

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

This statement has been developed by the Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44) Statement Development Panel and approved by the Women's Health Committee and associated working groups, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (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 the Pre-pregnancy and pregnancy-related vaccinations Clinical Guidance Statement (C-Obs 44) with the Influenza vaccination during pregnancy (and in women planning pregnancy) (C-Obs 45) Clinical Guidance Statement. 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 (<u>Appendix D</u>).

First developed by RANZCOG: November 2011 Current version: March 2023 Review due: March 2028

**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:	<ul> <li>This statement has merged with Influenza vaccination during pregnancy (and in women planning pregnancy) (C-Obs 45).</li> <li>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 last updated in March 2017.</li> <li>Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44) was first developed by the RANZCOG Women's Health Committee in March 2017.</li> <li>Pre-pregnancy and pregnancy-related vaccinations (C-Obs 44) was first developed by the RANZCOG Women's Health Committee in March 2011. It was updated in August 2019. The statement was most recently updated by a Statement Development Panel, a working group of the Women's Health Committee from July 2022- March 2023.</li> </ul>
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 (AGREE Next Steps Consortium, 2017).

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 acknowledges the existence of 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, including the schedule specifics (i.e., age criteria), 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 further 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 Pacific 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 older than six months of age and groups who have different vaccination requirements, were ruled out of scope for this statement update. Recommendations for the following special risk population groups not covered by this statement can be found below:

Australia: <u>Vaccination for special risk groups</u> (including women and infants who are immunocompromised (i.e., asplenia, long-term steroid use and other medication use); women and infants with complex medical needs; migrant and refugee women and infants; and women at occupational risk).



Aotearoa New Zealand: <u>Immunisation of special groups</u> (including immunocompromised individuals; chronic kidney disease; chronic liver disease; other special groups; immigrants and refugees; occupation-related vaccination and travel).

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>1, 2</sup>In Aotearoa New Zealand, research with Māori Māmā about vaccination reports that mothers (*Māmā*) 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> Increased 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>



4. Summary tables of information										
				This vaccination is safe to be given. It may be routinely recommended or given if clinically indicated						
						×			cated in pregnancy o ons has not been det	
Table 1. Vaccination recomm	endations- Australia					A	This vacc	ination is recommen	nded if international t	ravel is required
	Planning	Trimester	Trimester	Trimester	Postn	artum (ir	ncluding		Infants	
Disease/Vaccination	pregnancy	1	2	3		reastfeed		2 months	4 months	6 months
COVID-19	Recommended for people 5 years and older. <sup>i</sup>	for people 5 stage of pregnancy and postpartum for wom					y age.	Not indicated. <sup>i</sup>	Not indicated. <sup>i</sup>	Recommended for infants aged 6 months with severe immunocompromise, disability and those at greatest risk of severe outcomes from COVID-19 only.
<u>Hepatitis A</u>	Not routinely re travel to area of							Not	indicated < 12 mo	nths of age.

expected severe outcomes (lifestyle factors, pre-existing liver disease).

<u>Hepatitis B</u>

Women

planning

<sup>&</sup>lt;sup>i</sup> Please note, advice regarding the number and type of recommended additional doses of approved COVID-19 vaccines is subject to change. Please refer to <u>COVID-19 vaccines</u> | <u>Australian Government</u> <u>Department of Health and Aged Care</u> and the <u>COVID-19 vaccination in pregnant and breastfeeding women and those planning pregnancy - RANZCOG</u> advisory bulletin (information current at publication).

