







# Strategies for Advancing Sexual Orientation and Gender Identity Data Collection in Cancer Research

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## INTRODUCTION

Although over 7% of American adults identify as lesbian, gay, bisexual, transgender, queer, intersex, or asexual (LGBTQIA+),<sup>1</sup> there is a dearth of cancer research in these populations. As such, there is broadening awareness of the need to collect sexual orientation and gender identity (SOGI) data as part of cancer research to produce appropriate evidence-based guidelines to inform clinical care and prevention efforts for LGBTQIA+ individuals in the future.

The Sexual and Gender Minority (SGM) Interest Group of the National Cancer Institute (NCI) Cohort Consortium consists of extramural and intramural cancer researchers interested in conducting SGM research within the consortium. A committee was formed from the Interest Group to develop SOGI measures for use by consortium members to voluntarily implement into existing and newly developed cancer research studies. This committee is made up of seven researchers and clinicians with expertise in SGM health, cancer, study design, and SOGI data collection in clinical, research, and population surveillance contexts. The committee encourages SOGI data collection in all cancer research, as data can be pooled across studies to facilitate the type of high-quality research on cancer in SGM populations that is currently lacking.

## THE SIGNIFICANCE OF SOGI DATA IN CANCER RESEARCH

There are unique challenges related to cancer care that need specific attention when addressing disparities in LGBTQIA+ populations, including (1) elevated prevalence of risk factors for certain cancers,<sup>2</sup> (2) delayed diagnosis and treatment,<sup>3</sup> (3) tailored screening approaches,<sup>4,5</sup> (4) psychological and social factors,<sup>6,7</sup> and (5) oncofertility concerns.<sup>8</sup>

Another significant challenge in conducting research in this area is the relatively small number of LGBTQIA+ patients within individual cancer cohorts, which often limits the possibility of statistically robust analysis. Therefore, there is a pressing need to establish standardized data collection methods for LGBTQIA+ individuals within cancer cohorts. This will enable the aggregation of data across multiple cohorts, facilitating large-scale pooled analysis and ultimately leading to more meaningful and actionable conclusions. However, there is limited consensus on best practices for SOGI data collection in cancer research.

## CRITIQUE OF CURRENT SOGI DATA COLLECTION MECHANISMS

In 2022, the National Academies of Sciences, Engineering, and Medicine (NASEM) published a consensus report on the collection of sex, gender identity, and sexual orientation.<sup>9</sup> The NASEM report was commissioned by the National Institutes of Health to evaluate existing measures of SOGI and to recommend specific measures to be used in federal data collection efforts. The NASEM report also recommends that additional research should be conducted to improve the quality and inclusivity of these existing SOGI measures. As such, we found several opportunities to enhance these measures, which are outlined below.

First, some response options in the NASEM recommendations lacked face validity and were incomplete. For example, the NASEM report included response options “female” and “male” (constructs that refer to sex assigned at birth) rather than “man” and “woman” (constructs



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that refer to gender) for the gender identity question.<sup>9</sup> Additionally, NASEM indicates that respondents should select only one response option for this question (eg, “male,” “female,” or “transgender”), forcing a person assigned male at birth who identifies as a woman to choose between “female” and “transgender.” The lack of “cisgender” as a response option reinforces cisgender identities as the norm, resulting in the othering of transgender persons. It is imperative that the response options have validity among all LGBTQIA+ persons to prevent misclassification. Evidence suggests that SGM individuals identify with SOGIs beyond those in the current recommendation, which will only increase in younger cohorts.<sup>10</sup>

Some of the NASEM measures and response options for sexual orientation measures include unnecessary information, such as “that is not lesbian or gay” after the response option “straight.” The addition of this information was originally added to help with clarity for low-literacy groups and people who may be unfamiliar with sexual orientation terms; however, the growing awareness of these terms renders the language unnecessary and potentially more confusing.

We also found that the “select one” format is problematic. In our own research, the “select one” instructions limited the ability to capture how an individual thinks of their own identity. As a result, some respondents may perceive this as an indication that the researcher or clinician does not have an adequate understanding of the concept or lived experiences of SOGI, which may diminish their motivation to complete the questions. Although we acknowledge that allowing individuals to choose more than one category makes data analysis more challenging, the authors center this revision in the lived realities of people to advance meaningful science in real-world practice.

