Factors influencing the implementation of shared decision-making in breast cancer care: protocol for a mixed-methods study

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ABSTRACT

Introduction Chile is committed to actively involving patients in their healthcare. However, little is known about how this is translated into clinical encounters. Breast cancer (BC) is the first cause of cancer-related death in Chilean women. National policy guarantees standard care, and treatment decisions should be made along this process that can have long-term consequences for women. So, BC is a particularly well-suited case study to understand the complexity of patient participation in decision-making.

Objective To identify the factors that affect the active involvement of patients in the BC treatment decision-making process, considering the perspectives and practices of health professionals and women facing the disease.

Method and analysis We will conduct a mixed-method study through a convergent parallel design in three stages: (1) A qualitative study: non-participant observation of the tumour board (TB) meetings; semi-structured interviews with key informants from TBs; documentary analyses; semi-structured interviews with women facing BC; and non-participant observations of clinical encounters; (2) a cross-sectional study with 445 women facing BC stages I–III from three hospitals in Santiago, Chile. We will measure the level of expected participation, experienced participation, decisional conflict, quality of life (QoL) and satisfaction with healthcare. Descriptive analysis will be performed, and multivariable binary logistic regression models will be adjusted to identify factors associated with high levels of QoL or satisfaction; (3) an integration study will bring together the data through a joint display technique.

Ethics and dissemination The study has been conceived and will be conducted according to international and local agreements for ethical research. Ethical approval has been granted by two Ethics Committees in Chile. The results will be disseminated to scientific and lay audiences (publications in scientific journals and conferences, seminars and a website for plain language dissemination).

INTRODUCTION

Chile is committed to actively involving patients in their healthcare by promoting patient-centred care (PCC) as a core component of health policy. The practitioner–patient encounter in healthcare has evolved from a paternalistic relationship—where knowledge, power and authority are entirely held by health professionals (HPs)—to a more democratic relationship, where patients actively participate in their care.1 With this aim, Chile has established that patients have rights and responsibilities concerning their healthcare.2 Thus, the Health Reform implemented in Chile in 2003 has placed patients at the centre while focusing on their rights and promoting patient participation in healthcare to reduce health inequalities.3 4 This was also part of the Chilean National Health Plan that promoted a more horizontal relationship between patients and HPs.5 This strategy for the decade 2011–2020 stated, ‘There is no better doctor than oneself’, introducing the idea of patients’ involvement to improve both satisfaction and quality of care.6 Currently, sharing information with patients is a legal requirement.7 Patients find that receiving clear, continuous, detailed and participative information makes them feel respected and
dignified by the HPs. However, there is no clear indication of how exactly to involve people to allow them to participate in their healthcare. Clarifying this could improve patients’ satisfaction with healthcare services. Directly related to PCC, shared decision-making (SDM) has emerged in healthcare. SDM advocates for the involvement of patients as partners, and a good relationship between both parties is essential. In this way, HPs will support patients by providing the best available evidence while, at the same time, exploring their values and preferences to make the best decisions for them. SDM constitutes an ethical imperative because people have the right to participate in decisions that matter to them and affect their lives. It is also seen as Good Clinical Practice as it respects patients’ rights when considering their preferences and values. Therefore, SDM encourages the HP and the patient to become involved in decisions as they share information (the former will offer the best evidence available, and the second one will share their experiences, values and feelings).

Although the benefits of SDM have been largely reported, integrating this collaborative approach into clinical practice is still incipient. This is particularly relevant for Chile, where political and legal efforts have been insufficient to trigger its application in routine healthcare. The nature of this phenomenon could explain this. What SDM pursues is to democratise the clinical encounter. This space has been traditionally led by the ‘experts’, where HPs are now forced to acknowledge and promote the expertise of patients in their health and well-being. This implies that the power imbalance that characterises health is now balanced, and both parties—HP and patient—hold power in the decision-making process. SDM could have a direct impact on increasing treatment adherence, short-term and long-term health outcomes, patients’ experience, satisfaction with healthcare and quality of life (QoL). This is particularly important for people diagnosed with cancer, as this has reached the top one cause of death for Chileans. Breast cancer (BC) is the first cause of cancer-related death for Chilean women. National policy guarantees a well-established care protocol for women facing BC through the Explicit Guarantees Health System (GES). This includes screening strategies for early BC detection and treatment of all women through the GES. The side effects of BC treatments can be challenging as some sequelae can be permanent. Thus, dimensions like QoL have progressively acquired priority as an outcome, in this way making visible the multidimensional needs of both patients and survivors. Key treatment decisions are made through the process and decisions that can have profound long-term consequences for women.

