Access to mental healthcare among people in vulnerable situations across Europe: a multi-site mixed-methods study protocol

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Abstract

Background

Despite robust policy commitments across Europe, significant disparities in access to mental healthcare persist, particularly among populations experiencing vulnerable situations. Furthermore, research gaps exist in understanding mental healthcare access barriers faced by these populations. As part of the EQUICARES consortium, this protocol employs the Levesque healthcare access framework to examine the ability for populations experiencing vulnerable situations across Europe to perceive, seek, reach, pay for, and engage with care. The following aims will be investigated: 1) Examining associations between the five Levesque demand-side domains (ability to perceive, seek, reach, pay, engage), demographics, and quality of life within target populations; 2) Identifying additional barriers to accessing mental healthcare for these groups; and 3) Exploring the ability to engage with mental healthcare in depth.

Methods

This mixed-methods study aims to recruit *N* = 160 participants for Aims 1 and 2 (*n* = 20 in eight pilot sites), and a further N = 16 participants for Aim 3 (*n* = 2 per site). Aim 1 adopts a structured survey to quantitatively assess the five domains of the Levesque framework, demographics of participants, and quality of life (measured by the MHQoL). Aim 2 qualitatively investigates each of the five domains of the Levesque framework to identify additional barriers in the help-seeking journey for people in vulnerable situations. Reflective diaries will be applied for Aim 3, to explore the ability to engage in greater depth. The protocol also outlines measures taken to ensure a consistent data collection strategy across with different populations, supported by cultural mediators to ensure sensitivity to local context. For Aim 1, correlational tests will be conducted. Framework analysis will be conducted on qualitative data for Aim 2 and interpretative phenomenological analysis will be applied to reflective diary data (Aim 3). Findings from each aim will be integrated to develop a comprehensive account of mental healthcare access barriers between and within populations experiencing vulnerable situations.

Discussion

The findings of this study will identify common barriers for people in vulnerable situations, inform the co-design of inclusive, digitally supported mental health interventions and contribute to policy recommendations for more equitable European care systems.

1. Background

Despite the growing policy momentum across Europe relating to access to mental healthcare, persistent disparities in access and outcomes remain, particularly for people facing vulnerable situations (1–3). These disparities are shaped by a complex interplay of social determinants, historical exclusion, and systemic inequities that traditional health system research often fails to capture (4, 5). Recent EU policy briefs and national mental health strategies have highlighted the disproportionate mental health risks faced by specific groups facing vulnerabilities, for example young people, older adults, persons with disabilities, LGBTQIA+ individuals, migrants, refugees, the Roma community, ethnoreligious minorities, and people who have experienced natural disasters (1,

6). These populations have been identified in other EU-funded initiatives, such as the RESPOND (7) project, which draws attention to the mental health consequences of structural vulnerability and social exclusion. In line with international research literature in the area of health equity (8), these populations are referred to as “people in vulnerable situations” in the present study, emphasising that vulnerability is not attributed to individuals but instead is associated with negative social determinants, such as discrimination, housing and income disparities, displacement, or experiences of violence.

Previous research on mental health access has tended to focus on supply-side determinants, such as service availability, provider density, or resource distribution (9). However, increasingly research is acknowledging access as a complex, relational process shaped by both the organisation of services and the lived realities of those attempting to use them (10, 11). Levesque et al. (10) developed a patient-centred access framework that offers a comprehensive lens to examine this complexity, encompassing both supply-side characteristics (such as approachability, acceptability, availability and accommodation, affordability, and appropriateness of services) and service-user-side abilities (to perceive, seek, reach, pay for, and engage with care; herein referred to as the *Levesque framework*, see Fig. 1). This dual perspective enables a more nuanced exploration of how structural, cultural, and interpersonal dynamics interact to enable, or obstruct, access to mental health care (11). The Levesque framework has been applied to many areas of healthcare such as chronic conditions (12), patients with HIV/AIDS (13), primary care (14), and mental healthcare (9, 15–17). In addition, the framework has been applied using a health equity lens (16), with a focus on people in vulnerable situations, such as women experiencing family violence (18), Indigenous people (14), people with intellectual disabilities (19), Black perinatal women (15), and refugee and asylum-seekers (9). However, there is a gap in understanding which barriers are commonly faced across populations of people in vulnerable situations to accessing mental healthcare, and which barriers are unique to specific populations. Furthermore, while mental health conditions are more commonly experienced among people facing vulnerable situations (20), the relationship between quality of life and healthcare barriers as described in the Levesque framework in these groups is not well-understood.

