

The GOG Foundation, Inc. Diversity, Equity and Inclusion



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Inclusion, Diversity, Equity, and Access (IDEA) in Gynecologic Oncology Clinical Trials

In recent years it has become apparent that education is needed to address and mitigate the healthcare disparities affecting underrepresented racial and ethnic populations. In 2022, a call to action, led the GOG Foundation (GOG-F) to formalize efforts to address health disparities related to the sustained impact of structural racism in the healthcare system and clinical trial accrual. Under the leadership of Bhavana Pothuri, MD, The GOG Foundation Inclusion, Diversity, Equity and Access (IDEA) Initiative was launched. The first priority under this initiative was to publish a joint statement on Inclusion, Diversity, Equity, and Access (IDEA) with the Society for Gynecologic Oncology (SGO).¹

The Call for Diversity in Clinical Trials

Clinical trials provide patients with access to novel agents that may become the new standard, with the goal of improving outcomes and/or minimizing treatment-related adverse effects. While these discoveries are intended to improve oncologic outcomes, individuals from diverse ethnic and racial groups who have the highest need for improved cancer care are underrepresented in clinical trials. Race refers to a set of physical characteristics that is human invented and is a social, political and economic construct, not a biologic concept. Ethnicity describes a shared culture, heritage, religion, language, and customs within a geographic region. A guiding principle used to develop new therapeutic interventions in oncology is the inclusion of participants who accurately represent the population under study and expected to use the medicine.

Health disparities are related to the societal legacy of

structural racism and its sustained impact on present day practices and policies, which perpetuate diminished opportunity for at-risk populations. Identifying and addressing the barriers to enrolling a diverse population of patients into gynecologic cancer clinical trials is both critical and complex. Strategies must be multidimensional, multidisciplinary, place-based and systems-focused.

As the US population continues to become more diverse, it is critical that there is adequate and inclusive representation from various racial and ethnic populations. Clinical trial access is a key component of high-quality cancer care. Working with sponsors to overcome barriers to enrollment, design limitations, and lack of access in areas that provide care to under-represented populations is critical to improve IDEA in gynecologic cancer clinical trials.

Despite a call to increase participation in under-represented populations in The NIH Revitalization Act of 1993,² no standard for reporting race and ethnicity has been established. An analysis of all registered trials in ClinicalTrials.gov conducted in the US from 2000-2020 noted that prior to 2007, the rate of any race and ethnicity reporting in enrollment data was 26%, with 11% using the June 2010 US Census categories (White, Hispanic/Latino, Black, Asian (including Pacific Islander and Native Hawaiian), and American Indian (including Alaskan Native) and by 2018, these numbers increased to 91% for any mention of race and ethnicity (Turner 2022). Within gynecologic oncology, a review of the legacy Gynecologic Oncology Group (GOG) trials from 1985-2013 found that only 38% of publications included race and ethnicity data, with no trials prior to 1994 ever mentioning race.³ Analysis of disparity and race reporting

in clinical trials leading to cancer drug approvals from 2008-2018 found that less than 50% of trials leading FDA approval reported on non-White races.⁴ There is consensus that patient self-reported race and ethnicity is more accurate than administrative or other means of categorization.^{5,6} More specific guidance for race and ethnicity reporting utilizing “Racial and Ethnic Categories and Definitions for NIH Diversity Programs and for Other Reporting Purposes” should be utilized and can improve the accuracy of these data.⁷

Measuring Success in Terms of Diversity in Clinical Trials

As we improve collection of race and ethnicity data, our objective should be to determine the appropriate proportion of patients from different ethnic and racial groups who should be represented in the trials. Reports of accrual from underrepresented groups in trials compare the representation of a group in the trial to the representation of that group in the population (Mason, 2003); however, using this as a guide may be misleading because there is significant demographic variation in cancer incidence by disease site.⁸ Others calculate fractions based on cancer prevalence (which may not be readily available) stratified by race and/or ethnicity for all gynecologic cancers. Murthy et al assessed representation in cancer clinical trials using the enrollment fraction, or the number of trial enrollees divided by the estimated US cancer cases in each age and subgroup.⁹ Molecular subtyping of endometrial cancers has shown that tumors harboring p53 mutations are more aggressive and portend a worse prognosis. The racial distribution of patients with endometrial cancer is not the same as the racial distribution of patients with p53-mutated endometrial cancer where Black patients are over-represented and have higher mortality. Similarly, the racial distribution in primary and recurrent settings may also differ reflecting different intrinsic and/or extrinsic factors of disease biology. Racial clustering based on regional incidence or catchment area should also be considered.¹⁰

