hepatitis A</u>	travel to area of	ecommended, unless non-immune and at increased risk, including moderate to high endemicity or increased risk of exposure and/or evere outcomes (lifestyle factors, pre-existing liver disease) <sup>11</sup> .	Not ir	ndicated < 12 mont	hs of age.

<sup>&</sup>lt;sup>9</sup> Please note, advice regarding number of recommended doses is subject to change. Please refer to <u>COVID-19 vaccines</u> | <u>Australian Government Department of Health and Aged Care</u> for up-to-date information.

<sup>&</sup>lt;sup>10</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Clinical recommendations for COVID-19 vaccines. Canberra, 2022. Last updated 24 October 2022. <u>Clinical recommendations for COVID-19 vaccines</u> | Australian Government Department of Health and Aged Care.

<sup>&</sup>lt;sup>11</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccines that are not routinely recommended in pregnancy: inactivated viral vaccines. Canberra, 2018. <u>Table. Vaccines that are not routinely recommended in pregnancy: inactivated viral vaccines</u> | The Australian Immunisation Handbook (health.gov.au)



Disease/Vaccination	Planning	Trimester	Trimester	Trimester	Postpartum (including	Infants			
Disease/vaccination	pregnancy	1 2		3	breastfeeding)	2 months	4 months	6 months	
<u>Hepatitis B</u>	Women planning pregnancy should be up to date with this vaccination.			-	women <b>can receive if non-</b> c for hepatitis B.	<ul> <li>Plus a dose at birth.</li> <li>Recommende d as early as 6 weeks of age (usually given with DTPahepB-IPV-Hib for Doses 2 and 3<sup>12</sup>).</li> </ul>	ø	S	
<u>Haemophilus influenzae type b</u> (Hib-PRP) disease	Only recommended if high risk and clinically indicated.	Not routin		✓ nded. Pregname e if at increase	t women <b>can receive Hib</b> <b>d risk</b> <sup>14</sup> .	As early as 6 weeks of age.	Coses 1-3 given as DTPa-hepB- IPV-Hib combination vaccine <sup>20</sup> .	•	
<u>Human papillomavirus (HPV)</u>	Not routinely recommended for adults >18 years of age.	Not recommended. Women who become pregnant after starting HPV vaccination course should stop and receive the remaining doses after pregnancy. If required.						of age.	

<sup>&</sup>lt;sup>12</sup>Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Hepatitis B: Recommendations- Infants, children and adolescents. Canberra, 2021. <u>https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/hepatitis-b#infants-children-and-adolescents</u>



D'	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1	2	2 3	breastfeeding)	2 months	4 months	6 months
<u>Influenza</u>	Strongly recommended.	Recommended for all pregnant women at any trimester in <i>each</i> pregnancy, especially if pregnant during influenza season (autumn/winter).			Recommended and safe to receive during breastfeeding.	Not indicated- maternal immunisation may also provide infant with protective antibodies.		✓ Infants can receive an Influenza vaccine from 6 months of age.
<u>Japanese encephalitis (JE)</u>	Inactivated vaccine is considered safe to use in women planning pregnancy.	women. The pregnancy a <b>risk of</b> Also recom	e <u>Imojev (live a</u> and breastfeed <b>acquiring JE</b> mended for p	attenuated) va ding. However can receive in can rec	gnancy or breastfeeding accine is contraindicated in r, <b>pregnant women at high</b> activated vaccines <sup>13</sup> . Ilers spending 1 month or ng JE transmission season.		ed. Inactivated JE va d to infants from $\geq 2$	
<u>Meningococcal disease</u> Meningococcal B	Only recommended if high risk.	Pregr	more in endemic areas (Asia, PNG) during JE transmission season. Not routinely recommended. Pregnant women can receive if clinically indicated <sup>14</sup> .				✓ 8 weeks required between 1 <sup>st</sup> and 2 <sup>nd</sup> doses.	3 <sup>rd</sup> dose not required until 12 months of age.

<sup>&</sup>lt;sup>13</sup> NB: No specific data are available about using JEspect (inactivated vaccine) in breastfeeding women. <u>https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/japanese-encephalitis#women-who-are-pregnant-or-breastfeeding</u>

<sup>&</sup>lt;sup>14</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccination for women who are planning pregnancy, pregnant or breastfeeding- Table: Vaccines that are not routinely recommended in pregnancy- inactivated bacterial vaccines. Canberra, 2021. <u>https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-women-who-are-planning-pregnancy-pregnant-or-breastfeeding#recommended-vaccines-for-pregnant-women</u>

<sup>&</sup>lt;sup>15</sup> Please note, the Meningococcal B vaccine is <u>not free</u> for non-Indigenous children aged 2 months, 4 months, and 6 months under the National Immunisation Program, however the vaccine is still strongly recommended.



	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants		
Disease/Vaccination	pregnancy	1	2	3	breastfeeding)	2 months	4 months	6 months	
<u>Measles, mumps and rubella</u> ( <u>MMR)</u> or <u>measles, mumps,</u> rubella and varicella (MMRV)	Avoid pregnancy within 28 days of receiving vaccination.	Hypothetica P All pr recomm	× cated during p al risk only- ser ractical Advice egnant wome ended to be to unity to rubel	e Additional e. en are ested for	Susceptible women should receive the rubella vaccine as soon as possible after delivery and have serological status checked after vaccination <sup>16</sup> .	Not indicated < 12 months of age.			
<u>Monkeypox (mpox</u> ) <sup>17</sup>	Inactivated vaccine is considered safe to use in women planning pregnancy.	The inactiva	The inactivated vaccine is considered safe to use in women who are pregnant.				Limited studies available. The live attenuated vaccine is contraindicated for infants < 12 months of age <sup>17</sup> .		
Pertussis (whooping cough) dTpa combined vaccine- diphtheria, tetanus <sup>18</sup> , and acellular pertussis-containing vaccine	No advice identified specific to planning pregnancy.	<i>each</i> preg trimester	✓ nded as a sing nancy betwee and early 3 <sup>rd</sup> ⁄ between 20-	en mid-2 <sup>nd</sup> trimester	Vaccination is recommended as soon as possible after birth if not vaccinated during pregnancy and >10 years since last dose <sup>19</sup> .	As early as six weeks of age.	at 6 m Given as DTPa combination vac tetanus-acell hepatitis B, inact	onths, another dose nonths. a-hepB-IPV-Hib ccine- diphtheria-ular pertussis, tivated poliovirus, fluenzae type b).	