There can be many reasons for nonresponse of SOGI items. Nonresponse may reflect fears of disclosing one’s sexuality, political or personal aversion to the question, and/or limited understanding of the construct being collected. This is particularly true for cancer studies with older, mostly heterosexual, participants. A follow-up question to better understand “don’t know” or “prefer not to answer” responses can help refine SOGI questions.

Finally, the report did not provide a recommendation for an organ inventory. An organ inventory is relevant to studies that need to identify individuals eligible for certain cancer screenings or who are at risk for cancer at specific organ sites, such as those at risk for hormone-related cancers or those not at risk for a particular cancer because of organ removal. Although some individuals may be unaware of which organs were removed during surgery (eg, hysterectomy with removal of the cervix), studies, such as the Patient-Centered Outcomes Research Institute–funded PRIDE Study,<sup>11</sup> have successfully used these types of organ

inventories (Stanford University School of Medicine) to collect these data. Increased collection of these data will improve the accuracy of risk estimates and improve our understanding of cancer risk across all people, regardless of sexual orientation or gender identity.

## STRATEGIES FOR IMPROVEMENT

The SOGI committee of the SGM Interest Group met from April 2022 to June 2023 to discuss optimal collection of SOGI data elements in cancer research. The committee reviewed the NASEM recommendations, existing literature, and provided their own professional and lived experiences to refine the consensus strategies below, while acknowledging that the field continues to evolve as the evidence base grows. The proposed SOGI measures were developed on the basis of the consensus of the committee. The committee attempted to balance the need for inclusiveness of LGBTQIA+ individuals with the needs of the study population likely to make up the majority of participants in cancer cohorts and clinical trials (eg, heterosexual, cisgender adults, age 50 years and older).

Our proposed updates are summarized in [Tables 1](#) and [2](#). The original items and response options from the NASEM report (2022)<sup>9</sup> are outlined along with revised SOGI measures, and the committee’s rationale. On the basis of the research questions being investigated, we provide suggestions for core ([Table 1](#)) and ideal/optional ([Table 2](#)) SOGI measures that we suggest cancer researchers use. The Appendix shows the flow of the measures if implemented on a data collection form as suggested. We considered the following changes in five core areas.

1. Gender identity response options
  - Replace “female” and “male” options with “man” and “woman” to accurately represent gender rather than sex assigned at birth.
  - Introduce an option to select “all that apply” rather than limiting respondents to a single choice.
  - Include “cisgender” as a response option to prevent the othering of transgender persons.
2. Sexual orientation measures
  - Remove redundant clarifications, like “that is not lesbian or gay” following the option “straight.”
  - Include a well-known term, “heterosexual,” for clarity.
  - Change the instruction from “select one” to “select all that apply” to be more inclusive and avoid misinterpretations about the researcher’s understanding of queer experiences.
3. Understanding nonresponses
  - Add an optional question to ascertain reasons for choosing “don’t know” or “prefer not to answer” for the sexual orientation measure.
4. Intersex status collection
  - Avoid a purely medicalized frame for capturing intersex status, as it might be problematic for certain populations.

