

CATEGORY: BEST PRACTICE STATEMENT

Evidence-based Medicine, Obstetrics and Gynaecology

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

A list of Women's Health Committee Members can be found in [Appendix A](#).

Disclosure statements have been received from all members of this committee.

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

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RANZCOG recognises the NHMRC levels of evidence and associated grading of recommendations¹⁻³. These classify systematic reviews of randomised controlled trials (RCTs) and RCTs themselves as the strongest evidence types to estimate the effect of clinical interventions. RANZCOG upholds the principle that clinical decision-making should be based on the strongest and most relevant evidence available, as applied to the patient's particular situation. In an era of exponentially increasing complexity of disease and medicine, this calls on clinicians to integrate available evidence, representing summarised experiences of a population, with clinical experience and patient preferences to best individualise management.⁴

Systematic reviews and RCTs constitute the highest level of evidence, because their findings represent the systematic and unbiased findings of many individual doctors on the scientifically proven benefits and harms of a given intervention. Accordingly, RANZCOG strongly supports clinicians recruiting to randomised controlled trials to scientifically test interventions for which there is clinical uncertainty, and applying their findings.

Nevertheless, it is important to also acknowledge that the best available evidence may not come from randomised trials, and other sources of evidence may need to be considered. Firstly, it is unfortunately often the case that pregnant and breastfeeding women are systematically excluded from clinical trials of therapeutics.^{5,6} Because of their frequent exclusion from trials, RCT evidence is not always available for these unique, but not uncommon, populations. RANZCOG strongly advocates for the inclusion of pregnant and breastfeeding women in clinical trials. Secondly, a number of important adverse outcomes in obstetrics, are rare but due to the severity of the outcome, still occur at frequencies of clinical importance to some or most women.⁷ Where infrequent outcomes are endpoints, the number of subjects required for a meaningful RCT are necessarily massive and may be unattainable. In such situations, observational studies may provide additional meaningful evidence.⁸ Finally, not all clinical recommendations lend themselves to assessment by RCTs or even case-control, cohort or population studies. Sometimes the evidence is such that subjecting the matter to direct investigation is inappropriate or unnecessary. Gordon Smith's analogy with "use or non-use of the parachute" has been widely quoted as an example.⁹ Likewise in medicine, the evidence that guides some recommendations may be derived from a compelling rationale.¹⁰ For example, no one would suggest a trial of caesarean versus vaginal birth for a grade IV placenta praevia or enter their patients into a trial of placebo versus medication for a blood pressure of 200/150. These situations are however rare in medicine, and in the majority of situations such a compelling rationale cannot be derived from case-reports alone. Summarizing however, evidence-based medicine aims to help in getting the best estimate of the truth underlying medical interventions, be it from randomised clinical trials and meta-analysis or from studies more prone to bias, together with pathophysiological rationale and clinical expertise.

Recommendations for clinical practice in the form of Guidelines or College Statements are ultimately made by panels using their clinical expertise, and/or their expertise in the interpretation of all the available evidence. They aim to guide clinicians who simply lack the time and/or expertise to adequately find and assess the individual pieces of relevant evidence to support clinical decisions¹¹. It is essential that experienced clinicians are adequately represented on these panels to ensure appropriate interpretation and applicability to specified clinical situations. Maybe the most important success factor for evidence-based medicine is the continuous awareness that our own perception of the world around us is biased.

Although guidelines are semantically a "guide" to clinical practice, they should be followed where they are relevant to a clinical decision, informed by the best scientific evidence that is available. If the circumstances of an individual patient result in a care recommendation contrary to the guideline, the rationale for deviation from accepted clinical practice should be clearly documented.

References

1. NHMRC. How to use the evidence: assessment and application of scientific evidence. .
2. NHMRC. Additional levels of evidence and grades for recommendations. .
3. Craig JC, Irwig LM, Stockler MR. Evidence-based medicine: useful tools for decision making. *The Medical journal of Australia*. 2001;174(5):248-53.
4. Sturmberg JP. Evidence-based medicine-Not a panacea for the problems of a complex adaptive world. *J Eval Clin Pract*. 2019;25(5):706-16.
5. Whitehead CL, Walker SP. Consider pregnancy in COVID-19 therapeutic drug and vaccine trials. *Lancet*. 2020;395(10237):e92.
6. LaCourse SM, John-Stewart G, Adams Waldorf KM. Importance of inclusion of pregnant and breastfeeding women in COVID-19 therapeutic trials. *Clin Infect Dis*. 2020.
7. Walker SP, McCarthy EA, Ugoni A, Lee A, Lim S, Permezel M. Cesarean delivery or vaginal birth: a survey of patient and clinician thresholds. *Obstetrics and gynecology*. 2007;109(1):67-72.
8. Glezerman M. Five years to the term breech trial: the rise and fall of a randomized controlled trial. *American journal of obstetrics and gynecology*. 2006;194(1):20-5.
9. Smith GC, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *Bmj*. 2003;327(7429):1459-61.
10. Diaz M ND. Heroes and martyrs of quality and safety. Pasteur and parachutes: when statistical process control is better than a randomized controlled trial. *Quality and Safety in Health Care* 2005. 2005;14:140-3.
11. Mercuri M. The ever-shifting source of authority on what works in clinical medicine. *J Eval Clin Pract*. 2019;25(5):703-5.
12. Evidence. RANZCOG O&G Magazine 2012;14(2 Winter).RANZCOG endorses the principles of Evidence-based medicine and recognises the NHMRC levels of evidence and grades of recommendations.¹⁻³

Appendices

Appendix A: Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair and Board Member
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Scott White	Deputy Chair, Obstetrics and Subspecialties Representative
Associate Professor Ian Pettigrew	Member and EAC Representative
Dr Kristy Milward	Member and Councillor
Dr Will Milford	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Professor Sue Walker	Member
Dr Roy Watson	Member and Councillor
Dr Susan Fleming	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	ATSI Representative
Associate Professor Kirsten Black	Member
Dr Thangeswaran Rudra	Member
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative
Ms Ann Jorgensen	Community Representative
Dr Ashleigh Seiler	Trainee Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

Appendix B Contributing Authors

The Women's Health Committee acknowledges the contribution of Prof Ben W. Mol to this statement.

Appendix C Full Disclaimer

Purpose

This Guideline has been developed to provide general advice to practitioners about women's health issues concerning evidence based medicine, obstetrics and gynaecology and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person with an intent to use water immersion during labour and birth and the particular circumstances of each case.

Quality of information

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

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