<sup>&</sup>lt;sup>16</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccines that are contraindicated in pregnancy: live attenuated vaccines. Canberra, 2018. <u>Table.</u> Vaccines that are contraindicated in pregnancy: live attenuated vaccines | The Australian Immunisation Handbook (health.gov.au)

<sup>&</sup>lt;sup>17</sup> Please note the ATAGI Clinical Guidance on vaccination against monkeypox did not undergo a quality assessment using the AGREE II Framework. This resource is provided as it is currently absent from the Australian Immunisation Handbook, likely owing to the recency of the 2022 multi-country outbreak.

<sup>&</sup>lt;sup>18</sup> There is no minimum interval between a dose of dT (tetanus and diphtheria; for wound management) and dTpa when dTpa is being given for pertussis protection during pregnancy

<sup>&</sup>lt;sup>19</sup> See Australian Immunisation Handbook- Tetanus for further information on revaccination prior to 10 years since last dose- <u>https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/tetanus</u>



	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants		
Disease/Vaccination	pregnancy	1	2	3	breastfeeding)	2 months	4 months	6 months	
Pneumococcal disease	Women of child-bearing age with a risk condition for pneumococcal disease can receive the vaccine before a planned pregnancy.	Not routinely recommended. Pregnant women with a risk for invasive pneumococcal disease (IPD), <b>can receive the vaccine if required</b> .			Women of child-bearing age with a risk for pneumococcal disease can receive the vaccine as soon as practicable after birth <sup>14</sup> .	As early as 6 weeks of age.	•	3 <sup>rd</sup> dose not required until 12 months of age.	
<u>Poliomyelitis</u>	Not routinely <b>poliovi</b> i		-	to <b>endemic co</b> men can receiv	Given as DTPa- hepB -IPV-Hib combination vaccine for Doses 1-3 <sup>20</sup> .	•	0		
<u>Q Fever</u>	Only if indicated. Safe use in women planning pregnancy not established.				se of Q fever vaccine in as not been established.	No recommendations found.			
<u>Rabies</u>	No advice identified specific to planning pregnancy.				pregnancy and while part of post-exposure		ed for infants <12 r ost-exposure proph	-	

<sup>&</sup>lt;sup>20</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Poliomyelitis: Infants and children, Australian Government Department of Health and Aged Care, Canberra, 2021. https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/poliomyelitis#infants-and-children



	Planning	Trimester	Trimester Trimester T		Trimester Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1	2	3	breastfeeding)	2 months	4 months	6 months
<u>Rotavirus</u>		Chil	dhood immun	isation only.		<b>⊘</b> Rotarix.	✓ Rotarix.	Only required if vaccination course of RotaTeq is given.
<u>Typhoid fever</u>	Not rout	inely recomm	Anended, unless	endemic regions.	Not indicated < 2 years of age.			
<u>Yellow fever</u>	Only if travelling to area with a risk of yellow fever virus transmission.	should be a rural are transmiss <b>travel is</b>	Anended. Pregr advised to avo eas where yello ion is a risk. Ho unavoidable, p ould receive the	id going to ow fever owever <b>, if</b> oregnant	Should be avoided during breastfeeding (< 9 months) unless mother has high risk of acquiring yellow fever or cannot avoid/postpone travel <sup>21</sup> .	Contraindica	× ated in infants <9 m	onths of age <sup>22</sup> .

 <sup>&</sup>lt;sup>21</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Yellow fever: Women who are pregnant or breastfeeding, Australian Government Department of Health and Aged Care, Canberra, 2022, <a href="https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#women-who-are-pregnant-or-breastfeeding">https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#women-who-are-pregnant-or-breastfeeding</a>
 <sup>22</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Yellow fever- Infants, Australian Government Department of Health and Aged Care, Canberra, 2022. <a href="https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#infants">https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#infants</a>



### Table 2. Vaccination recommendations- Aotearoa New Zealand

Disease/Vaccination	Planning	Postpartum		Postpartum		Infant	ts		
	pregnancy			3	i ostpartam	2 months	4 month	ns 6 r	months
<u>COVID-19</u>	All individuals from 5 years of age are eligible to be vaccinated	Doses 1-3 <sup>23</sup> , mRNA type only. Any stage of pregnancy and Not indicated <sup>23</sup> . postpartum for women of any age.					ated <sup>23</sup> .		
<u>Measles, mumps and rubella</u> (MMR) or measles, mumps, rubella and varicella (MMRV)	Avoid pregnancy for four weeks after MMR vaccination <sup>24</sup> .	Follow-up inadverter pregnancy teratogenic her fe All pregnant	cated during p o studies of wo otly received M show no evide or harmful to etus or her new women are re d for immunity	omen who IMR during once MMR is the mother, vborn.	Can be given safely after birth (if required) and to breastfeeding women <sup>25</sup> .	Not ind	licated < 12	months of age	<u>.</u>
<u>Haemophilus influenzae type b</u> (Hib) disease	Only if high risk <sup>26</sup> .			recommended astfeeding won		✓ At 6 weeks of a	ge <sup>26</sup> .	✓ At 3 months of age.	At 5 months of age.

