Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update

Kutluk Oktay, Brittany E. Harvey, Ann H. Partridge, Gwendolyn P. Quinn, Joyce Reinecke, Hugh S. Taylor, W. Hamish Wallace, Erica T. Wang, and Alison W. Loren

ABSTRACT

Purpose
To provide current recommendations about fertility preservation for adults and children with cancer.

Methods
A systematic review of the literature published from January 2013 to March 2017 was completed using PubMed and the Cochrane Library. An Update Panel reviewed the identified publications.

Results
There were 61 publications identified and reviewed. None of these publications prompted a significant change in the 2013 recommendations.

Recommendations
Health care providers should initiate the discussion on the possibility of infertility with patients with cancer treated during their reproductive years or with parents/guardians of children as early as possible. Providers should be prepared to discuss fertility preservation options and/or to refer all potential patients to appropriate reproductive specialists. Although patients may be focused initially on their cancer diagnosis, providers should advise patients regarding potential threats to fertility as early as possible in the treatment process so as to allow for the widest array of options for fertility preservation. The discussion should be documented. Sperm, oocyte, and embryo cryopreservation are considered standard practice and are widely available. There is conflicting evidence to recommend gonadotrophin-releasing hormone agonists (GnRHa) and other means of ovarian suppression for fertility preservation. The Panel recognizes that, when proven fertility preservation methods are not feasible, and in the setting of young women with breast cancer, GnRHa may be offered to patients in the hope of reducing the likelihood of chemotherapy-induced ovarian insufficiency. GnRHa should not be used in place of proven fertility preservation methods. The panel notes that the field of ovarian tissue cryopreservation is advancing quickly and may evolve to become standard therapy in the future. Additional information is available at www.asco.org/survivorship-guidelines.

INTRODUCTION

The goal of this update is to provide oncologists, other health care providers, and caregivers with recommendations regarding fertility preservation for adults, adolescents, and children with cancer.

The American Society of Clinical Oncology (ASCO) first published evidence-based clinical practice guidelines on fertility preservation in 2006, and an updated guideline was published in 2013. The goal of this 2018 guideline update is to provide current guidance regarding fertility preservation options for people with cancer anticipating treatment. The current 2018 update assesses whether the 2013 recommendations remain valid. A complete list of 2013 and 2018 recommendations is available at www.asco.org/survivorship-guidelines and in Data Supplement 1.

METHODS

Guideline Update Process
ASCO uses a signals approach to facilitate guideline updating. This approach is intended to identify new, potentially practice-changing data—signals—that might translate into revised practice recommendations. The approach relies on routine literature searching and the expertise of ASCO guideline panel members to identify signals. The Methodology Supplement
Fertility Preservation in Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update

Guideline Question
What are fertility preservation options for patients with cancer who will receive anticancer treatment?

Target Population
Patients with cancer at risk for infertility due to anticancer treatment.

Target Audience
Medical oncologists, radiation oncologists, gynecologic oncologists, urologists, hematologists, pediatric oncologists, surgeons, nurses, social workers, psychologists, and other nonphysician providers.

Methods
A systematic review of the literature published from January 2013 to March 2017 was completed using PubMed and the Cochrane Library. An Update Panel reviewed the identified publications, and relevant evidence was evaluated for inclusion into this updated clinical practice guideline.

Recommendations
Recommendation 1.1. People with cancer are interested in discussing fertility preservation. Health care providers caring for adult and pediatric patients with cancer (including medical oncologists, radiation oncologists, gynecologic oncologists, urologists, hematologists, pediatric oncologists, surgeons, and others) should address the possibility of infertility as early as possible before treatment starts.

Recommendation 1.2. Health care providers should refer patients who express an interest in fertility preservation (and those who are ambivalent) to reproductive specialists.

Recommendation 1.3. To preserve the full range of options, fertility preservation approaches should be discussed as early as possible, before treatment starts. The discussion can ultimately reduce distress and improve quality of life. Another discussion and/or referral may be necessary when the patient returns for follow up after completion of therapy and/or if pregnancy is being considered. The discussions should be documented in the medical record.