<sup>&</sup>lt;sup>ii</sup> See ATAGI statement on defining 'up-to-date' status for COVID-19 vaccination, 10 February 2022 (information current at publication)- <u>https://www.health.gov.au/news/atagi-statement-on-defining-up-</u> to-date-status-for-covid-19-vaccination.

iii Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Vaccines that are not routinely recommended in pregnancy: inactivated viral vaccines. Canberra, 2018. Table. Vaccines that are not routinely recommended in pregnancy: inactivated viral vaccines | The Australian Immunisation Handbook (health.gov.au)



Discoss	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1	2	2 3 breastfeeding)		2 months	4 months	6 months
	pregnancy should be up to date with this vaccination.			-	women <b>can receive if non-</b> <b>k for hepatitis B</b> .	Plus a dose at birth (dose 0). Recommended as early as 6 weeks of age (usually given with DTPa- hepB-IPV-Hib for additional doses). <sup>iv</sup>		
<u>Haemophilus influenzae type b</u> (Hib-PRP) disease	Only recommended if high risk and clinically indicated.	Not routin	Not routinely recommended. Pregnant women <b>can receive Hib</b> vaccine if at increased risk. <sup>viii</sup>				Coses 1-3 given as DTPa-hepB- IPV-Hib combination vaccine. <sup>xiii</sup>	<
<u>Human papillomavirus (HPV)</u>	Not routinely recommended for adults >19 years of age (however risk profile should be considered for eligibility).	become pre vaccinatior	nmended. Wo egnant after s n course shoul e remaining d pregnancy.	tarting HPV d stop and	Sreastfeeding women can receive HPV vaccines if required.	No	ot indicated < 9 year	rs of age.

<sup>&</sup>lt;sup>w</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>



Discoss Alexan	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1	2	3	breastfeeding)	2 months	4 months	6 months
<u>Influenza</u>	Strongly recommended. <sup>vii</sup> i	women a <b>pregnanc</b> durin	ended for all p at any trimeste y, especially if ng influenza se utumn/winter)	r <b>in <i>each</i></b> pregnant ason	Recommended and safe to receive during breastfeeding. <sup>viii</sup>	immunisation r	ed- maternal nay also provide ective antibodies.	Infants can receive first Influenza vaccine from 6 months of age (2 doses- 4 weeks apart within 12 months of age).
<u>Japanese encephalitis (JE)</u>	Not routinely recommended. Inactivated vaccine is considered safe to use in women planning pregnancy. <sup>v</sup>	women. The pregnancy a <b>risk o</b> t	e <u>Imojev (live a</u> and breastfeed <b>f acquiring JE</b> mmended for p	ittenuated) v. ling. Howeve can receive ir A regnant trave	gnancy or breastfeeding accine is contraindicated in r, <b>pregnant women at high</b> activated vaccines. <sup>vi</sup> Ilers spending 1 month or ng JE transmission season. <sup>v</sup>		✓ ▲ tivated JE vaccines fants from ≥2 month	can be administered to hs of age.
<u>Measles</u> and <u>mumps</u>	Avoid pregnancy within 28 days of receiving vaccination.		Additio t women are re	onal Practical	to be tested for immunity	Susceptible women should receive the rubella vaccine as soon as possible after	Not indicated < 12 months of age.	

<sup>&</sup>lt;sup>v</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Japanese-encephalitis- Contraindications and precautions: Women who are pregnant or breastfeeding. Canberra, 2021. Japanese encephalitis | The Australian Immunisation Handbook (health.gov.au)

<sup>&</sup>lt;sup>vi</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-</u> encephalitis#women-who-are-pregnant-or-breastfeeding

vii 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)



Disease/Vaccination	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants	
Disease/vacciliation	pregnancy	1	1 2 3 breastfeeding)				4 months	6 months
						delivery and have serological status checked after vaccination. <sup>vii</sup>		
Meningococcal disease Meningococcal B	Only recommended if at increased risk.	Pregn		tinely recom an receive if c	mended. linically indicated <sup>viii</sup>	As early as 6 weeks of age. <sup>ix</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.
<u>Monkeypox (mpox)</u> ×	Recommended for anyone categorised by public health authorities as high risk mpox contact <14 days. <sup>×</sup>	deficient) is	Not routinely recommended. The JYNNEOS® vaccine (replication- deficient) is considered safe to use in women who are pregnant and a high risk mpox contact <14 days. Risk-benefit analysis recommended. <sup>x</sup>					studies available. Both Ifants < 12 months of
Pertussis (whooping cough) dTpa combined vaccine- diphtheria, tetanus <sup>xi</sup> , and acellular pertussis-containing vaccine	No advice identified specific to planning pregnancy.	<i>each</i> preg trimester	<ul> <li>Recommended as a single dose in Vaccination is recommended as soon trimester and early 3<sup>rd</sup> trimester</li> <li>(preferably between 20-32 weeks).</li> </ul>					✓ onths, another dose at 6 nonths.

