Contraception guidelines Methodology summary

Advice on development for the Ministry of Health, Health Pathways and professional colleges

August 2020

ALLEN+CLARKE

Document status:	Draft for comment
Version and date:	FINAL 15 September 2020
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Filing Location:	W:\MoH Public Health\Contraception guidelines\Deliverables\Draft guidelines
Peer / technical review:	Joanna Clarke
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GLOSSARY

AGREE II	The Appraisal of Guidelines for Research & Evaluation Instrument
DMPA	Depot medroxyprogesterone acetate
FSRH	Faculty of Sexual and Reproductive Healthcare
LARC	Long-acting reversible contraception
NZCOM	New Zealand College of Midwives
NZFP	New Zealand Family Planning
NZNO	New Zealand Nurses Organisation
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RNZCGP	Royal New Zealand College of General Practitioners

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EXECUTIVE SUMMARY

Allen + Clarke was contracted by the Ministry to lead the development of national contraception guidelines for health practitioners. This work was overseen by the National Contraception Guidelines Steering Group.

This report provides a short summary that the Ministry of Health, Health Pathways and professional colleges can use to understand the processes used to develop Aotearoa New Zealand's guidance on contraception.

The diagram below (Table 1) summarises the methodology applied.

Table 1: Summarised methodology

	Aug - Oct	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Aug
Planning + scoping	Project plan prepared + agreed with MOH	Project plan approved by Steering Group	Project plan reviewed	Project plan reviewed	Project plan reviewed
National Contraception Guidelines Steering Group	Steering Group established	Meeting 1 to approve project plan, stakeholder engagement + terms of reference	Meeting 2 to review engagement findings, gap analysis and next steps	Meeting 3 to review recommendations and guidelines Out of session advice as needed	Meeting 4 to finalise guidelines Out of session advice as needed
Stakeholder engagement	Phase 1 Stakeholder plan agreed with MOH Engagement with NZFP	Phase 1 stakeholder interviews Engage with NZFP	Engage with NZFP Engage with HealthPathways	Engage with NZFP + HealthPathways	Engage with NZFP + HealthPathways Focus groups with women Re barriers to + enablers of access
Stocktake of existing NZ and offshore resources	Develop TOR and tools	TOR + tools approved by Steering Group Stocktake completed			
Literature review	Complete lit review to identify current guidelines + gaps		TOR for detailed mini-reviews on areas requiring consensus approved by Steering Group	Complete literature reviews + summaries	
Gap analysis and drafting		Phase 1 gap analysis completed (stocktake, lit reviews, interviews)	Gap analysis considered by Steering Group	Guidelines drafted	
Consultation + finalisation				Written consultation paper and interviews with key stakeholders	Submissions analysis Finalise guidelines + implementation

Blue boxes in this document describe which AGREE II items the following content is relevant to. Further information is included in the draft final guidelines and the chapters that sit behind the guidelines.

1. THE NEED FOR GUIDELINES

1.1. Background

Allen + Clarke was contracted by the Ministry of Health to lead the development of national contraception guidelines. This work was overseen by the National Contraception Guidelines Steering Group[1]. Through our work, we found that health practitioners:

- already know about, like and use a considerable number of guidelines (especially those developed by the UK-based Faculty of Sexual and Reproductive Healthcare, FSRH), guidance and resources about contraception counselling and contraception methods: they did not want more stand-alone guidelines that repeated existing accepted practices/advice
- acknowledged that, in many cases, effective and acceptable contraception guidance is already well documented, robust and produced by competent authorities like New Zealand Family Planning, FSRH and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- wanted concise, evidence-based, and accessible guidance
- wanted specific national consensus for some clinical issues for which specific Aotearoa New Zealand guidance could improve services and access to contraception, especially where new evidence suggests practice change is needed, and
- supported adapting existing robust guidelines to Aotearoa New Zealand and improving access to information at the point of care, including through tools like Health Pathways.

Existing up-to-date guidelines from FSRH, RANZCOG and others can be relied upon for most clinical information: there is no need to further repeat the evidence reviews that underpin existing robust guidance.

1.2. Aims and objectives

The overall objective(s) of the guideline is (are) specifically described (AGREE II 1)

The health question(s) covered by the guideline is (are) specifically described (AGREE II 2)

Access to contraception has important life consequences for individuals and their whānau (family) in terms of education, learning potential, finances, physical and mental wellbeing, and child health. Everyone should be encouraged to consider their contraception needs if they are sexually active and not wanting a pregnancy. Effective contraception counselling increases access to, and uptake of, contraception. Health practitioners should adopt a person-centred approach when providing contraceptive counselling. They should support every individual to make an informed decision about the contraception that meets their needs and circumstances. These

[1] More information about the National Contraception Guidelines Steering Group is included in *section 2.1* of this report.

conversations should be conducted respectfully, without judgement and with understanding of culture, sexuality, and gender.

The Ministry of Health would like to see individuals making informed choices about contraception and see long-acting reversible contraception (LARC) offered as regularly as other methods of contraception. The Ministry wants to build the quality and consistency of contraception services in New Zealand by developing national guidance on contraception. The national best practice guidelines will assist health practitioners to proactively provide consistent, evidence-based advice and information to individuals about their contraception choices. This includes providing up-to-date evidence that may result in practice changes related to the uptake of very effective LARC.

1.3. Intended users of the guidelines

The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described (AGREE II 3)

The target users of the guideline are clearly defined (AGREE II 6)

The population to whom the guidelines applies is sexually active New Zealanders who do not wish to become pregnant (i.e., contraception users).

The guidelines are intended for use by any health practitioner who provides advice on contraception to individuals. It includes any setting in which individuals receive contraceptive advice from a health practitioner, including primary care, community health services and maternity services (including individual's homes if maternity services are delivered there). Key users are likely to include:

- general practitioners
- nurses
- midwives
- obstetricians/gynaecologists
- specialist sexual and reproductive health medical practitioners, and
- pharmacists.

Health service planners and funders may also find the guidance on contraceptive counselling useful as it contains items that relate specifically to the provision of confidential, non-judgemental and welcoming services.

1.4. Conflicts of interest

The views of the funding body have not influenced the content of the guideline (AGREE II 22)

The development of Aotearoa New Zealand's guidelines on contraception has been funded by the Ministry of Health. No industry funding was received.

2. DEVELOPING EVIDENCE-BASED GUIDELINES

The methods for formulating the recommendations are clearly described (AGREE II 10)

The health benefits, side effects, and risks have been considered in formulating the recommendations (AGREE II 11)

There is an explicit link between the recommendations and the supporting evidence. (AGREE II 12)

Part 2 of this report summarises the methodological steps used to develop evidence-based guidelines on contraception that are applicable to Aotearoa New Zealand. Key methodological steps included:

1. The establishment of the National Contraception Guidelines Steering Group
2. A literature review on the barriers and enablers to effective contraceptive counselling and access
3. A survey to stocktake existing resources and guidelines currently used by New Zealand health practitioners for advice on contraception
4. Stakeholder interviews to discuss the need for, scope of and presentation/access to contraception guidelines for Aotearoa New Zealand
5. Targeted literature reviews to identify the latest clinical evidence on areas requiring consensus within New Zealand's contraceptive practice
6. Written and face-face consultation on the draft guidelines
7. Liaison with HealthPathways on proposed implementation, and
8. Development of the Aotearoa New Zealand's contraception guidelines, under the advice of the National Contraception Guidelines Steering Group.

A summary of the process is included in the Executive Summary (Table 1).

2.1. National Contraception Guidelines Steering Group

The guideline development group includes individuals from all the relevant professional groups (AGREE II 4)

Competing interests of guideline development group members have been recorded and addressed (AGREE II 23)

To guide this mahi, *Allen + Clarke* convened the multidisciplinary National Contraception Guidelines Steering Group.

2.1.1. Terms of reference

The National Contraception Guidelines Steering Group was responsible for providing guidance to *Allen + Clarke* on the development of the guidelines.

It:

- provided strategic leadership to the project, from inception through to delivery of the final guidelines for endorsement
- advised on all project planning documents, providing advice on the scope of the national best practice guidelines, commenting on the stocktake terms of reference and key stakeholder interview scope/questions, reviewing the terms of reference for initial literature review (barriers/enablers, cost-effectiveness, data about use of contraception in New Zealand) and agreeing PICO(T) for clinical questions
- reviewed the gap analysis prepared by *Allen + Clarke* and provided sense-making advice on the proposed next steps
- confirmed the range of best practice guidelines from which to base specific advice on individual contraceptive options (including considering consensus statements)
- provided a space for *Allen + Clarke* and the separate training provider to receive joint advice to ensure that the two components of the project fit well together
- supported the development of consensus statements on any areas of discordance raised during the development of the guidelines
- reviewed the draft guidelines prior to external consultation, and
- reviewed the feedback received through the external consultation process,
- advised on engagement with Health Pathways, and
- provided advice on and approved the final draft guidelines.