INSERT Fig. 1 here – Overview of Levesque Framework

Patient engagement is increasingly recognised as a critical pillar of high-quality, equitable mental health care (21–23), encompassing how individuals participate in healthcare and navigate care over time. However, engagement is not experienced equally, with populations facing vulnerable situations often facing profound barriers to trust, empowerment, and continuity of care (24). In addition, while many theoretical models of healthcare engagement have been developed (25), few have been integrated effectively into the Levesque framework and mapped to the ability to engage with mental healthcare. The Patient Health Engagement (PHE; see Fig. 2; (24)) model outlines the role of self-management, health information use, collaborative communication, and healthcare navigation within engagement with healthcare. Theoretically, these components align with the ability to engage outlined in the Levesque framework, but with a greater focus on the self-efficacy of service users in difficult contexts. Research that integrates the PHE model into the Levesque framework would help to better understand the factors affecting the agency of service users in vulnerable situations as they engage with mental healthcare.

INSERT Fig. 2 here – Patient Health Engagement Model

To address these gaps, the European Horizon funded EQUICARES project adopts the Levesque framework to investigate the real-world, micro-level conditions affecting mental health access across eight pilot sites in

Europe. The distinct research objectives of this study are exploratory guided by the five abilities in the Levesque framework:

- To examine the interactions/associations between the five abilities (perceive, seek, reach, pay, engage), demographics, and quality of life within populations facing vulnerable situations.
- To identify barriers to accessing mental healthcare from the perspective of people facing vulnerable situations, in the areas of ability to perceive, seek, reach, pay, and engage with mental health services
- To explore the ability to engage with mental healthcare in depth among service users in priority populations, using the PHE model

2. Methods

This study is underpinned by a critical realist philosophy of science (26), adopting a realist ontological stance, and employing relativist and phenomenological epistemologies. This approach has been employed regularly in health research, facilitating mixed methods research, with an emphasis on understanding the lived experience of participants within a real-world context (27). Critical realism also emphasises the need to understand the agency of individuals within a context of social determinants that create positive or negative conditions impacting upon lived experiences (26). This approach aligns with the focus of this study with people experiencing vulnerable situations accessing mental healthcare.

2.1 Study Design

This study adopts a multi-site, mixed-method design to investigate user-side barriers to mental health care. This approach enables the collection of both generalisable data on patterns of access and rich, contextualised insights into lived experiences of engagement and exclusion.

The study comprises two core data collection tools: a structured survey and a reflective diary/testimony component. These are deliberately mapped onto different dimensions of the Levesque framework and the PHE. The structured survey focuses on all domains of the Levesque framework—specifically the ability to perceive, seek, reach, pay for, and engage with care. The reflective diary/testimony is designed to solely explore the ability to engage, capturing relational, emotional, and cultural aspects of service use that are often underrepresented in conventional evaluations, as informed by both the Levesque framework and the PHE.

The study is designed via consultation with EQUICARES partner organisations to ensure that data collection methods are both methodologically rigorous and locally responsive. The eight pilot sites are summarised in Table 1. Harmonised tools are adapted across sites to support linguistic diversity, cultural appropriateness, and participant accessibility. A participatory and trauma-informed approach underpins the design, ensuring that people in vulnerable situations can safely share their perspectives on access to care.

Table 1
– EQUICARES Pilot Sites

Site Name	Country (Region)	Study Populations
LGBT Ireland	Ireland (CHO Area 6)	LGBTQIA+ community
LADAPT	France (Normandy)	People with disabilities (physical, sensory, psychosocial or intellectual)
FISEVI	Spain (Seville municipality)	Roma community (focus on women) Migrants
GIVMED	Greece (Attica region)	Migrants Refugees Unaccompanied minors (represented by legal guardian as proxy) Youth aged 18–25
South-East European Research Centre (SEERC)	Greece (Thessaloniki region)	Elderly women Migrants Refugees
Amalipe	Bulgaria (North-central region)	Roma community Ethnoreligious minorities
Zentralinstitut für Seelische Gesundheit	Germany (Baden-Württemberg)	Elderly Elderly migrants
Koç University	Türkiye (Hatay sub-region)	Survivors of the Hatay Earthquake (2023) Elderly Migrants

2.2 Participants and Sampling

The proposed sample size is *N* = 160 for the structured survey, and *N* = 16 for the reflective diary. This sample will be gathered across the eight pilot sites, who will aim to recruit *n* = 20 participants each for the survey, and *n* = 2 each for the diary.