Adult Men
Recommendation 2.1. Sperm cryopreservation: Sperm cryopreservation is effective, and health care providers should discuss sperm banking with postpubertal males receiving cancer treatment.

Recommendation 2.2. Hormonal gonadoprotection: Hormonal therapy in men is not successful in preserving fertility. It is not recommended.

Recommendation 2.3. Other methods to preserve male fertility: Other methods, such as testicular tissue cryopreservation and reimplantation or grafting of human testicular tissue, should be performed only as part of clinical trials or approved experimental protocols.

Recommendation 2.4. Postchemotherapy: Men should be advised of a potentially higher risk of genetic damage in sperm collected after initiation of therapy. It is strongly recommended that sperm be collected before initiation of treatment because the quality of the sample and sperm DNA integrity may be compromised after a single treatment. Although sperm counts and quality of sperm may be diminished even before initiation of therapy, and even if there may be a need to initiate chemotherapy quickly such that there may be limited time to obtain optimal numbers of ejaculate specimens, these concerns should not dissuade patients from banking sperm. Intracytoplasmic sperm injection allows the future use of a very limited amount of sperm; thus, even in these compromised scenarios, fertility may still be preserved.

(continued on following page)
Adult Women

Recommendation 3.1. Embryo cryopreservation: Embryo cryopreservation is an established fertility preservation method, and it has routinely been used for storing surplus embryos after in vitro fertilization.

Recommendation 3.2. Cryopreservation of unfertilized oocytes: Cryopreservation of unfertilized oocytes is an option, and may be especially well suited to women who do not have a male partner, do not wish to use donor sperm, or have religious or ethical objections to embryo freezing. Oocyte cryopreservation should be performed in centers with the necessary expertise. As of October 2012, the American Society for Reproductive Medicine no longer deems this procedure experimental.

Qualifying statement. More flexible ovarian stimulation protocols for oocyte collection are now available. Timing of this procedure no longer depends on the menstrual cycle in most cases, and stimulation can be initiated with less delay compared with old protocols. Thus, oocyte harvesting for the purpose of oocyte or embryo cryopreservation is now possible on a cycle day–independent schedule. Of special concern in estrogen-sensitive breast and gynecologic malignancies is the possibility that these fertility preservation interventions (eg, ovarian stimulation regimens that increase estrogen levels) and/or subsequent pregnancy may increase the risk of cancer recurrence. Aromatase inhibitor–based stimulation protocols are now well established and may ameliorate this concern. Studies do not indicate increased cancer recurrence risk as a result of aromatase inhibitor–supplemented ovarian stimulation and subsequent pregnancy.

Recommendation 3.3. Ovarian transposition: Ovarian transposition (oophoropexy) can be offered when pelvic irradiation is performed as cancer treatment. However, because of radiation scatter, ovaries are not always protected, and patients should be aware that this technique is not always successful. Because of the risk of remigration of the ovaries, this procedure should be performed as close to the time of radiation treatment as possible.

Recommendation 3.4. Conservative gynecologic surgery: It has been suggested that radical trachelectomy (surgical removal of the uterine cervix) should be restricted to stage IA2 to IB cervical cancer with diameter \( \leq 2 \text{ cm} \) and invasion \( \leq 10 \text{ mm} \). In the treatment of other gynecologic malignancies, interventions to spare fertility have generally centered on doing less radical surgery, with the intent of sparing the reproductive organs as much as possible. Ovarian cystectomy can be performed for early-stage ovarian cancer.

Recommendation 3.5 (updated). Ovarian suppression: There is conflicting evidence to recommend GnRHa and other means of ovarian suppression for fertility preservation. The Panel recognizes that, when proven fertility preservation methods such as oocyte, embryo, or ovarian tissue cryopreservation are not feasible, and in the setting of young women with breast cancer, GnRHa may be offered to patients in the hope of reducing the likelihood of chemotherapy-induced ovarian insufficiency. However, GnRHa should not be used in place of proven fertility preservation methods.

