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Co-designing consumer engagement strategies with ethnic minority consumers in Australian cancer services: The CanEngage Project Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048389
Article Type:	Protocol
Date Submitted by the Author:	28-Dec-2020
Complete List of Authors:	Harrison, Reema; UNSW, Population Health Walton, Merrilyn; The University of Sydney, Public Health Manias, Elizabeth; Deakin University, School of Nursing and Midwifery; University of Melbourne VCCC, Melbourne School of Health Sciences Wilson, Carlene; Austin Health, Psychology Girgis, Afaf; UNSW, Ingham Institute of Applied Research Chin, Melvin; Prince of Wales Hospital and Community Health Services, Medical Oncology Leone, Desiree; Western Sydney Local Health District, Multicultural Health Seale, Holly; UNSW, Population Health Smith, Allan; UNSW, Ingham Institute of Applied Research Chauhan, Ashfaq; UNSW, Population Health
Keywords:	Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult oncology < ONCOLOGY, QUALITATIVE RESEARCH

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4 **Title: Co-designing consumer engagement strategies with ethnic**
5 **minority consumers in Australian cancer services: The CanEngage**
6 **Project Protocol**
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31 **Abstract:**

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33 **Introduction:** Consumer engagement is central to high quality cancer service delivery and is
34
35 a recognised strategy to minimise healthcare-associated harm. Strategies developed to
36
37 enhance consumer engagement specifically in relation to preventing healthcare harm
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39 include questioning health professionals, raising concerns about possible mistakes or risks
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41 in care, and encouraging patients and caregivers to report suspected errors. Patients from
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43 ethnic minority backgrounds are particularly vulnerable to unsafe care, but current
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45 engagement strategies have not been developed specifically for (and with) this population.
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47 Using an adapted approach to Experience-Based Co-Design (EBCD) to support the target
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49 population, the aim of the project is to co-design consumer engagement interventions to
50
51 increase consumer engagement and safety in New South Wales (NSW) and Victorian (VIC)
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53 cancer inpatient, outpatient and day procedure services.
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57 **Methods and analysis:** A mixed-methods project will be undertaken at six study sites. Our
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59 EBCD approach includes a preparatory phase in which we will provide training and support
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3 to the co-design participants, in addition to recruiting and training consumer co-facilitators for
4 the co-design workshops. The project will follow the EBCD process of gathering and
5 synthesising observational data from each cancer service, with interview data from
6 consumers and staff. With the resulting in-depth understanding of the safety threats
7 commonly experienced by ethnic minority consumers in each site, we will work through
8 feedback events and co-design groups with consumers and staff to determine how they can
9 be more involved with their care to minimise the potential for patient harm. Consumer
10 engagement interventions will be co-produced in each of the six participating services that
11 are tailored to the ethnic minority populations served.

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22 **Ethics and dissemination:** Ethics approval has been obtained. The project will provide
23 strategies for ethnic minority consumers to engage with cancer services to minimise
24 healthcare-associated harm that may be applied to diverse healthcare settings.
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31 **Strengths and limitations of this study**

- 32 • Novel co-design method with bilingual fieldworkers, consumer co-facilitators and
33 ethnic minority cancer service consumers will be evaluated in this research;
- 34 • This co-design study involves multiple ethnic minority populations across multiple
35 sites and states in Australia;
- 36 • This is the first study to develop patient involvement in patient safety interventions
37 specifically, and with multiple ethnic minority populations;
- 38 • The protocol provides a group of innovative interventions that could be transferable
39 for wider replication and testing in other care settings and internationally.
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51 **Introduction**

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54 Effective consumer engagement is identified as the cornerstone of safe and high quality care
55 in contemporary healthcare systems.(1) Consumers include patients, family members,
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3 friends and other caregivers. Engagement, achieved by involving consumers in the
4 prioritisation, planning, design and evaluation of health services, can provide safer care
5 through mutual accountability for quality and by supporting patient-centred allocation of
6 resources.(2) Approaches to consumer engagement are multi-faceted and varied; and occur
7 on a continuum from consultation through to partnership.(1, 3) In the context of minimising
8 patient harm, strategies employed internationally primarily focus on patients being
9 encouraged to ask questions, provide information, and to report when their safety has been
10 compromised.(4-7) A recent evidence synthesis confirms current consumer engagement
11 strategies aiming to improve healthcare safety predominantly focus on communication that
12 takes place at the clinical interface.(4, 8-11)

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Consumers from ethnic minority backgrounds include those who speak languages other than
the official national languages, or who have lower proficiency in native or national languages,
and may include those born overseas or who have parents who were born overseas. Review
findings confirm that these population groups are more likely to experience adverse safety
events in their care; factors that contributing to this are language barriers, lack of social
support, lower health literacy, lower socio-economic status, greater incidence of ill health,
other settlement related issues taking greater precedence over health concerns, and a
sense of disempowerment.(12-16) Limited numbers of culturally competent staff within
health systems has also been identified as an underlying contributor to inequities in
healthcare safety for this population.(17) Delayed diagnosis or access to timely and
adequate care, extended length of stay, inadequate follow-up of abnormal screening results,
medication errors and healthcare-associated infections also occur more commonly amongst
those from ethnic minority backgrounds.(18-21)

Current strategies for preventing harm to patients such as encouraging 'questioning' health
professionals and using verbal communication practices, are challenging for many patients
but may be particularly unsuitable or not culturally appropriate for patients with limited

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3 language proficiency, different beliefs about health and wellness or perspectives on the
4 patient-professional relationship in healthcare than the majority population.(16) A recent
5 review of current strategies used at the point-of-care confirms that consumer engagement
6 interventions have not been purposively developed or evaluated with those from ethnic
7 minority backgrounds to determine whether these interventions are suitable and/or
8 feasible.(4) Consumer engagement frameworks acknowledge health literacy and patient
9 diversity are key factors in shaping policy and research priorities.(22) Notwithstanding this
10 acknowledgement, there is limited evidence that health services take into account to address
11 the diversity between and within ethnic minority populations, in terms of settlement status or
12 settlement-related matters, cultural and linguistic backgrounds, time spent in the country and
13 other factors that may impact the development of patient engagement interventions
14 designed to minimise harm.(12) Developing consumer engagement strategies designed to
15 minimise harm with a diverse range of ethnic minority patients and families addresses this
16 knowledge gap and aims to ultimately reduce inequities in the safety of care for these
17 populations.

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36 Co-design and the associated term of co-production is a methodological approach that
37 facilitates democratic dialogue between different stakeholders in developing and
38 implementing change-focused interventions and service improvement.(23-25) Using co-
39 design provides an avenue for health services to ensure that healthcare improvements or
40 innovations and their implementation are tailored to meet the unique needs identified by the
41 user group(s).(26) It also establishes a collaborative platform for promoting the views of
42 communities who typically excluded, and provides a space for them to participate in the
43 design of healthcare resources and services.(27, 28) Despite the potential value of co-
44 design for amplifying diverse perspectives, it is still unclear how the key principles and
45 practice of codesign are meaningfully employed for populations who experience healthcare
46 disparities, such as those from ethnic minority backgrounds(29-31).

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3 Experience-based co-design (EBCD) has been adopted in healthcare to enable a user-
4 centric collaborative process of developing changes to improve consumer and staff
5 experiences.⁽³²⁾ Users are experts in their own lived experiences. In the present study,
6 EBCD is used to achieve the primary aim of enhancing (patient-reported) patient safety and
7 engagement with cancer services amongst ethnic minority patients in Australia. We seek to
8 achieve this goal through co-designing adaptations of consumer engagement strategies that
9 aim to improve safety with consumers from ethnic minority backgrounds and their healthcare
10 staff and applying these strategies in Australian cancer services. The study employs a novel
11 adaptation of EBCD by integrating consumer co-facilitators and their training into the EBCD
12 process. Consumer co-facilitators are past and/or current cancer services consumers who
13 work in partnership with the research team to co-facilitate the leadership of the process of
14 the co-design, guiding and supporting participants through the process. This adaptation aims
15 to widen participation to the co-design process, the depth of engagement between co-
16 design members and to improve consumer experience of the co-design process itself. The
17 secondary aim is therefore to evaluate our adapted model of EBCD for its impacts on
18 consumer experience and engagement in the co-design process. The project is embedded
19 within a larger program of work; the CanEngage Project, which explores consumer
20 experience and engagement in their healthcare as a means of improving healthcare safety
21 for ethnic minority populations accessing cancer services.
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47 **Methods and analysis:**

48 *Ethical approval*

49 Ethics approval has been obtained for the observation and semi-structured interview
50 components of the co-design for all six sites (2020/ETH00965) by a National Health and
51 Medical Research Council (NHMRC) recognised ethics committee. A further ethics
52 application is now underway for the co-design workshop process at the six study sites.
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Ensuring study quality

This program of work has been through two independent scientific peer review processed by 1) the National Health and Medical Research Council under the Ideas Funding Scheme (Project number: 1180925) and 2) by Cancer Australia under the Supporting People with Cancer Funding Scheme, Round 11. Both schemes have competitively funded this research based on the scientific quality of the proposals.

Patient or public involvement

Consumer involvement has been central to all elements of the research process from the project inception to execution. It is recognised as critical within the context of safety and quality in healthcare and associated programs of research.⁽³³⁾ The investigator team, who conceptualised the project and applied for research funding, includes a consumer investigator (TT) from an ethnic minority background. The consumer investigator has both experience of cancer as a patient and also in supporting those experiencing cancer from a range of ethnic minority backgrounds through a charitable organisation. Ahead of project development, the project idea was presented to a cancer consumer panel at the Translational Cancer Research Network in Sydney. The panel comprised patients (current and past) and members of the public with interests in cancer care and utilised their feedback to inform the proposal. Once funding was secured, we advertised across a range of cancer and consumer networks for individuals from a range of ethnic and language backgrounds to form a project consumer advisory panel for the project. Eight consumers have been active members since June 2019 and regularly meet to inform the project direction and progress. The consumer advisory panel also reviews any materials or processes of research proposed with patients and their carers in detail. Finally, as part of the co-design process, the project team will work with the consumers from the consumer advisory panel who are interested in

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3 co-facilitating the co-design process in partnership with research team members. The co-
4 facilitators who have expressed interest are from a range of ethnic backgrounds and will be
5 provided training and support ahead of and during the co-design process. The nature of
6 training and support needed for the co-facilitators has been identified collaboratively with the
7 consumer advisory panel through our regular meetings as well as through further input from
8 the consumer co-facilitators.
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19 *Study design*

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21 An exploratory mixed-method design will integrate observations and semi-structured
22 interviews. We will use Experience-Based Co-Design (EBCD), which proceeds through
23 observations of the services, patient and staff interviews followed by a series of patient and
24 staff feedback events and subsequent co-design workshops.(34) We will adapt this process
25 of EBCD by adding an initial phase (phase 1 in Figure 1) in which we will recruit and train
26 ethnic minority consumer co-facilitators along with providing training and establishing the
27 support needs of co-design participants.(35)
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45 *Setting*

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47 Inpatient, outpatient and day procedure cancer services in six hospitals in the two most
48 populous Australian states of New South Wales (NSW) and Victoria (VIC) have been
49 recruited for involvement in order to engage a heterogeneous ethnic minority population in
50 the project. The sites are geographically located such that different ethnic minority groups
51 are service users. The major ethnic minority populations served by the study sites
52 predominantly include communities originating from countries in Southern Europe, East and
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3 Central or South-East Asia, the Middle-East, including refugee populations. All included
4 cancer services provide surgery, medical oncology, radiotherapy, and palliative care
5 services.
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10 11 12 *Study sample*

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15 Approximately 15 clinical and non-clinical staff employed by the participating cancer services
16 (including administrative and management staff) and 15 ethnic minority consumers (patients
17 and/or their informal carers) will be initially recruited at each site, totaling 90 healthcare staff
18 and 90 patient/carers across the six sites. The sample size proposed seeks to capture an
19 initial group of individuals from a range of the ethnic groups attending each service, which
20 will then be utilised to explore further sample size requirements. Interviews and subsequent
21 analysis will be an iterative process with the research team regularly reflecting on and
22 reviewing the sampling strategy throughout the data collection period. The final sample size
23 will be informed by the emerging analysis based on principles of information power, taking
24 into account adequate representation of multiple ethnic minority perspectives.(36) For the
25 series of co-design workshops, least three staff and between three and five patient/carer
26 members will be included in the group at each site who have lived experience relevant to the
27 subject matter.(32)
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46 *Recruitment*

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48 The first phase of recruitment will be for the semi-structured interviews. Recruitment will be
49 facilitated by the clinician members of the research team embedded at each participating
50 site. We will use study advertisement materials in a range of languages relevant to the
51 communities served by each service. We will use poster and video-screen advertisements in
52 each service and community healthcare centres, as well as publicity in newsletters and
53 emails to staff and service user distribution lists. Those who take part in the interviews will be
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3 asked to indicate in their consent form whether they agree to be contacted about the
4 subsequent stage of the study – the co-design workshops. In the second phase of
5 recruitment, those who indicate willingness to be contacted will provide their email and
6 telephone contact details for this purpose and be invited to take part in a co-design group.
7
8 One consumer co-facilitator will be recruited to co-facilitate each group via the consumer
9 advisory group for the project and the member's networks. Where participants withdraw at
10 any stage from the study, we will invite new members to join the co-design process
11 accompanied by the same training. If joining later in the process, the recordings of the initial
12 sessions will be shared with new members to ensure they are able to engage with the
13 process at the stage that they join. The addition of new and different perspectives in the
14 context of co-designing the strategies would not impact the validity of the process and may
15 enhance the process by introducing a broader range of perspectives.
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32 *Training and support*

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35 In phase one, training will be provided over two 90-minute sessions, with online and
36 recorded options. Bilingual fieldworkers will support the sessions in the relevant languages.
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38 The first session will be provided for all participants and consumer co-facilitators regarding
39 the purpose and process of co-design and outline the role of co-design members and
40 facilitators. The second session will be provided separately with one session for consumer
41 co-facilitators and the other for participants and will provide detailed information about what
42 is expected to occur during each session, with an extended open forum for questions and
43 discussion. The opportunity for further one-to-one discussions will also be offered to enable
44 participants to ask questions, request specific supports or clarify any aspects of the process.
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46 We will be flexible in our approach to the location, timing and format of the sessions to meet
47 the needs of the members attending.
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Data Collection

In phase two, data collection will occur through observations and interviews, which will then be reported and discussed with participants through feedback events.