The Group met formally four times over the course of the project and provided out-of-session feedback on issues throughout the project.

2.1.2. Members

Members of the Group were nominated by their College. Nominated members were appointed for the New Zealand College of Midwives (NZCOM), New Zealand Nurses Organisation (NZNO), RANZCOG, and the Royal New Zealand College of General Practitioners (RNZCGP) and the Pasifika Medical Association. Other members included those with an academic interest in contraception, representatives from district health boards, the New Zealand Sexual and Reproductive Health Society, youth health practitioners, and consumer representatives. *Allen + Clarke* and New Zealand Family Planning (NZFP) also had representatives. Members were:

- Annette Milligan (NZNO)
- Dr Beth Messenger (NZFP)
- Briony Raven (NZCOM)
- Carmen Timu-Parata
- Dr Debbie Hughes (RNZCGP)
- Eunique Kitiseni (Consumer)
- Dr Fionna Bell (Pasifika Medical Association)

- Dr Helen Patterson (New Zealand College of Sexual and Reproductive Health)
- Jesse Solomon
- Lizzie Earles (NZNO)
- Dr Ruth Swarbrick (RANZCOG)
- Dr Sue Tutty (project team representative), and
- Marion Clark (Chair).

Advice was also sought from the Pharmaceutical Society at several stages throughout the project.

Conflicts of interest were identified and managed throughout the Group. No conflicts of interest specifically resulted in Group members being unable to participate in the process.

2.2. Preliminary literature review

Systematic methods were used to search for evidence (AGREE II 7)

The criteria for selecting the evidence are clearly described (AGREE II 8)

The strengths and limitations of the body of evidence are clearly described (AGREE II 9,)

Please see detailed chapters behind the guidelines

We completed a literature review to describe existing contraception guidelines produced by competent authorities, as well as information about existing barriers and enablers that individuals experience when accessing contraception in New Zealand. This helped us understand what baseline guidance was already available, and the known barriers and enablers specific to the New Zealand context, so that we could identify any gaps in the existing guidance and use this to identify where New Zealand specific guidance might be required. The terms of reference for this literature review is included in *Annex A*.

2.2.1. What we did

To conduct the literature search, *Allen + Clarke* developed an initial terms of reference. After discussion and confirmation with the Ministry, these terms were provided to its library services to conduct the searches. The Ministry searched databases such as Embase, CINAHL, Scopus, PsycINFO, the Cochrane Library and others to identify systematic reviews (with/without meta-analysis), narrative literature reviews, randomised controlled trials, observational studies, clinical guidelines, qualitative research, New Zealand theses, and grey literature related to the research questions.

The literature search was conducted by the Ministry's library services between the 26th of September and the 3rd of October 2019. The Ministry's librarian removed duplicates and false drops from the searches and provided *Allen + Clarke* with the resulting XML files, as well as a list of the abstracts and links to grey literature found online. Citations were managed with Zotero and the subsequent references were managed using NVivo.

The total number of sources included in this literature review, following exclusions, was fifty-six. Thirty-one were clinical guidelines, twenty-two were peer reviewed journal articles and three were New Zealand theses.

A validation exercise to check that all the key literature and documents had been captured was undertaken. While typically this involves reviewing the bibliographies from systematic or narrative reviews, our returns on the barriers and enablers for access were almost entirely comprised of primary literature describing specific interventions for certain population groups. Thus, a broad and general sweep of the bibliographies of these studies was undertaken to identify further potentially relevant literature and validate the Ministry's findings. This resulted in *Allen + Clarke* independently sourcing two additional peer reviewed journal articles for inclusion.

2.2.2. How we used information

Information collected through the literature review was used to inform the development of questions for our first round of stakeholder engagement. Information from the literature review was also presented to the National Contraception Guidelines Steering Group for its review and consideration and this then informed the collated gap analysis (from which topics for the second suite of technical clinical literature reviews were drawn). Content from this review also informed the development of the contraception counselling pathway.

2.3. Survey to stocktake existing guidance used by health practitioners

Between 18 November and 16 December 2019, *Allen + Clarke* conducted a contraception survey. The purpose of the survey was to seek information from organisations and individual health practitioners about existing contraception guidelines and resources currently used in New Zealand, perceived gaps or missing information within existing guidelines and resources, and preferences for format and style of guidelines and resources.

2.3.1. What we did

Data was collected through a dedicated SurveyMonkey Project developed by *Allen + Clarke*. The survey included two question streams: one seeking advice from organisational respondents and one from individual health practitioners. Respondents were routed through one stream only, depending on whether they responded as an individual health practitioner or on behalf of an organisation. The survey asked responders about the following areas:

- identifying information
- questions about existing guidelines and resources developed/used/recommended
- advice about current gaps or missing information
- format and style preferences for guidelines and supporting resources
- questions about barriers and enablers to accessing contraception in New Zealand, and
- other comments.

2.3.2. Who was involved?

The survey was sent to the following groups:

- Each District Health Board
- Each Primary Health Organisation

- Professional colleges/associations including the RNZCGP; NZNO; New Zealand College of Nurses; NZCOM; Nga Maia Māori Midwives Aotearoa; RANZCOG; New Zealand Sexual Health Society (NZSHS); Pasifika Medical Association
- NZFP
- Pharmaceutical Society New Zealand
- Professional Association for Transgender Health Aotearoa
- University and Polytechnic Student Health Services, and
- Women's Health Action.

Each organisation was asked to respond to the survey as developers/promoters of guidelines/guidance material on contraception. We also asked that each organisation circulate the survey to health practitioners working within their organisation/members.

2.3.3. Response rate

In total, the survey received 563 responses from individual health practitioners (194 GPs, 102 nurses, 78 specialists, 37 nurse practitioners, 12 midwives, ten health service managers, and six pharmacists)and 91 organisations involved in health or social service delivery and/or developing or using contraception guidelines and resources in New Zealand.

2.3.4. How we used information

Information collected through the survey was reviewed and analysed and used to inform the development of questions for our first round of stakeholder engagement. Information from the stocktake was also presented to the National Contraception Guidelines Steering Group for its review and consideration and this then informed the collated gap analysis (from which topics for the second suite of technical clinical literature reviews were drawn).

2.4. Stakeholder interviews

Between November 2019 and January 2020, the *Allen + Clarke* project team met with 30+ sexual and reproductive health experts to discuss existing guidelines and their use, the need for and format of national contraception guidelines in New Zealand and gaps. Interviewees included professional colleges/associations, individual or small groups of health practitioners, academics, education programme managers and policy/planning representatives. Individuals were identified or nominated in coordination with the Ministry of Health, NZFP, relevant professional medical associations, and the National Contraception Guidelines Steering Group.

2.4.1. What we did

Interviews were conducted through a combination of face-face engagements and teleconferences via Zoom. Interviews were conducted in a semi-structured style, covering the following topics:

- existing contraception guidelines/resources and endorsement processes (where relevant) and including questions about the need for and scope of national guidelines on contraception for New Zealand
- advice on gaps/issues where national guidance would be useful

- facilitating culturally competent and youth friendly conversations about contraception and how health practitioners should be supported in this, and
- barriers and/or enablers for different groups of New Zealanders in accessing effective contraceptive care.

2.4.2. Who was involved?

We met with the following stakeholders:

- Abortion Providers Group Aotearoa New Zealand (APGANZ) (Dr Helen Patterson)
- Auckland Nurses Group (Kerrie Salwey)
- Dr Helen Roberts (Obstetrics and Gynaecology*)*
- Community Health Pathways (Dr Justine Lancaster)
- Jade Le Grice (University of Auckland)
- Mangere Refugee Resettlement Centre (Dr Alison McLeod)
- New Zealand Sexual Health Society (Dr Helen Patterson)
- NZ College of Nurses (Jessica Irvine, Lucy Halsey)
- NZCOM (Claire MacDonald, Jacqui Anderson, Robyn McDougal)
- NZFP (Dr Catriona Murray, Rose Stewart, Dr Luci Montgomerie)
- NZNO (Anna Marshall, Fionna Kennedy, Katie Mullord)
- Pauline Fakalata (Nurse Unit Manager - Gynaecology Services*)*
- Pharmaceutical Society (Chloe Campbell, Shirena Vasan)
- Rainbow Youth (Frances Arns)
- RANZCOG (Dr Leigh Duncan, Dr Ruth Swarbrick, Dr Sarah Tout)
- RNZCGP (Dr Liza Lack), and
- Village Collective (Letoa Jenkins).

