LGBTQ+ Inclusion in Cancer Clinical Trials

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LGBTQ+ Inclusion in Cancer Clinical Trials

Report

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Prepared for:

ACON and Cancer Institute NSW

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Acknowledgement of country

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Executive summary

This report presents the findings from a research project on current LGBTQ+ inclusion in cancer clinical trials in NSW and recommendations on initiatives to increase LGBTQ+ participation in these trials. The project is part of the NSW LGBTIQ+ Health Strategy and the ongoing partnership between ACON and Cancer Institute NSW.

The project centres on current practices in data collection and reporting, and underlying issues for researchers, clinicians and patients in collecting data and disclosing sexuality and gender. Key questions that guided the research are:

- What are current practices in collecting and using gender and sexuality data within cancer clinical trials?
- Why is gender and sexuality data
    - clinically relevant for cancer clinical trials?
    - socially relevant for cancer clinical trials?
    - scientifically relevant for cancer clinical trials?
- How would collecting and reporting gender and sexuality data affect
    - cancer care and outcomes for LGBTQ+ cancer patients?
    - cancer clinical trials?
- What barriers exist to asking cancer patients their gender and sexuality?
- What gender and sexuality data should be collected and reported in cancer clinical trials?
- What needs to be considered in using the ABS Standard 2020?
- What needs to be considered for the forthcoming single medical record across the NSW Health system?

This study involved two key stages, a **scoping review** to map out what is known about the collection of gender and sexuality data in cancer clinical trials, and **key informant interviews** with professionals working in cancer clinical trials to understand current practices and attitudes, and barriers and facilitators.

Scoping review

The evidence base on the collection of gender and sexuality data in cancer clinical trials, and perceptions among healthcare professionals as to the barriers and facilitators to collecting this data, is small, but our scoping review identified a range of important insights regarding data collection protocols, processes and practices that might aid greater inclusion of LGBTQ+ people in cancer research. The most important of these are:

- There is a lack of clarity around the definition of ‘under-served’ or ‘under-represented’ population groups, as LGBTQ+ communities are frequently described. Gender and sexuality are not one category of ‘under-served’ groups, and LGBTQ+ communities should be specifically recognised

rather than bundled into broader categories of under-representation.

- There is scope to make changes to data collection practices in trials, and to improve data on gender and sexual identity.
- Opportunities to improve strategies to reach LGBTQ+ communities could encourage greater cancer trial participation. One study, for example, developed a roadmap (detailed below) to respond to under-representation in trials through the wider study processes, which provides a structure for both future research and for initiatives to address barriers to participation.

Interviews

The analysis of key informants identified several key themes:

- Key barriers to LGBTQ+ inclusivity in cancer clinical trials included:
    - a lack of LGBTQ+ training, which left some key informants reporting that they felt underprepared, either in terms of communication or on specific issues such as interactions between hormone replacement therapy for trans people and specific cancer treatments. Indicative of the need for further training, one key informant did not believe that LGBTQ+ patients needed to be approached any differently, and that they treat all patients the same.
    - clinicians and the health system often make assumptions about the gender and sexuality of patients, primarily by not asking people about their sexual orientation or gender identity. Key informants who attempted to avoid assumptions and directly ask patients (e.g., 'what is your sexual orientation?') sometimes found this challenging with some patients, such as older populations.
    - systemic and structural issues, such as exclusionary language in trial eligibility and information (being cisnormative or heteronormative), and some areas of cancer care being particularly gendered (e.g., relating to reproductive organs).
- Key facilitators of LGBTQ+ inclusivity in cancer clinical trials included:
    - the use of inclusive signs and symbols, such as badges and posters, could help to create an inclusive space and help patients to feel comfortable disclosing their sexual orientation and gender identity.
    - engaging with LGBTQ+ training was useful for key informants who had the opportunity to do so, as they felt more confident about working with LGBTQ+ patients.
    - emphasising that inclusivity is a key part of building capability for the workplace and person-centred quality care and has benefits for promoting care and outcomes.
- Regarding data collection related to LGBTQ+ people, key informants generally wanted this data collection to be mandated as a requirement of running cancer clinical trials, and they believed questions about sexual orientation and gender identity could be asked as part of intake forms for trials or for the clinic.
    - Some key informants also explained that referrals from other clinical services would be an ideal place to emphasise that a patient is LGBTQ+, although as part of the trial intake process, key informants explained that they tend to take their own history in any case.

Recommendations

The following bullet points summarise key recommendations based on the findings of this report. Action items based on these recommendations can be found in Table 1:

- To improve LGBTQ+ inclusivity of cancer clinical trials, all institutions involved in cancer clinical trials should collect data in line with the 2020 Australian Bureau of Statistics standard on sex, gender, variations in sex characteristics, and sexual orientation (Australian Bureau of Statistics, 2020), and the 2024 NHMRC Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research (National Health & Medical Research Council, 2024):
    - Human ethics committees should promote and monitor these standards across applications, including cancer clinical trials.
    - Leading institutions supporting cancer clinical trials should promote standards in data collection forms and quality assurance.
    - Governments should mandate policy to reinforce these standards.
    - In addition to collecting data in line with the ABS standard, particular attention needs to be paid to the use of language across clinical trial materials, including clarifying whether instances of man/woman or male/female are inclusive of cis and trans people, and avoiding implying that particular organs only belong to certain genders.

- Clinical settings involved in cancer clinical trials should review and improve medical record systems to be able to display information in line with ABS standard and enable collection and display of patient pronouns:
    - Trials databases should include fields reflecting the ABS standard, along with patient pronouns.
    - Single electronic medical record should include fields reflecting the ABS standard, along with patient pronouns.

- Enhanced training opportunities and resources are needed to support LGBTQ+ inclusive care and inclusion of LGBTQ+ in cancer clinical trials. Where possible, this training should be mandated, including by developing a standard training package for those involved in cancer care and cancer clinical trials:
    - Promote existing LGBTQ+ cancer care training available on eviQ to all cancer clinical trials networks. See: LGBTQ communities and cancer care | eviQ Education
    - Consolidate existing LGBTQ+ inclusive resources to make available to support clinics.
    - Develop new LGBTQ+ inclusive resources and training to promote to cancer clinical trial teams, including supporting staff on how to collect data according to the ABS standard.

Table 1: Action Items Based on Recommendations

Action Items	Who is it targeting?	When?	Who is responsible?
1. Develop list of existing LGBTQ+ inclusive resources (links to guidelines and websites, training packages, support organisations, where to find LGBTQ+ flags and pronoun badges, easy summary of ABS statement questions) that can be used to promote to cancer clinical trial teams.	Cancer clinical trial teams	6 months	ACON
2. With support from the Ministry of Health, write letters to chairs of human ethics committees in NSW at local health districts and universities to promote the ABS standard, the ACON RERC, and other LGBTQ+ inclusive resources (action item 1).	Human research ethics committees in NSW	12 months	ACON Ministry of Health
3. Advocate to NHMRC to promote ABS standard to ethics committees and in the national ethics statement.	NHMRC	12 months	ACON
4. Advocate to Cancer Australia for minimum dataset that includes ABS standard questions.	Cancer Australia	12 months	ACON Cancer Institute NSW
5. Co-design guidelines for LGBTQ+ inclusivity in cancer clinical trials that includes a focus on integrating ABS statement questions, recording pronouns and preferred names in electronic medical systems, improving language in trial information (e.g., participant information statements), discussing hormone replacement therapy and trial eligibility, and how to approach conversations about fertility and pregnancy.	Cancer clinical trial teams	24 months	ACON Cancer Institute NSW
6. Develop co-designed training package for LGBTQ+ inclusivity in cancer clinical trials. Co-design should involve both LGBTQ+ people and health providers and address similar range of activities as action item 1.	Cancer clinical trial teams	24 months	ACON Cancer Institute NSW

1. Introduction

Ensuring that LGBTQ+ individuals have access to clinical trials is vital for scientific representativeness and upholding human rights, particularly the right to health. It's important that trials neither exclude sexuality and gender diverse people explicitly – through direct exclusion criteria – nor implicitly, through the use of exclusionary cisnormative and heteronormative language. It is also essential that their participation is accurately documented. Without proper data on sexuality and gender, trials risk reinforcing cisnormative and heteronormative biases, limiting their applicability and effectiveness in these communities.

