Standard Operating Procedure

6.5.3 Collection of Participant Demographic Information

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Introduction/background

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6 R2 guideline requires careful consideration and description of participant selection, as described within a study protocol. Accurate selection and description of the study population is necessary to meet specific primary and/or secondary outcomes and ensure the safety of study participants.

The response of participants to study interventions may be affected by factors such as sex, gender, and ethnicity (for example, ethnicity has been consistently documented to influence drug metabolism and the prevalence of participant side effects, a phenomenon discussed by Zhou and Liu 2000, among others). There has additionally been growing discussion of accurate sex and gender recording as a component of public health service obligation (Australian Government 2013) and health research quality (Wainer et al. 2019). As well as this, information solicited through the collection of demographic factors may have significant implications for elements of study data analysis, such as group comparisons. As a result, the ability of researchers to most accurately reflect the characteristics of the study population in the information they record is a core aspect of research integrity. This is especially the case in palliative care research, where data generalisability and high-quality findings have sometimes been acknowledged to be lacking.

Historical attitudes to the collection of demographic data often did not adequately consider concerns such as individual expression. This has led to demographic information being collected in a variety of ways across time, with categories such as ethnicity and gender being applied with little or no consideration of population description or relevance to the study. Data recorded may then conflict with data collected elsewhere or may skim over nuances in an increasingly large participant population. As a result, in recent years, there has been evolving awareness of the need to observe participant preferences in the reporting of information such as their ethnicity and gender identity.

In keeping with changing awareness of how modes of data collection can influence participants and the usefulness of study data, a standard operating procedure (SOP) detailing best-practice methods for collecting demographic information is needed to ensure that current approaches of studies within the Improving Palliative, Aged, and Chronic Care through Clinical Research and Translation (IMPACCT) research centre, accurately reflect study populations.

Objective

This SOP provides guidance about questions and categories that may be used in trials conducted with the IMPACCT and the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), in order to most accurately capture the demographic characteristics of the study population.

Scope

This SOP outlines recommended and standardised methods for the collection of study participant demographic information for ITCC/PaCCSC/CST studies and applies to all staff involved in such studies, irrespective of individual organisational employment, role, or position.

The scope of this SOP also extends to studies conducted in collaboration with research institutions in New Zealand (NZ) and other countries with locally-specific ethnic/cultural milieus, for which IMPACCT/ITCC will coordinate the Australian arm of the study.

This SOP also includes the data collection requirements for CST studies for Cancer Australia reporting.

Clarification of the terms used in this SOP:

This SOP follows the Australian Bureau of Statistics (ABS) definitions and classification:

- The Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG)

  https://www.abs.gov.au/statistics/classifications/australian-standard-classification-cultural-and-ethnic-groups-ascceg/latest-release

- The Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables

  https://www.abs.gov.au/statistics/standards/standard-sex-gender-variations-sex-characteristics-and-sexual-orientation-variables/latest-release

Ownership and Responsibility

Responsibilities of the Coordinating Principal Investigator (CPI)

- To ensure adequate consideration is given to the protocol requirements relating to demographics and justify the underlying reasons the information is collected in a specific manner
- To ensure the collection of ethnicity, sex, and gender information reflects current knowledge of such concepts and best practice
- To ensure country-specific and funder-specific expectations about social and cultural awareness of diverse populations in studies (including the necessity to provide the suggested questions in alternative language formats to generate the most accurate data) are reflected in the protocol and study design and agreed upon with the study investigators
- To ensure those working on the study have received appropriate training when it comes to the difference between sex and gender, and the potential implications of that for data collection, as well as training regarding the role of accurate ethnicity data

Procedure

For ITCC/PaCCSC/CST studies, it is recommended that the following demographic data are collected:

1. Age (Year of Birth)

As a minimum, in order to describe the study population and ascertain the capacity to consent to the study, the age of participants should be recorded. This is additionally a requirement for all CST studies. Actual birth date collection may be protocol-specific, bearing in mind that in some sites with specific diagnoses and very small numbers of potential participants, the actual date of birth may provide de-identification of the individual. This possibility should be discussed within the relevant study protocol.