However, in the Chilean context, there is a lack of evidence about patients’ participation in health-related decisions and the reasons that might affect them. BC and its treatment constitute a particularly well-suited case study to understand better the human and technical complexity of participation in the clinical encounter. Although different explanatory models have been proposed to understand the implementation of SDM, they have been developed in Europe or North America. Thus, the features and factors that might influence, by promoting or affecting, the implementation of SDM in the Chilean context remain unknown. Nevertheless, there is an increasing interest in measuring potential associations between promoting women’s active participation in SDM and the QoL for BC, where some evidence has reported that women who actively participate in SDM could experience higher levels of QoL. Furthermore, research reports on BC concord with the vast literature linking SDM and quality of care or satisfaction. Thus, further research is needed to understand this association, considering the particularities of a Latin American context.

**OBJECTIVE**

The main objective of this research is to identify the factors that affect the active involvement of patients in the BC treatment decision-making process, considering the perspectives and practices of HPs and women facing the disease. As a secondary objective, we aim (1) to identify the factors (eg, women’s characteristics and preferences; family influence; cancer severity; GES and health insurance; organisational, legal structures and interpersonal dynamics) considered by tumour boards (TB) when discussing treatment options for women facing BC; (2) to describe how HPs involve women in the medical decision-making process in BC; (3) to understand how women experience the decision-making process about BC treatment; (4) to determine the level of expected participation, experienced participation, decisional conflict (constructs of SDM) and satisfaction with the decision reported by women who faced BC treatment decisions; (5) to propose a model that explains the satisfaction and QoL of women with BC by using the SDM constructs, such as desire for participation, experienced participation and decisional conflict; and (6) to identify key elements to be considered for designing effective interventions to promote SDM in BC treatment, based on the proposed model.

**METHODS AND ANALYSIS**

We will conduct a convergent parallel mixed-methods study. In this type of study, quantitative and qualitative data are collected in parallel, the analysis is conducted separately and then the results are merged to better understand the phenomenon. The project will be conducted in three stages (see figure 1): (1) A qualitative study that includes an in-depth description of the decision-making process for BC treatment through non-participant observation of TB meetings; semi-structured interviews with key informants; documentary analysis of relevant documents; semi-structured interviews with women facing BC to explore their perspectives; and non-participant observations of clinical encounters. (2)
A cross-sectional study with 445 women facing BC stages I–III from three hospitals in Santiago. Participants will complete a set of questionnaires that measure the level of expected participation, experienced participation, decisional conflict, QoL, and satisfaction with healthcare. Descriptive analysis will be performed, and multivariable binary logistic regression models will be adjusted to identify factors associated with high levels of QoL or satisfaction.

Stage 1: qualitative study
We will conduct a case study to understand the experience and practices in the BC decision-making process for HPs and women. We will follow Guba’s criteria to ensure methodological rigour. This will be done through three complementary phases:

- Non-participant observation of TB meetings
- Semi-structured interviews with key informants
- Documentary analysis
- Semi-structured interviews with women
- Observation of clinical encounters
- Recruitment of 445 women
- Data input
- Construction of the model
- Visual illustration of both methods
- Propose a strategy for SDM in practice

In-depth description of the medical decision-making process for BC treatment

Non-participant observation of TB meetings where decisions regarding treatment options are discussed from a medical perspective without the patient’s presence

