Screening of gestational carriers in the United States

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Objective: To assess medical and psychosocial screening and evaluation received by gestational carriers and compare those using agencies to those not using agencies.
Design: Cross-sectional questionnaire.
Setting: Online.
Patient(s): A total of 204 women who completed a survey on their experiences as gestational carriers in the United States.
Intervention(s): None.
Main Outcome Measure(s): Self-reported screening received before gestational carrier pregnancies.
Result(s): Overall, 97.1% of gestational carriers had a complete medical evaluation and 94.6% had an evaluation or counseling by a mental health professional. Most participants indicated that they had been informed of at least some medical risks (92.6%) and psychological considerations (89.7%). Participants most often recalled being informed of the risks of multiple pregnancy (89.2%) and medical procedures and medications (87.2%), but least often recalled being informed about the risks of impact on their own employment (46.6%) and to their own children (61.3%). There were no differences in outcome measures between those using an agency and those who did not.
Conclusion(s): Self-reported screening and evaluation was high, but still not 100% on all measures. Further education of providers regarding guidelines for the screening and evaluation of gestational carriers may be needed. (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)
Key Words: Gestational carrier, screening, infertility, surrogate

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The use of gestational carriers (women who carry the embryo of the intended parent) (1) has increased in the United States, with gestational carrier cycles representing 2.5% of all assisted reproductive technology (ART) cycles in 2013 (2). Like other pregnancies, gestational carrier pregnancies expose women to medical and psychological health risks. Obstetric complications are not well documented, but high rates of multiple pregnancy and preterm delivery have been reported (2). A recent review indicates that gestational carriers and traditional surrogates (women who are inseminated with the intended father's or a donor's sperm, carry the pregnancy, and relinquish the child(ren) to the intended parent(s) at birth) (3) have favorable outcomes on personality tests and most do not have problems relinquishing the children, but the quality of evidence in these studies was reported to be very low (3), thus, additional studies are needed.

There are a variety of legal issues that may be present in gestational carrier arrangements, including those involving coverage of medical bills and custody of the resultant child(ren) (4). Laws regarding gestational carrier contracts vary by state within the United States, from no laws to surrogacy-friendly laws to complete bans (5). Private agencies specialize in the coordination of gestational carrier arrangements, which may be nonprofit or for-profit and may assist with providing or coordinating legal representation and other kinds of support. There are no federal or state laws regulating agencies or who can own or operate these agencies. Private agencies may also assist with matching a potential gestational carrier with the intended parent(s) and coordinating medical care, communication, travel, and compensation (6). Alternatively, potential gestational carriers and intended parents may meet online or in other ways and go on to make arrangements privately. Gestational carriers and intended parents may also already know one another as family members,

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friends, or acquaintances. Regardless of how the involved parties meet, they may choose to use an agency or create a private agreement with or without legal representation.

To "…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 the intended parents," the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) released recommendations in 2012 for the use of gestational carriers (7), which were updated in 2015 (8). These recommendations include guidelines for the evaluation of potential gestational carriers based on a variety of physical and mental health factors, guidelines for advising potential gestational carriers about various risks, and a recommendation that compensation to the gestational carrier be noted in a legal contract before treatment. Guidance is also provided for the evaluation of the intended parent(s). Previous research has examined agency and clinic compliance with ASRM/SART guidelines for advertising, recruitment, and compensation for egg donors or gestational carriers (9–13). However, there have been no reports on compliance with guidelines for the screening of gestational carriers or whether the use of an agency affects compliance. The purpose of this study was to compare demographic, behavioral, and screening characteristics of gestational carriers residing in the United States who did and did not use agencies.

MATERIALS AND METHODS

From November 2015 through February 2016, a cross-sectional study was conducted. Women $\geq$18 years living in the United States who had previously delivered a baby as the result of being a gestational carrier or with a traditional surrogacy arrangement in 2009 or later were eligible to participate. Participants were recruited by posting study announcements in various online groups, including websites and message boards, geared toward gestational carriers. Recruitment materials were also sent to staff who maintain e-mail lists for infertility support groups, lawyers, and agencies. These staff then sent out the study announcements to their e-mail lists. Eligible participants were invited to complete an online survey about their experiences and were reimbursed with a $5 Amazon.com gift card for their time. The first screen of the online survey included a consent form. Participants indicated that they understood the consent form by responding to the question, "Do you agree to the above terms? By selecting "Yes" and clicking the "Next" button, you are indicating that you are at least 18 years old, have read and understood this consent form, and agree to participate in this research study."

The survey included questions about participants' experiences as gestational carriers or traditional surrogates, medical and mental health screenings, health behaviors and characteristics, use of attorneys and agencies, social support, pregnancy outcomes, compensation and reimbursement, and demographic characteristics. Most participants completed the survey in <20 minutes. Participants who were gestational carriers or traditional surrogates more than once were asked to respond regarding their most recent arrangement and delivery.

Sample size calculations were conducted using Stata SE version 14.0 (14) and were based on a *t* test to detect age differences between traditional surrogates (not included in the present analyses) and gestational carriers at the time of last delivery. One of the original aims of the study was to examine differences between traditional surrogates and gestational carriers. Based on previous studies (15, 16), a mean age of 31 years and an SD of 5.5 were used in the calculations. Multiple potential sample sizes were calculated based on different potential mean ages, ranging from 26–33 years, in the gestational carriers and traditional surrogates, with total sample sizes ranging from 42–240 women (21–120 women/group). Due to the lack of research in this area and to account for potential missing data and possible unequal group sizes, the largest N (240) was selected and was increased by 25% for a total target sample of 300 women. Recruitment ended per protocol on February 29, 2016. Traditional surrogates were excluded from these analyses, as the ASRM guidance was intended to be applied to gestational carriers. Incomplete surveys were also excluded from these analyses.

The primary exposure of interest was the use of an agency in arranging the gestational carrier agreement. Gestational carriers (n = 204) were asked to indicate how their most recent agreement was arranged: through an agency (n = 143), privately or independently (n = 57), or other, please specify (n = 4). Those who selected the privately or independently option were considered to not have used an agency, whereas those who selected other were categorized into agency (n = 2) or no agency (n = 2) based on their text responses.

Outcomes of interest included the receipt of medical and psychosocial screening and evaluation before the start of the women's most recent gestational carrier arrangement. These items were based on the screening and evaluation items recommended by the ASRM and SART (8). Participants were asked to indicate whether they had each of the following: their own lawyer, received medical screenings, received a psychosocial evaluation, been advised about several medical and psychosocial risks and considerations, support from their partner, family, and friends, and discussed medical and lifestyle issues with the intended parent(s). Participants were also asked about their alcohol use and their cigarette, tobacco, and nicotine use in the 6 months before their most recent arrangement. Whether each participant had at least one previous term, uncomplicated pregnancy was assessed, as well as the number of live births (categorized as $\leq$5 live births and >5 live births) and cesarean sections (categorized as $\leq$3 cesarean sections and >3 cesarean sections) before the arrangement.

Differences between gestational carriers using agencies and those not using agencies in age at delivery and number of own children (including biological, adopted, and stepchildren) were assessed using two sample *t* tests with equal variances. Differences between groups for all other demographic and outcome variables were assessed using χ^2 tests and Fisher's exact tests for categorical variables. Statistical