<sup>&</sup>lt;sup>viii</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 routinely recommended in pregnancy. 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>ix</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.

<sup>\*</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. See Updated ATAGI Clinical Guidance on Vaccination against Monkeypox (MPOX) Version 4 (current as at publication of statement)- <a href="https://www.health.gov.au/sites/default/files/2022-12/atagi-clinical-guidance-on-vaccination-against-monkeypox.pdf">https://www.health.gov.au/sites/default/files/2022-12/atagi-clinical-guidance-on-vaccination-against-monkeypox.pdf</a>

x<sup>i</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.



Discoss Alessination	Planning	Trimester	Trimester	Trimester	Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1	1 2 3		breastfeeding)	2 months	4 months	6 months
					pregnancy and >10 years since last dose <sup>xii</sup>		vaccine- diphth pe hepatitis B, ina	pB-IPV-Hib combination eria-tetanus-acellular ertussis, activated poliovirus, <i>influenzae</i> type b).
<u>Pneumococcal disease</u>	Women of child- bearing age with a risk condition for pneumococcal disease can receive the vaccine before a planned pregnancy.	Pregnant invasive pne	tinely recomn t women with eumococcal di <b>e the vaccine</b> i	a risk for isease (IPD),	Women of child-bearing age with a risk for pneumococcal disease can receive the vaccine <b>as soon as practicable</b> after birth. <sup>viii</sup>	As early as 6 weeks of age.		3 <sup>rd</sup> dose not required until 12 months of age.
<u>Poliomyelitis</u>					ountry or at high risk of ve IPV vaccine. <sup>iii</sup>	Given as DTPa- hepB -IPV-Hib combination vaccine for Doses 1-3 <sup>xiii</sup>	⊘	⊘
<u>Q Fever</u>	Only if indicated. Safe use in women planning Not routinely recommended. Safe pregnancy and while breastfeeding					Not recommend	▼ led for off-label use age.	in people < 15 years of

x<sup>ii</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-</u> <u>diseases/tetanus</u>

x<sup>iii</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



Discoss	Planning	Trimester	Trimester	Trimester	Postpar	tum (including		Infants	
Disease/Vaccination	pregnancy	1	2	3	3 breastfeeding)		2 months	4 months	6 months
	pregnancy not established.								
<u>Rabies</u>	Not routinely recommended but <b>registered</b> <b>for use in any</b> <b>age</b> .		y and while br		required,	nistered during i.e., as part of			gistered for use in any risk-benefit balance.
<u>Rubella</u> (given as MMR)	C Immunisation providers should make every effort to identify and immunise non-pregnant seronegative women of child- bearing age. Pregnancy should be avoided for 28 days after vaccination.xiv	MMR- cont	taining vaccine in pregnant v		ndicated	C Breastfeeding women can receive MMR vaccines. Postpartum vaccination of non-immune women does not need to be delayed due to breastfeeding. xviii			
Rotavirus		Chil	dhood immur	isation only.			✓ Rotarix.	✓ Rotarix.	<b>Ø</b>

xiv Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Rubella- Pregnant women, Australian Government Department of Health and Aged Care, Canberra, 2022. https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/rubella#pregnant-women



	Planning	Trimester Trimester Trimes	ter Postpartum (including		Infants	
Disease/Vaccination	pregnancy	1 2 3	breastfeeding)	2 months	4 months	6 months
						Only required if vaccination course of RotaTeq is given.
<u>Typhoid fever</u>	Not rout	inely recommended, unless travellir	g to endemic regions.	Ν	lot indicated < 2 ye	ars of age.
<u>Varicella (chickenpox)</u>	Immunisation providers should make every effort to identify and immunise non- pregnant seronegative women of childbearing age. Avoid pregnancy for 28 days after vaccination. <sup>xv</sup>	¥ Varicella- containing vaccines ar contraindicated in pregnant women. <sup>xv</sup>	Non-immune breastfeeding women can receive varicella vaccine. No effects on breastfed infants have been reported. <sup>xv</sup>	Not recor	mmended for infan	ts <2 years of age.
<u>Yellow fever</u>	Not routinely recommended- only if travelling to area with a risk of yellow	Not recommended. Pregnant won should be advised to avoid going rural areas where yellow fever		Contraind	× licated in infants <9	) months of age. <sup>xviii</sup>