These TBs function in all Chilean healthcare centres that provide cancer treatment, and the members can include several HPs, such as oncologists, radiologists, and surgeons, among others. For 6 months, non-participant observations will occur in three healthcare centres that provide BC treatment in Santiago: one public, one private, and one not-for-profit. Following the authorisation of each hospital director and the TB, fieldwork will comprise the observation of weekly meetings, looking for negotiations, tensions, and forms of knowledge that lead to specific treatment decisions. After each meeting, the researcher will write down field notes to describe the observation, which the research team will read, and they will not be made public. In addition, the researcher will
take some precautions to be as unobtrusive as possible. This is done to protect the identity of the participants and the clinical and personal information of patients shared by the TB members; a protocol for non-participant observation will be used.

Recruitment/sample size
Three TBs focusing on BC treatment at the involved hospitals will be invited to participate. The participants of each TB will be made aware of the researcher’s presence, her/his role as a researcher and the study objectives. In the early stages of the fieldwork, participating in weekly activities will help the researcher build rapport with the TB members and redefine the observation protocol according to the knowledge gained by ‘being there’. Long-term fieldwork stays will help understand the TB members’ opinions, beliefs, preconceived ideas and expectations regarding women’s cancer treatment and their role in decision-making.

Data analysis
All data collected during observation sessions will be transcribed and coded. The analysis of observation session notes will occur in tandem with the analysis of data collected from in-depth interviews (please, see below) and through videotaped cancer consultations. This will enable an analysis of the incongruences and congruences of what the participants say and what they do in making decisions regarding cancer treatment and patients’ participation. The interpretation of incongruences would highlight areas that need to be addressed in developing care plans for choosing a treatment for women with BC. Data will be analysed using thematic analysis.

Semi-structured, in-depth interviews with key informants who participate in TB or participate in the BC treatment decision-making process
After discussing the plain language statement and gaining consent, key informants will be asked to share their experiences and understandings with the researcher. It is anticipated that these interviews will take up to 60 min and be tape-recorded, and an interview guide will be used. Key informants will be asked about their experiences of working with women with BC in general, the issues that they face when being diagnosed and beginning to deal with cancer treatment, their views on how the treatment is chosen (and their intention to include women in the process), the considerations about QoL in this decision, about the challenges they face as service providers concerning cancer treatment and their ideas about patients’ participation in decision-making processes related to cancer treatment.

Recruitment/sample size
At least 15 members of the observed TB will be invited to participate. Interviews will be conducted until saturation is reached.

Data analysis
The tape-recorded interviews will be transcribed ad verbatim by trained transcribers. Data will be analysed using thematic analysis.

Documentary analysis of clinical records reporting the outcomes of the TB meetings, norms, clinical protocols, policy documents and any other relevant written text related to BC treatment
Analysing documents is important as texts can influence how people think and act because they mirror organisational activity. In healthcare, documents are integral to clinical practice, providing guidelines or pathways for patients and HPs to perform. The team will search using keywords and following inclusion criteria to select relevant documents. These documents will be sourced from the National Congress webpage, the electronic library of the Ministry of Health and local documents produced in the hospitals that will take part in this study.

Exploring women’s perspectives on the decision-making process
Participants
A purposeful sample will be used. The potential participants will be recruited through three hospitals participating in this study by gaining access through their HPs. This will allow us to access potential participants in emotional conditions, according to the HPs who are in direct contact with women and (by following the GES protocol) have assessed their needs and provided support when needed. We will include women who: (1) Are 18 years old or above; (2) have received a diagnosis of BC in stages I–III; (3) have received their primary treatment (breast surgery, either conservative or total mastectomy); and (4) have not received any adjuvant treatment yet. The exclusion criteria include: (1) For ethical concerns, women who are facing BC stage IV (ie, metastatic) will be excluded from this study, as some might be facing emotional challenges; and (2) women who are unable to provide their consent as for their mental or emotional status (according to their health provider). After discussing the plain language statement and gaining consent, women will be asked to share their experiences and understandings with the interviewer.