Some interviews were not able to progress at the time (cancellations or lack of interest); however, we engaged with those stakeholders with the written guidelines feedback.

2.4.3. How we used information

Information collected through the interviews was used to frame up the final approach to preparing guidelines for Aotearoa New Zealand and to finalise the scope of the work. Advice from stakeholders was presented to the National Contraception Guidelines Steering Group for its review and consideration and this then informed the collated gap analysis (from which topics for the second suite of technical clinical literature reviews were drawn). Content from the interviews strongly informed the development of the contraception counselling pathway and the method-specific chapters.

Information received to this point was used to complete a gap analysis, which was shared with the National Contraception Guidelines Steering Group. The gap analysis set out the Project Team's understanding of the current contraception guidelines/resources landscape in New Zealand to ensure our final product would meet needs and fill gaps in the existing resource pool, rather than repeat existing material that is already fit for purpose, well-accepted and known/used by health practitioners in New Zealand. The gap analysis and thematic findings, based on these three methodological steps (*sections 2.2-2.4 refer*), was then used to drive the project's next steps (literature on clinical issues and preparing the draft guidelines). The main methodological points agreed by the Steering Group were:

- Use existing guidelines where these are robust but adapt for the New Zealand context
- Further investigate specific clinical areas requiring national consensus or 'myth-busting'
- Development of concise, easily accessible resources/tools for use during short consultation times was preferred, and
- Health Pathways' platform is an acceptable way to disseminate guidance at the point-of-care and in a way that can positively influence practice; however, stand-alone access to the guidance is needed for those health practitioners who may not use Health Pathways

2.5. Literature review of clinical questions requiring consensus and preparation of the draft guidance

Systematic methods were used to search for evidence (AGREE II 7)

The criteria for selecting the evidence are clearly described (AGREE II 8)

The strengths and limitations of the body of evidence are clearly described (AGREE II 9,)

Please see detailed chapters behind the guidelines

Specific clinical questions regarding individual contraceptive methods (either needing national consensus or 'myth-busting') were raised by stakeholders during the earlier phases of the project. In responding to these questions, we wanted to identify new literature, not yet reflected in existing clinical guidelines produced by competent authorities (primarily the FSRH), to understand the most recent evidence base that should/may influence practice. Once we had agreed the list of areas requiring further exploration with the National Contraception Guidelines Steering Group, we initiated a suite of targeted literature reviews.

2.5.1. What we did

To conduct each literature search, *Allen + Clarke* developed an initial terms of reference (see *Annex B*). After discussion and confirmation with the Ministry, these terms were provided to its library services to conduct the searches. The Ministry searched databases such as Embase, the Cochrane Library and others to identify systematic reviews (with/without meta-analysis), randomised controlled trials and robust observational studies. Different PICO(T) criteria were applied to each research question depending on whether existing robust guidelines (usually in the form of the

guideline published by FSRH, RANZCOG or similar) was available and the date of the latest comprehensive review of that guideline.

The literature search was conducted by the Ministry's library services during Alert Level 3 of New Zealand's COVID-19 response (13-24 March 2020). The Ministry's librarian removed duplicates and false drops from the searches and provided *Allen + Clarke* with the resulting XML files, as well as a list of the abstracts. Because the numbers of returns were generally very small (due both to the very specific nature of the research question and the restricted date ranges), no reference management software was needed.

Returned articles were reviewed for relevance to the research question, prior inclusion in the main guideline underpinning the contraceptive option or population group (where appropriate), and the quality of the study/paper assessed using either AMSTAR or SIGN tools. Because we had agreed that many of the contraceptive options were already well-supported by a robust and up-to-date guideline (albeit one appropriate for the United Kingdom or Canada), articles that were already included in a specific, relevant guideline were excluded. Further advice on the critical appraisal process is provided in *Annex C*.

The number of returned and included articles varied for each research question. This is summarised in *Table 2* (overleaf).

Table 2: Number of returned and included articles by research question

Research question	Number of returned articles	Number of articles excluded for reasons including incorrect intervention and because; already covered in the relevant guideline	Number of included articles
Extended use of IUD	9	0	7
Extended use of implant IUD	2	0	1
Use of IUD in younger and nulliparous people	29	23	3
Use of implant LARC in younger and nulliparous people	9	8	1
Immediate post-partum insertion of IUD	26	22	4
Immediate post-partum insertion of implant LARC	0	0	0
Problematic bleeding with immediate post-partum insertion of LARC (IUD or implant)	6	5	1
Hormonal contraception + breastfeeding	16	13	3
Tailored use of combined oral contraception	6	6	0
Emergency contraceptive pill: timing of administration	6	5	1
Extended use of DMPA	7	7	0

2.5.2. How we used the literature reviews + guidelines to develop draft national guidance for Aotearoa New Zealand

The recommendations are specific and unambiguous (AGREE II 15)

The different options for management of the condition or health issue are clearly presented (AGREE II 16)

Key recommendations are easily identifiable (AGREE II 17)

Please see guidelines for specific content.

Once reviewed and critically appraised, each included study was written up (study description, notes on the strength of the study and its findings, key findings data as relevant to the research question). This information was incorporated into contraception-specific chapters, which summarised new evidence + existing guidance relating to each specific contraception method and the clinical questions asked.

The recommendations and practice points included in each relevant FSRH, Canadian or RANZCOG guideline (which the National Contraception Guidelines Steering Group had agreed would form the basis of New Zealand's guidance) were reviewed and their relevance to the New Zealand content ascertained. Some recommendations/practice points from each guideline were not carried forward as they related to medications, products or procedures that are not available in New Zealand. In other recommendations, wording was altered slightly to reflect the importance of having gender-neutral language throughout Aotearoa New Zealand's guidance or to provide consistency with terminology used here (such as the use of 'health practitioner' rather than 'clinician' or 'medical practitioner').

The chapters developed included:

- An overarching chapter containing recommendations to support health practitioners to facilitate effective and consistent contraception consultations with patients (including youth and transgender patients and advice for specific cultural groups)
- Eight method-specific chapters: LARC, DMPA, combined oral contraceptive pill, progestogen-only pill, emergency contraception, permanent contraception, barrier methods, and fertility awareness methods (based on current FSRH or RANZCOG guidelines), and
- One population-specific chapter: contraception after pregnancy (based on FSRH guidelines) with links to other FSRH guidelines for young people and individuals aged over 40 years.

These chapters form the basis of Aotearoa New Zealand's guidance on contraception. Each chapter was considered by the National Contraception Steering Group, which made a number of suggested amendments and refinements (all of which were taken on board). The chapters are available on request.

2.6. Consultation

The patients' views and preferences have been sought (AGREE II 5)

Following finalisation of the draft chapters, the Project Team prepared a consultation paper (based on the chapters prepared). This consultation paper described our overall approach (including the adaptation of existing guidelines produced by competent authorities) and asked stakeholders to comment on the:

- guidelines that would form the basis of Aotearoa New Zealand's guidance
- issues requiring national consensus and the draft recommendations and practice points related to these, and
- specific recommendations and practice points relating to contraceptive counselling, each contraception option and advice for specific populations.