Participant recruitment for both data collection will follow a purposive, site-specific strategy across the eight EQUICARES pilot sites. This sampling strategy is designed to reflect the study's equity-centred ethos and aligns with Horizon Europe's commitment to the meaningful inclusion of people in vulnerable situations in shaping future digital mental health infrastructures. Local partner organisations at each pilot site have identified populations based on contextual relevance, feasibility, and alignment with EQUICARES' inclusion goals. Target populations include young adults (aged 18–25), the Roma community, the elderly, ethnoreligious minorities, migrants, LGBTQIA+ individuals, persons with physical, sensory, psychosocial or intellectual disabilities, refugees, people facing natural disasters, and unaccompanied minors (see Table 1). These populations reflect those most

affected by structural inequities across Europe and are aligned to EU mental health priorities and national mental health research strategies in Europe (1, 6).

Eligibility criteria are method-specific and aligned with the study's conceptual focus (see Table 2). The structured survey includes individuals from identified vulnerable groups, regardless of whether they have accessed mental health services. This allows exploration of early-stage barriers, such as the ability to perceive, seek, reach, and pay for care. Additionally, the reflective diary/testimony method is limited to those who have used formal mental health services within the past 12 months and are able to reflect on that experience. This ensures data richness in relation to the ability to engage with care, including trust, communication, and continuity.

Table 2
– Eligibility Criteria

Category	Structured Survey	Reflective Diary / Testimony
Inclusion Criteria	• Aged 18+ • Self-identifies with ≥ 1 included population (see below) • Can provide informed consent (self or via representative)	• Aged 18+ • Self-identifies with ≥ 1 included population (see below) • Can provide informed consent (self or via representative) • Must have accessed MH services in past 12 months
Exclusion Criteria	• Under 18 • In acute MH crisis or recent trauma • Unable to consent and no representative • Shows distress or dysregulation during recruitment	*Same as survey*
Included Populations	• Youth (aged 18–25) • Elderly (aged 65+; including elderly migrants) • Member of Roma Community • Member of ethnoreligious minority • Migrants (including refugees, asylum seekers) • LGBTQIA+ individuals • People with disabilities (physical, intellectual, sensory, mental) • Survivor of natural disaster • Unaccompanied minors (represented in the study by their legal guardian who is aged over 18)	*Same as survey*

2.3 Data Collection

2.3.1 Structured Survey

The structured survey component of the study was designed to capture descriptive, cross-contextual data on participants' experiences of access to mental health care. The survey consists of demographic questions, quality of life questions, quantitative questions focused on service user domains of the Levesque framework, and qualitative questions relating to the same domains. Demographic questions (e.g., age, gender, migration background, disability) allow for disaggregated analysis across populations included in the study. Quality-of-life is measured by the Mental Health Quality of Life measure (MHQOL; (28)). The MHQOL is a multi-dimensional concept commonly used to examine the impact of health status on quality of life (e.g., mood, sleep, and personal relationships).

As there was no existing measure of the service-user-side domains of the Levesque framework specific to mental health identified by the research team, quantitative questions were developed in consultation with pilot sites across Europe and informed by previous research from Cu et al. (11). Twenty quantitative questions are included in the survey, consisting of four items per domain in the Levesque framework, encompassing two questions each framed positively (e.g., *"I know where to go if I need mental health support from a professional."*) or negatively (e.g., *"I believe my health insurance or public coverage would not provide enough support to afford mental health care")*. Qualitative items in the survey consist of one brief open-ended questions per domain of the Levesque framework (e.g., ability to seek: "*What makes it harder for you to look for mental health support?"*). The wording of the questions was also designed in consultation with pilot sites and informed by previous research (11).

