Recommendations for practices utilizing gestational carriers: a committee opinion

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This document provides the latest recommendations for evaluation of gestational carriers and intended parents. It incorporates recent information from the US Centers for Disease Control and Prevention, the US Food and Drug Administration, and the American Association of Tissue Banks, with which all programs offering gestational carrier services must be thoroughly familiar. This document replaces the previous document of the same name, last published in 2015 (Fertil Steril 2016;103:e1–8). (Fertil Steril 2017;107:e3–10. ©2016 by American Society for Reproductive Medicine.)

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STATEMENT OF PURPOSE

The following recommendations are intended to provide guidance for when it is appropriate to consider using a gestational carrier, provide guidelines for screening and testing of genetic parents and gestational carriers to reduce the possibility of complications, and to address the complex medical and psychological issues that confront the gestational carrier and intended parents, as well as the children. A gestational carrier is defined as a woman who carries a pregnancy and is not sexually intimate with the genetic parents or gamete donors. These guidelines incorporate recent information about optimal screening and testing for sexually transmitted infections (STI) and psychological assessments.

The current document represents an effort to make the screening procedures for individuals involved in third-party reproduction using a gestational carrier more consistent and incorporates recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). These recommendations use terminology from the federal agencies in addition to the AATB. In that context, the term “screening” refers to specific historical factors that place an individual at a higher risk for a given disease, such as human immunodeficiency virus (HIV) and transmissible spongiform encephalopathy (TSE), or Creutzfeldt-Jakob disease (CJD). “Testing” refers to specific laboratory studies, such as serologic tests. The distinction between screening and testing is consistent within the document. The term “ineligible” does not mean excluded, but eligible with appropriate informed consent. These recommendations for the screening and testing of gestational carriers and the genetic parents apply to individuals in the United States. Because the prevalence of STIs and genetic diseases may vary in other geographic areas, these recommendations may not be appropriate for other countries or individuals who come to the United States from other countries. Whereas the FDA does not require screening or testing of the gestational carrier, the American Society for Reproductive Medicine (ASRM) recommends testing these individuals as described.

Other areas where the ASRM recommendations may be more stringent than the FDA minimum requirements are noted in the text. Additionally, state requirements may be more restrictive than the FDA, and clinics should be aware of minimum screening and testing requirements for their state.

1. Indications for the use of a gestational carrier
   a. Gestational carriers may be used when a true medical condition precludes the intended parent from carrying a pregnancy or would pose a significant risk of death or harm to the woman or the fetus. The indication must be clearly documented in the patient’s medical record. Examples of such medical indications would include:
i. Absence of uterus (congenital or acquired)
ii. Significant uterine anomaly (e.g., irreparable Asherman syndrome; unicornuate uterus associated with recurrent pregnancy loss)
iii. Absolute medical contraindication to pregnancy (e.g., pulmonary hypertension)
iv. Serious medical condition that could be exacerbated by pregnancy or cause significant risk to the fetus
v. Biologic inability to conceive or bear a child, such as single male or homosexual male couple

b. Gestational carriers may be considered when an unidentified endometrial factor exists, such as for patients with multiple unexplained previous in vitro fertilization (IVF) failures despite transfer of good-quality embryos.

c. No owner, operator, laboratory director, or employee of that practice may serve as a carrier or intended parent in that practice.

2. Intended parents

a. Psychosocial education
The decision to use a gestational carrier is complex, and patients and their partners (if applicable) may benefit from psychosocial education to aid in this decision. The physician should strongly recommend psychosocial education and counseling by a qualified mental health professional to all intended parents. The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological test data should be handled in accordance with American Psychological Association ethical standards (1). The clinician should refer patients in whom factors appear to warrant further evaluation to a qualified mental health professional. The potential impact of the relationship between the intended parent and carrier should be explored, as should any plans that may exist relating to disclosure and future contact (see section titled “Psychosocial consultation for gestational carriers and intended parents,” 4.a.).