Data collection
Semi-structured in-depth, and individual interviews will be conducted with women who face BC by following a validated interview guide designed by the team. The interviewer will ask women for permission to conduct interviews to gain a deep understanding of their everyday experiences. The interview will take approximately
60 min and will be tape-recorded. Participants will be asked about the experience of deciding on a treatment for their condition, how they participated in the decision-making process, how they perceived their role and their oncologist’s performance and how the decision impacted their QoL.

We expect to conduct between 25 and 30 interviews. However, interviews will be conducted until saturation is reached. The interview location will be discussed with the participants before the interview; the goal is to find a place where they feel comfortable and safe, which is quiet enough to conduct an interview. The interviewer will notify the principal investigator of all the details related to the timing and location of the interviews and will report back on completion of the interview. A trained transcriber will transcribe the tape-recorded interviews. Data will be analysed using thematic analysis.

Observation of clinical encounters
The final stage of the qualitative component will involve observing the clinical encounter between women with BC and their head doctor (medical oncologist/surgical oncologist/radiation oncologist). We will observe the consultation during which the specialist informs a woman of the stage of her BC, as this is closely related to her treatment options. A total of 45 consultations will be observed (15 at each participating hospital). This third phase will enrich these views by allowing us to observe what happens ‘there’ during the medical consultation. This will be done through a non-participant observation of a previous videotaped clinical encounter. This method has been selected because it reduces the uncomfortable intrusion of a third party during the clinical encounter. It is important to clarify that both, the patient and the HP, will be aware that the consultation could be recorded and that this procedure will not take place if any of them do not give her/his consent to do so. The logistics of video-recording the encounter will be discussed locally with each hospital.

The observation will focus on the specialist’s performance and how he/she can engage with the patient. All data collected through notes from observation sessions will be transcribed and coded. In Chile, there are no validated instruments to measure this construct. However, a self-reported instrument captures uncertainty in decision-making. It has 16 items, with five dimensions (uncertainty, informed values clarity, support and effective decision), with a 5-point scale. This instrument has been previously validated and tested in the Chilean population. Cronbach’s \( \alpha \) was 0.80.

3. Health Centre Assessment Questionnaire. This Chilean instrument assesses the quality of care from the patient’s perspective. Three of the 10 subscales of this questionnaire that are relevant to the purpose of this study will be used, that is, (i) communication care from a medical doctor, (ii) communication care from a nurse and (iii) communication care from a midwife. Cronbach’s \( \alpha \) was 0.95, 0–93 and 0–93, respectively.

4. C30 and Br23. Numerous tools for measuring QoL in patients with cancer exist. Recommended approaches consider tailored measurements depending on tumour location and socio-demographic characteristics. The European Organisation for Research and Treatment of Cancer offers one of the most comprehensive and widely used measures for patients with cancer, developing a modular model of measurements, including general modules and site-specific questionnaires. Both Quality of Life Questionnaire C30 (QLQ-C30, general module for patients with cancer) and the Quality of Life Questionnaire Br23 (QLQ-Br23, BC module) have been translated and psychometrically validated in our country.

Sample size
A sample size was calculated to achieve objectives 4 and 5 of this research. To estimate the percentages of high preference for participation (around 75% with high
levels of preference; high levels of experienced participation (around 85%); high decisional conflict (around 73%); and high satisfaction (approximately 90%), the minimal sample size should be 289, 196, 303 and 139 respectively, to estimate the percentages with a <5% error of estimation and a confidence of 95%. To adjust a model that explains satisfaction with healthcare and QoL of women facing BC treatment, and assuming that the logistic regression model will be used to explain high levels in both dependent variables, it was considered that satisfaction and QoL would probably be less than 90% for the participants. Suppose it is assumed that these percentages will be around 85%. In that case, 400 women are needed for the binary logistic regression model with a maximum of six explanatory variables (eg, level of education, stage of BC/treatment received, type of hospital, SDM observed, SDM reported by women and family history of BC). Considering a 10% of sample loss, the final sample size for the study is 445 women. According to personal conversations with head doctors at each participating hospital, this number is achievable within the length of the study. As conducted in the qualitative stage, the recruitment will be first explored by the health professionals who attend the woman to secure their eligibility criteria and avoid any harm as part of this project.

