Scope of practice distinctions based on primary work setting for genetic counselors in assisted reproductive technologies

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Objective: To elucidate the tasks within various work settings that assisted reproductive technologies (ART) genetic counselors believe to be within their scope of practice.
Design: A survey was constructed and administered to genetic counselors who practice in the field of ART.
Setting: Genetic counselors were asked to self-identify with a primary ART work setting: genetic testing laboratory (preimplantation genetic testing, carrier screening, or both), in vitro fertilization clinic, gamete donor agency, telegenetic practice (either private practice or telemedicine company), or other.
Patient(s): N/A.
Intervention(s): N/A.
Main Outcome Measure(s): The number of years of practice in ART, tasks performed within various ART work settings representing the reality or the ideal, and perception of understanding of the scope of practice by nongenetics colleagues.
Result(s): The majority of respondents reported <10 years of experience in this field. There were differences in what was considered the scope of practice among the various work settings. ART genetic counselors believed that their scope of practice was not well understood by their nongenetics colleagues. They also reported differences between the actual duties performed and what they ideally believed would be within their job function.
Conclusion(s): The genetic counseling specialty of ART is a new work setting for genetic counselors. There is a need for education regarding the various roles of genetic counselors in ART. Better definition of the appropriate duties for genetic counselors in the various ART work settings is needed to foster effective working relationships with their nongenetics colleagues and optimize patient care. (Fertil Steril Rep® 2021;2:80–7. ©2020 by American Society for Reproductive Medicine.)
Key Words: Genetic counselor, scope of practice, assisted reproductive technologies, work setting

Genetic counselors have taken on an increasingly significant role in the care of fertility patients over the past 2 decades. Although it was once rare to have a genetic counselor affiliated with a fertility clinic or preimplantation genetic testing (PGT) laboratory, there are now growing numbers of genetic counselors in the assisted reproductive technologies (ART) specialty. The Assisted Reproductive Technology and Infertility Special Interest Group (ART/Infertility SIG) of the National Society of Genetic Counselors (NSGC) was founded in 1996. The Genetic Counseling Special Interest Group, now the Genetic Counseling Professional Group (GCPG) of the American Society for Reproductive Medicine (ASRM; formerly The American Fertility Society) was founded in 2003. The establishment and growth of these groups over the years signaled the increasing interest of genetic counselors in the ART specialty as well as the increasing demand for genetic counselors in the field. This demand has been fostered by the ever increasing availability and complexity of reproductive genetic testing and by the need for specialized training in genetics when ordering and interpreting the results of these tests. The 2020 NSGC Professional Status Survey (1) indicated

Received July 28, 2020; revised November 20, 2020; accepted December 4, 2020.
All authors have nothing to disclose.
Supported by funding from the American Society for Reproductive Medicine (ASRM), Birmingham, AL; Assisted Reproductive Technology and Infertility Special Interest Group of the National Society of Genetic Counselors (NSGC), Chicago, IL; and Laboratory/Industry Special Interest Group of the NSGC, Chicago, IL.
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Fertil Steril Rep® Vol. 2, No. 1, March 2021 2666-3341

https://doi.org/10.1016/j.xfre.2020.12.001

that out of 2,500 total respondents, a total of 54 genetic counselors reported their primary work setting to be preconception/reproductive screening and 51 genetic counselors reported PGT, ART/in vitro fertilization (IVF), infertility to be their primary work setting.

Within the profession of genetic counseling, there are many subspecialties, including prenatal, pediatric, and cancer, as well as ART. Genetic counselors specializing in ART may be found in a variety of settings, including IVF centers, laboratories providing genetic testing services to IVF centers, gamete donor agencies, and independent or telegenetics practices. Although there is overlapping expertise among these ART genetic counselors, there are also differences in their role in patient care and scope of practice based on their different work settings. Even with the greater familiarity of genetic counselors as members of the ART care team, there remains a general lack of understanding regarding the distinctions between the roles of the clinic-based, laboratory-based, and gamete donor agency-based genetic counselors.

