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

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

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Abstract:

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

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

to the co-design participants, in addition to recruiting and training consumer co-facilitators for the co-design workshops. The project will follow the EBCD process of gathering and synthesising observational data from each cancer service, with interview data from consumers and staff. With the resulting in-depth understanding of the safety threats commonly experienced by ethnic minority consumers in each site, we will work through feedback events and co-design groups with consumers and staff to determine how they can be more involved with their care to minimise the potential for patient harm. Consumer engagement interventions will be co-produced in each of the six participating services that are tailored to the ethnic minority populations served.

Ethics and dissemination: Ethics approval has been obtained. The project will provide strategies for ethnic minority consumers to engage with cancer services to minimise healthcare-associated harm that may be applied to diverse healthcare settings.

Strengths and limitations of this study

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

Introduction

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

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

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

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

Methods and analysis:

Ethical approval

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

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

Study design

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

<INSERT FIGURE 1 HERE>

Setting

Inpatient, outpatient and day procedure cancer services in six hospitals in the two most populous Australian states of New South Wales (NSW) and Victoria (VIC) have been recruited for involvement in order to engage a heterogeneous ethnic minority population in the project. The sites are geographically located such that different ethnic minority groups are service users. The major ethnic minority populations served by the study sites predominantly include communities originating from countries in Southern Europe, East and

Central or South-East Asia, the Middle-East, including refugee populations. All included cancer services provide surgery, medical oncology, radiotherapy, and palliative care services.

Study sample

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

Recruitment

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

Training and support

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

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

iii. *Feedback events:* The Experience-Based Co-Design toolkit identifies the importance of feedback events in which co-design participants come together to discuss and share their views throughout the co-design process. In the present project, these events will be held as facilitated online meetings lasting around two hours at two time points. The first will occur before the codesign groups. The first feedback event will aim to generate a shortlist of areas in which patient safety could be improved for ethnic minority patients using patient engagement strategies. The findings from observations and interviews undertaken will be discussed in this event. Both staff and patients from the six sites will jointly identify priority areas for developing or adapting current engagement strategies. The facilitators will support the discussions to ensure balance in the range of perspectives that are heard. The feedback event will be used to discuss and agree the focus of the co-design groups in each site including whether these focus on a particular ethnic minority population/language or cultural group, or to focus on heightened inclusivity of patient engagement strategies to be suitable for a range of ethnic minority consumers. Online events enable participants from all sites to meet together across the broad geographical region of Victoria and New South Wales. Both consumer and healthcare staff participants will attend both feedback events.

iv. *Co-design groups and subsequent feedback event:* A small co-design group will be formed in each of the six sites; six groups in total, with 6-8 members per group. Each group will comprise of a mix of patients, carers and healthcare staff. The co-design groups will be convened to adapt, design and implement solutions to the priority issues identified through feedback events with reference to the patient safety strategies identified and explored with stakeholders during the preliminary stages of the research. Each group will have a facilitator from the research team and an ethnic minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the study population. The groups will meet for no more than 10 hours in total; approximately 2-3 hours every fortnight over a six-week period. Each group will develop terms of reference that will determine their ways of working and their preferred mode of meeting (online, face to face or hybrid) and meeting duration and frequency as proposed by the consumer advisory group. The terms of reference will be reviewed at the commencement of each sessions. The co-design workshop process is shown in Figure 2. Following the co-design group meetings, all participants will attend a second online feedback event, along with the consumer advisory and project reference group members. In the second feedback event, the attendees will determine the interventions for implementation in each site for the six months following the end of the co-design period. The activities will be evaluated for feasibility and acceptability over a six-month period when implemented in the participating cancer services in the next stage of the CanEngage Project.

<INSERT FIGURE 2 HERE>

i. *Evaluation of adapted EBCD approach*: To address the secondary aim we will evaluate the approach to EBCD employed in the study for its impacts on consumer experience and involvement in the co-design process. Members of the co-design groups and the co-facilitators will be asked to complete a brief end of project interview. One researcher who is external to the CanEngage Project (ENS) will work with bilingual fieldworkers to conduct online or face-to-face interviews based on the participants preference. We will review the terms of reference they have developed, and capture adaptations made to these. These data will be synthesised with data from the recordings and summary notes of the co-design workshops to produce a narrative synthesis of experiences of the co-design process, and the nature and extent of their engagement when using the adapted EBCD model. Towards the evaluation, we will seek to conduct exit interviews with those who dropped out of the study at any stage to explore factors contributing to drop-out and consider their mitigation for future work.

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

Co-design process analysis: Inductive analyses drawing upon grounded theory will be utilised to generate new understanding of the adapted model of co-design in the present study, replicating a method that has been used to explore the implementation of EBCD in health service improvement.(39, 40) Analyses will be via the constant comparative method with multiple researchers. Open codes will be independently generated from the transcripts and fieldwork notes; as patterns and themes emerge from the data they will be grouped into higher order organising themes.(41) Analysis will be recursive, constantly moving from the specific to the more general to develop more transferable categories and explanations for the findings, but also explore local level findings and disparities between groups. Commonalities and patterns across settings will be identified and deviant cases will be sought to check the emerging constructs. A summary of the ground theory analysis will be shared with participants of the co-design groups and the co-facilitators for input and final reflections.

Co-designed strategies: The co-designed strategies developed will be collated and reported in terms of the nature of the adaptations made; the safety issues each strategy sought to address; the populations who co-designed the strategy and the target population, along with considerations regarding further populations to whom they may or may not be relevant.

Ethics and dissemination:

Ethical considerations have been explored, identified and a risk mitigation plan created for each matter arising through the process of applying for ethical approval for the conduct of the study, which has been granted for all sites through the NHMRC accredited ethics committee (281775). The study findings will be disseminated at multiple events and through a range of formats to ensure that all stakeholder groups with interest in the project and its outcomes are able to access the findings. Dissemination will occur through practice-based and local-level presentations in the participating sites for staff and consumers, with key findings also reported through the social media outlets of the research team and affiliated institutions to reach a wider public audience. Scientific reports of the findings will be developed and submitted to high-quality, peer-reviewed outlets in the field of health services and cancer-services research relevant to the emergent evidence.