Recognising the prevalence of mental health difficulties among the priority groups targeted for this study, the survey has been deliberately designed to minimise emotional burden. Each item was screened for clarity, cultural appropriateness, and emotional safety with pilot partners and researchers. As is recommended when conducting research with a diverse range of populations (29), a variety of data collection modes will be available to researchers to collect this structured survey (e.g. paper-based, digital).

2.3.2 Reflective Diary and Testimony Methods

This aspect of the study draws on the PHE model (24) to develop a reflective diary tool aligned with the fifth user-side dimension in the Levesque framework: the ability to engage with care. This data collection strategy is designed to elicit rich, narrative accounts of user-provider relationships, shared decision-making, and continuity, with attention to the cultural, institutional, and interpersonal dimensions that shape experiences of engagement.

The reflective diary/testimony method is rooted in participatory and ethnographic traditions (30) offering a flexible, user-led approach that prioritises emotional safety and lived experience. Unlike structured interviews or surveys, diaries allow for narrative depth and temporal reflection, key to understanding access from the perspective of those at the margins of care systems (31, 32).

Participants will be invited to reflect on a specific care-seeking episode from the past 12 months. Open-ended prompts are structured around the four domains of the PHE model (Self-Management, Health Information Use, Collaborative Communication, and Healthcare Navigation) and are designed to capture both subjective meaning and structural context. To support participant choice and accessibility, the diary is available in two formats: paper-based (using locally adapted materials) and digital (using voice notes via the secure Typeform platform), ensuring usability across varying levels of literacy, digital access, and personal preference. Voice notes have been found to produce a similar quality of data to interviews (33) but provide greater convenience for participants to complete data collection asynchronously than interviews (34), as well as providing an inclusive method for participants with literacy difficulties to ensure they do not need to complete written testimonies.

2.4 Data Management Plan

A joint data controller memorandum of understanding has been signed by all research consortium partners to ensure full compliance with GDPR. To support the diverse needs of participants, a range of formats will be provided including paper forms, typed responses, audio recordings, and scanned documents. The research team will manage a secure data system allowing secure data storage and transfer.

2.4.1 Collection, Storage, and Transfer

Data will be collected both digitally and through paper-based methods to support the inclusion of participants across pilot sites. Typeform, a secure, GDPR-compliant digital platform, will be used to provide participants with a digital option for surveys and diary entries. Data collected manually by pilot sites (paper-based surveys or audio recordings) will be digitised by pilot partners and uploaded securely via Typeform to the research team, with paper forms securely destroyed after digitisation.

2.4.2 Third-Party Data Processing

Third-party providers involved in transcription, storage, or analysis must comply with GDPR. Data Processing Agreements (DPAs) will be signed and monitored. The research team will oversee data protection and ensure compliance across all sites. This will be highlighted in the participant information and consent forms.

2.4.3 Access and Dissemination

Raw data will remain closed due to its sensitive nature. De-identified summaries will be shared with stakeholders. Aggregated findings will be made publicly available through platforms such as Zenodo and the EQUICARES website.

2.4.4 Data Protection and Compliance

All data practices comply with GDPR and national regulations. A Data Protection Impact Assessment (DPIA) has been completed. All pilot sites are governed by a Memorandum of Understanding (MoU) naming them joint data controllers. Key GDPR safeguards include data minimisation and anonymisation; participant rights (access, correction, withdrawal), encrypted storage and secure transfer, and contracts with compliant third-party processors.

2.5 Ethical Safeguards and Participant Safety

2.5.1 Informed Consent and Accessibility

Participant information materials and consent procedures were co-designed in consultation with EQUICARES pilot sites to ensure they are culturally relevant, accessible, and contextually appropriate. Participants are provided with plain-language information outlining the study’s aims, procedures, potential risks and benefits, and their data protection rights. Consent may be obtained in writing or verbally, with the support of trained cultural mediators to facilitate understanding and build trust. These processes are designed to uphold participants’ autonomy, ensure voluntary participation, and support equitable engagement across diverse populations.

2.5.2 Trauma-Informed and Inclusive Approach

The protocol integrates trauma-informed principles and rights-based safeguards. Participants may withdraw at any time without consequence. Materials are adapted to support varied literacy levels and communication preferences. All cultural mediators and researchers involved in data collection have received training in trauma-informed practice.