2.6.1. What we did

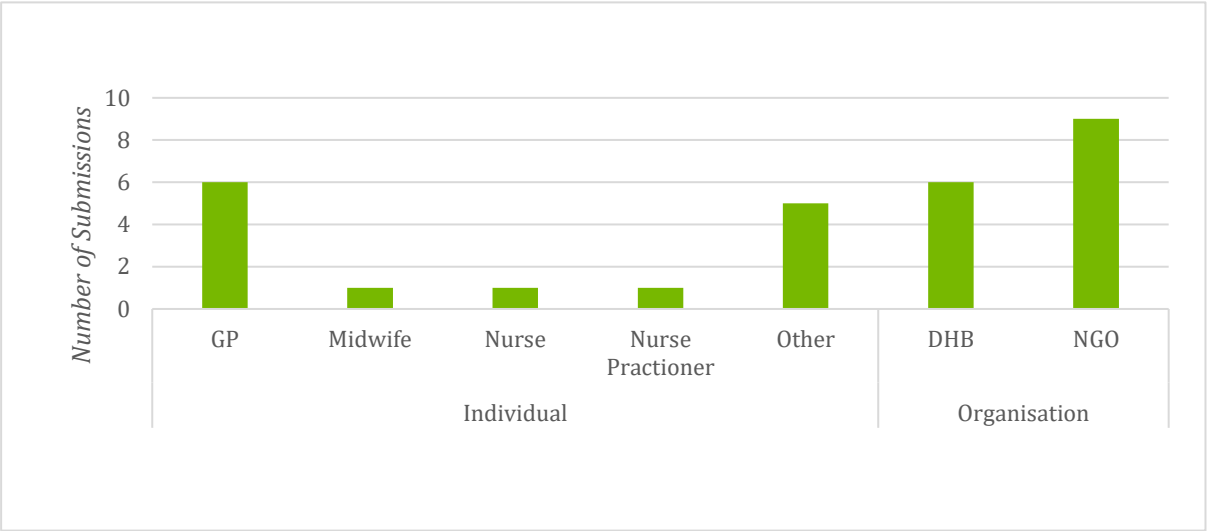
The consultation paper was released on 19 June 2020, with the round open for four weeks. The consultation paper was sent to:

- all those who the Project Team met with during Phase 1 (see *section 2.4.2*)
- Christine Roke
- Community Health Pathways
- Council of Māori Nurses
- DHB funding and planning staff
- Karen Benattar
- National Contraception Guidelines Steering Group members
- Pasifika Midwives Collective
- Professional colleges including a request to share within its network, (New Zealand College of Nurses Aotearoa NZCOM, NZNO, Nga Maia, Pharmaceutical Society, RANZCOG, RNZCGP, NZ Sexual and Reproductive Health Society)
- Professor Lesley McCowan
- T Morison
- Te Kaha o te Rangitahi
- Te ORA
- Te Whariki Takapou, and
- Transgender Health Aotearoa (PATHA).

We asked that the consultation paper be shared within networks where appropriate.

We received 29 submissions on the draft guidance. Submitters' details are summarised in Graphic 1 (overleaf).

Graphic 1: Summary of submitters' details



Each submission was logged, reviewed and coded to a framework based on the chapters and clinical questions. Once the coding process was complete, the Project Team reviewed all content and developed a short thematic analysis that summarised feedback and:

- recorded the level of support/disagreement for the approach to use baseline guidelines adapted for the Aotearoa New Zealand context
- recorded the level of support/disagreement for specific recommendations and practice statements (especially those relating to areas requiring national consensus), and
- identified any suggested amendments to the recommendations and practice statements.

The Project Team also met with the following professional colleges to discuss the development process and to receive feedback directly: New Zealand College of Nurses Aotearoa, NZCOM, NZNO, Nga Maia, RANZCOG, and RNZCGP. A short conversation was also held with MedSafe. Feedback from these meetings was fed into the submissions process noted above.

Once the submissions process was complete, the final draft guidelines (inclusive of submission summaries) was presented to the National Contraception Guidelines Steering Group for its review and consideration. The Group made a number of suggested amendments and refinements (all of which were taken on board) and the final draft guidance on contraception for Aotearoa New Zealand was prepared for College endorsement.

2.7. Endorsement

The guideline has been externally reviewed by experts prior to its publication (AGREE II 13)

The following organisations have been asked to endorse Aotearoa New Zealand's national contraception guidelines:

- College of Sexual Reproductive Health
- NZCOM
- New Zealand College of Nurses Aotearoa

- NZFP
- NZNO
- Pharmaceutical Society
- RANZCOG, and
- RNZCGP.

3. IMPLEMENTATION

The guideline provides advice and/or tools on how the recommendations can be put into practice (AGREE II 18)

The guideline describes facilitators and barriers to its application (AGREE II 19)

The potential resource implications of applying the recommendations have been considered (AGREE II 20)

Guidelines should be flexible and adaptable to local conditions.

The means of ensuring that guidelines reach their target audience should be outlined.

Strategies for implementing the guidelines should be specified.

We understand that the guidelines will be implemented in three ways:

1. Through the Community Health Pathways (main portal content)
2. A standalone summary document available on the Ministry of Health's website
3. Through review + updates to the Pharmaceutical Schedule's online content and the New Zealand Formulary.

3.1. Community Health Pathways

Health Pathways is a web-based information portal supporting health practitioners to plan patient care through primary, community and secondary health care systems. It contains a range of information about contraception, but this is not complete. Implementing the guidelines through the Health Pathways portal results in an online, easy to use, well-used and known about platform from which health practitioners can access information at the point-of-care (i.e., meets what stakeholders told us they want). Information can be tiered (from simple to complex), making it easy to locate the information needed (including links to other health issues). Health Pathways also allows links to a wide range of clinical and patient resources (including content hosted on other websites so no need to develop repetitious content).

It is proposed that the guidelines be implemented through the Health Pathways platform. Conversations and work to progress this is underway. It is important that local referral pathways be included in the pathways so that health practitioners who need further support/advice can ensure that they access this or that individual patients are referred on to other services that meet there needs.

3.2. Other options

Some groups of health practitioners may not be as engaged with HealthPathways as others (namely pharmacists and midwives) and so having the guidelines as a standalone summary will also be important for their Colleges to share. Updates to the Pharmaceutical Schedule and the New Zealand Formulary to ensure consistency with the guidelines would also be needed; however, it is anticipated that there would be a high degree of consistency due to all platforms drawing on the same source material (i.e., guidelines produced by FSRH).

3.3. Who decides?

Decisions about the full scale of implementation will ultimately be made by the Ministry of Health and District Health Boards. Professional colleges will play an important role in disseminating these guidelines to members as well (especially important for those for whom the majority of members are not using Health Pathways at this time).

4. EVALUATION + REVIEW

A procedure for updating the guideline is provided (AGREE II 14)

The guideline presents monitoring and/ or auditing criteria (AGREE II 21)

To be trusted, Health Pathways information needs a strong evidence-base for content, and it needs to be kept up to date as new evidence comes to hand.

Decisions about the review + evaluation of the guidelines (including the process to be used and the timing of this review) are the responsibility of the Ministry of Health.

Table 3 Scheduled review dates for each of the key FSRH guidelines underpinning Aotearoa New Zealand's guidance on contraception

Guideline	Date of publication	Amended	Scheduled routine review date
Contraception after pregnancy[1]	2017	-	2022
Intrauterine contraception[2]	2015	2019	2020
Progestogen-only implant[3]	2014	-	2019
Progestogen-only injectable contraception[4]	2014	2020	-
Quick-starting contraception[5]	2017	-	2022
Combined hormonal contraception[6]	2019	2019	2024
Problematic bleeding with hormonal contraception[7]	2015	-	2020
Recommended actions after incorrect use of combined hormonal contraception	2020	-	2025
Progestogen-only pills[9]	2015	2019	2021
Emergency contraception[10]	2017	2017	2022
Male and female sterilisation[11]	2014	-	2019
Barrier methods for contraception and sterilisation[12]	2012	2015	-
Fertility awareness methods[13]	2015	-	2020
Switching or starting methods of contraception[14]	2017	2019	2022
Contraceptive Choices for Young People[15]	2010	2019	-
Contraception for Women Aged over 40 Years[16]	2017	2019	2022
UKMEC[17]	2016	2019	-

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ANNEX A PRELIMARY LITERATURE REVIEW TERMS OF REFERENCE

Background

The Ministry of Health has contracted *Allen + Clarke* to develop national best practice guidelines on contraception services to build the quality and consistency of contraception available to New Zealand women. The Ministry would like to see women making informed choices about contraception and see LARCs offered as regularly as other methods of contraception such as the oral contraceptive pill. The national best practice guidelines will assist primary care health practitioners to proactively provide consistent, evidence-based advice and information to women about their contraception choices[2]. The guidelines will be concise but supported by detailed, layered information.

The National Contraception Guidelines will be prepared in parts:

- Preamble about the importance of access to effective contraception suitable to a woman's choices about how she manages her fertility, including advice on barriers or enablers women may experience when accessing advice on managing fertility.
- Best practice advice on culturally safe and competent conversations that fully inform women about contraception options so they can take control of their own fertility.
- Links to **existing** best practice clinical advice prepared by competent authorities on the provision of the following contraceptive options, available in New Zealand:
    - inserting and removing LARC (including sub-cutaneous hormonal implants like Jadelle and intrauterine contraceptive devices such as Mirena and Jaydess)
    - hormonal contraception like the combined oral contraceptive pill, depot medroxyprogesterone acetate injections, and emergency contraception
    - barrier methods like condoms
    - fertility awareness, and
    - permanent contraception.
- Referral pathways.

