DOI: 10.1111/ajo.13028

POSITION PAPER

ANZSREI consensus statement on elective oocyte cryopreservation

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Conflict of interest statement: BK and MC are shareholders in Virtus Health. CB owns a facility offering oocyte cryopreservation.

Received: 29 December 2018;
Accepted: 29 May 2019

Abstract

Background: One in six Australian women and couples suffer infertility. A rising proportion relates to advanced maternal age, associated with poorer oocyte quality and *in vitro* fertilisation (IVF) outcomes. Internationally, oocyte cryopreservation technology applied to oocytes vitrified before 35 years provides similar live-birth statistics compared to IVF treatment using fresh oocytes. Oocyte cryopreservation is accessible in Australasian settings and elective uptake is increasing. For women accessing treatment, oocyte cryopreservation may expand future family building options.

Aims: To develop the first Australasian Certification in Reproductive Endocrinology and Infertility (CREI) subspecialist-led consensus guideline on oocyte cryopreservation.

Methods: The ANZSREI ACCEPT (Australasian CREI Consensus Expert Panel on Trial evidence group) met in 2017 and 2018 and identified clinical aspects of care for inclusion and review. Review of the available evidence was conducted and consensus statements prepared. Areas of dissent of expert opinion and for further research were noted.

Results: Consensus was reached on definition and best practice in oocyte cryopreservation for freeze method, controlled ovarian stimulation, medical risk reduction and treatment and outcomes counselling. The term 'social egg freezing' may marginalise, stigmatise or attribute social blame to women, and there is a need to revise this to a neutral and non-judgemental term such as elective or planned oocyte cryopreservation.

Conclusion: Oocyte cryopreservation has the potential to improve cumulative live birth outcomes for women. Implementation of this guideline should facilitate an optimal approach for providing care.

KEYWORDS

egg freezing, elective egg freezing cryopreservation, elective oocyte, oocyte, social egg freezing

INTRODUCTION

With changes in societal structure and expectations, there is an increased prevalence of female age-related infertility. Increasing numbers of Australian women are delaying childbearing, resulting in a rise in median age of mothers and a fall in Australia's total fertility rate.[1] Single-child families are more common and large families (defined as having three or more children) are less common than in previous generations, related to a higher average age of mothers.[2]

Infertility is most prevalent among women beyond the age of 35 years. The burden of infertility is very high in women aged 40 years and over.[3] Risk factors for involuntary and circumstantial childlessness include a university education, single relationship status and female gender.[4,5]

Oocyte cryopreservation, often called 'egg freezing' can be used electively to allow a woman to conceive biologically-related children at a later age.

Women with age-related infertility may attempt to conceive through *in vitro* fertilisation (IVF) using donated oocytes (from a younger donor).[6]

Since the first birth from a slow-frozen oocyte in 1986,[7] oocyte vitrification has transformed a promising experimental technology into an accepted clinical application of assisted reproductive therapy (ART).[8-10] The Australian & New Zealand Assisted Reproduction Database (ANZARD) reports a growing number of Australian women have stored their oocytes (pers. comm. Oisin Fitzgerald, ANZARD). However, data of how many Australian women have cryopreserved oocytes electively have not been documented in ANZARD annual ART statistical reporting.[11,12]

The term 'medical oocyte cryopreservation' has been applied to oocyte cryopreservation in the following settings: planned oophorotoxic cancer treatment, significant gynaecological pathology threatening fertility (eg endometriosis), premature ovarian insufficiency, unexpected failure to find sperm on the day of IVF oocyte retrieval, co-ordination of microtese sperm extraction, prior to gender confirmation therapy, or at the time of IVF due to ethical objection to creating and freezing supernumerary embryos.[10] This consensus statement does not refer to 'medical oocyte cryopreservation'.

In an effort to provide guidance to clinicians working with women considering elective oocyte cryopreservation, this document, produced by the Australasian Certificate of Reproductive Endocrinology and Infertility (CREI) Consensus Expert Panel on Trial evidence (ACCEPT) group, provides an Australasian consensus statement on the best practice of elective oocyte cryopreservation. These recommendations may change as new evidence becomes available and will be updated as necessary.