Recommendation 3.6 (updated). Ovarian tissue cryopreservation and transplantation: Ovarian tissue cryopreservation for the purpose of future transplantation does not require ovarian stimulation and can be performed immediately. In addition, it does not require sexual maturity and hence may be the only method available in children. Finally, this method may also restore global ovarian function. However, it should be noted further investigation is needed to confirm whether it is safe in patients with leukemias.

Qualifying statement. As of the time of this publication, ovarian tissue cryopreservation remains experimental. However, emerging data may prompt reconsideration of this designation in the future (this technique is already considered nonexperimental in some countries, and its experimental status is undergoing evaluation in the United States).

Role of Health Care Providers

Recommendation 4.1. All oncologic health care providers should be prepared to discuss infertility as a potential risk of therapy. This discussion should take place as soon as possible once a cancer diagnosis is made and can occur simultaneously with staging and the formulation of a treatment plan. There are benefits for patients in discussing fertility information with providers at every step of the cancer journey.

Recommendation 4.2. Encourage patients to participate in registries and clinical studies, as available, to define further the safety and efficacy of these interventions and strategies.

(continued on following page)
THE BOTTOM LINE (CONTINUED)

Recommendation 4.3. Refer patients who express an interest in fertility, as well as those who are ambivalent or uncertain, to reproductive specialists as soon as possible.

Recommendation 4.4. Refer patients to psychosocial providers when they are distressed about potential infertility.

Special Considerations: Children

Recommendation 5.1. Suggest established methods of fertility preservation (e.g., semen or oocyte cryopreservation) for postpubertal children, with patient assent and parent or guardian consent. For prepubertal children, the only fertility preservation options are ovarian and testicular cryopreservation, which are investigational.

Additional Resources

More information, including a Data Supplement with new studies, a Methodology Supplement, slide sets, clinical tools and resources, is available at www.asco.org/survivorship-guidelines. Patient information is available at www.cancer.net

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate.
Gonadotrophin-Releasing Hormone Agonists in Fertility Preservation

Seven randomized controlled trials, four systematic reviews, and seven guidelines provide the evidence base for gonadotrophin-releasing hormone agonists (GnRHa) in fertility preservation.

Seven randomized controlled trials reported pregnancy outcomes (Table 1). One major limitation of the trials evaluating GnRHa has been reliance on surrogate markers, such as menstrual status or un timed estradiol or follicle-stimulating hormone evaluation, to determine the potential for fertility. The criteria used for defining ovarian insufficiency also varies widely between reports, which makes a uniform comparison challenging. Use of long-term live birth rates is the most appropriate marker of fertility, but few studies have evaluated this outcome or have sufficient length of follow-up or numbers of patients to make definitive conclusions. The only trial that reported number of pregnancies as a preplanned end point was the POEMS (Prevention of Early Menopause Study) trial.7 The POEMS trial reported significantly higher rates of pregnancy in women with hormone receptor-negative breast cancer receiving chemotherapy plus goserelin versus chemotherapy alone (21% vs 11%; P = .03), although these findings are weakened by missing data and lack of adjustment for pregnancy intent. In contrast, the remaining six randomized trials did not report significant differences in pregnancies between treatment groups, although it was not a prespecified outcome for most.3-6,8,9 A definitive trial with proper end points, including live birth rates, adjustment for pregnancy intent, and sufficient power, is needed to answer the controversy on the effectiveness of GnRHa in preserving ovarian function.