Authors' contributions: RH, MW and EM conceived the project, with all authors substantial involved in developing the project design and study methods described in the protocol as project investigators. All authors edited, contributed content and review the final draft of the protocol.

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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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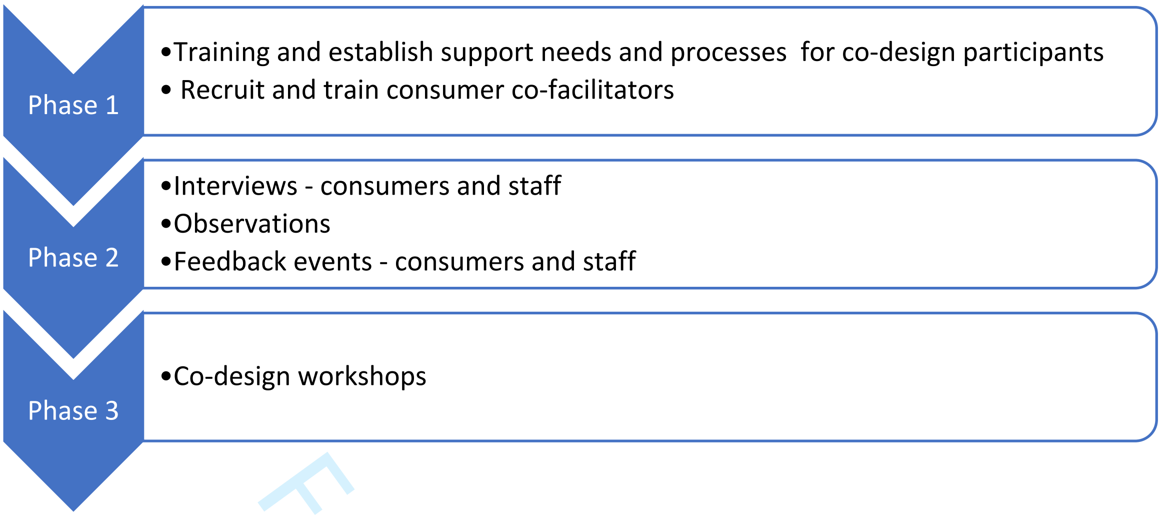

Figure 1 Adapted EBCD Approach

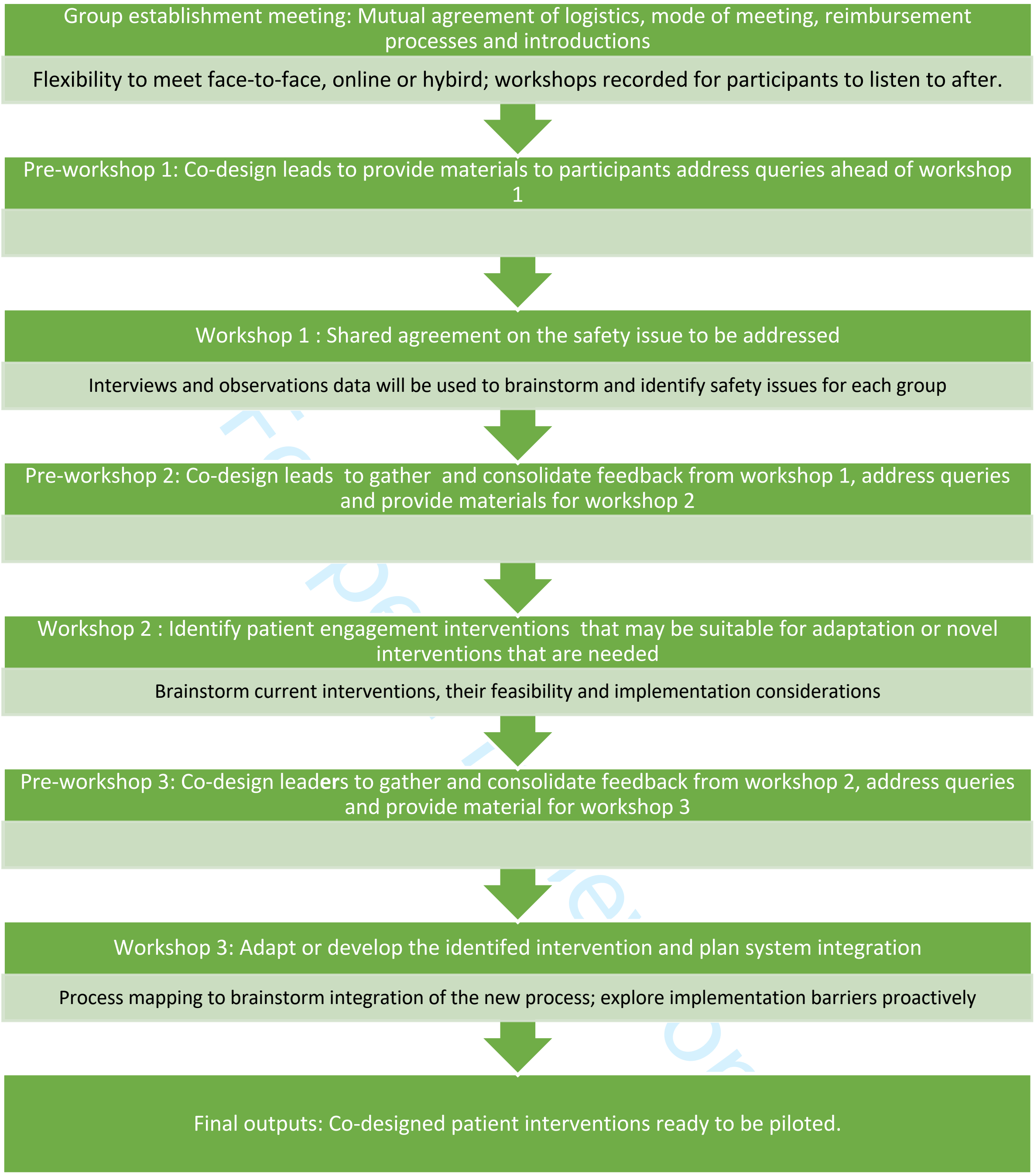

Figure 2: Co-design Workshop Schedule

BMJ Open

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

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

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Abstract:

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

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

to the co-design participants, in addition to recruiting and training consumer co-facilitators for the co-design workshops. The project will follow the EBCD process of gathering and synthesising observational data from each cancer service, with interview data from consumers and staff. With the resulting in-depth understanding of the safety threats commonly experienced by ethnic minority consumers in each site, we will work through feedback events and co-design groups with consumers and staff to determine how they can be more involved with their care to minimise the potential for patient harm. Consumer engagement interventions will be co-produced in each of the six participating services that are tailored to the ethnic minority populations served.