MATERIALS AND METHODS

The ACCEPT group met in 2017 and identified scope for these guidelines and search terms for inclusion and review. Medline, Embase and the Cochrane Database of Systematic Reviews were searched using the terms 'oocyte', 'ovum', 'egg', 'cryopreservation', 'freeze', 'freezing', 'vitrification', 'social egg freezing', 'guidelines' and limited to humans and English language. The date of the last search was July 2018. Reference lists of all relevant primary and review articles were hand-searched for articles not identified in the initial search. Searches were conducted independently by RL and JF.

This document uses the National Health and Medical Research Council levels of evidence (Table 1) and GRADE (Grading of Recommendations, Assessment, Development and Evaluations) (Table 2).[13]

Consistent with previous ACCEPT guidelines, the following nomenclature was used to define the levels of agreement regarding individual statements (Table 3).

All consensus statements derived by the authors from the search outlined earlier were modified as required and voted on by the CREI expert group in Sydney on 28 July 2018. Those clinicians in attendance are listed in the Acknowledgements section. All contributing ACCEPT group clinicians were again invited to have input into the final statement prior to consensus voting.

RESULTS AND DISCUSSION

Four hundred and sixty-nine published abstracts were reviewed on the subject of oocyte cryopreservation, of which 270 articles were included in the evidence-review. Articles reporting on oocyte cryopreservation associated with medical indications were excluded. Listed in the following are the ACCEPT group's position statementsrelating to elective oocyte cryopreservation (Figs 1–17).

Many oocyte cryopreservation cycles conducted in Australia and New Zealand are now undertaken electively; however, until

TABLE 1 National Health and Medical Research Council levels of evidence

1a	Systematic review or meta-analysis of randomised controlled trials
1b	One or more randomised controlled trials
2a	One or more well-designed study/studies, controlled, non-randomised
2b	One or more well-designed, quasi-experimental study/studies
3	One or more well-designed descriptive study/studies
4	Expert opinion

TABLE 2 GRADE (Grading of Recommendations, Assessment, Development and Evaluations)

Strength of the recommendation	Definition
Strong	Highly confident of the balance between desirable and undesirable consequences (ie desirable consequences outweigh the undesirable consequences; or undesirable consequences outweigh the desirable consequences).
Weak	Less confident of the balance between desirable and undesirable consequences.
Quality level of a body of evidence	**Definition**
High ++++	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate +++0	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low ++00	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect
Very low + 000	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect

now collective data on elective oocyte cryopreservation have not been published in ANZARD reports.[1411] Elective oocyte cryopreservation is ethically permissible for women attempting to safeguard their reproductive potential for the future. ART and surgical procedures involved in elective oocyte cryopreservation are well established, used worldwide, and are regarded as safe.[15] For personal reasons, women are taking up oocyte cryopreservation technology in a bid to expand their reproductive potential. Due to high treatment costs, access to elective oocyte preservation is limited to socioeconomically advantaged women (Table 3).[16]

TABLE 3 ACCEPT (Australasian Certification in Reproductive Endocrinology and Infertility Consensus Expert Panel on Trial evidence) consensus

Unanimous	α
Unanimous with caveat	β
Majority	γ
No consensus	δ

Societal trends have impacted the age at which we form relationships and the degree to which relationships are expected to mature prior to starting our families.[17,18] The majority of women who freeze their oocytes are single or have a partner who is not