<sup>&</sup>lt;sup>xv</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Varicella (chickenpox)- Women who are pregnant or breastfeeding, Australian Government Department of Health and Aged Care, Canberra, 2022. <u>https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/varicella-chickenpox#women-who-are-pregnant-orbreastfeeding</u>

xviii Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Yellow fever- Infants, Australian Government Department of Health and Aged Care, Canberra, 2022. https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#infants



Disease Alessination	Planning	Trimester	Trimester	Trimester	Postpartum (including breastfeeding)	Infants			
Disease/Vaccination	pregnancy	1	2	3		2 months	4 months	6 months	
	fever virus transmission.	<b>travel is</b> wome	ion is a risk. Ho unavoidable, p n <b>should</b> recei <sup>.</sup> vaccine. <sup>xvi</sup> . <sup>xvii</sup>	pregnant	yellow fever or cannot avoid/postpone travel. <sup>xvii</sup>				

Disease/Vaccination	Planning	Trimester	Trimester	Trimester 3	Postpartum		Infants	
COVID-19	encouraged to b	↓ is pregnant, or e routinely vac ny stage of pre	cinated with i	gnancy is	There are no safety concerns about giving mRNA-CV to those lactating. <sup>xix</sup>	<b>6 weeks</b> Not availab	3 months	<b>5 months</b> 5 years of age.
<u>Haemophilus influenzae type b</u> (Hib) disease	Only if high risk. <sup>xx</sup>	1	,	recommended astfeeding wor		Ø	Ø	0

x<sup>vi</sup> Please note, women who are pregnant at the time of receiving their yellow fever vaccine may be required to receive a booster dose if they do not respond optimally to a single dose. Seehttps://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/yellow-fever#travellers

xvii 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>

xix Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- COVID-19. Section 5.5.3 Breastfeeding and 5.5.4- Pregnancy: Online, 2020. 5. Coronavirus disease (COVID-19) | Ministry of Health NZ

<sup>&</sup>lt;sup>xx</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



Disease Alexination	Planning	Trimester	Trimester	Trimester	Destructions		Infants	
Disease/Vaccination	pregnancy	1	2	3	Postpartum	6 weeks	3 months	5 months
<u>Hepatitis A</u>	Only if high risk <sup>xxi</sup>	been detern expected t precaution, t	nined, <sup>xxi</sup> howev o be any risk to the HepA <b>vacci</b>	ver as an inactiv o the developing i <b>ne should only</b> l	breastfeeding has not yet ated vaccine, there is not g fetus and infant. <sup>xxi</sup> As a <b>be used during pregnancy</b> a high-risk country).	Not routinely recommended. Only if immunosuppressed or during community outbreak. <sup>xxii</sup>		
<u>Hepatitis B</u>	Women planning pregnancy should be up to date with this vaccination.	pregnan	cy and while b		and can receive during <b>non-immune and at</b> infection <sup>xxiii</sup>	Plus a dose at birth for infants born to carrier mothers. <sup>xxiii</sup> Recommended at 6 weeks of age.	0	
<u>Human papillomavirus (HPV)</u>	Women <26yo are eligible for the HPV vaccine. Enquiring about possibility of woman being	become pregnant after starting HPV vaccination course <b>should be delayed</b> Breastfeeding women can receive HPV Not indicated < 9 years of ag						of age.