The scope of practice for the first genetic counselor in an IVF clinic is often not well understood by the other members of the health care team. It is common for clinics that do not have an employed or affiliated genetic counselor to utilize the services of laboratory-based genetic counselors to consult with patients being referred for genetic carrier screening or PGT. Subsequently, laboratory-based genetic counselors may receive requests for services that fall outside of their scope of practice. Recognition of these challenges drove this investigation.

Although all certified genetic counselors are cross-trained in various genetics specialties, the scope of practice becomes refined by the work setting. The Accreditation Council for Genetic Counseling defines genetic counselors' scope of practice as the following:

> Genetic Counselors work as members of a healthcare team in a medical genetics program or other specialty/subspecialty; including oncology, neurology, cardiology, obstetrics and gynecology, among others. They are uniquely trained to provide information, counseling and support to individuals and families whose members have genetic disorders or who may be at risk for these conditions. The genetic counseling scope of practice is performed through collaborative relationships with clinical geneticists and other physicians, as well as other allied healthcare professionals such as nurses, physicians and social workers. (2)

Furthermore, the NSGC Code of Ethics (3) states genetics counselors should:

- Provide genetic counseling services to their clients within their scope of practice regardless of personal interests or biases, and refer clients, as needed, to appropriately qualified professionals.
- Make employers aware of genetic counselors' ethical obligations as set forth in the NSGC Code of Ethics.

This article aimed to clarify the scope of practice for genetic counselors practicing in the field of assisted reproduction and illuminate the distinctions in the scope of practice among the various roles and work settings. This article provides specific examples of the tasks performed and not performed by genetic counselors in this specialty area, which was further broken down into the subspecialties of clinic-based, laboratory-based, gamete donor facility-based, and telegenetics.

MATERIALS AND METHODS

Study population

The investigators constructed a survey via Survey Monkey and made it available to genetic counselors who self-identify as practicing in the field of ART. An invitation to participate along with a link to the survey was posted through the ASRM GCPG and NSGC ART/Infertility SIG discussion forums for members to access. An initial survey was drafted and distributed in September 2019. However, based on feedback received from survey participants, the survey was revised for clarity and redistributed in December 2019. Because there were many genetic counselors who were members of both groups, it was requested that the survey be completed only once regardless of the access point. The inclusion criteria specified that participants must be a certified genetic counselor who was currently practicing or who had practiced in preconception reproductive genetics. Each participant was asked to self-identify with a primary ART work setting. The work setting options included: genetic testing laboratory (PGT, carrier screening, or both), IVF clinic, gamete donor agency, telegenetics practice (either private practice or telemedicine company), or other. Additionally, respondents were asked about various tasks and whether they currently performed these tasks (the "reality") and also whether they believed that they should be performing these tasks as part of their job function (the "ideal"). The survey, which detailed the tasks that were queried, can be found in the Supplemental Materials (available online).

Survey and Data analysis

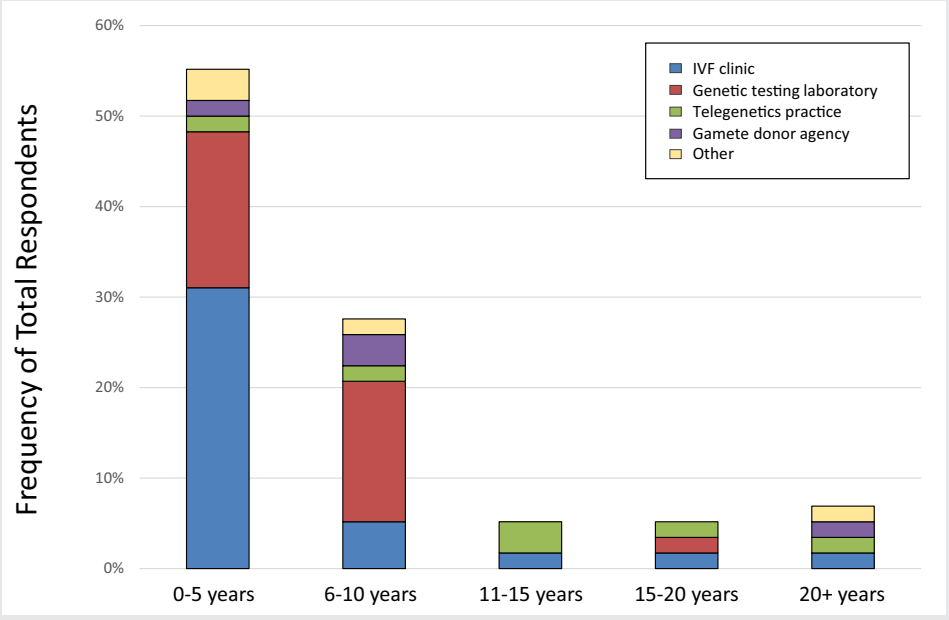
Data collection and analysis was performed with the use of Survey Monkey by examining frequencies and percentages, as well as cross-tabulation and filtering by self-reported ART work setting. The survey was open from December 2019 through January 2020. This study was deemed exempt from approval by the Advarra Institutional Review Board (Pro00040101) because the research involved survey procedures and the information obtained was recorded in such a manner that the identity of the participants could not readily be ascertained.