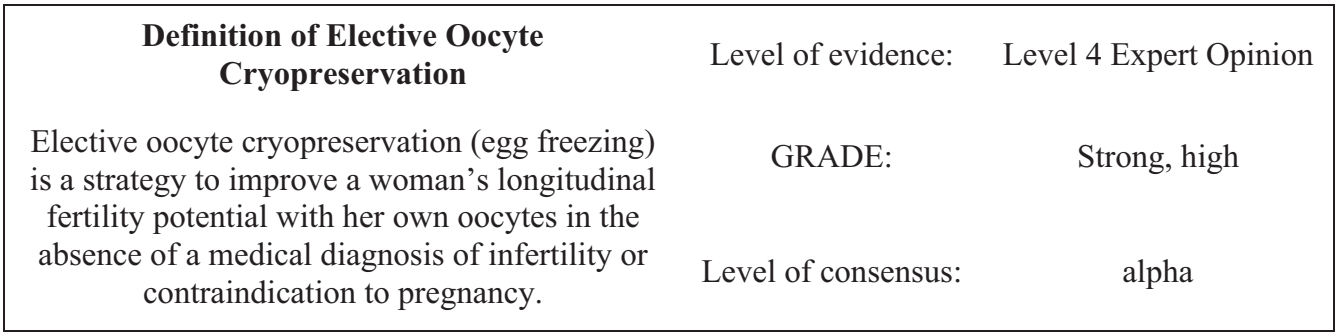

FIGURE 1 Definition of elective oocyte cryopreservation.

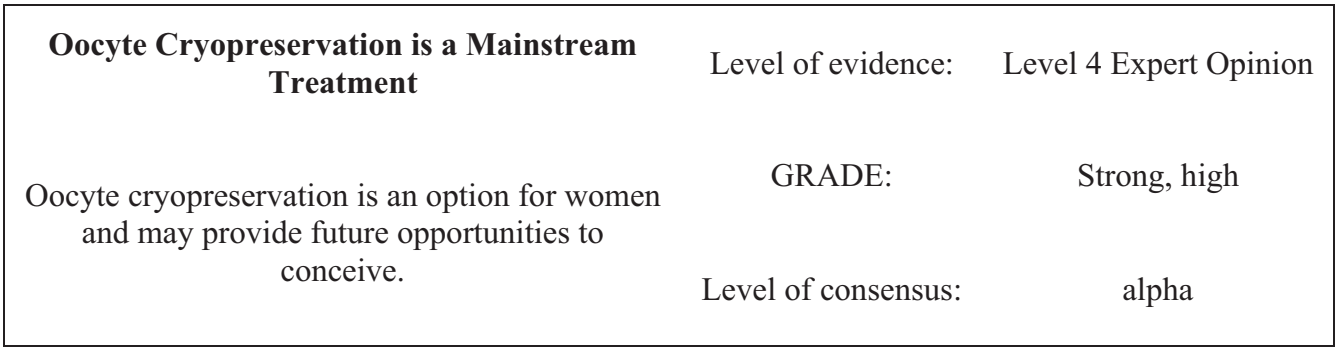

FIGURE 2 Oocyte cryopreservation is a mainstream treatment.

Method of freezing:	Level of evidence:	Level 1A
Vitrification is currently the most effective method for mature (MII) oocyte cryopreservation.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 3 Method of freezing.

Oocyte Survival:	Level of evidence:	Level 1A
Women should be made aware that not all oocytes will survive warming.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 4 Oocyte survival.

Treatment risks:	Level of evidence:	Level 4 Expert Opinion
Treatment risks include OHSS, risks of oocyte collection and anaesthesia. Pre-treatment risk counselling should be undertaken.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 5 Treatment risks.

yet willing to commit to parenthood.[19] International data suggest that oocyte cryopreservation may reduce involuntary childlessness (Fig. 3).[20-22]

Oocyte cryopreservation is technically challenging due to the biological characteristics of the metaphase II (MII) oocyte. These include large cell size, high water content and a delicate, active meiotic spindle structure.[23] Oocyte cryopreservation by vitrification is the standard practice to maximise the probability of oocyte survival (Fig. 4).[24-29]

Trials reporting the chance of a live birth from vitrified oocytes have been performed overseas but not in Australasia. With the widespread practice of commercial oocyte donation overseas, ART programs internationally report live birth rates (LBR) using warmed oocytes from young fertile oocyte donors. Australian data reporting LBR from electively vitrified oocytes has not been published.

A meta-analysis of studies up to June 2013 estimated that 80–90% of all cryopreserved oocytes (donor programs and elective autologous oocyte cryopreservation) survive warming (Table 4).[30] Data from elective oocyte cryopreservation, show reduced mean oocyte survival, inferring oocytes from older women may be intrinsically of poorer quality and are less physically robust to the freeze-warming process than oocytes from younger oocyte donor populations. Women choosing to cryopreserve oocytes electively require higher numbers of oocytes per pregnancy achieved compared to young oocyte donors.[31]

Oocyte survival is strongly influenced by laboratory processes and experience and outcomes achieved in world-leading laboratories may not be replicated in all Australian and New Zealand laboratories (Figs 5 and 6).