<sup>&</sup>lt;sup>23</sup> Please note, advice is subject to change. Please refer to <u>5. Coronavirus disease (COVID-19) | Ministry of Health NZ</u> for up-to-date information.

<sup>&</sup>lt;sup>24</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Measles (MMR). Section 12.5.4- Pregnancy and breastfeeding: Online, 2020. <u>12. Measles – Immunisation</u> Handbook 2020 | Ministry of Health NZ

<sup>&</sup>lt;sup>25</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Rubella (MMR). Section 19.5.3- Pregnancy and breastfeeding: Online, 2020 <u>19. Rubella – Immunisation Handbook</u> <u>2020</u> | Ministry of Health NZ

<sup>&</sup>lt;sup>26</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Hib Disease. Section 7.5- Recommended immunisation schedule and Section 7.5.5- Pregnancy and breastfeeding: Online, 2020. 7. Haemophilus influenzae type b (Hib) disease – Immunisation Handbook 2020 | Ministry of Health NZ



	Planning	Trimester	Trimester Trimest		Destructions		Infants	
Disease/Vaccination	pregnancy	1	2	3	Postpartum	2 months	4 months	6 months
<u>Hepatitis A</u>	Only if high risk <sup>27</sup>	Safety of HepA during pregnancy and while breastfeeding has not yet been determined <sup>27</sup> , however as an inactivated vaccine, there is not expected to any risk to the developing fetus and infant <sup>27</sup> . As a precaution, the HepA vaccine should only be used during pregnancy only when clearly needed (i.e., travel to a high-risk country).						found.
<u>Hepatitis B</u>	Women planning pregnancy should be up to date with this vaccination.	Pregnant women should be screened and can receive during pregnancy and while breastfeeding if non-immune and at increased risk for acute HBV infection <sup>28</sup> .				Plus a dose at birth <sup>28</sup> . Recommended at 6 weeks of age.	At 3 months of age.	At 5 months of age.
<u>Human papillomavirus (HPV)</u>	Women <26yo are eligible for the HPV vaccine. Enquiring about possibility of woman being pregnant is not necessary before vaccination (no adverse effects shown on pregnancy outcomes) <sup>29</sup> .	become pr vaccination	mmended. Wo egnant after s course <b>shoulc</b> a <b>fter pregnar</b>	tarting HPV I be delayed	✓         Breastfeeding women         can receive HPV         vaccines.	Not	of age <sup>33</sup> .	

<sup>&</sup>lt;sup>27</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Hepatitis A. Section 8.5.1- Recommendations and Section 8.5.3- Pregnancy and breastfeeding: Online, 2020. <u>8.</u>
Hepatitis A – Immunisation Handbook 2020 | Ministry of Health NZ

<sup>&</sup>lt;sup>28</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Hepatitis B. Section 9.5 Recommended immunisation schedule and Section 9.5.5- Pregnancy and breastfeeding. Online, 2020. 9. Hepatitis B – Immunisation Handbook 2020 | Ministry of Health NZ

<sup>&</sup>lt;sup>29</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- HPV. Section 10.5- Recommended immunisation schedule and Section 10.5.3 Pregnancy and breastfeeding. <u>10.</u> Human papillomavirus – Immunisation Handbook 2020 | Ministry of Health NZ



	Planning	Trimester Trimester 1 2		Trimester		Infants			
Disease/Vaccination	pregnancy			3	Postpartum	2 months	4 months	6 months	
<u>Influenza</u>	Recommended for all adults.	at any trime durir (autumn/	ed for all preg ster, especiall ng influenza se 'winter, typica September) <sup>30</sup>	y if pregnant eason Ily May to	Recommended and safe to receive during breastfeeding <sup>30</sup> .	Not indicated passive antibod infant with so	Only indicated from 6 months of age if infant has chronic illness or history of significant respiratory disease <sup>30</sup> .		
<u>Meningococcal disease</u> <u>Meningococcal B</u>		t routinely rec eceive prior to dverse effects vaccinated rej	or during pre among pregna		Only if indicated. Safe to be administered during breastfeeding <sup>31</sup> .	✓ From 6 weeks of age.	<ul> <li>✓</li> <li>8 weeks required</li> <li>between 1<sup>st</sup> and 2<sup>nd</sup> doses<sup>31</sup>.</li> </ul>	3 <sup>rd</sup> dose not required until 12 months of age.	
Pertussis (Whooping cough) dTpa combined vaccine- diphtheria, tetanus, and acellular pertussis-containing vaccine	No advice identified specific to planning pregnancy.	16 wee pregnancy <sup>3</sup> mother and Tdap combin	✓ ded as a single d	of every otection for nity provided e- diphtheria,	Vaccination is recommended if not administered during pregnancy.	From 6 weeks of age. dTpa combined vaccine- diphtheria, tetanus, and acellular pertussis- containing vaccine <sup>32</sup> .	At 3 months of age.	At 5 months of age.	