Ethics and dissemination: Ethics approval has been obtained. The project will provide strategies for ethnic minority consumers to engage with cancer services to minimise healthcare-associated harm that may be applied to diverse healthcare settings.

Strengths and limitations of this study

- We employ and evaluate a novel co-design approach that prepares facilitators and participants for the co-design.
- Co-facilitator development and training with ethnic minority consumers is integrated in the methodology.
- Prior to this study, patient involvement in patient safety interventions have not been developed for or evaluated with ethnic minority populations.
- The protocol provides methodological detail transferable to other co-design work with ethnic minority populations in other care settings and internationally.

Introduction

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

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

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

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

Methods and analysis:

Study design

An exploratory mixed-method design will integrate observations and semi-structured interviews. We will use Experience-Based Co-Design (EBCD), which proceeds through observations of the services, patient and staff interviews followed by a series of patient and staff feedback events and subsequent co-design workshops.(33) We will adapt this process of EBCD by adding an initial phase (phase 1 in Figure 1) in which we will recruit and train ethnic minority consumer co-facilitators along with providing training and establishing the support needs of co-design participants.(34)

<INSERT FIGURE 1 HERE>

Setting

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

Study sample

Approximately 15 clinical and non-clinical staff employed by the participating cancer services (including administrative and management staff) and 15 ethnic minority consumers (patients and/or their informal carers) will be initially recruited at each site, totaling 90 healthcare staff and 90 patient/carers across the six sites. Consumers who are aged 18 and over will be eligible to take part in the study if they self-identify as from an ethnic minority background and have accessed one of the participating sites as a patient or support person in the past two years. Healthcare staff will be eligible if they have worked within one of the participating services for at least six months and are a current staff member in any role. The sample size proposed seeks to capture an initial group of individuals from a range of the ethnic groups attending each service, which will then be utilised to explore further sample size requirements. Interviews and subsequent analysis will be an iterative process with the research team regularly reflecting on and reviewing the sampling strategy throughout the data collection period. The final sample size will be informed by the emerging analysis based on principles of information power, taking into account adequate representation of multiple ethnic minority perspectives.(35) For the series of co-design workshops, least three staff and between three and five patient/carer members will be included in the group at each site who have lived experience relevant to the subject matter.(32)

Recruitment

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

Training and support

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

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. The environmental audit tool comprises four components totalling 17 items and 29 questions. The four components that capture evidence of the observable features of the health service environment that reflect the elements of consumer engagement based on the Carmen's Patient and Family Engagement framework.(1) The tool was validated in one of the participating sites. It was independently completed by two researchers over three observation periods. Internal reliability analysis revealed substantial agreement between reviewers in applying the tool (k = 0.85). 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, and the potential for healthcare-associated harm in their care. Face-to-face, videoconferencing or phone interviews will be conducted, with the latter modes being utilised when covid restrictions are in place or upon request of the participant. Interviews with ethnic minority cancer consumers will be conducted in their preferred language. For languages other than English, bilingual fieldworkers, and interpreters (when bilingual fieldworkers are not available) will be used to complete the interviews. This is an approach that have been used in previously published work undertaken by the team in Australian healthcare services in conjunction with multicultural health team at Western Sydney Local Health District (WSLHD). The bilingual fieldworkers will be provided with appropriate training prior to conducting the interviews. This approach will be used to enhance trust and comfort between the research participants and the researcher; previous research has indicated that bilingual fieldworkers who understand the language and culture of the participant can support participants to feel at ease and share their experiences.

iii. *Feedback events:* The Experience-Based Co-Design toolkit identifies the importance of feedback events in which co-design participants come together to discuss and share their views throughout the co-design process. In the present project, these events will be held as facilitated online meetings lasting around two hours at two time points. The first will occur before the codesign groups. The first feedback event will aim to generate a shortlist of areas in which patient safety could be improved for ethnic minority patients using patient engagement strategies. The findings from observations and interviews undertaken will be discussed in this event. Both staff and patients from the six sites will jointly identify priority areas for developing or adapting current engagement strategies. The facilitators will support the discussions to ensure balance in the range of perspectives that are heard. The feedback event will be used to discuss and agree the focus of the co-design groups in each site including whether these focus on a particular ethnic minority population/language or cultural group, or to focus on heightened inclusivity of patient engagement strategies to be suitable for a range of ethnic minority consumers. Online events enable participants from all sites to meet together across the broad geographical region of Victoria and New South Wales. Both consumer and healthcare staff participants will attend both feedback events.

iv. *Co-design groups and subsequent feedback event:* A small co-design group will be formed in each of the six sites; six groups in total, with 6-8 members per group. Each group will comprise of a mix of patients, carers and healthcare staff. The co-design groups will be convened to adapt, design and implement solutions to the priority issues identified through feedback events with reference to the patient safety strategies identified and explored with stakeholders during the preliminary stages of the research. Each group will have a facilitator from the research team and an ethnic minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the study population. The groups will meet for no more than 10 hours in total; approximately 2-3 hours every fortnight over a six-week period. Each group will develop terms of reference that will determine their ways of working and their preferred mode of meeting (online, face to face or hybrid) and meeting duration and frequency as proposed by the consumer advisory group. Once again, online and hybrid modes will be utilised in the context of covid restrictions. The terms of reference will be reviewed at the commencement of each sessions. The co-design workshop process is shown in Figure 2. Following the co-design group meetings, all participants will attend a second online feedback event, along with the consumer advisory and project reference group members. In the second feedback event, the attendees will determine the interventions for implementation in each site for the six months following the end of the co-design period. The activities will be evaluated for feasibility and acceptability over a six-month period when implemented in the participating cancer services in the next stage of the CanEngage Project.