RESULTS

Respondent demographics

A total of 58 genetic counselors responded to the survey with 71% of the respondents completing all questions in the survey. All individuals met the inclusion criteria and reported being a certified genetic counselor practicing or having

FIGURE 1



Cumulative years practiced in preconception reproductive medicine. Survey respondents were asked how many cumulative years they had been practicing in preconception reproductive genetics. Most had practiced in the field for ≤5 years. Of the genetic counselors who had been practicing for ≤5 years, the most were based in in vitro fertilization clinics. Most laboratory-based genetic counselors had been practicing for ≤10 years. A few respondents had been practicing in the field for >0 years (N = 58).

Snider. ART genetic counselors' practices. Fertil Steril Rep 2020.

practiced in preconception reproductive genetics. Of the 58 respondents, 24 individuals selected an IVF clinic, 20 individuals selected a genetic testing laboratory, 6 individuals chose a telegenetics practice, 4 selected a gamete donor agency, and 4 selected "other" as their primary work setting. Individuals selecting "other" worked in hospitals or prenatal clinics and had received referrals for patients undergoing fertility treatment. Respondents were asked the number of years they practiced in the field of preconception reproductive genetics but were not asked the total number of years they practiced as a certified genetic counselor in any specialty. Most survey respondents (32, 55%) were relatively new to the field, having practiced in the field for ≤5 years. Sixteen (28%) had been practicing in the field for 6–10 years. The remaining 10 (17%) had been practicing in the field for >11 years. All survey respondents were members of either the ASRM GCPG or the NSGC ART/Infertility SIG, and most survey respondents (67%) were members of both (Fig. 1).

Clinic-based genetic counselors

Of the total 58 survey respondents, 24 identified themselves as IVF clinic-based genetic counselors. The majority (75%) reported being in practice ≤5 years and an additional 12.5% reported 6–10 years of practice in this setting, indicating that working in an IVF clinic was a relatively new role for genetic counselors.

With regard to their reported job functions, 67% of the respondents reported taking a family history during every patient or gamete donor consultation, whereas the remaining 33% reported taking a pedigree as indicated based on the referral type or test being ordered. All of the respondents stated that a family history review was part of their job function, indicating that this was a standard for clinic-based genetic counselors. Additionally, 83% of respondents reported that a broad, 3-generation pedigree was their means of family history obtainment and risk assessment.

Twenty respondents answered questions related to genetic carrier screening. At least 80% stated that carrier screening tasks were within their scope of practice in both the reality and the ideal situations. These tasks included discussing carrier screening options, the option of PGT for at-risk couples, and reviewing results of genetic testing from *any* lab.

Regarding the tasks related to PGT, again 20 respondents answered. At least 75% reported PGT tasks were currently part of their jobs with at least 90% believing that it should be part of their responsibilities. The exception to PGT-related tasks believed to be within their scope of practice was reviewing personal health management recommendations for the affected patient. Only 53% of the respondents performed this task, and 42% believed that this should be part of their duties. Discussing health management for a specific genetic diagnosis would be within the scope of practice for a genetic counselor and/or a medical geneticist (MD) specializing in that condition.