<sup>&</sup>lt;sup>30</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Influenza. Section 11.5.1- Pregnancy and breastfeeding and Section 11.5.1- Children at increased risk: Online, 2020. <u>11. Influenza – Immunisation Handbook 2020 | Ministry of Health NZ</u>

<sup>&</sup>lt;sup>31</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Meningococcal disease. Section 13.5- Recommended immunisation schedule and Section 13.5.3 Pregnancy and breastfeeding. <u>13. Meningococcal disease – Immunisation Handbook 2020 | Ministry of Health NZ</u>

<sup>&</sup>lt;sup>32</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Pertussis (whooping cough). Section 15.5: Recommended immunisation schedule. Online, 2020. <u>15. Pertussis</u> (whooping cough) – Immunisation Handbook 2020 | Ministry of Health NZ



Disease Alexanization	PlanningTrimesterTrimesterTrimesterpregnancy123		Infants					
Disease/Vaccination		1	2	3	Postpartum	2 months	4 months	6 months
<u>Pneumococcal disease</u>	Women of child- bearing age with risk condition for pneumococcal disease can receive the vaccine before a planned pregnancy.	Not routine	ely recomment indicated <sup>33</sup> .	ded. Only if	Only if indicated. Safe to be administered during breastfeeding <sup>33</sup> .	As early as 6 weeks of age.		3 <sup>rd</sup> dose not required until 12 months of age.
<u>Rotavirus</u>				caused by vac vaccination of	ccine exposure during the infant) <sup>34</sup> .	✓ At 6 weeks of age <sup>34</sup> .	At 3 months of age.	Not indicated.

<sup>&</sup>lt;sup>33</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Pneumococcal disease. Section 16.5- Recommended immunisation schedule and Section 16.5.5 Pregnancy and breastfeeding. <u>16. Pneumococcal disease – Immunisation Handbook 2020 | Ministry of Health NZ</u>

<sup>&</sup>lt;sup>34</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Rotavirus. Section 18.5.1- Recommended immunisation schedule and Section 18.5.5- Pregnancy and breastfeeding: Online, 2020. <u>18. Rotavirus – Immunisation Handbook 2020 | Ministry of Health NZ</u>



### Table 3. Additional vaccinations recommended for higher-risk population groups- Australia and Aotearoa New Zealand

Group	Additional vaccinations recommended	Time period	Country
	<b>BCG:</b> Neonates living in areas with high tuberculosis cases in NT, QLD, and northern SA ( <u>Infographic</u> ).	Within first 28 days of life.	
Aboriginal and Torres Strait Islander women and infants up to	Japanese encephalitis: <u>Recommended</u> for residents of the outer islands in Torres Strait and non-residents who will be living or working on the outer islands of Torres Strait for a cumulative total of 30 days or more during December- May.	>2 months- 3 years ( <u>Table- Recommended doses of</u> <u>Japanese encephalitis vaccines</u> ). Infants <9 months of age should only receive the inactivated vaccine.	Australia
<u>6 months of age<sup>35</sup></u>	<b>Meningococcal B:</b> Aboriginal and Torres Strait Islander children.	At 2 months, 4 months, and 6 months of age <sup><math>36</math></sup> .	
	<b>Pneumococcal (13vPCV):</b> Infants living in NT, QLD, SA and WA are recommended to have an additional dose.	At 6 months of age.	Australia

<sup>&</sup>lt;sup>35</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccination for Aboriginal and Torres Strait Islander people, Australian Government Department of Health and Aged Care, Canberra, 2022. <u>Vaccination for Aboriginal and Torres Strait Islander people | The Australian Immunisation Handbook (health.gov.au)</u>

<sup>&</sup>lt;sup>36</sup> The Meningococcal B vaccine is free under the National Immunisation Program for Aboriginal and Torres Strait Islander children aged 2 months, 4 months, and 6 months (certain medical conditions). See- Meningococcal vaccine | Australian Government Department of Health and Aged Care



Group	Additional vaccinations recommended	Time period	Country
	Pneumococcal: An <u>additional dose</u> (4 doses in total) of 13vPCV (13-valent pneumococcal conjugate vaccine).	2, 4, 6 and 12 months of age.	Australia
<u>Pre-term infants, born &lt;28 weeks</u> gestation <sup>37</sup>	<b>Pertussis:</b> A single dose of Tdap is recommended for <b>primary caregivers of infants</b> who are patients in a Neonatal Intensive Care Unit (NICU) or special baby care unit for > 3 days and whose mother did not receive a maternal Tdap vaccination at least <14 days prior to the birth ( <u>4.2.2</u> ).	Within infant's period in NICU.	Aotearoa New Zealand
Vaccination for infants born to mothers who received immunosuppressive therapy, including biological disease- modifying anti-rheumatic drugs (bDMARDs) and other biological agents <sup>38</sup> <sup>39</sup>	Any live attenuated vaccine (including rotavirus, BCG and oral polio): If an infant's mother received bDMARDs during pregnancy, especially in the 3 <sup>rd</sup> trimester, it is <u>not</u> recommended the infant receives the rotavirus vaccine.	<ul> <li>Seek expert advice. Decision to be made based on individual clinical data, including serum testing &lt;15 weeks of age. If no detectable bDMARD levels, rotavirus vaccine can be safely given at this stage. If infant still has detectable bDMARD levels at 15 weeks of age, they should not receive the rotavirus vaccine.</li> <li>BCG vaccination is not recommended within the first few months of life. No specific interval is indicated; however, the infant should be at least 6 months of age before receiving a BCG vaccine.</li> </ul>	Australia
		Assessed on a risk-benefit, case by case ( <u>Table 4.2</u> ) basis with specialist advice required ( <u>18.6.2</u> ). If an infant turns 15 weeks of age before Dose 1 of the rotavirus vaccine, they <u>will not be able to receive any rotavirus vaccine doses</u> .	Aotearoa New Zealand

<sup>&</sup>lt;sup>37</sup>Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccination for preterm infants, Australian Government Department of Health and Aged Care, Canberra, 2022. Vaccination for preterm infants | The Australian Immunisation Handbook (health.gov.au)

<sup>&</sup>lt;sup>38</sup>Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccination for women who are planning pregnancy, pregnant or breastfeeding- live attenuated vaccines and immunosuppressive therapy. Australian Government Department of Health and Aged Care, Canberra, 2022. <u>https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-women-who-are-planning-pregnancy-pregnant-or-breastfeeding#inactivated-vaccines-and-immunosuppressive-therapy</u>