Two separate literature reviews will be conducted during the development of the national clinical guidelines. The first (and focus of this ToR) will solicit information regarding existing effective contraception guidelines as well as information about existing barriers and enablers to accessing contraception in New Zealand. A second literature review will follow a subsequent gap analysis to address specific clinical questions or gaps in the research. The National Contraception Guidelines Steering Group will provide advice on the clinical questions to be considered.

Why is this literature review important?

All women should be able to access appropriate advice and affordable contraception when they choose and need it. LARC are increasingly recommended by health practitioners as a first-line choice for women of all ages to regulate their fertility. Use of LARC is safe, effective, reversible and associated with a much lower rate of unintended pregnancy.

[2] Note the guidelines will only consider contraceptive options that are currently available in New Zealand.

Barriers to access may include a sense of stigma/embarrassment in having conversations about sexual behaviour, women's knowledge about LARC as a contraceptive option, health practitioner competence and/or preferences for recommending and inserting LARC, access to trained providers with the knowledge and ability to support informed decision-making about a full suite of reversible contraceptive options, funding/cost of travel to and attending appointments, prescriptions, medical devices, potential issues with the cultural competence of health practitioners, and access to information. Removing these barriers will make it easier for all women to manage their fertility.

The Ministry of Health wants to increase the skill of and support for health practitioners so that they can have useful, competent and culturally safe conversations about sexual health and contraception, ensuring that women get the contraception that is right for them. It is thought that increasing health practitioner comfort and competence in relation to these conversations will support an increase in the use of LARC and increased informed choice by women about their contraceptive choices. To do this, the Ministry wishes to develop national best practice guidelines on contraception services, which will be complemented by the development and implementation of national training and competencies (to be designed and delivered by New Zealand Family Planning).

Purpose of this document

This document sets out the terms of reference for the search strategy to identify published literature to inform the development of national guidelines on contraception advice and the provision of contraception services. The Ministry of Health's library services will use this information to conduct the search of published literature. *Allen + Clarke* will use a range of tools to assess the quality of individual studies (including AMSTAR-2 and/or the Scottish Intercollegiate Guidelines Network tools), and GRADE to rate the level of evidence for identified outcomes presented across the included research.

Scope

This literature review focuses on contraception services in New Zealand (including the provision of advice to women from health practitioners and the provision of contraceptives available here). We want to know:

- the range of existing clinical guidelines produced by competent authorities and used by health practitioners to provide advice to New Zealand women *NB this includes information about the indications/contraindications, side effects, efficacy and effectiveness and safety considerations associated with the following: LARC, hormonal contraception, barrier methods, fertility awareness and permanent contraception*
- the barriers related to the provision of culturally safe contraception advice during a consultation and access to services
- the enablers for the provision of culturally safe contraception advice and services
- whether identified barriers and enablers differ between different groups of women, and
- if there are guidelines for health practitioners on providing youth friendly consultations.

Health practitioners include GPs, nurse practitioners, midwives, nurses, obstetricians and gynaecologists, youth heath workers and pharmacists.

We are specifically interested in New Zealand literature but recognise that there may be some literature from other communities that may provide useful context. Specific jurisdictions of interest include New Zealand, Australia, the United Kingdom, Ireland, Canada and Pacific Island countries.

We are also interested in some specific groups of women: young women aged under 25 years, wāhine Māori, Pacific women, women living complex lives (such as those living with alcohol or other drug dependencies), women with very large families, and those living in poverty or lower socioeconomic areas.

The literature review will not explore primary research on the indications/contraindications, side effects, efficacy/effectiveness and safety considerations associated with specific contraceptives.

Research questions

QUESTION 1: What current clinical guidelines exist for the following contraceptives[3]:

(1) LARC including inserting and removing sub-cutaneous hormonal implants like Jadelle and intrauterine contraceptive devices such as Mirena and Jaydess

(2) hormonal contraception like the combined oral contraceptive pill, depot medroxyprogesterone acetate injections, and emergency contraception

(3) barrier methods like condoms

(4) fertility awareness, and

(5) permanent contraception (vasectomy/tubal ligation)?

QUESTION 2: Are there guidelines for health practitioners on providing contraception advice to women aged under 25 years, and if so, what do these guidelines cover?

QUESTION 3: What competencies do health practitioners require to insert or remove LARC, and where can this be performed?

Criterion	Description
Study type	Systematic review (with/without meta-analysis), narrative literature review, randomized control trials, observational studies, clinical guidelines
Timeframe	Relevant literature/studies published from 2009
Countries	Australia, Canada, Ireland, United Kingdom, International, NZ

QUESTION 4: What makes it harder for women in New Zealand to access effective contraception and advice, including any research on barriers related to the provision of culturally safe contraception advice during a consultation and access to services?

QUESTION 5: What supports women in New Zealand to access the contraception that they want and which is best suited to them, including any research on enablers for the provision of culturally safe contraception advice and services?

[3] Note the project team already has copies of some key guidelines, outlined in Annex C.

Criterion	Description
Study type	Systematic reviews (with/without meta-analysis), observational studies, qualitative research, New Zealand theses, grey literature
Timeframe	Including relevant literature/studies published from 2000 onwards
Countries	New Zealand

Breadth of search

- Embase (including OVID Medline and OVID Nursing)
- CINAHL
- Scopus
- PsycINFO
- Cochrane Library database
- National Institute for Health and Clinical Excellence
- NZ research, including theses
- Sources of published guidelines, consensus statements, position statements and standing orders: Royal Australian College of Obstetricians and Gynaecologists, Royal New Zealand College of General Practitioners, College of Nurses, New Zealand Nurses Organisation, College of Midwives, Nga Maia Māori Midwives Aotearoa, Faculty of Sexual and Reproductive Health Care (Royal College of Obstetricians and Gynaecologists), Center for Disease Control, BPAC, New Zealand Family Planning, American College of Obstetricians and Gynaecologists, and Pharmaceutical Society.

Inclusions

From the results of the search, literature will be prioritised according to the following criteria:

- Relevance to primary research questions
- English language
- Human
- Material that exhibits methodological rigour (eg, the SIGN level of evidence), and
- Material related to New Zealand women.

Exclusions

The literature review will exclude any material that does not relate to the abovementioned research questions, non-English language sources, and any male-centric returns.[4] False drops and duplicates will be removed. Grey literature will be excluded unless it relates specifically to New Zealand women.

[4] The guidelines are intended to focus exclusively on women's contraceptive choices, options and experiences.

Search terms

Where possible (subject to the flexibility of database search functions), the keywords included in the search strategy are outlined below.

- Long-acting reversible contraception, LARC, oral contraceptive, Jadelle, sub-cutaneous hormonal implant, intrauterine contraceptive devices, Mirena, Jaydess; hormonal contraception, combined oral contraceptive pill, depot medroxyprogesterone acetate, Depo-Provera, emergency contraception; condoms; birth control; contraception; fertility awareness, natural family planning; tubal ligation, vasectomy.
- Contraception advice, consultation, conversation, safe, culturally appropriate
- Clinical guideline; referral pathway, consensus statement
- Health practitioner, doctor, midwife, nurse
- Barrier, enabler, uptake, choice, informed decision
- Systematic review; meta-analysis randomised controlled trial; cohort; observational; longitudinal, thesis
- Woman, Māori, Pacific, young, New Zealand, Aotearoa

Provision of materials

The Ministry of Health will provide a list of returns that includes citations and abstracts. *Allen + Clarke* will review this list of returns and identify the documents for which we require full-text. The Ministry of Health can then provide access to these full-text articles through a Zotero group.

LIST OF WEBSITES

- Best Practice Advocacy Centre: www.bpac.org.nz
- College of Midwives: www.midwife.org.nz
- College of Nurses Aotearoa: www.nurse.org.nz
- New Zealand Family Planning: www.familyplanning.org.nz
- New Zealand Nurses Organisation: www.nzno.org.nz
- Nga Maia Māori Midwives Aotearoa: www.ngamaia.co.nz
- Royal Australian College of Obstetricians and Gynaecologists: www.ranzcog.edu.au
- Royal New Zealand College of General Practitioners: www.rnzcgp.org.nz
- Faculty of Sexual and Reproductive Health Care (Royal College of Obstetricians and Gynaecologists): www.fsrh.org
- International Consortium for Emergency Contraception: www.cecinfo.org
- International Federation of Obstetricians and Gynaecologists: www.figo.org
- National Institute of Clinical Excellence: www.nice.org.uk
- American College of Obstetricians and Gynaecologists: www.acog.org
- Center for Disease Control; www.cdc.gov
- Up to date: www.uptodate.com

- World Health Organization: www.who.int
- Pharmaceutical Society: www.psnz.org.nz.