- i. *Observations*: Observations of the physical environment of the public areas in each service will be undertaken by two researchers independently from one another at each study site to understand the service, and the professional and specialty contexts that surround healthcare delivery, which may impact on patient engagement. An environmental observational audit tool has been developed collaboratively by the research team for the study purpose based on existing environmental audit tools used in other public spaces. Sixty hours of observations will be conducted in two-hour blocks at each site by each researcher over a six-week period to provide observations that include a range of times of day and days of the week. The audit tool will be used by the researchers to collate field notes and checklist information regarding the opportunities for consumer engagement in the physical environment in each service, along with the observable barriers and facilitators to this type of engagement for ethnic minority service users. Patient and staff interactions will not be examined in the observational study because of the ethical considerations associated with gaining consent for the more than 40 language groups attending the services, coupled with the health status of the patient group. We will instead seek to explore experiences of patient and staff interactions through the interview study described below that will occur in parallel to the observational study.
- ii. *Semi-structured interviews*: Semi-structured interviews will be conducted with healthcare staff and the patients and caregivers associated with each of the six study sites. An interview schedule has been developed by the research team based on our preliminary literature reviews, which seeks to explore experiences of patient engagement amongst ethnic minority patients and healthcare staff in cancer settings,

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3 and the potential for healthcare-associated harm in their care. Face-to-face,
4 videoconferencing or phone interviews will be conducted. Interviews with ethnic
5 minority cancer consumers will be conducted in their preferred language. For
6 languages other than English, bilingual fieldworkers, and interpreters (when bilingual
7 fieldworkers are not available) will be used to complete the interviews. This is an
8 approach that have been used in previously published work undertaken by the team
9 in Australian healthcare services in conjunction with multicultural health team at
10 Western Sydney Local Health District (WSLHD). The bilingual fieldworkers will be
11 provided with appropriate training prior to conducting the interviews. This approach
12 will be used to enhance trust and comfort between the research participants and the
13 researcher; previous research has indicated that bilingual fieldworkers who
14 understand the language and culture of the participant can support participants to
15 feel at ease and share their experiences.

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33 iii. *Feedback events*: The Experience-Based Co-Design toolkit identifies the importance
34 of feedback events in which co-design participants come together to discuss and
35 share their views throughout the co-design process. In the present project, these
36 events will be held as facilitated online meetings lasting around two hours at two time
37 points. The first will occur before the codesign groups. The first feedback event will
38 aim to generate a shortlist of areas in which patient safety could be improved for
39 ethnic minority patients using patient engagement strategies. The findings from
40 observations and interviews undertaken will be discussed in this event. Both staff and
41 patients from the six sites will jointly identify priority areas for developing or adapting
42 current engagement strategies. The facilitators will support the discussions to ensure
43 balance in the range of perspectives that are heard. The feedback event will be used
44 to discuss and agree the focus of the co-design groups in each site including whether
45 these focus on a particular ethnic minority population/language or cultural group, or
46 to focus on heightened inclusivity of patient engagement strategies to be suitable for
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3 a range of ethnic minority consumers. Online events enable participants from all sites
4 to meet together across the broad geographical region of Victoria and New South
5 Wales. Both consumer and healthcare staff participants will attend both feedback
6 events.
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14 iv. *Co-design groups and subsequent feedback event:* A small co-design group will be
15 formed in each of the six sites; six groups in total, with 6-8 members per group. Each
16 group will comprise of a mix of patients, carers and healthcare staff. The co-design
17 groups will be convened to adapt, design and implement solutions to the priority
18 issues identified through feedback events with reference to the patient safety
19 strategies identified and explored with stakeholders during the preliminary stages of
20 the research. Each group will have a facilitator from the research team and an ethnic
21 minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the
22 study population. The groups will meet for no more than 10 hours in total;
23 approximately 2-3 hours every fortnight over a six-week period. Each group will
24 develop terms of reference that will determine their ways of working and their
25 preferred mode of meeting (online, face to face or hybrid) and meeting duration and
26 frequency as proposed by the consumer advisory group. The terms of reference will
27 be reviewed at the commencement of each sessions. The co-design workshop
28 process is shown in Figure 2. Following the co-design group meetings, all
29 participants will attend a second online feedback event, along with the consumer
30 advisory and project reference group members. In the second feedback event, the
31 attendees will determine the interventions for implementation in each site for the six
32 months following the end of the co-design period. The activities will be evaluated for
33 feasibility and acceptability over a six-month period when implemented in the
34 participating cancer services in the next stage of the CanEngage Project.
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9 i. *Evaluation of adapted EBCD approach:* To address the secondary aim we will
10 evaluate the approach to EBCD employed in the study for its impacts on consumer
11 experience and involvement in the co-design process. Members of the co-design
12 groups and the co-facilitators will be asked to complete a brief end of project
13 interview. One researcher who is external to the CanEngage Project (ENS) will work
14 with bilingual fieldworkers to conduct online or face-to-face interviews based on the
15 participants preference. We will review the terms of reference they have developed,
16 and capture adaptations made to these. These data will be synthesised with data
17 from the recordings and summary notes of the co-design workshops to produce a
18 narrative synthesis of experiences of the co-design process, and the nature and
19 extent of their engagement when using the adapted EBCD model. Towards the
20 evaluation, we will seek to conduct exit interviews with those who dropped out of the
21 study at any stage to explore factors contributing to drop-out and consider their
22 mitigation for future work.
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Data analysis plan

Observational data: The quantitative observational data from the environmental audit tool checklist will be transferred to SPSS (IBM version 19) for analysis, with descriptive statistics used to determine the number and types of opportunities in the cancer service environment observed that may impact consumer engagement. As outlined below, the field notes will be subject to thematic analysis and synthesised with the qualitative interview data.

Interview data: Interview and field note data will be subject to thematic analysis to draw out
a) common experiences and perceptions regarding patient safety amongst ethnic minority

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3 consumers and their engagement in patient safety practices in the participating cancer
4 services and b) the key elements of the cancer service environment that enable or may
5 inhibit consumer engagement. (37, 38) Following transcription, two researchers will
6 independently listen to the audio recordings repeatedly to become familiar with the data.
7
8 Transcripts and field notes will be subject to line-by-line coding. The researchers will
9 independently identify key words, phrases and sentences and explore themes within the
10 data.(38) Coding will be iterative and refinement of themes and subthemes will evolve over
11 the course of the analysis. The data will be organised and displayed via diagrams and
12 figures to identify patterns and interrelationships within the data. Discrepancies will be
13 discussed and themes and subthemes refined until agreement.

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28 *Co-design process analysis:* Inductive analyses drawing upon grounded theory will be
29 utilised to generate new understanding of the adapted model of co-design in the present
30 study, replicating a method that has been used to explore the implementation of EBCD in
31 health service improvement.(39, 40) Analyses will be via the constant comparative method
32 with multiple researchers. Open codes will be independently generated from the transcripts
33 and fieldwork notes; as patterns and themes emerge from the data they will be grouped into
34 higher order organising themes.(41) Analysis will be recursive, constantly moving from the
35 specific to the more general to develop more transferable categories and explanations for
36 the findings, but also explore local level findings and disparities between groups.
37
38 Commonalities and patterns across settings will be identified and deviant cases will be
39 sought to check the emerging constructs. A summary of the ground theory analysis will be
40 shared with participants of the co-design groups and the co-facilitators for input and final
41 reflections.
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3 *Co-designed strategies:* The co-designed strategies developed will be collated and reported
4 in terms of the nature of the adaptations made; the safety issues each strategy sought to
5 address; the populations who co-designed the strategy and the target population, along with
6 considerations regarding further populations to whom they may or may not be relevant.
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15 **Ethics and dissemination:**

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18 Ethical considerations have been explored, identified and a risk mitigation plan created for
19 each matter arising through the process of applying for ethical approval for the conduct of
20 the study, which has been granted for all sites through the NHMRC accredited ethics
21 committee (281775). The study findings will be disseminated at multiple events and through
22 a range of formats to ensure that all stakeholder groups with interest in the project and its
23 outcomes are able to access the findings. Dissemination will occur through practice-based
24 and local-level presentations in the participating sites for staff and consumers, with key
25 findings also reported through the social media outlets of the research team and affiliated
26 institutions to reach a wider public audience. Scientific reports of the findings will be
27 developed and submitted to high-quality, peer-reviewed outlets in the field of health services
28 and cancer-services research relevant to the emergent evidence.
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45 **Authors' contributions:** RH, MW and EM conceived the project, with all authors
46 substantial involved in developing the project design and study methods described in
47 the protocol as project investigators. All authors edited, contributed content and
48 review the final draft of the protocol.
49
50
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54

55 **Funding statement:** This work is supported by the National Health and Medical
56 Research Council project number: 1180925
57
58
59
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Competing interest statement.

No competing interests to declare.

Figure legends

Figure 1 – Adapted EBCD Process

Figure 2 – Co-design Workshop Schedule

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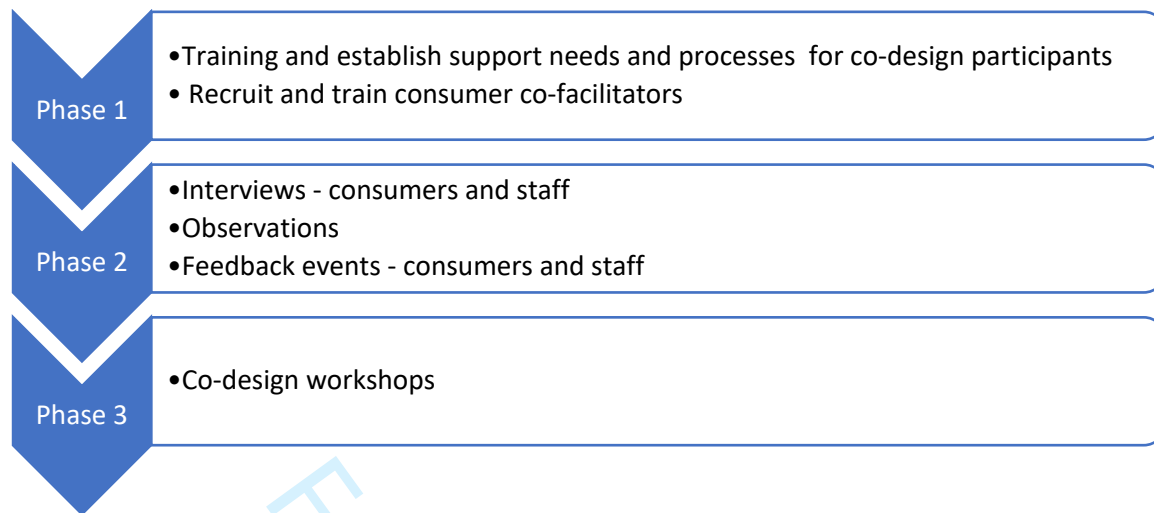


