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Causal explanations for patient engagement with primary care services in Saudi Arabia: A realist review protocol

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Primary care, General practice, Patient engagement.

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ABSTRACT

Introduction

Saudi Arabia (SA) has a rapidly developing universal healthcare system which is maturing from its hospital focussed origins. However, health service usage suggests that up to 65% of the cases seen in emergency departments (ED) were classified as non-urgent and could have been appropriately managed in primary healthcare (PHC) settings. Primary care development in SA has lagged behind secondary care, and evidence suggests that Saudi citizens are currently ambivalent or dissatisfied with their PHC services.

Previous research has focused on the quality and patient satisfaction of PHC services in SA. Yet, uncertainty still exists about causal explanations for patient engagement with PHC services and what refinements are needed for PHC. Less attention has been paid to how patient engagement strategies might work differently, which is increasingly recognised as important in PHC services.

The aim of this review is to understand the causal explanations for patient engagement with PHC and to generate theory of how the intended outcome of patient engagement with PHC in SA might be achieved through identified contexts and mechanisms.

Methods and analysis

A realist review approach will be used to synthesise the evidence, which includes peer-reviewed, relevant grey literature and related media items.

Stakeholders' feedback will also inform our review. A realist approach is suitable for this review because patient engagement with PHC services is a complex phenomenon. A range of different relevant data will be included in the following stages: developing an initial programme theory, searching the evidence, selecting data, extracting data, synthesising data, and refining the programme theory.

Ethics and dissemination

This study will use secondary data, and stakeholders are involved only to shape our understanding of the important contexts in patient engagement; hence, a formal ethics review is not required. Findings will be disseminated in a peer-reviewed journal and at relevant conferences.

PROSPERO registration number

CRD42020175955.

Strengths and limitations of this study

• The first realist review in the Saudi PHC context that will produce a theoretical conceptualisation of patient engagement with PHC services through a rigorous approach;

- Stakeholder input during the programme theory development to ensure that domains important to patients will be understood;
- Inclusion of different study designs, including English and Arabic language data;
- Limited to the PHC services that belong to the Ministry of Health (MOH), which might not sufficiently capture how and why patients choose other PHC services in SA;
- Limited to the patient perspective, which might increase the risk of missing important domains from other perspectives in PHC services, such as the health professional perspective.

Background

Primary health care (PHC) is an integral component of a healthcare system and is vital for long-term healthcare system sustainability. Each country attempts to find its own formula for providing better ways to engage patients with PHC services (1). Patient engagement with PHC has become an increasing area of interest, with the aim of minimising non-urgent secondary care use (2).

SA has a rapidly developing universal healthcare system and is maturing from its hospital-focused origins, with a PHC-based health system that is being prioritised within Saudi government policy. However, in SA, patients are not utilising PHC services as much as they could, and evidence suggests that emergency department (ED) services are frequently utilised for non-urgent, PHC-treatable conditions (3)(4). Proposed reasons for this include a lack of trust, and the patient's perception of poor quality of PHC services in SA (5). In addition, several studies have shown low patient satisfaction with current PHC services in SA including availability, accessibility, and communication (3)(6)(7)(8).

Whilst existing research may indicate a lack of satisfaction and mistrust as reasons for patient disengagement with PHC services, these are a few elements of a complex 'mess' determining patient engagement with PHC services and it remains unclear why SA citizens bypass PHC. For example, while patients reported high satisfaction in the latest review of Saudi PHC services (8), up to 65% of cases seen in secondary emergency hospitals are classified as non-urgent and could have been appropriately managed in PHC setting (5). Thus, uncertainty still surrounds what would constitute appropriate engagement and utilisation of PHC in SA. Less attention has been paid to causal explanations for patient engagement with PHC services, a focus which PHC services increasingly recognise as important. There is also less understanding of how PHC should be tailored to enhance patient engagement.

This uncertainty calls for a review providing causal explanations for the complexity of patient engagement with PHC services. Therefore, this review will address *how*, *why*, *for whom*, *in what circumstances*, and *to what extent* SA citizens engage with PCH services or not.

Unlike traditional systematic reviews, which focus on producing judgements (e.g., 'Are patients satisfied or not satisfied?'), realist reviews provide explanations and an understanding of phenomena – e.g. answering instead questions such as 'Why are patients satisfied? When?' Thus, the present review will not only be used to develop and refine a theory but also to understand the causal processes behind the programme theory by producing contexts, mechanisms, and outcomes (9).

This review also offers potential relevance for policymakers who need to know not merely whether patients are satisfied but also what sorts of services to resource. In order to explore and understand the causal explanations for patient engagement with Saudi PHC services, as well as the challenges to patient engagement, a realist approach for evidence synthesis will be conducted.

Aim

This review aims to understand the causal explanations for patient engagement with the PHC services in SA.

Review objectives

- To review empirical research and grey literature exploring the key factors in Saudi patient engagement with PHC services;
- To identify key contexts, mechanisms, and outcomes at each step of our identified patient engagement pathway;
- To engage stakeholders in order to shape the review direction and provide a better understanding of the factors influencing patient engagement with PHC.

Review research questions

This review will be structured around the following questions:

Primary question:

From the patients' perspective, what are the causal explanations for their engagement (or not)
 with PHC services in SA?

Sub-questions:

• What are the "contexts" that influence whether patients engage with PHC services in SA or not?

- What "mechanisms" trigger patient engagement with PHC services in SA are believed to result in the desired outcomes?
- How are the desired "outcomes" of patient engagement with PHC services in SA will be achieved?

Approach

A realist review is a theory-driven interpretive approach to synthesising evidence. This approach will be undertaken because of its ability to move beyond a description of the literature to an explanation of how and why contexts and mechanisms interact and influence outcomes. A realist review can also synthesise a range of relevant data – such as qualitative, quantitative, and mixed-methods research – as well as grey literature. Multiple iterative cycles of realist review allow a further understanding of the causal processes behind the programme theory (9).

Through reviewing published and grey literature, a gradually refined programme theory will be developed using data drawn from the included documents. Within this programme theory, a realist logic of analysis will be used to analyse the data. The analysis-building pillars are context-mechanism-outcome configurations (CMOCs). CMOCs establish a relationship between the key conceptual components of a realist analysis – that is, how mechanisms are triggered under specific contexts to cause intended outcomes (10).

In this review, such contexts (c) are the settings, conditions, and circumstances that trigger causal mechanisms, which in turn cause patient engagement with PHC services. Mechanisms (m) are causal processes triggered in specific contexts that lead to changes or outcomes, while outcomes (o) are the impact resulting from interactions between mechanisms and contexts.

Because the concept of 'patient engagement' means different things in different healthcare systems (11), patient engagement will be clearly defined before starting the review. Previous research has restricted the definition of patient engagement in PHC to consultations between patients and general practitioners (GPs) (12). However, engagement with PHC services is a more complex process that goes beyond GP services. In this review, the term 'patient engagement' will be used to describe all the processes that lead to patient utilisation of PHC services, with greater reflection on the Saudi population's needs.

At the start of the review we will develop an initial programme theory that explains patient engagement with Saudi PHC services. The review process will then use data from included

documents to develop CMOCs that are situated within the programme theory by using a realist analysis to synthesise the evidence.

Since patients are the intended beneficiaries of healthcare services, and their input helps concerned authorities rectify systemic weaknesses (13) and is essential in improving healthcare services (14), this review will focus on the patient perspective. This review also aims to complement previous PHC research in SA from the patient perspective and identify gaps to build upon existing PHC research in SA from the patient perspective.

Patient and Public Involvement

This protocol has been developed with consideration to the Saudi patients' experiences and needs from PHC services. Patients will be included as stakeholders, as will be described in section 1.2.

Study design

The review will be designed based on Pawson's five iterative steps for a realist review (15):

- 1. Finding existing theories
- 2. Searching for evidence
- 3. Selecting articles
- 4. Extracting data
- 5. Synthesising evidence and drawing conclusions

Since this process will be viewed as iterative, the cycle of these steps will be repeated many times in order to reach theoretical saturation (15). (Please see figure 1 for further explanation of the study approach.)

Step 1: Finding existing theories

This step's purpose will be to identify theories that provide initial explanations of patient engagement with PHC in SA, how mechanisms of patient engagement are supposed to work, and when they do work (16). Characteristically, realist reviews begin with an initial programme theory (IPT) and ends with a more realist refined programme theory. This theory includes sets of assumptions that explain how the mechanism might achieve outcomes (17)(18).