<sup>&</sup>lt;sup>39</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Immunisation of special groups- Pregnancy and lactation- Individuals receiving non-corticosteroid immunomodulatory agents. Online. Last updated 14 October 2022. <u>4. Immunisation of special groups – Immunisation Handbook 2020 | Ministry of Health NZ</u>



### 5. Links to relevant College Statements

- Pre-pregnancy Counselling (<u>C-Obs 3a</u>)
- Guidelines for HPV vaccine (<u>C-Gyn 18</u>)

### 6. Links to relevant Consumer resources

- <u>MumBubVax</u> (Signposted resource)
- <u>Travelling during Pregnancy</u> (RANZCOG Patient Information Pamphlet)
- <u>Planning for Pregnancy</u> (RANZCOG Patient Information Pamphlet)



## Appendices

### Appendix A: Statement Development Panel Membership

Name	Position on Committee
Professor Cindy Farquhar	Chair
Dr Andrea Atkinson	Member
Dr Praneel Kumar	Member
Ms Adrienne Priday	Midwifery representative (Aotearoa New Zealand)
Research & Policy Team	Position
Professor Cindy Farquhar	Dean of Research & Policy
Ms Jinty Wilson	Head of Research & Policy
Ms Katie Coulthard	Senior Co-ordinator, Research & Policy

### Appendix B: Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Anna Clare	Deputy Chair, Obstetrics
Associate Professor Amanda Henry	Member and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Dr Jessica Caudwell-Hall	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	Aboriginal and Torres Strait Islander Representative
Professor Kirsten Black	SRHSIG Chair
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, Aotearoa New Zealand
Ms Leigh Toomey	Community Representative
Dr Rania Abdou	Trainee Representative
Dr Philip Suisted	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Steve Resnick	Co-opted member



### Appendix C: Overview of the development and review process for this statement

### *i.* Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of RANZCOG Women's Health Committee or working groups.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. All members of the Statement Development Panels, Statement and Guideline Advisory Group (SaGG) and Women's Health Committee were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement, however Statement Development Panel member Ms Adrienne Priday disclosed involvement in two clinical trials related to RSV vaccinations in pregnancy and as a midwife consultant and champion for Novavax Clinical Trial NZ and Australia. This included work on the 'Prepare Trial' in 2018 and for Optimal Clinical Trials Auckland (midwifery governance role). Ms Priday's involvement in vaccination clinical trials concluded at the start of 2022.

### *ii.* Steps in developing and updating this statement

This statement was developed in **September and October 2022** by the C-Obs 44 Pre-pregnancy and pregnancy-related vaccination Statement Development Panel, a working group established by the Women's Health Committee. It was most recently reviewed by the Women's Health Committee in **November 2022**. The Statement Development Panel carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- A board approved Chair and members were appointed to the Statement Development Panel
- The Statement Development Panel proposed the combination of C-Obs 44 Pre-pregnancy and pregnancy-related vaccinations and C-Obs 45 Influenza vaccination in pregnancy (and in women planning pregnancy). C-Obs 44 would replace C-Obs 45. C-Obs 45 would be retired, if agreed by the Women's Health Committee.
- The Statement Development Panel identified seven pre-existing national guidelines and resources covering vaccination before, during and post pregnancy. The quality of these guidelines was assessed using the AGREE II Instrument.
- At the November 2022 meeting of the Women's Health Committee, the signposting statement and proposal to combine C-Obs 44 with C-Obs 45 was reviewed and preliminarily approved.

The recommendations published by RANZCOG are approved by the RANZCOG Women's Health Committee, Council and Board respectively. The processes used to develop RANZCOG clinical guidance statements are described in detail at: <u>https://ranzcog.edu.au/wp-content/uploads/2022/08/Manual-for-developing-and-updating-clinical-guidance-statements.pdf</u>



### Appendix D: Full Disclaimer

### Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning vaccination before, during and post pregnancy and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any person. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person and the particular circumstances of each case.

### Quality of information

The information available in this statement is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has endeavoured to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available. The use of this information is entirely at your own risk and responsibility.

For the avoidance of doubt, the materials were not developed for use by patients, and patients must seek medical advice in relation to any treatment. The material includes the views or recommendations of third parties and does not necessarily reflect the views of RANZCOG or indicate a commitment to a particular course of action.

#### Third-party sites

Any information linked in this statement is provided for the user's convenience and does not constitute an endorsement or a recommendation or indicate a commitment to a particular course of action of this information, material, or content unless specifically stated otherwise.

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#### Exclusion of liability

The College disclaims, to the maximum extent permitted by law, all responsibility and all liability (including without limitation, liability in negligence) to you or any third party for any loss or damage which may result from your or any third party's use of or reliance of this statement, including the materials within or referred to throughout this document being in any way inaccurate, out of context, incomplete or unavailable for all expenses, losses, damages, and costs incurred.

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These terms and conditions will be constructed according to and are governed by the laws of Victoria, Australia.



### Appendix E: Description of signposted guidelines and resources

### Australia

Australian Immunisation Handbook, including:

- Vaccination for special risk groups (pre-term infants): Information regarding additional recommended vaccinations for extreme pre-term infants born < 28 weeks gestation.
- Vaccination for special risk groups (Women who are planning pregnancy, who are pregnant or breastfeeding): Information regarding recommended vaccinations, vaccinations which can be given if indicated and vaccinations where pregnancy is a known contraindication and should be avoided.

National COVID-19 Clinical Evidence Taskforce Living Guidelines- (Chapter 14- Pregnancy and perinatal care): Regularly updated guidelines developed by a Steering Committee, in collaboration with medical colleges and healthcare organisations in Australia regarding care, including provision of vaccinations against COVID-19 to pregnant women.