For the remaining survey questions, 19 respondents answered. Pertaining to tasks related to gamete donor

screening, most stated that these duties were currently part of their job (53%–79% for the various tasks), but even more believed that these duties should be part of their jobs (72%–94% for those same tasks). This disparity indicated that these clinic-based genetic counselors felt that they are being underutilized in this capacity. A notable exception was the task of collecting information and assessing adverse outcomes for donor-conceived offspring. Only 47% of the clinic-based genetic counselors currently performed this duty, roughly in line with the 53% who believed that they should be performing this task. This point is exemplified by the following statement:

> *... regarding donor adverse event follow up – our donors are partnered with a national egg bank. If one of our donors has an AE I will also speak to patients OUTSIDE my clinic who have used that donor and counsel them about the genetic abnormality. I feel that is within my scope because the egg donor was screened at my clinic.*

Most clinic-based genetic counselors were, and believed they should be, doing additional patient-focused tasks (tasks involving direct patient care). The clear exception was consent for and interpretation of nonreproductive genetic tests (e.g., Huntington disease testing, cancer genetic testing). A number of comments illustrate this sentiment:

> *I will order nonreproductive genetic tests for patients if it is for an indication that I do not think requires a physical exam/medical geneticist such as non-syndromic hearing loss or a known familial variant. I will also order genetic testing if the patient already has a clinical diagnosis (e.g. Treacher-Collins), but just never had genetic testing.*

> *Although I will not perform nonreproductive related genetic testing (i.e. neuro, cancer, etc.) I will however, perform direct mutation testing on a patient that has a family history and can provide a family members test result and if the rationale is that they would do PGT-M. But I won't order panel testing or test if someone isn't interested in PGT-M.*

When patient needs fell outside of their area of specialty and expertise, 90% of respondents were able to provide direct contact information when referring to other specialty genetic counselors and medical geneticists.

Most clinic-based genetic counselors (84%) believed that the scope of practice defined by their employer, the clinic, was appropriate for their role. However, as few as 32% of the clinic-based genetic counselors answered "yes" when asked if they believed that the other health care providers that they worked with recognized their scope of practice. An additional 63% believed that they "somewhat" recognized the scope of practice. The following comments exemplify this view:

> *The most common issue where I find my colleagues do not always understand my scope of practice is receiving referrals that should go to a geneticist vs. referrals for genetic counseling. For example, every couple of months there will be a referral for an IVF patient with a history of hypermobility who is on a 2 year wait list to see a geneticist, but our clinic will refer to me since I can usually see them within a week or two and think that I can do the evaluation for hypermobility and make recommendations about pregnancy management. It usually takes some explaining that what I do as an ART GC is vastly different from what a clinical geneticist in a general genetics clinic does.*

> *At first my clinic saw me as the "one stop shop" for everything genetic. For example they would ask me to perform cancer counseling. Throughout my time here I've had success educating them regarding my scope and they are accepting. Something unique about fertility clinics is that we are almost like a concierge clinic. We do everything to make patients happy. So I still sometimes struggle with physician AND patient expectations regarding what is appropriate. "Just because I can doesn't mean we should" is basically my mantra. My biggest belief about a clinic-based vs lab is that the lab counselors can only talk to my patients regarding that labs testing.*

Other ART genetic counselors

Few genetic counselors who responded to the survey identified with the category of "other" (4) and thus patterns were difficult to cull out of the data. However, each of the "other" genetic counselors described that they worked in a clinic that was either affiliated with or received referrals from an IVF clinic. Their collective responses were similar to the genetic counselors who worked in IVF clinics.

Telegenetics-based genetic counselors

Six genetic counselors identified as being based in telegenetics, defined as either working in private practice or for a telemedicine company. With regard to the tasks portion of the survey, 3–4 respondents completed these questions. In general, the tasks within the respondents' scope of practice were similar to the tasks performed by IVF clinic-based genetic counselors.

All respondents indicated that they performed nearly all carrier screening and PGT-related tasks, and felt that these tasks were within their scope of practice. In addition, it appears that most telegenetics counselors were involved in gamete donor screening and counseling, as well as counseling of intended parents. However, similar to the clinic-based genetic counselors, there were mixed responses with respect to collecting/assessing adverse outcome reports on donor-conceived offspring. Only one respondent felt that this task was within their scope of practice; 3 respondents indicated it was unclear.

