



Sexual and Gender Minority Representation in Clinical Research: A Message from the President's Task Force

With this issue, the ACCC Research Review looks at how community oncology can begin to address a significant gap in cancer research—knowledge and information on care for sexual and gender minority (SGM) patients with cancer. Recognition of the myriad inequities in care access, screening, intervention, and post-treatment survivorship experienced by SGM patients with cancer continues to grow.

In 2016, the National Institutes of Health (NIH) designated SGMs as a health disparity population for NIH research. As defined by NIH, sexual and gender minorities include “lesbian, gay, bisexual, and transgender populations, as well as those whose sexual orientation, gender identity and expressions, or reproductive development varies from traditional, societal, cultural, or physiological norms.”¹

Announcing the designation, the then-Director of the National Institute of Minority Health Eliseo J. Perez-Stable, MD, acknowledged that “Mounting evidence indicates that SGM populations have less access to health care and higher burdens of certain diseases, such as depression, cancer, and HIV/AIDS. But the extent and causes of health disparities are not fully understood, and research on how to close these gaps is lacking.”

In 2019, the NIH released an updated SGM definition after consulting with several groups at the agency with “contemporary expertise in SGM health and research.” The revised definition states that:

SGM populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or

*expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.*²

The American Society of Clinical Oncology (ASCO) released a position statement in 2017 on [Strategies for Reducing Cancer Health Disparities Among Sexual and Gender Minority Populations](#).³ The statement includes recommendations in five areas aimed at addressing the needs of both SGM people with cancer and SGM individuals in the oncology workforce:²

- Patient education and support
- Workforce development and diversity
- Quality improvement strategies
- Policy solutions
- Research strategies

ASCO's statement recommends adoption of the NIH strategic plan for addressing the research needs of SGM populations. To advance research among SGM populations, ASCO recommends championing to promote "inclusion of SGM status as a required data element in cancer registries and clinical trials."³

At present, these data are still not routinely collected in clinical trials, surveys, or epidemiological studies. Without the ability to identify and reach out to SGM patient populations, research efforts are stymied.

To introduce this issue of the Research Review, we've invited 2020 ASCO Young Investigator Award recipient **Ash Alpert, MD, MFA**, to share their perspective on the path to engaging SGM patients in cancer research. With grant funding from the Conquer Cancer Foundation, Dr. Alpert is working in collaboration with a community advisory board composed of transgender people who have been diagnosed with cancer to develop gender identity data collection tools that are patient-centered and non-stigmatizing as well as to look at connections between violence, including clinician mistreatment, and cancer risk for transgender people. Dr. Alpert is a third-year hematology and medical oncology fellow at the University of Rochester Medical Center's (URMC) Wilmot Cancer Center.

Before the conversation turned to data collection, Dr. Alpert emphasized the importance of framing the discussion in the broader context of the need for inclusive healthcare services and systems.

Dr. Alpert: It's important to consider the ways that oncologic healthcare systems and healthcare systems in general render the experiences and identities of sexual and gender minorities invisible. It's in the fabric of the way we do our day-to-day business . . . in the titles of our clinics, what we mean when we use the word "sex," what bathrooms are accessible to

people, the assumptions we make about the connections between anatomy and gender, the ways we word our intake forms. The list goes on and on.

ACCC: Is greater consideration for the environment of care a step toward reducing barriers that contribute to SGM patients feeling as though there is no place that allows them to be “seen” in our healthcare delivery systems?

Dr. Alpert: There is a lot of subtlety about the ways we explicitly and implicitly communicate a sense of safety for SGM patients in our cancer centers and our clinics . . . [it] includes a lot of things that are institutional and concrete like bathrooms, names of clinics, intake forms, the way we call patients out of the waiting room, the way that we use ID bands, the gowns that we provide, and the ways that we talk about peoples’ bodies. It’s important to think about data collection as part of an overall effort to create a sense of safety and to create real safety as well.

ACCC: Yet data collection is essential so that clinicians are able to identify SGM patients in order to promote research to reduce disparities.

Dr. Alpert: The issue of data collection is complicated because there’s such a strong current moving in the direction of default assumptions around heterosexual and cisgender identities. So, we really have to go out of our way to figure out what the sexual orientation and gender identities (SOGI) of our patients are.

ACCC: Why is data collection important?

Dr. Alpert: Particularly for transgender patients, we have no good data about cancer prevalence or outcomes. We know that transgender people face incredible health disparities across medical settings, but the specific disparities in the context of cancer are unknown. Because of that, there is no good starting place to develop interventions to improve the experiences and outcomes of transgender people [with cancer]. And even if we decided that we knew what would make the experiences of transgender people better, we wouldn’t have any way to benchmark our progress because we wouldn’t know where we’d started. We don’t know what the prevalence of specific cancers are and how those may be impacted by problems accessing preventative and primary care. We don’t know what the disparities in outcomes are, and so we can’t begin to figure out how to make those better. We can’t even track patient engagement in care, which could be a way to understand if interventions that we develop and implement are making care any more accessible for patients.

