variant upgrades and downgrades. Determination of this responsibility is outside of the scope of this author group. However, clinicians should be aware of the protocols for the labs they use and address this question within their organization as appropriate.

3.8 | Patient anxiety & stress

It is reasonable to expect that many results from ECS will come back "abnormal" or "positive." For example, nearly half of all tested females screened positive on a 115 gene panel (Fecteau et al., 2019), and when examining 415 genes associated with a severe autosomal recessive disorder, exome data suggests a cumulative carrier rate of >60% in individuals reporting Ashkenazi Jewish ancestry (Guo & Gregg, 2019). This positivity rate is higher than that encountered in routine lab work (e.g., complete blood count, comprehensive metabolic panel, thyroid stimulating hormone, sexually transmitted infection tests, etc.) when physical symptoms have not been recognized. Patients should be directly counseled through the informed consent process that "abnormal" or "positive" results from ECS are expected and will usually not have an impact on one's own health status.

The completion of any medical laboratory test creates the potential for stress and anxiety in the patient, yet the medical necessity of such testing is essential to consider when determining if the chance for stress and anxiety is worthwhile. With ECS, the risk/benefit analysis for testing must be decided by the patient based on their values and goals for information regarding inheritable disease, rather than the provider's impression of what information is meaningful and/or actionable for the patient. Indeed, the provider's perception of what may or may not cause anxiety or stress in their patient may be quite different from the patient's own experience.

The completion of genetic testing, in the broadest sense, is no longer uniquely exclusive to those individuals who present for specialized care. Millions of Americans have undergone direct-to-consumer genetic testing for many reasons, which may not be considered medically necessary, such as exploration of ancestry, understanding of metabolic markers, or identification of risk-conferring single nucleotide polymorphisms (SNPs) for various medical conditions. This is virtually always completed with an out-of-pocket expense to the consumer and thus is disproportionately skewed towards individuals who possess sufficient resources to pursue genetic testing information for personal curiosity. A cost-effectiveness study evaluating >60,000 patients who underwent a 176-condition ECS panel noted that ~10% of claims were billed to government-sponsored insurers, demonstrating a disproportionate population of privately insured individuals compared to the US as a whole (Beauchamp et al., 2019). Researchers in a predominantly white US academic medical center's patient population found that 41% of gynecology patients who were offered information about ECS desired a preconception genetic counseling referral, and that possession of an advanced degree was associated with genetic counseling visit attendance to discuss ECS upon referral (Nesbit et al., 2021). A 2014 survey of 222 OB/GYNs revealed that nearly half of respondents offered ECS to all of their patients, with providers in solo private practice offering ECS to all patients more frequently (31%) than those in group practices (12.5%) and those in university practices (3.6%) (Benn et al., 2014). The practice of gatekeeping ECS to only those persons with access to medical care who know to ask about ECS within the visit, and furthermore only those who are perceived to be able to handle the potential stress of results, upholds systemic inequalities in the practice of medicine by ensuring that individuals with fewer medical resources and/or lower health literacy levels will encounter more difficulties in obtaining information about their own genetic code. If these issues are not carefully and thoughtfully confronted in the near future, severe inherited disease may become associated with a preventable outcome observed disproportionately in our most marginalized communities, rather than a real possibility for all human offspring, regardless of socioeconomic status or privilege.

3.9 | Patient satisfaction

It may be challenging to distinguish whether considerations surrounding patient satisfaction with the ECS experience center upon the testing experience itself (for example, ease of sample collection), the billing process associated with ECS, the patient's relationship with the provider(s), and/or the actual results from ECS. Individuals undergoing ECS may report receiving very valuable information from this testing and feeling grateful for the education and counseling supplied by their provider, yet simultaneously report experiencing frustration, confusion, and inconvenience upon receiving an explanation of benefits quoting a higher anticipated out-of-pocket cost than expected, potentially several months after testing was completed. For example, 54.5% of surveyed patients undergoing ECS at a university-affiliated reproductive endocrinology and infertility (REI) clinic reported that ECS was not covered by their insurance, and 47.6% paid >$300 out-of-pocket for the testing, yet the majority (82.6%) would still choose to undergo ECS if presented with the option again (Shapiro & Quinn, 2020). There are many possible confounding factors both within and outside of the control of the provider, patient, payor, and laboratory, which can contribute to the overall satisfaction of the patient with ECS. While, given its subjectivity, patient satisfaction may be a subsidiary consideration in whether to offer ECS in clinical practice, it is relevant to consider what elements of patient satisfaction are most important within one's personal practice to aid in determining which ECS laboratory or product offers an optimal patient care experience.

3.10 | Perceived barriers to ECS

At present, there are many potential barriers to equitable implementation of ECS for both providers and patients. Counseling, obtaining informed consent, results reporting, researching results, clinical documentation, and following-up on positive results requires a substantial amount of time. A 2018 time cost study found that the time