Figure 1 Adapted EBCD Approach

For peer review only

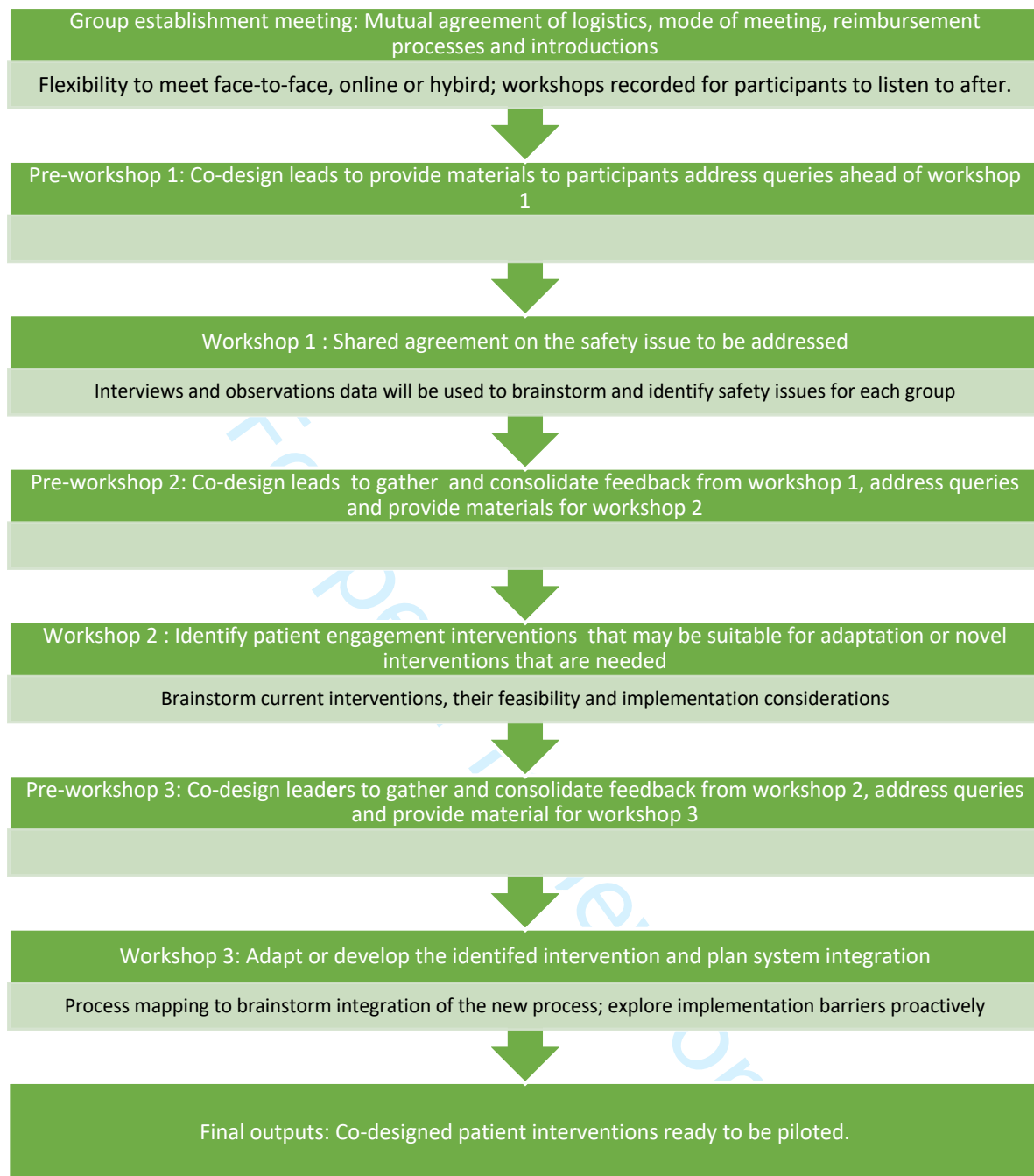


Figure 2: Co-design Workshop Schedule

BMJ Open

Co-designing consumer engagement strategies with ethnic minority consumers in Australian cancer services: The CanEngage Project Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048389.R1
Article Type:	Protocol
Date Submitted by the Author:	23-May-2021
Complete List of Authors:	Harrison, Reema; Macquarie University, Australian Institute of Health Innovation Walton, Merrilyn; The University of Sydney, Public Health Manias, Elizabeth; Deakin University, School of Nursing and Midwifery; University of Melbourne VCCC, Melbourne School of Health Sciences Wilson, Carlene; Austin Health, Psychology Girgis, Afaf; UNSW, Ingham Institute of Applied Research Chin, Melvin; Prince of Wales Hospital and Community Health Services, Medical Oncology Leone, Desiree; Western Sydney Local Health District, Multicultural Health Seale, Holly; UNSW, Population Health Smith, Allan; UNSW, Ingham Institute of Applied Research Chauhan, Ashfaq; UNSW, Population Health
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Oncology, Research methods, Patient-centred medicine
Keywords:	Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult oncology < ONCOLOGY, QUALITATIVE RESEARCH

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4 1 **Title: Co-designing consumer engagement strategies with ethnic**
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7 2 **minority consumers in Australian cancer services: The CanEngage**
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10 3 **Project Protocol**
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31 34 **Abstract:**
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34 35 **Introduction:** Consumer engagement is central to high quality cancer service delivery and is
35
36 36 a recognised strategy to minimise healthcare-associated harm. Strategies developed to
37
38 37 enhance consumer engagement specifically in relation to preventing healthcare harm
39
40 38 include questioning health professionals, raising concerns about possible mistakes or risks
41
42 39 in care, and encouraging patients and caregivers to report suspected errors. Patients from
43
44 40 ethnic minority backgrounds are particularly vulnerable to unsafe care, but current
45
46 41 engagement strategies have not been developed specifically for (and with) this population.
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48 42 Using an adapted approach to Experience-Based Co-Design (EBCD) to support the target
49
50 43 population, the aim of the project is to co-design consumer engagement interventions to
51
52 44 increase consumer engagement and safety in New South Wales (NSW) and Victorian (VIC)
53
54 45 cancer inpatient, outpatient and day procedure services.
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56

57 46 **Methods and analysis:** A mixed-methods project will be undertaken at six study sites. Our
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59 47 EBCD approach includes a preparatory phase in which we will provide training and support
60

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3 48 to the co-design participants, in addition to recruiting and training consumer co-facilitators for
4
5 49 the co-design workshops. The project will follow the EBCD process of gathering and
6
7 50 synthesising observational data from each cancer service, with interview data from
8
9 51 consumers and staff. With the resulting in-depth understanding of the safety threats
10
11 52 commonly experienced by ethnic minority consumers in each site, we will work through
12
13 53 feedback events and co-design groups with consumers and staff to determine how they can
14
15 54 be more involved with their care to minimise the potential for patient harm. Consumer
16
17 55 engagement interventions will be co-produced in each of the six participating services that
18
19 56 are tailored to the ethnic minority populations served.

20
21
22 57 **Ethics and dissemination:** Ethics approval has been obtained. The project will provide
23
24 58 strategies for ethnic minority consumers to engage with cancer services to minimise
25
26 59 healthcare-associated harm that may be applied to diverse healthcare settings.
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31 **Strengths and limitations of this study**

- 32
33 62 • We employ and evaluate a novel co-design approach that prepares facilitators and
34
35 63 participants for the co-design.
- 36
37 64 • Co-facilitator development and training with ethnic minority consumers is integrated
38
39 65 in the methodology.
- 40
41 66 • Prior to this study, patient involvement in patient safety interventions have not been
42
43 67 developed for or evaluated with ethnic minority populations.
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45 68 • The protocol provides methodological detail transferable to other co-design work with
46
47 69 ethnic minority populations in other care settings and internationally.
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51 **Introduction**

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54 71 Effective consumer engagement is identified as the cornerstone of safe and high quality care
55
56 72 in contemporary healthcare systems.(1) Consumers include patients, family members,
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3 74 friends and other caregivers. Engagement, achieved by involving consumers in the
4
5 75 prioritisation, planning, design and evaluation of health services, can provide safer care
6
7 76 through mutual accountability for quality and by supporting patient-centred allocation of
8
9 77 resources.(2) Approaches to consumer engagement are multi-faceted and varied; and occur
10
11 78 on a continuum from consultation through to partnership.(1, 3) In the context of minimising
12
13 79 patient harm, strategies employed internationally primarily focus on patients being
14
15 80 encouraged to ask questions, provide information, and to report when their safety has been
16
17 81 compromised.(4-7) A recent evidence synthesis confirms current consumer engagement
18
19 82 strategies aiming to improve healthcare safety predominantly focus on communication that
20
21 83 takes place at the clinical interface.(4, 8-11)
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25 84 Consumers from ethnic minority backgrounds include those who speak languages other than
26
27 85 the official national languages, or who have lower proficiency in native or national languages,
28
29 86 and may include those born overseas or who have parents who were born overseas. Review
30
31 87 findings confirm that these population groups are more likely to experience adverse safety
32
33 88 events in their care; factors that contributing to this are language barriers, lack of social
34
35 89 support, lower health literacy, lower socio-economic status, greater incidence of ill health,
36
37 90 other settlement related issues taking greater precedence over health concerns, and a
38
39 91 sense of disempowerment.(12-16) Limited numbers of culturally competent staff within
40
41 92 health systems has also been identified as an underlying contributor to inequities in
42
43 93 healthcare safety for this population.(17) Delayed diagnosis or access to timely and
44
45 94 adequate care, extended length of stay, inadequate follow-up of abnormal screening results,
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47 95 medication errors and healthcare-associated infections also occur more commonly amongst
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49 96 those from ethnic minority backgrounds.(18-21)
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54 97 Current strategies for preventing harm to patients such as encouraging 'questioning' health
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56 98 professionals and using verbal communication practices, are challenging for many patients
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58 99 but may be particularly unsuitable or not culturally appropriate for patients with limited
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3 100 language proficiency, different beliefs about health and wellness or perspectives on the
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5 101 patient-professional relationship in healthcare than the majority population.(16) A recent
6
7 102 review of current strategies used at the point-of-care confirms that consumer engagement
8
9 103 interventions have not been purposively developed or evaluated with those from ethnic
10
11 104 minority backgrounds to determine whether these interventions are suitable and/or
12
13 105 feasible.(4) Consumer engagement frameworks acknowledge health literacy and patient
14
15 106 diversity are key factors in shaping policy and research priorities.(22) Notwithstanding this
16
17 107 acknowledgement, there is limited evidence that health services take into account to address
18
19 108 the diversity between and within ethnic minority populations, in terms of settlement status or
20
21 109 settlement-related matters, cultural and linguistic backgrounds, time spent in the country and
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23 110 other factors that may impact the development of patient engagement interventions
24
25 111 designed to minimise harm.(12) Developing consumer engagement strategies designed to
26
27 112 minimise harm with a diverse range of ethnic minority patients and families addresses this
28
29 113 knowledge gap and aims to ultimately reduce inequities in the safety of care for these
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31 114 populations.

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36 115 Co-design and the associated term of co-production is a methodological approach that
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38 116 facilitates democratic dialogue between different stakeholders in developing and
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40 117 implementing change-focused interventions and service improvement.(23-25) Using co-
41
42 118 design provides an avenue for health services to ensure that healthcare improvements or
43
44 119 innovations and their implementation are tailored to meet the unique needs identified by the
45
46 120 user group(s).(26) Co-design also establishes a collaborative platform for promoting the
47
48 121 views of communities who typically excluded, and provides a space for them to participate in
49
50 122 the design of healthcare resources and services.(27, 28) Despite the potential value of co-
51
52 123 design for amplifying diverse perspectives, it is still unclear how the key principles and
53
54 124 practice of codesign are meaningfully employed for populations who experience healthcare
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56 125 disparities, such as those from ethnic minority backgrounds(29-31).