<sup>&</sup>lt;sup>xxi</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

xxii Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Hepatitis A. Section 8.5.1 Recommendations- Routine immunisation for children and Section 8.5.2 Immunisation Schedule. Online, 2020. <u>8. Hepatitis A – Immunisation Handbook 2020 | Ministry of Health NZ</u>

x<sup>xiii</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



Discoss	Planning	Trimester	Trimester	Trimester	Destreature		Infants	
Disease/Vaccination	pregnancy	1 2 3		3	Postpartum	6 weeks	3 months	5 months
	pregnant is not necessary before vaccination (no adverse effects shown on pregnancy outcomes.) <sup>xxiv</sup>							
<u>Influenza</u>	✓ Recommended for all adults.	at any trime durir (autumn/		ally May to	Recommended and safe to receive during breastfeeding. <sup>xxv</sup>	passive antibody	Maternal-fetal transfer provides ne protection. <sup>xxv</sup>	Only indicated from 6 months of age if infant has chronic illness or history of significant respiratory disease. <b>17F</b> <sup>xxy</sup>
<u>Measles and mumps</u>	Avoid pregnancy for four weeks after MMR vaccination <sup>xxvi</sup>	Follow-up inadverten pregnancy s <b>teratogenic</b>	× ated during p studies of we tly received N show <b>no evide</b> or harmful to tus or her new	omen who MMR during ence MMR is the mother,	Can be given safely after birth (if required) and to breastfeeding women <sup>xxvii</sup>	Not indicated < 1	12 months of age.	

xxiv 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

xw 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</u>. Influenza – Immunisation Handbook 2020 | Ministry of Health NZ

xxvi 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

xxvii Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Rubella (MMR). Section 19.5.3- Pregnancy and breastfeeding: Online, 2020 19. Rubella – Immunisation Handbook 2020 | Ministry of Health NZ



	Planning	Trimester	Trimester	Trimester	Destrouture		Infants	
Disease/Vaccination	pregnancy	1 2		3	Postpartum	6 weeks	3 months	5 months
		All pregnant women are recommended to be tested for immunity to rubella.						
<u>Meningococcal disease</u> <u>Meningococcal B</u>	Women can r indicated. No a	t routinely recommended. eceive prior to or during pregnancy if dverse effects among pregnant women vaccinated reported. <sup>xxviii</sup>			Only if indicated. Safe to be administered during breastfeeding. <sup>xxviii</sup>	✓ From 6 weeks of age.	✓ 8 weeks required between 1 <sup>st</sup> and 2 <sup>nd</sup> doses. <sup>xxviii</sup>	3 <sup>rd</sup> dose not required until 12 months of age.
<u>Monkeypox (mpox)</u>	S25 of Medic con Experience	Not yet approved by Medsafe. May be prescribed under S29 ar S25 of Medicines Act 1981 for high-risk individuals (pre-exp contacts of people with mpox (post-exposure) vac Experience in women planning pregnancy, women who a breastfeeding is limited- <b>may be given after risk-benef</b> it				No advice ident	ified specific to infants	s < 6 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>x</sup>	✓ oded as a single ded as a single	of every rotection for	Vaccination is recommended for women who were <b>not</b> vaccinated during pregnancy.	From 6 weeks of age. dTpa combined vaccine-	At 3 months of age.	✔ At 5 months of age.

xxviii 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>

xxix Advice provided directly by the Immunisation Advisory Centre New Zealand, dated 23/01/2023, in recognition of frequent updates to eligibility criteria and availability of vaccine only under section 29 of the Medicines Act 1981. Available on request. See also-<u>Monkeypox vaccination available to eligible people from next week</u> | <u>Beehive.govt.nz</u> (current at publication)

<sup>&</sup>lt;sup>xxx</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



	Planning	Trimester Trii	mester Trimester	Destructions		Infants	
Disease/Vaccination	pregnancy	1	2 3	Postpartum	6 weeks	3 months	5 months
		Tdap combination vaccine- diphtheria, tetanus, and pertussis. <sup>xxx</sup>			diphtheria, tetanus, and acellular pertussis- containing vaccine. <sup>xxx</sup>		
<u>Pneumococcal disease</u>	Women of child- bearing age with risk condition for pneumococcal disease can receive the vaccine before a planned pregnancy.	,	commended. Only if cated <sup>xxxi</sup>	Only if indicated. Safe to be administered during breastfeeding. <sup>xxxi</sup>	As early as (	✓ 5 weeks of age.	Second dose at 5 months of age. xxxii Booster not required until 12 months of age.
<u>Rubella</u>	Women of child- bearing age should be assessed to determine immunity to rubella. <sup>xxxiii</sup>		× MMR- containing vaccines are contraindicated during pregnancy.		Not indicated <12 months of age.		s of age.