b. Screening and testing of genetic parents
   i. Genetic parents should undergo appropriate genetic evaluation. Universal testing should be considered for diseases that are common in all genetic backgrounds (such as cystic fibrosis and spinal muscular atrophy). Targeted testing based on ethnicity should be considered for diseases that are common to certain ethnicities (such as sickle cell, Tay-Sachs, etc.).
   ii. The genetic parents should undergo a complete medical evaluation, including a thorough history and physical examination, to ensure that they are healthy enough to proceed with procedures involving assisted reproductive technology (ART).
   iii. Genetic parents must undergo a complete physical examination (Society for Assisted Reproductive Technology [SART] physical examination forms, www.sart.org). When any of the following is present, the genetic parents are considered ineligible (see above).
      1. Physical evidence for risk of sexually transmitted disease, such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge
      2. Physical evidence of risk for syphilis or evidence of syphilis
      3. Physical evidence of anal intercourse in the male partner, including perianal condylomata
      4. Physical evidence of nonmedical percutaneous drug use, such as needle tracks; the examination should include examination of tattoos, which might obscure needle tracks
      5. Physical evidence of recent tattooing, ear piercing, or body piercing (within the past 12 months) where sterile technique was not used
      6. Disseminated lymphadenopathy
      7. Unexplained oral thrush
      8. Blue or purple spots consistent with Kaposi sarcoma
      9. Unexplained jaundice, hepatomegaly, or icterus
      10. Large scab consistent with recent history of smallpox immunization
      11. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosus), or corneal scarring (consistent with vaccinal keratitis)
   v. Laboratory testing
There is no method that completely ensures that infectious agents will not be transmitted to the gestational carrier. However, the following guidelines, combined with an adequate medical history and
specific exclusion of individuals at high risk for HIV
and other STIs should significantly reduce these
risks. The FDA requires that the following tests be
performed within 30 days of oocyte retrieval and
within 7 days of sperm collection, using methods
approved specifically for purposes of determining
donor eligibility, and that negative results be docu-
mented before use of the genetic parent’s gametes.
Tests using nucleic acid testing (NAT) technology
to target sequences located in specific genes
adequately and appropriately reduce the risk of
transmission of these relevant communicable
agents. The list of test methods approved by the
FDA for the purpose of donor screening is available
at the following website, http://www.fda.gov/Bio-
logicsBloodVaccines/BloodBloodProducts/Approved
Products/LicensedProductsBLAs/BloodDonorScreen-
ing/InfectiousDisease/UCM080466

1. Human immunodeficiency virus (HIV)-1
antibody and NAT
2. HIV-2 antibody
3. HIV group O antibody. Establishments that
do not use an FDA-licensed test for HIV
group O antibodies must evaluate the genetic
parents for risk associated with HIV group O
infection with additional screening ques-
tions (see “risk factor questionnaire for do-
4. Hepatitis C antibody and NAT
5. Hepatitis B surface antigen
6. Hepatitis B core antibody immunoglobulin
G [IgG] and immunoglobulin M [IgM]
7. Serologic test for syphilis
8. Additional testing for the female genetic
parent must include:
a. Neisseria gonorrhoeae and Chlamydia tra-
chomatis NAT on urine or a swab obtained
from the cervix, urethral meatus, or vagina.
Because there are no tests licensed, approved,
or cleared by the FDA for screening donors
for N. gonorrhoeae and C. trachomatis, the
laboratory must use an FDA-licensed,
- approved, or - cleared test labeled for the
detection of these organisms in an asymptom-
omatic, low-prevalence population.
9. Additional testing for the male genetic parent
must include:
a. N. gonorrhoeae and C. trachomatis testing
using a NAT on urine or a swab obtained
from the urethral meatus using an FDA-
licensed, - approved, or - cleared test labeled
for the detection of these organisms in an
asymptomatic, low-prevalence population.
b. (Human T-lymphotropic virus HTLV)-1
and HTLV-2

c. Cytomegalovirus (CMV) [IgG and IgM]
10. ASRM recommends testing the genetic par-
ents’ blood type and Rhesus (Rh) factor. If

there is the potential for Rh incompatibility,
couples should be informed about the obstet-
ric significance of this condition.