Initial exploratory searching will be carried out to develop the IPT, which will be formulated as a starting point for this review. This IPT is important as it surfaces explicit assumptions which can then be confirmed, refuted or refined against the data included in the review as it progresses (15). The IPT will be developed based on the following:

- Informal search of academic and grey literature on PHC services in SA using two terms only: 'Primary healthcare' and 'Saudi Arabia'. This informal search is exploratory and differs from the substantive search in step 2 and serves two purposes. First, a variety of documents from this exploratory search will provide data and information about current patient engagement with PHC. Second, the information obtained from the documents will serve as indicators of the aspects that require greater understanding and hence will inform the formal search and stakeholder involvement process. The selection criteria for this initial search will be broad as we seek to explore PHC services in SA;
- Related media items, such as the official Twitter account of the Saudi Ministry of Health (MOH);
- Stakeholders' input, through iterative discussions about their perceptions, knowledge, and experience of MOH primary care services.

1.1. Initial Programme Theory

The IPT's purpose is to specify possible CMOCs, with which the reviewer then seeks a more refined programme theory after multiple realist review cycles (19). Exploring patient engagement with PHC services in SA requires understanding the effect of many contextual factors and the mechanisms at play. For example, the last review indicates that overall PHC satisfaction in SA exceeds 75% (8), while 65% of cases seen in the emergency department of secondary healthcare are classified as 'non-urgent' (5). Thus, part of our IPT suggests the following (figure 2):

- When patients have had positive experiences of PHC service in SA (C), they are more likely to be satisfied with PHC services (O) because they have confidence in the service providers (M);
- When patients believe ED provide a 'better' service than PHC (C) they are more likely to attend ED (O) because they value high quality care (O).

1.2. Stakeholders Involvement

In this review, patients with different healthcare needs, having experience with MOH-PHC services, will be involved as stakeholders. Conversation with these patients will include questions related to their perceptions towards the current PHC services, their perceptions of the quality of PHC services, the reasons behind preferring secondary care, and the factors that influence their engagement with PHC. Open-ended questions will be used to allow stakeholders to contribute as broad and varied knowledge as possible and to make visible any gaps in the existing researchers' approach or assumptions (20). This will result in better insights into the contexts identified for patient engagement that lead to the expected outcomes while understanding the mechanisms behind patient engagement (figure 3). It should be noted that stakeholder involvement will be conducted

only to improve our understanding, establish the review's direction, and refine the ITP – not as primary data for analysis; hence, ethical approval will not be required.

A further substantive exploratory search will be carried out to refine the IPT and develop the review's focus. Frequent discussions within the research team will be considered in order to refine the initial programme theory.

Step 2: Searching for evidence

2.1. Substantive search

A substantive search will be carried out to allow the review to focus on issues emerging as significant (15). This search will be conducted with the help of an expert librarian and will identify the data needed to develop a patient engagement pathway with PHC in SA. The search will then be further focused on identifying the data needed to develop different CMOs in each step of the patient engagement pathway with PHC in SA. The purpose of this search is also to concentrate on the relevant literature that focuses only on the patient perspective and to provide an explanatory backbone for the contextual influences identified from the literature screening in the initial search.

The substantive search will examine five databases: MEDLINE, EMBASE, CINAHL, the Global Health Database, and PsychINFO. Additionally, hand searching and forward citation chasing (using Google Scholar) will identify further relevant studies. We will also manually search citations found in the reference lists of the identified articles that are important for the development of programme theory. Local Saudi journals were also included in the search: the *Saudi Medical Journal, Annals of Saudi Medicine*, and the *Journal of Family and Community Medicine*. All searches will be performed in English and Arabic — the two languages used in SA. Different regions and cities in SA will be included to capture a wider range of studies. A combination of keywords and synonyms for the concepts 'patient engagement' will be used, combined with different PHC terms including 'family medicine', 'community medicine', and 'general practice'. Studies will be included if they discuss the features of patient engagement with the MOH primary care services in SA (any setting of primary care services), regardless of the study design. Grey literature will also be searched, using the same search terms, in Ethos (a UK thesis database) as well as the MOH website.

2.1.1. Screening

The selection criteria for the substantive search will be focused, and the following inclusion and exclusion criteria will be considered:

• Inclusion criteria:

- Qualitative, quantitative, and mixed research designs including observational and experimental studies on PHC services in SA;
- Studies from 2005 to 2019;
- Studies in English or Arabic;
- Studies examining any steps of the patient engagement pathway;
- Adult participants;
- Interventions or resources focused on improving SA's PHC services;
- Outcome measures all studies that discuss patient satisfaction with PHC or non-urgent utilisation of secondary healthcare.

• Exclusion criteria:

- Any studies beyond the scope of the MOH's PHC services assessing private-PHC services sponsored by private companies or non-MOH providers – since the MOH is SA's main healthcare provider;
- Studies conducted before 2005.

The date range of the inclusion criteria was selected for two reasons. First, this review complements the latest systematic review of SA's PHC setting (8) but with a more in-depth understanding of the causal explanations for patient engagement with PHC. Second, the initial search result shows that many changes have occurred in Saudi PHC services that do not apply to the currently provided services. Thus, literature before 2005 would provide an inaccurate explanation of the current rationales for patient engagement with PHC.

All titles and abstracts will be screened by A.A. Articles will be included if they match our selection criteria. A 10% random subsample will be reviewed independently by another reviewer, and any disagreements will be resolved by discussion. A discussion with the whole project team will be considered if disagreements persist.

2.2. Additional searches

Additional searches will be considered whenever more data or explanations are needed in refining the programme theory. The research team will meet, and a selection criterion will be developed with the same previous screening processes.

An area in which we might need further searches is the MOH interventions towards enhancing patient engagement with PHC services, as well as studies that highlight the non-urgent presentations to the emergency departments in SA and the late presentation of serious conditions in secondary healthcare. This further search will be more purposive and might significantly increase the amount of related data to refine our programme theory.

Step 3: Articles selection

Material selection will be mainly focused on the extent to which data might help develop and refine the programme theory. The database search results will be exported to EndNote X8 bibliographic management software. Then, they will be exported to Rayyan QCRI software and de-duplicated using automated and manual review.

All titles and abstracts will be screened by AA and a full-text screening will then be considered if a reference's relevance is indeterminable. AA will read the remaining articles' complete texts. A 10% random subsample will be reviewed independently by another reviewer. Uncertainty will be resolved with research-team discussion.

The data selection will be based on *relevance* to the programme theory's development and the *rigour* in which the methods used to produce the relevant data are reliable and trustworthy (10). Each study's reliability and rigour will also be assessed subjectively; the studies will be included based on relevance and, if the data is sufficiently relevant and reliable, will be used in our interpretations of whether they function as a context, mechanism, or outcome within CMOCs. This screening and appraisal aims at theoretical saturation, in which sufficient evidence is identified to meet a review's aim (9).

Step 4: Data extraction

AA will review the included papers and will extract the data regarding the characteristics of the included papers. Relevant sections of text from within the included document will be categorised from the included articles, and potential contexts, mechanisms, and outcomes will then be manually coded to an Excel spreadsheet (see Step 5 below for more details om the analysis processes). An independent reviewer will review a 10% random subsample of coded papers for reliability. Any disagreements will be resolved by discussion or whole-team discussion if required. A realist explanatory logic of analysis (e.g., how each of the outcomes within the programme theory might be achieved and what interactions between contexts and mechanisms might lead to the outcome) will be applied to each step in the patient engagement pathway.

This analysis will provide sets of CMOCs explaining patient engagement with PHC. The developing CMOCs will be regularly compared with the developing programme theory in order to understand the place and relationships between each CMOC and the programme theory. As the review progresses, the programme theory will be iteratively refined.

The coding will be deductive (informed by the IPT), inductive (informed by the data in the included studies), and retroductive (having made an assumption based on data analysis within documents about underlying causal processes – i.e., mechanisms) (21).

Diagrams will be used to explain the data, especially the relationships between CMOs. The coding will not be limited to the data's results section but will also include analysis and interpretation of data from sections of a paper such as relevant background, study characteristics, discussion, and recommendations.

This analysis will be aimed at a theoretical saturation that provides sufficient information to explain the wide range of patient engagement rationales with SA's PHC services.

Step 5: Synthesising the evidence and drawing conclusions

By consolidating data from the previous steps, a realist logic for data synthesis will be used to refine the programme theory. Throughout the review, the following questions will be used to aid the analysis process:

- 1. Does this part of the text refer to a context, mechanism, or outcome? If so, in which CMOC?
- 2. How does this context, mechanism, and outcome relate to build a CMO configuration, and is this CMOC partial or complete?
- 3. How does this CMOC relate to our patient engagement pathway?
- 4. Do any data support how the CMOC relates to our patient engagement pathway?
- 5. Does our identified patient engagement pathway apply to our CMOC, or must it change?
- 6. Is the evidence sufficiently reliable and rigorous for consideration as a CMOC?

The data analysis and synthesis process will be conducted from the most recent articles. Also, to generate the CMOCs for each step in our patient engagement pathway, we may need to start with the immediate outcome in that step and work backwards.

It should be noted that the data that informs the interpretation of the relationships between CMOCs from one document may also be used to explain CMOCs in a different document. In addition, when sections of text describe the context without exploring the underlying mechanism, mechanisms will

be elucidated from different included documents to compile CMOCs, as not all parts of the configurations are always found in the same document (21).