Research indicates that LGBTQ+ individuals may have unique experiences with cancer compared to cisgender and heterosexual people, particularly trans and gender diverse individuals who may encounter barriers due to gender affirming hormone use or exclusionary language in clinical trials, especially for cancers affecting reproductive or genital systems (Lee & Streed, 2024). Despite assumptions of underrepresentation, a 2012 US survey found higher participation rates among lesbian, gay, and bi+ individuals in cancer clinical trials, possibly due to later cancer diagnoses, meaning people had fewer evidence-based treatments or they had exhausted available treatment options. However, there is a lack of documented trans participation in clinical trials, as shown in clinicaltrials.gov (Ludmir et al., 2020). Ensuring equal trial opportunities for LGBTQ+ people and making their participation visible is crucial for equity, non-discrimination, and research integrity, allowing for a thorough analysis of sex and gender-based impacts on trial outcomes.

In addition, previous studies highlight a scarcity of evidence guiding design of cancer screening and prevention interventions for LGBTQ+ communities (Drysdale et al., 2021). Effective inclusion in clinical trials requires careful consideration of recruitment and adaptation strategies tailored to LGBTQ+ needs. This includes a call for stronger links between community-based research on LGBTQ+ cancer needs and intervention development (Drysdale et al., 2021).

Rationale

Recommendations from national guidelines offer guidance for how and when to collect data on gender and sexuality (Australian Bureau of Statistics, 2020; National Health & Medical Research Council, 2024). There is strong evidence that most gender and sexuality diverse people are willing to report or disclose their gender and sexuality (Cahill et al., 2014; Kamen et al., 2015; Haider et al., 2017; Haider et al., 2018). Equally, research by Drysdale et al. (2024) indicated that health promotion policymakers and practitioners support using inclusive, de-gendered, or gender-neutral language in medical specialities often grouped under ‘gendered’ terms, such as ‘women’s health’. Systematic collection of gender and sexuality data in cancer clinical trials would allow researchers to document, and explore further, any disparities in cancer incidence, morbidity, and mortality; to assess differences in treatment outcomes by gender and sexual orientation; and, enable the appropriate annotation of gender and sexuality in medical records – all of which would facilitate tailoring of interventions for gender and sexuality diverse people to ensure equity in the healthcare system. Despite clear benefits of gender and sexuality data collection, there is evidence that many healthcare providers do not routinely ask about gender identity and sexual orientation (Dahan et al., 2008, Durso

& Meyer, 2013, Quinn et al., 2015). Beyond gender and sexuality, the structure and infrastructure of clinical trials are recognised as barriers to inclusion, given that they often seek narrowly defined, homogenous populations to reduce variance (Cherubini et al., 2011). Recruitment and trial logistics also present barriers, with funders often demanding rapid recruitment, hence over representation of easier-to-recruit groups (Quay et al., 2017).

Study objectives

The primary objectives of this study were to develop:

- a clear understanding of the current state of LGBTQ+ data collection: rationale and importance, current practices and attitudes, and barriers and facilitators.
- recommendations for practicable actions and behaviours to support healthcare workers and researchers to facilitate inclusion of LGBTQ+ data in cancer clinical trials in NSW.

2. Methods

This study involved two key stages, a **scoping review** to map out what is known about the collection of gender and sexuality data in cancer clinical trials, and **key informant interviews** with professionals working in cancer clinical trials to understand current practices and attitudes, and barriers and facilitators.

2.1 Scoping review

A scoping review provides a transparent, rigorous and structured process for mapping the literature in order to explore the breadth of existing research—and to identify knowledge and research gaps—on a specific topic of interest, especially where there is limited published research (Arksey & O'Malley 2005). Unlike narrative reviews, scoping reviews require 'analytical reinterpretation' of the published study findings, rather than only repeating results, which is valuable for assessing the scope and contribution of the research available (Levac et al., 2010). However, compared to systematic reviews, scoping reviews do not focus on evaluating the methodological quality of the studies appraised, thus there is greater flexibility in looking across a diverse range of study types and determining what their findings add that is useful (Arksey & O'Malley 2005).

The following question was used to guide the scoping review: What do we know about the collection of gender and sexuality data in cancer clinical trials, current practices, and perceptions among healthcare professionals as to the barriers and facilitators to collecting this data?

This review examined peer-reviewed academic literature published from 1 January 2019 to 3 June 2024. Relevant literature was identified by searching key databases with consistent search parameters and using EndNote as a data management tool (see Table 2 for a list of databases and search parameters and Figure 1 for a chart of the selection process). Because scoping review methodology recommends search parameters which result in a relatively limited number of eligible studies, we focussed on the peer-reviewed literature – which also provides an additional level of trustworthiness to our findings. Independent screening was conducted by one author, which was reviewed and verified by other members of the research team. Six publications were identified as eligible for inclusion in the final analysis, an amount that is well aligned with the scoping review methodology (see Table 3). Following the scoping review processes outlined by Arksey and O'Malley (2005), we did not screen studies for methodological rigor or quality.