The risk of ovarian hyper-stimulation syndrome can and should be minimised by patient selection, follicle-stimulating

Recommended stimulation regimen:	Level of evidence:	Level 4 Expert Opinion
To minimise the risk of OHSS the recommended stimulation strategy is an FSH/GnRH antagonist regimen with planned GnRH agonist trigger.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 6 Recommended stimulation regimen.

Ovarian reserve assessment:	Level of evidence:	Level 4 Expert Opinion
Ovarian reserve testing should be offered to women prior to oocyte cryopreservation and counselling provided regarding expected oocyte yield per stimulated cycle.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 7 Ovarian reserve assessment.

Fertilisation of warmed oocytes requires ICSI (intracytoplasmic sperm injection):	Level of evidence:	Level 4 Expert Opinion
Women should be informed that microinjection of sperm is required to fertilise warmed oocytes.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 8 Fertilisation of warmed oocytes requires intracytoplasmic sperm micro-injection (ICSI).

hormone (FSH) dose individualisation and gonadotrophin-releasing hormone (GnRH) antagonist protocol choice.[32] Women considering oocyte cryopreservation should be fully informed of the surgical risk at ovum pick up (OPU) (1/1500 risk of a surgical complication; Fig. 7).[33]

Ovarian reserve assessment prior to oocyte cryopreservation is indicated in order to allow realistic counselling with regard to the approximate number of oocytes that might be achieved in a single treatment and to optimise the efficiency and safety of controlled ovarian stimulation treatment.[34] Multiple treatments may be required for women with lower ovarian reserves who wish to store a particular number of oocytes.

Antimullerian hormone (AMH) measurement, ultrasound follicular phase antral follicle count and follicular phase FSH level can be assessed separately or in combination to predict a woman's response to treatment.[35] AMH assessment is a poor predictor of immediate fertility (Fig. 8).

Intra-cytoplasmic sperm micro-injection (ICSI) is required to fertilise warmed oocytes, and this has associated risks and costs. Fertilisation of warmed oocytes surviving the thaw is reported as 70–85%.[30] However, there are many factors that will influence fertilisation rates, including oocyte quality and the quality of sperm used for ICSI (Fig. 9).[36-38]

Blastocyst formation may be compromised after using vitrified oocytes compared to fresh oocytes but reports are conflicting. Some studies have shown no difference[20,39] but others showed reduced blastulation.[21,40,41] The difference in blastocyst formation rates between vitrified and fresh oocytes is small (2.5 ± 2.3 vs 2.0 ± 2.1; Fig. 10).[41]

Blastocyst formation:	Level of evidence:	Level 1B
Women should be aware that warmed oocytes may create fewer blastocysts compared with fresh oocytes.	GRADE:	Moderate/weak
	Level of consensus:	alpha

FIGURE 9 Blastocyst formation.

Recommended age for treatment:	Level of evidence:	Level 4 Expert Opinion
The best age to freeze oocytes is before the age of 35 years. Women over 35 years achieve poorer pregnancy outcomes from vitrified oocytes related to oocyte quality deterioration with advancing maternal age.	GRADE:	Strong, high
	Level of consensus:	beta

FIGURE 10 Recommended age for treatment.

Oocyte utilisation:	Level of evidence:	Level 3
Women should be informed that there is a chance that they may not need to use their frozen oocytes and oocyte cryopreservation does not guarantee future live birth.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 11 Oocyte utilisation.

The recommended age for women to undertake oocyte cryopreservation is controversial. From a biological perspective oocytes obtained at a younger age are of higher quality and of greater number, which translates to higher chances of live birth. A higher chance of live birth is obtained from oocytes cryopreserved prior to 36 years.[22,42] However, elective oocyte cryopreservation has been calculated to be most cost-effective for women aged 37 years, demonstrating the greatest comparative improvement in probability of live birth versus no action.[43] This observation occurs in context of the rapid and progressive biological fertility decline

Safety outcomes:	Level of evidence:	Level 3
Safety outcomes for births from vitrified oocytes are to date reassuring with no evidence of increased risk compared with IVF births. Safety data remains preliminary. Long-term follow-up studies for all cryopreservation techniques remain essential.	GRADE:	Strong, moderate
	Level of consensus:	alpha

FIGURE 12 Safety outcomes.

