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A study of the nature and level of trust in healthcare between patients and providers, its dimensions and determinants: a scoping review protocol.

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A study of the nature and level of trust in healthcare between patients and providers, its dimensions and determinants: a scoping review protocol.

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2. Dr Teguh Haryo Sasongko Associate Professor Human biology, School of Medicine International Medical University, Kuala Lumpur, Malaysia who assisted in the final review of the paper.

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ABSTRACT

Introduction

The aim of this scoping review is to systematically search the literature to identify the level of trust between the patient, the users of health services (e.g. carers) and the individual health care providers, and or the institutions which provide health care / and or the health system, across public and private health care sectors, at all levels of care from primary through secondary to tertiary care. It also aims to identify the factors that influence trust between patients and providers of healthcare at all levels and across all sectors, and to identify the tools used to measure trust in health care.

Methods and Analysis

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's[1] scoping review methodology, and Levac et al's methodological enhancement.

Quantitative (frequencies) and qualitative analysis (generation of descriptive) will be conducted. Thematic analysis will be used to categorise study findings associated with factors associated with trust. A consultation exercise with stakeholders may be incorporated as a knowledge translation component of the scoping study methodology.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board. The International Medical University will use the findings of this scoping review research to improve the understanding of trust in health care, in its endeavour to improve health services delivery in its health care clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence based decisions to focus resources and research as well as help to advance the science in this area. Dissemination of the results of the scoping review will be made through peer reviewed publications, research reports and presentations at conferences and seminars.

Key words: level of Trust in health care, scoping review protocol

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Article summary

Strengths and limitations of this study

Strengths:

- This study seeks to identify the level and nature of trust in health care between patients, users and healthcare providers of health care
- It will review the literature across all levels of care from primary care to tertiary care, and in the private and public sector
- It also seeks to identify the factors that influence trust and the tools used to measure trust in healthcare
- The scoping review is based on the methodology developed by Arksey &O'Malley and Levac et al's enhancement methods.

Limitation

- The study reviews articles published only in English and over a period of 10 years between 2007 - 2018.

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1. INTRODUCTION

Context of Healthcare provision

The provision of health care occurs in a setting characterised by uncertainty and an element of risk as to the competence and intentions of the health practitioner. Traditionally it has been widely accepted that the users or consumers of the service (i.e. the patients or public) trust the judgement knowledge and expertise of the health professional to provide a competent service. The effective delivery of health care requires both the supply of health care as well as the acceptance and use of services by the patient. Patient/provider interaction is at the heart of health care provision. The nature and environment of health care provision occurs on a relational basis – relationships between the providers and users of the service which consequentially impact upon health outcomes and wellness.

Trust and its importance in healthcare

Trust is a relational notion between people, people and organisations, and, people and events[2]. Patient **trust** in the physician can be defined as a collection of expectations that the patients have from their doctor[3] . It can also be defined as a feeling of reassurance or confidence in the doctor[4]. It is an unwritten agreement between two or more parties for each party to perform a set of agreed upon activities without fear of change from any party"[5]. This is especially true in relationships that result from a lack of choice or occur in a context of asymmetry, such as that between the health care provider and patient. Thus trust is a set of expectations that the healthcare provider will do the best for the patient, and with good will, recognising the patient's vulnerability. Trust facilitates cooperation between people (known to each other and/or strangers) that is catalysed, facilitated and sustained by trust[7]. Trust is fundamental to effective interpersonal relations and community living[6]. It forms a fundamental basis in provision of healthcare.

Trust between the patient and the healthcare professional / provider *(doctors, nurses,physiotherapists)* is important in doctor-patient interaction and rapport. It influences patient management outcomes especially in treatment of long term illness where it can have a direct therapeutic effect, as well as influences outcomes of health promotion and prevention initiatives. A trusting relationship between provider and patient can have a direct therapeutic effect[7]. Trust relations can be distinguished at the micro and macro levels. At the micro level, Trust can be interpersonal trust – which is that trust between the individual patient and the individual clinician, or between two clinicians, whilst organisational or institutional trust is that between the clinician and the manager of the organisation. Trust at the macro level includes trust between patients and the public and the organisation or institution.