Throughout our review, the CMOCs will be frequently discussed with the research team to refine the programme theory. As part of a realist analysis and synthesis, the relevance and rigour of the sources will be evaluated frequently for each document.

The data synthesis and findings will be reported in accordance with the RAMESES publication guidelines for quality and reporting (22).

Ethics and dissemination

We will produce relevant and suitable outputs that target a range of audiences. We anticipate that there will be three main audiences interested in the findings and recommendations from our review:

Audience 1: Healthcare providers and medical educators

Audience 2: Policymakers, regulators in MOH and other healthcare institutions

Audience 3: Academics who are interested in the realist approach

Our findings will be published in a peer-reviewed journal and will also be presented at academic conferences. We will provide evidence-based recommendations that can be useful for policymakers to develop strategies for appropriate utilisation and engagement with PHC services in SA. Also, our causal explanations are anticipated to produce review findings that may provide guidance for health providers and medical educators to support patient engagement with PHC.

Discussion

Primary healthcare services form a crucial aspect of a country's healthcare system to provide comprehensive and continuous healthcare. Patients are important appraisers of healthcare services. Until now, we have not had a clear understanding of the rationales that drive patient engagement (or not) in Saudi PHC or how appropriate engagement and utilisation might be achieved. The literature so far has focused only on patient satisfaction with PHC services in SA. This realist review seeks to inform our understanding by looking beyond patient satisfaction to the wider contextual drivers of patient engagement with PHC. This increased understanding of why patients engage (or not) will be used to develop recommendations for improving appropriate engagement with PHC.

Importance of the research

Appropriate engagement and utilisation of PHC is a global health concern not restricted to the Saudi PHC context. In Saudi Arabia, concerns affecting appropriate PHC engagement are mainly due to (1) dissatisfaction with PHC in SA and (2) ED over-utilisation for non-urgent, PHC-treatable conditions. This 'misuse' of healthcare facilities contributes to several negative consequences that lead to a reduction in healthcare quality (23). Patient engagement is a complex process, and little is known about what drives patient engagement with PHC services and how such engagement might be achieved. No previous realist review has been undertaken on this or any related topic in the PHC setting in SA. This realist review will expand our understanding of this topic area by focusing on contextually relevant explanations and will develop outputs to inform future interventions aiming to improve patient engagement with primary care services in SA. We believe our findings have important implications to be considered for healthcare providers and policymakers in SA, especially with the country's vision of 2030 that might also be useful in any PHC system.

Contributors

All authors contributed to the design of this protocol. The study protocol was developed by AA, PA and SP. The manuscript was drafted by AA and was refined by all authors (AA, RA, JB, PA and SP). SP is the principal supervisor for the study protocol. JB and PA provide supervision and have had input to all aspects of the study. RA advised on the design of the protocol. All authors edited the manuscript and read and approved the final version.

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Transparency declaration

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing

No additional data available.

Ethical approval

Not required

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Competing interests

None declared.

All authors have completed the Unified Competing Interest form (available on request from the ponding author,
]; no financial relationships
: in the previous three years, no other recommendate work.

Itient consent for publication
of required.

Provenance and peer review

Not commissioned; externally peer reviewed. corresponding author) and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced

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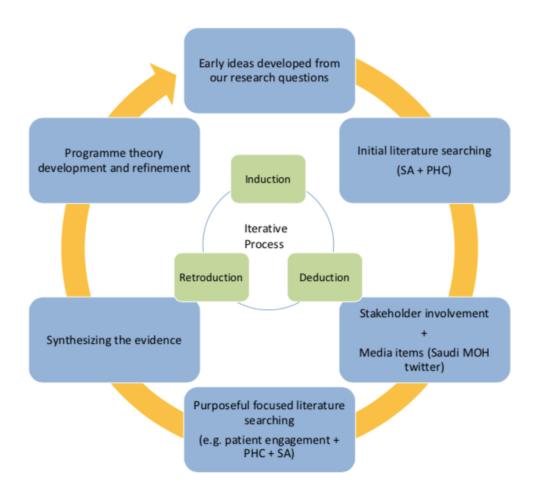


Figure 1: The review's approach to patient engagement with primary healthcare in SA. 168x159mm~(96~x~96~DPI)



Figure 2: An initial programme theory of patient engagement with PHC in SA. 240x73mm~(150~x~150~DPI)

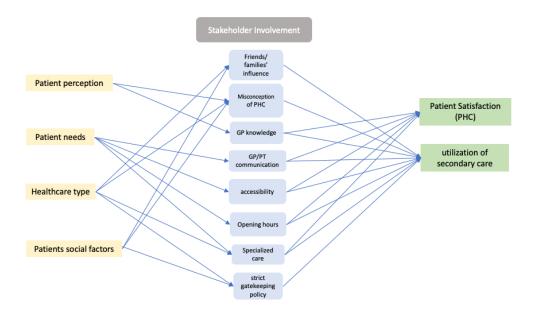


Figure 3: An early refinement of the IPT after stakeholder involvement.

230x135mm (96 x 96 DPI)

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

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			Page
		Reporting Item	Number
Title			
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration			
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors			
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	13,14
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	14,15

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Amendments			
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support			
Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	15
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	15
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	15
Introduction			
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	2,3,4
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
Methods			
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6,7,8,9,10
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6,8,9
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	10,11,12
Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10
Study records - data		Describe planned method of extracting data from reports (such as eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	11,12

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(such as GRADE)

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Causal explanations for patient engagement with primary care services in Saudi Arabia: A realist review protocol

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Causal explanations for patient engagement with primary care services in Saudi Arabia: A realist review protocol

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ABSTRACT

Introduction

Saudi Arabia (SA) has a rapidly developing universal healthcare system which is maturing from its hospital focussed origins. However, health service usage suggests that up to 65% of the cases seen in emergency departments (ED) were classified as non-urgent and could have been appropriately managed in primary healthcare (PHC) settings. Primary care development in SA has lagged behind secondary care, and evidence suggests that Saudi citizens are currently ambivalent or dissatisfied with their PHC services.

Previous research has focused on the quality and patient satisfaction of PHC services in SA. Yet, uncertainty still exists about causal explanations for patient engagement with PHC services and what refinements are needed for PHC. Less attention has been paid to how patient engagement strategies might work differently, which is increasingly recognised as important in PHC services.

The aim of this review is to understand the causal explanations for patient engagement with PHC and to generate theory of how the intended outcome of patient engagement with PHC in SA might be achieved through identified contexts and mechanisms.

Methods and analysis

A realist review approach will be used to synthesise the evidence. Databases including Medline, EMBASE and CINAHL will be searched. Literature will be included if it has relevance to the research question, and is trustworthy in nature. All document types will be screened including peer reviewed articles, relevant grey literature and related media items. All study types will be included. Stakeholders' feedback will also inform our review. A realist approach is suitable for this review because patient engagement with PHC services is a complex phenomenon. A range of different relevant data will be included in the following stages: developing an initial programme theory, searching the evidence, selecting data, extracting data, synthesising data, and refining the programme theory.

Ethics and dissemination

This study will use secondary data, and stakeholders are involved only to shape our understanding of the important contexts in patient engagement; hence, a formal ethics review is not required. Findings will be disseminated in a peer-reviewed journal and at relevant conferences.

PROSPERO registration number

CRD42020175955.

Strengths and limitations of this study

- The first realist review in the Saudi PHC context that will produce a theoretical conceptualisation of patient engagement with PHC services through a rigorous approach;
- Stakeholder input during the programme theory development to ensure that domains important to patients will be understood;
- Inclusion of different study designs, including English and Arabic language data;
- Limited to the PHC services that belong to the Ministry of Health (MOH), which might not sufficiently capture how and why patients choose other PHC services in SA;
- Limited to the patient perspective, which might increase the risk of missing important domains from other perspectives in PHC services, such as the health professional perspective.

Background

Primary health care (PHC) is an integral component of a healthcare system and is vital for long-term healthcare system sustainability. Each country attempts to find its own formula for providing better ways to engage patients with PHC services (1). Patient engagement with PHC has become an increasing area of interest, with the aim of minimising non-urgent secondary care use (2).

SA has a rapidly developing universal healthcare system and is maturing from its hospital-focused origins, with a PHC-based health system that is being prioritised within Saudi government policy. However, in SA, patients are not utilising PHC services as much as they could, and evidence suggests that emergency department (ED) services are frequently utilised for non-urgent, PHC-treatable conditions (3)(4). Proposed reasons for this include a lack of trust, and the patient's perception of poor quality of PHC services in SA (5). In addition, several studies have shown low patient satisfaction with current PHC services in SA including availability, accessibility, and communication (3)(6)(7)(8).