For patient-focused tasks, all respondents consented patients for reproductive genetic tests, discussed the natural history of a condition, evaluated family history, and discussed

post-ART prenatal genetic testing options and felt that these tasks were within their scope of practice. There were mixed responses on the remainder of the tasks questions. Notably, although 2 respondents stated that they routinely convey IVF clinic policies pertaining to embryo transfer or disposition, all respondents indicated that they do not feel that this is within their scope of practice. Although none of the respondents established a genetic diagnosis in patients by physical examination or by ordering genetic testing, one individual provided a noteworthy statement in regard to this task:

> *I obviously would not perform a physical exam, but if I feel there is a straightforward genetic test available in conjunction with a firm clinical diagnosis from a specialist (medical records confirming this, with a specialist outside of genetics), I will help coordinate ordering a genetic test after counseling, since the patient is often coming for PGT-M and a genetic diagnosis is needed before they can go that route. If it is a complicated genetic picture (multiple potential avenues for testing, unclear detection rates, etc.) or if the clinical diagnosis is less clear or only a suspicion, I will refer to clinical genetics for a more comprehensive workup. I feel that question left a little bit of room for interpretation, so I wanted to clarify my own practices. This is how I do it, though ideally they would all come with genetic diagnoses.... In the real world, there are not enough genetic counselors and the wait times are excessive for clinical genetics and we know time is of the essence for patients making IVF decisions, so I will handle the more straightforward cases, explaining the limitations of my involvement at the outset.*

Gamete donor facility-based genetic counselors

Four individuals identified as being based at a gamete donor facility and referred to the donor as their primary client throughout the survey. All 4 respondents indicated that they collected a 3-generation pedigree on every gamete donor. Only 3 individuals completed the tasks portion of the survey.

The respondents indicated that they performed most carrier screening-related tasks and felt that it was within their scope of practice. However, only one respondent indicated that "consenting patients for carrier screening" should be within their scope of practice. The other respondents may have perceived the term "patients" to refer to intended parents. Genetic counselors at gamete facilities do not typically order or facilitate carrier screening for intended parents.

With regard to PGT-related tasks, 2 respondents indicated that they generally did not perform these tasks and did not feel that it was within their scope of practice. One exception included an individual who indicated that it was within their scope of practice to counsel donors regarding age-related or translocation/inversion-dependent aneuploidy rates as well as provide comprehensive counseling regarding newly identified chromosome rearrangements. As some gamete facilities perform a karyotype analysis as part of their donor qualification process, these tasks may fall within the genetic counselor's scope of practice if a chromosome rearrangement was identified in a donor. As expected, all respondents indicated that they performed all gamete donor screening-related tasks and felt that it was within their scope of practice.

When asked about other patient-focused genetics tasks, all respondents indicated that they consent donors to reproductive genetic tests and felt that it was appropriately within their scope of practice. Two individuals stated that they consent donors to nonreproductive genetic tests. Only one respondent felt that consenting donors to nonreproductive genetic tests should be within her scope of practice and one stated that it was unclear. All respondents stated that they performed family history risk assessments as well as discussed the natural history of a condition identified via family history assessment or carrier screening, and all felt that it was within their scope of practice.

Laboratory-based genetic counselors

Twenty respondents identified as being laboratory-based genetic counselors; 14 respondents answered all questions. The majority (60%) worked in laboratories that provided both carrier screening and PGT. The remaining 40% worked in laboratories that provided only PGT.

As seen in the overall responses, genetic counselors based in a genetic testing laboratory were relatively new to the field of preconception reproductive genetic counseling. Half of the respondents had been practicing in the field for 0–5 years and 45% had been practicing for 6–10 years.

Most (63%) laboratory-based genetic counselors collected a family history only as indicated by the referral type or requested test. A minority (26%) reviewed family history for every patient, and 11% typically did not review family history at all. When family history was reviewed, a 3-generation pedigree was collected 35% of the time. The data suggested that patients might be more likely to receive a comprehensive family history risk assessment when seen by a clinic-based genetic counselor who could provide the necessary follow up.