Data analysis
Continuous variables without outliers will be presented as mean, SD and skewed variables as median and IQR. Categorical variables will be presented as number of cases and percentages. When the variable has a normal distribution or central limit theorem applies, Student’s t-test for paired samples will be used. To control the effect of possible confounding variables, an analysis of the covariance will be used. The Kruskall-Wallis non-parametric test will be used to compare numerical variables between centres or one-way analysis of variance in normal cases. The normality of each numerical variable will be determined with the Kolmogorov-Smirnov test. Categorical variables will be compared using the Pearson’s χ² test. Multivariable binary logistic regression models will be adjusted to identify factors associated with high QoL or satisfaction. The goodness of fit of the models will be assessed using Hosmer and Lemeshow test and Receiver Operating Characteristic (ROC) curve analysis. Relationships between the scales will be analysed through structural equation modelling. All p values will be two-tailed, and a value of <0.05 will be considered statistically significant. The SAS/STAT program package V.9.3 (SAS Institute, Cary, North Carolina, USA) and Stata V.14 will be used for all data processing.

Stage 3: integration study
This mixed-methods study considers integration at the interpretation and reporting level. This considers a joint display analysis, which means that data will be analysed separately and organised by themes and then brought together through a visual illustration to show the new insights, that is, data coming from the qualitative case study will be complemented by the data retrieved in the cross-sectional phase. We will follow the four-stage technique developed by Johnson et al to build up a table that illustrates the integration of data: (i) relevant data from the qualitative stage will be listed in a column; (ii) quantitative data reflecting content that relates to the initial listed data will be matched with the previous list in another column; (iii) accuracy of the match will be checked to ensure quality; and (iv) after comparing and contrasting them, a central pillar column with new insights and possible explanations will be built. This graphical representation will be provided to understand better the factors influencing the decision-making process in BC treatment and how this impacts the satisfaction and QoL of women who face this disease. It is expected that key elements will be revealed to propose strategies for the effective practice of SDM in Chile by using the BC case study.

Patient and public involvement
Patients have been involved since the conception of this study. The research team has approached several patient organisations to obtain their insights on the protocol. One of the coauthors (MEG) of this manuscript is a cancer survivor, and she has provided her feedback on the interview guides and recommendations to approach patients better. The team has also set-up an advisory board to audit the work and provide feedback on the preliminary results. As part of this board, one patient organisation is actively involved. The research team is currently setting-up a website in plain language where information about the protocol, findings and opportunities for dissemination will be shared with the community.

ETHICS AND DISSEMINATION
This innovative project will deeply explore the decision-making process for BC in Chile. The results will inform strategies to promote patient involvement and mechanisms to include their voices throughout the care pathway. Ethical approval was granted from the Ethics Committee for Health Sciences at the Pontificia Universidad Católica de Chile (ref number: 200622007) and the Ethics Committee of the Instituto Oncológico Fundación Arturo López Pérez (ref number: 200622007).

By the end of this project, we will have a description of the factors that influence the implementation of SDM in the Chilean context. Also, we will have a model that explains the influence of SDM on women’s satisfaction with healthcare and their QoL. We will also propose recommendations for the clinical implementation of SDM in BC for Chile. Academic reports will be produced at each stage of the study (including scientific papers and presentations at scientific conferences), and lay audiences will be engaged through specific seminars. Also, there will be a website with up-to-date information on the project and the continuous work with patient organisations.
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**Contributors**  
All authors contributed significantly to this paper’s conceptualisation, design and drafting. PB wrote the manuscript, conceived the study and secured the funding. AD, MG-A and AM refined the qualitative component of the protocol. LF-G and CS provided valuable clinical knowledge to solidify the methods in accordance with clinical practices. LV drafted the quantitative stage. MH provided feedback for the complete protocol. VT, AM MEG and CQ supported the refinement of the qualitative component of the study and the fieldwork strategy. All authors have read and approved the manuscript.

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**Competing interests**  
None declared.

**Patient and public involvement**  
Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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