Medical nomenclature:	Level of evidence:	Level 4 Expert Opinion
We recommend the use of neutral, non-stigmatising terminology to replace terms that marginalise, stigmatise or attribute blame to women e.g. social egg freezing.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 13 Medical nomenclature.

Pregnancy risk counselling:	Level of evidence:	Level 3
Women should be counselled at the time of cryopreservation of oocytes that if they achieve pregnancy at an advanced maternal age they will be at increased risk of perinatal and obstetric complications.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 14 Pregnancy risk counselling.

experienced by women aged over 35 years.[34] Women aged significantly under 35 years should consider that they may have a high chance of future natural conception and need not consider oocyte cryopreservation. Women considering oocyte cryopreservation aged >40 years should be counselled to expect a significantly lower probability of live birth per oocyte vitrified than expected for younger women.[44] Options to assist immediate conception as an alternative to oocyte cryopreservation should be discussed.

However, from the largest longitudinal studies conducted to date, only 10–12% of women who have electively frozen their oocytes have returned to use them.[22,31] Women aged >35 years at the time of OPU were more likely to return to use vitrified oocytes to attempt conception compared with younger women.[31] However, given the fact that studies are relatively recent, it may be that younger women who access elective oocyte cryopreservation ultimately demonstrate a longer delay to oocyte

Broad fertility counselling:	Level of evidence:	Level 4 Expert Opinion
We recommend women be provided with information about oocyte cryopreservation as part of a broader reproductive health plan.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 15 Broad fertility counselling.

Prognosis for achieving live birth from vitrified oocytes:	Level of evidence:	Level 2A, caveat
The probability of live birth is mainly dependent on the number of mature oocytes and the age of the woman at the time of storage.	GRADE:	Strong, high
	Level of consensus:	alpha
Caveat: Data on LBR (Live Birth Rate) from elective oocyte freezing is to date quite limited. Most studies are from oocyte donor populations.		

FIGURE 16 Prognosis for achieving live birth from vitrified oocytes.

Multiple treatments may be advised:	Level of evidence:	Level 4 Expert Opinion
Women considering oocyte cryopreservation should be counselled that more that one cycle may be needed to obtain their target number of mature oocytes.	GRADE:	Strong, high
	Level of consensus:	alpha

FIGURE 17 Multiple treatments may be advised.

utilisation, compared to older women. Oocyte cryopreservation for all young women would result in unnecessary treatment as most younger women will conceive naturally without the need for medical intervention.

From a clinical perspective, the best age at which oocytes should be stored is determined by balance between perceived future need to access vitrified oocytes and a woman's age (Fig. 12).

TABLE 4 Meta-analysis of vitrified oocyte survival[30]

	Donor cycles	Autologous cycles, infertility	Elective cycles
Number of studies/total patients	3/3615	4/1561	1/1080
Number of randomised controlled trials/patients	2/3517	3/278	0
Number of observational studies/patients	1/98	1/1283	1/1080
Mean age (years)	26.5	35.3	37.2
Average oocyte survival	92%	88%	81%

Three studies have examined live birth outcomes from oocyte vitrification and warming and are reassuring.[45-47] Together, these studies followed more than 2950 live births with no increased risk of congenital abnormalities noted in any study (abnormality rate 0.9–1.3%). Outcomes reported in these studies show a lower than expected risk of congenital abnormalities compared to larger perinatal populations studied (both spontaneous and IVF/ICSI conception).[48]

While babies born through IVF/ICSI using vitrified oocytes have so far been healthy, larger outcome studies regarding risk of congenital abnormalities and longer-term health into adulthood are needed (Fig. 13).