ANNEX B TARGETED LITERATURE REVIEW TERMS OF REFERENCE

Background

The Ministry of Health is seeking to build the quality and consistency of contraception services in New Zealand by developing national guidelines on contraception, which will be complemented by the development and implementation of national training. It is hoped that the guidelines and training will:

- increase access to effective contraception options for New Zealanders
- support informed choice
- increase uptake of long-acting reversible contraception (LARC), and
- support health practitioners to have consistent, culturally safe and youth friendly conversations on sexual health and contraception.

The Ministry of Health has contracted *Allen + Clarke* to develop the national contraception guidelines. To inform the guidelines, *Allen + Clarke* will carry out a series of literature reviews (described by this Terms of Reference [TOR]) considering a range of specific clinical questions. The clinical questions have been informed by the project's previous phase of research, which included:

- a national stock-take of resources
- a contraception survey, and
- stakeholder interviews with contraception experts.

Why is this literature review important?

During previous phases of research, we found that health practitioners currently have access to a wide range of contraception resources, produced, monitored and updated by competent authorities such as New Zealand Family Planning (NZFP), the UK-based Faculty of Sexual and Reproductive Health (FSRH), and New Zealand Community HealthPathways (HealthPathways).

We also found that the multitude of contraception resources available to New Zealand health practitioners were not always consistent in terms of practice recommendations. Some are not relevant in New Zealand because of the different contraceptive methods available in other jurisdictions. There was also limited uniformity in terms of the actual resources being used to guide practice within New Zealand. Stakeholders frequently highlighted the resulting inconsistencies in practice, including within specific health practitioner groups mandated to provide contraception services in New Zealand.

Health practitioners called for national guidance to address these inconsistencies, as well as a central repository of nationally recommended resources, for in-depth information on specific clinical issues. They also noted some areas where evidence may be new and may have practice implications. This rapid review seeks to address specific clinical questions requiring consensus about approach. The rapid review will be considered by the National Contraception Guidelines Steering Group as it considers the necessary national recommendations that will improve access to LARC and enhance consistency of contraceptive counselling practices.

Purpose of this document

This document sets out the terms of reference for the search strategy to identify published literature to inform national recommendations for contraception care in New Zealand. The Ministry of Health's library services will use this information to conduct the search of published literature. *Allen + Clarke* will use GRADE to rate the level of evidence for identified outcomes presented across the included research where possible (see Annex A).

Scope and topics

The review will investigate a range of clinical questions about specific contraceptive methods, which will inform the development of national recommendations. Most focus on the prevention of pregnancy rather than other therapeutic indications.

- *Reduction in efficacy and the timing of removal of LARC, including sub-cutaneous implants and IUCD:* latest evidence on extended-use.
- *Efficacy, safety, risks and benefits of IUCD and sub-cutaneous implants as the first choice of contraception for adolescents and nulliparous women.*
- *Efficacy, safety, risks and benefits of immediate post-partum insertion of Jadelle or Mirena/Jaydess.*
- *Safety, risks and side-effects of using hormonal contraception (including progesterone-only methods) during breastfeeding.*
- *Continuous use of COC/4-7 day break*: the latest evidence regarding continuous use of COC and non-continuous use i.e., taking some (e.g., 4) or all (i.e., 7) of the inactive pills, including comparative efficacy, side-effects, risk, benefit and best practice.
- *Depo Provera + efficacy: how long does it last?:* the latest evidence regarding the effective life-span of Depo Provera in patients to effectively prevent pregnancy.
- *Timing of ECP prescription:* the latest evidence/consensus regarding the appropriate timeframe (i.e., between 72-120 hrs) within which a health practitioner may prescribe an ECP, following unprotected sex, including efficacy, risk and best practice.

Research questions

QUESTION 1	What is the impact on efficacy, benefits, risk factors and side effects of not immediately removing IUCD (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard) when it reaches its recommended end of use?
QUESTION 2	What is the impact on efficacy, benefits, risk factors and side effects of not immediately removing Jadelle when it reaches its recommended end of use?

Criterion	Description
Populations	Women

Criterion	Description
Intervention	Intrauterine contraceptive devices available and subsided in New Zealand (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard) Jadelle
Comparator	Removing IUCD at or before 5 years Removing Jadelle at or before 5 years
Outcomes	Pregnancy prevention
Study types[5]	Systematic Reviews, Randomized Controlled Trials

QUESTION 3 What are the therapeutic indications/contraindications, efficacy, side effects, risks and benefits of using IUCD (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard) to prevent pregnancy in adolescents (aged 12-20 years) and nulliparous women?

QUESTION 4 What are the therapeutic indications/contraindications, efficacy, side effects, risks and benefits of using Jadelle to prevent pregnancy in adolescents (aged 12-20 years) and nulliparous women?

Criterion	Description
Populations	Adolescent girls/women (aged 12 to 20 years) Nulliparous women
Intervention	Intrauterine contraceptive devices available and subsided in New Zealand (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard) Jadelle
Comparator	Other forms of contraception for adolescents and nulliparous women
Outcomes	Pregnancy prevention
Study types[6]	Systematic Reviews, Randomized Controlled Trials

QUESTION 5 What are the risk factors, side effects and indications/contraindications of immediate postpartum insertion of IUCD (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard)?

QUESTION 6 What are the risk factors, side effects and indications/contraindications of immediate postpartum insertion of jadelle?

[5] Note the project team already has access to a number of Prospective Cohort Studies, which will also be considered.
[6] As above.

QUESTION 7 What is best practice health practitioner recourse for managing problematic bleeding following postpartum insertion of IUCD or sub-cutaneous implant?

Criterion	Description
Populations	Women six weeks' post-partum period Breastfeeding women
Intervention	Intrauterine contraceptive devices available and subsided in New Zealand (Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard) Jadelle
Comparator	Other forms of contraception for women six weeks' postpartum
Outcomes	Indications for immediate insertion Contraindications for immediate insertion Prevention of short-interval pregnancy Expulsion rates and timing Expulsion complications Involution of the uterus Lactation
Study types[7]	Systematic Reviews, Randomized Controlled Trials, Clinical guidelines

QUESTION 8 What are the risk factors, side effects and indications/contraindications of using hormonal contraception during breastfeeding, and is it safe to do so?

Criterion	Description
Population	Women postpartum Breastfeeding women
Intervention	Hormonal contraception including progestogen-only methods
Outcomes	Healthy babies Lactation Pregnancy prevention
Study types	Systematic Reviews, Randomized Control Trials

QUESTION 9 For prevention of pregnancy, is it safer and more effective to take the Combined Oral Contraceptive (COC) pill continuously, or with a 4 to 7 day interval using the inactive non-hormone pills?

[7] Note the project team already has access to a number of Prospective Cohort Studies, which will also be considered.

QUESTION 10 For how many hours following unprotected sex will an Emergency Contraceptive Pill (ECP) safely and effectively prevent pregnancy?

QUESTION 11 For how many weeks will a Depo Provera injection safely and effectively prevent pregnancy?

Criterion	Description
Population	Women
Intervention	Method-specific contraception (tubal ligation; IUCD [Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard]; sub-cutaneous implant [jadelle]; Combined Oral Contraceptive pills; Emergency Contraceptive Pill (ECP); and Depo Provera)
Outcomes	Pregnancy prevention
Study types	Systematic Reviews, Randomized Control Trials

Terms of reference for literature search

Breadth of search

- Embase (including OVID Medline and OVID Nursing)
- Cochrane Library database
- MedSafe datasheets.

Inclusions

From the results of the search, literature will be prioritised according to the following criteria:

- Currency (published between 1 March 2015 and 1 March 2020, depending on currency of most relevant FSRH guideline)
- Relevance to primary research questions
- Human
- English language, and
- Material that exhibits methodological rigour (eg, the SIGN level of evidence).

Exclusions

The literature review will exclude any material that does not relate to the research questions, non-English language sources, and material published before 1 March 2015. False drops and duplicates will be removed.

Search terms

Where possible (subject to the flexibility of database search functions), the keywords included in the search strategy are outlined below.