Laboratory-based genetic counselors performed some tasks perceived to be outside their scope of practice. This phenomenon was most evident in the category of "additional, patient-focused genetic tasks," especially the tasks of "conveying IVF clinic policies," "interpreting and/or reviewing ANY clinical genetic testing results from any genetic testing laboratory unrelated to the referral indication," and "discussing risk associated with ART-related procedures."

Laboratory-based genetic counselors also believed that they were performing PGT-related tasks outside their scope of practice. None of the laboratory-based genetic counselors felt that they should review or interpret the PGT results issued by other laboratories, and yet 21% of respondents performed this task at least occasionally. Similarly, none of the laboratory-based genetic counselors felt that they should review the personal health management recommendations with a patient carrying a variant for which PGT for monogenic/

single gene disorders (PGT-M) was requested, yet 14% of the respondents indicated that they performed this task. Most laboratory-based genetic counselors (64%) reviewed the natural history of a condition for which PGT-M was requested, but only 43% felt that this was a task that should fall within their scope of practice. Similarly, most laboratory-based genetic counselors (79%) facilitated decision-making regarding PGT results based on a patient's personal values, but only 64% felt that this task should fall within their scope of practice.

Most genetic counselors based in laboratories (64%) could not provide patients with direct contact information for a referral to another area of specialty. Just over half of the laboratory-based respondents (57%) indicated that they felt that their employer appropriately defined their scope of practice. When asked whether they felt that other health care providers recognized their scope of practice, including the limitations in their practice, 64% responded "no," 36% responded "somewhat," and none responded "yes" (Fig. 2).

DISCUSSION

The results of this survey indicated that ART genetic counselors have varying roles and duties among the different work settings. Among clinic-, telegenetics-, gamete donor facility-, and laboratory-based genetic counselors, there were notable differences in the daily tasks being performed as well as whether these tasks were perceived to be within the respondents' scope of practice (Fig. 3).

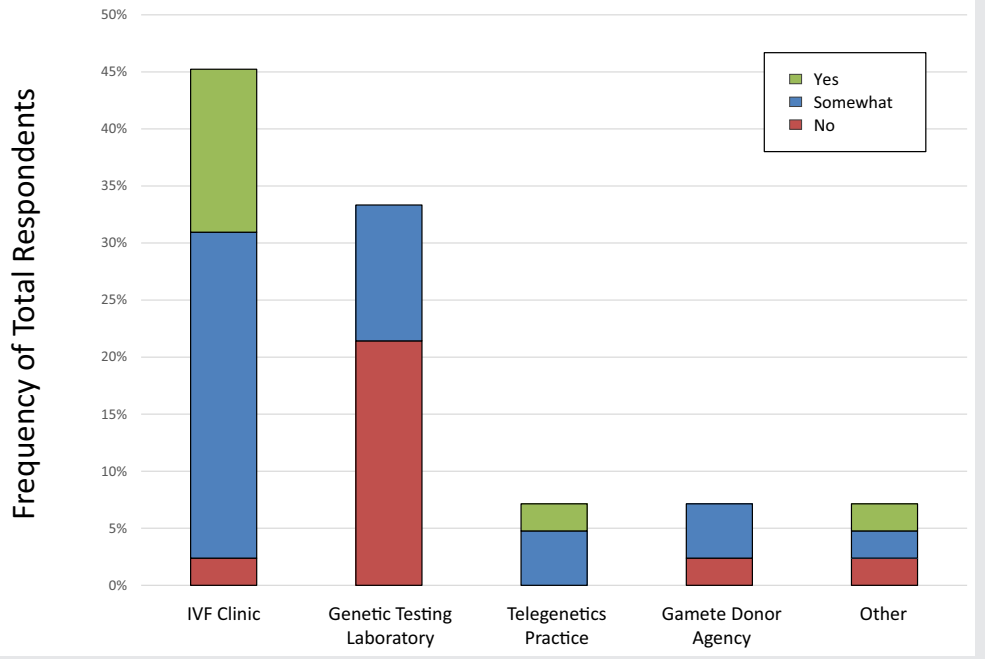
ART genetic counseling is a relatively new subspecialty, and this was reflected by most survey respondents stating that they have been practicing in the field for $\leq$10 years. This was markedly true for clinic-based genetic counselors, the majority of whom had been practicing in the field for $\leq$5 years. Notably, some respondents indicated that they were the first genetic counselor at their clinic:

> *As the first genetic counselor for my IVF clinic, I was largely responsible for defining my own role within the practice.*

This underscored the need to better standardize and communicate the scope of practice in this relatively new subspecialty.