The term 'social egg freezing' has been widely used to describe women who electively choose to cryopreserve oocytes. This terminology can be interpreted to attribute blame to women for delaying motherhood.[15,49-51] Much of the early publicity around oocyte cryopreservation cited educational and career goals as key motivators for women. The most common motivation cited by women who choose to freeze eggs is their single status coupled with their strong desire for future motherhood.[52] International bodies have rejected the label 'social egg freezing', agreeing the terminology should be changed.[15,50,51] The ANZREI ACCEPT group reached consensus that the terminology 'social egg freezing' should be abandoned, favouring the terminology elective or planned egg freezing (Fig. 14).

When women undergo elective oocyte cryopreservation, it increases their chance of experiencing pregnancy at an advanced maternal age. The RANZCOG position statement on ART for women of advanced maternal age defines the category from age 45 years onward.[53] The statement recommends that women seeking pregnancy beyond the age of 45 years should seek a cardiovascular disease assessment and be counselled that they are at an *a priori* increased risk of adverse maternal and fetal complications. Multiple gestation pregnancy should be avoided (Fig. 15).

Oocyte cryopreservation should be discussed with women in the context of their broader fertility options. Studies have shown that both men and women overestimate their current and future fertility.[54,55] Counselling should include a discussion about the boundaries of natural fertility and the ideal timing from a biological perspective to conceive naturally. Options to conceive with the assistance of donor gametes should be discussed.

Most women report feeling empowered by elective oocyte cryopreservation but a minority of women express regret.[56] Psychological support and counselling should be offered to women considering elective oocyte cryopreservation to assist in complex decision making (Fig. 16).

While international studies reporting live birth following the use of vitrified oocytes have been reassuring,[20-22,31,42,57,58] there are no reports of Australasian data on the use of electively vitrified oocytes.

In the largest study conducted to date following women returning to use autologous cryopreserved oocytes, 641/5289 women returned to utilise their oocytes. Seventy percent of women in the study were aged >35 years when oocytes were cryopreserved. Cumulative LBR in this study was highest in women who cryopreserved oocytes aged <35 years (68.8%) and considerably lower in women who were aged >35 years at OPU (25.5%) (Fig. 17).[31]

A numerical recommendation of the ideal quota of oocytes to cryopreserve to achieve a live birth cannot be definitively made. ANZARD IVF statistics for infertile women and couples show that of those who achieve a live birth, a significant proportion require several attempts to do so.[3] Important prognostic factors are age at the time of oocyte storage, oocyte quality and other male and female fertility factors at the time of oocyte thaw.

CONCLUSION

Oocyte cryopreservation is an accepted and standard treatment that has the potential to improve cumulative live birth outcomes for women. Medical professionals can inform women and set realistic fertility treatment goals while minimising risks of treatment. The term 'social egg freezing' should be replaced by non-stigmatising terminology. Pregnancy outcomes from oocyte warming cycles vary with laboratory expertise and women's ages at the time of oocyte cryopreservation. Longitudinal Australasian studies concerning pregnancy and safety outcomes for people conceiving after oocyte cryopreservation are needed. Until such data are published, authors caution that live birth estimates based on younger donor oocyte thaw programs are likely to significantly overestimate the prognosis for older women who electively cryopreserve their oocytes.

ACKNOWLEDGEMENTS

Those clinicians present at the CREI expert group meeting in Sydney on 28 July 2018 were: Raewyn Teirney, Alejandra Izurieta, Jeffrey Persson, Bill Ledger, Iris Wang, David Greening, Gabrielle

Dezarnaulds, Marcin Stznkiewicz, Peter Leung, Michelle Kwik, Louise Hull, Anne Clark, Ian Fraser, Rabia Shaikh, Charley Zheng, Hayden Homer, Luk Rombauts, Simon McDonnell, Devashna Gupta, Shannon Zawada, Warren Chan, Derek Lok, Tze Yoong Wong, Ujvala Rao, Sarah Hunt, Rashi Kalra, Anusch Yazdani, Sonal Karia, Giselle Crawford, Leigh Searle, Priya Sivadas, Cheryl Phua, Sameer Jatkar, Elizabeth Maxwell, Natasha Andreadis, Nicole Hope, Katrina Rowan, Hossam Elzeiny, Janelle McDonald, Nalini Gayer, Shadi Khashaba, Gab Kovacs, Kim Matthews, Pete Benny, Emily Liu. The authors were also present. No funding was accepted for the development of this consensus statement.

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