- Pregnancy, prevention
- Nulliparous; parous; youth, obese; overweight; perimenopausal; transgender; women

- Long Acting Reversible Contraception, LARC, sub-cutaneous implant, Intra-Uterine Contraceptive Device, IUCD, Intra-Uterine Device, IUD, Emergency Contraception, Emergency Contraceptive Pill, ECP, Hormonal Contraception, Oral Contraception[8], Combined Oral Contraception, COC, combined pill, Progestogen-only contraceptive Pill, POP, Depo Provera
- Oestrogen, ethinylestradiol, Levonorgestrel, Desogestrel, Drospirenone, Norethisterone, Cyproterone
- Mirena, Jaydess, Choice Load 375, Choice TT380 short, Choice TT380 standard, Copper IUD, Jadelle
- Mode of action; eligibility; efficacy; effectiveness; safety; safely; indication; contraindication; side-effect; risk; benefit; management; health concerns; complications; interactions
- Best practice, practice points, clinical practice, recommendation

Provision of materials

The Ministry of Health will provide a list of returns that includes citations and abstracts. *Allen + Clarke* will review this list of returns and identify the documents for which we require full-text. The Ministry of Health can then provide access to these full-text articles through a Zotero group.

[8] Including brands available in New Zealand such as Microgynon 20 Loette, Mercilon, Yaz, Levlen ED, Microgynon 30, Microgynon 30 (ED formulation), Monofeme, Marvelon, Yasmin, Brevinor, Norimin, Brevinor-1 21 Day, Brevinor-1 28 Day ED, Estelle-35, Estelle-35 ED, Ginet, Diane-35 ED, Microgynon 50 ED

ANNEX C ASSESSMENT OF EVIDENCE TABLES

AMSTAR 2 tool

The AMSTAR 2 tool was used to appraise the methodological quality of systematic reviews included in the method specific and population chapters. AMSTAR 2 is a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both.[9]

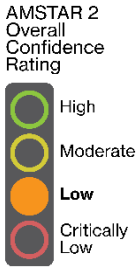
AMSTAR 2 is not designed to generate and overall 'score'. In making an overall rating of a systematic review, it is important to take account of flaws in critical domains, which may greatly weaken the confidence that can be placed in a systematic review. To rate overall confidence in the results of the systematic reviews included in the method specific and population chapters we used the following criteria, as advised by the authors of AMSTAR 2.

Table 1: Rating overall confidence in the results of the review

High	*No or one non-critical weakness*: the systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest
Moderate	*More than one non-critical weakness**: the systematic review has more than one weakness but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review
Low	*One critical flaw with or without non-critical weaknesses*: the review has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest
Critically low	*More than one critical flaw with or without non-critical weaknesses*: the review has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies

*Multiple non-critical weaknesses may diminish confidence in the review, and it may be appropriate to move the overall appraisal down from moderate to low confidence.

[9] Shea, B.J., Reeves, B., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E., Henry, D.A. (2017) AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ 135:j4008 doi: 10.1136/bmj.j4008



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	AMSTAR 2 TOOL QUESTION[10] [11]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?[12]	Yes	Followed PRISMA guidelines
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	
4	Did the review authors use a comprehensive literature search strategy?	Yes	
5	Did the review authors perform study selection in duplicate?	Not stated	
6	Did the review authors perform data extraction in duplicate?	Not stated	

[10] AMSTAR 2 'critical domains' are presented in bold in the table.
[11] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf
[12] It is common practice to use PICO description (population, intervention, control group and outcome) as an organising framework for a study question. Sometimes timeframe should be added if this is critical in determining the likelihood of a study capturing relevant clinical outcomes (e.g. an effect of the intervention is only expected after several years). PICO identifies the elements that should be described in detail in the report of the systematic review and should enable the appraiser to judge selection of studies, and their combinability, and enable the user of the review to determine applicability of the results. Authors of systematic reviews do not always make the elements of PICO explicit but they should be discernable through a careful reading of the abstract, introduction and methods sections. To score 'Yes' appraisers should be confident that the 4 elements of PICO are described somewhere in the report.

	AMSTAR 2 TOOL QUESTION[10 11]	Answer	Comment
7	Did the review authors provide a list of excluded studies and justify the exclusion?	Yes	PRISMA flow diagram included. No list provided but stated that 335 were excluded (dups, based on abstract review, relevance)
8	Did the review authors describe the included studies in adequate detail?	Yes	Table included, with relevant info recorded.
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[13]	Yes	Used the Cochrane risk of bias assessment tool.
10	Did the review authors report on the sources of funding for the studies included in the review?	No	
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	Methods are described
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Unsure	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	No	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	Used Cochrane's Review Manager 5.3 for Windows
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Reported there to be no conflicts of interest

[13] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Berry-Bibee, E. N., N. K. Tepper, T. C. Jatlaoui, M. K. Whiteman, D. J. Jamieson, and K. M. Curtis. 'The Safety of Intrauterine Devices in Breastfeeding Women: A Systematic Review'. *Contraception* 94, no. 6 (2016): 725–38.

	AMSTAR 2 TOOL QUESTION[14] [15]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	Used PRISMA
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	Implied: conducted in preparation for a meeting at the CDC in Aug 2015 for updating the *US Medical Eligibility Criteria fro Contraceptive Use, 2010*.
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	This is a companion systematic review to one that studied progestin-only contraception (Phillips, Tepper, Knapp et al. 2016 – which is already included in this present literature review.
4	Did the review authors use a comprehensive literature search strategy?	Yes	Search terms provided as Appendix
5	Did the review authors perform study selection in duplicate?	Yes	
6	Did the review authors perform data extraction in duplicate?	Yes	
7	Did the review authors provide a list of excluded studies and justify the exclusion?	No	
8	Did the review authors describe the included studies in adequate detail?	Yes	

[14] AMSTAR 2 'critical domains' are presented in bold in the table.
[15] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[14 15]	Answer	Comment
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[16]	Yes	PRISMA covers bias
10	Did the review authors report on the sources of funding for the studies included in the review?	Yes	Implies that the work was commissioned by CDC.
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	NA	
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	NA	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	No	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	

[16] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

AMSTAR 2 Overall Confidence Rating

Jatlaoui TC, Riley HEM, Curtis KM. 'The safety of intrauterine devices among young women: a systematic review.' Contraception. 1;95(1):17–39

	AMSTAR 2 TOOL QUESTION[17] [18]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	PRISMA guidelines
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	
4	Did the review authors use a comprehensive literature search strategy?	Yes	
5	Did the review authors perform study selection in duplicate?	Yes	
6	Did the review authors perform data extraction in duplicate?	Unknown	
7	Did the review authors provide a list of excluded studies and justify the exclusion?	No	
8	Did the review authors describe the included studies in adequate detail?	Yes	Tabularised and annexed

[17] AMSTAR 2 'critical domains' are presented in bold in the table.
[18] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[17] [18]	Answer	Comment
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[19]	Yes	The quality of each article was independently evaluated using the US Preventive Services Task Force grading system.
10	Did the review authors report on the sources of funding for the studies included in the review?	No	The review notes only that the report was originally prepared for an Expert Working Group meeting to update the WHOMEC for contraceptive use in March 2014.
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	n/a	
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	n/a	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	Meta-analysis not performed for this reason.
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	n/a	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	

[19] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Patseadou M, Michala L. 'Usage of the levonorgestrel-releasing intrauterine system (LNG-IUS) in adolescence: what is the evidence so far?' Arch Gynecol Obstet. 2017 Mar;295(3):529–41

	AMSTAR 2 TOOL QUESTION[20] [21]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	
4	Did the review authors use a comprehensive literature search strategy?	Yes	
5	Did the review authors perform study selection in duplicate?	Yes	
6	Did the review authors perform data extraction in duplicate?	Unknown	
7	Did the review authors provide a list of excluded studies and justify the exclusion?	No	However, numbers of/reasons for exclusions were provided in Figure 1: summary of the study selection process
8	Did the review authors describe the included studies in adequate detail?	Partial	Tabularised study data was provided, however, study weaknesses were not adequately described.

[20] AMSTAR 2 'critical domains' are presented in bold in the table.
[21] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[20] [21]	Answer	Comment
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[22]	Unknown	
10	Did the review authors report on the sources of funding for the studies included in the review?	Yes	No funding was required for the present study
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	n/a	
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	n/a	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	n/a	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	

[22] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Phillips, S. J., N. K. Tepper, N. Kapp, K. Nanda, M. Temmerman, and K. M. Curtis. 'Progestogen-Only Contraceptive Use among Breastfeeding Women: A Systematic Review'. Contraception 94, no. 3 (2016): 226–52. https://doi.org/10.1016/j.contraception.2015.09.010.