vi. Managing laboratory results
1. A positive test should be confirmed before
notifying the potential genetic parent. If a
test is confirmed positive, the individual
should be referred for appropriate counseling
and management.
2. Individuals with false-positive test results for
syphilis using non-treponemal assays that
are confirmed to be negative using a
treponemal-based assay are considered
eligible.
3. Individuals with positive tests for syphilis, N.
gonorrhoeae, or C. trachomatis should be
treated, retested, and deferred from creating
embryos for use in a gestational carrier for
12 months after documentation that treatment
was successful before being reconsidered. If
evidence is presented documenting successful
treatment more than 12 months prior, no
further deferral is needed as long as current
testing does not indicate an active infection.
4. Men who test positive for active CMV infec-
tion (positive urine or throat culture or paired
serum samples demonstrating a 4-fold rise in
IgG antibody and IgM antibody at least 30%
of the IgG level) should be excluded until signs
of active infection are no longer present.
There are many strains of CMV, and superin-
fection in the gestational carrier is possible
even if she is CMV IgG positive. The risk of
CMV transmission and newborn CMV infec-
tion from an embryo transfer is extremely
low, and such infants appear to have no sig-
nificant illness or other abnormality.
5. Individuals who initially test positive for HIV-
1 antibody and NAT, HIV-2 antibody, HIV
group O antibody, hepatitis C antibody and
NAT, hepatitis B surface antigen, hepatitis B
core antibody (IgG and IgM), and HTLV-1
and HTLV-2 are considered ineligible. Ac-
cording to current FDA guidelines, embryos
created by such individuals can still be trans-
ferred into a gestational carrier provided that
the tissue is labeled to indicate any associated
increased risks and that physicians transferr-
ing the embryos are aware of the status of
the results. Although the FDA does not require
that recipients be informed of the test results,
in the opinion of the ASRM, recipients must be
informed and counseled appropriately before
such embryos can be transferred into a gesta-
tional carrier.

vii. Quarantining of embryos
All potential gestational carriers should be
offered the option of cryopreserving and
quarantining embryos derived from the genetic parents for 180 days, with release of embryos only after the genetic parents have been retested with confirmed negative results (see section on Laboratory Testing for intended parents, 2.v.1–10). However, couples also should be informed that historically embryo cryopreservation had lower implantation rates. The gestational carrier should be counseled appropriately in the event of seroconversion of a genetic parent after cryopreservation of the embryos.

viii. Record keeping
The FDA requires that records pertaining to each genetic parent (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each intended parent’s initial screening, testing, and subsequent follow-up evaluations should be maintained. To the extent possible, the clinical outcome for each cycle should be recorded. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

1. Protection of confidentiality: Individuals participating in gestational carrier programs should be assured that their confidentiality and medical information will be protected insofar as federal and local statutes permit. Medical records detailing the eligibility of the intended parents should be maintained as stipulated by federal and local requirements.

ix. Legal issues and informed consent
1. The genetic parents should be counseled regarding the risks and adverse effects of ovarian stimulation and retrieval, with such counseling documented in the patients’ permanent medical records.
2. Intended parents must have ongoing legal counsel by an appropriately qualified legal practitioner who is experienced with third-party reproduction and licensed to practice in the relevant state or states, or in the event of an international arrangement, in addition to any relevant states, in the intended parent(s)’ home country.

3. Gestational carriers
a. Selection and evaluation of gestational carriers
i. Psychosocial evaluation and counseling by a qualified mental health professional area strongly recommended for all potential gestational carriers and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological test data should be handled in accordance with American Psychological Association ethical standards (1). The clinician should refer patients in whom factors appear to warrant further evaluation to a qualified mental health professional. The potential impact of the relationship between the gestational carrier and intended parent should be explored, as well as any plans that may exist relating to disclosure and future contact (see section on Laboratory Testing, 4.a.).