Existing research may indicate a lack of satisfaction and mistrust as reasons for patient disengagement with PHC services. However, these are a few elements of a complex 'mess' determining patient engagement with PHC services, and it remains unclear why SA citizens bypass PHC. For example, while patients reported high satisfaction in the latest review of Saudi PHC services (8), up to 65% of cases seen in secondary emergency hospitals are classified as non-urgent and could have been appropriately managed in PHC setting (5). Thus, uncertainty still surrounds what would constitute appropriate engagement and utilisation of PHC in SA. Less attention has been paid to causal explanations for patient engagement with PHC services, a focus which PHC services

increasingly recognise as important. There is also less understanding of how PHC should be tailored to enhance patient engagement.

This uncertainty calls for a review providing causal explanations for the complexity of patient engagement with PHC services. Therefore, this review will address *how*, *why*, *for whom*, *in what circumstances*, and *to what extent* SA citizens engage with PHC services or not.

Unlike traditional systematic reviews, which focus on producing judgements (e.g., 'Are patients satisfied or not satisfied?'), realist reviews provide explanations and an understanding of phenomena – e.g. answering instead questions such as 'Why are patients satisfied? When?'

Thus, the present review will not only be used to develop and refine a theory but also to understand the causal processes behind the programme theory by identifying and configuring contexts, mechanisms, and outcomes (9).

This review also offers potential relevance for policymakers who need to know not merely whether patients are satisfied but also what sorts of services to resource. In order to explore and understand the causal explanations for patient engagement with Saudi PHC services, as well as the challenges to patient engagement, a realist approach for evidence synthesis will be conducted.

Methods

Review aim, questions and objectives

Aim

This review aims to understand the causal explanations for patient engagement with the PHC services in SA.

Review objectives

- To review empirical research and grey literature exploring the key factors in Saudi patient engagement with PHC services;
- To identify key contexts, mechanisms, and outcomes at each step of our identified patient engagement pathway;
- To engage stakeholders in order to shape the review direction and provide a better understanding of the factors influencing patient engagement with PHC.
- To generate a patient engagement pathway with PHC in SA.

Review research questions

This review will be structured around the following questions:

Primary question:

From the patients' perspective, what are the causal explanations for their engagement (or not)
 with PHC services in SA?

Sub-questions:

- What are the "contexts" that influence whether patients engage with PHC services in SA or not?
- What "mechanisms" trigger patient engagement with PHC services in SA are believed to result in the desired outcomes?
- How the desired outcome "patient engagement" with PHC services in SA will be achieved? And
 What are the associated "outcomes" of patient engagement with PHC services in SA?

Approach

A realist review is a theory-driven interpretive approach to synthesising evidence. This approach will be undertaken because of its ability to move beyond a description of the literature to an explanation of how and why contexts and mechanisms interact and influence outcomes. A realist review can also synthesise a range of relevant data – such as qualitative, quantitative, and mixed-methods research – as well as grey literature. Multiple iterative cycles of realist review allow a further understanding of the causal processes behind the programme theory (9).

Through reviewing published and grey literature, a gradually refined programme theory will be developed using data drawn from the included documents. Within this programme theory, a realist logic of analysis will be used to analyse the data. The analysis-building pillars are context-mechanism-outcome configurations (CMOCs). CMOCs establish a relationship between the key conceptual components of a realist analysis – that is, how mechanisms are triggered under specific contexts to cause intended outcomes (10).

In this review, such contexts (c) are the settings, conditions, and circumstances that trigger causal mechanisms, which in turn cause patient engagement with PHC services. Mechanisms (m) are causal processes triggered in specific contexts that lead to changes or outcomes, while outcomes (o) are the impact resulting from interactions between mechanisms and contexts.

Because the concept of 'patient engagement' means different things in different healthcare systems (11), patient engagement will be clearly defined before starting the review. Previous research has restricted the definition of patient engagement in PHC to consultations between patients and general practitioners (GPs) (12). However, engagement with PHC services is a more complex process that goes beyond GP services. In this review, the term 'patient engagement' will be used to describe all the processes that lead to patient utilisation of PHC services, with greater reflection on the Saudi population's needs.

At the start of the review we will develop an initial programme theory that explains patient engagement with Saudi PHC services. The review process will then use data from included documents to develop CMOCs that are situated within the programme theory by using a realist analysis to synthesise the evidence.

Since patients are the intended beneficiaries of healthcare services, and their input helps concerned authorities rectify systemic weaknesses (13) and is essential in improving healthcare services (14), this review will focus on the patient perspective. This review also aims to complement previous PHC research in SA and identify gaps to build upon existing PHC research in SA from the patient perspective.

Patient and Public Involvement

This protocol has been developed with consideration to the Saudi patients' experiences and needs from PHC services. Patients will be included as stakeholders, as will be described in section 1.2.

Study design

The review will be designed based on Pawson's five iterative steps for a realist review (15):

- 1. Finding existing theories
- 2. Searching for evidence
- 3. Selecting articles
- 4. Extracting data
- 5. Synthesising evidence and drawing conclusions

Since this process will be viewed as iterative, the cycle of these steps will be repeated many times in order to reach theoretical saturation (15). (Please see figure 1 for further explanation of the study approach.)

We anticipate that the review will be conducted for a 14-month period, from September 2021.

Step 1: Finding existing theories

This step's purpose will be to identify theories that provide initial explanations of patient engagement with PHC in SA, how mechanisms of patient engagement are supposed to work, and when they do work (16). Characteristically, realist reviews begin with an initial programme theory (IPT) and ends with a more realist refined programme theory. This theory includes sets of assumptions that explain how the mechanism might produce outcomes (17)(18).

Initial exploratory searching will be carried out to develop the IPT, which will be formulated as a starting point for this review. This IPT is important as it surfaces explicit assumptions which can then be confirmed, refuted or refined against the data included in the review as it progresses (15). The IPT will be developed based on the following:

- Informal search of academic and grey literature on PHC services in SA using two terms only: 'Primary healthcare' and 'Saudi Arabia'. This informal search is exploratory and differs from the main search in step 2 and serves two purposes. First, a variety of documents from this exploratory search will provide data and information about current patient engagement with PHC. Second, the information obtained from the documents will serve as indicators of the aspects that require greater understanding and hence will inform the formal search and stakeholder involvement process. The selection criteria for this initial search will be broad as we seek to explore PHC services in SA;
- Related media items, such as the official Twitter account of the Saudi Ministry of Health (MOH).
 The MOH Twitter account is the main media platform used in SA to share patients' views.
 Therefore, we would expect to see certain types of relevant grey literature published here;
- Stakeholders' input, through iterative discussions about their perceptions, knowledge, and experience of MOH primary care services.

1.1. Initial Programme Theory

The IPT's purpose is to specify possible CMOCs, with which the reviewer then seeks a more refined programme theory after multiple realist review cycles (19). Exploring patient engagement with PHC services in SA requires understanding the effect of many contextual factors and the mechanisms at play. For example, the last review indicates that overall PHC satisfaction in SA exceeds 75% (8), while 65% of cases seen in the emergency department of secondary healthcare are classified as 'non-urgent' (5). Thus, part of our IPT suggests the following (figure 2):

- When patients have had positive experiences of PHC service in SA (C), they are more likely to be satisfied with PHC services (O) because they have confidence in the service providers (M);
- When patients believe ED provide a 'better' service than PHC (C) they are more likely to attend ED (O) because they value high quality care (M).

1.2. Stakeholders Involvement

In this review, 13 Saudi patients with different healthcare needs, having experience with MOH-PHC services, will be involved as stakeholders. Conversation with these patients will include questions related to their perceptions towards the current PHC services, their perceptions of the quality of PHC services, the reasons behind preferring secondary care, and the factors that influence their engagement with PHC. Open-ended questions will be used to allow stakeholders to contribute as broad and varied knowledge as possible and to make visible any gaps in the existing researchers' approach or assumptions (20). This will result in better insights into the contexts identified for patient engagement that lead to the expected outcomes while understanding the mechanisms behind patient engagement (figure 3). It should be noted that stakeholder involvement will be conducted only to improve our understanding, establish the review's direction, and refine the ITP – not as primary data for analysis. Conversations will not be recorded or extensively analysed with our stakeholders; hence, ethical approval will not be required.

Frequent discussions within the research team will be considered in order to refine the initial programme theory. Then, a main exploratory search will be carried out to refine the IPT and develop the review's focus.

Step 2: Searching for evidence

2.1. Primary search

A main search will be carried out to allow the review to focus on issues emerging as significant (15). This search will be conducted with the help of an expert librarian and will identify the data needed to develop a patient engagement pathway with PHC in SA. The search will then be further focused on identifying the data needed to develop different CMOs in each step of the patient engagement pathway with PHC in SA. The purpose of this search is also to concentrate on the relevant literature that focuses only on the patient perspective and to provide an explanatory backbone for the contextual influences identified from the literature screening in the initial search.