2.5.3 Safeguarding and Distress Protocols

Local researchers and mediators have been trained to identify and respond to emotional distress. This included a tiered safeguarding protocol, encompassing both immediate emotional support and referral pathways for participants expressing harm or suicidality.

2.5.4 Ethics Oversight

Ethical approval

s have been obtained (or are pending) at all participating sites through local or national Research Ethics Committees. A harmonised ethics protocol was adapted to local jurisdictions. Training on safeguarding and research ethics is mandatory for all fieldworkers and partner staff.

2.6 Analytic Plan

This study will employ an integrated analytic strategy, combining qualitative and quantitative methods to explore demand-side barriers to mental health care. The analysis is structured around the Levesque framework, ensuring conceptual coherence across data types and pilot sites.

2.6.1 Qualitative Analysis

The primary analytical approaches for qualitative data will be framework analysis (35) and Interpretative Phenomenological Analysis (IPA (36)). Framework analysis is a method well-suited for applied health research with policy relevance, which will be applied to qualitative findings from open-ended questions in the survey. This approach balances deductive analysis, guided by predefined theoretical constructs, with inductive exploration of emergent themes. Data will be analysed in five stages: Familiarisation with the data to capture initial impressions and contextual nuance. Identification of a thematic framework, initially guided by the five Levesque user-side domains. Indexing (coding) data into the framework while allowing for emergent codes not captured by the original model. Charting, using thematic matrices to summarise and compare data across cases and sites. Mapping and interpretation, drawing analytical connections between themes, barriers, and contextual conditions.

IPA will be conducted on reflective diary entries/testimonies in line with guidelines from Smith et al. (36) to help understand participants' lived experiences with help-seeking. IPA emphasises treating each participant transcript as a case study, before comparing identified themes across cases. These steps are 1) immersion in the transcript; 2) initial noting of descriptive, conceptual, or linguistic comments within the case; 3) searching for connections to develop themes across cases; 4) repeating the steps for each case; 5) identifying connections across cases; 6) developing superordinate themes across cases.

Analysis will be supported by NVivo, allowing for transparent coding, cross-site comparisons, and audit trails. The analytic framework will be collaboratively refined through dialogue between EQUICARES researchers across the eight sites. Emphasis will be placed on equity-informed coding—particularly attending to intersecting forms of

marginalisation (e.g., migration status, disability, ethnicity, and gender identity). Cross-tabulations will be developed to explore how multiple vulnerabilities intersect to shape patterns of exclusion or inclusion in mental health access. At least five percent of qualitative coding will be cross-checked by members of the research team to support the validity of the analysis.

2.6.2 Quantitative Analysis

Quantitative data from the structured survey will be analysed using SPSS or R Studio. Descriptive statistics (means, medians, frequencies) will be calculated to profile participants and characterise access conditions across pilot sites. Where sample size permits, bivariate comparisons (e.g., by age, gender, ethnicity, sexual orientation, disability) may be conducted to explore subgroup trends. These findings will not serve inferential purposes but will inform deeper qualitative interpretation and site-level contextualisation.

Findings will be integrated at two levels. First, we will triangulate data types to explore each domain of the access framework. Secondly, we will triangulate across methods aligning diary narratives with quantitative profiles to examine consistencies or tensions. This integration will support multi-layered interpretation, ensuring both the structural dimensions of exclusion (e.g., affordability, geography) and the relational dimensions (e.g., trust, stigma, cultural safety) are accounted for. This approach supports EQUICARES' broader objective: to inform inclusive, community-driven solutions that meaningfully address the real-world needs of populations experiencing vulnerable situations.

3. Discussion

3.1 Study Design Considerations to Address Anticipated Challenges

This study is an example of real-world research (27), which does not follow a traditional study design, adopts mixed-methodology, and involves implementation of the research within healthcare services and NGOs across Europe. Levesque et al. (10) described healthcare access as a "patient-centred process", which is reflected in the methodology of this study to understand the lived experiences of service users and populations experiencing vulnerable situations.