Trust is typically associated with high quality communication and interaction, which facilitates disclosure by the patient, enables the practitioner to encourage necessary behaviour changes and may permit the patient greater autonomy in decision-making about treatment. (Mechanic, 1996, 1998).

Understanding the issues that influence a person's trust in the healthcare system will assist in drawing up suitable operating policies in the delivery of healthcare, as well as healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical education will create an emerging practitioner who will be more aligned to the patients' needs.

Erosion of trust in health care

Few critical incidents and sentinel events have contributed to erosion of the patients' trust in health care, the institutions and health systems. The changing socio political environment in health care, the impact of the era of information technology, and, the fact that patients have become increasingly empowered to make informed decisions, have influenced the nature of trust in health.

The aim of this scoping review is

1. To systematically search the literature to identify the nature or level of trust between the patient, the users of health services (e.g. carers) and the individual health care providers, and or the institutions which provide health care / and or the health system, across public and private health care sectors, at all levels of care from primary through secondary to tertiary care.

2. To identify the factors that influence trust between patients and providers of healthcare at all levels and across all sectors.

3. To identify the tools used to the tools used to measure trust in health care between patients and providers of healthcare.

Conceptual framework

Figure 1 depicts the conceptual framework of the study. The study will explore the nature of trust at the micro-level between patients / users of health services and the individual health care provider, and the nature of trust at the macro-level between patients / users of health services and the institutions which provide health care and or the health system. The study will also explore the factors that influence trust, between patients and healthcare providers (individual or institution) or the health system.

2. METHODS

Commissioning Agency

This study is commissioned by the International Medical University, Kuala Lumpur Malaysia. The university has identified research on "Trust in Healthcare" as one of its research thrust areas in its journey towards becoming the centre for research on trust in healthcare.

Study design

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's[8] scoping review methodology, and Levac et al's[iv] methodological enhancement. This framework identifies six stages in undertaking a scoping review: (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting the data; (5) collating, summarising and reporting the results.

Stage 1: Identifying the research question

The research questions are:

i. What is the nature or level of trust between the patient, the users of health services (e.g. carers) and the individual health care providers across public and private health care sectors, at all levels of care from primary through secondary to tertiary care - (micro level of trust)
ii. What is the level of trust between the patient, the users of health services (e.g. carers) and the institutions which provide health care / and or the health system, across public and private health care sectors, at all levels of care from primary through secondary to tertiary care - (macro level of trust)
iii. What are the factors that influence trust between patients and providers of healthcare;

Stage 2: Identifying relevant studies

The scoping review will be as comprehensive as possible in identifying primary studies and reviews answering the research questions. There will be no restrictions on the time frame for the search. The research will be restricted to publications in English.

Information sources and search strategy:

An experienced information specialist (HM) will search the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms will be as both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results will be downloaded and imported and stored into a "Refworks" folder specifically created for reference management.

A variety of grey literature will also be searched through the websites of relevant agencies such as the National Institutes of Health, National Institute of Clinical Excellence, and Agency for Healthcare Research and Quality, to identify studies, reports and conference abstracts of relevance to the research questions of this review. We will also conduct a targeted search of the grey literature in local, provincial, national and international organisations' websites and related health or scientific organisations. Supplementary articles may be obtained by contacting field experts and searching references of relevant articles.

Stage 3: Study selection –

Study selection process

First step: Study selection was initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested *apriory* on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Levels of Trust in Healthcare". Any discrepancies are resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*.

In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through a discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed.

Eligibility criteria:

Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to level of trust in health-care professionals. We will include studies that fulfil the following criteria:

(1) The study reported qualitative and or quantitative data on the trust levels between health-care providers and patients
(2) The study took place in a health care setting
(3) The study was published or reported in the English Language
(4) The study was published in journals, reports or in conference proceedings as literature
(5) The study measured interpersonal trust (e.g. trust in the nurse, physician, GP, psychiatrist) with a valid, reliable and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire
(6) The study measured Trust at the Macro level
(7) The study looked at factors affecting Trust.

Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded.