Working to Break down Barriers Related to Clinicians and Care Teams

As important as educating those who design clinical trials, addressing clinician- and team-related barriers, including conscious and unconscious bias, compositional diversity of the clinical research team, insufficient structure, and lack of open clinical trials are vital to improving diversity in trials. The misconception that patient mistrust or lack of interest is the central barrier has been disputed with recent evidence noting that up to two-thirds of patients are willing to enroll in trials, but were never offered a trial as a treatment option.¹¹ An acclaimed ovarian cancer survivor, staunch research advocate, Chair of GOG

Patient Advocate Committee (2006-2014) and NRG Patient Advocate Committee (2014-2019), and champion of diversity in gynecologic cancers, Mary “Dicey” Scroggins, focused much of her work on equitable clinical trial access. She notably remarked, “Clinical trials are like a party for which one needs an invitation. If patients are not invited, they cannot participate.”¹²

Bias, both explicit and implicit among the care team, could be more important than patients’ willingness to enroll on trials. Implicit bias training of all team members will increase awareness of subconscious and unfair decisions regarding a patient’s willingness or suitability to enroll. Implicit bias among providers regarding perceived lack of trust, understanding/education, or inability to follow protocol procedures among patients are important barriers to self-identify and overcome.¹³ In addition, compositional diversity should be evaluated; teams that have diverse memberships are more collaborative, are better critical thinkers, and better able to solve complex problems.

Creating clinical research teams with diverse representation from all races, ethnicities, creeds, and life experiences can increase patient engagement through shared experiences and comfort. Several studies investigating the benefit of race-concordant patient-physician dyads have shown that education and empathy around diverse life experiences can overcome actual race or gender concordance and can be achieved by actively practicing cultural humility.¹⁴ Cultural humility is a way of incorporating multiculturalism through self-reflection and life-long learning to increase providers’ awareness and understanding to respect, accept and value.

Structural barriers in the medical system accounted for 77% of patients who did not participate in trials.¹¹ In a study evaluating the experience of nine university and four community cancer centers, no trial was available 56% of the time or the patients were not eligible 22% of the time. University centers enrolled eligible patients 14.8% and community centers 7% of the time. Concerted efforts focusing on the creation of alliances between university-based centers and community-based settings will require strategic partnerships to ensure clinical trial access to those who were historically excluded due to physical and financial travel constraints. Furthermore, physicians need more trial education, time, resources, and salary support to commit to clinical research and achieve this goal especially with the current robust drug development pipeline. Institutions and sponsors need to support programs for clinical trial infrastructure and make concerted efforts to increasing IDEA.

Addressing Patient-Related Barriers to IDEA in Clinical Trials

The patient-related barriers to enrolling underrepresented populations in clinical trials are classified into three broad categories- education, mistrust, and social determinants of health (SDOH). The first category is limited and/or biased education about clinical trials among patients. This is a result of gaps in knowledge and education surrounding the importance of clinical trials specific to the treatment of gynecologic cancers. The limited dissemination of information to patients regarding the importance of clinical trials to improve the outcomes of patients with gynecologic cancers has resulted in poor uptake in marginalized and underrepresented populations. This has created disparities in the availability of therapeutic options across the United States.¹⁵ The second category is mistrust of healthcare providers, healthcare systems, and sponsored clinical research, which are all well documented in underrepresented groups. While the rate of enrollment in underrepresented populations is similar when a clinical trial is offered, mistrust is the primary reason recorded when patients of diverse race/ethnicity decline to participate. The final category falls under the auspices of SDOH(s), which is defined by the Office of Disease Prevention and Health Promotion as the environmental conditions into which people are born, live, learn, work, play, worship, and age that impact health, function, and quality of life outcomes. SDOH(s) are recorded as lack of transportation, lack of childcare, inadequate insurance, time commitment, and interruption of work resulting in loss of income as key factors limiting access to health care and acceptance of clinical trials (which often require additional visits and or prolonged visits). Such challenges translate to patients as indirect, yet consequential, costs of clinical trials. In addition to these three categories, language and cultural belief systems are barriers that limit access and enrollment.

Well-described methods have been used to increase awareness about therapeutic options in underrepresented communities. Initially, education should be specifically directed towards improving knowledge about the cancer diagnosis and treatment, the disease process of the individual patient, and the role of clinical trials in both. Successful examples of enhancing education are through in person interactions and web-based and written materials¹⁶ that are adapted to the cultural and linguistic specifications of the specific population.¹⁷ Education and utilization of community health workers (CHW) (the non-clinical, public health workers) who are either trusted members of a community or have a personal understanding of the community can improve relationships and trust between individual patients and their healthcare system.¹⁸ The directed education of a community selected

CHW about gynecologic cancer and the role of clinical trials can promote dissemination of knowledge to the community being served. Similarly, patient navigators (PN) can provide support and guidance to individual patients as they enter the health care system and progress through the cancer and clinical trial process. Moreover, the involvement of CHW/PNs in medical care is associated with a higher acceptance of clinical trials.¹⁹

Building trust between the health system and under-represented communities can occur through ongoing meaningful community partnerships and outreach at churches, social clubs, local health fairs, and other events with assistance from community leaders. This is essential to improving health literacy, access to medical care, and participation in clinical trials. Engaging individual communities through the creation of community advisory boards is another example of this implementation strategy. These provide a forum for disseminating disease and treatment-related information, sharing research results, and identifying specific community needs.²⁰ Recommendations from community advisory boards should be communicated to health systems or research leadership along with action plans. The value of strategic, multifaceted, community-based approaches to promote sustainable acceptance and increase enrollment of underrepresented populations must not be undervalued or overlooked.