Table 1. Randomized Controlled Trials

<table>
<thead>
<tr>
<th>First Author, Year, Trial</th>
<th>No. of Patients</th>
<th>Agents</th>
<th>Disease Sites</th>
<th>Follow-Up (years)</th>
<th>Primary Outcome</th>
<th>No. of Pregnancies (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leonardi, 2017, OPTION8</td>
<td>106 65</td>
<td>GnRHa</td>
<td>Breast</td>
<td>5.0*</td>
<td>POV</td>
<td>9 (9)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>6 (6)</td>
<td></td>
</tr>
<tr>
<td>Demeestere, 20169</td>
<td>65 64</td>
<td>GnRHa</td>
<td>Lymphoma</td>
<td>5.33</td>
<td>POF</td>
<td>17 (53.1)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>15 (42.8)</td>
<td></td>
</tr>
<tr>
<td>Moore, 2015, POEMS7</td>
<td>126 131</td>
<td>GnRHa</td>
<td>Breast</td>
<td>4.1</td>
<td>POV</td>
<td>22 (21)</td>
<td>.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>12 (11)</td>
<td></td>
</tr>
<tr>
<td>Lamberti, 2015, PROMISE-GIM68</td>
<td>148 133</td>
<td>GnRHa</td>
<td>Breast</td>
<td>7.3</td>
<td>POV</td>
<td>8 (5)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>3 (2)</td>
<td></td>
</tr>
<tr>
<td>Elgindy, 20135</td>
<td>25 25</td>
<td>GnRHa</td>
<td>Breast</td>
<td>1.0</td>
<td>Resumption of menses</td>
<td>1 (4)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 25</td>
<td>GnRHa</td>
<td>Breast</td>
<td>1.6</td>
<td>POV</td>
<td>0 (0)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>2 (10)</td>
<td></td>
</tr>
<tr>
<td>Munster, 20124</td>
<td>27 22</td>
<td>GnRHa</td>
<td>Breast</td>
<td>4.0</td>
<td>Resumption of menses</td>
<td>1 (3)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td>1 (3)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: GnRHa, gonadotrophin-releasing hormone agonist; NR, not reported; NS, not significant; OPTION, Ovarian Protection Trial In Premenopausal Breast Cancer Patients; POEMS, Prevention of Early Menopause Study; POF, premature ovarian failure; POV, preservation of ovarian function; PROMISE-GIM68, Prevention of Menopause Induced by Chemotherapy: A Study in Early Breast Cancer Patients—Gruppo Italiano Mammella 6.

One systematic review reporting six versus five births with GnRHa when compared with control did not report further analyses,10 and one systematic review did not report a significant difference between treatment groups.11 Three of the systematic reviews analyzed patients with breast cancer,10,12,13 and one systematic review included both patients with breast cancer and patients with lymphoma.11 Additionally, Lamberti et al presented a pooled analysis of individual patient data of five randomized trials, analyzing three of the identified trials’ rates of pregnancy at the 2017 San Antonio Breast Cancer Symposium. This analysis revealed a statistically greater number of pregnancies in the GnRHa group, with all pregnancies occurring in women ≤ 40 years. However, these data were not corrected for pregnancy intent. The panel will await full publication but does not anticipate any changes to the recommendations based on the data presented.

Of the seven guidelines15-21 identified (Table 3), two recommend the use of GnRHa for fertility preservation in premenopausal patients with breast cancer,15,16 three recommend GnRHa for fertility preservation for premenopausal patients with estrogen receptor–negative breast cancer,16,18,21 and two do not recommend GnRHa as a method of fertility preservation.19,20

Therefore, given the current state of the evidence, GnRHa should not be considered a proven fertility preservation method, and patients should always be counseled to rely on methods with proven effectiveness in fertility preservation. Providers may have a discussion about GnRHa that includes careful counseling on the controversy and uncertainty regarding its role as an ovarian preservation strategy. The Panel recognizes that, when proven fertility preservation methods are not feasible, GnRHa is offered by many providers in the hope of reducing the likelihood of chemotherapy-induced ovarian insufficiency, especially in breast cancer. However, the panel wishes to stress that studies have shown conflicting results regarding the risk reduction for premature ovarian insufficiency, especially when all cancer types are considered. Therefore, GnRHa should not be used in place of proven fertility preservation methods.
The Expert Panel acknowledges that GnRHa may have other medical benefits, such as reduction of vaginal bleeding when patients have low platelet counts as a result of chemotherapy or prevention of menometrorrhagia in patients with pancytopenia. The adverse events associated with GnRHa are generally reversible and limited and include hot flashes, headaches, sweating, and vaginal dryness. The panel agrees that there is conflicting evidence to recommend GnRHa as a method of fertility preservation but that it may be considered in young women with breast cancer, recognizing the limitations, controversy, and potential risks. While the use of GnRHa may have other medical benefits, those benefits and recommendations for use in that setting are beyond the scope of this document.