2. Gender

Changes to guidance about sex/gender are intended to align with shifting methods of data collection in relevant population surveys such as the Australian Census. The following data should be collected, as applicable to the study.

Where biological sex at birth is influential for study results, the following is suggested:

a) *Biological sex at birth*

Male, Female, Intersex

For studies likely unaffected by sex assigned at birth, an alternative may be preferable to use:

b) *Gender as you identify now*

Male, Female, Other (please specify) _______, Prefer not to say

3. Availability of primary caregiver

Identifying the percentage of people who have or do not have an identifiable caregiver may be an important indicator of care and understanding key differences in a patient population, as set out in the Framework for Generalisability in Palliative care (Currow et al. 2009). The following parameters are recommended for consideration:

a) *Lives with carer*
b) *Lives alone, but carer available*
c) *Lives with non-carer;*
d) *Lives alone, no carer*

4. Postcode

Postcode data (within Australia and equivalent data internationally) helps describe the spread of participants across states/territories, provides metropolitan vs regional information, and can also provide proxy information for socio-economic indices. The reason for postcode collection should be specified within the study protocol. Collection of a participants' postcode is required for all CST studies.

5. Educational attainment

This provides important socio-economic information about the study population. ITCC recommends defining sub-categories relevant to the local context (e.g., Australia, NZ, etc.)

6. Employment status

This provides important socio-economic information about the study population. ITCC recommends defining sub-categories relevant to the local context (e.g., Australia, NZ, etc.)

7. Language

Participant language data is to be collected to ascertain participant capacity to complete study assessments and describe the study population. Language information further enables the study results to be applied to the broader community. In general, the study protocol should ask:

a) *Current language spoken at home*

This can either be presented to participants as either a free text answer field or a list of commonly encountered languages within the Australian community (if this is important to know). In addition, for studies being conducted under CST, the following question should also be asked:

b) *Language spoken as a child*

This can be as free text or a list of options, if applicable.

8. Ethnicity

For studies conducted within Australia, it is recommended that the Australian Bureau of Statistics (ABS) classifications of cultural/ethnic groups are used. Categories include the following:

a) *Oceanian*
b) *Aboriginal or Torres Strait Islander*
   Inclusion of this category is a requirement for all studies with Australian participants and is mandatory for CST for reporting to Cancer Australia
c) *New Zealand Maori*
d) *Northwest European*
e) *Southern and Eastern European*
f) *North African and Middle Eastern*
g) *South-East Asian*
h) *North-East Asian*
i) *Southern and Central Asian*
j) *People of the Americas*
k) *Sub-Saharan African*
l) *Unknown*
m) *Prefer not to say*

Studies conducted in collaboration with New Zealand (NZ) would **additionally** include the following categories (as per 2018 NZ Census).

a) *New Zealand European*
b) *Maori*
c) *Samoan*
d) *Cook Island Maori*
e) *Tongan*
f) *Niuean*
g) *Chinese*
h) *Indian*
i) *Other e.g. Dutch, Japanese, Tokeluan*

Where an international collaboration is with a country or region other than NZ (such as the US or the UK), it is recommended that investigators consult with the international collaborator to establish the best method for collecting locally relevant ethnicity data. Discussion may include compliance with funding requirements, what needs to be coded for international data analysis, and what can be changed for Australia/NZ to make the data meaningful for the region (Oceania)

9. Country of Birth

This information is a requirement for all CST studies.

Related SOPs

4.0: Investigator Roles and Responsibilities
6.0: Protocol Development

Related documents

Template 28: Protocol Template
Guidance 13: CST Pilot/Feasibility Studies

References

Australian Bureau of Statistics. (2019). *Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG)*, https://www.abs.gov.au/statistics/classifications/australian-standard-classification-cultural-and-ethnic-groups-ascceg/latest-release#data-download

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History			
Version	Date	Author	Reason
1.0	05/08/2021	M Agar	New procedure
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