Although it is becoming increasingly common for fertility clinics to employ an in-house genetic counselor, the majority do not, and thus they must rely more heavily on the services of the genetic counselors at their reference laboratory. Many laboratories provide complementary genetic counseling services with specific tests ordered by the referring providers. Although some respondents believed that other health care providers understood their scope of practice, none of the laboratory-based genetic counselors

FIGURE 2



Responses to "Do you feel that other health care providers recognize your scope of practice, including the limitations of your practice?" The respondents were asked the following question: "Do you feel that other health care providers recognize your scope of practice, including the limitations of your practice?" Some clinic-based genetic counselors responded that yes, other health care providers recognized their scope of practice, but most felt that other health care providers only somewhat recognized their scope of practice. Laboratory-based genetic counselors felt that other health care providers either do not recognize or only somewhat recognized their scope of practice (N = 42).

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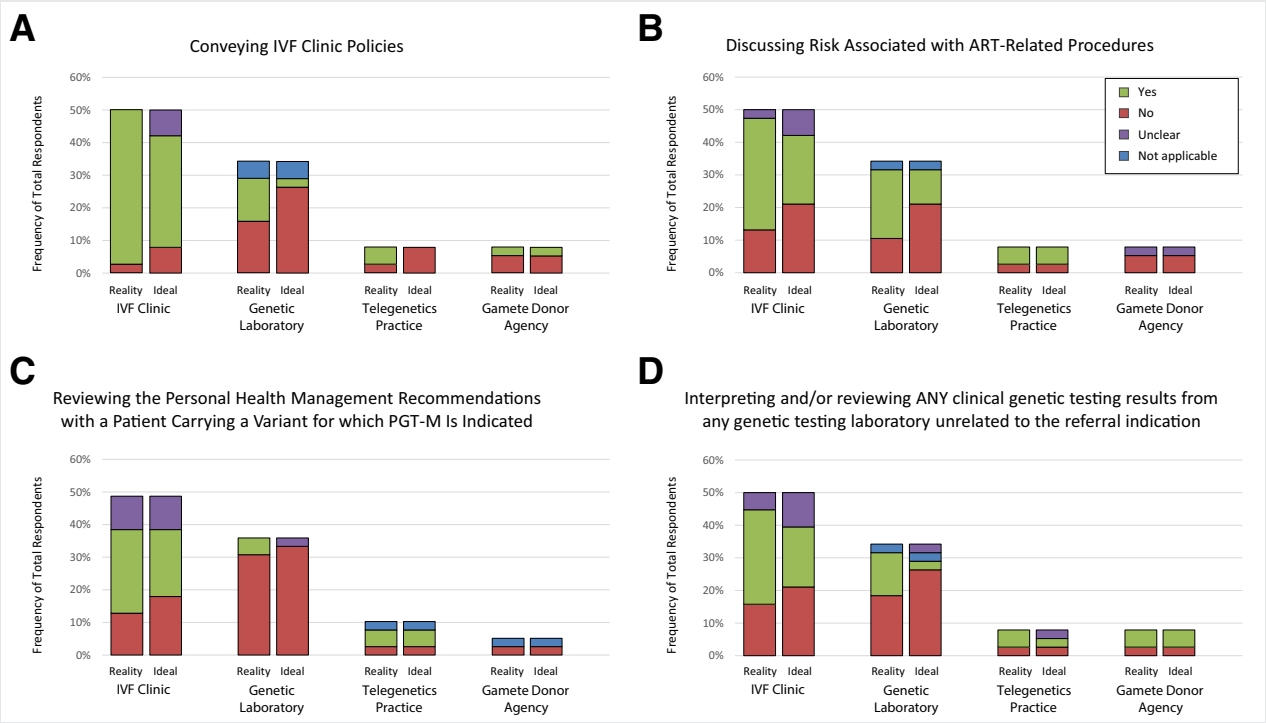
FIGURE 3