	AMSTAR 2 TOOL QUESTION[23] [24]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	Used PRISMA
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	Inferred through statement that the review was for WHO.
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	
4	Did the review authors use a comprehensive literature search strategy?	Yes	But search was limited to PubMed
5	Did the review authors perform study selection in duplicate?	Yes	Two authors assessed the quality of each study
6	Did the review authors perform data extraction in duplicate?	Not stated	
7	Did the review authors provide a list of excluded studies and justify the exclusion?	Yes	No list provided, but numbers provided and reasons for exclusion
8	Did the review authors describe the included studies in adequate detail?	Yes	Table included

[23] AMSTAR 2 'critical domains' are presented in bold in the table.
[24] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[23] [24]	Answer	Comment
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[25]	Yes	PRISMA covers bias
10	Did the review authors report on the sources of funding for the studies included in the review?	Yes	WHO
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	NA	
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	NA	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Note the overall low quality of the studies
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	NA	
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	NA	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	

[25] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Thaxton L, Lavelanet A. 'Systematic review of efficacy with extending contraceptive implant duration'. Int J Gynaecol Obstet. 2019 Jan;144(1):2–8

	AMSTAR 2 TOOL QUESTION[26] [27]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	P: women using ENG and LNG releasing implants past their approved duration I: ENG and LNG releasing implants C: women who initiate use of a new implant (however, none of the primary research identified included cohorts randomized in this way) O: pregnancy occurring during extended use
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Partial	This review uses the Preferred Reporting Items for Systematic Review and Meta- Analyses (PRISMA) guidelines for reporting. No further explanation is provided
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	Using the United States Preventative Services Task Force (USPSTF) guidelines, each article's study quality was rated as "poor," "fair," or "good"
4	Did the review authors use a comprehensive literature search strategy?	Yes	PubMed and EMBASE
5	Did the review authors perform study selection in duplicate?	Yes	
6	Did the review authors perform data extraction in duplicate?	Yes	

[26] AMSTAR 2 'critical domains' are presented in bold in the table.
[27] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[26 27]	Answer	Comment
7	Did the review authors provide a list of excluded studies and justify the exclusion?	No	The article notes that reasons for exclusion were documented but provided no further commentary. Numbers of excluded returns are provided; a list of titles is not.
8	Did the review authors describe the included studies in adequate detail?	Yes	Included studies were clearly identified in the text and relevant data extractions described in tables
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[28]	Yes	USPSTF guidelines were used to assess risk of bias in each included study
10	Did the review authors report on the sources of funding for the studies included in the review?	n/a	There was no meta-analysis
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	n/a	
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	n/a	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	n/a	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	This research did not receive any specific grant from funding agencies in the public, commercial, or not- for- profit sectors.

[28] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Ti AJ, Roe AH, Whitehouse KC, Smith RA, Gaffield ME, Curtis KM. 'Effectiveness and safety of extending intrauterine device duration: a systematic review'. Am J Obstetric Gynaecology 2020;15:15

	AMSTAR 2 TOOL QUESTION[29 30]	Answer	Comment
1	Did the research questions and inclusion criteria for the review include the components of the PICO?	Yes	P: women using Cu or LNG IUDs past their approved duration I: Copper T380A and LNG IUDs (52 mg, 18.5 mg, 13.5 mg) C: not required O: pregnancy occurring during extended use
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	Used PRISMA guidelines and prospectively registered a protocol for the review in PROSPERO, an international prospective register of systematic reviews
3	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	
4	Did the review authors use a comprehensive literature search strategy?	Yes	PubMed, Embase CINAHL and Global Index Medicus were searched
5	Did the review authors perform study selection in duplicate?	Yes	
6	Did the review authors perform data extraction in duplicate?	Yes	
7	Did the review authors provide a list of excluded studies and justify the exclusion?	Partial	Exclusion criteria were described, and numbers of returns and exclusions clearly identified. Reasons for exclusions were provided but a list of excluded titles was not

[29] AMSTAR 2 'critical domains' are presented in bold in the table.
[30] For supporting information about AMSTAR2, see the AMSTAR2 Guidance document, available at https://amstar.ca/docs/AMSTAR%202-Guidance-document.pdf

	AMSTAR 2 TOOL QUESTION[29 30]	Answer	Comment
8	Did the review authors describe the included studies in adequate detail?	Yes	Included studies were clearly identified in the text and relevant data extractions described in tables
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?[31]	Yes	Cochrane Risk of Bias Assessment tool used
10	Did the review authors report on the sources of funding for the studies included in the review?	Yes	
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	All calculations, formulas and assumptions were clearly described
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes	
13	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes	
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	No funding sources were involved in the conduct of this review

[31] For example, Newcastle Ottawa Scale, SIGN, Mixed methods Appraisal Tool (MMAT), ROBINS-I

Prospective cohort studies

Roke C, Roberts H, Whitehead A. New Zealand women's experience during their first year of Jadelle R contraceptive implant. J Prim Health Care. 2016;8(1):13–9

INTERNAL VALIDITY		Yes	Can't say	No	NA
1.1	The study addresses an appropriate and clearly focused question.	☐	☐	☐	☐
SELECTION OF SUBJECTS		**Yes**	**Can't say**	**No**	**NA**
1.2	The cases and controls are taken from comparable populations.	☐	☐	☐	☐
1.3	The same exclusion criteria are used for both cases and controls.	☐	☐	☐	☐
1.4	What percentage of each group (cases and controls) participated in the study?				
1.5	Comparison is made between participants and non-participants to establish their similarities or differences.	☐	☐	☐	☐
1.6	Cases are clearly defined and differentiated from controls.	☐	☐	☐	☐
1.7	It is clearly established that controls are non-cases.	☐	☐	☐	☐
ASSESSMENT		**Yes**	**Can't say**	**No**	**NA**
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment.	☐	☐	☐	☐
1.9	Exposure status is measured in a standard, valid and reliable way.	☐	☐	☐	☐
CONFOUNDING		**Yes**	**Can't say**	**No**	**NA**
1.10	The main potential confounders are identified and taken into account in the design and analysis.	☐	☐	☐	☐
STATISTICAL ANALYSIS		**Yes**	**Can't say**	**No**	**NA**
1.11	Confidence intervals are provided.	☐	☐	☐	☐
OVERALL ASSESSMENT OF THE STUDY					

2.1	How well was the study done to minimise the risk of bias or confounding?	High quality (++)	☐	
		Acceptable (+)		☐
		Low quality (-)		☐
		Unacceptable – reject		☐
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Yes ☐	Can't say ☐	No ☐
2.3	Are the results of this study directly applicable to the patient group targeted in this Statement?	Yes ☐	No ☐	

Observational cohort studies

Shaaban, O. M., A. M. Abbas, H. R. Mahmoud, E. M. Yones, A. Mahmoud, and M. S. Zakherah. 'Levonorgestrel Emergency Contraceptive Pills Use during Breastfeeding; Effect on Infants' Health and Development'. *Journal of Maternal-Fetal & Neonatal Medicine*, 2018, 1-5. https://doi.org/10.1080/14767058.2018.1439470.

INTERNAL VALIDITY		Yes	Can't say	No	NA
1.1	The study addresses an appropriate and clearly focused question.	☒	☐	☐	☐
SELECTION OF SUBJECTS		**Yes**	**Can't say**	**No**	**NA**
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	☒	☐	☐	☐
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	☐	☒	☐	☐
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	☐	☐	☐	☒
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	NA: Used data from first 100 participants from each group			
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	☐	☐	☐	☒
ASSESSMENT		**Yes**	**Can't say**	**No**	**NA**
1.7	The outcomes are clearly defined.	☒	☐	☐	☐
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.	☐	☐	☐	☒
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	☐	☐	☐	☒
1.10	The method of assessment of exposure is reliable	☒	☐	☐	☐
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	☒	☐	☐	☐
1.12	Exposure level or prognostic factor is assessed more than once.	☐	☐	☐	☒

CONFOUNDING		Yes	Can't say	No	NA
1.13	The main potential confounders are identified and taken into account in the design and analysis.	☒	☐	☐	☐

STATISTICAL ANALYSIS		Yes	No
1.13	Have confidence intervals been provided?	☒	☐

OVERALL ASSESSMENT OF THE STUDY				
2.1	How well was the study done to minimise the risk of bias or confounding?	High quality (++)	☐	
		Acceptable (+)	☒	
		Low quality (-)	☐	
		Unacceptable – reject	☐	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Yes ☒	Can't say ☐	No ☐
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Yes ☒	No ☐	