**TABLE 1. Original and Revised Sexual Orientation and Gender Identity Items and Rationale for the Core Measures**

Construct	Original Item	Original Response Options	Source	Revised Item	Revised Response Options	Rationale
Sexual orientation	Which of the following best represents how you think of yourself? [select one]	Lesbian or gay Straight (ie, not lesbian or gay) Bisexual [If respondent is AIAN:] Two-spirit I use a different term [free text] Don't know Prefer not to answer	NASEM Guidelines	Q1. Which of the following best represents how you think of yourself? [check all that apply]	Straight or heterosexual Lesbian or gay Bisexual [If respondent is AIAN:] Two-spirit I use a different term [free text] I don't know Prefer not to answer	The committee felt it best to reorder the question so that the majority of the population would have their answer at the top of the response option list We also changed the instructions to allow respondents to choose all that apply. Restricting responses to one option has been perceived as a sign of untrustworthiness for some LGBTQIA+ respondents For the option of two-spirit for American Indian/Alaska Native individuals, please note this is a modern pan-Indian term and not all individuals will identify with this description
Sex assigned at birth	What sex were you assigned at birth, on your original birth certificate?	Female Male Don't know Prefer not to answer	NASEM Guidelines	Q2. What sex were you assigned at birth, on your original birth certificate?	Female Male Something else (for example, "X," the legal designation used in some states) I don't know Prefer not to answer	To ensure face validity, the committee added a third option, so that someone with a sex marker other than male or female has an appropriate response option The committee acknowledges that adding an option for "something else," such as X, should be considered for addition in the future. X has only recently been provided as an option in some states
Intersex conditions	Option 2: Were you born with a variation in your physical sex characteristics? (this is sometimes called being intersex or having a difference in sex development)?	Yes No (don't know) (prefer not to answer)	NASEM Guidelines	Q3. Were you born with a variation in your physical sex characteristics? (this is sometimes called being intersex or having a difference in sex development)?	Yes No I don't know Prefer not to answer	This option is preferred by InterACT and the committee felt that this was the simplest and most direct way of asking this question of all options currently used in the literature
Gender identity	What is your current gender? [mark only one]	Female Male Transgender [If respondent is AIAN:] Two-spirit I use a different term: [free text] Don't know Prefer not to answer	NASEM Guidelines	Q4. Which of these apply to you? [check all that apply]	Man Woman Cisgender (for example, you were assigned female at birth and you're a woman) Transgender (for example, you were assigned male at birth and you're a woman) Nonbinary [If respondent is AIAN:] Two-spirit I use a different term: [free text] Prefer not to answer	The committee felt that it was important to allow people to check all that apply to them and to allow transgender people to identify as "man" or "woman" (rather than "male" or "female" per the NASEM report) in addition to or instead of "transgender" if they choose. The committee also felt it was important to add "cisgender" so as not to assume cisgender status with the selection of "man" or "woman," and to define the terms cisgender and transgender to minimize potential confusion Both Q2 and Q4 should be included together to accurately collect sex assigned at birth and gender identity. Consider including Q2 on all follow-up questionnaires as well as baseline assessments as gender identity may change over time. For studies that wish to examine biologic exposures, cancer screening, or cancer risk, an organ inventory (below) should also be included. Q2 is not a substitute for a comprehensive organ inventory

Abbreviations: AIAN, American Indian/Alaska Native; NASEM, National Academies of Sciences, Engineering, and Medicine.

**TABLE 2.** Original and Revised Sexual Orientation and Gender Identity Items and Rationale for the Optional Measures

Construct	Original Item	Original Response Options	Source	Revised Item	Revised Response Options	Rationale
Sexual orientation				Q1a. (If "I don't know" or "prefer not to answer" is selected). You did not enter an answer for the previous question. Is that because	You don't understand the words You understand the words, but you have not figured out your sexuality or are in the process of figuring it out You mean something else, please specify [free text] You don't want to answer the question You don't know	The committee added this optional question to understand why respondents might answer "don't know" or "prefer not to answer."
Organ inventory	To understand your health and customize this survey for you, we need to know what organs you were born with. People have a wide range of language or terms for their physical anatomy (not all of which are listed here). Which of the following organs were you born with? (check all that apply)	Cervix Ovaries Penis/phallus (not including a prosthetic) Prostate Testicles Uterus/womb Vagina/frontal genital opening	PRIDE Study	Q5a. To understand your health, we need to know what organs you were born with. People have a wide range of language or terms for their physical anatomy (not all of which are listed here). Which of the following organs were you born with? [check all that apply]	If you were assigned female sex at birth, you may have had Cervix Ovaries Fallopian tubes Uterus/womb Vagina/frontal genital opening If you were assigned male sex at birth, you may have had Penis/phallus (not including a prosthetic) Prostate Testicles	These items and response options were adapted and separated for clarity and response succinctness
Organ inventory	Have you ever had breasts or breast tissue?	Yes No I don't know	PRIDE Study	Q5b. Have you ever had breasts or breast tissue growth as a result... [add skip logic to exclude cisgender men from this question]	Puberty/hormones already in your body Hormones you took (pills, shots, patches, etc) No I don't know	These organ inventories were adapted from The PRIDE Study's <sup>1</sup> organ inventories. We have included organs that are sometimes removed to help research inform future clinical care management and epidemiologic studies
Organ inventory	Which of the following organs do you have now? (check all that apply)	Breasts or breast tissue Cervix (you likely have this if you have a uterus or womb) Ovaries Penis/phallus (not including a prosthetic) Prostate (you likely have this if you were assigned male sex at birth) Testicles Uterus/womb Vagina/frontal genital opening	PRIDE Study	Q5c. Please indicate if you've had any of these organs removed. [check all that apply]	Appendix Breasts or breast/chest tissue Cervix Fallopian tubes Gallbladder Kidney Ovaries Penis/phallus Prostate Testicles Tonsils Uterus/womb Vagina/frontal genital opening Any other organ not listed [free text]	