1. The psychosocial evaluation and counseling should consider the impact of the pregnancy on family and community dynamics.
2. Carriers must be of legal age, and preferably between the ages of 21 and 45 years. Certain situations may dictate the use of a carrier older than 45 years of age, but all parties involved must be informed about the potential risks of pregnancy with advancing maternal age.
3. Ideally, the carrier should have had at least term, uncomplicated pregnancy before being considered as a gestational carrier for another couple.
4. Ideally, the carrier should not have had more than a total of five previous deliveries or three deliveries via cesarean section.
5. Ideally, the carrier should have a stable family environment with adequate support to help her cope with the added stress of pregnancy.

b. Screening and testing of a gestational carrier
i. A complete personal and sexual history should be obtained to identify individuals who might be at high risk for HIV, STIs, or other acquired infections that might be transmissible to the fetus. Although the FDA does not require screening or testing of gestational carriers for possible transmissible infectious diseases to the fetus, ASRM recommends testing of all gestational carriers and their partners within 30 days before embryo transfer to protect the health and interests of all parties involved (see www.sart.org for screening questionnaire).

ii. Before acceptance, the potential gestational carrier should undergo a complete medical evaluation by a qualified medical professional and be cleared for pregnancy before being considered.
iii. The carrier should not be used when any of the following findings are present:
1. Physical evidence for risk of sexually transmitted disease, such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge
2. Physical evidence of risk for syphilis or evidence of syphilis
3. Physical evidence of nonmedical percutaneous drug use, such as needle tracks; the examination should include examination of tattoos, which might obscure needle tracks
4. Physical evidence of recent tattooing, ear piercing, or body piercing (within the past 12 months) where sterile technique was not used.
5. Disseminated lymphadenopathy
6. Unexplained oral thrush
7. Blue or purple spots consistent with Kaposi sarcoma
8. Unexplained jaundice, hepatomegaly, or icterus
9. Large scab consistent with recent history of smallpox immunization
10. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinial keratitis)

iv. Laboratory testing
There is no method to completely ensure that the carrier will not have infectious agents that could be transmitted to the fetus. However, the following guidelines, combined with an adequate medical history and specific exclusion of individuals at high risk for HIV and other STIs, should dramatically reduce these risks. The ASRM recommends the following tests be performed on the carrier and her partner and that negative results be documented before use of the gestational carrier.
1. Carrier and her sexually intimate partner
   a. HIV-1 antibody as well as NAT
   b. HIV-2 antibody
   c. HIV group O antibody
   d. HTLV-1 and HTLV-2 (male partner only)
   e. Hepatitis C antibody and NAT
   f. Hepatitis B surface antigen
   g. Hepatitis B core antibody (IgG and IgM)
   h. Serologic test for syphilis
   i. CMV (IgG and IgM)
   j. N. gonorrhoeae and C. trachomatis testing using NAT on urine or a cervical or urethral swab using an FDA-licensed, -approved, or -cleared test labeled for the detection of these organisms in an asymptomatic, low-prevalence population
2. Carrier only
   a. Blood type and Rh factor. If there is the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.
   b. Papanicolaou smear
   c. Mammogram according to American College of Obstetricians and Gynecologists guidelines
   d. Titers for varicella and rubella
   e. Urine drug screen

vi. Legal issues and informed consent
a. Gestational carriers and their partners/spouses should be advised explicitly of the risks of the procedures and medications as well as potential complications of pregnancy, including the possibility of prolonged bed rest or hospitalization. This counseling should be documented in the patients’ permanent medical record.
b. Gestational carriers must have ongoing independent legal representation by an appropriately qualified legal practitioner who is experienced with gestational carrier contracts and who is licensed in the relevant state or states, or in the event of an international arrangement, in addition to any relevant states, the intended parent(s)’ home country.
c. Special consideration should be given to transferring a single embryo in an effort to limit the risks of multiple pregnancy for the carrier. After appropriate counseling and agreement by all parties, additional embryos may be transferred based on the age of the genetic parent, in an effort to improve the probability of pregnancy.
d. Protection of confidentiality: Individuals participating in gestational carrier programs should be assured that their confidentiality and medical/psychological information will be protected insofar as federal and local statutes permit.
e. Issues regarding screening and testing of the fetus during pregnancy should be discussed and the discussion documented in the medical record or legal contract between the carrier and the intended parents. Contingency plans for management of specific complications (i.e., abnormal genetic testing of the fetus, birth defects, etc.) should be discussed and agreed upon in advance of treatment. The possibility of pregnancy termination for pregnancy complications (in the gestational carrier or fetus) or for multifetal gestations also should be discussed before treatment.