**MumBubVax:** An <u>online resource</u> and project produced by several Australian and International research institutes, providing information and data on the safety, efficacy, and suitability of vaccinations in pre-pregnancy, antepartum and postpartum periods, in addition to newborn and early childhood immunisations.

#### Aotearoa New Zealand

**New Zealand Immunisation Handbook:** Information regarding vaccinations which can prevent or reduce the severity of 18 diseases in Aotearoa New Zealand. This includes for women planning pregnancy, who are pregnant and women who are breastfeeding, as well as their infants until six months of age.

**New Zealand Ministry of Health COVID-19 vaccine: Pregnancy and breastfeeding:** Information for women who are pregnant or breastfeeding about the efficacy, safety and recommendations on COVID-19 vaccinations.



### Appendix F: AGREE II Framework and Results

				Signposted	l Guidelines and Reso	ources		
Results AGREE II Domains	AGREE II Key Items	Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	<u>Australian</u> Immunisation <u>Handbook-</u> Vaccination for infants <6mo	<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation <u>Handbook 2020</u>	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	1. The overall objective(s) of the guideline is (are) specifically described	7- Strongly agree	7- Strongly Agree	7- Strongly Agree	5	6	7- Strongly agree	5
	Comments		About the handbook section		Page 1, outlined in 2 sentences.	All excellent except Covid vaccination not added into pregnancy schedule. Difficult to find	Intro indicates guideline fully endorsed by RANZCOG as part of steering committee	These online guidelines are 'living guidelines' and the content is updated once appraisal of new evidence.
Domain 1: Scope and Purpose	2. The health question(s) covered by the guideline is (are) specifically described.	6	6	7- Strongly agree	5	7- Strongly agree	6	3
i u pose	Comments	Not 'questions' but subheadings	Specific groups are outlined	Preterm infants and vaccination- safety, differences, considerations of chronological age vs birth age	Health questions for specific groups are easy to find under "Immunisation of special groups"	Great in audio, video and print and IT	Divided into categories	This is not specified in the online guideline/website. Check other sources.
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7- Strongly agree	7- Strongly agree	6	6	7- Strongly agree	7- Strongly agree	7- Strongly agree



				Signposted	d Guidelines and Reso	urces		
Results AGREE II Domains	AGREE II Key Items	Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for</u> infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation <u>Handbook 2020</u>	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	Comments		About the handbook section	Only in general handbook info- not in chapter	Target audience health professionals- intended recipient of vaccines clearly outlined	Covers gen public, HP, Women, Nurse, GP		Target audience: Women who read about the COVID-19 vaccine if pregnant, breastfeeding or trying for a baby. However, it is unclear if the same advice is available for Māori women.
	Score	97%	97%	94%	72%	94%	94%	66%
Domain 2:	4. The guideline development group includes individuals from all relevant professional groups.	5	5	5	4	6	7- Strongly agree	3
Domain 2: Stakeholder involvement	Comments	Assume ATAGI list, but not specific to this section, no midwives/O&G in ATAGI team	ATAGI group but names not provided	ATAGI are the GDG but no details on who/professional affiliations etc immediately available- would require further research	Advisory group on page (v): 2 GPs and 3 Paediatric ID specialists; no adult immunologists or consumer representatives; acknowledgements on page (vi)	Can't see WHO nor specific midwifery input		



				Signpostec	l Guidelines and Reso	urces		
Results AGREE II Domains	AGREE II Key Items	Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for</u> infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> <u>Immunisation</u> <u>Handbook 2020</u>	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	5. The views and preferences of the target population (patients, public, etc.) have been sought.	1- Strongly Disagree	3	1- Strongly Disagree	5	5	6	3
	Comments	Not found	Consumer representative noted in the development group	Not mentioned	Addressing concerns about immunisation on Page 82 addresses concerns patients may have	Can't specifically see if consumer input, but maybe Telethon Kids represents community/ consumers?	Consumer panel via EOI	The site does not detail methodology, or a consultation process.
	6. The target users of the guideline are clearly defined.	5	6	5	6	7- Strongly agree	7- Strongly agree	7
	Comments	Healthcare professionals and others'	Health professionals and others	Only in general handbook info- not in sub-section	Health professionals	General public and health professionals	In technical report	Clearly defined: pregnant, breastfeeding or trying for a baby.
	Score	44%	61%	44%	66%	83%	94%	55%



				Signpostec	l Guidelines and Reso	ources		
Results AGREE II Domains	AGREE II Key Items	Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	Australian Immunisation Handbook- Vaccination for infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	7. Systematic methods were used to search for evidence	6	6	6	6	6	7- Strongly agree	6
Domain 3: Rigour of development	Comments	Not detailed enough to be replicated.	Some general details of the search strategy and databases used described	Yes, but search strategy not provided so cannot be replicated	Detailed reference list for each vaccine; multiple updates to guidelines suggest evidence-based recommendations are updated	References are quite old but appears to have been updated. This is quite common in Immunisation space as the historical evidence is repeatedly used in a reassuring manner. Later references do often back up older references.	Detailed in technical report	A section on research and data provides links to MedSafe, and international studies (Public Health Agency Canada SR and MA on impact of COVID-19; PAN-COVID investigators and the National Perinatal COVID-19 Registry Study Group observational study; US CDC COVID-19 Response team incl Keiser Permanente Washington Health Research Institute, USA) and US/Israel studies on breastfeeding.
	8. The criteria for selecting the evidence are clearly described	5	5	6	4	4	7- Strongly agree	4
	Comments	Implied	High quality studies if available		Not explicitly stated	Unsure - criteria not described as such but relevant references used and critique relevant		Not explicitly stated