<INSERT FIGURE 2 HERE>

i. *Evaluation of adapted EBCD approach*: To address the secondary aim we will evaluate the approach to EBCD employed in the study for its impacts on consumer experience and involvement in the co-design process. Members of the co-design groups and the co-facilitators will be asked to complete a brief end of project interview. One researcher who is external to the CanEngage Project (ENS) will work with bilingual fieldworkers to conduct online or face-to-face interviews based on the participants preference. We will review the terms of reference they have developed, and capture adaptations made to these. These data will be synthesised with data from the recordings and summary notes of the co-design workshops to produce a narrative synthesis of experiences of the co-design process, and the nature and extent of their engagement when using the adapted EBCD model. Towards the evaluation, we will seek to conduct exit interviews with those who dropped out of the study at any stage to explore factors contributing to drop-out and consider their mitigation for future work.

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 consumers and their engagement in patient safety practices in the participating cancer services and b) the key elements of the cancer service environment that enable or may inhibit consumer engagement. (36, 37) Following transcription, two researchers will independently listen to the audio recordings repeatedly to become familiar with the data. Transcripts and field notes will be transferred into NVivo software and subject to line-by-line coding. The researchers will independently identify key words, phrases and sentences and explore themes within the data.(37) Coding will be iterative and refinement of themes and subthemes will evolve over the course of the analysis. The data will be organised and displayed via diagrams and figures to identify patterns and interrelationships within the data. Discrepancies will be discussed and themes and subthemes refined until agreement, with resolution by a third party should this be required.

Co-design process analysis: Inductive analyses drawing upon grounded theory will be utilised to generate new understanding of the adapted model of co-design in the present study, replicating a method that has been used to explore the implementation of EBCD in health service improvement.(38, 39) Analyses will be via the constant comparative method with multiple researchers. Open codes will be independently generated from the transcripts and fieldwork notes; as patterns and themes emerge from the data they will be grouped into higher order organising themes.(40) Analysis will be recursive, constantly moving from the specific to the more general to develop more transferable categories and explanations for the findings, but also explore local level findings and disparities between groups. Commonalities and patterns across settings will be identified and deviant cases will be sought to check the emerging constructs. A summary of the ground theory analysis will be shared with participants of the co-design groups and the co-facilitators for input and final reflections.

Co-designed strategies: The co-designed strategies developed will be collated and reported in terms of the nature of the adaptations made; the safety issues each strategy sought to address; the populations who co-designed the strategy and the target population, along with considerations regarding further populations to whom they may or may not be relevant.

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 and require progress reporting biannually. Throughout the project, study quality will be ensured by our project governance process which comprises primarily of an external stakeholder reference group and an external consumer advisory group. The stakeholder reference group meets quarterly to provide independent oversight of the project processes and progress against milestones. The consumer advisory group meets biannually to provide specific review and advice of consumer involvement activities and project processes to ensure that we retain a consumer-centric approach.

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

Ethics and dissemination:

Ethical considerations have been explored, identified and a risk mitigation plan created for each matter arising through the process of applying for ethical approval for the conduct of the study. Ethics approval has been obtained for all components of the co-design for all six sites (2020/ETH00965, 2021/ETH00532) by Western Sydney Local Health District Human Research Ethics Committee (WSLHD HREC) which is a National Health and Medical Research Council (NHMRC) recognised ethics committee. During the study, data will be stored on the OneDrive system of the leading institution with the primary investigator and retained in this secure location for at least seven years following the end of the project in accordance with the national ethical requirements. Through the project development process, a number of key risks and mitigation strategies were identified and developed. Four strategies will ensure that research activities will be managed and coordinated effectively. Firstly, we have established approval from the research sites in each state to conduct this work to mitigate the risk of not being able to access the services and individuals within these. Secondly, to address risks of working across the two states in complex patient safety research, we have recruited local project managers in each state to ensure local oversight. Thirdly, we are cognisant of the complexities, associated risks and mitigation practices needed to work with a highly diverse consumer group. To address the risk of not being able to interact with the diverse target population of consumers effectively, we access relevant translation services, bilingual fieldworkers and have budgeted for the associated costs and complexity. Finally, annual meetings, monthly virtual meetings and the project reference group mitigates risk and enhances our ability to respond effectively. The study findings will be disseminated at multiple events and through a range of formats to ensure that all stakeholder groups with interest in the project and its outcomes are able to access the findings. Dissemination will occur through practice-based and local-level presentations in the participating sites for staff and consumers, with key findings also reported through the social media outlets of the research team and affiliated institutions to reach a wider public audience. Scientific reports of the findings will be developed and submitted to high-quality, peer-reviewed outlets in the field of health services and cancer-services research relevant to the emergent evidence.

Authors' contributions: RH, MW and EM conceived the project. All authors collectively developed the project design through creating the NHMRC project proposal that forms the basis of this protocol. We work collaboratively through a series of meetings and working across multiple drafts. In these ways, all authors contributed to developing the project design and study methods described in the protocol as project investigators. RH prepared the initial draft of the protocol based on the project protocol and contributions were made by all authors to all aspects of the protocol manuscript. The authorship team meet monthly to plan the project processes. AC and RH will be primarily responsible for data acquisition, preparation and analysis across the sites, with local project team members CW, DL, MC, EM, AG, AS, MW, HS contributing to data acquisition, preparation and analysis at each study site. All authors edited, contributed content and reviewed the final draft of the protocol.