Stage 4: Data collection –

Data items and data abstraction process

A data extraction form will be created by the research team. This form will be reviewed and pretested by all reviewers before implementation to ensure that it captures the information accurately. All reviewers will be trained and be given an exercise using a random sample of articles to be included in the study. The data extraction form will also be piloted on a sample of five articles by the reviewers involved in the scoping study. The aim is to assess for completeness, ease of use. The percentage of agreement between reviewers will also be measured with a target of not less than 80 percent agreement. To ensure that study relevance the various study characteristics are listed below and, this includes but is not limited to the following:

1. Author
2. Publication year
3. Source origin/country of origin
4. Aims / purpose of the study
5. Research / Study design
6. Methodology
7. Population characteristics (e.g., number of participants, country, physician specialty,
8. Nature of Healthcare settings – hospital, and clinic types, unit/department, primary care, public or private sector)
9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment)

10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources),
11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and
12. Any factors reported to be associated with hospital physician engagement

- demographics,
- characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment)
- work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance

13. Key findings that relate to the review questions

The information extracted will then be summarised and tabulated in an *Excel file*. Each article will be assigned to 2 reviewers. The reviewers will work independently to extract the data; the data extracted by the pair of reviewers will be compared, and any discrepancies will be further discussed to ensure consistency between the reviewers. Conflicts will be discussed between the reviewers and consensus obtained. If there is difficulty in reaching a consensus, a third reviewer's opinion will be obtained. This process is undertaken so as to ensure accurate and reliable data collection.

Stage 5: Data summary and synthesis of results

Quantitative (frequencies) and qualitative analysis (generation of descriptives) will be conducted. Thematic analysis will be used to categorise study findings associated with factors associated with trust.

Stage 6: Consultation

A consultation exercise with stakeholders will be incorporated as a knowledge translation component of the scoping study methodology[9].

Patient and Public involvement:

Patients and public were not involved in the development of this scoping review protocol.

3. DISCUSSION

Implications

The International Medical University will use the findings of this scoping review research to improve the understanding of trust in health care, in its endeavour to improve health services delivery in its health care clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence based decisions to focus resources and research as well as help to advance the science in this area.

Dissemination

Dissemination of the scoping review findings will be done through peer reviewed publications, research reports and conference / seminar presentations.

A. CONTRIBUTORSHIP:

Supathiratheavy Rasiah[1] – main author, conceived the project, developed the conceptual framework for the study, analysed the preliminary data and wrote the manuscript, and also independent reviewer in the preliminary review.
Safurah Ja'afar[1], - contributed in writing the manuscript and was one of the independent reviewers in the preliminary review.
Gnanajothy Ponnudurai[1] – contributed in writing the manuscript.
Sasikala Devi Amirthalingam [1] – contributed in writing the manuscript.
Chung Poi Yee Katrina[1] – contributed in writing the manuscript.
Safiah Yusof[2], contributed in performing the search working with the librarian to search for and compile the list of relevant journal articles and store in the specific "Refworks" folder.

All authors read and approved the final version of the manuscript.