f. Behavior of the gestational carrier: Individuals who smoke, consume alcohol (>1 drink per day), or have other potentially harmful habits should not be considered as gestational carriers. Activity of the carrier (travel, exercise, diet, sexual activity, vitamin supplements, etc.) should be discussed between the parties and agreed upon in advance of treatment.

g. Compensation to the gestational carrier: Compensation to the gestational carrier should be agreed upon in writing in the legal contract between the intended parents and carrier before any treatment begins. The amount of compensation paid to the carrier can be prorated based on the procedure(s) performed.

vii. Quarantining of embryos
All potential gestational carriers should be offered the option of cryopreserving and quarantining embryos derived from the intended parents for 6 months, with release of embryos only after the intended parents have been retested with confirmed negative results (see section on Laboratory testing of gestational carriers, 3.b.iv.1.a-j.). In the event of seroconversion of an intended parent after cryopreservation of the embryos, the ASRM recommends that the embryos should not be transferred into a gestational carrier.

viii. Record keeping
A permanent record of each gestational carrier’s initial selection process, medical evaluation, eligibility, and subsequent follow-up evaluations should be maintained indefinitely. The clinical outcome for each cycle should be recorded. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

4. Psychosocial consultation for gestational carriers and intended parents
a. Psychosocial consultation for intended parents includes:
   i. A clinical interview and psychological assessment including the intended parent(s)’ history of infertility and methods of coping

   ii. Psychological evaluation of each intended parent is strongly recommended as a means to alert the team to significant psychological issues that could compromise successful collaboration with the gestational carrier

   iii. Informing intended parent(s) of potential psychological issues and risks associated with the gestational carrier process

   iv. Discussion of the medical protocol, scheduling demands, risks of cancelled cycles or unsuccessful cycles, number of embryos transferred, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination

   v. Requirement of intended parent(s)’ agreement with the gestational carrier regarding all medical issues

   vi. Definition of the role/function of qualified mental health professionals

vii. Counseling topics include:
1. Management during pregnancy of expectations and relationship with the gestational carrier and her family
2. Meeting the emotional and physical needs of the gestational carrier and her family
3. Understanding the gestational carrier’s right to make choices for her body over the rights of the intended parents
4. Rights of the gestational carrier to refuse or to accept medical interventions or testing
5. Number of embryos to be transferred and number of cycles planned to be determined by the gestational carrier and physician
6. Multiple pregnancy and associated risks
7. Multifetal pregnancy reduction and discussion of psychological risks and concerns
8. Possibility of abortion in the event of an abnormal fetus
9. Gestational carrier’s behavior during pregnancy and methods for resolving conflicts (e.g., eating habits, prescription drugs, alcohol)
10. Disclosure to offspring
11. Disclosure to family members and friends
12. Expectations of relationship between gestational carrier, intended parent(s), and children after birth
13. Need for gestational carrier and her children to interact with baby after birth
14. Disposition of extra embryos
15. Need for separate legal consultation and a written contract
16. Potential guilt reaction of gestational carrier associated with failed attempts or problems that may arise
17. Matching of gestational carrier and intended parent(s)
18. Relationship issues, expectations, and impact of failed cycle
b. Criteria for rejection of intended parents
   i. Absolute criteria for rejection include:
      1. Inability to maintain respectful and caring relationship with gestational carrier
      2. Abnormal psychological evaluation as determined by the qualified mental health professional
      3. Unresolved or untreated addiction, child abuse, sexual or physical abuse, depression, eating disorder
      4. Unresolved or untreated major depression, bipolar disorder, psychosis, or significant anxiety disorder or personality disorder
      5. Current marital or relationship instability
      6. Intended parent(s)’ failure to agree with gestational carrier’s decision on number of embryos transferred
   ii. Relative criteria for rejection include:
      1. Ongoing legal disputes
      2. Significant ongoing problematic interpersonal relationships
      3. History of noncompliance or ongoing problematic interactions with program or medical staff