Patients from less represented populations may need more resources as family, financial, and/or emotional support may not be as readily available. Individual support with transportation/parking, food, childcare, loss of wages, lodging, reminder calls, and insurance enrollment are examples of steps that can be taken that could minimize the burden of participation. The identification of “sub-population” specific barriers to care are also critical and efforts to understand these will be important as we develop further mitigation strategies.

Improving Clinical Trial Design Limitations

Eligibility criteria, schedule of events, and study design may unintentionally limit IDEA to clinical trials. Each patient selection criterion should be judiciously evaluated and scientifically justified. Often, the stringency of inclusion and exclusion criteria inadvertently creates a barrier to enrollment of diverse populations. A loosening of exclusion criteria can be achieved without sacrificing safety, and while preserving the scientific integrity of the clinical trial. The ASCO/NCI friends^{21,22} document which promotes less stringent inclusion/exclusion criteria should guide inclusion of patients with HIV, Hepatitis, and prior malignancies. Furthermore, following special risk/benefit consideration there should be a compelling scientific rea-

son based on the study drug metabolism, clearance and/or toxicity profile to exclude “high risk” populations such as those with end organ impairment or who are lactating or of childbearing potential.

Lack of flexibility in scheduling can limit enrollment for those with less flexible work schedules or home responsibilities. Screening windows should be lengthened, and study procedures simplified with deference to local guidelines. Omitting the requirement for central laboratory studies and the incorporation of flexible windows for remote or home assessments, when possible, will further alleviate barriers to patient enrollment and participation. Telemedicine technology can be leveraged to facilitate access to clinical trials by permitting virtual toxicity assessments.²³ Oral drugs can be shipped directly to patients. Many of these strategies were adopted with the COVID-19 pandemic and provide proof that these are feasible, and that clinical trials can continue effectively with these adaptations.²⁴ Furthermore, a flexible tiered model for the acquisition of translational specimens could facilitate accrual to phase 1 trials in under-resourced settings. Complex, multiple time-point biomarker and tumor biopsy collections could be conducted in the larger centers with a more limited panel of translational studies collected in the community setting. Finally, an adaptive trial design can permit pre-specified modifications to be made to the study design as new data become available and also enable enrichment for participants with a particular characteristic thought to.²⁵

Sponsor Engagement to Address IDEA in Clinical Trials
Engaging pharmaceutical companies and cooperative group sponsors is an integral step to promoting IDEA in gynecologic cancer trials. Enhancing their understanding of the rapidly evolving disease landscape, importance of targeted site selection, and increasing resources for sites and patients. Key opinion leaders (KOL’s) will provide insight regarding the evolving landscape of gynecologic cancers. The disease landscape differs based on the type of gynecologic malignancy, molecular subtype and biomarkers, and survival may vary across race and ethnicity. Educating sponsors on the nuances of the disease, prognostic factors, and underlying biology is necessary to highlight the need for IDEA in trials and identify ways to overcome these barriers.

Site selection is either directed or approved by sponsors. Selecting centers for study accrual is a crucial component of ensuring a diverse study population. Sponsor goals for accrual have traditionally been based on study start up time (IRB approval and contracting), velocity of accrual, and total number of patients that can be accrued. While

these continue to be key factors in the selection process, focusing on sites that serve underrepresented populations, including community-based sites and academic affiliated public hospitals, should also be prioritized. These sites are often under-resourced, and many don’t have a centralized clinical trials office or clinical trials programs. Sponsor support of these sites is crucial; more resources and time may be needed to get these sites open to enroll and continue patients on trial. While it may take longer and add expense, the yield of a more diverse patient population warrants this effort.

Sponsors need to ensure appropriate financial resources are available.³⁵ For example, public hospitals, which often serve diverse communities, may need more financial support than tertiary comprehensive cancer centers.²⁶ Individual patient needs are greater in diverse communities. The implementation of diversity programs requires resources budgeted in the contracts between sponsors, site management organizations, and the individual sites. This includes funding to support issues related to SDOH (see Section III), to translate consents into languages other than English (see section VI) as well as in person interpreters. Individual sites can budget for newer AI based pre-screening programs such as Deep6²⁷ where provider implicit bias can be removed by leveraging technology; these programs require financial resources and sponsor support is critical. As previously discussed, sponsoring support of patient navigators on site and virtually to enroll and maintain these patients on trial is also key.