The main search will examine five databases: MEDLINE, EMBASE, CINAHL, the Global Health Database, and PsycINFO. Additionally, hand searching and forward citation chasing (using Google Scholar) will identify further relevant studies. We will also manually search citations found in the reference lists of the identified articles that are important for the development of programme theory. Local Saudi journals were also included in the search: the *Saudi Medical Journal, Annals of Saudi Medicine*, and the *Journal of Family and Community Medicine*. All searches will be performed in English and Arabic — the two languages used in SA. Different regions and cities in SA will be included to capture a wider range of studies. A combination of keywords and synonyms for the concepts 'patient engagement' will be used, combined with different PHC terms including 'family medicine', 'community medicine', and 'general practice'. Studies will be included if they discuss the features of patient engagement with the MOH primary care services in SA (any setting of primary care services), regardless of the study design. Grey literature will also be searched, using the same search terms, in Ethos (a UK thesis database) as well as the MOH website. We will extract document characteristics including authors, dates, country, study aims, key findings, methods used and sample details. These will be extracted into an excel document and will only be done for selected articles.

2.1.1. Screening

The selection criteria for the main search will be focused, and the following inclusion and exclusion criteria will be considered:

- Inclusion criteria:
 - Qualitative, quantitative, and mixed research designs including patient experience, patient satisfaction, observational and experimental studies on PHC services in SA;
 - Studies from 2005 to 2019;
 - Studies in English or Arabic;
 - Studies examining any steps of the patient engagement pathway;
 - Adult participants;
 - Interventions or resources focused on improving SA's PHC services;
 - Outcome measures all studies that discuss patient satisfaction with PHC or non-urgent utilisation of secondary healthcare.
- Exclusion criteria:
 - Any studies beyond the scope of the MOH's PHC services assessing private-PHC services sponsored by private companies or non-MOH providers – since the MOH is SA's main healthcare provider;

Studies conducted before 2005.

The date range of the inclusion criteria was selected for two reasons. First, this review complements the latest systematic review of SA's PHC setting (8) but with a more in-depth understanding of the causal explanations for patient engagement with PHC. Second, the initial search result shows that many changes have occurred in Saudi PHC services that do not apply to the currently provided services. Thus, literature before 2005 would provide an inaccurate explanation of the current rationales for patient engagement with PHC.

2.2. Additional searches

Additional searches will be considered whenever more data or explanations are needed in refining the programme theory. The research team will meet, and a selection criterion will be developed with the same previous screening processes.

An area in which we might need further searches is the MOH interventions towards enhancing patient engagement with PHC services, as well as studies that highlight the non-urgent presentations to the emergency departments in SA and the late presentation of serious conditions in secondary healthcare. This further search will be more purposive and might significantly increase the amount of related data to refine our programme theory.

Step 3: Articles selection

Material selection will be mainly focused on the extent to which data might help develop and refine the programme theory. The database search results will be exported to EndNote X8 bibliographic management software. Then, they will be exported to Rayyan QCRI software and de-duplicated using automated and manual review.

All titles and abstracts will be screened by AA and a full-text screening will then be considered if a reference's relevance is indeterminable. AA will read the remaining articles' complete texts. A 10% random subsample will be reviewed independently by another reviewer. Uncertainty will be resolved with research-team discussion.

The data selection will be based on *relevance* to the programme theory's development and the *rigour* in which the methods used to produce the relevant data are reliable and trustworthy (10). Each study's reliability and rigour will also be assessed subjectively; the studies will be included based on relevance and, if the data is sufficiently relevant and reliable, will be used in our

interpretations of whether they function as a context, mechanism, or outcome within CMOCs. This screening and appraisal aims at theoretical saturation, in which sufficient evidence is identified to meet a review's aim (9).

Step 4: Data extraction

AA will review the included papers and will extract the data regarding the characteristics of the included papers. Relevant sections of text from within the included document will be categorised from the included articles, and potential contexts, mechanisms, and outcomes will then be manually coded to an Excel spreadsheet (see Step 5 below for more details on the analysis processes). An independent reviewer will review a 10% random subsample of coded papers for reliability. Any disagreements will be resolved by discussion or whole-team discussion if required. A realist explanatory logic of analysis (e.g., how each of the outcomes within the programme theory might be achieved and what interactions between contexts and mechanisms might lead to the outcome) will be applied to each step in the patient engagement pathway.

This analysis will provide sets of CMOCs explaining patient engagement with PHC. The developing CMOCs will be regularly compared with the developing programme theory in order to understand the place and relationships between each CMOC and the programme theory. As the review progresses, the programme theory will be iteratively refined.

The coding will be deductive (informed by the IPT), inductive (informed by the data in the included studies), and retroductive (having made an assumption based on data analysis within documents about underlying causal processes – i.e., mechanisms) (21).

Diagrams will be used to explain the data, especially the relationships between CMOs. The coding will not be limited to the data's results section but will also include analysis and interpretation of data from sections of a paper such as relevant background, study characteristics, discussion, and recommendations.

This analysis will be aimed at a theoretical saturation that provides sufficient information to explain the wide range of patient engagement rationales with SA's PHC services. This will be undertaken until no new information is provided by the evidence (15).

Step 5: Synthesising the evidence and drawing conclusions

By consolidating data from the previous steps, a realist logic for data synthesis will be used to refine the programme theory. Throughout the review, the following questions will be used to aid the analysis process:

- 1. Does this part of the text refer to a context, mechanism, or outcome? If so, in which CMOC?
- 2. How does this context, mechanism, and outcome relate to build a CMO configuration, and is this CMOC partial or complete?
- 3. How does this CMOC relate to our patient engagement pathway?
- 4. Do any data support how the CMOC relates to our patient engagement pathway?
- 5. Does our identified patient engagement pathway apply to our CMOC, or must it change?
- 6. Is the evidence sufficiently reliable and rigorous for consideration as a CMOC?

The data analysis and synthesis process will be conducted from the most recent articles. Also, to generate the CMOCs for each step in our patient engagement pathway, we may need to start with the immediate outcome in that step and work backwards.

It should be noted that the data that informs the interpretation of the relationships between CMOCs from one document may also be used to explain CMOCs in a different document. In addition, when sections of text describe the context without exploring the underlying mechanism, mechanisms will be elucidated from different included documents to compile CMOCs, as not all parts of the configurations are always found in the same document (21).

Throughout our review, the CMOCs will be frequently discussed with the research team to refine the programme theory. As part of a realist analysis and synthesis, the relevance and rigour of the sources will be evaluated frequently for each document.

The data synthesis and findings will be reported in accordance with the RAMESES publication guidelines for quality and reporting (22).

Ethics and dissemination

We will produce relevant and suitable outputs that target a range of audiences. We anticipate that there will be three main audiences interested in the findings and recommendations from our review:

Audience 1: Healthcare providers and medical educators

Audience 2: Policymakers, regulators in MOH and other healthcare institutions

Audience 3: Academics who are interested in the realist approach

Our findings will be published in a peer-reviewed journal and will also be presented at academic conferences. We will provide evidence-based recommendations that can be useful for policymakers to develop strategies for appropriate utilisation and engagement with PHC services in SA. Also, our causal explanations are anticipated to produce review findings that may provide guidance for health providers and medical educators to support patient engagement with PHC.

Discussion

Primary healthcare services form a crucial aspect of a country's healthcare system to provide comprehensive and continuous healthcare. Patients are important appraisers of healthcare services. Until now, we have not had a clear understanding of the rationales that drive patient engagement (or not) in Saudi PHC or how appropriate engagement and utilisation might be achieved. The literature so far has focused only on patient satisfaction with PHC services in SA. This realist review seeks to inform our understanding by looking beyond patient satisfaction to the wider contextual drivers of patient engagement with PHC. This increased understanding of why patients engage (or not) will be used to develop recommendations for improving appropriate engagement with PHC.

Importance of the research

Appropriate engagement and utilisation of PHC is a global health concern not restricted to the Saudi PHC context. In Saudi Arabia, concerns affecting appropriate PHC engagement are mainly due to (1) dissatisfaction with PHC in SA and (2) ED over-utilisation for non-urgent, PHC-treatable conditions. This 'misuse' of healthcare facilities contributes to several negative consequences that lead to a reduction in healthcare quality (23). Patient engagement is a complex process, and little is known about what drives patient engagement with PHC services and how such engagement might be achieved. No previous realist review has been undertaken on this or any related topic in the PHC setting in SA. This realist review will expand our understanding of this topic area by focusing on contextually relevant explanations and will develop outputs to inform future interventions aiming to improve patient engagement with primary care services in SA. We believe our findings have important implications to be considered for healthcare providers and policymakers in SA, especially with the country's vision of 2030 that might also be useful in any PHC system.

Contributors

All authors contributed to the design of this protocol. The study protocol was developed by AA, PA and SP. The manuscript was drafted by AA and was refined by all authors (AA, RA, JB, PA and SP). SP is the principal supervisor for the study protocol. JB and PA provide supervision and have had input to all aspects of the study. RA advised on the design of the protocol. All authors edited the manuscript and read and approved the final version.

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Transparency declaration

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing

No additional data available.