Challenges have been identified in previous research in engaging with people in vulnerable situations in research, for example challenges in recruiting youth as participants in research projects in mental health services (37). To counteract anticipated challenges, the eight pilot sites participating in the study were identified due to their expertise in working directly with specific populations as NGOs, healthcare providers, and research organisations with longstanding relationships established with groups such as migrants, people with disabilities, and ethnoreligious minorities. In addition, multiple data collection methods (paper-based or digital surveys, voice notes or manual recordings) are employed in the study to account for digital literacy and preferences of participants, which is in line with best practice when working with people experiencing vulnerable situations (29). This approach intends to foster inclusive practice within the study and to facilitate participation.

The study design incorporates data collection from eight pilot sites across Europe, and as a result each site applies the shared methodology within its own sociopolitical and institutional context. As a result, data will be collected through multiple languages, including English, Spanish, French, German, Turkish, Greek, Bulgarian, and

Albanian, but all data will be translated into English. In addition, it is anticipated that some groups may collect data via an interpreter, to ensure the comfort of participants in sharing their experiences in their native language, including minority and indigenous languages. Where possible, automated translation of anonymised participant accounts will be conducted through the EU Commission eTranslation programme, and in other cases, manual translation of participant accounts will take place. Anonymised automated translations will be cross-checked between the research teams and pilot sites to ensure accuracy in representing the accounts of participants' lived experience.

3.2 Implications – EQUICARES Context

This study is part of the broader EQUICARES consortium, an EU-Horizon-funded project that focuses on addressing mental health disparities among people in vulnerable situations. Therefore, the findings of this study will inform subsequent parts of the EQUICARES project, specifically in the areas of co-designing solutions and developing effective, implementable mental health policy for the communities represented in this study. The application of the Levesque framework in this study using a mixed-methods approach will provide in-depth insights into current barriers to accessing care in these groups, enabling the development of solutions and policy. Findings will be applied within a broader co-design process with people experiencing vulnerable situations known as Smart Health Labs, which will inform the creation of solutions to address barriers identified within this study.

In addition, findings will be relevant to mental health policy at the international and national level in Europe. For example, *Sharing the Vision* – the national mental health policy in Ireland (38) – highlights mental health inequalities among populations such as LGBTQIA+ individuals, people seeking asylum, and the Travelling community, but current policy does not specify the actions services need to take to tailor mental healthcare to these populations. The use of IPA (36) as an analytic framework within this study facilitates identifying barriers that are common across groups, whilst also emphasising the factors that are specific within groups (e.g., experiences that are pertinent to the Roma community but may not be as relevant to people with intellectual disabilities).

3.3 Conclusion

The present study uses a robust, mixed-method protocol to centre lived experience in understanding barriers to mental health access. The design is participatory, cross-national, and grounded in both conceptual and ethical rigour. Findings will inform EQUICARES interventions with people in vulnerable situations and feed into policy recommendations for inclusive, equitable mental health care systems in Europe.

Declarations

Ethics approval and consent to participate: All pilot sites in this study have sought ethical approval to collect data, and the host institution overseeing the project has received ethical approval for data management and analysis (Jigsaw Research Ethics Committee; Ref. 2025-011).

Consent for publication: Consent for publication of findings is included in information sheets and consent forms for all participants in the study

Availability of data and materials: Due to the sensitive nature of the study, participant data will not be made publicly available. Demographic questions and qualitative study materials are included as supplementary materials. The quantitative questionnaire relating to the Levesque framework is not publicly available due to

planned future validation. One quantitative questionnaire used in this study (MHQoL) is publicly available here but is the intellectual property of Erasmus University Rotterdam.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: JM and NMD led the coordination of data collection and writing the manuscript. JM, NMD, and IK led the study design planning and preparations of materials with pilot sites. SOB, EDo, AB, EDi, OT, IK all contributed to writing and reviewing the manuscript. JM, NMD, SOB, EDo, AB, EDi will all contribute to data analysis.