**Ovarian Tissue Cryopreservation and Transplantation**
Since the publication of the guideline, success rates of ovarian tissue transplantation have been published in a recent meta-analysis, reporting live birth and ongoing pregnancy rates of 37.7%. Additionally, the prospective cohort study by Jadoul et al. reported from a cohort of 545 patients; 21 underwent ovarian cortex auto-transplantation, and seven of these 21 patients (33%) conceived post-transplantation. In addition, successful recovery and cryopreservation of oocytes following in vitro maturation in tandem with ovarian tissue freezing have raised the possibility to expand the scope of this technique.

The panel has updated Recommendation 3.6 on ovarian tissue cryopreservation and transplantation to reflect these emerging data.

### Recommendations
The 2018 recommendations are listed in the Bottom Line Box. The panel updated Recommendations 3.5 and 3.6 and combined the statement from previous Recommendation 3.7 into Recommendation 3.2. Additional edits were made for clarity to the 2013 recommendations. ASCO believes cancer clinical trials are vital to inform medical decisions and improve cancer care and that all patients should have the opportunity to participate.

### Health Disparities
Although ASCO clinical practice guidelines represent expert recommendations on the best practices in disease management to provide the highest level of cancer care, it is important to note that many patients have limited access to medical care. Racial and ethnic disparities in health care contribute significantly to this problem in the United States. Patients with cancer who are members of racial/ethnic minorities suffer disproportionately from comorbidities, experience more substantial obstacles to receiving care, are more likely to be uninsured, and are at greater risk of receiving care of poor quality than other Americans. Many other patients lack access to care because of their geographic location and distance from appropriate treatment facilities. Awareness of these disparities in access to care should be considered in the context of this clinical practice guideline, and health care providers should strive to deliver the highest level of cancer care to these vulnerable populations.

Reproductive care is part of the standard care of all oncology patients. Cost, access, and time for proven fertility preservation methods may prevent patients from receiving optimal reproductive care.

### Systematic Reviews

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Total Studies Included</th>
<th>RCTs Addressing Pregnancy</th>
<th>No. of Patients</th>
<th>Agents</th>
<th>No. of Pregnancies (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Munhoz, 2016</td>
<td>7</td>
<td>NR</td>
<td>NR</td>
<td>GnRHa</td>
<td>NR</td>
<td>1.85</td>
<td>1.02 to 3.36</td>
<td>.04</td>
</tr>
<tr>
<td>Elgindy, 2015</td>
<td>10</td>
<td>8</td>
<td>427</td>
<td>GnRHa</td>
<td>Control</td>
<td>1.63</td>
<td>0.94 to 2.82</td>
<td>NS</td>
</tr>
<tr>
<td>Lambertini, 2015</td>
<td>12</td>
<td>5</td>
<td>359</td>
<td>GnRHa</td>
<td>Control</td>
<td>1.83</td>
<td>1.02 to 3.28</td>
<td>.041</td>
</tr>
<tr>
<td>Turner, 2013</td>
<td>12</td>
<td>4</td>
<td>347</td>
<td>GnRHa</td>
<td>Control</td>
<td>1.81</td>
<td>1.02 to 3.28</td>
<td>.041</td>
</tr>
</tbody>
</table>

Abbreviations: GnRHa, gonadotrophin-releasing hormone agonist; NR, not reported; NS, not significant; OR, odds ratio; RCT, randomized controlled trial.
For recommendations and strategies to optimize patient-clinician communication, see Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline.30

### COST IMPLICATIONS

Increasingly, individuals with cancer are required to pay a larger proportion of costs through deductibles and coinsurance.31,32 Higher patient out-of-pocket costs have been shown to be a barrier to initiating and adhering to recommended treatments.33,34 Discussion of cost can be an important part of shared decision making.35 Providers should discuss with patients the use of less expensive alternatives when it is practical and feasible for treatment of the patient’s disease and there are two or more treatment options that are comparable in terms of benefits and harms.35