- Adopt the NASEM suggested intersex measure (option 2) but acknowledge its limitations regarding variations over one's lifespan.
5. Organ inventory questions
- Incorporate optional questions about organs at birth and current organs to inform clinical care and research data.
  - Frame questions about organs removed rather than retained, as individuals are more likely to be aware of their surgical history.
  - Include nonreproductive organs in the inventory to prevent the othering of certain groups and to gather data on surgeries that can affect cancer risk measurements (eg, cholecystectomy).

## RELEVANCE TO BROADER CLINICAL PRACTICES AND POLICIES

These measures can be used as a resource for principal investigators of cohort studies within the NCI Cohort Consortium and other studies to advance cancer research and clinical practice through the addition of SOGI data collection. These data collection refinements are highly relevant as national bodies—such as the US Preventive Services Task Force (USPSTF), ASCO, and the National Comprehensive Cancer Network<sup>12</sup>—are increasingly recognizing that SOGI data collection is a critical to optimize screening and clinical care guidelines for all persons. The USPSTF, which creates guidelines for clinical preventive services, have changed how they are assessing sex and gender when creating and revising guidelines. They recognize that the constructs of sex and gender need to be clearly and systematically collected in clinical care and research settings to advance clinical care.<sup>13</sup>

## MOVING FORWARD: NEXT STEPS AND CONSIDERATIONS

Our proposed SOGI measures need to be evaluated for face validity, acceptability, inclusivity, and comprehension among LGBTQIA+ and straight, cisgender populations. The next step for the committee is to conduct cognitive testing of the measures (currently underway). Cognitive testing of these items is essential to ensure that they have face validity and are understood by a broad spectrum of people (eg, diverse queer and older cisgender straight adults). These measures should not be viewed as static. The expression of SOGI is dynamic and may change over the individual's lifetime. Therefore, we encourage researchers who adopt

these measures to ask SOGI again in follow-up surveys past the baseline assessment. Furthermore, as our understanding grows of how individuals' identities are expressed, we may need to modify these data elements again in the future.

## LIMITATIONS AND CAUTIONS

The working group acknowledges that the refinements articulated here do not represent the preferences or experiences of all queer people. Notably, terms such as “same gender loving” that are more often used in communities of color have not been included in these structured data options—likely, because they have not been included in past data collection instruments and were not available for the evidentiary review of NASEM committee. Although write-in options are intentional and encouraged, it will be important to monitor how respondents use language and how it changes over time to ensure inclusive and equitable data collection. We also acknowledge the challenges of allowing “select all” for all questions. However, the risks of forcing an individual to falsely select one box is antithetical to many queer peoples' identity; thus, we encourage the research community to test ways to stratify and analyze data in ways that align with the lived experiences of the people we ask to participate in our research. Finally, a note of caution that researchers should examine data carefully to ensure that “two spirit” refers to those with American Indian and Alaska Native family history (including individuals with multiethnic heritage) and is not co-opted by other communities.

In conclusion, we are grateful to the NASEM committee for starting the conversation on the collection of SOGI data as these are critical constructs to measure. However, as the authors of the NASEM report note, current options for data collection lack face validity and inclusivity. The strategies we present aim to remedy some of these limitations and develop standardized data collection methods for use in cancer research while the field continues to evolve. The committee believes we should not be constrained by the limitations of previous research that used constructs that limited the degree of LGBTQIA+ -identifying persons' endorsement and experience. We provide these measures to add to the evidence on the basis of lived experience as LGBTQIA+ people, as well as researchers and allies invested in more accurate, affirming, and person-centered data collection, measurement, and analysis.

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## DISCLAIMER

The opinions expressed by the authors are their own and this material should not be interpreted as representing the official viewpoint of the US Department of Health and Human Services, the National Institutes of Health, or the National Cancer Institute.

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