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3 127 Experience-based co-design (EBCD) has been adopted in healthcare to enable a user-
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5 128 centric collaborative process of developing changes to improve consumer and staff
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7 129 experiences.(32) Users are experts in their own lived experiences. In the present study,
8
9 130 EBCD is used to achieve the primary aim of enhancing (patient-reported) patient safety and
10
11 131 engagement with cancer services amongst ethnic minority patients in Australia. We seek to
12
13 132 achieve this goal through co-designing adaptations of consumer engagement strategies that
14
15 133 aim to improve safety with consumers from ethnic minority backgrounds and their healthcare
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17 134 staff and applying these strategies in Australian cancer services. The study employs a novel
18
19 135 adaptation of EBCD by integrating consumer co-facilitators and their training into the EBCD
20
21 136 process. Consumer co-facilitators are past and/or current cancer services consumers who
22
23 137 work in partnership with the research team to co-facilitate the leadership of the process of
24
25 138 the co-design, guiding and supporting participants through the process. This adaptation aims
26
27 139 to widen participation to the co-design process, the depth of engagement between co-
28
29 140 design members and to improve consumer experience of the co-design process itself. The
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31 141 secondary aim is therefore to evaluate our adapted model of EBCD for its impacts on
32
33 142 consumer experience and engagement in the co-design process. The project is embedded
34
35 143 within a larger program of work; the CanEngage Project, which explores consumer
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37 144 experience and engagement in their healthcare as a means of improving healthcare safety
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39 145 for ethnic minority populations accessing cancer services.
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147 **Methods and analysis:**

148 *Study design*

149 An exploratory mixed-method design will integrate observations and semi-structured
150 interviews. We will use Experience-Based Co-Design (EBCD), which proceeds through
151 observations of the services, patient and staff interviews followed by a series of patient and
152 staff feedback events and subsequent co-design workshops.(33) We will adapt this process
153 of EBCD by adding an initial phase (phase 1 in Figure 1) in which we will recruit and train

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3 154 ethnic minority consumer co-facilitators along with providing training and establishing the
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5 155 support needs of co-design participants.(34)
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16 159 *Setting*

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18 160 Inpatient, outpatient and day procedure cancer services in six hospitals in the two most
19 161 populous Australian states of New South Wales (NSW) and Victoria (VIC) have been
20 162 recruited for involvement in order to engage a heterogeneous ethnic minority population in
21 163 the project. The sites are geographically located such that different ethnic minority groups
22 164 are service users. The major ethnic minority populations served by the study sites
23 165 predominantly include communities originating from countries in Southern Europe, East and
24 166 Central or South-East Asia, the Middle-East, including refugee populations. All included
25 167 cancer services provide surgery, medical oncology, radiotherapy, and palliative care
26 168 services.
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41 170 *Study sample*

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43 171 Approximately 15 clinical and non-clinical staff employed by the participating cancer services
44 172 (including administrative and management staff) and 15 ethnic minority consumers (patients
45 173 and/or their informal carers) will be initially recruited at each site, totaling 90 healthcare staff
46 174 and 90 patient/carers across the six sites. Consumers who are aged 18 and over will be
47 175 eligible to take part in the study if they self-identify as from an ethnic minority background
48 176 and have accessed one of the participating sites as a patient or support person in the past
49 177 two years. Healthcare staff will be eligible if they have worked within one of the participating
50 178 services for at least six months and are a current staff member in any role. The sample size
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1
2
3 179 proposed seeks to capture an initial group of individuals from a range of the ethnic groups
4
5 180 attending each service, which will then be utilised to explore further sample size
6
7 181 requirements. Interviews and subsequent analysis will be an iterative process with the
8
9 182 research team regularly reflecting on and reviewing the sampling strategy throughout the
10
11 183 data collection period. The final sample size will be informed by the emerging analysis based
12
13 184 on principles of information power, taking into account adequate representation of multiple
14
15 185 ethnic minority perspectives.(35) For the series of co-design workshops, least three staff and
16
17 186 between three and five patient/carer members will be included in the group at each site who
18
19 187 have lived experience relevant to the subject matter.(32)
20
21
22
23 188

24 25 189 *Recruitment*

26
27
28 190 The first phase of recruitment will be for the semi-structured interviews. Recruitment will be
29
30 191 facilitated by the clinician members of the research team embedded at each participating
31
32 192 site. We will use study advertisement materials in a range of languages relevant to the
33
34 193 communities served by each service. We will use poster and video-screen advertisements in
35
36 194 each service and community healthcare centres, as well as publicity in newsletters and
37
38 195 emails to staff and service user distribution lists. Those who take part in the interviews will be
39
40 196 asked to indicate in their consent form whether they agree to be contacted about the
41
42 197 subsequent stage of the study – the co-design workshops. In the second phase of
43
44 198 recruitment, those who indicate willingness to be contacted will provide their email and
45
46 199 telephone contact details for this purpose and be invited to take part in a co-design group.
47
48 200 One consumer co-facilitator will be recruited to co-facilitate each group via the consumer
49
50 201 advisory group for the project and the member's networks. Where participants withdraw at
51
52 202 any stage from the study, we will invite new members to join the co-design process
53
54 203 accompanied by the same training. If joining later in the process, the recordings of the initial
55
56 204 sessions will be shared with new members to ensure they are able to engage with the
57
58 205 process at the stage that they join. The addition of new and different perspectives in the
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3 206 context of co-designing the strategies would not impact the validity of the process and may
4
5 207 enhance the process by introducing a broader range of perspectives.
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8 208

10 209 *Training and support*

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12
13
14 210 In phase one, training will be provided over two 90-minute sessions, with online and
15
16 211 recorded options. Bilingual fieldworkers will support the sessions in the relevant languages.
17
18 212 The first session will be provided for all participants and consumer co-facilitators regarding
19
20 213 the purpose and process of co-design and outline the role of co-design members and
21
22 214 facilitators. The second session will be provided separately with one session for consumer
23
24 215 co-facilitators and the other for participants and will provide detailed information about what
25
26 216 is expected to occur during each session, with an extended open forum for questions and
27
28 217 discussion. The opportunity for further one-to-one discussions will also be offered to enable
29
30 218 participants to ask questions, request specific supports or clarify any aspects of the process.
31
32 219 We will be flexible in our approach to the location, timing and format of the sessions to meet
33
34 220 the needs of the members attending.
35
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38 221

40 222 *Data Collection*

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42
43 223 In phase two, data collection will occur through observations and interviews, which will then
44
45 224 be reported and discussed with participants through feedback events.
46
47

48 225 i. *Observations:* Observations of the physical environment of the public areas in each
49
50 226 service will be undertaken by two researchers independently from one another at
51
52 227 each study site to understand the service, and the professional and specialty
53
54 228 contexts that surround healthcare delivery, which may impact on patient
55
56 229 engagement. An environmental observational audit tool has been developed
57
58 230 collaboratively by the research team for the study purpose based on existing
59
60

1
2
3 231 environmental audit tools used in other public spaces. The environmental audit tool
4
5 232 comprises four components totalling 17 items and 29 questions. The four
6
7 233 components that capture evidence of the observable features of the health service
8
9 234 environment that reflect the elements of consumer engagement based on the
10
11 235 Carmen's Patient and Family Engagement framework.(1) The tool was validated in
12
13 236 one of the participating sites. It was independently completed by two researchers
14
15 237 over three observation periods. Internal reliability analysis revealed substantial
16
17 238 agreement between reviewers in applying the tool (k = 0.85). Sixty hours of
18
19 239 observations will be conducted in two-hour blocks at each site by each researcher
20
21 240 over a six-week period to provide observations that include a range of times of day
22
23 241 and days of the week. The audit tool will be used by the researchers to collate field
24
25 242 notes and checklist information regarding the opportunities for consumer
26
27 243 engagement in the physical environment in each service, along with the observable
28
29 244 barriers and facilitators to this type of engagement for ethnic minority service users.
30
31 245 Patient and staff interactions will not be examined in the observational study because
32
33 246 of the ethical considerations associated with gaining consent for the more than 40
34
35 247 language groups attending the services, coupled with the health status of the patient
36
37 248 group. We will instead seek to explore experiences of patient and staff interactions
38
39 249 through the interview study described below that will occur in parallel to the
40
41 250 observational study.

42
43 251
44
45 252 ii. *Semi-structured interviews:* Semi-structured interviews will be conducted with
46
47 253 healthcare staff and the patients and caregivers associated with each of the six study
48
49 254 sites. An interview schedule has been developed by the research team based on our
50
51 255 preliminary literature reviews, which seeks to explore experiences of patient
52
53 256 engagement amongst ethnic minority patients and healthcare staff in cancer settings,
54
55 257 and the potential for healthcare-associated harm in their care. Face-to-face,
56
57 258 videoconferencing or phone interviews will be conducted, with the latter modes being

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2
3 259 utilised when covid restrictions are in place or upon request of the participant.
4
5 260 Interviews with ethnic minority cancer consumers will be conducted in their preferred
6
7 261 language. For languages other than English, bilingual fieldworkers, and interpreters
8
9 262 (when bilingual fieldworkers are not available) will be used to complete the
10
11 263 interviews. This is an approach that have been used in previously published work
12
13 264 undertaken by the team in Australian healthcare services in conjunction with
14
15 265 multicultural health team at Western Sydney Local Health District (WSLHD). The
16
17 266 bilingual fieldworkers will be provided with appropriate training prior to conducting the
18
19 267 interviews. This approach will be used to enhance trust and comfort between the
20
21 268 research participants and the researcher; previous research has indicated that
22
23 269 bilingual fieldworkers who understand the language and culture of the participant can
24
25 270 support participants to feel at ease and share their experiences.
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31 272 iii. *Feedback events:* The Experience-Based Co-Design toolkit identifies the importance
32
33 273 of feedback events in which co-design participants come together to discuss and
34
35 274 share their views throughout the co-design process. In the present project, these
36
37 275 events will be held as facilitated online meetings lasting around two hours at two time
38
39 276 points. The first will occur before the codesign groups. The first feedback event will
40
41 277 aim to generate a shortlist of areas in which patient safety could be improved for
42
43 278 ethnic minority patients using patient engagement strategies. The findings from
44
45 279 observations and interviews undertaken will be discussed in this event. Both staff and
46
47 280 patients from the six sites will jointly identify priority areas for developing or adapting
48
49 281 current engagement strategies. The facilitators will support the discussions to ensure
50
51 282 balance in the range of perspectives that are heard. The feedback event will be used
52
53 283 to discuss and agree the focus of the co-design groups in each site including whether
54
55 284 these focus on a particular ethnic minority population/language or cultural group, or
56
57 285 to focus on heightened inclusivity of patient engagement strategies to be suitable for
58
59 286 a range of ethnic minority consumers. Online events enable participants from all sites
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1
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3 287 to meet together across the broad geographical region of Victoria and New South
4
5 288 Wales. Both consumer and healthcare staff participants will attend both feedback
6
7 289 events.
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9 290
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11 291 iv. *Co-design groups and subsequent feedback event:* A small co-design group will be
12
13 292 formed in each of the six sites; six groups in total, with 6-8 members per group. Each
14
15 293 group will comprise of a mix of patients, carers and healthcare staff. The co-design
16
17 294 groups will be convened to adapt, design and implement solutions to the priority
18
19 295 issues identified through feedback events with reference to the patient safety
20
21 296 strategies identified and explored with stakeholders during the preliminary stages of
22
23 297 the research. Each group will have a facilitator from the research team and an ethnic
24
25 298 minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the
26
27 299 study population. The groups will meet for no more than 10 hours in total;
28
29 300 approximately 2-3 hours every fortnight over a six-week period. Each group will
30
31 301 develop terms of reference that will determine their ways of working and their
32
33 302 preferred mode of meeting (online, face to face or hybrid) and meeting duration and
34
35 303 frequency as proposed by the consumer advisory group. Once again, online and
36
37 304 hybrid modes will be utilised in the context of covid restrictions. The terms of
38
39 305 reference will be reviewed at the commencement of each sessions. The co-design
40
41 306 workshop process is shown in Figure 2. Following the co-design group meetings, all
42
43 307 participants will attend a second online feedback event, along with the consumer
44
45 308 advisory and project reference group members. In the second feedback event, the
46
47 309 attendees will determine the interventions for implementation in each site for the six
48
49 310 months following the end of the co-design period. The activities will be evaluated for
50
51 311 feasibility and acceptability over a six-month period when implemented in the
52
53 312 participating cancer services in the next stage of the CanEngage Project.
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3 314 <INSERT FIGURE 2 HERE>
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8 316 i. *Evaluation of adapted EBCD approach:* To address the secondary aim we will
9
10 317 evaluate the approach to EBCD employed in the study for its impacts on consumer
11
12 318 experience and involvement in the co-design process. Members of the co-design
13
14 319 groups and the co-facilitators will be asked to complete a brief end of project
15
16 320 interview. One researcher who is external to the CanEngage Project (ENS) will work
17
18 321 with bilingual fieldworkers to conduct online or face-to-face interviews based on the
19
20 322 participants preference. We will review the terms of reference they have developed,
21
22 323 and capture adaptations made to these. These data will be synthesised with data
23
24 324 from the recordings and summary notes of the co-design workshops to produce a
25
26 325 narrative synthesis of experiences of the co-design process, and the nature and
27
28 326 extent of their engagement when using the adapted EBCD model. Towards the
29
30 327 evaluation, we will seek to conduct exit interviews with those who dropped out of the
31
32 328 study at any stage to explore factors contributing to drop-out and consider their
33
34 329 mitigation for future work.
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42 331 *Data analysis plan*

43
44 332 *Observational data:* The quantitative observational data from the environmental audit tool
45
46 333 checklist will be transferred to SPSS (IBM version 19) for analysis, with descriptive statistics
47
48 334 used to determine the number and types of opportunities in the cancer service environment
49
50 335 observed that may impact consumer engagement. As outlined below, the field notes will be
51
52 336 subject to thematic analysis and synthesised with the qualitative interview data.
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58 338 *Interview data:* Interview and field note data will be subject to thematic analysis to draw out
59
60 339 a) common experiences and perceptions regarding patient safety amongst ethnic minority