Other Strategies to Enhance IDEA in Gynecologic Cancer Trials

Other strategies to advance IDEA in clinical trials include addressing language and consent translations, and data disaggregation. Lack of appropriately translated clinical trial documents is hypothesized to contribute to disparities in clinical trial enrollment. In the United States, 60 million individuals do not speak English, and 25 million are defined as having limited English proficiency.²⁸ Numerous studies have established that patients with limited English proficiency are routinely excluded from clinical trials.²⁹ Of the 14,367 clinical trials registered on ClinicalTrials.gov between January 2019 and December 2020, 19% required the ability to read, speak, and/or understand English and only 2.7% specifically mentioned accommodation of languages other than English.³⁰ Interestingly, of approximately 2,500 federally funded clinical trials, nearly 29% required English language proficiency. Recent data in endometrial cancer studies from clinicaltrials.gov from 1998-2021 noted exclusion of 1 in 10 patients who were non-English speaking. Studies of behavior/quality of life were most likely to have language

exclusion as a criteria at 57%.^{31,32} Exclusion of non-English speakers from clinical trials also results from inadequate processes, limited availability of interpreters, and concerns regarding cost. The average consent form for a single clinical trial is between 20 to 30 pages, with cost to translate averaging about \$1,500 per consent in 2022. This is compounded by many amendments requiring a re-consent. Furthermore, delays in obtaining translated documentation may adversely impact enrollment on trial, as patients may be reluctant to delay initiation of anti-cancer directed therapy. Studies are commonly multinational, and efforts to enable non-English language consents to be readily available at the outset should be undertaken.

Data disaggregation, or the process of breaking up collected data into independent groups will be an important part of IDEA initiatives. Although commonly addressed in the context of Asian populations, this remains a problem across races and will require comprehensive initiatives to overcome. Asia consists of over 40 countries, and the Pacific Islands are grouped into three separate sub-regions, highlighting the importance of improved granularity in understanding therapeutic implications for these patient populations.³³ Analogously, although individuals self-identifying as White represent over two-thirds of the U.S. population, and were predominantly of Western European ancestry, persons of Middle East, North African and Eastern European descent make up an increasing proportion of this diverse population.³⁴ Lack of disaggregation may perpetuate health care inequities and limit access to novel therapeutics, and there is a strong need to continue to evolve the understanding and characterization of race and ethnicity as it pertains to clinical trials.

Lack of disaggregation may perpetuate health care inequities and limit access to novel therapeutics. Efforts to mitigate this issue include recruitment focus on small racial/ethnic groups in US; designing global studies to enhance recruitment of specific populations (Asian, Hispanic), reporting on pooled data with the same agent, and post-marketing data review to evaluate efficacy in sub-populations. Moreover, how to incorporate and account for multiracial identity and geographic factors (i.e., efficacy in Asians born in the US compared to Asian countries) in evaluating drug efficacy are other challenges. Thus, there is a strong need to improve understanding and characterization of race and ethnicity, as well as environmental, dietary and other factors, as they pertain to health-related disparities and clinical trials.

GOG Efforts to Improve Diversity in Clinical Trials

The GOG Improve Diversity in Clinical Trials (IDEA) initia-

tive is focused on four areas of improvement to better serve underrepresented patients in clinical trials: Education, Access, Research and Policy. Educational efforts include the development of DEI education modules to address commitment to DEI, community engagement, protocol design, study conduct/accountability, and advocacy. Access efforts include evaluating racial and ethnic enrollment data at all sites to determine where specific underrepresented populations receive clinical care to improve targeted site selection. Research efforts include working with trial sponsors to increase the capturing of race, ethnicity, preferred language, gender and sexual orientation, SDOH data and disaggregation of the race in upcoming phase III trials. Policy efforts include advocating for policy change such as the HR 6584 Diverse and Equitable Participation in Clinical Trials (DEPICT) Act in partnership with SGO and ASCO. This legislation would codify the draft guidance issued by the FDA in April 2022 regarding the importance of diversity in clinical trials and remove any stigmas perceived as coercion with providing resources to enable underrepresented patients to enroll on trials as well as to desegregate clinical trials by making them more physically accessible to diverse communities.

Conclusion

Health equity and social justice work to bridge the gap between the realities of clinical trials and the goal to enable access to all patients regardless of race or ethnicity is critical. Leaders in gynecologic oncology clinical trials benefit from a close-knit community where esprit de corps is a driving factor. We must home in on our shared feeling of pride, fellowship and loyalty in our commitment to clinical trial health equity initiatives to bring new treatments to all patients and ultimately improve the care for all patients.

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