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Figures

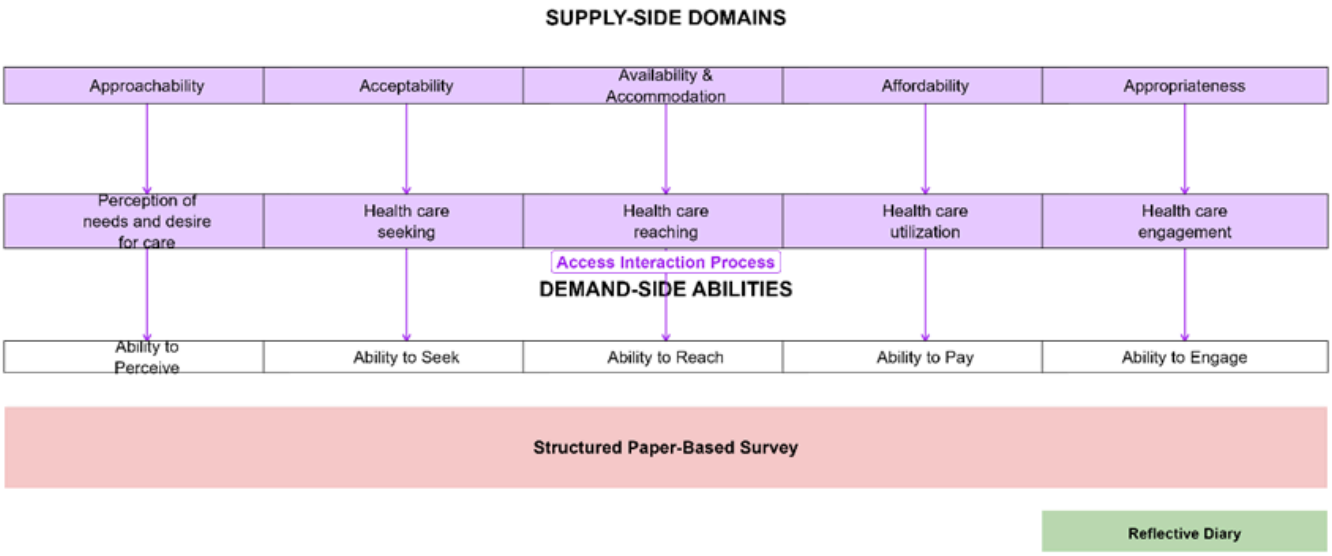

Figure 1

Overview of the Levesque Framework (adapted from Levesque et al. (10))

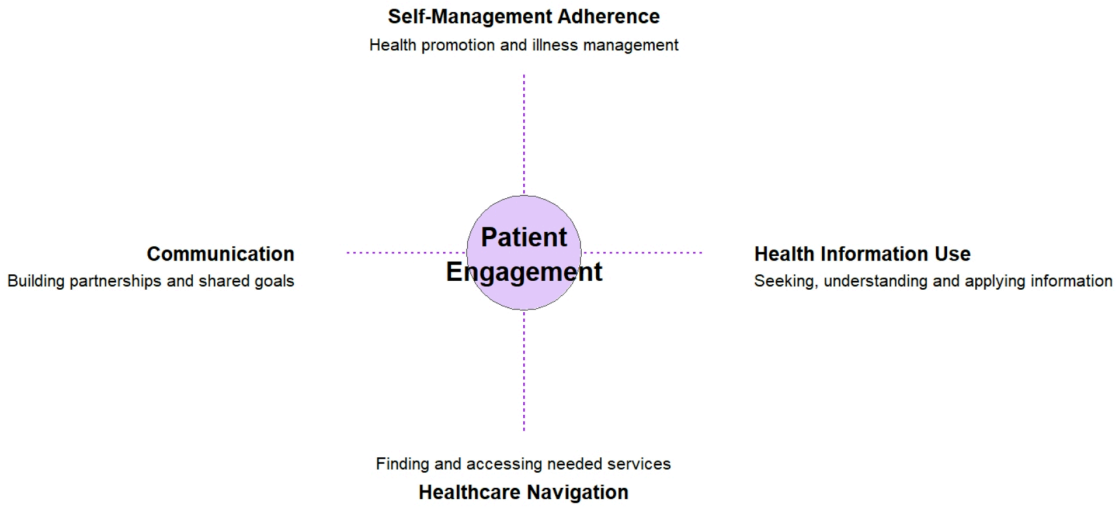

Figure 2

Patient Health Engagement (PHE) model (adapted from Kimerling et al. (24))

Supplementary Files

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