Because SGM people have the pervasive experience of having our identities feel invisible, [SOGI data collection] can also suggest to patients that we know SGM people exist and that we’re ready to be present and comfortable with them.

On the other hand, a potential pitfall of SOGI data collection is that some transgender patients have had the experience of being asked about gender identify when it isn't relevant and having gender identity dwelt upon in contexts that aren't always comfortable for patients. I think we do need to be careful about how we ask and ensure that we are asking questions because they will inform our data or clinical care.

ACCC: It's a conundrum: The need to collect data while at the same time trying to establish trust and culturally appropriate education for this marginalized patient population.

Dr. Alpert: It is like we're trying to put our shoes on and run at the same time. Unfortunately, transgender patients face consistent stigmatization across healthcare contexts. We need to start collecting this data so we can begin to improve medical care, however, in some ways, we're not ready to collect the data because patients are still being so routinely stigmatized.

ACCC: The impetus for your current research grew out of an interest to collect SOGI data at URMC, is that correct?

Dr. Alpert: Yes, I was interested in collecting SOGI data at our cancer center. I went to the community advisory board I work with to talk about it. We talked about the current standard questions in use, which include two questions: one about gender and one about sex assigned-at-birth. The community advisory board didn't feel comfortable with implementing so-called two-step questions, which have been the only ones that have been tested. The advisory board members] wrote their own questions, and we received a grant from the Conquer Cancer Foundation to further develop and test them. We assembled an expert panel of transgender health researchers, talked through the questions with them, and we are piloting the questions via cognitive interviews with a small group of people. Lastly, we will test them with a survey aimed at patients and providers, which asks respondents to rate how comfortable the questions are to answer, how clear they are, and how much they allow patients to reflect their actual identities. We'll ask survey participants to evaluate them in comparison to the current questions in use.

ACCC: If we think about community oncology and the many gaps that exist in cancer research and then the gaps specifically for marginalized patient groups, what do you think needs to happen so that trials can be more inclusive?

Dr. Alpert: Throughout history, racist violence has happened under the guise of clinical trials. That remains in our thinking about relating to each other in the context of clinical trials. In order to shift that background, we're going to need to look to marginalized communities to lead us to creating clinical trials that truly meet their needs both in terms of filling gaps in communal knowledge but also in terms of safety. For SGM populations specifically, there are

ongoing issues around language that we could work on improving, which would potentially change people's relationship to clinical trials.

It would be helpful for all of us to go back to the language of our trials and consider deleting gender-exclusive language. Especially for cancers in which anatomy and gender are often implicitly linked with our language, such as breast cancer, prostate cancer, ovarian cancer, endometrial cancer, etc. It will be important to assess the ways we've linked gender and anatomy and undo this such that our trials are truly inclusive of transgender people and other people whose anatomy does not match assumptions based on gender. This would also ensure that transgender people don't need to come out in order to know if they are eligible for the trial.

In the context of clinical trial design, we must also work with marginalized community members to set priorities for clinical trials and design the trials including the exclusion and inclusion criteria. Regarding clinical care, I urge all community practices to build a formal means of getting input from local communities, especially local marginalized community members, regarding how the practices may be meeting or not meeting their needs. If we begin to build deep relationships with the communities we serve, we may be able to do work that's truly moving toward health justice for all people.

References

1. National Institutes of Health. National Institute of Minority Health and Health Disparities. Director's Message. Oct. 6, 2016. Available at https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html.
2. National Institutes of Health. Sexual and Gender Minority Research Office. "Sexual and Gender Minority Populations in NIH-Supported Research." Notice Number: NOT-OD-19-139. Released August 28, 2019. Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-139.html>.
3. American Society of Clinical Oncology. [American Society of Clinical Oncology Position Statement: Strategies for Reducing Cancer Health Disparities Among Sexual and Gender Minority Populations](#). *J Clin Oncol*. 2017;38(19):2203-2208.

Additional Resources

Alpert A, Kamen C, Schabath MB, Hamel L, Seay J, Quinn GP. [What exactly are we measuring? Evaluating sexual and gender minority culture humility training for oncology care clinicians](#). *J Clin Oncol*. 2020;38(23):2605-2609.

Griggs JJ, Alpert A. Cancer Care for Transgender and Gender-diverse Populations. ASCO elearning course. Available at <https://elearning.asco.org/product-details/cancer-care-for-transgender-and-gender-diverse-populations>.