<sup>&</sup>lt;sup>xxxi</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>

xxxii Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Pneumococcal disease. Section 16.5- Recommended immunisation schedule and Section 16.5.1 Usual childhood schedule- Children aged under 5 years. <u>16. Pneumococcal disease – Immunisation Handbook 2020 | Ministry of Health NZ</u>

xxiii Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Rubella. Section 19.5.3- Pregnancy and breastfeeding. <u>19. Rubella – Immunisation Handbook 2020 | Ministry of</u> Health NZ



Disease Alessingtion	Planning Trimester Ti		Trimester	Trimester	Postpartum		Infants	
Disease/Vaccination	pregnancy	1	2	3	Postpartum	6 weeks	3 months	5 months
<u>Rotavirus</u>				rn caused by vacc r vaccination of th	ine exposure during ne infant) <sup>xxxiv</sup>	At 6 weeks of age. <sup>xxxiv</sup>	At 3 months of age.	Not indicated.
<u>Varicella (chickenpox)</u>	Avoid pregnancy after varice	× for at least fou la vaccination.		Contraindicated during pregnancy <sup>xxvii</sup>	Can be given safely after birth (if required) and to breastfeeding women	Not in	ndicated < 12 montl	ns of age.

xxxiv 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>

xxxv 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



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

Group	Additional vaccination recommendations	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 6 months of age <sup>xxxvi</sup>	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	
	Meningococcal B: Aboriginal and Torres Strait Islander children.	At 2 months, 4 months, and 6 months of age <sup>xxxvii</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. <sup>xxxviii</sup>	Australia	

xxxxi 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. Vaccination for Aboriginal and Torres Strait Islander people | The Australian Immunisation Handbook (health.gov.au)

xxxii 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

xxxviii Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Pneumococcal disease- Recommendations- Aboriginal and Torres Strait Islander people, Australian Government Department of Health and Aged Care, Canberra, 2022. <u>https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/pneumococcal-disease#aboriginal-</u> and-torres-strait-islander-people



Group	Additional vaccination recommendations	Time period	Country
	<b>Pneumococcal:</b> An additional dose (3 initial	Additional dose at 6 months of age for non-Indigenous infants. <sup>xli</sup>	Australia
<u>Pre-term infants, born &lt;28 weeks</u> gestation <sup>xxxix, xl</sup>	doses and one additional- 4 in total) of 13vPCV (13-valent pneumococcal conjugate vaccine).	Additional dose at 3 months of age (or as per age- appropriate catch-up schedule). <sup>xlii</sup>	Aotearoa New Zealand
	Pertussis: A single dose of Tdap is recommended for primary caregivers of infants 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 within 14 days prior to the birth ( <u>4.2.2</u> ).	Within infant's period in NICU.	Aotearoa New Zealand
	Hepatitis B: An additional dose is recommended for infants born < 32 weeks and/or with low birth weight <2000g. Preterm infants born to hepatitis B surface antigen (HBsAg) +ve mothers should receive both the vaccine and Hep B immunoglobulin.	At birth, then at 2, 4 and 6 months of age.	Australia
	Rotavirus: Premature infants can receive without correction for gestational age, including hospitalised infants who are medically stable.	From chronological age of at least 6 weeks.	Australia

xxxixAustralian 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)

x<sup>I</sup> Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Immunisation of special groups. Section 4.2.2 Preterm and/or low birthweight infants. <u>4. Immunisation of special groups – Immunisation Handbook 2020 | Ministry of Health NZ</u>

x<sup>li</sup> Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook- Pneumococcal disease- People with medical risk factors, Australian Government Department of Health and Aged Care, Canberra, 2022. People with medical risk factors | Pneumococcal disease | The Australian Immunisation Handbook (health.gov.au)

xlii Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Pneumococcal disease. Section 16.5.2- Extended pneumococcal immunisation for high-risk groups. <u>16.</u> Pneumococcal disease – Immunisation Handbook 2020 | Ministry of Health NZ