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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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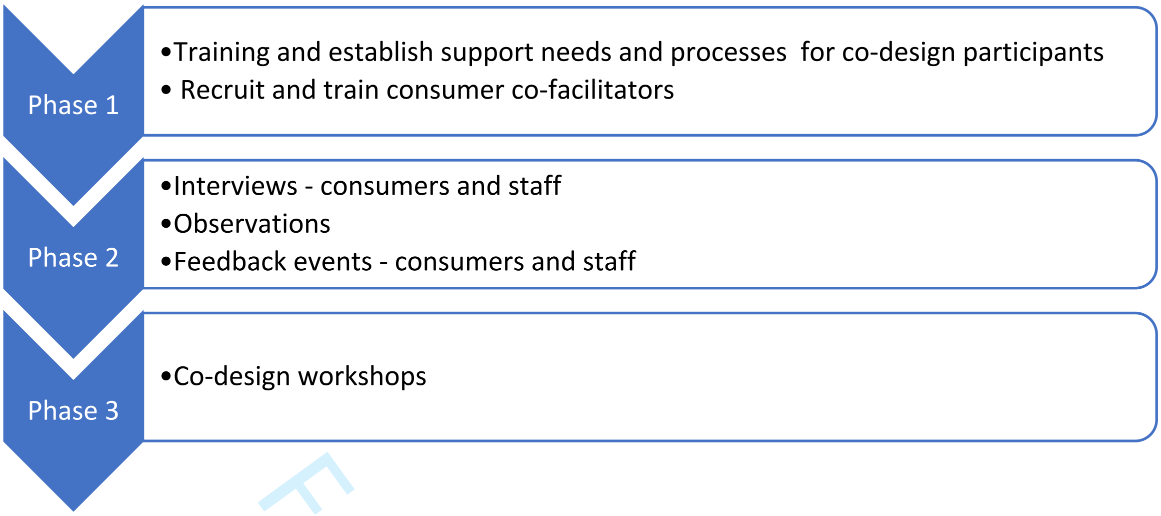

Figure 1 Adapted EBCD Approach

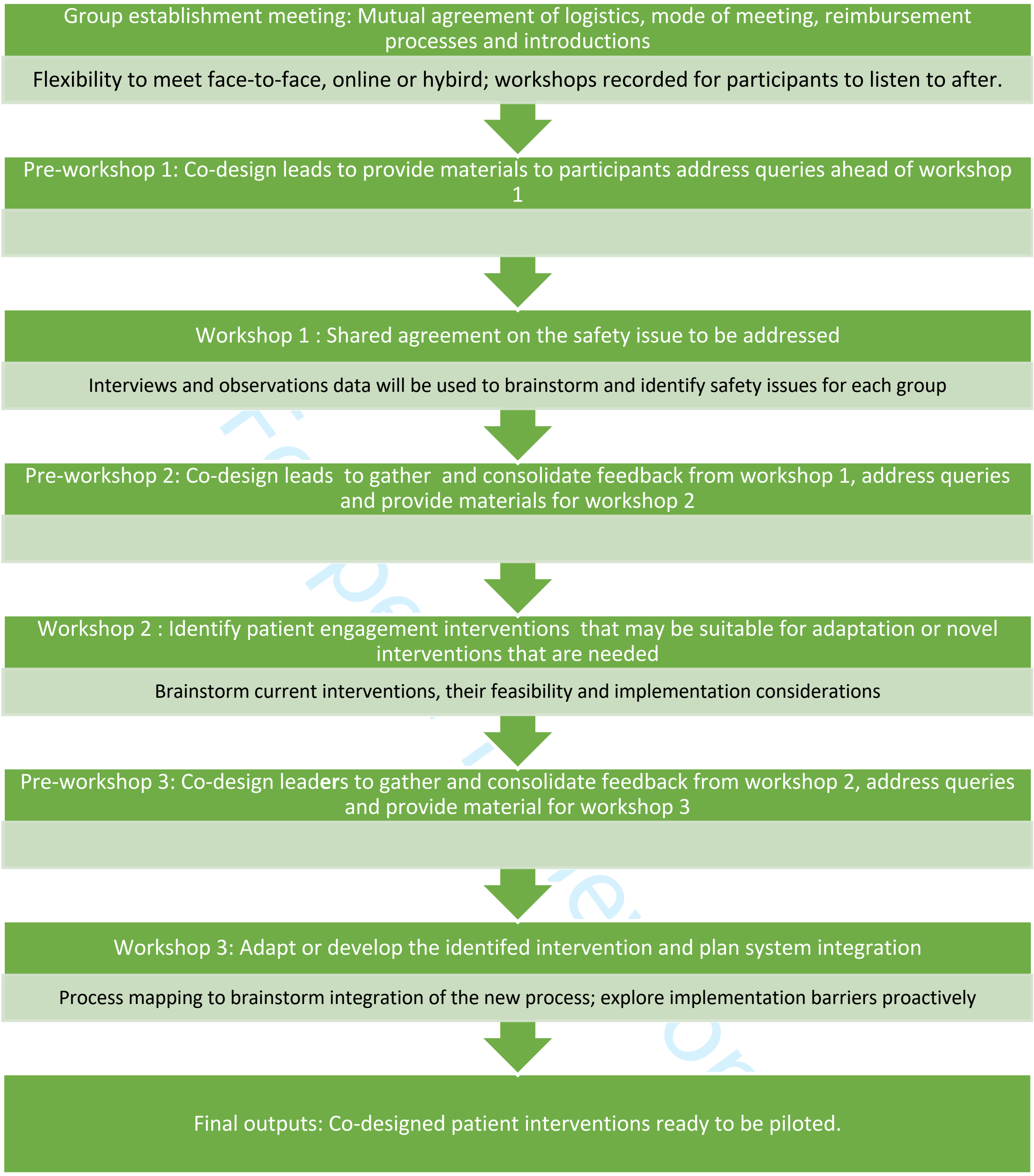

Figure 2: Co-design Workshop Schedule

BMJ Open

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

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

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Abstract:

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

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

to the co-design participants, in addition to recruiting and training consumer co-facilitators for the co-design workshops. The project will follow the EBCD process of gathering and synthesising observational data from each cancer service, with interview data from consumers and staff. With the resulting in-depth understanding of the safety threats commonly experienced by ethnic minority consumers in each site, we will work through feedback events and co-design groups with consumers and staff to determine how they can be more involved with their care to minimise the potential for patient harm. Consumer engagement interventions will be co-produced in each of the six participating services that are tailored to the ethnic minority populations served.

Ethics and dissemination: Ethics approval has been obtained from the Western Sydney Local Health District Human Research Ethics Committee. The project will provide strategies for ethnic minority consumers to engage with cancer services to minimise healthcare-associated harm that may be applied to diverse healthcare settings.