Loftus EG. [Examining Cancer Health Disparities in the LGBTQ Community](#). Cancer Research Catalyst. [Blog post] September 22, 2019. American Association for Cancer Research.

National Institutes of Health. National Institutes of Health Sexual and Gender Minority Research Office. [NIH FY 2021–2025 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities](#).

Quinn GP, Alpert AB, Sutter M, Schabath MB. [What oncologists should know about treating sexual and gender minority patients with cancer](#). *J Oncol Pract*. 2020;16:309-316.

See accompanying commentary:

Griggs JJ. [Improving the care of lesbian, gay, bisexual, transgender, and queer people with cancer through transformational approaches](#). *J Oncol Pract*. 2020;16:317-318.

More on Data Variables and Collection from the MRCT Guidance

The Multiregional Clinical Trials (MRCT) Center of Brigham and Women’s Hospital and Harvard comprehensive guidance document on [Achieving Diversity, Inclusion, and Equity in Clinical Research](#) discusses the critical role that collection of demographic and non-demographic data variables play in clinical research in Chapter 11. The authors note that “lack of uniformity in the collection and reporting of common demographic and non-demographic variables, including age, race, ethnicity, sex, gender, and social determinants of health, both within and across different therapeutic areas in clinical research” currently constrains data utility and progress.¹ (p.150)

Section 11.4 (pp. 170–75) discusses sex and gender in relation to data variables and collection. The MRCT diversity framework “draws on” the World Health Organization (WHO) definitions of “sex” and “gender.” However, Table 9 (pp. 171–72) illustrates current variations in definitions of “sex” and “gender” among U.S. federal agencies, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and WHO.

Data standards for collecting sex and gender information are covered in section 11.4.1, which includes examples of several models for capturing gender categories (pp. 173–74). In concluding the discussion, the authors state that: “Future work is necessary to standardize data collection fields and variables for gender and gender identity in order to understand their influence and impact on health, disease, and treatment.”¹ (p. 175) For the present, to help with “consistent data collection of clinical research demographic and nondemographic data,” a standard data collection tool, titled the “Data Variables Tool,” devised by the MRCT Center Diversity Workgroup, is included in the guidance’s companion Toolkit.² (p. 20)

References

1. Bierer BE, White SA, Meloney LG, Ahmed HR, Strauss DH, Clark LT. (2020) *Achieving Diversity, Inclusion, and Equity in Clinical Research Version 1.0*. Cambridge and Boston, MA: Multi-

Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Available at <https://mrctcenter.org/diversity-in-clinical-trials/>.

2. Bierer BE, White SA, Meloney LG, Ahmed HR, Strauss DH, Clark LT. Achieving Diversity, Inclusion, and Equity in Clinical Research: Toolkit. Available at <https://mrctcenter.org/diversity-in-clinical-trials/>.

National LGBT Cancer Network Shares Resources to Close Care Gaps for LGBTQI+ People

By Scout, MA, PhD

Scout, MA, PhD, is Executive Director of the National LGBT Cancer Network.

The [National LGBT Cancer Network](#) is a resource that can help community cancer care providers reduce barriers to care and become more inclusive for LGBTQI+ communities. The Network works to improve the lives of LGBTQI+ cancer survivors and those at risk of cancer by:

- Educating the LGBTQI+ community about increased cancer risks and the importance of screening and early detection;
- Training healthcare providers to offer more culturally competent, safe, and welcoming care; and
- Advocating for LGBTQI+ survivors in mainstream cancer organizations, the media, and research.

As outlined in [Cancer and the LGBT Community: Unique Perspectives from Risk to Survivorship](#), LGBTQI+ communities have a history of barriers to healthcare, increased risk factors for cancer, and decreased satisfaction with care. A decade ago, the National LGBT Cancer Network conducted a study that asked LGBTQI+ cancer survivors what they wanted their healthcare providers to know about their care experience. The [findings were stark](#): struggles to find welcoming providers, fear with every new provider interaction, and emotional scars from previous lived experience of discrimination and rejection such as being shunned by our family. The topline takeaways from the study: Show us you are welcoming and put some effort into making that welcome real.

Where to Start?

At every one of our provider trainings, we recommend starting with a scan of your services. Look from the outside in. How and where could LGBTQI+ patients learn that your cancer program and providers are welcoming? Is it pushed out in your media? Is it on your website? In your forms? On your office walls? In the training of clinical and non-clinical staff, including front-desk personnel?

The National LGBT Cancer Network has resources that can make many of these steps easier. Healthcare organizations can take advantage of [free membership in the LGBT Cancer Network](#) and cobrand our resources with your facility's logo.