				Signposted	d Guidelines and Resc	ources		
Results AGREE II Domains	AGREE II Key Items	Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	Australian Immunisation Handbook- Vaccination for infants <6mo	Australian Immunisation Handbook- Vaccination for special risk groups (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding</u> )
	9. The strengths and limitations of the body of evidence are clearly described	1- Strongly Disagree	2	4	5	7- Strongly agree	7- Strongly agree	4
	Comments	Not described	States overall efficacy but does not critique the literature supporting the statistics	Described in a general sense but not specific to the evidence relied upon for this sub-section of the guideline	Critical appraisal of data under "efficacy and effectiveness" for each vaccine	Although not that applicable to this site as the site is interactive and enabling in nature to support immunisation.		The individual studies discuss limitations of the studies but the site does not detail the methodology used to back recommendations.
	10. The methods for formulating the recommendations are clearly described	6	5	6	4	7- Strongly agree	7- Strongly agree	4
	Comments	Name of technique not given	Mentioned GRADE technique however specific GRADE recommendations not provided	Yes- 'systematically derived, based on the identification and synthesis of the best available scientific evidence'	Not explicitly stated, however based on trial data presented	Although not that applicable to this site as the site is interactive and enabling in nature to support immunisation.		The site does not detail the methodology used to Back recommendations
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations	7- Strongly Agree	7- Strongly Agree	7- Strongly Agree	6	7- Strongly agree	7- Strongly agree	4



	AGREE II Key Items			Signposted	d Guidelines and Reso	ources		
Results AGREE II Domains		Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	Australian Immunisation Handbook- Vaccination for infants <6mo	Australian Immunisation Handbook- Vaccination for special risk groups (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	Comments				Efficacy and contraindications section for each vaccine	This information is mostly for the general public, and it presents facts, science and underpins a meaningful informed consent process. It uses four different presentation formats thus addressing many levels of health literacy		Limited to the MedSafe website Vaccine Safety Q&A
	12. There is an explicit link between the recommendations and the supporting evidence	4	5	5	4	7- Strongly agree	7- Strongly agree	4
	Comments	Recommendations are not referenced	References are provided in the efficacy section	The context to the recommendation is supported by evidence	No explicit link however references supporting recommendation presented	Links well the references, facts, and variables for vulnerable communities to enable meaningful consent processes	Referenced and graded	Not explicit: the site includes a section on research and data provides links to MedSafe, and international studies
	13. The guideline has been externally reviewed by experts prior to its publication	5	5	5	6	1- Strongly disagree	7- Strongly agree	1



				Signposted	I Guidelines and Resc	ources		
Results AGREE II Domains	AGREE II Key Items	<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for special</u> <u>risk groups (women</u> <u>who are planning</u> <u>pregnancy, pregnant</u> <u>or breastfeeding)</u>	Australian Immunisation Handbook- Vaccination for infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	Comments	Chief medical officer review only- unclear if others reviewed	NHMRC and other external parties		Acknowledgements and Immunisation Advisory Group	Information unable to be located, with exception of 'we developed materials in partnership with pregnant women, midwives and GPs because we wanted to be sure we were providing them with information they really want and need'	Detailed in technical report	Unable to comment
	14. A procedure for updating the guideline is provided	7- Strongly Agree	7- Strongly Agree	7- Strongly Agree	5	7- Strongly agree	5	3
	Comments	3 x per year	3x per year following ATAGI meeting	In general information	It Is clear what recommendations have been updated and when, however the process for updating the guidelines are not explicitly stated	Updates appear to be frequent to ensure unambiguous. Added Covid in, although tricky to find.	Updated April- September 2020. Updates after this time- current V62 published 17/8/2022	The site does not determine the frequency of updates.
	Score	37.50%	70.80%	79.00%	66%	79%	95.80%	45.80%



	AGREE II Key Items	Signposted Guidelines and Resources							
Results AGREE II Domains		Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for</u> <u>infants &lt;6mo</u>	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>	
	15. The recommendations are specific and unambiguous	6	6	7- Strongly Agree	6	7- Strongly agree	6	6	
Domain 4: Clarity of presentation	Comments	'Lifestyle factors' comment not specific		Very specific- only relevant to preterm infants	National Immunisation schedule, extended immunisation program for special groups, Key information section for each vaccine	Specific guidance is given, specifically concerns linking MMR with autism. Well critiqued and discussed so information about quality of research is discussed in such a way I think most would find it understandable, therefore know the previous research with these statements about MMR and autism was not quality research publication and has been retracted, therefore not a linked.	Mild due to rapidly evolving information	Rapidly evolving information	
	16. The different options for management of the condition or health issues are clearly presented	4	6	5	6	4	7- Strongly agree	2	



	AGREE II Key Items			Signposted	l Guidelines and Reso	ources		
Results AGREE II Domains		<u>Australian</u> <u>Immunisation</u> <u>Handbook-</u> <u>Vaccination for special</u> <u>risk groups (women</u> <u>who are planning</u> <u>pregnancy, pregnant</u> <u>or breastfeeding)</u>	Australian Immunisation Handbook- Vaccination for infants <6mo	Australian Immunisation Handbook- Vaccination for special risk groups (preterm infants)	<u>New Zealand</u> I <u>mmunisation</u> Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	Comments	Brief info re hesitancy/counselling	Catch up schedules, different vaccine brands		Catch up schedules and how to manage contacts provided	Vaccination hesitant and anti-vaccination stance not mentioned directly but common Side effects and other concerns directly or indirectly associated with vaccination well explored. Also includes excellent links to adverse effects and how to gain non urgent to urgent help, specific to each territory in Australia.		The is a site on vaccination, not treatment
	17. Key recommendations are easily identifiable	7- Strongly Agree	7- Strongly Agree	7- Strongly Agree	7- Strongly agree	6	7- Strongly agree	7
	Comments	Tables			Provided for each vaccine	Difficult to find recommendations on COVID-19 vaccination but it's there. Should be with the pregnancy timeline recommendations.	Drop down menus	Specific advice for population groups - a level of health literacy is required.
	Score	77%	89%	89%	77%	77%	94%	61%