Strengths and limitations of this study

- We employ and evaluate a novel co-design approach that prepares facilitators and participants for the co-design.
- Co-facilitator development and training with ethnic minority consumers is integrated in the methodology, which is transferable to other co-design work with ethnic minority populations in other care settings and internationally.
- Prior to this study, patient involvement in patient safety interventions have not been developed for or evaluated with ethnic minority populations.
- This project is limited to cancer services in Australia and findings may not be directly transferable to other specialty areas or systems.
- Whilst we aim to assess intervention impacts on consumer engagement and perceptions of safety, we will not gather evidence of impacts of the resulting engagement strategies on objective safety outcomes.

Introduction

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

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

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

Experience-based co-design (EBCD) has been adopted in healthcare to enable a user-centric collaborative process of developing changes to improve consumer and staff experiences.(32) Whilst the value of co-design, including EBCD, for improving long term healthcare outcomes has been contested, it is supported as a method by which to achieve user-centric design.(33-35) A recognition that users are experts in their own lived experiences and that user-centric design is therefore important, has driven increasing use of co-design to improve healthcare and create change for quality improvement (33, 36-39) in patient safety interventions, (40) the development of frailty pathways (39), the development of telehealth services (41) and within lean a structured quality improvement approach in healthcare.(42) In the present study, EBCD is used to provide a user centric approach to achieve enhance (patient-reported) patient safety and engagement with cancer services amongst ethnic minority patients in Australia. We seek to achieve this goal through co-designing adaptations of consumer engagement strategies that aim to improve safety with consumers from ethnic minority backgrounds and their healthcare staff and applying these strategies in Australian cancer services. The study employs a novel adaptation of EBCD by integrating consumer co-facilitators and their training into the EBCD process. Consumer co-facilitators are past and/or current cancer services consumers who work in partnership with the research team to co-facilitate the leadership of the process of the co-design, guiding and supporting participants through the process. This adaptation aims to widen participation to the co-design progress, the depth of engagement between co-design members and to improve consumer experience of the co-design process itself. The secondary aim is therefore to evaluate our adapted model of EBCD for its impacts on consumer experience and engagement in the co-design process. The project is embedded within a larger program of work; the CanEngage Project, which explores consumer experience and engagement in their healthcare as a means of improving healthcare safety for ethnic minority populations accessing cancer services.

Methods and analysis:

Study design

An exploratory mixed-method design will integrate observations and semi-structured interviews. We will use Experience-Based Co-Design (EBCD), which proceeds through observations of the services, patient and staff interviews followed by a series of patient and staff feedback events and subsequent co-design workshops.(43) We will adapt this process of EBCD by adding an initial phase (phase 1 in Figure 1) in which we will recruit and train ethnic minority consumer co-facilitators along with providing training and establishing the support needs of co-design participants.(44)

<INSERT FIGURE 1 HERE>

Setting

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

Study sample

Approximately 15 clinical and non-clinical staff employed by the participating cancer services (including administrative and management staff) and 15 ethnic minority consumers (patients and/or their informal carers) will be initially recruited at each site, totaling 90 healthcare staff and 90 patient/carers across the six sites. Consumers who are aged 18 and over will be eligible to take part in the study if they self-identify as from an ethnic minority background and have accessed one of the participating sites as a patient or support person in the past two years. Healthcare staff will be eligible if they have worked within one of the participating services for at least six months and are a current staff member in any role. The sample size proposed seeks to capture an initial group of individuals from a range of the ethnic groups attending each service, which will then be utilised to explore further sample size requirements. Interviews and subsequent analysis will be an iterative process with the research team regularly reflecting on and reviewing the sampling strategy throughout the data collection period. The final sample size will be informed by the emerging analysis based on principles of information power, taking into account adequate representation of multiple ethnic minority perspectives.(45) For the series of co-design workshops, least three staff and between three and five patient/carer members will be included in the group at each site who have lived experience relevant to the subject matter.(32)

Recruitment

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

Training and support

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

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. The environmental audit tool comprises four components totalling 17 items and 29 questions. The four components that capture evidence of the observable features of the health service environment that reflect the elements of consumer engagement based on the Carmen's Patient and Family Engagement framework.(1) The tool was validated in one of the participating sites. It was independently completed by two researchers over three observation periods. Internal reliability analysis revealed substantial agreement between reviewers in applying the tool (k = 0.85). 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, and the potential for healthcare-associated harm in their care. Face-to-face, videoconferencing or phone interviews will be conducted, with the latter modes being utilised when covid restrictions are in place or upon request of the participant. Interviews with ethnic minority cancer consumers will be conducted in their preferred language. For languages other than English, bilingual fieldworkers, and interpreters (when bilingual fieldworkers are not available) will be used to complete the interviews. This is an approach that have been used in previously published work undertaken by the team in Australian healthcare services in conjunction with multicultural health team at Western Sydney Local Health District (WSLHD). The bilingual fieldworkers will be provided with appropriate training prior to conducting the interviews. This approach will be used to enhance trust and comfort between the research participants and the researcher; previous research has indicated that bilingual fieldworkers who understand the language and culture of the participant can support participants to feel at ease and share their experiences.

iii. *Feedback events:* The Experience-Based Co-Design toolkit identifies the importance of feedback events in which co-design participants come together to discuss and share their views throughout the co-design process. In the present project, these events will be held as facilitated online meetings lasting around two hours at two time points. The first will occur before the codesign groups. The first feedback event will aim to generate a shortlist of areas in which patient safety could be improved for ethnic minority patients using patient engagement strategies. The findings from observations and interviews undertaken will be discussed in this event. Both staff and patients from the six sites will jointly identify priority areas for developing or adapting current engagement strategies. The facilitators will support the discussions to ensure balance in the range of perspectives that are heard. The feedback event will be used to discuss and agree the focus of the co-design groups in each site including whether these focus on a particular ethnic minority population/language or cultural group, or to focus on heightened inclusivity of patient engagement strategies to be suitable for a range of ethnic minority consumers. Online events enable participants from all sites to meet together across the broad geographical region of Victoria and New South Wales. Both consumer and healthcare staff participants will attend both feedback events.