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3 340 consumers and their engagement in patient safety practices in the participating cancer
4
5 341 services and b) the key elements of the cancer service environment that enable or may
6
7 342 inhibit consumer engagement. (36, 37) Following transcription, two researchers will
8
9 343 independently listen to the audio recordings repeatedly to become familiar with the data.
10
11 344 Transcripts and field notes will be transferred into NVivo software and subject to line-by-line
12
13 345 coding. The researchers will independently identify key words, phrases and sentences and
14
15 346 explore themes within the data.(37) Coding will be iterative and refinement of themes and
16
17 347 subthemes will evolve over the course of the analysis. The data will be organised and
18
19 348 displayed via diagrams and figures to identify patterns and interrelationships within the data.
20
21 349 Discrepancies will be discussed and themes and subthemes refined until agreement, with
22
23 350 resolution by a third party should this be required.
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30 352 *Co-design process analysis:* Inductive analyses drawing upon grounded theory will be
31
32 353 utilised to generate new understanding of the adapted model of co-design in the present
33
34 354 study, replicating a method that has been used to explore the implementation of EBCD in
35
36 355 health service improvement.(38, 39) Analyses will be via the constant comparative method
37
38 356 with multiple researchers. Open codes will be independently generated from the transcripts
39
40 357 and fieldwork notes; as patterns and themes emerge from the data they will be grouped into
41
42 358 higher order organising themes.(40) Analysis will be recursive, constantly moving from the
43
44 359 specific to the more general to develop more transferable categories and explanations for
45
46 360 the findings, but also explore local level findings and disparities between groups.
47
48 361 Commonalities and patterns across settings will be identified and deviant cases will be
49
50 362 sought to check the emerging constructs. A summary of the ground theory analysis will be
51
52 363 shared with participants of the co-design groups and the co-facilitators for input and final
53
54 364 reflections.
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3 366 *Co-designed strategies*: The co-designed strategies developed will be collated and reported
4
5 367 in terms of the nature of the adaptations made; the safety issues each strategy sought to
6
7 368 address; the populations who co-designed the strategy and the target population, along with
8
9 369 considerations regarding further populations to whom they may or may not be relevant.
10

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12 37013
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15 371 *Ensuring study quality*

16
17
18 372 This program of work has been through two independent scientific peer review processed by
19
20 373 1) the National Health and Medical Research Council under the Ideas Funding Scheme
21
22 374 (Project number: 1180925) and 2) by Cancer Australia under the Supporting People with
23
24 375 Cancer Funding Scheme, Round 11. Both schemes have competitively funded this research
25
26 376 based on the scientific quality of the proposals and require progress reporting biannually.
27
28 377 Throughout the project, study quality will be ensured by our project governance process
29
30 378 which comprises primarily of an external stakeholder reference group and an external
31
32 379 consumer advisory group. The stakeholder reference group meets quarterly to provide
33
34 380 independent oversight of the project processes and progress against milestones. The
35
36 381 consumer advisory group meets biannually to provide specific review and advice of
37
38 382 consumer involvement activities and project processes to ensure that we retain a consumer-
39
40 383 centric approach.
41
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46 385 *Patient or public involvement*

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49 386 Consumer involvement has been central to all elements of the research process from the
50
51 387 project inception to execution. It is recognised as critical within the context of safety and
52
53 388 quality in healthcare and associated programs of research.(41) The investigator team, who
54
55 389 conceptualised the project and applied for research funding, includes a consumer
56
57 390 investigator (TT) from an ethnic minority background. The consumer investigator has both
58
59 391 experience of cancer as a patient and also in supporting those experiencing cancer from a

1
2
3 392 range of ethnic minority backgrounds through a charitable organisation. Ahead of project
4
5 393 development, the project idea was presented to a cancer consumer panel at the
6
7 394 Translational Cancer Research Network in Sydney. The panel comprised patients (current
8
9 395 and past) and members of the public with interests in cancer care and utilised their feedback
10
11 396 to inform the proposal. Once funding was secured, we advertised across a range of cancer
12
13 397 and consumer networks for individuals from a range of ethnic and language backgrounds to
14
15 398 form a project consumer advisory panel for the project. Eight consumers have been active
16
17 399 members since June 2019 and regularly meet to inform the project direction and progress.
18
19 400 The consumer advisory panel also reviews any materials or processes of research proposed
20
21 401 with patients and their carers in detail. Finally, as part of the co-design process, the project
22
23 402 team will work with the consumers from the consumer advisory panel who are interested in
24
25 403 co-facilitating the co-design process in partnership with research team members. The co-
26
27 404 facilitators who have expressed interest are from a range of ethnic backgrounds and will be
28
29 405 provided training and support ahead of and during the co-design process. The nature of
30
31 406 training and support needed for the co-facilitators has been identified collaboratively with the
32
33 407 consumer advisory panel through our regular meetings as well as through further input from
34
35 408 the consumer co-facilitators.
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410 **Ethics and dissemination:**

411 Ethical considerations have been explored, identified and a risk mitigation plan created for
412 each matter arising through the process of applying for ethical approval for the conduct of
413 the study. Ethics approval has been obtained for all components of the co-design for all six
414 sites (2020/ETH00965, 2021/ETH00532) by Western Sydney Local Health District Human
415 Research Ethics Committee (WSLHD HREC) which is a National Health and Medical
416 Research Council (NHMRC) recognised ethics committee. During the study, data will be
417 stored on the OneDrive system of the leading institution with the primary investigator and
418 retained in this secure location for at least seven years following the end of the project in

1
2
3 419 accordance with the national ethical requirements. Through the project development
4
5 420 process, a number of key risks and mitigation strategies were identified and developed. Four
6
7 421 strategies will ensure that research activities will be managed and coordinated effectively.
8
9 422 Firstly, we have established approval from the research sites in each state to conduct this
10
11 423 work to mitigate the risk of not being able to access the services and individuals within these.
12
13 424 Secondly, to address risks of working across the two states in complex patient safety
14
15 425 research, we have recruited local project managers in each state to ensure local oversight.
16
17 426 Thirdly, we are cognisant of the complexities, associated risks and mitigation practices
18
19 427 needed to work with a highly diverse consumer group. To address the risk of not being able
20
21 428 to interact with the diverse target population of consumers effectively, we access relevant
22
23 429 translation services, bilingual fieldworkers and have budgeted for the associated costs and
24
25 430 complexity. Finally, annual meetings, monthly virtual meetings and the project reference
26
27 431 group mitigates risk and enhances our ability to respond effectively. The study findings will
28
29 432 be disseminated at multiple events and through a range of formats to ensure that all
30
31 433 stakeholder groups with interest in the project and its outcomes are able to access the
32
33 434 findings. Dissemination will occur through practice-based and local-level presentations in the
34
35 435 participating sites for staff and consumers, with key findings also reported through the social
36
37 436 media outlets of the research team and affiliated institutions to reach a wider public
38
39 437 audience. Scientific reports of the findings will be developed and submitted to high-quality,
40
41 438 peer-reviewed outlets in the field of health services and cancer-services research relevant to
42
43 439 the emergent evidence.
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50
51 441 **Authors' contributions:** RH, MW and EM conceived the project. All authors
52
53 442 collectively developed the project design through creating the NHMRC project
54
55 443 proposal that forms the basis of this protocol. We work collaboratively through a
56
57 444 series of meetings and working across multiple drafts. In these ways, all authors
58
59 445 contributed to developing the project design and study methods described in the
60

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3 446 protocol as project investigators. RH prepared the initial draft of the protocol based
4
5 447 on the project protocol and contributions were made by all authors to all aspects of
6
7 448 the protocol manuscript. The authorship team meet monthly to plan the project
8
9 449 processes. AC and RH will be primarily responsible for data acquisition, preparation
10
11 450 and analysis across the sites, with local project team members CW, DL, MC, EM,
12
13 451 AG, AS, MW, HS contributing to data acquisition, preparation and analysis at each
14
15 452 study site. All authors edited, contributed content and reviewed the final draft of the
16
17 453 protocol.
18
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22

23 454 **Funding statement:** This work is supported by the National Health and Medical
24
25 455 Research Council project number: 1180925
26
27

28 456 **Competing interest statement.**

29
30
31
32 457 No competing interests to declare.
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35 458 **Figure legends**

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38 459 Figure 1 – Adapted EBCD Process
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41 460 Figure 2 – Co-design Workshop Schedule
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46 462 **References**

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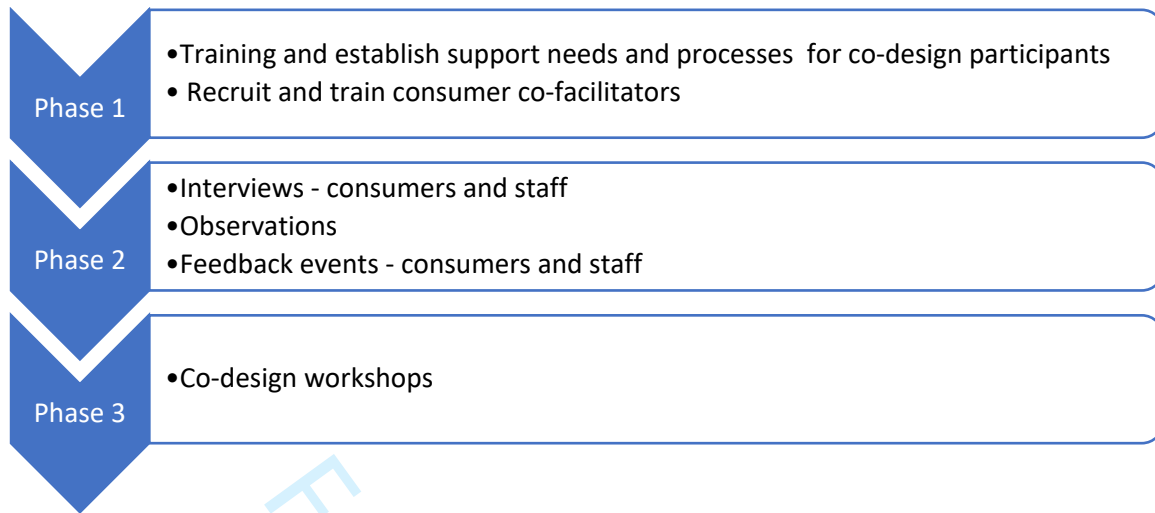