Figure 1 Study selection for the scoping review

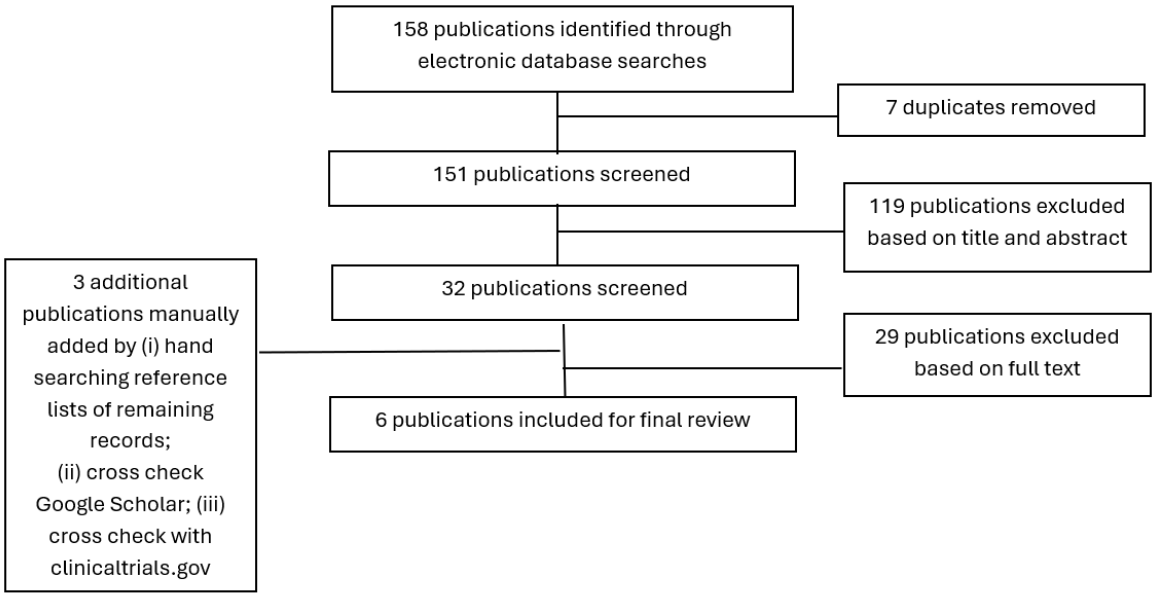

Table 2: Outline of steps undertaken for the scoping review

Stage 1 – Identifying the research question	Research question: What do we know about the collection of gender and sexuality data in cancer clinical trials, current practices, and perceptions among healthcare professionals as to the barriers and facilitators to collecting this data?
Stage 2 – Identifying relevant studies	Databases: ProQuest, Pub Med Reference checks: Google Scholar, clinicaltrials.gov Publication period: 2019 – 3 June 2024 (the date the search was conducted) Language: English only Type of publication: peer reviewed only Search terms: A four-tier search term system (in article title, abstract, key words). T1: (populations): LGB* OR “gay” OR “lesbian” OR “homosexual” OR “bisexual” OR “queer” OR “transgender” OR “non-binary” OR “nonbinary” OR “sexual minority” OR “gender minority” OR gender divers* OR “gender fluid” OR “gender nonconforming” OR sexuality divers* OR “sexual orientation” T2: (subject):

	"cancer" OR “oncology” OR “tumour” OR “carcinoma” T3: (context) “clinical trial” OR “clinical research” OR “study” OR trial* T4: (subtypes): (“data” AND collec*) OR (“participant” AND demograph*) OR (“participant” AND character*)
Stage 3 – Study selection	Exclusion criteria: Publication not in English; published before 2019; not relevant to research question; editorials and conference papers (not peer reviewed). Inclusion criteria: English language; published in 2019 or after; relevant to research question; peer-reviewed articles only. Articles were included in initial analysis and checked for eligibility if they were studies on broader clinical research or cancer care if they held implications for clinical trials.
Stage 4 – Charting the data	All included references were charted in Excel where relevant information was synthesised and interpreted by sifting, charting and sorting according to key issues and themes. Studies were categorised into direct or indirect implications, or no direct or indirect implications, for clinical cancer trials’ inclusion of gender and sexuality diversity. A ‘descriptive-analytical’ method was used, which involves applying an analytical framework to the literature and collating information on each. The list of included references will be exported into the ‘data charting form’, and a coding framework developed to characterise key features of each.
Stage 5 – Reporting the results	Results were collated to provide an overview of the material reviewed, categorised into themes that responded to the following questions: - How does the publication contribute to knowledge on clinical cancer trial inclusion of sexuality and gender diversity? - What are the current practices on data collection of gender and sexuality? - What are healthcare professionals’ perceptions around data collection of gender and sexuality? - What are facilitators of data collection of gender and sexuality? What are the barriers to data collection of gender and sexuality? What recommendations are made to improve data collection of gender and sexuality?

2.2 Key informant interviews

Interpretive Description (ID) was the theoretical lens applied in this study as it aims to answer questions of clinical relevance (Thorne, 2017; Thorne et al., 1997). The aims of ID are two-fold: i) to produce a coherent and meaningful description of clinical phenomena, in this instance perspectives on the state of data collection regarding gender and sexuality in cancer clinical trials and, ii) to undertake an interpretive approach beyond descriptive claims to identify how results may inform

practice (Thompson Burdine et al., 2021). The approach allows flexible use of varying analytic techniques to identify recurring themes in clinician perspectives and providing key insights into barrier and enablers for improving the inclusion of LGBTQ+ people in cancer clinical trials.

Qualitative structured interviews were conducted with professionals working in cancer clinical trials ('key informants') to document their perspectives about the state of data collection regarding gender and sexuality, and perceptions about barriers and enablers for improving the inclusion of LGBTQ+ people in cancer clinical trials. Ethical approval to undertake this research was received from the UNSW Human Research Ethics Committee (iRECS6660) and the ACON Research Ethics Review Committee (202405).

The interview guide was developed based on an initial literature review, and in consultation between the research team, ACON, and the Cancer Institute NSW. Interviews involved asking questions about participants' professional background and their perspectives on the inclusion of LGBTQ+ people in cancer clinical trials, including challenges and opportunities for putting this into practice. Participants were recruited through email invitations shared through the Psycho-Oncology Cooperative Research Group (POCOG) to other ANZ Cancer Cooperative Clinical Trials Groups, professional networks of the investigators, and by ACON and the Cancer Institute NSW, who identified relevant stakeholders and other organisations. Additionally, passive snowballing recruitment was allowed. Prospective participants were directed to contact the research team to participate in a telephone or Zoom interview and provided written or verbal informed consent prior to participation. No compensation was offered to participants.

A total of 11 participants were interviewed between July and September 2024, however one participant was excluded from analysis as they were involved in cancer care, but not in any clinical trials. Participants included professionals working in frontline care, trial coordination, and directing clinical services; and representing generalist oncology care as well as specialties such as radiation, gastroenterology and hepatology, and genitourinary cancers. Five participants were cis men, four were cis women, and one was non-binary. All participants worked in publicly funded clinics, with seven working at clinics located in 'Major Cities of Australia' and three in 'Inner Regional Australia', per the Australian Statistical Geography Standard Edition 3. Interviews lasted an average of 22.5 minutes (range 13 to 38).

Following each interview, fieldnotes were written about the content of the interview and any emerging analytical insights. The interview recordings were transcribed through Trint, a secure transcription software, and verified and deidentified by a member of the research team. Two members of the research team independently coded four transcripts and met together to discuss the coding and emerging analysis. The team then developed an analysis of key themes, as presented in section 4.

3. Scoping review

The six articles included in this scoping review reported on research conducted through national assessments and audits of clinical cancer trials (Cathcart-Rake et al., 2019; Patel et al., 2023), literature reviews (Witham et al., 2020), and surveys with healthcare professionals (Jones, Reyes et al. 2020; Witham et al., 2020; Kamen et al., 2022) or targeted population groups (Geffen et al., 2023) in the US (n=4) and UK (n=2) (see Table 3). The research focus varied greatly and included sexual orientation and gender identity data collection practices (Cathcart-Rake et al. 2019; Patel et al., 2023) and perceptions on data collection (Kamen et al., 2022), minority population recruitment into trials (Witham et al., 2020, Geffen et al., 2023), and biobank record annotation (Jones et al., 2020). While cancer clinical trial data collection was not the focus of some articles, they were included in this review because they held direct or indirect implications for gender and sexuality data collection. Findings are organised into the components of what the research question sought to explore.