c. Psychosocial consultation for gestational carriers includes:
   i. Informing the potential gestational carrier and her partner regarding the potential psychological issues and risks associated with the process
   ii. Discussion of the medical protocol, including scheduling demands, risks of cancelled cycle and unsuccessful cycle, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination
   iii. Discussion of requirement of intended parent(s)’ agreement with gestational carrier regarding all medical issues
   iv. Definition of role/function of the qualified mental health professional
   v. Counseling topics include:
      1. Management of the relationship between the intended parent(s) and the gestational carrier; past, present, and future
      2. Coping appropriately with the pregnancy
      3. Risks of attachment to the child and risk to the gestational carrier’s children
      4. Impact on gestational carrier’s marriage or partnership
      5. Impact on gestational carrier’s employment
      6. The balance between the gestational carrier’s right to privacy and the intended parent(s)’ right to information
   vi. Offer of group/individual counseling with qualified mental health professional
   vii. Separate, ongoing legal counsel and representation for gestational carrier and intended parents
   viii. Informing the gestational carrier of source of gametes before legal consent

ix. Social history, including family of origin
x. Psychiatric history including prior hospitalizations, suicide attempts, medication, and counseling
xi. Occupational and financial history
xii. Sexual and reproductive history
xiii. History of smoking, substance use, and physical, emotional, or sexual abuse
xiv. History of postpartum disorder(s) and other unresolved negative reproductive events
xv. Religious beliefs that may influence behavior
xvi. Maturity, judgment, assertiveness, and decision-making skills
xvii. Legal history
xviii. Negative medical history as it relates to the psychosocial adjustment of being a gestational carrier (e.g., bed rest, gestational diabetes, preeclampsia)
xix. Personality style and coping skills, capacity for empathy
xx. Current major life stressors or anticipated changes within the next 2 years
xxi. Previous gestational carrier experience or application to another facility
xxii. Motivation to become a gestational carrier
xxiii. Support of significant other
xxiv. Social network
xxv. Desire for more children of her own
xxvi. Anticipated impact of gestational experience upon her children and significant other
xxvii. Anticipated type and duration of relationship with intended parents
xxviii. Ability to separate from and relinquish the child
xxix. Anticipated feelings toward the child
xxx. Feelings about multiple pregnancy, bed rest, hospitalization, and pregnancy loss
xxxi. Feelings about possible sexual abstinence
xxxii. Feelings and decisions about termination of pregnancy, multifetal pregnancy reduction, amniocentesis, chorionic villi sampling, and other prenatal diagnostic testing
xxxiii. Reactions to the possibility of becoming infertile as a result of the process
xxxiv. Agreement with the financial compensation arrangement

d. Criteria for rejection of a gestational carrier
   i. Absolute rejection criteria include:
      1. Cognitive or emotional inability to comply or consent
      2. Evidence of financial or emotional coercion
      3. Abnormal psychological evaluation/testing as determined by the qualified mental health professional
      4. Unresolved or untreated addiction, child abuse, sexual abuse, physical abuse, depression, eating disorders, or traumatic pregnancy, labor and/or delivery
5. History of major depression, bipolar disorder, psychosis, or a significant anxiety disorder
6. Current marital or relationship instability
7. Chaotic lifestyle, current major life stressor(s)
8. Evidence of emotional inability to separate from/surrender the child at birth

ii. Relative rejection criteria include:
1. Failure to exhibit altruistic commitment to become a gestational carrier
2. Problematic personality disorder
3. Insufficient emotional support from partner/spouse or support system
4. Excessively stressful family demands
5. History of conflict with authority
6. Inability to perceive and understand the perspective of others
7. Motivation to use compensation to solve own infertility
8. Unresolved issues with a negative reproductive event

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This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.


REFERENCES