Organization social media outlets can be a good jumping off point. As an example, tobacco use in LGBTQI+ communities is 50% higher than in the general population. For programs conducting quality or process improvement initiatives related to reduction of cancer risk through tobacco cessation and screening programs, the LGBT Cancer Network has two series of social media shareable ads (in English and Spanish) that can be customized and added to your feed as part of our Out, Proud & Free campaign. We have cancer-focused shareables and resources on COVID, as well. Other materials available include:

- [The LGBT Cancer Network newsletter](#) with articles to share.
- Cancer information cards for the waiting room, which can be branded and printed for your organization.
- Welcoming wall signs—available soon, our “Good to See You” signage for physician offices.
- Self-standing counter cards for use in cancer clinic offices.
- Webinar on how to collect LGBTQI+ data on your EHR.

These resources and many more are available in our [online resource library](#). Do you need cultural competency training for your staff, customized technical assistance (TA), or even just a few small questions answered? Email us at info@cancer-network.org.

Building Trust

The first step in engaging the LGBTQI+ communities in cancer research is building trust. The truth is we are not used to seeing this kind of welcome at health facilities, so taking the above actions will be noticed and begin to foster community trust. Of course, we always suggest you do this with internal advisors. As our [best practices document](#) outlines, consider convening an expert advisory group from your own staff first, then recruit community leaders (with compensation) to fill in gaps and further spread the news that you are serious about this work.

One more powerful thing we can offer to accelerate your organizational engagement with the LGBTQI+ communities. That decade old cancer survivor survey is getting updated! **Out: The National Cancer Survey** is now in the field. Help improve knowledge of the experience of cancer survivors from LGBTQI+ communities. Organizations that commit to promoting the survey three times through social media channels,



or through posters on-site, will be listed as promotional partners in the final report. All partners will receive a set of tools to promote their participation in this key benchmark study. If your organization is committed to improving diversity and equity in cancer research, please partner with us. Access the partner form [here](#).

Related Resources

Upcoming FDA Webcast on Diversity in Clinical Trials

On **December 16, 1:00 – 2:30 PM EST**, the Food and Drug Administration (FDA) will host a webcast on CDER's most recent assessment of clinical trial diversity and discuss efforts to advance diverse participation in clinical trials, including FDA guidance and regulations. In this era of globalization, meeting various regulatory authorities' expectations in recruitment of diverse trial population is challenging. The need for faster drug development and shorter recruitment timelines make this important part of drug development even harder. CDER has pooled and analyzed five-years of demographic data from NME and original BLA approvals presented in Drug Trials Snapshot 2015-2019. In addition to sharing the observations and trends from trials of over 290,000 participants, the webinar will provide the FDA's expectations regarding representation in clinical trials and various initiatives that were developed to help industry, recruitment sites and the public in general achieving these expectations. [Learn more and register](#).

Leaning In: MRCT on Inclusivity and Equity in Clinical Research

The Multi-Regional Clinical Trials Center's *Leaning In* webinar series explores the organization's guidance on [Achieving Diversity, Inclusion, and Equity in Clinical Research](#). A recording and slides from the November 18 webinar on "[Study Design, Eligibility, Site Selection & Feasibility](#)" features Rachael T. Fones, Director, Government & Public Affairs, IQVIA, and Theresa Devins, DrPH, Associate Director, Global Trial Optimization, Global Clinical Operations, Regeneron. In her presentation, Dr. Fones discusses how lessons learned during the COVID-19 pandemic will likely change clinical trial design going forward.

The Role of Tissue Acquisition in Advancing Community Precision Oncology

As clinical research becomes a larger part of community cancer center operations, strengthening tissue collection procedures and considering the establishment of biospecimen repositories are critical concerns. On **December 17, 3:00 – 3:45 PM EST**, ACCC will host a live discussion about key issues in high integrity tissue acquisition facing community cancer programs. Panelists Lawrence D. Wagman, MD, and Michelle Shiller, DO, AP/CP/MGP, will share their perspectives and best practices on how much, when, and from

which sites tissue and other biopsy samples should be collected, how the goals and aims of tissue acquisition impact precision patient care, and more. [Learn more and register](#).

The **ACCC Research Review** newsletter is developed as part of the 2020-21 ACCC President's Theme. Its goal is to help bring research opportunities into community practices/programs to ensure that all Americans may benefit equally from cancer research. For additional resources and to learn how your cancer center can become involved, please visit acc-cancer.org/president-20-21.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit acc-cancer.org or call 301.984.9496. Follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), and [Instagram](#); read our blog, [ACCCBuzz](#); and tune in to our podcast, [CANCER BUZZ](#).