3.1 Contribution to knowledge on clinical cancer trial inclusion

All articles eligible for inclusion in this scoping review bore some connection to sexuality and gender inclusivity in cancer clinical trials. Two articles assess data collection of gender and sexuality, though not in the specific context of cancer clinical trials. Cathcart-Rake et al. (2019) report on the rate that community oncology clinics and medical centres collect data on gender and sexuality, and factors associated with higher rates of data collection, such as clinic location, and the proportion of gender, sexuality, and racially diverse patients. Kamen et al. (2022) report drivers of gender and sexuality data collection in oncology practice, including institutional policies and respondents' knowledge, beliefs and attitudes on such data collection, finding factors that predict gender and sexuality data collection are linked and self-reinforcing.

Two articles contribute to knowledge about the proactive inclusion or retrospective recognition of gender (Jones et al., 2020) and sexuality (Geffen et al., 2023) in cancer research more broadly. One of these has a focus on gender diversity only. Jones et al. (2020) report on the acceptability and feasibility of annotating trans and other gender diverse clients in cancer biospecimen collection and other biobanking practices, as well as respondents' knowledge, beliefs and attitudes on such data annotation. The authors determined data annotation requirements in collecting sex assigned at birth, gender identity and whether the patient has pursued gender affirming interventions. Another study by Geffen et al. (2023) assessed recruitment strategies in engaging Black sexuality diverse women in breast cancer research to demonstrate the value of community partnerships and intersectional approaches.

Finally, two articles hold indirect relevance to gender and sexuality diverse inclusion in cancer clinical trials. Witham et al. (2020) reported on the development of a roadmap to include under-served population groups in clinical research trials. Patel et al. (2023) audited cancer clinical trials to assess whether identified 'under-served' groups were explicitly excluded from trial participation. Both studies included gender and sexuality diverse populations in their categorisation of under-represented population groups in clinical cancer trials.

The definition of gender and sexuality varied in the articles included in the review. Gender and sexuality were collapsed into one demographic group, 'LGBT/sexual orientation', which was categorised separately from 'male or female sex' in two articles (Witham et al., 2020; Patel et al., 2023). Here, gender diversity (as signified by the inclusion of 'T' in the LGBT acronym) was categorised in the same group as sexuality diversity (lesbian, gay, bisexual). Sex and gender were synonymous in the assessment of effective recruitment strategies, as the designator 'women' could conceivably include both sex assigned at birth and gender identity (Geffen et al., 2023). In that study, however, 'sexuality minority' was categorised as distinct from 'straight or heterosexual'. Gender identity and sexual orientation were both included in studies on assessment of gender and sexual minority populations' data collection (Cathcart-Rake et al., 2019; Kamen et al., 2022), but only one provided a definition of gender identity that was distinct from sex assigned at birth (noted as 'the standard male-female sex field') (Cathcart-Rake et al., 2019). There was only one only study that looked at two-step questions pertaining to gender by listing sex assigned at birth (or organs present at birth) separately to gender identity (Jones et al., 2020).

Table 3: Eligible articles included in the scoping review

Citation	Focus of study	Jurisdiction	Study population	Data source
Cathcart-Rake, E. J., Zemla, T., Jatoi, A., Weaver, K. E., Neuman, H., Kazak, A. E., Carlos, R., Gansauer, L., Unger, J. M., Pajewski, N. M., & Kamen, C. (2019). Acquisition of sexual orientation and gender identity data among NCI Community Oncology Research Program practice groups. *Cancer*, *125*(8), 1313–1318.	Assessment of nationwide rates of routine collection rates of sexual orientation and gender identity data within community oncology settings, specifically within NCI Community Oncology Research Program (NCORP) network, and the characteristics of institutions that collected this data in the US.	US	Administrators and research staff employed at NCORP (US nationally funded research infrastructure that supports community oncology clinics recruit for clinical trials). (N=221 distinct practice groups)	2017 NCORP Cancer Care Delivery Research Program Landscape Assessment-developed survey; subset) on routine gender and sexuality data collection.
Geffen, S. R., Poteat, T., Dean, L. T., Malone, J., Greene, N., & Adams, M. A. (2023). Engaging Black sexual minority women in breast cancer research: Lessons in community partnerships. *Cancer*, 129(21), 3439–3447.	Assessment of feasibility and effectiveness of community-based recruitment strategies in breast cancer prevention and treatment in the US.	US	Black sexual minority women who have - been diagnosed with - received an abnormal screening result - for, breast cancer. (n=374)	Comparison of full survey results, subset of Black and White women who provided recruitment source data, categorised into cancer focused, Black OR sexual minority women focussed, or Black AND sexual minority women focussed social media, and other recruitment sources.

Citation	Focus of study	Jurisdiction	Study population	Data source
Jones, N. C., Reyes, M. E., Quinn, G. P., & Schabath, M. B. (2020). Survey of Principal Investigators in Biobanking: Knowledge, Attitudes, and Research Behaviors About Transgender and Gender-Diverse Patients. *JCO Oncology Practice*, 16(10), e1192–e1201.	Biology of tissues in biobanking, specifically sex assigned at birth/organs present at birth, gender identity and gender affirmation interventions to better capture trans and gender diverse experience in the US.	US	Investigators using or has used Tissue Core (central biorepository in Florida) (n=47)	Survey measuring knowledge, attitudes, and research practices regarding annotating trans and gender diverse status in cancer biospecimen collection.
Kamen, C. S., Pratt-Chapman, M. L., Meersman, S. C., Quinn, G. P., Schabath, M. B., Maingi, S., Merrill, J. K., Garrett-Mayer, E., Kaltenbaugh, M., Schenkel, C., & Chang, S. (2022). Sexual Orientation and Gender Identity Data Collection in Oncology Practice: Findings of an ASCO Survey. *JCO Oncology Practice*, 18(8), e1297–e1305.	Drivers of gender identity and sexual orientation data collection in cancer clinical care and research settings in the US.	US	Clinicians providing care to patients with cancer or working in cancer research (n=257).	Survey as to barriers and facilitators of sexual orientation and gender identity data collection, and institutional policies.

Citation	Focus of study	Jurisdiction	Study population	Data source
Patel, D., Kilburn, L., Fox, L., Hall, E., Bliss, J., & Lewis, R. (2023). Equality, diversity, and inclusion in oncology clinical trials: An audit of essential documents and data collection against INCLUDE under-served groups in a UK academic trial setting. *BMC Medical Ethics*, 24(1), 105.	Audit on trial protocols for exclusion of underrepresented populations	UK	Demographic factors included in their audit include: - Age - Ethnicity - Sex (binary categories only) - Sexual orientation (or absence of it as not collected) - Socio-economic - health status (n= 30 trials audited)	Audit of phase 2 and 3 oncology trial documentation (PIS, protocol, patient-completed survey, case report forms) (n=30) to identify underrepresentation from data collection.
Witham, M. D., Anderson, E., Carroll, C., Dark, P. M., Down, K., Hall, A. S., Knee, J., Maier, R. H., Mountain, G. A., Nestor, G., Oliva, L., Prowse, S. R., Tortice, A., Wason, J., & Rochester, L.. (2020). Developing a roadmap to improve trial delivery for under-served groups: Results from a UK multi-stakeholder process. *Trials*, 21(1), 694.	Multi-armed study to determine responses to the under-representation of populations groups in clinical trials	UK	Stakeholders from under-represented groups (n=70), and professional healthcare providers/researchers (n=101) in UK. “Under-served groups”, including demographic profiles of: - Age extremes - Women of childbearing age - Black, Asian and Ethnic Minorities - Male or female sex - LGBTQ/sexual orientation - Educational disadvantage	1. Literature 2. Survey with stakeholders identified from potentially under-represented groups 3. Surveys with professional stakeholders 4. Workshop and consultation processes to achieve consensus.