B. COMPETING INTERESTS: NONE.

C. FUNDING: None to report

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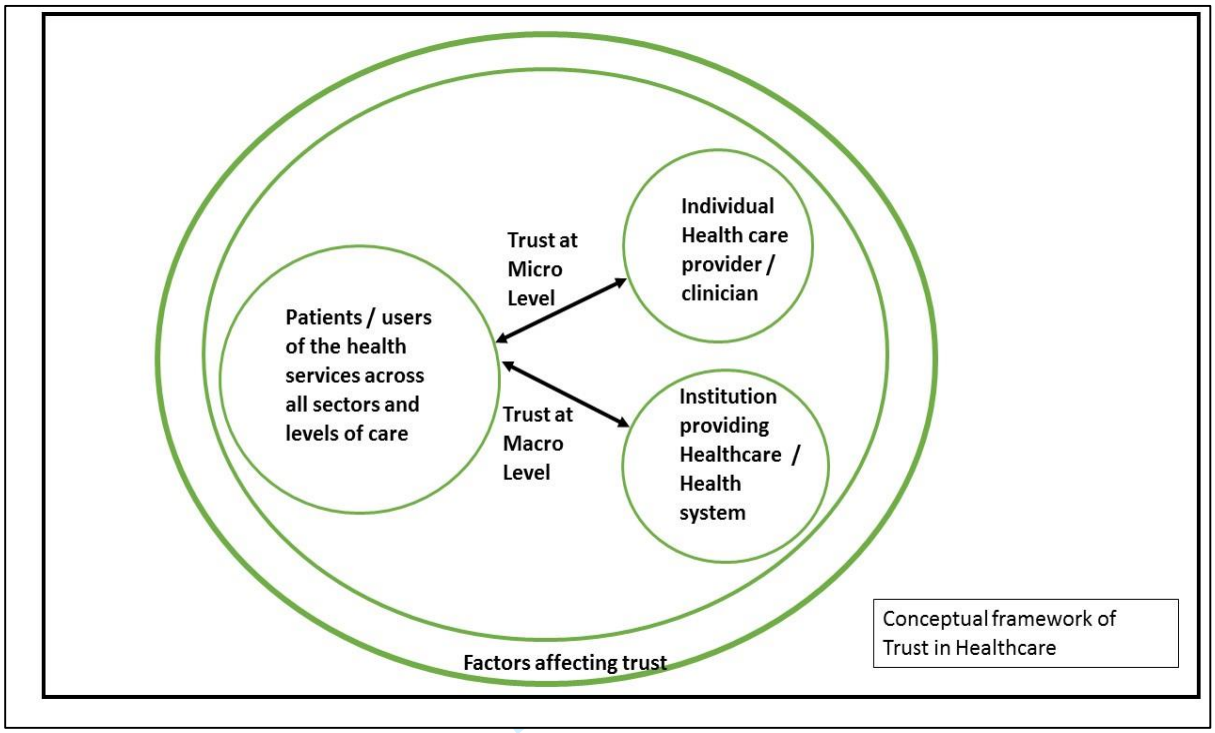
Figures

Figure 1: Conceptual Framework for Research on Trust in Healthcare

Figure 1: Conceptual Framework of Trust in Healthcare.



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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health, Health policy
Keywords:	trust in healthcare, scoping review protocol, nature of trust, Level of trust

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ABSTRACT

Introduction

This scoping review aims to systematically search the literature to identify the nature and or level of trust between the patient, the users of health services (clients) and the individual healthcare providers, across public and private healthcare sectors, at all levels of care from primary to tertiary care. It also aims to identify the factors that influence trust between patients and healthcare providers and to identify the tools used to measure trust in healthcare.

Methods and Analysis

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's scoping review methodology, and Levac et al's methodological enhancement.

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded, imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted. A consultation exercise with stakeholders may be incorporated as a knowledge translation component of the scoping study methodology.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board of the International Medical University. The university will use the findings of this research to improve the understanding of trust in healthcare in its endeavour to improve health services delivery and in its teaching and learning curriculum. Dissemination of the results of the scoping review will be made through peer reviewed publications, research reports and presentations at conferences and seminars.

Key words: Nature and level of Trust in healthcare, scoping review protocol

Article summary

Strengths and limitations of this study

Strengths:

- This study seeks to identify the level and nature of trust in healthcare between patients, clients and specific individual healthcare providers.
- It will review the literature across all levels of care from primary care to tertiary care, and in the private and public sector.
- It also seeks to identify the factors that influence trust and the tools used to measure trust in healthcare.

Limitations

- The study reviews articles published only in English and over a period of 10 years between January 2007 – December 2017.
- The scoping review will not encompass trust between patients, clients of health services and the organisations or institutions involved in providing health services or the health system.

1. INTRODUCTION

Context of Healthcare provision

The provision of healthcare occurs in a setting characterised by uncertainty and an element of risk as to the competence and intentions of the healthcare practitioner[1]. Traditionally it has been widely accepted that the users or consumers of the service (i.e. the patients, and, the clients who come for health promotion and preventive healthcare services) trust the judgement, knowledge and expertise of the health professional to provide a competent service[2]. The effective delivery of healthcare requires both the supply of healthcare as well as the acceptance and use of services by the patient and clients. Patient/provider interaction is at the heart of healthcare provision[2]. The nature and environment of healthcare provision occurs on a relational basis – relationships between the providers and users of the service which consequentially impact upon health outcomes and wellness.