Patient out-of-pocket costs may vary depending on insurance coverage. Coverage may originate in the medical or pharmacy benefit, which may have different cost-sharing arrangements. Patients should be aware that different products may be preferred or covered by their particular insurance plan. Even with the same insurance plan, the price may vary between different pharmacies. When discussing financial issues and concerns, patients should be made aware of any financial counseling services available to address this complex and heterogeneous landscape.35

### ADDITIONAL RESOURCES

More information, including Data and Methodology Supplements, slide sets, and clinical tools and resources, is available at www.asco.org/survivorship-guidelines. Patient information is available at www.cancer.net.

**Related ASCO Guidelines**

Patient-Clinician Communication30 (http://ascopubs.org/doi/10.1200/JCO.2017.75.2311)

**AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

Disclosures provided by the authors are available with this article at jco.org.

**AUTHOR CONTRIBUTIONS**

Manuscript writing: All authors

Final approval of manuscript: All authors

### REFERENCES


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<th>Table 3. Guidelines</th>
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<tr>
<td><strong>Guideline</strong></td>
</tr>
<tr>
<td>NCCN Breast Cancer 201721</td>
</tr>
<tr>
<td>NCCN AYA Oncology 201720</td>
</tr>
<tr>
<td>AIOM 201615</td>
</tr>
<tr>
<td>SEOM 201614</td>
</tr>
<tr>
<td>BCY2 201617</td>
</tr>
<tr>
<td>St Gallen 201518</td>
</tr>
<tr>
<td>ESMO 201319</td>
</tr>
</tbody>
</table>

Abbreviations: AIOM, Italian Association of Medicine; AYA, Adolescent and Young Adult; BCY2, International Consensus Conference for Breast Cancer in Young Women; ER, estrogen receptor; ESMO, European Society for Medical Oncology; GnRHa, gonadotrophin-releasing hormone agonist; LHRH, luteinizing hormone-releasing hormone; LHRHa, luteinizing hormone-releasing hormone agonists; NCCN, National Comprehensive Cancer Network; SEOM, Sociedad Española de Oncología Médica.


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The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO’s conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/jco/site/ifc.

Kutluk Oktay
No relationship to disclose

Brittany E. Harvey
No relationship to disclose

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No relationship to disclose

Gwendolyn P. Quinn
Research Funding: Boehringer Ingelheim (Inst)

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No relationship to disclose

Hugh S. Taylor
Stock or Other Ownership: Bristol-Myers Squibb
Honoraria: Pfizer, Abbvie, Bayer, Dot Laboratories, ObsEva
Consulting or Advisory Role: OvaScience
Research Funding: Pfizer (Inst), OvaScience (Inst)
Patents, Royalties, Other Intellectual Property: Patent pending on endometriosis biomarkers (Inst)
Travel, Accommodations, Expenses: Abbvie, Pfizer, ObsEva

W. Hamish Wallace
No relationship to disclose

Erica T. Wang
No relationship to disclose

Alison W. Loren
No relationship to disclose
Acknowledgment

The Expert Panel thanks Mariana Chavez MacGregor, Eric Singer, and the Clinical Practice Guidelines Committee for their thoughtful reviews and insightful comments on this guideline.

Appendix

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<thead>
<tr>
<th>Table A1. Fertility Preservation Guideline Update Panel Membership</th>
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<tbody>
<tr>
<td>Member</td>
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<tr>
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<tr>
<td>Alison W. Loren, MD</td>
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<tr>
<td>Kutluk Oktay, MD, PhD, FACOG</td>
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<td>Anthony J. Magdalinski, DO</td>
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<td>Ann H. Partridge, MD, FASCO</td>
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<tr>
<td>Erica T. Wang, MD</td>
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<td>Brittany E. Harvey</td>
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Abbreviation: PGIN, Practice Guideline Implementation Network.