3.2 Current practices reported on gender and sexuality data collection

Five articles reported current practices within their field of study (data collection, annotation of records, trial documentation, and trial processes) that relate to gender and sexuality diversity. Overwhelmingly, routine or reported gender and sexuality data collection were low across these studies.

For example, Cathcart-Rake et al. (2019) reported that the majority of 221 survey respondents from community oncology clinics (71.9% of their sample) did not routinely collect data on gender identity and sexual orientation from their patients. Of those that did, 6.3% routinely collected both gender identity and sexual orientation from their patients; 17.6% reported routine collection of sexual orientation only; and 4.1% reported routine collection of gender identity only. Likewise, Kamen et al. (2022) reported that of 257 survey respondents working in cancer clinical care or research, 40% reported their institution routinely collects data on sexual orientation and 46% data on gender identity. Conversely, 34% of respondents reported their institution did not collect data on sexual orientation and 32% did not collect data on gender identity (21% and 17% respectively were unsure of routine data collection). Jones et al. (2020) based their assessment of gender identity annotation acceptability and feasibility on three "practice" survey questions (that is, whether a biorepository allowed for entry of: 1. Gender identity; 2. Sex assigned at birth beyond a male/female binary (to enable annotation of intersex status); and, 3. details of gender affirmation interventions, if any. Of their 47 respondents, 17% enabled the assignation of sex at birth beyond male/female, 15% reported their biorepository practices allow for gender identity annotation and 9% for annotating gender affirming interventions (HRT, genital reassignment, gonadectomy, breast augmentation or removal, feminising/masculinising procedures, etc.).

Two studies were broadly assessing inclusion of under-served or under-represented population groups in clinical research, among which LGBT populations were listed (Witham et al., 2020; Patel et al., 2023). Witham et al. (2020) reported on a scoping review that confirmed under-representation was prevalent in trials, with many clinics not collecting or reporting on under-represented demographic characteristics (i.e., unable to identify under-representation in trials because of lack of data). Patel et al. (2023) align with Witham et al.'s (2020) process recommendations by auditing cancer clinical trial documentation. Of the audited trials, nine and seven of the 30 trials were for cancers affecting male sex and female sex characteristics respectively, and 14 of 30 trials were specific to one sex only. Patel et al. (2023) also found that 47% of trial protocols used gendered language (man/woman, male/female) but none specifically stated if the gendered term was related to sex assigned sex at birth or gender identity. Of trials using gendered terms, 50% included only one sex (male or female) due to type/location of cancer but seven trials that used gendered terms were for non-sex-specific cancers, of which trials were open to both men and women. Fifty-two percent of audited case report forms collected data on gender (11/15 specifically noted 'sex', one noted 'sex at birth, and three 'gender'). Of trials not collecting sex or gender 86% were sex-specific cancers. Sexuality was not collected on any case report forms or collected in participant questionnaires. Data collection on sex/gender captured only binary male or female, and there was no assessment available on intersex, non-binary, or transgender inclusion in the documentation available for audit (Patel et al., 2023).

3.3 Healthcare professionals' perceptions on gender and sexuality data collection

Of the six studies included in this scoping review, three articles reported on healthcare professionals' perceptions on the acceptability and feasibility of colleting gender and sexual data collection.

Kamen et al. (2022), in their survey of healthcare professionals, found that the factors that predict gender and sexuality data collection are linked and reinforcing. That is, institutional data collection in oncology practice and research in the US was significantly associated with the healthcare professional's belief that knowing patient gender identity and sexual orientation is important for high-quality care provision. The motivation to collect data on gender and sexuality depended on clinician's belief, knowledge, and attitudes of patient diversity. Those respondents who identified as LGBTQ+ were more likely to agree on importance of collecting data on gender and sexuality. Those respondents who did not disclose race and who identified as politically conservative were more likely to disagree it was important to know sexuality.

Likewise, Jones et al.'s (2020) survey of principal investigators involved in biobanking studies revealed a deficiency in annotating gender diversity in cancer biospecimen collection. While 96% of respondents reported it was important to collect sex assigned at birth, only 77% of respondents agreed it was important to collect data on gender identity and 79% agreed it was important to collect data on history of gender affirming interventions. That is, respondents rated gender and gender affirmation information as less important than the biology associated with sex assigned at birth (as proxy for sex characteristics). Despite these lower rates supporting collection of this information, 80% of respondents had no concerns about recording gender identity and history of gender affirming interventions in biobank data. In terms of training and/or knowledge, 74% of respondents reported high knowledge of what gender affirming interventions are, and 68% recognised gender diverse people avoid healthcare because of interactions with healthcare professionals. At the same time, their findings point to the acceptability of increasing knowledge around gender diversity: 77% of respondents thought it important to learn more about bodily and tissue changes following gender affirming interventions, and 74% were interested in learning more about gender diverse cancer care needs. Post-survey, confidence in knowledge of gender diverse health care needs decreased from 48.9% to 36.2%, suggesting that self-assessed perception of knowledge was decreased by questions prompting self-reflection.

In their broader assessment of the processes of greater inclusion of under-served populations in clinical cancer trials, Witham et al. (2020) survey of healthcare professionals found of 101 respondents, 55% agreed that a universal definition of 'under-representation' could not be given. Alternative definitions provided by respondents were grouped into three categories: 1. inclusion (defined by poor access to trials); 2. epidemiology (population level comparisons); and 3. miscellaneous (not relevant to the question of comparison). Stakeholder consultations conducted as part of the study agreed 'under-served' is the preferred term yet, a single universal definition of what constitutes under-served groups was not possible. Rather, there was recognition the definition needs to be context specific.

3.4 Facilitators and barriers to gender and sexuality data collection

Each of the articles indicate facilitators and barriers to gender and sexuality data collection, either directly related to participation in clinical trials or in findings on broader oncology practice (recruitment, biobanking) relevant to data collection aspirations and practices. These include aspirational principles, systemic and/or structural issues, healthcare professionals' traits and experiences, and population and/or partner outreach efforts.

Kamen et al. (2022) reported on the most comprehensive list of facilitators and barriers. They found nine separate factors facilitating sexuality data collection, and 11 facilitating gender data collection. Similar across gender and sexuality data collection were five structural or systemic facilitators (type of cancer institution; leadership support; coworker support; resources; feeling empowered to collect) and three derived from individual trials or experience (belief that knowing sexuality is important in providing care; belief that knowing gender is important in providing care; and receipt of cancer-specific gender and sexuality diversity training). However, additional factors were identified for collecting data on gender identity (person's sexuality; person's political views; person's associations with gender and sexuality diversity), while the survey respondents' race was identified as an additional factor for collecting data on sexuality. These data suggest that individual traits and experiences were equally (if not more) relevant than a broad and universal set of structural facilitators. At the same time, the authors also identified a set of barriers to routine gender and sexuality data collection, which included structural barriers: lack of institutional culture of routine collection and leadership awareness that gender/sexuality matters in cancer care; electronic medical record infrastructure; and a lack of training, resources and time. Individual barriers of provider belief and level of comfort; and providers' perception of patient discomfort) were also identified (however, they note that while there is a need for multilevel interventions to support routine data collection, institutional cultural change would likely have a 'trickle down' effect in changing people's attitudes).