Ethical approval

Not required

Funding

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Award/grant number: Not applicable

Competing interests

None declared.

All authors have completed the <u>Unified Competing Interest form</u> (available on request from the corresponding author) and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Figure 1: The review's approach to patient engagement with primary healthcare in SA.

Figure 2: An initial programme theory of patient engagement with PHC in SA.

Figure 3: An early refinement of the IPT after stakeholder involvement

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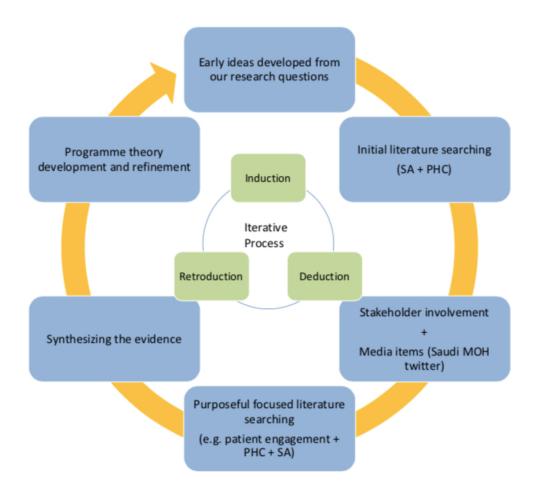


Figure 1: The review's approach to patient engagement with primary healthcare in SA. 168x159mm~(96~x~96~DPI)



Figure 2: An initial programme theory of patient engagement with PHC in SA. 240x73mm~(150~x~150~DPI)

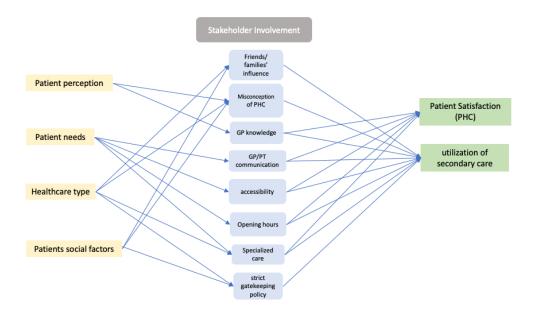


Figure 3: An early refinement of the IPT after stakeholder involvement.

230x135mm (96 x 96 DPI)

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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			Page
		Reporting Item	Number
Title			
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration			
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors			
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	13,14
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	14,15

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Amendments			
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support			
Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	15
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	15
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	15
Introduction			
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	2,3,4
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
Methods			
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6,7,8,9,10
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6,8,9
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	10,11,12
Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10
Study records - data		Describe planned method of extracting data from reports (such as eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	11,12

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(such as GRADE)

BMJ Open

Causal explanations for patient engagement with primary care services in Saudi Arabia: A realist review protocol

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Causal explanations for patient engagement with primary care services in Saudi Arabia: A realist review protocol

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ABSTRACT

Introduction

Saudi Arabia (SA) has a rapidly developing universal healthcare system which is maturing from its hospital focussed origins. However, health service usage suggests that up to 65% of the cases seen in emergency departments (ED) were classified as non-urgent and could have been appropriately managed in primary healthcare (PHC) settings. Primary care development in SA has lagged behind secondary care, and evidence suggests that Saudi citizens are currently ambivalent or dissatisfied with their PHC services.

Previous research has focused on the quality and patient satisfaction of PHC services in SA. Yet, uncertainty still exists about causal explanations for patient engagement with PHC services and what refinements are needed for PHC. Less attention has been paid to how patient engagement strategies might work differently, which is increasingly recognised as important in PHC services.

The aim of this review is to understand the causal explanations for patient engagement with PHC and to generate theory of how the intended outcome of patient engagement with PHC in SA might be achieved through identified contexts and mechanisms.

Methods and analysis

A realist review approach will be used to synthesise the evidence. Databases including Medline, EMBASE and CINAHL will be searched. Literature will be included if it has relevance to the research question, and is trustworthy in nature. All document types will be screened including peer reviewed articles, relevant grey literature and related media items. All study types will be included. Stakeholders' feedback will also inform our review. A realist approach is suitable for this review because patient engagement with PHC services is a complex phenomenon. A range of different relevant data will be included in the following stages: developing an initial programme theory, searching the evidence, selecting data, extracting data, synthesising data, and refining the programme theory.

Ethics and dissemination

This study will use secondary data, and stakeholders are involved only to shape our understanding of the important contexts in patient engagement; hence, a formal ethics review is not required. Findings will be disseminated in a peer-reviewed journal and at relevant conferences.

PROSPERO registration number

CRD42020175955.

Strengths and limitations of this study

- Stakeholder input during the programme theory development to ensure that domains important to patients will be understood;
- Inclusion of different study designs, including English and Arabic language data;
- Limited to the PHC services that belong to the Ministry of Health (MOH), which might not sufficiently capture how and why patients choose other PHC services in SA;
- Limited to the patient perspective, which might increase the risk of missing important domains from other perspectives in PHC services, such as the health professional perspective.

Background

Primary health care (PHC) is an integral component of a healthcare system and is vital for long-term healthcare system sustainability. Each country attempts to find its own formula for providing better ways to engage patients with PHC services (1). Patient engagement with PHC has become an increasing area of interest, with the aim of minimising non-urgent secondary care use (2).

SA has a rapidly developing universal healthcare system and is maturing from its hospital-focused origins, with a PHC-based health system that is being prioritised within Saudi government policy. However, in SA, patients are not utilising PHC services as much as they could, and evidence suggests that emergency department (ED) services are frequently utilised for non-urgent, PHC-treatable conditions (3)(4). Proposed reasons for this include a lack of trust, and the patient's perception of poor quality of PHC services in SA (5). In addition, several studies have shown low patient satisfaction with current PHC services in SA including availability, accessibility, and communication (3)(6)(7)(8).

Existing research may indicate a lack of satisfaction and mistrust as reasons for patient disengagement with PHC services. However, these are a few elements of a complex 'mess' determining patient engagement with PHC services, and it remains unclear why SA citizens bypass PHC. For example, while patients reported high satisfaction in the latest review of Saudi PHC services (8), up to 65% of cases seen in secondary emergency hospitals are classified as non-urgent and could have been appropriately managed in PHC setting (5). Thus, uncertainty still surrounds what would constitute appropriate engagement and utilisation of PHC in SA. Less attention has been paid to causal explanations for patient engagement with PHC services, a focus which PHC services increasingly recognise as important. There is also less understanding of how PHC should be tailored to enhance patient engagement.

This uncertainty calls for a review providing causal explanations for the complexity of patient engagement with PHC services. Therefore, this review will address *how*, *why*, *for whom*, *in what circumstances*, and *to what extent* SA citizens engage with PHC services or not.

Unlike traditional systematic reviews, which focus on producing judgements (e.g., 'Are patients satisfied or not satisfied?'), realist reviews provide explanations and an understanding of phenomena – e.g. answering instead questions such as 'Why are patients satisfied? When?'

Thus, the present review will not only be used to develop and refine a theory but also to understand the causal processes behind the programme theory by identifying and configuring contexts, mechanisms, and outcomes (9).

This review also offers potential relevance for policymakers who need to know not merely whether patients are satisfied but also what sorts of services to resource. In order to explore and understand the causal explanations for patient engagement with Saudi PHC services, as well as the challenges to patient engagement, a realist approach for evidence synthesis will be conducted.

Methods

Review aim, questions and objectives

Aim

This review aims to understand the causal explanations for patient engagement with the PHC services in SA.

Review objectives

- To review empirical research and grey literature exploring the key factors in Saudi patient engagement with PHC services;
- To identify key contexts, mechanisms, and outcomes at each step of our identified patient engagement pathway;
- To engage stakeholders in order to shape the review direction and provide a better understanding of the factors influencing patient engagement with PHC.
- To generate a patient engagement pathway with PHC in SA.

Review research questions

This review will be structured around the following questions:

Primary question:

From the patients' perspective, what are the causal explanations for their engagement (or not)
 with PHC services in SA?

Sub-questions:

- What are the "contexts" that influence whether patients engage with PHC services in SA or not?
- What "mechanisms" trigger patient engagement with PHC services in SA are believed to result in the desired outcomes?
- How the desired outcome "patient engagement" with PHC services in SA will be achieved? And
 What are the associated "outcomes" of patient engagement with PHC services in SA?

Approach

A realist review is a theory-driven interpretive approach to synthesising evidence. This approach will be undertaken because of its ability to move beyond a description of the literature to an explanation of how and why contexts and mechanisms interact and influence outcomes. A realist review can also synthesise a range of relevant data – such as qualitative, quantitative, and mixed-methods research – as well as grey literature. Multiple iterative cycles of realist review allow a further understanding of the causal processes behind the programme theory (9).