Figure 1 Adapted EBCD Approach

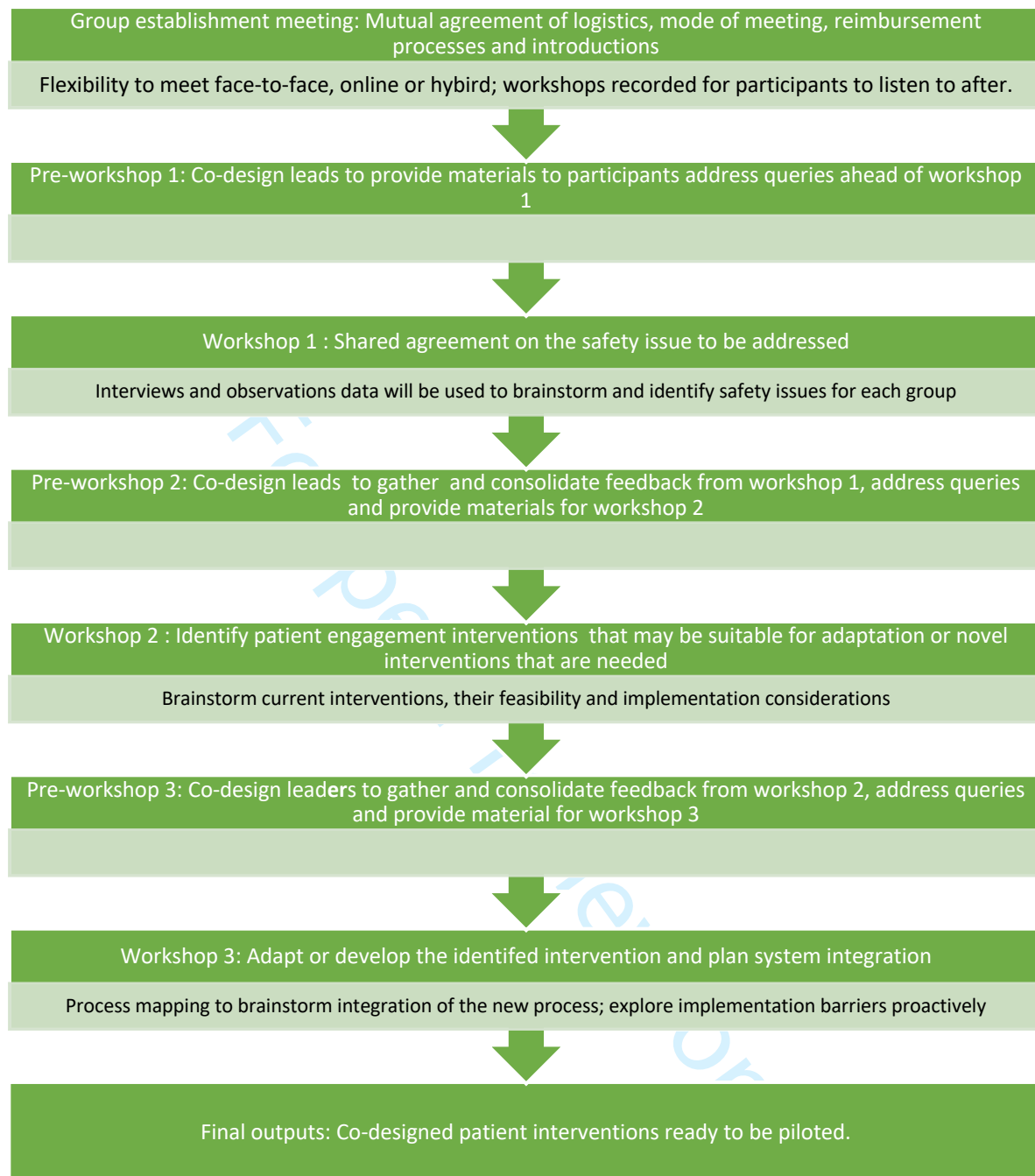


Figure 2: Co-design Workshop Schedule

BMJ Open

Co-designing consumer engagement strategies with ethnic minority consumers in Australian cancer services: The CanEngage Project Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048389.R2
Article Type:	Protocol
Date Submitted by the Author:	21-Jul-2021
Complete List of Authors:	Harrison, Reema; Macquarie University, Australian Institute of Health Innovation; UNSW Walton, Merrilyn; The University of Sydney, Public Health Manias, Elizabeth; Deakin University, School of Nursing and Midwifery; University of Melbourne VCCC, Melbourne School of Health Sciences Wilson, Carlene; Austin Health, Psychology Girgis, Afaf; UNSW, Ingham Institute of Applied Research Chin, Melvin; Prince of Wales Hospital and Community Health Services, Medical Oncology Leone, Desiree; Western Sydney Local Health District, Multicultural Health Seale, Holly; UNSW, Population Health Smith, Allan; UNSW, Ingham Institute of Applied Research Chauhan, Ashfaq; UNSW, Population Health
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Oncology, Research methods, Patient-centred medicine
Keywords:	Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult oncology < ONCOLOGY, QUALITATIVE RESEARCH

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3
4 1 **Title: Co-designing consumer engagement strategies with ethnic**
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6
7 2 **minority consumers in Australian cancer services: The CanEngage**
8
9
10 3 **Project Protocol**
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31 34 **Abstract:**
32
33

34 35 **Introduction:** Consumer engagement is central to high quality cancer service delivery and is
35
36 36 a recognised strategy to minimise healthcare-associated harm. Strategies developed to
37
38 37 enhance consumer engagement specifically in relation to preventing healthcare harm
39
40 38 include questioning health professionals, raising concerns about possible mistakes or risks
41
42 39 in care, and encouraging patients and caregivers to report suspected errors. Patients from
43
44 40 ethnic minority backgrounds are particularly vulnerable to unsafe care, but current
45
46 41 engagement strategies have not been developed specifically for (and with) this population.
47
48 42 Using an adapted approach to Experience-Based Co-Design (EBCD) to support the target
49
50 43 population, the aim of the project is to co-design consumer engagement interventions to
51
52 44 increase consumer engagement and safety in New South Wales (NSW) and Victorian (VIC)
53
54 45 cancer inpatient, outpatient and day procedure services.
55

56
57 46 **Methods and analysis:** A mixed-methods project will be undertaken at six study sites. Our
58
59 47 EBCD approach includes a preparatory phase in which we will provide training and support
60

1
2
3 48 to the co-design participants, in addition to recruiting and training consumer co-facilitators for
4
5 49 the co-design workshops. The project will follow the EBCD process of gathering and
6
7 50 synthesising observational data from each cancer service, with interview data from
8
9 51 consumers and staff. With the resulting in-depth understanding of the safety threats
10
11 52 commonly experienced by ethnic minority consumers in each site, we will work through
12
13 53 feedback events and co-design groups with consumers and staff to determine how they can
14
15 54 be more involved with their care to minimise the potential for patient harm. Consumer
16
17 55 engagement interventions will be co-produced in each of the six participating services that
18
19 56 are tailored to the ethnic minority populations served.

20
21
22 57 **Ethics and dissemination:** Ethics approval has been obtained from the Western Sydney
23
24 58 Local Health District Human Research Ethics Committee. The project will provide strategies
25
26 59 for ethnic minority consumers to engage with cancer services to minimise healthcare-
27
28 60 associated harm that may be applied to diverse healthcare settings.
29

30
31 61

32 33 62 **Strengths and limitations of this study.**

- 34
35 63 • We employ and evaluate a novel co-design approach that prepares facilitators and
36
37 64 participants for the co-design.
38
39 65 • Co-facilitator development and training with ethnic minority consumers is integrated
40
41 66 in the methodology, which is transferable to other co-design work with ethnic minority
42
43 67 populations in other care settings and internationally.
44
45 68 • Prior to this study, patient involvement in patient safety interventions have not been
46
47 69 developed for or evaluated with ethnic minority populations.
48
49 70 • This project is limited to cancer services in Australia and findings may not be directly
50
51 71 transferable to other specialty areas or systems.
52
53 72 • Whilst we aim to assess intervention impacts on consumer engagement and
54
55 73 perceptions of safety, we will not gather evidence of impacts of the resulting
56
57 74 engagement strategies on objective safety outcomes.
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75

76 Introduction

77 Effective consumer engagement is identified as the cornerstone of safe and high quality care
78 in contemporary healthcare systems.(1) Consumers include patients, family members,
79 friends and other caregivers. Engagement, achieved by involving consumers in the
80 prioritisation, planning, design and evaluation of health services, can provide safer care
81 through mutual accountability for quality and by supporting patient-centred allocation of
82 resources.(2) Approaches to consumer engagement are multi-faceted and varied; and occur
83 on a continuum from consultation through to partnership.(1, 3) In the context of minimising
84 patient harm, strategies employed internationally primarily focus on patients being
85 encouraged to ask questions, provide information, and to report when their safety has been
86 compromised.(4-7) A recent evidence synthesis confirms current consumer engagement
87 strategies aiming to improve healthcare safety predominantly focus on communication that
88 takes place at the clinical interface.(4, 8-11)

89 Consumers from ethnic minority backgrounds include those who speak languages other than
90 the official national languages, or who have lower proficiency in native or national languages,
91 and may include those born overseas or who have parents who were born overseas. Review
92 findings confirm that these population groups are more likely to experience adverse safety
93 events in their care; factors that contributing to this are language barriers, lack of social
94 support, lower health literacy, lower socio-economic status, greater incidence of ill health,
95 other settlement related issues taking greater precedence over health concerns, and a
96 sense of disempowerment.(12-16) Limited numbers of culturally competent staff within
97 health systems has also been identified as an underlying contributor to inequities in
98 healthcare safety for this population.(17) Delayed diagnosis or access to timely and
99 adequate care, extended length of stay, inadequate follow-up of abnormal screening results,
100 medication errors and healthcare-associated infections also occur more commonly amongst
101 those from ethnic minority backgrounds.(18-21)

1
2
3 102 Current strategies for preventing harm to patients such as encouraging 'questioning' health
4
5 103 professionals and using verbal communication practices, are challenging for many patients
6
7 104 but may be particularly unsuitable or not culturally appropriate for patients with limited
8
9 105 language proficiency, different beliefs about health and wellness or perspectives on the
10
11 106 patient-professional relationship in healthcare than the majority population.(16) A recent
12
13 107 review of current strategies used at the point-of-care confirms that consumer engagement
14
15 108 interventions have not been purposively developed or evaluated with those from ethnic
16
17 109 minority backgrounds to determine whether these interventions are suitable and/or
18
19 110 feasible.(4) Consumer engagement frameworks acknowledge health literacy and patient
20
21 111 diversity are key factors in shaping policy and research priorities.(22) Notwithstanding this
22
23 112 acknowledgement, there is limited evidence that health services take into account to address
24
25 113 the diversity between and within ethnic minority populations, in terms of settlement status or
26
27 114 settlement-related matters, cultural and linguistic backgrounds, time spent in the country and
28
29 115 other factors that may impact the development of patient engagement interventions
30
31 116 designed to minimise harm.(12) Developing consumer engagement strategies designed to
32
33 117 minimise harm with a diverse range of ethnic minority patients and families addresses this
34
35 118 knowledge gap and aims to ultimately reduce inequities in the safety of care for these
36
37 119 populations.

40
41
42 120 Co-design and the associated term of co-production is a methodological approach that
43
44 121 facilitates democratic dialogue between different stakeholders in developing and
45
46 122 implementing change-focused interventions and service improvement.(23-25) Using co-
47
48 123 design provides an avenue for health services to ensure that healthcare improvements or
49
50 124 innovations and their implementation are tailored to meet the unique needs identified by the
51
52 125 user group(s).(26) Co-design also establishes a collaborative platform for promoting the
53
54 126 views of communities who typically excluded, and provides a space for them to participate in
55
56 127 the design of healthcare resources and services.(27, 28) Despite the potential value of co-
57
58 128 design for amplifying diverse perspectives, it is still unclear how the key principles and
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3 129 practice of codesign are meaningfully employed for populations who experience healthcare
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5 130 disparities, such as those from ethnic minority backgrounds(29-31).
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9 132 Experience-based co-design (EBCD) has been adopted in healthcare to enable a user-centric
10 133 collaborative process of developing changes to improve consumer and staff experiences.(32)
11 134 Whilst the value of co-design, including EBCD, for improving long term healthcare outcomes
12 135 has been contested, it is supported as a method by which to achieve user-centric design.(33-
13 136 35) A recognition that users are experts in their own lived experiences and that user-centric
14 137 design is therefore important, has driven increasing use of co-design to improve healthcare
15 138 and create change for quality improvement (33, 36-39) in patient safety interventions, (40) the
16 139 development of frailty pathways (39), the development of telehealth services (41) and within
17 140 lean a structured quality improvement approach in healthcare.(42) In the present study, EBCD
18 141 is used to provide a user centric approach to achieve enhance (patient-reported) patient safety
19 142 and engagement with cancer services amongst ethnic minority patients in Australia. We seek
20 143 to achieve this goal through co-designing adaptations of consumer engagement strategies
21 144 that aim to improve safety with consumers from ethnic minority backgrounds and their
22 145 healthcare staff and applying these strategies in Australian cancer services. The study
23 146 employs a novel adaptation of EBCD by integrating consumer co-facilitators and their training
24 147 into the EBCD process. Consumer co-facilitators are past and/or current cancer services
25 148 consumers who work in partnership with the research team to co-facilitate the leadership of
26 149 the process of the co-design, guiding and supporting participants through the process. This
27 150 adaptation aims to widen participation to the co-design process, the depth of engagement
28 151 between co-design members and to improve consumer experience of the co-design process
29 152 itself. The secondary aim is therefore to evaluate our adapted model of EBCD for its impacts
30 153 on consumer experience and engagement in the co-design process. The project is embedded
31 154 within a larger program of work; the CanEngage Project, which explores consumer experience
32 155 and engagement in their healthcare as a means of improving healthcare safety for ethnic
33 156 minority populations accessing cancer services.
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54 158 **Methods and analysis:**

55 159 *Study design*

56 160 An exploratory mixed-method design will integrate observations and semi-structured
57
58 161 interviews. We will use Experience-Based Co-Design (EBCD), which proceeds through
59
60

1
2
3 162 observations of the services, patient and staff interviews followed by a series of patient and
4
5 163 staff feedback events and subsequent co-design workshops.(43) We will adapt this process
6
7 164 of EBCD by adding an initial phase (phase 1 in Figure 1) in which we will recruit and train
8
9 165 ethnic minority consumer co-facilitators along with providing training and establishing the
10
11 166 support needs of co-design participants.(44)
12
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14 167

17 168 <INSERT FIGURE 1 HERE>
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20 169

23 170 *Setting*

25 171 Inpatient, outpatient and day procedure cancer services in six hospitals in the two most
26
27 172 populous Australian states of New South Wales (NSW) and Victoria (VIC) have been
28
29 173 recruited for involvement in order to engage a heterogeneous ethnic minority population in
30
31 174 the project. The sites are geographically located such that different ethnic minority groups
32
33 175 are service users. The major ethnic minority populations served by the study sites
34
35 176 predominantly include communities originating from countries in Southern Europe, East and
36
37 177 Central or South-East Asia, the Middle-East, including refugee populations. All included
38
39 178 cancer services provide surgery, medical oncology, radiotherapy, and palliative care
40
41 179 services.
42
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45 180