The implications of Kamen et al.'s (2022) findings align with those of Jones et al. (2020) who found respondents noted concerns around the complexity of gender terminology and statistical methods to determine correlates of gendered data, which could be alleviated with training and education. Infrastructure and design elements, such as modifying clinical intake forms and demographic questionnaires, were identified as necessary to facilitate better data collection, pointing to broader, yet achievable, aims. Patel et al.'s (2023) audit of cancer clinical trial documentation likewise concluded that while there was no evidence of overt systematic exclusion of population groups identified as previously under-represented in cancer research, there was a need to update templates and guidance to recommend removal of gendered terms and be clear whether gendered language referred to sex assigned at birth (proxy for sex characteristics) or gender identity. In their audit of clinical trial documentation, 83% of the patient information sheets used gendered terms; and 77% used gendered pronoun when referring to participants and 7% used gendered terms referring to clinicians (71% used gendered terms to address participants despite being non-sex specific cancers). Jones et al. (2020) pointed to a lack of clarity around sex and gender affecting data collection processes and rigor, also emphasising degendered language in trial documentation could encourage trans and gender diverse people's participation in clinical trials.

Witham et al.'s (2020) stakeholder consultation processes also identified priorities for inclusive cancer research, many of which echo Kamen et al.'s (2022) emphasis on the need to attend to structural and/or systemic factors. They identify principles and institutional considerations including:

- accessibility: the need to embed research within existing health care provision
- inclusivity: the need for resources and training to support healthcare professionals to build capacity to engage with under-served populations
- funding infrastructure: the need for funders to make provision for under-served population
- promotion: the need for national publicity of value in cancer trial participation
- research design, including the need for patient-centred processes
- data: the need for baseline measurements to assess current under-representation and evidence of improvement in trial recruitment and retention.

Cathcart-Rake et al. (2019) found similar structural and systemic barriers that need to be addressed to achieve parity in oncology research. In their assessment of the practice group characteristics (that is, clusters of like hospital, clinic, or physician-owned clinics), the authors found that groups less likely to routinely collect gender identity were owned by large regional or multistate health systems, and those with more than 10% of patients on government assisted health programs (Medicare; Medicaid). Groups more likely to routinely collect gender identity were those in the western region of the US, and those groups independently owned were more likely to collect gender identity data. Overall, of the practice groups that routine collecting gender identity and sexual orientation data, location, whether the site had a lower proportion of ethnic diversity (measured by proportion of non-Hispanic patients), and whether the site had a higher proportion of LGBT patients, were associated with higher rates of routine data collection. This suggests the need to look inwards to institutional policies and protocols, and outwards to community engagement, to encourage a more inclusive institutional culture to address research barriers.

While focussing on recruitment to cancer research, Geffen et al. (2023) offer insight into data collection practices, arguing that intersectional approaches are capable of achieving greater recruitment overall. They assessed five recruitment strategies for including Black sexuality diverse women into breast cancer studies; Black *or* sexual minority women focussed; Black *and* sexual minority women focussed; social media; and other recruitment sources. Their findings were that while cancer focussed strategies recruited 43% of eligible women irrespective of race, strategies that included race and sexual orientation recruited this population group more effectively. As such, Geffen et al. (2023) point to the need for community engagement throughout research processes to facilitate greater recruitment of marginalised populations, which they note can be achieved via inclusion of diverse collaborations, partnerships with community organisations, sharing leadership with relevant representative organisations, and reviewing and refining recruitment strategies iteratively following feedback – which have implications for developing best practice in comprehensive, appropriate and culturally safe data collection processes. Yet, these processes also require the type of capacity building outreach that Kamen et al. (2022) similarly identified to mitigate against barriers to community participatory strategies, which Geffen et al. (2023) specify as the exhaustion of resources from limited partner organisations and networks, a lack of intersectional representative organisations, and organisational homophobia in not wanting to engage with recruitment of gender and sexuality diverse people.

3.5 Implications and options for policy and practice change

There is a clear need for an evidence base to guide the design and implementation of processes to encourage greater inclusion of gender and sexuality diverse people in clinical cancer trials. One foundational component of this greater aim is to ensure adequate and appropriate data collection processes. Our scoping review of what is known about the collection of gender and sexuality data in cancer clinical trials, current practices, and perceptions among healthcare professionals as to the barriers and facilitators to collecting this data confirmed that only a small number of studies fit the criteria for inclusion. Although scoping reviews do not evaluate the methodological quality of the included research, we observed a limitation on generalisability, including an overwhelming dominance of studies conducted in the USA (which may not be generalisable to other jurisdictions) a lack of clarity over whether sex refers to sex assigned at birth (i.e. a legal category) or the presence/absence of sex characteristics. We did not include evaluated interventions that were not peer reviewed, nor research published prior to 2019, which may still have resonance today. However, despite these limitations, we have identified a range of important insights regarding data collection protocols, processes and practices that might aid great inclusion of LGBTQ+ people in cancer research.

First, there was a lack of clarity around the definition of 'under-served' or 'under-represented' population groups, as LGBTQ+ communities are frequently described. Witham et al. (2020) reported issues from their survey respondents (with representatives from under-represented groups and with health care professionals) around the definition of 'under-represented groups' in clinical trials, with stakeholder consultations suggesting a single definition may not capture all groups likely to be under-represented. An implication for practice from this finding is that gender and sexuality are not one category of 'under-served' groups, and LGBTQ+ communities should be specifically recognised rather than bundled into broader categories of under-representation. Indeed, Patel et al. (2023) highlighted the need for greater clarity in sex and gender terminology/definition to ensure comprehensive annotation of sex, gender and gender affirming interventions in biospecimen biobanking, which relates to data collection processes more broadly. Best practice in data collection on sex and gender, sexual orientation, and trans and gender diverse classifications are set out in the *Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables* (Australian Bureau of Statistics, 2020) and specify that the gender two-step question (sex reported at birth and gender identity) are more appropriate to collect data on gender diversity. While not identified in the literature that was included in this review, a further implication is a potential need for training of the clinical trials workforce: that sex and gender are not always immutable or independent; that gender identity might change over the lifecourse, so might the sex characteristics assumed of a person's sex assignation at birth; and that cancer treatments may affect and be affected by gender affirming interventions.

Second, there are inward-facing considerations that can be made to improve gender and sexuality data collection. Cathcart-Rake et al. (2019) suggest educating oncology staff on cultural awareness of gender and sexuality diversity and recruiting LGBT-identifying staff may enhance routine data collection of gender identity and sexual orientation. Similarly, Jones et al. (2020) identify gender diversity training as enabling researchers to translate beliefs and attitudes into practice, which

provides a multileveled (structural and individual) approach to greater inclusion. Kamen et al. (2022) also point to structural/systemic issues that need to be addressed, such as developing protocols and processes, including a designated space in the electronic medical record to record gender and sexuality data to record, before culture change within organisations around diversity, and specific training on how and why to collect data, can take place.

Finally, there are outward facing strategies to reach LGBTQ+ communities so as to encourage greater cancer trial participation. Witham et al. (2020) developed a roadmap to respond to under-representation in trials through the wider study processes that provides a structure for both future research and for initiatives to address barriers to participation. This roadmap identifies potential checkpoints for decision-making, but crucially, also identifies areas for collaboration, stakeholder engagement and co-design/co-delivery throughout. Kamen et al. (2022) likewise highlights the need to improve community trust to mitigate against healthcare professionals' perception that patients are not comfortable being asked or disclosing their gender and sexuality. To this end, Geffen et al. (2023) highlight the need to engage in collaborative, shared leadership practices with community leaders; build trust with stakeholders who engage or represent marginalised populations; and engage with community influencers/experts in order to recruit historically under-represented LGBTQ+ population groups.