Trust and its importance in healthcare

Trust is a relational notion between people, people and organisations, and, people and events[3]. Patient's trust in the physician can be defined as a collection of expectations that the patients have from their doctor[4]. It can also be defined as a feeling of reassurance or confidence in the doctor[5]. It is an unwritten agreement between two or more parties for each party to perform a set of agreed upon activities without "fear of change from any party"[6]. This is especially true in relationships that result from a lack of choice or occur in a context of asymmetry, such as that between the healthcare provider and patient. Thus, trust is a set of expectations that the healthcare provider will do the best for the patient, and with good will, recognising the patient's vulnerability. Trust facilitates cooperation between people (known to each other and/or strangers) that is catalysed, facilitated and sustained by trust[7]. Trust is fundamental to effective interpersonal relations and community living[7]. It forms a fundamental basis in the provision of healthcare.

Trust between the patient and the healthcare provider *(doctors, nurses, physiotherapists/occupational therapists)* is important in doctor-patient interaction and rapport. It influences patient management outcomes, especially in the treatment of long term illness, as well as influences outcomes of health promotion and prevention initiatives. A trusting relationship between provider and patient can have a direct therapeutic effect[8]. Trust relations can be distinguished at the micro and macro levels. At the micro level, Trust can be interpersonal trust – which is that trust between the individual patient or individual client and the individual clinician, or between two clinicians; organisational or institutional trust is that between the clinician and the manager of the organisation. Trust at the macro level includes trust between patients, the public and the organisation or institution. This study will focus on interpersonal trust between the patient or client and the individual healthcare provider.

Trust is typically associated with high quality communication and interaction, which facilitates disclosure by the patient, enables the practitioner to encourage necessary behaviour changes and may permit the patient greater autonomy in decision-making about treatment[9].

Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical education will create an emerging practitioner who will be more aligned to the patients' needs.

Erosion of trust in health care

Critical incidents and sentinel events have contributed to erosion of the patients' trust in healthcare, the institutions and health systems[10]. The changing socio-political environment in healthcare, the impact of the era of information technology, and, the fact that patients have become increasingly empowered to make informed decisions, have influenced the nature of trust in health[11].

The aim of this scoping review is

1. To systematically search the literature to identify the nature and or level of trust between the patient, the users of health services and the individual healthcare providers, across public and private healthcare sectors, at all levels of care from primary through secondary to tertiary care.

2. To identify the factors that influence trust between patients and healthcare providers or practitioners, at all levels of care from primary through to tertiary level of care, and across all sectors- public and private.

3. To identify the tools used to measure trust in healthcare between patients, clients and providers of healthcare.

Conceptual framework

Figure 1 depicts the conceptual framework for trust in healthcare. The study will explore the nature and the level of trust at the micro-level between patients and users of health services and the individual healthcare provider. The study will also explore the factors that influence trust, between patients and healthcare providers.

2. METHODS

Commissioning Agency

This study is commissioned by the International Medical University, Kuala Lumpur Malaysia. The university has identified research on "Trust in Healthcare" as one of its research thrust areas in its journey towards becoming the centre for research on trust in healthcare.

Study design

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's[12] scoping review methodology, and Levac et al's [13] methodological enhancement. This framework identifies six stages in undertaking a scoping review: (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting the data; (5) collating, summarising and reporting the results. The PRISMA checklist and the PRISMA 2009 flow Diagram will be used as a checklist in designing, reviewing, and reporting this scoping review.

Stage 1: Identifying the research question

The research questions are:

i. What is the nature and or level of trust between the patient, the users of health services (clients) and the individual healthcare providers (interpersonal trust) across public and private health care sectors, at all levels of care from primary through secondary to tertiary care?
ii. What are the factors that influence trust between patients, users of health services and providers of healthcare?
iii. What are the tools used to measure trust in healthcare at the interpersonal level?

Stage 2: Identifying relevant studies

The scoping review will be as comprehensive as possible in identifying primary studies and reviews answering the research questions. The research will be restricted to publications in English between the time period of January 2007-December 2017 and adhere to the eligibility criteria. A preliminary search was conducted between 7 December 2017 – 14 December 2017.