48 181 *Study sample*

50 182 Approximately 15 clinical and non-clinical staff employed by the participating cancer services
51
52 183 (including administrative and management staff) and 15 ethnic minority consumers (patients
53
54 184 and/or their informal carers) will be initially recruited at each site, totaling 90 healthcare staff
55
56 185 and 90 patient/carers across the six sites. Consumers who are aged 18 and over will be
57
58 186 eligible to take part in the study if they self-identify as from an ethnic minority background
59
60

1
2
3 187 and have accessed one of the participating sites as a patient or support person in the past
4
5 188 two years. Healthcare staff will be eligible if they have worked within one of the participating
6
7 189 services for at least six months and are a current staff member in any role. The sample size
8
9 190 proposed seeks to capture an initial group of individuals from a range of the ethnic groups
10
11 191 attending each service, which will then be utilised to explore further sample size
12
13 192 requirements. Interviews and subsequent analysis will be an iterative process with the
14
15 193 research team regularly reflecting on and reviewing the sampling strategy throughout the
16
17 194 data collection period. The final sample size will be informed by the emerging analysis based
18
19 195 on principles of information power, taking into account adequate representation of multiple
20
21 196 ethnic minority perspectives.(45) For the series of co-design workshops, least three staff and
22
23 197 between three and five patient/carer members will be included in the group at each site who
24
25 198 have lived experience relevant to the subject matter.(32)
26
27
28
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30

199

200 *Recruitment*

201 The first phase of recruitment will be for the semi-structured interviews. Recruitment will be
202 facilitated by the clinician members of the research team embedded at each participating
203 site. We will use study advertisement materials in a range of languages relevant to the
204 communities served by each service. We will use poster and video-screen advertisements in
205 each service and community healthcare centres, as well as publicity in newsletters and
206 emails to staff and service user distribution lists. Those who take part in the interviews will be
207 asked to indicate in their consent form whether they agree to be contacted about the
208 subsequent stage of the study – the co-design workshops. In the second phase of
209 recruitment, those who indicate willingness to be contacted will provide their email and
210 telephone contact details for this purpose and be invited to take part in a co-design group.
211 One consumer co-facilitator will be recruited to co-facilitate each group via the consumer
212 advisory group for the project and the member's networks. Where participants withdraw at
213 any stage from the study, we will invite new members to join the co-design process

1
2
3 214 accompanied by the same training. If joining later in the process, the recordings of the initial
4
5 215 sessions will be shared with new members to ensure they are able to engage with the
6
7 216 process at the stage that they join. The addition of new and different perspectives in the
8
9 217 context of co-designing the strategies would not impact the validity of the process and may
10
11 218 enhance the process by introducing a broader range of perspectives.
12
13

14 219

17 220 *Training and support*

18
19
20 221 In phase one, training will be provided over two 90-minute sessions, with online and
21
22 222 recorded options. Bilingual fieldworkers will support the sessions in the relevant languages.
23
24 223 The first session will be provided for all participants and consumer co-facilitators regarding
25
26 224 the purpose and process of co-design and outline the role of co-design members and
27
28 225 facilitators. The second session will be provided separately with one session for consumer
29
30 226 co-facilitators and the other for participants and will provide detailed information about what
31
32 227 is expected to occur during each session, with an extended open forum for questions and
33
34 228 discussion. The opportunity for further one-to-one discussions will also be offered to enable
35
36 229 participants to ask questions, request specific supports or clarify any aspects of the process.
37
38 230 We will be flexible in our approach to the location, timing and format of the sessions to meet
39
40 231 the needs of the members attending.
41
42
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47 233 *Data Collection*

48
49 234 In phase two, data collection will occur through observations and interviews, which will then
50
51 235 be reported and discussed with participants through feedback events.
52
53

- 54 236 i. *Observations:* Observations of the physical environment of the public areas in each
55
56 237 service will be undertaken by two researchers independently from one another at
57
58 238 each study site to understand the service, and the professional and speciality
59
60

1
2
3 239 contexts that surround healthcare delivery, which may impact on patient
4
5 240 engagement. An environmental observational audit tool has been developed
6
7 241 collaboratively by the research team for the study purpose based on existing
8
9 242 environmental audit tools used in other public spaces. The environmental audit tool
10
11 243 comprises four components totalling 17 items and 29 questions. The four
12
13 244 components that capture evidence of the observable features of the health service
14
15 245 environment that reflect the elements of consumer engagement based on the
16
17 246 Carmen's Patient and Family Engagement framework.(1) The tool was validated in
18
19 247 one of the participating sites. It was independently completed by two researchers
20
21 248 over three observation periods. Internal reliability analysis revealed substantial
22
23 249 agreement between reviewers in applying the tool ($k = 0.85$). Sixty hours of
24
25 250 observations will be conducted in two-hour blocks at each site by each researcher
26
27 251 over a six-week period to provide observations that include a range of times of day
28
29 252 and days of the week. The audit tool will be used by the researchers to collate field
30
31 253 notes and checklist information regarding the opportunities for consumer
32
33 254 engagement in the physical environment in each service, along with the observable
34
35 255 barriers and facilitators to this type of engagement for ethnic minority service users.
36
37 256 Patient and staff interactions will not be examined in the observational study because
38
39 257 of the ethical considerations associated with gaining consent for the more than 40
40
41 258 language groups attending the services, coupled with the health status of the patient
42
43 259 group. We will instead seek to explore experiences of patient and staff interactions
44
45 260 through the interview study described below that will occur in parallel to the
46
47 261 observational study.
48
49
50
51 262
52
53
54 263 ii. *Semi-structured interviews*: Semi-structured interviews will be conducted with
55
56 264 healthcare staff and the patients and caregivers associated with each of the six study
57
58 265 sites. An interview schedule has been developed by the research team based on our
59
60 266 preliminary literature reviews, which seeks to explore experiences of patient

1
2
3 267 engagement amongst ethnic minority patients and healthcare staff in cancer settings,
4
5 268 and the potential for healthcare-associated harm in their care. Face-to-face,
6
7 269 videoconferencing or phone interviews will be conducted, with the latter modes being
8
9 270 utilised when covid restrictions are in place or upon request of the participant.
10
11 271 Interviews with ethnic minority cancer consumers will be conducted in their preferred
12
13 272 language. For languages other than English, bilingual fieldworkers, and interpreters
14
15 273 (when bilingual fieldworkers are not available) will be used to complete the
16
17 274 interviews. This is an approach that have been used in previously published work
18
19 275 undertaken by the team in Australian healthcare services in conjunction with
20
21 276 multicultural health team at Western Sydney Local Health District (WSLHD). The
22
23 277 bilingual fieldworkers will be provided with appropriate training prior to conducting the
24
25 278 interviews. This approach will be used to enhance trust and comfort between the
26
27 279 research participants and the researcher; previous research has indicated that
28
29 280 bilingual fieldworkers who understand the language and culture of the participant can
30
31 281 support participants to feel at ease and share their experiences.
32
33 282
34
35 283 iii. *Feedback events:* The Experience-Based Co-Design toolkit identifies the importance
36
37 284 of feedback events in which co-design participants come together to discuss and
38
39 285 share their views throughout the co-design process. In the present project, these
40
41 286 events will be held as facilitated online meetings lasting around two hours at two time
42
43 287 points. The first will occur before the codesign groups. The first feedback event will
44
45 288 aim to generate a shortlist of areas in which patient safety could be improved for
46
47 289 ethnic minority patients using patient engagement strategies. The findings from
48
49 290 observations and interviews undertaken will be discussed in this event. Both staff and
50
51 291 patients from the six sites will jointly identify priority areas for developing or adapting
52
53 292 current engagement strategies. The facilitators will support the discussions to ensure
54
55 293 balance in the range of perspectives that are heard. The feedback event will be used
56
57 294 to discuss and agree the focus of the co-design groups in each site including whether

1
2
3 295 these focus on a particular ethnic minority population/language or cultural group, or
4
5 296 to focus on heightened inclusivity of patient engagement strategies to be suitable for
6
7 297 a range of ethnic minority consumers. Online events enable participants from all sites
8
9 298 to meet together across the broad geographical region of Victoria and New South
10
11 299 Wales. Both consumer and healthcare staff participants will attend both feedback
12
13 300 events.
14
15
16 301

17
18 302 iv. *Co-design groups and subsequent feedback event:* A small co-design group will be
19
20 303 formed in each of the six sites; six groups in total, with 6-8 members per group. Each
21
22 304 group will comprise of a mix of patients, carers and healthcare staff. The co-design
23
24 305 groups will be convened to adapt, design and implement solutions to the priority
25
26 306 issues identified through feedback events with reference to the patient safety
27
28 307 strategies identified and explored with stakeholders during the preliminary stages of
29
30 308 the research. Each group will have a facilitator from the research team and an ethnic
31
32 309 minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the
33
34 310 study population. The groups will meet for no more than 10 hours in total;
35
36 311 approximately 2-3 hours every fortnight over a six-week period. Each group will
37
38 312 develop terms of reference that will determine their ways of working and their
39
40 313 preferred mode of meeting (online, face to face or hybrid) and meeting duration and
41
42 314 frequency as proposed by the consumer advisory group. Once again, online and
43
44 315 hybrid modes will be utilised in the context of covid restrictions. The terms of
45
46 316 reference will be reviewed at the commencement of each sessions. The co-design
47
48 317 workshop process is shown in Figure 2. Following the co-design group meetings, all
49
50 318 participants will attend a second online feedback event, along with the consumer
51
52 319 advisory and project reference group members. In the second feedback event, the
53
54 320 attendees will determine the interventions for implementation in each site for the six
55
56 321 months following the end of the co-design period. The activities will be evaluated for
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3 322 feasibility and acceptability over a six-month period when implemented in the
4
5 323 participating cancer services in the next stage of the CanEngage Project.
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10 325 <INSERT FIGURE 2 HERE>
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15 327 i. *Evaluation of adapted EBCD approach:* To address the secondary aim we will
16
17 328 evaluate the approach to EBCD employed in the study for its impacts on consumer
18
19 329 experience and involvement in the co-design process. Members of the co-design
20
21 330 groups and the co-facilitators will be asked to complete a brief end of project
22
23 331 interview. One researcher who is external to the CanEngage Project (ENS) will work
24
25 332 with bilingual fieldworkers to conduct online or face-to-face interviews based on the
26
27 333 participants preference. We will review the terms of reference they have developed,
28
29 334 and capture adaptations made to these. These data will be synthesised with data
30
31 335 from the recordings and summary notes of the co-design workshops to produce a
32
33 336 narrative synthesis of experiences of the co-design process, and the nature and
34
35 337 extent of their engagement when using the adapted EBCD model. Towards the
36
37 338 evaluation, we will seek to conduct exit interviews with those who dropped out of the
38
39 339 study at any stage to explore factors contributing to drop-out and consider their
40
41 340 mitigation for future work.
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45 341 *Data analysis plan*

46
47 342 *Observational data:* The quantitative observational data from the environmental audit tool
48
49 343 checklist will be transferred to SPSS (IBM version 19) for analysis, with descriptive statistics
50
51 344 used to determine the number and types of opportunities in the cancer service environment
52
53 345 observed that may impact consumer engagement. As outlined below, the field notes will be
54
55 346 subject to thematic analysis and synthesised with the qualitative interview data.
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3 348 *Interview data:* Interview and field note data will be subject to thematic analysis to draw out
4
5 349 a) common experiences and perceptions regarding patient safety amongst ethnic minority
6
7 350 consumers and their engagement in patient safety practices in the participating cancer
8
9 351 services and b) the key elements of the cancer service environment that enable or may
10
11 352 inhibit consumer engagement. (46, 47) Following transcription, two researchers will
12
13 353 independently listen to the audio recordings repeatedly to become familiar with the data.
14
15 354 Transcripts and field notes will be transferred into NVivo software and subject to line-by-line
16
17 355 coding. The researchers will independently identify key words, phrases and sentences and
18
19 356 explore themes within the data.(47) Coding will be iterative and refinement of themes and
20
21 357 subthemes will evolve over the course of the analysis. The data will be organised and
22
23 358 displayed via diagrams and figures to identify patterns and interrelationships within the data.
24
25 359 Discrepancies will be discussed and themes and subthemes refined until agreement, with
26
27 360 resolution by a third party should this be required.
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34 362 *Co-design process analysis:* Inductive analyses drawing upon grounded theory will be
35
36 363 utilised to generate new understanding of the adapted model of co-design in the present
37
38 364 study, replicating a method that has been used to explore the implementation of EBCD in
39
40 365 health service improvement.(48, 49) Analyses will be via the constant comparative method
41
42 366 with multiple researchers. Open codes will be independently generated from the transcripts
43
44 367 and fieldwork notes; as patterns and themes emerge from the data they will be grouped into
45
46 368 higher order organising themes.(50) Analysis will be recursive, constantly moving from the
47
48 369 specific to the more general to develop more transferable categories and explanations for
49
50 370 the findings, but also explore local level findings and disparities between groups.
51
52 371 Commonalities and patterns across settings will be identified and deviant cases will be
53
54 372 sought to check the emerging constructs. A summary of the ground theory analysis will be
55
56 373 shared with participants of the co-design groups and the co-facilitators for input and final
57
58 374 reflections.
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6 376 *Co-designed strategies:* The co-designed strategies developed will be collated and reported
7
8 377 in terms of the nature of the adaptations made; the safety issues each strategy sought to
9
10 378 address; the populations who co-designed the strategy and the target population, along with
11
12 379 considerations regarding further populations to whom they may or may not be relevant.