4. Key informant interviews

Through the 10 interviews included in this analysis, we identified a range of barriers and facilitators to collection of gender identity and sexual orientation data in cancer clinical trials. We present themes below with illustrative quotes and make recommendations for strategies to address these barriers.

4.1 Barriers

4.1.1 Lack of training

Most key informants reported not having received any specific training regarding gender identity and sexual orientation, and potential impacts on healthcare and engagement. This lack of training was reflected in that some key informants had never considered whether gender identity and sexual orientation data collection were important:

> "Well, I guess everyone needs to be treated at the end of the day. And it's the same for clinical trials. I mean, for us, we want every participant possible that can match the clinical trial and numbers become very important. You know, and I guess everyone needs treatment. It's sort of, you know, I guess we get asked this all the time. We wouldn't even, collect statistics, but I wouldn't even know how many Aboriginal patients we treat most of the time. We wouldn't unless someone specified there's a specific need to know for that specific illness or someone makes an overt statement or declares themselves in a certain way that makes it very obvious, and it's mostly not going to make a difference, to be quite frank." (P10)

Further, a few key informants described that "I treat everyone the same", indicating that they did not believe knowledge of a patient's gender identity or sexual orientation was important to delivering person-centred care:

> "I don't think there's no one who's said I'm not coming into a trial or their partner or family or something that says you're not being you know, you're not being treated appropriately because of your sexual affiliation or gender or whatever. So, I just don't think we can do better. I think we do well." (P10)

Notably, this key informant was not against LGBTQ+ data collection but expressed that all patients are treated well regardless of their sexual orientation and gender identity, despite not knowing if patients at the clinic are LGBTQ+.

Key informants who had received training – in the form of online modules or workshops – found it insightful and helpful and would recommend it to others. While most key informants welcomed the idea of LGBTQ+ training, and those who had experienced were enthusiastic, there was a view that older or more conservative colleagues would not be receptive and that this could be a barrier to improving LGBTQ+ inclusivity:

> "I know one of my colleagues, you know, it's mostly. [...] I would have never spoken about it. I would have actually no idea what his thoughts are or whether he feels his religion sort of clashes with it. So, I don't know. It's a simple answer, but I imagine that

> for a lot of my senior colleagues, they would definitely, they should be upskilled in that area. I think there's also sort of those who are there, 50 [years old] are more likely to embrace it than those who are in the 60s and 70s, although one could argue that those colleagues should be looking at retirement. That's a different story." (P06)

Beyond general LGBTQ+ inclusivity training, key informants indicated areas of specific training that would be helpful for cancer clinical trials. For example, some indicated that they were uncertain about the management of hormone therapy that trans patients may be taking and its impact on trial eligibility. Key informants were unsure about the potential impacts on treatment, and had not considered potential psychosocial implications if patients were asked to cease hormone therapy:

> "As a clinical trial nurse, we don't have much information or training about looking after this group of patients. We don't know whether the treatment itself will affect the trial. I guess if I have those patients, I will have to clarify with the study team to see whether they will accept this group [in a trial]." (P05)

Key informants also shared that they experienced awkwardness around discussing sex and contraception or the need for improved communication skills to discuss the specifics of contraception:

> "We will tell the patient 'We suggest you don't get pregnant' during their treatment. But we don't very often talk about the contraception method. We don't want to talk about sexual activities, this is not our priority. But that is part of life, and particularly for the young people I think, what's the kind of communication skills we [need] to start this topic and make both parties feel comfortable to continue this topic? It's very important. Also, cultural background. Some patients probably [do] not feel very comfortable to talk to strangers or their health providers about their private life. So, communication skills is very important." (P05)

Some key informants were familiar with the issues involved in clinical trials of chemotherapy, where discussion of safer sex practices is standard to protect patients' partners from cytotoxic agents, but little consideration had been given to is tailoring this information for LGBTQ+ people.

4.1.2 Clinicians and the systems result in making assumptions

Key informants were aware that the system overall, and individuals working within it, largely do not consider the sexuality of patients, and only employ basic approaches to understand a patient's gender (e.g., a single question about sex or gender, or assuming gender based on presentation):

> "It's usually just their gender, but we don't really ask sexuality, identification or orientation. So, if patients don't tell us we wouldn't know they are gay or they are lesbians. So that's the thing if they don't tell us, we wouldn't know." (P05)

> "As clinicians, we make assumptions about people's sexuality. Definitely their gender. And I don't think we routinely ask questions to clarify aspects of these. And in turn, whilst it may or may not be relevant to the person's trial involvement, it may inadvertently exclude them from accessing clinical care. And in the event that they don't feel comfortable, it adds an additional barrier to clinical trials where there already exist multiple barriers to enrolling." (P11)

As noted by these quotes, these assumptions were often made because referral processes (e.g., from a GP to a trial clinic) and intake forms did not routinely ask standardised questions about gender and sexual orientation. Key informants noted some of the consequences of these assumptions:

> "In my space, which is largely genitourinary, where we are dealing with a lot of cancers that are traditionally identified as male cancers. I think we are going to inadvertently exclude, you know, trans females, who are not getting care and being inadvertently excluded both from normal clinical practice as well as access to clinical trials because they identified differently to what we would expect for somebody with prostate cancer or testicular cancer." (P11)

> "You can't assume that this person is only engaging in sex with one individual, and that individual is the same sex as them. Equally, some clinicians might make an assumption that a gay couple or a trans person may not want children and that their fertility is less important or should be a less of a consideration when we're talking about potentially damaging treatments from a fertility standpoint." (P11)

Participants who attempted to use inclusive language in their consultations to avoid making assumptions explained that it could be challenging to maintain, particularly with specific populations:

> "Trying to reflect back, when I was more junior, I asked questions, particularly to older people, one about pronouns and about relationships. And it's probably a generational thing, but the older males feel quite confronted with a question about sexuality. So, you know, I backed off a little bit with that. I mean, I had clarified with some people, but usually in a more conversational way, asking questions about their life. And at some point, they will use a pronoun or otherwise, rather than asking directly, has been my approach. And until then, I just, you know, use sort of non-gendered language to describe their partner or other." (P11)

Because questions about sexual orientation and gender identity were not routinely employed by everyone, participants described that asking cisgender straight people these questions could be awkward. One key informant emphasised that it was important to ask regardless:

> "It's worth me pissing off one straight person and then, you know, upsetting every other LGBTQ patient that walks into my door today. And, you know, we talked about rapport. They had a bad experience because I changed my practice for one straight person who, you know, took umbrage to it. That's how I look at it." (P06)

4.1.3 Language

Key informants who identified that inclusive language was important explained that it was common to see exclusionary language used in clinical trial information, or that it was difficult to implement inclusive language in consultations. Exclusionary language included trial eligibility or information talking about men or women but not clarifying if it was specific to cis or trans people, implying that particular sexual organs exclusively belong to particular genders (e.g., implying that only men have testes), and using language that might assume the gender of a partner (e.g., assuming a woman who is married has a husband).