iv. *Co-design groups and subsequent feedback event:* A small co-design group will be formed in each of the six sites; six groups in total, with 6-8 members per group. Each group will comprise of a mix of patients, carers and healthcare staff. The co-design groups will be convened to adapt, design and implement solutions to the priority issues identified through feedback events with reference to the patient safety strategies identified and explored with stakeholders during the preliminary stages of the research. Each group will have a facilitator from the research team and an ethnic minority consumer co-facilitator, supported by bilingual fieldworkers relevant to the study population. The groups will meet for no more than 10 hours in total; approximately 2-3 hours every fortnight over a six-week period. Each group will develop terms of reference that will determine their ways of working and their preferred mode of meeting (online, face to face or hybrid) and meeting duration and frequency as proposed by the consumer advisory group. Once again, online and hybrid modes will be utilised in the context of covid restrictions. The terms of reference will be reviewed at the commencement of each sessions. The co-design workshop process is shown in Figure 2. Following the co-design group meetings, all participants will attend a second online feedback event, along with the consumer advisory and project reference group members. In the second feedback event, the attendees will determine the interventions for implementation in each site for the six months following the end of the co-design period. The activities will be evaluated for feasibility and acceptability over a six-month period when implemented in the participating cancer services in the next stage of the CanEngage Project.

<INSERT FIGURE 2 HERE>

i. *Evaluation of adapted EBCD approach*: To address the secondary aim we will evaluate the approach to EBCD employed in the study for its impacts on consumer experience and involvement in the co-design process. Members of the co-design groups and the co-facilitators will be asked to complete a brief end of project interview. One researcher who is external to the CanEngage Project (ENS) will work with bilingual fieldworkers to conduct online or face-to-face interviews based on the participants preference. We will review the terms of reference they have developed, and capture adaptations made to these. These data will be synthesised with data from the recordings and summary notes of the co-design workshops to produce a narrative synthesis of experiences of the co-design process, and the nature and extent of their engagement when using the adapted EBCD model. Towards the evaluation, we will seek to conduct exit interviews with those who dropped out of the study at any stage to explore factors contributing to drop-out and consider their mitigation for future work.

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 consumers and their engagement in patient safety practices in the participating cancer services and b) the key elements of the cancer service environment that enable or may inhibit consumer engagement. (46, 47) Following transcription, two researchers will independently listen to the audio recordings repeatedly to become familiar with the data. Transcripts and field notes will be transferred into NVivo software and subject to line-by-line coding. The researchers will independently identify key words, phrases and sentences and explore themes within the data.(47) Coding will be iterative and refinement of themes and subthemes will evolve over the course of the analysis. The data will be organised and displayed via diagrams and figures to identify patterns and interrelationships within the data. Discrepancies will be discussed and themes and subthemes refined until agreement, with resolution by a third party should this be required.

Co-design process analysis: Inductive analyses drawing upon grounded theory will be utilised to generate new understanding of the adapted model of co-design in the present study, replicating a method that has been used to explore the implementation of EBCD in health service improvement.(48, 49) Analyses will be via the constant comparative method with multiple researchers. Open codes will be independently generated from the transcripts and fieldwork notes; as patterns and themes emerge from the data they will be grouped into higher order organising themes.(50) Analysis will be recursive, constantly moving from the specific to the more general to develop more transferable categories and explanations for the findings, but also explore local level findings and disparities between groups. Commonalities and patterns across settings will be identified and deviant cases will be sought to check the emerging constructs. A summary of the ground theory analysis will be shared with participants of the co-design groups and the co-facilitators for input and final reflections.

Co-designed strategies: The co-designed strategies developed will be collated and reported in terms of the nature of the adaptations made; the safety issues each strategy sought to address; the populations who co-designed the strategy and the target population, along with considerations regarding further populations to whom they may or may not be relevant.

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 and require progress reporting biannually. Throughout the project, study quality will be ensured by our project governance process which comprises primarily of an external stakeholder reference group and an external consumer advisory group. The stakeholder reference group meets quarterly to provide independent oversight of the project processes and progress against milestones. The consumer advisory group meets biannually to provide specific review and advice of consumer involvement activities and project processes to ensure that we retain a consumer-centric approach.

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

Ethics and dissemination:

Ethical considerations have been explored, identified and a risk mitigation plan created for each matter arising through the process of applying for ethical approval for the conduct of the study. Ethics approval has been obtained for all components of the co-design for all six sites (2020/ETH00965, 2021/ETH00532) by Western Sydney Local Health District Human Research Ethics Committee (WSLHD HREC) which is a National Health and Medical Research Council (NHMRC) recognised ethics committee. During the study, data will be stored on the OneDrive system of the leading institution with the primary investigator and retained in this secure location for at least seven years following the end of the project in accordance with the national ethical requirements. Through the project development process, a number of key risks and mitigation strategies were identified and developed. Four strategies will ensure that research activities will be managed and coordinated effectively. Firstly, we have established approval from the research sites in each state to conduct this work to mitigate the risk of not being able to access the services and individuals within these. Secondly, to address risks of working across the two states in complex patient safety research, we have recruited local project managers in each state to ensure local oversight. Thirdly, we are cognisant of the complexities, associated risks and mitigation practices needed to work with a highly diverse consumer group. To address the risk of not being able to interact with the diverse target population of consumers effectively, we access relevant translation services, bilingual fieldworkers and have budgeted for the associated costs and complexity. Finally, annual meetings, monthly virtual meetings and the project reference group mitigates risk and enhances our ability to respond effectively. The study findings will be disseminated at multiple events and through a range of formats to ensure that all stakeholder groups with interest in the project and its outcomes are able to access the findings. Dissemination will occur through practice-based and local-level presentations in the participating sites for staff and consumers, with key findings also reported through the social media outlets of the research team and affiliated institutions to reach a wider public audience. Scientific reports of the findings will be developed and submitted to high-quality, peer-reviewed outlets in the field of health services and cancer-services research relevant to the emergent evidence.

Authors' contributions: RH, MW and EM conceived the project. All authors collectively developed the project design through creating the NHMRC project proposal that forms the basis of this protocol. We work collaboratively through a series of meetings and working

across multiple drafts. In these ways, all authors contributed to developing the project design and study methods described in the protocol as project investigators. RH prepared the initial draft of the protocol based on the project protocol and contributions were made by all authors to all aspects of the protocol manuscript. The authorship team meet monthly to plan the project processes. AC and RH will be primarily responsible for data acquisition, preparation and analysis across the sites, with local project team members CW, DL, MC, EM, AG, AS, MW, HS contributing to data acquisition, preparation and analysis at each study site. All authors edited, contributed content and reviewed the final draft of the protocol.