Through reviewing published and grey literature, a gradually refined programme theory will be developed using data drawn from the included documents. Within this programme theory, a realist logic of analysis will be used to analyse the data. The analysis-building pillars are context-mechanism-outcome configurations (CMOCs). CMOCs establish a relationship between the key conceptual components of a realist analysis – that is, how mechanisms are triggered under specific contexts to cause intended outcomes (10).

In this review, such contexts (c) are the settings, conditions, and circumstances that trigger causal mechanisms, which in turn cause patient engagement with PHC services. Mechanisms (m) are causal processes triggered in specific contexts that lead to changes or outcomes, while outcomes (o) are the impact resulting from interactions between mechanisms and contexts.

Because the concept of 'patient engagement' means different things in different healthcare systems (11), patient engagement will be clearly defined before starting the review. Previous research has restricted the definition of patient engagement in PHC to consultations between patients and

general practitioners (GPs) (12). However, engagement with PHC services is a more complex process that goes beyond GP services. In this review, the term 'patient engagement' will be used to describe all the processes that lead to patient utilisation of PHC services, with greater reflection on the Saudi population's needs.

At the start of the review we will develop an initial programme theory that explains patient engagement with Saudi PHC services. The review process will then use data from included documents to develop CMOCs that are situated within the programme theory by using a realist analysis to synthesise the evidence.

Since patients are the intended beneficiaries of healthcare services, and their input helps concerned authorities rectify systemic weaknesses (13) and is essential in improving healthcare services (14), this review will focus on the patient perspective. This review also aims to complement previous PHC research in SA and identify gaps to build upon existing PHC research in SA from the patient perspective.

Patient and Public Involvement

This protocol has been developed with consideration to the Saudi patients' experiences and needs from PHC services. Patients will be included as stakeholders, as will be described in section 1.2.

Study design

The review will be designed based on Pawson's five iterative steps for a realist review (15):

- 1. Finding existing theories
- 2. Searching for evidence
- 3. Selecting articles
- 4. Extracting data
- 5. Synthesising evidence and drawing conclusions

Since this process will be viewed as iterative, the cycle of these steps will be repeated many times in order to reach theoretical saturation (15). (Please see figure 1 for further explanation of the study approach.)

We anticipate that the review will be conducted for a 14-month period, from September 2021.

Step 1: Finding existing theories

This step's purpose will be to identify theories that provide initial explanations of patient engagement with PHC in SA, how mechanisms of patient engagement are supposed to work, and

when they do work (16). Characteristically, realist reviews begin with an initial programme theory (IPT) and ends with a more realist refined programme theory. This theory includes sets of assumptions that explain how the mechanism might produce outcomes (17)(18).

Initial exploratory searching will be carried out to develop the IPT, which will be formulated as a starting point for this review. This IPT is important as it surfaces explicit assumptions which can then be confirmed, refuted or refined against the data included in the review as it progresses (15). The IPT will be developed based on the following:

- Informal search of academic and grey literature on PHC services in SA using two terms only: 'Primary healthcare' and 'Saudi Arabia'. This informal search is exploratory and differs from the main search in step 2 and serves two purposes. First, a variety of documents from this exploratory search will provide data and information about current patient engagement with PHC. Second, the information obtained from the documents will serve as indicators of the aspects that require greater understanding and hence will inform the formal search and stakeholder involvement process. The selection criteria for this initial search will be broad as we seek to explore PHC services in SA;
- Related media items, such as the official Twitter account of the Saudi Ministry of Health (MOH).
 The MOH Twitter account is the main media platform used in SA to share patients' views.
 Therefore, we would expect to see certain types of relevant grey literature published here;
- Stakeholders' input, through iterative discussions about their perceptions, knowledge, and experience of MOH primary care services.

1.1. Initial Programme Theory

The IPT's purpose is to specify possible CMOCs, with which the reviewer then seeks a more refined programme theory after multiple realist review cycles (19). Exploring patient engagement with PHC services in SA requires understanding the effect of many contextual factors and the mechanisms at play. For example, the last review indicates that overall PHC satisfaction in SA exceeds 75% (8), while 65% of cases seen in the emergency department of secondary healthcare are classified as 'non-urgent' (5). Thus, part of our IPT suggests the following (figure 2):

- When patients have had positive experiences of PHC service in SA (C), they are more likely to be satisfied with PHC services (O) because they have confidence in the service providers (M);
- When patients believe ED provide a 'better' service than PHC (C) they are more likely to attend ED (O) because they value high quality care (M).

1.2. Stakeholders Involvement

In this review, 13 Saudi patients with different healthcare needs, having experience with MOH-PHC services, will be involved as stakeholders. Conversation with these patients will include questions related to their perceptions towards the current PHC services, their perceptions of the quality of PHC services, the reasons behind preferring secondary care, and the factors that influence their engagement with PHC. Open-ended questions will be used to allow stakeholders to contribute as broad and varied knowledge as possible and to make visible any gaps in the existing researchers' approach or assumptions (20). This will result in better insights into the contexts identified for patient engagement that lead to the expected outcomes while understanding the mechanisms behind patient engagement (figure 3). It should be noted that stakeholder involvement will be conducted only to improve our understanding, establish the review's direction, and refine the ITP – not as primary data for analysis. Conversations will not be recorded or extensively analysed with our stakeholders; hence, ethical approval will not be required.

Frequent discussions within the research team will be considered in order to refine the initial programme theory. Then, a main exploratory search will be carried out to refine the IPT and develop the review's focus.

Step 2: Searching for evidence

2.1. Primary search

A main search will be carried out to allow the review to focus on issues emerging as significant (15). This search will be conducted with the help of an expert librarian and will identify the data needed to develop a patient engagement pathway with PHC in SA. The search will then be further focused on identifying the data needed to develop different CMOs in each step of the patient engagement pathway with PHC in SA. The purpose of this search is also to concentrate on the relevant literature that focuses only on the patient perspective and to provide an explanatory backbone for the contextual influences identified from the literature screening in the initial search.

The main search will examine five databases: MEDLINE, EMBASE, CINAHL, the Global Health Database, and PsycINFO. Additionally, hand searching and forward citation chasing (using Google Scholar) will identify further relevant studies. We will also manually search citations found in the reference lists of the identified articles that are important for the development of programme theory. Local Saudi journals were also included in the search: the *Saudi Medical Journal*, *Annals of Saudi Medicine*, and the *Journal of Family and Community Medicine*. All searches will be performed

in English and Arabic — the two languages used in SA. Different regions and cities in SA will be included to capture a wider range of studies. A combination of keywords and synonyms for the concepts 'patient engagement' will be used, combined with different PHC terms including 'family medicine', 'community medicine', and 'general practice'. Studies will be included if they discuss the features of patient engagement with the MOH primary care services in SA (any setting of primary care services), regardless of the study design. Grey literature will also be searched, using the same search terms, in Ethos (a UK thesis database) as well as the MOH website. We will extract document characteristics including authors, dates, country, study aims, key findings, methods used and sample details. These will be extracted into an excel document and will only be done for selected articles.

2.1.1. Screening

The selection criteria for the main search will be focused, and the following inclusion and exclusion criteria will be considered:

- Inclusion criteria:
 - Qualitative, quantitative, and mixed research designs including patient experience, patient satisfaction, observational and experimental studies on PHC services in SA;
 - Studies from 2005 to 2019;
 - Studies in English or Arabic;
 - Studies examining any steps of the patient engagement pathway;
 - Adult participants;
 - Interventions or resources focused on improving SA's PHC services;
 - Outcome measures all studies that discuss patient satisfaction with PHC or non-urgent utilisation of secondary healthcare.
- Exclusion criteria:
 - Any studies beyond the scope of the MOH's PHC services assessing private-PHC services sponsored by private companies or non-MOH providers – since the MOH is SA's main healthcare provider;
 - Studies conducted before 2005.

The date range of the inclusion criteria was selected for two reasons. First, this review complements the latest systematic review of SA's PHC setting (8) but with a more in-depth understanding of the causal explanations for patient engagement with PHC. Second, the initial search result shows that many changes have occurred in Saudi PHC services that do not apply to the currently provided

services. Thus, literature before 2005 would provide an inaccurate explanation of the current rationales for patient engagement with PHC.

2.2. Additional searches

Additional searches will be considered whenever more data or explanations are needed in refining the programme theory. The research team will meet, and a selection criterion will be developed with the same previous screening processes.

An area in which we might need further searches is the MOH interventions towards enhancing patient engagement with PHC services, as well as studies that highlight the non-urgent presentations to the emergency departments in SA and the late presentation of serious conditions in secondary healthcare. This further search will be more purposive and might significantly increase the amount of related data to refine our programme theory.

Step 3: Articles selection

Material selection will be mainly focused on the extent to which data might help develop and refine the programme theory. The database search results will be exported to EndNote X8 bibliographic management software. Then, they will be exported to Rayyan QCRI software and de-duplicated using automated and manual review.