Selected tasks comparing the reality and ideal states among the various work settings. The respondents were asked whether they performed the indicated tasks and if they felt that this task should be within their scope of practice. (A) Most clinic-based genetic counselors conveyed in vitro fertilization (IVF) clinic policies to patients and felt that it was within their scope of practice to do so. In contrast, most laboratory-based genetic counselors felt that discussing IVF clinic policies was not within their scope of practice, although some did perform this task if requested by a client (N = 41). (B) Most clinic-based and laboratory-based genetic counselors would discuss the risks associated with assisted reproductive technologies-related procedures if requested by a client; however, fewer felt that this was within their scope of practice (N = 41). (C) Some clinic-based genetic counselors would review the personal health management recommendations for a patient pursuing preimplantation genetic testing for monogenic/single gene disorders (PGT-M; e.g., reviewing prophylactic surgery options for a *BRCA1* carrier), but few felt that this task was within their scope of practice and some felt that it was unclear. In contrast, very few laboratory-based genetic counselors would review personal health management recommendations with patients who were pursuing PGT-M (N = 42). (D) Some clinic-based and laboratory-based genetic counselors would interpret or review genetic reports regardless of the testing laboratory or referral indication; however, fewer felt that this was within their scope of practice, and some felt that it was unclear (N = 41).

Snider. ART genetic counselors' practices. Fertil Steril Rep 2020.

believed this to be true. One respondent provided additional context on this finding:

> *I have found that health care providers generally do not understand the scope of practice of a PGT-M counselor, and that we are not able to provide all of the services that an in-house genetic counselor might. I frequently received requests for counseling assistance outside of my scope of practice*

Both laboratory-based and telegenetics-based genetic counselors stated that they performed tasks that they believed to be outside of their scope of practice. This finding, combined with the data suggesting that other ART health care providers did not fully understand the genetic counselors' scope, implied that there may be pressure to perform tasks that do not support best clinical practices. Both laboratory and telegenetics genetic counselors work with many IVF clinics, all of whom have varying policies and procedures, making it difficult to tailor their counseling on an individual client basis. The varying and evolving business models incorporating genetic counseling in the laboratory and telegenetics arenas may be promoting confusion among the ordering providers.

According to our study, most clinic-based respondents were able to offer referrals to specific other specialty genetic counselors and medical geneticists. This finding supported the belief that ART genetic counselors recognized the boundaries in the scope of practice within their area of expertise. Furthermore, this ability for clinic-based genetic counselors to make specific referrals suggested that they may be more involved in directly coordinating patient care. In contrast, laboratory-based genetic counselors were most often unable to make specific referrals. It was considered good practice for the reference laboratories to communicate solely with the ordering provider as the coordinator of a patient's care.

Although all genetic counselors shared a core set of competencies governed by the Accreditation Council for Genetic Counseling, they then developed additional expertise in their

area of practice. In addition to specialty, genetic counselors functioned in many different capacities based on their work setting. For example, a genetic counselor in a pediatric setting works in a team with a medical geneticist to review family history, perform a physical evaluation, and order genetic tests to establish a diagnosis. A genetic counselor in an ART setting would refer to medical genetics if a genetic condition was undiagnosed in a family pursuing PGT-M, but would not coordinate such an evaluation in the ART setting.

A limitation of this research lay in the survey distribution and that only members of the NSGC ART/Infertility SIG or ASRM GCPG would have received an invitation to participate. These members were, however, invited to share the survey link with colleagues in the field of ART.

An additional limitation was the relatively small population of ART genetic counselors and the exploratory nature of the survey. Subsequently, the study was not powered to achieve statistical significance.

The results of this study indicated a need for education within the reproductive medicine community regarding the various roles of genetic counselors practicing in ART. Because ART is a relatively new subspecialty in genetic counseling, it is necessary to better define the appropriate duties for genetic counselors in the various ART work settings. This will foster effective working relationships with their nongenetics colleagues and optimize patient care. Further engagement with providers in the field of reproductive medicine to more clearly define the scope of practice for ART genetic counselors is needed.

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