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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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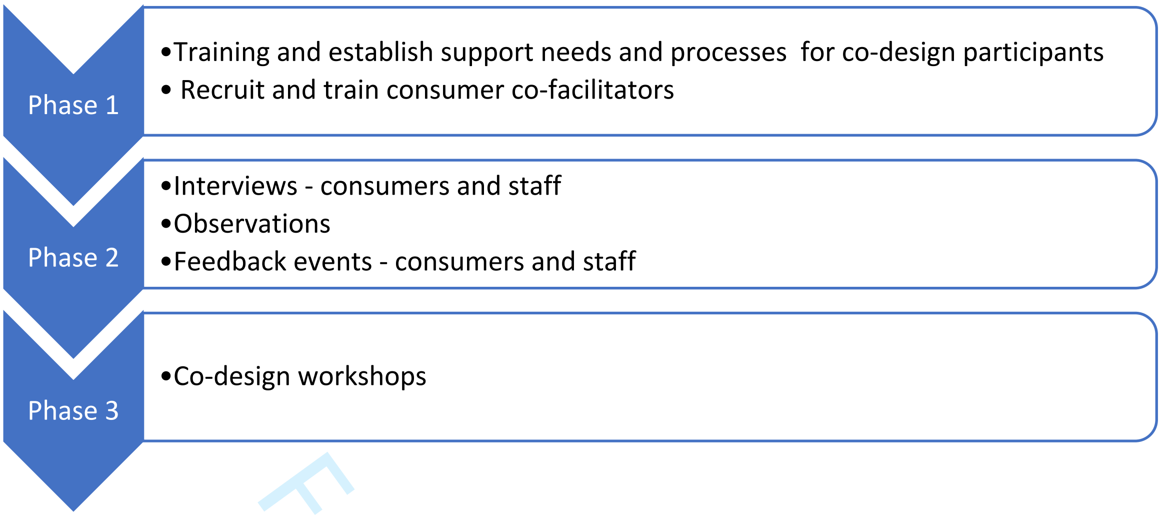

Figure 1 Adapted EBCD Approach

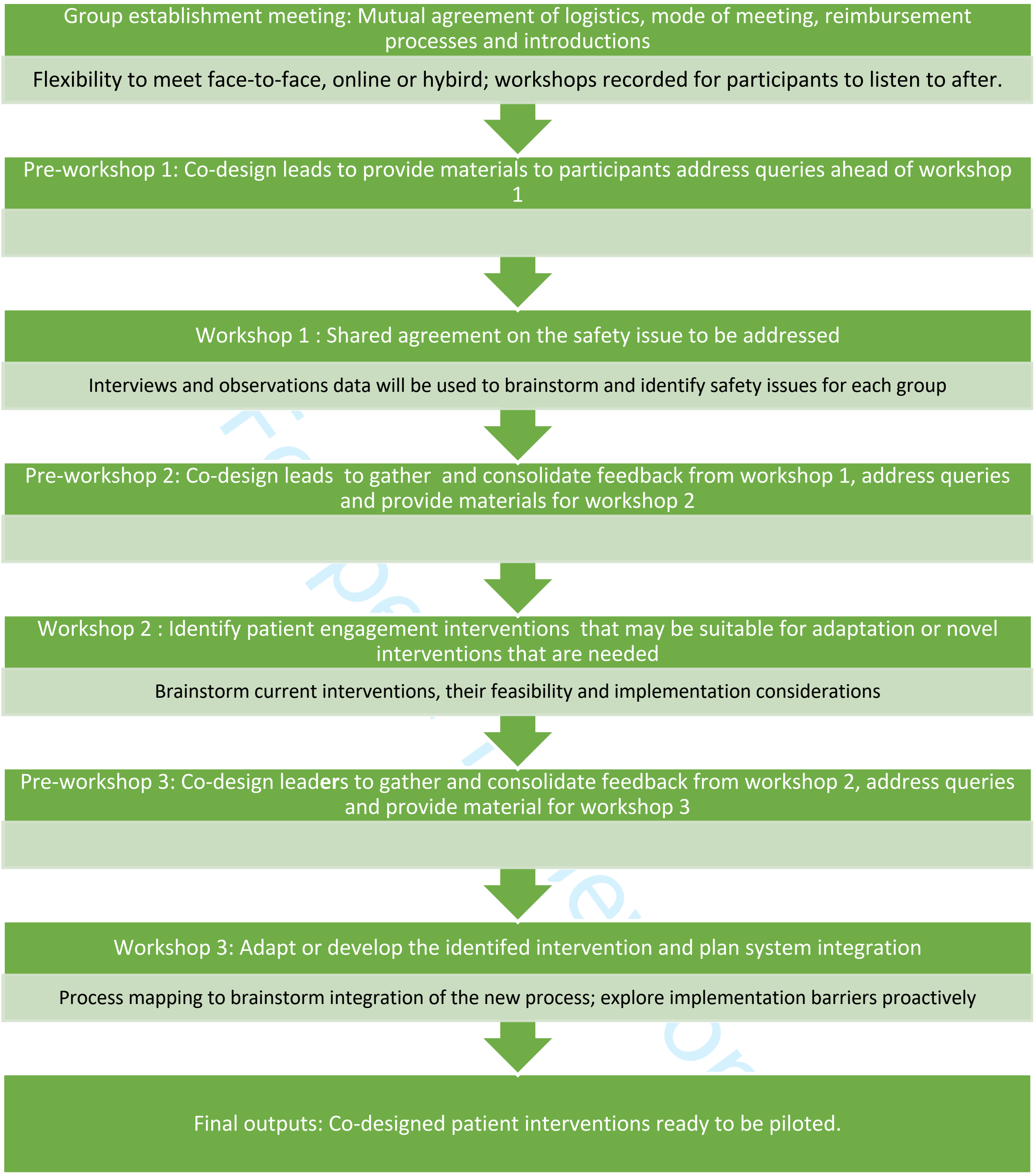

Figure 2: Co-design Workshop Schedule