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18 381 *Ensuring study quality*

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20 382 This program of work has been through two independent scientific peer review processed by
21
22 383 1) the National Health and Medical Research Council under the Ideas Funding Scheme
23
24 384 (Project number: 1180925) and 2) by Cancer Australia under the Supporting People with
25
26 385 Cancer Funding Scheme, Round 11. Both schemes have competitively funded this research
27
28 386 based on the scientific quality of the proposals and require progress reporting biannually.
29
30 387 Throughout the project, study quality will be ensured by our project governance process
31
32 388 which comprises primarily of an external stakeholder reference group and an external
33
34 389 consumer advisory group. The stakeholder reference group meets quarterly to provide
35
36 390 independent oversight of the project processes and progress against milestones. The
37
38 391 consumer advisory group meets biannually to provide specific review and advice of
39
40 392 consumer involvement activities and project processes to ensure that we retain a consumer-
41
42 393 centric approach.

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49 395 *Patient or public involvement*

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52 396 Consumer involvement has been central to all elements of the research process from the
53
54 397 project inception to execution. It is recognised as critical within the context of safety and
55
56 398 quality in healthcare and associated programs of research.(51) The investigator team, who
57
58 399 conceptualised the project and applied for research funding, includes a consumer
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3 400 investigator (TT) from an ethnic minority background. The consumer investigator has both
4
5 401 experience of cancer as a patient and also in supporting those experiencing cancer from a
6
7 402 range of ethnic minority backgrounds through a charitable organisation. Ahead of project
8
9 403 development, the project idea was presented to a cancer consumer panel at the
10
11 404 Translational Cancer Research Network in Sydney. The panel comprised patients (current
12
13 405 and past) and members of the public with interests in cancer care and utilised their feedback
14
15 406 to inform the proposal. Once funding was secured, we advertised across a range of cancer
16
17 407 and consumer networks for individuals from a range of ethnic and language backgrounds to
18
19 408 form a project consumer advisory panel for the project. Eight consumers have been active
20
21 409 members since June 2019 and regularly meet to inform the project direction and progress.
22
23 410 The consumer advisory panel also reviews any materials or processes of research proposed
24
25 411 with patients and their carers in detail. Finally, as part of the co-design process, the project
26
27 412 team will work with the consumers from the consumer advisory panel who are interested in
28
29 413 co-facilitating the co-design process in partnership with research team members. The co-
30
31 414 facilitators who have expressed interest are from a range of ethnic backgrounds and will be
32
33 415 provided training and support ahead of and during the co-design process. The nature of
34
35 416 training and support needed for the co-facilitators has been identified collaboratively with the
36
37 417 consumer advisory panel through our regular meetings as well as through further input from
38
39 418 the consumer co-facilitators.
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47 420 **Ethics and dissemination:**

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49 421 Ethical considerations have been explored, identified and a risk mitigation plan created for
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51 422 each matter arising through the process of applying for ethical approval for the conduct of
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53 423 the study. Ethics approval has been obtained for all components of the co-design for all six
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55 424 sites (2020/ETH00965, 2021/ETH00532) by Western Sydney Local Health District Human
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57 425 Research Ethics Committee (WSLHD HREC) which is a National Health and Medical
58
59 426 Research Council (NHMRC) recognised ethics committee. During the study, data will be
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3 427 stored on the OneDrive system of the leading institution with the primary investigator and
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5 428 retained in this secure location for at least seven years following the end of the project in
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7 429 accordance with the national ethical requirements. Through the project development
8
9 430 process, a number of key risks and mitigation strategies were identified and developed. Four
10
11 431 strategies will ensure that research activities will be managed and coordinated effectively.
12
13 432 Firstly, we have established approval from the research sites in each state to conduct this
14
15 433 work to mitigate the risk of not being able to access the services and individuals within these.
16
17 434 Secondly, to address risks of working across the two states in complex patient safety
18
19 435 research, we have recruited local project managers in each state to ensure local oversight.
20
21 436 Thirdly, we are cognisant of the complexities, associated risks and mitigation practices
22
23 437 needed to work with a highly diverse consumer group. To address the risk of not being able
24
25 438 to interact with the diverse target population of consumers effectively, we access relevant
26
27 439 translation services, bilingual fieldworkers and have budgeted for the associated costs and
28
29 440 complexity. Finally, annual meetings, monthly virtual meetings and the project reference
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31 441 group mitigates risk and enhances our ability to respond effectively. The study findings will
32
33 442 be disseminated at multiple events and through a range of formats to ensure that all
34
35 443 stakeholder groups with interest in the project and its outcomes are able to access the
36
37 444 findings. Dissemination will occur through practice-based and local-level presentations in the
38
39 445 participating sites for staff and consumers, with key findings also reported through the social
40
41 446 media outlets of the research team and affiliated institutions to reach a wider public
42
43 447 audience. Scientific reports of the findings will be developed and submitted to high-quality,
44
45 448 peer-reviewed outlets in the field of health services and cancer-services research relevant to
46
47 449 the emergent evidence.
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54
55 451 **Authors' contributions:** RH, MW and EM conceived the project. All authors collectively
56
57 452 developed the project design through creating the NHMRC project proposal that forms the
58
59 453 basis of this protocol. We work collaboratively through a series of meetings and working
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3 454 across multiple drafts. In these ways, all authors contributed to developing the project design
4
5 455 and study methods described in the protocol as project investigators. RH prepared the initial
6
7 456 draft of the protocol based on the project protocol and contributions were made by all
8
9 457 authors to all aspects of the protocol manuscript. The authorship team meet monthly to plan
10
11 458 the project processes. AC and RH will be primarily responsible for data acquisition,
12
13 459 preparation and analysis across the sites, with local project team members CW, DL, MC,
14
15 460 EM, AG, AS, MW, HS contributing to data acquisition, preparation and analysis at each
16
17 461 study site. All authors edited, contributed content and reviewed the final draft of the protocol.
18
19
20

21 462 **Funding statement:** This work is supported by the National Health and Medical Research
22
23 463 Council project number: 1180925
24
25

26 464 **Competing interest statement.**

27
28
29
30 465 No competing interests to declare.
31

32 466 **Figure legends**

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35 467 Figure 1 – Adapted EBCD Process
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38 468 Figure 2 – Co-design Workshop Schedule
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43 470 **References**
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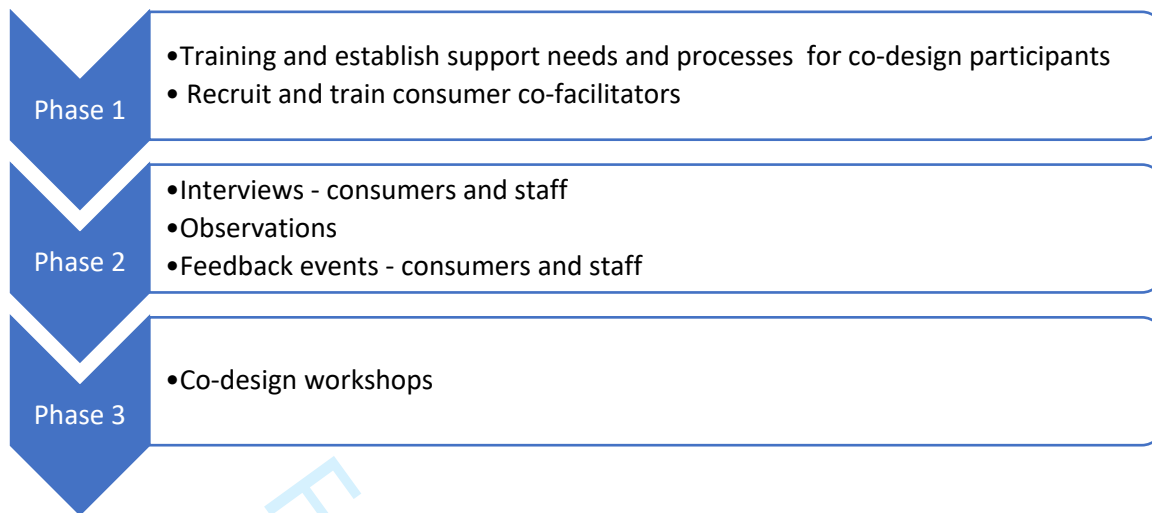


Figure 1 Adapted EBCD Approach

For peer review only

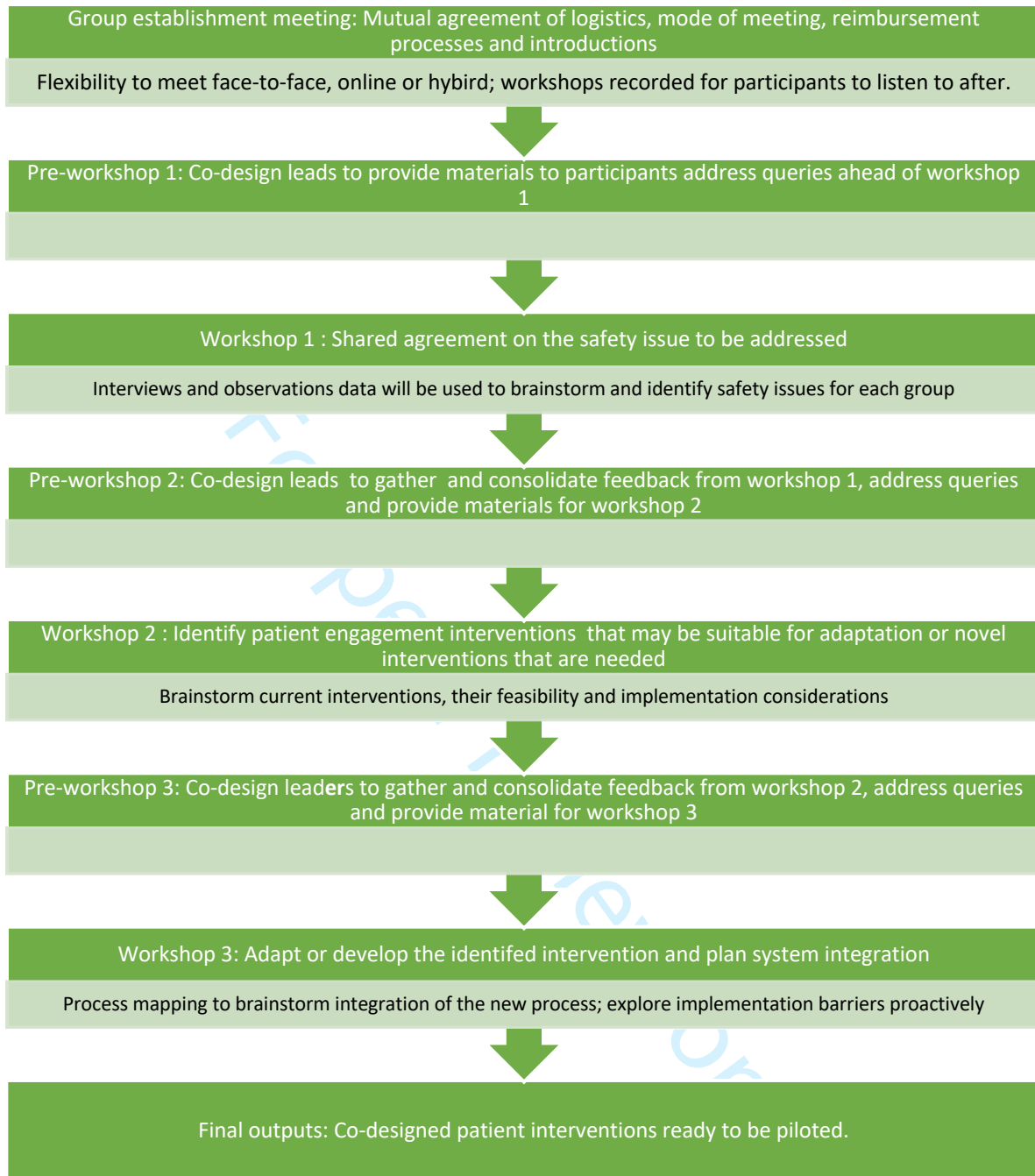


Figure 2: Co-design Workshop Schedule