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

Group	Additional vaccination recommendations	Time period	Country
Vaccination for infants born to mothers who received immunosuppressive therapy, including biological disease- modifying anti-rheumatic drugs (bDMARDs) and other biological agents <sup>kilii, kliv</sup>	Any live attenuated vaccine (including rotavirus, BCG and oral polio): Contraindicated: If an infant's mother received bDMARDs during pregnancy, especially in the 3rd trimester, it is not recommended the infant receives the rotavirus vaccine.	<ul> <li><u>Seek expert advice</u>. 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 (who meets neonatal BCG eligibility criteria<sup>xlv</sup>) should be at least 6 months of age before receiving a BCG vaccine.</li> </ul>	Australia
<u>agents<sup>xliii, xliv</sup></u>		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 will not be able to receive any rotavirus vaccine doses.	Aotearoa New Zealand

x<sup>liii</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>

xiv 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>

xlv Manatu Hauora (Ministry of Health) Aotearoa New Zealand. Immunisation Handbook- Tuberculosis- Recommended immunisation schedule. Section 21.5.2, Table 21.1 Neonatal BCG eligibility criteria. 21. Tuberculosis – Immunisation Handbook 2020 | Ministry of Health NZ



### 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)

### 7. References

- 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)
- 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</u> with parents - PubMed (nih.gov)
- 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
- 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: 10.1080/21645515.2019.1649552. Epub 2019 Sep 6. PMID: 31368832; PMCID: PMC7062431.
- 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>
- 6. 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-riskgroups/vaccination-for-women-who-are-planning-pregnancy-pregnant-orbreastfeeding#inadvertently-giving-a-live-attenuated-viral-vaccine-during-pregnancy-or-shortlybefore-pregnancy</u>
- 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>
- 8. 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>



## Appendices

## Appendix A: 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 B: 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 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 **February 2023**. 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.

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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.



				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)	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>
	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
	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	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	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> ( <u>Pregnancy and</u> <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
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	<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> 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> )
	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%



				Signposted	l Guidelines and Reso	ources		
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	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 Guidelines and Resources						
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> <u>Vaccination for</u> infants <6mo	Australian Immunisation Handbook- Vaccination for special risk groups (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> Ministry of Health <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	



				Signpostec	l 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)	<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> 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> ( <u>Pregnancy and</u> <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 underserved 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	l Guidelines and Resc	ources		
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	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%



				Signpostec	Guidelines and Reso	urces		
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	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



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	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%	



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	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



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	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 underserved 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%



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	22. The views of the funding body have not influenced the content of the guideline	6	6	6	4	4	6	7		
	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		
Domain 6: Editorial Independence	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%		



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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



#### Version history for C-Obs 44

Version	Date of Version	Pages revised / Brief Explanation of Revision
V1.0	March 2011	First developed/RANZCOG Women's Health Committee
V2.0	August 2019	Updated/ RANZCOG Women's Health Committee
V3.0	March 2023	Updated and merged with C-Obs 45 / Pre-pregnancy and pregnancy-related vaccinations Statement Development Group, RANZCOG Women's Health Committee

### Version history for C-Obs 45

Version	Date of Version	Pages revised / Brief Explanation of Revision
V1.0	November 2011	First developed/ RANZCOG Women's Health Committee
V2.0	November 2013	Reviewed/ RANZCOG Women's Health Committee
V3.0	March 2017	Updated/ RANZCOG Women's Health Committee
V4.0	March 2023	Retired/ RANZCOG Board

Policy Version:	Version 3.0
Policy Owner:	Women's Health Committee
Policy Approved by:	RANZCOG Council/Board
Review of Policy:	March / 2023