All titles and abstracts will be screened by AA and a full-text screening will then be considered if a reference's relevance is indeterminable. AA will read the remaining articles' complete texts. A 10% random subsample will be reviewed independently by another reviewer. Uncertainty will be resolved with research-team discussion.

The data selection will be based on *relevance* to the programme theory's development and the *rigour* in which the methods used to produce the relevant data are reliable and trustworthy (10). Each study's reliability and rigour will also be assessed subjectively; the studies will be included based on relevance and, if the data is sufficiently relevant and reliable, will be used in our interpretations of whether they function as a context, mechanism, or outcome within CMOCs. This screening and appraisal aims at theoretical saturation, in which sufficient evidence is identified to meet a review's aim (9).

Step 4: Data extraction

AA will review the included papers and will extract the data regarding the characteristics of the included papers. Relevant sections of text from within the included document will be categorised from the included articles, and potential contexts, mechanisms, and outcomes will then be manually coded to an Excel spreadsheet (see Step 5 below for more details on the analysis processes). An independent reviewer will review a 10% random subsample of coded papers for reliability. Any disagreements will be resolved by discussion or whole-team discussion if required. A realist explanatory logic of analysis (e.g., how each of the outcomes within the programme theory might be achieved and what interactions between contexts and mechanisms might lead to the outcome) will be applied to each step in the patient engagement pathway.

This analysis will provide sets of CMOCs explaining patient engagement with PHC. The developing CMOCs will be regularly compared with the developing programme theory in order to understand the place and relationships between each CMOC and the programme theory. As the review progresses, the programme theory will be iteratively refined.

The coding will be deductive (informed by the IPT), inductive (informed by the data in the included studies), and retroductive (having made an assumption based on data analysis within documents about underlying causal processes – i.e., mechanisms) (21).

Diagrams will be used to explain the data, especially the relationships between CMOs. The coding will not be limited to the data's results section but will also include analysis and interpretation of data from sections of a paper such as relevant background, study characteristics, discussion, and recommendations.

This analysis will be aimed at a theoretical saturation that provides sufficient information to explain the wide range of patient engagement rationales with SA's PHC services. This will be undertaken until no new information is provided by the evidence (15).

Step 5: Synthesising the evidence and drawing conclusions

By consolidating data from the previous steps, a realist logic for data synthesis will be used to refine the programme theory. Throughout the review, the following questions will be used to aid the analysis process:

1. Does this part of the text refer to a context, mechanism, or outcome? If so, in which CMOC?

- 2. How does this context, mechanism, and outcome relate to build a CMO configuration, and is this CMOC partial or complete?
- 3. How does this CMOC relate to our patient engagement pathway?
- 4. Do any data support how the CMOC relates to our patient engagement pathway?
- 5. Does our identified patient engagement pathway apply to our CMOC, or must it change?
- 6. Is the evidence sufficiently reliable and rigorous for consideration as a CMOC?

The data analysis and synthesis process will be conducted from the most recent articles. Also, to generate the CMOCs for each step in our patient engagement pathway, we may need to start with the immediate outcome in that step and work backwards.

It should be noted that the data that informs the interpretation of the relationships between CMOCs from one document may also be used to explain CMOCs in a different document. In addition, when sections of text describe the context without exploring the underlying mechanism, mechanisms will be elucidated from different included documents to compile CMOCs, as not all parts of the configurations are always found in the same document (21).

Throughout our review, the CMOCs will be frequently discussed with the research team to refine the programme theory. As part of a realist analysis and synthesis, the relevance and rigour of the sources will be evaluated frequently for each document.

The data synthesis and findings will be reported in accordance with the RAMESES publication guidelines for quality and reporting (22).

Ethics and dissemination

We will produce relevant and suitable outputs that target a range of audiences. We anticipate that there will be three main audiences interested in the findings and recommendations from our review:

Audience 1: Healthcare providers and medical educators

Audience 2: Policymakers, regulators in MOH and other healthcare institutions

Audience 3: Academics who are interested in the realist approach

Our findings will be published in a peer-reviewed journal and will also be presented at academic conferences. We will provide evidence-based recommendations that can be useful for policymakers to develop strategies for appropriate utilisation and engagement with PHC services in SA. Also, our causal explanations are anticipated to produce review findings that may provide guidance for health providers and medical educators to support patient engagement with PHC.

As explained in section 1.2., ethics approval is not required.

Discussion

Primary healthcare services form a crucial aspect of a country's healthcare system to provide comprehensive and continuous healthcare. Patients are important appraisers of healthcare services. Until now, we have not had a clear understanding of the rationales that drive patient engagement (or not) in Saudi PHC or how appropriate engagement and utilisation might be achieved. The literature so far has focused only on patient satisfaction with PHC services in SA. This realist review seeks to inform our understanding by looking beyond patient satisfaction to the wider contextual drivers of patient engagement with PHC. This increased understanding of why patients engage (or not) will be used to develop recommendations for improving appropriate engagement with PHC.

Importance of the research

This is the first realist review in the Saudi PHC context that will produce a theoretical conceptualisation of patient engagement with PHC services through a rigorous approach.

Appropriate engagement and utilisation of PHC is a global health concern not restricted to the Saudi PHC context. In Saudi Arabia, concerns affecting appropriate PHC engagement are mainly due to (1) dissatisfaction with PHC in SA and (2) ED over-utilisation for non-urgent, PHC-treatable conditions.

This 'misuse' of healthcare facilities contributes to several negative consequences that lead to a reduction in healthcare quality (23). Patient engagement is a complex process, and little is known about what drives patient engagement with PHC services and how such engagement might be achieved. No previous realist review has been undertaken on this or any related topic in the PHC setting in SA. This realist review will expand our understanding of this topic area by focusing on contextually relevant explanations and will develop outputs to inform future interventions aiming to improve patient engagement with primary care services in SA. We believe our findings have important implications to be considered for healthcare providers and policymakers in SA, especially with the country's vision of 2030 that might also be useful in any PHC system.

Contributors

All authors contributed to the design of this protocol. The study protocol was developed by AA, PA and SP. The manuscript was drafted by AA and was refined by all authors (AA, RA, JB, PA and SP). SP is the principal supervisor for the study protocol. JB and PA provide supervision and have had input to all aspects of the study. RA advised on the design of the protocol. All authors edited the manuscript and read and approved the final version.

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Transparency declaration

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing

No additional data available.

Ethical approval

Not required

Funding

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Award/grant number: Not applicable

Competing interests

None declared.

All authors have completed the <u>Unified Competing Interest form</u> (available on request from the corresponding author) and declare: no support from any organisation for the submitted work [or describe if any]; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

- Figure 1: The review's approach to patient engagement with primary healthcare in SA.
- Figure 2: An initial programme theory of patient engagement with PHC in SA.
- Figure 3: An early refinement of the IPT after stakeholder involvement

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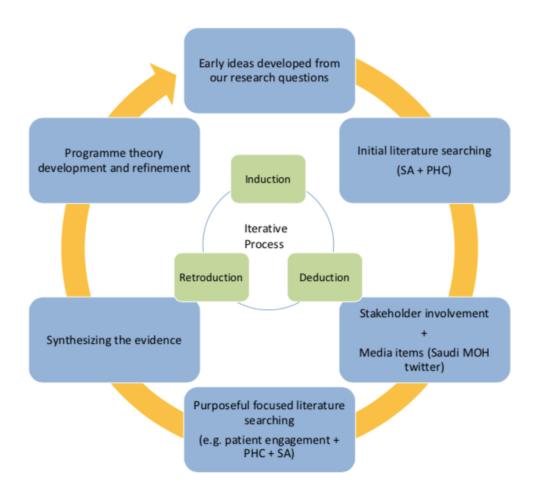


Figure 1: The review's approach to patient engagement with primary healthcare in SA. 168x159mm~(96~x~96~DPI)



Figure 2: An initial programme theory of patient engagement with PHC in SA. 240x73mm~(150~x~150~DPI)

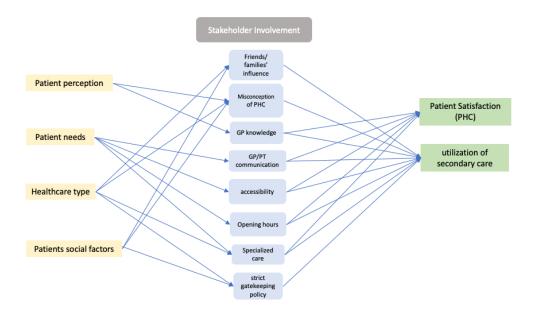


Figure 3: An early refinement of the IPT after stakeholder involvement.

230x135mm (96 x 96 DPI)

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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			Page
		Reporting Item	Number
Title			
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration			
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors			
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	13,14
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	14,15

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Amendments			
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support			
Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	15
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	15
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	15
Introduction			
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	2,3,4
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
Methods			
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6,7,8,9,10
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6,8,9
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	10,11,12
Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10
Study records - data		Describe planned method of extracting data from reports (such as eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	11,12

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(such as GRADE)