Results AGREE II Domains	AGREE II Key Items	Signposted Guidelines and Resources								
		Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	Australian Immunisation Handbook- Vaccination for infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>		
	18. The guideline describes facilitators and barriers to its application	3	3	3	5	7- Strongly agree	1- Strongly disagree	6		
	Comments	Some discussion re cost and PBS coverage	Facilitator: national immunisation program; no explicit discussion of barriers e.g., hesitancy		Addresses concerns about vaccines and authorisation of vaccinators	Question not applicable as the guidance supports vaccinations and accurate information is there.	Not found	Enablers: Call to Action; Site links to a webinar "ask an expert pregnancy livestream" (accessible via NZSL).		
Domain 5: Applicability	19. The guideline provides advice and/or tools on how the recommendations can be put into practice	5	6	4	6	7- Strongly agree	6	5		
	Comments	Preparing for vaccination, school and community clinics only discussed	Vaccination procedures		Protocols for vaccinators, vaccine storage, immunisation schedule	Yes - visually, audio, print and IT formats. All excellent	Details re dissemination in technical report			
	20. The potential resource implications of applying the recommendations have been considered	5	5	5	6	5	6	7		



	AGREE II Key Items			Signposted	I Guidelines and Resc	ources		
Results AGREE II Domains		Australian Immunisation Handbook- Vaccination for special risk groups (women who are planning pregnancy, pregnant or breastfeeding)	Australian Immunisation Handbook- Vaccination for infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> special risk groups (preterm infants)	<u>New Zealand</u> Immunisation Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding)</u>
	Comments	Mentioned PBS and special access groups but otherwise difficult to determine	States that PBAC considers cost effectiveness; mentions cold chain transport/equipment needed		List of minimum staff and equipment provided	I think some vulnerable communities would find trying to navigate the site a little challenging for finding the adverse reactions and where to find help for these, had to go to SKAI specifically. Although the site did describe well the places to access vaccination.	Included in GRADE scoring	Site details access to free vaccinations, online booking services, and vaccine resources.
	21. The guideline presents monitoring and/or auditing criteria	1- Strongly Disagree	2	1- Strongly Disagree	5	7- Strongly agree	1- Strongly disagree	5
	Comments	Not found	Data on local disease prevalence presented, nil data on vaccination rates in the community	Not found	Reporting side effects page 27; NZ epidemiology data presented for each vaccine	Tells how and where to record vaccination, and how to link into own records at other times.	Monitoring for new research but not of implementation/ adherence to guidelines	Links to MedSafe data reports
	Score	41%	50%	38%	75%	91%	44%	79%



	AGREE II Key Items	Signposted Guidelines and Resources								
Results AGREE II Domains		<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for special</u> <u>risk groups (women</u> <u>who are planning</u> <u>pregnancy, pregnant</u> <u>or breastfeeding)</u>	Australian Immunisation Handbook- Vaccination for infants <6mo	<u>Australian</u> Immunisation <u>Handbook-</u> <u>Vaccination for</u> <u>special risk groups</u> (preterm infants)	<u>New Zealand</u> I <u>mmunisation</u> Handbook 2020	<u>MumBubVax</u>	ATAGI COVID-19 Living Guideline (Chptr 14- Pregnancy and perinatal care)	<u>New Zealand</u> <u>Ministry of Health</u> <u>COVID-19 vaccines</u> (Pregnancy and <u>Breastfeeding</u> )		
	22. The views of the funding body have not influenced the content of the guideline	6	6	6	4	4	6	7		
Domain 6: Editorial Independence	Comments	Explicit statement not found	Developed by ATGI technical staff and approved by NHMRC	Implied but specific mention of this is not available	Ministry of Health is funding body; not explicitly stated	The funding bodies are overtly supportive of vaccination, and this is what the site is for, clear accurate science and vax information.	Explicit statement not found	MOH funded program		
	23. Competing interests of guideline development group members have been recorded and addressed	1- Strongly Disagree	1- Strongly Disagree	1- Strongly Disagree	4	1- Strongly disagree	7- Strongly agree	1- Strongly disagree		
	Comments	Not found	Not stated	Not recorded	Not explicitly stated	N/A in a way as the funding bodies are overtly vax positive and this is what the site is for; to provide clear, accurate science and vax information.	In technical report	Not explicitly stated		
	Score	41%	41%	41%	50%	25%	91.60%	50%		



	AGREE II Key Items	Signposted Guidelines and Resources								
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	1. Rate the overall quality of this guideline	5	6	5	6	7	6	5		
	2. I would recommend this guideline for use	Yes- with modifications	Yes	Yes- with modifications	Yes	Yes	Yes	Yes		
Overall Guideline Assessment	Notes	In regard to use for pregnant individuals- requires more detail. RANZCOG guideline could supplement this with more specific considerations re gestational weeks for vaccination, options for giving vaccination (in clinic, post-partum on ward), further discussion regarding specific risks and benefits in pregnancy, in particular passive immunisation and which vaccines benefit the pregnant person vs neonate vs both. Additional mention or elaboration regarding theoretical risk of live vaccines. Prefer referenced guidelines. Rh D IgG advice contradicts Canadian immunisation guideline but is unreferenced.				Need something like this in New Zealand. Covid vaccination in pregnancy could be more overt and easier to find on the website. Uses mostly non-emotive language throughout. I think this site really addresses the facts in an understandable and meaningful way.	Already endorsed by RANZCOG according to introduction. No references for some consensus recommendations e.g., VTE prophylaxis, many consensus-based recommendations in pregnancy.	Currently used as the national guidance		