Clinical trial protocols and participant information statements were also described as excluding LGBTQ+ people through the explicitly exclusionary language used. This highlighted the lack of

consideration of trans people, particularly trials in sex organ cancers:

> "I think that the language we use in clinical trial protocols does exclude patients, or at least, isolate them in, you know, defining, for example, that in a prostate cancer trial, patients must be male. I mean, I personally think [gender is] irrelevant as long as they have a prostate. And so, I think there are small things like that where for the majority of people it's not a problem. And, but for the people who it matters to the most is really isolating." (P11)

> "A lot of people from the trans community specifically find the very stringent requirements of clinical trial pregnancy testing to be quite confronting at times. So, people are assigned female at birth during clinical trials, they are required to have pregnancy testing regularly. And I think that can be for some individuals who have never had to do it. It can be a bit confronting perhaps. I think that the terminology that we use in registration forms. Again, and a very clear division between male and female can be at times a bit confronting. And I think also that, I guess, there is still to some extent a little bit of there remains a somewhat complex relationship with the health care system generally for some people within these communities, and that that therefore bleeds into cancer care as well." (P04)

Discussion of contraception however was a more familiar issue to most participants, as clinical trials generally require the use of contraception for people with capacity to become pregnant and may also stipulate regular pregnancy testing during a trial for these patients. As noted above in relation to training, some participants indicated that more communication skills were needed to address these topics, and it was also identified that the use of language regarding contraception and pregnancy needed to be LGBTQ+ inclusive.

4.2 Facilitators

Key informants were all supportive of the inclusion of standardised questions about LGBTQ+ data in patient intake forms or during history taking. One participant was supportive of data collection but did not believe that LGBTQ+ patients needed to be treated any differently (see above on 'lack of training'). All other participants reported a belief that improved data collection and training would be helpful in reducing assumptions, improving care, and documenting and increasing the participation of LGBTQ+ people in cancer clinical trials. Key informants supported and suggested several ways to improve LGBTQ+ inclusivity.

Inclusive signs, e.g., badge, can promote patients feeling comfortable to disclose. Some key informants were proactive in using signs and symbols to indicate LGBTQ+ allyship and inclusivity, a strategy that is evidence based.

> "I usually wear a little badge with my pronouns. Usually that is sort of a way of people sort of saying flag of this person is a safe person to talk to. So, I have, come across people that are within the queer community." (P03)

> "I think creating kind of comforting, warm spaces for people that include a celebration of LGBTQ+ slogans or logos. It's really, really important in the same way that we increasingly celebrate, First Nations peoples. And I should also say, I think many of my colleagues who would not identify as being part of the [LGBTQ+] community simply

> don't have the vernacular or repertoire of skills needed to perhaps skilfully navigate those spaces. So, training would be important." (P04)

Training helps to be prepared to ask about LGBTQ+ identity and create a safe space: Key informants who had undergone LGBTQ+ training were enthusiastic about the confidence it instilled:

> "I feel confident with the vernacular. I feel confident knowing terms like bisexual, pansexual, trans. These terms make sense to me, [but] for many of my colleagues I doubt they would know many of those words. So certainly, knowing the language is important, I think. The other thing that makes me comfortable is that I know if I get an answer [from a patient] that is outside of heterosexual, I'll kind of know what to do with that information. So, if somebody says to me, oh, I'm trans. I'm not going to get nervous because I'll say, oh, okay, perfect. Should we talk about how that's going to inform our relationship together? Should we talk about your pronouns? Should we talk about how we can navigate that together? Because I want to make sure that I do so in a really respectful way" (P04)

Increasing the capability of the clinical trial workforce to cater specifically for LGBTQ+ patients was viewed by many key informants as part of providing person-centred care, and identified that it improved overall quality of care:

> "I want patients feel comfortable being treated and respected. I don't want to make any [mistakes]. For example, I made a name wrong or mistake when I call their name or call their gender, I don't want them to feel uncomfortable. So that's very important. Also, like compliance [treatment adherence]. If they don't feel comfortable, they probably wouldn't be complying. Regardless of whether they are on trial or not. And also, if they don't trust a health care provider, they probably wouldn't tell their side effects, which is very important in clinical trials because we need to collect all the adverse events. So, they need to really trust us to tell us everything. I don't know whether some patients will feel comfortable to tell us some very private information, like if your topic is very sensitive to them and if they don't feel very comfortable to tell us, we may miss that data collection as well." (P05)

Improvements are about respect, building trust, and therefore improving care and outcomes. Care is improved if people feel supported; and should be a necessary precondition before referring someone to a trial:

> "You have to make people feel supported; they need to feel comfortable to share information with you. So, like I mentioned, the rapport really kicked off once we broke through the ice with her saying something like that's my partner, not my friend." (P06)

4.3 Where could data about sexual orientation and gender identity be collected?

Key informants indicated multiple points in the system where data could be collected to improve clinical cancer care and trial participation. Key informants stated that if sexual orientation and gender identity questions were mandated as a requirement of running cancer clinical trials, this would make it easy for them to implement as part of intake forms:

> "I think for clinical trials, if it mandated, then it's like, we just have to do it, right? And if

> it’s a routine question, then it's very, very easy to ask. And equally, if patients are filling their own documentation, then they can complete it in a really non-confrontational manner.” (P11)

> “In the waiting room, while they're filling out forms. I mean, [we ask] what's your age, what's your date of birth, where do you live, male or female? Are you Aboriginal background or not? Do you identify as. That's probably where we should be having a question of this element. It shouldn't be well into the interview, well into this process to say, oh, hold on, how do you want to be managed?” (P08)

Outside of that, several participants talked about the history taking as the point for learning about patients’ sexuality through questions about social support. Others talked about the formal trial enrolment when forms are filled out as being the ‘natural’ place, while a third group relied on information collected through referrals:

> “I mean, I guess the way we do things is that we sometimes we get external referrals. So, if we do the external referrals, for trials at the hospitals usually [there] is [a] pretty decent social history. But of course, we still go through it again in the unlikely circumstance that wasn't covered. But I guess we see our patients even before they go into trials and take social histories. So that's sort of a big part of that, and I'm very big on the social history, especially when I meet the new patients with the registrar.” (P06)

5. Conclusion

The findings of this project emphasise that improved data collection of sexual orientation and gender identity in cancer clinical trials could support better understanding of cancer treatment outcomes for LGBTQ+ people and support the goal of patient-centred care. Findings from the scoping review highlight the need to disaggregate gender from sexuality in the LGBTQ+ acronym, instead of bundling gender and sexuality diversity together with other 'under-served' populations. The literature also suggests that education and workforce training increase clinicians' uptake of data collection on LGBTQ+ patients, and LGBTQ+ inclusion in clinical cancer trials should be designed from the outset, including developing a roadmap to guide research implementation. In key informant interviews, it was identified that lack of training with LGBTQ+ inclusivity, assumptions being made about patients, and exclusionary language were key barriers to realising LGBTQ+ inclusivity. However, key informants suggested several facilitators to support improvements in cancer clinical trials, including access to training, displaying inclusive signs, and emphasising how LGBTQ+ inclusivity improves patient-centred care and health outcomes. Overall, key informants were supportive of questions about sexual orientation and gender identity being standardised and mandated in intake forms or other processes, which would help to normalise asking these questions. Accompanying this with training and capacity building for the workforce is vital to improving LGBTQ+ inclusivity in cancer clinical trials.

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