Information sources and search strategy:

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded and imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

A variety of grey literature will also be searched through the websites of relevant agencies such as the National Institutes of Health, National Institute of Clinical Excellence, and Agency for Healthcare Research and Quality, to identify studies, reports and conference abstracts of relevance to the research questions of this review. We will also conduct a targeted search of the grey literature in local, provincial, national and international organisations' websites and related health or scientific organisations. Supplementary articles may be obtained by contacting field experts and searching references of relevant articles.

Stage 3: Study selection –

Study selection process

First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*.

In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed.

Eligibility criteria:

Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between healthcare providers and patients or users of health services. We will include studies that fulfil the following criteria:

(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between healthcare providers and patients or users of health services.
(2) The study took place in a healthcare setting.
(3) The study was published or reported in the English Language.
(4) The study was published in journals, reports or in conference proceedings as literature.
(5) The study measured interpersonal trust (e.g. trust in the nurse, physician, healthcare practitioner) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire.
(6) The study looked at factors affecting trust in healthcare between patients, clients and the healthcare provider or practitioner.

Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded.

Stage 4: Data collection –

Data items and data abstraction process

A data extraction form will be created by the research team. This form will be reviewed and pretested by all reviewers before implementation to ensure that it captures the information accurately. All reviewers will be trained and be given an exercise using a random sample of articles to be included in the study. The data extraction form will also be piloted on a sample of five articles by the reviewers involved in the scoping study. The aim is to assess for completeness and ease of use. The percentage of agreement between reviewers will also be measured with a target of at least 80 percent agreement.
To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following:

1. Author
2. Publication year
3. Source origin/country of origin
4. Aims / purpose of the study
5. Research / Study design
6. Methodology
7. Population characteristics (e.g., number of participants, country, physician specialty,
8. Nature of healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector,

9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment),
10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources),
11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and
12. Any factors reported to be associated with hospital physician engagement

- demographics,
- characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment)
- work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance

13. Key findings that relate to the review questions.

The information extracted will then be summarised and tabulated in an *Excel file*. Each article will be assigned to 2 reviewers. The reviewers will work independently to extract the data; the data extracted by the pair of reviewers will be compared, and any discrepancies will be further discussed to ensure consistency between the reviewers. Conflicts will be discussed between the reviewers and consensus obtained. If there is difficulty in reaching a consensus, a third reviewer's opinion will be obtained. This process is undertaken so as to ensure accurate and reliable data collection.

Stage 5: Data summary and synthesis of results

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. The collection of studies will be also examined for heterogeneity. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted; it allows clear identification of themes arising from the data, facilitating prioritization, higher order abstraction and theory development. The findings will be analysed (including descriptive numerical summary analysis and qualitative thematic analysis), reported and discussed.

Stage 6: Consultation

A consultation exercise with stakeholders will be incorporated as a knowledge translation component of the scoping study methodology.

Patient and Public involvement:

Patients and public were not involved in the development of this scoping review protocol.

Data Management: All data will be kept confidential and a master index of all studies reviewed will be maintained.

3. DISCUSSION

Implications

The findings will be discussed as they relate to the study purpose and implications for future research, practice and policy. The International Medical University will use the findings of this scoping review research to improve the understanding of trust in healthcare, in its endeavour to improve health services delivery by its faculty in its healthcare clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence based decisions to focus resources and research as well as help to advance the science in this area.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board of the International Medical University. Dissemination of the scoping review findings will be done through peer reviewed publications, research reports and conference / seminar presentations.

A. CONTRIBUTORSHIP:

Supathiratheavy Rasiah[1] – main author, conceived the project, developed the conceptual framework for the study, analysed the preliminary data and wrote the manuscript, and also independent reviewer in the preliminary review.

Safurah Ja'afar[1], - contributed in writing the manuscript and was one of the independent reviewers in the preliminary review.

Safiah Yusof[2], contributed in performing the search working with the librarian to search for and compile the list of relevant journal articles and store in the specific "Refworks" folder.

Gnanajothy Ponnudurai[1] – contributed in writing the manuscript.

Chung Pooi Yin Katrina[1] – contributed in writing the manuscript.

Sasikala Devi Amirthalingam [1] – contributed in writing the manuscript.

All authors read and approved the final version of the manuscript.

B. COMPETING INTERESTS: NONE.

C. FUNDING: None to report.

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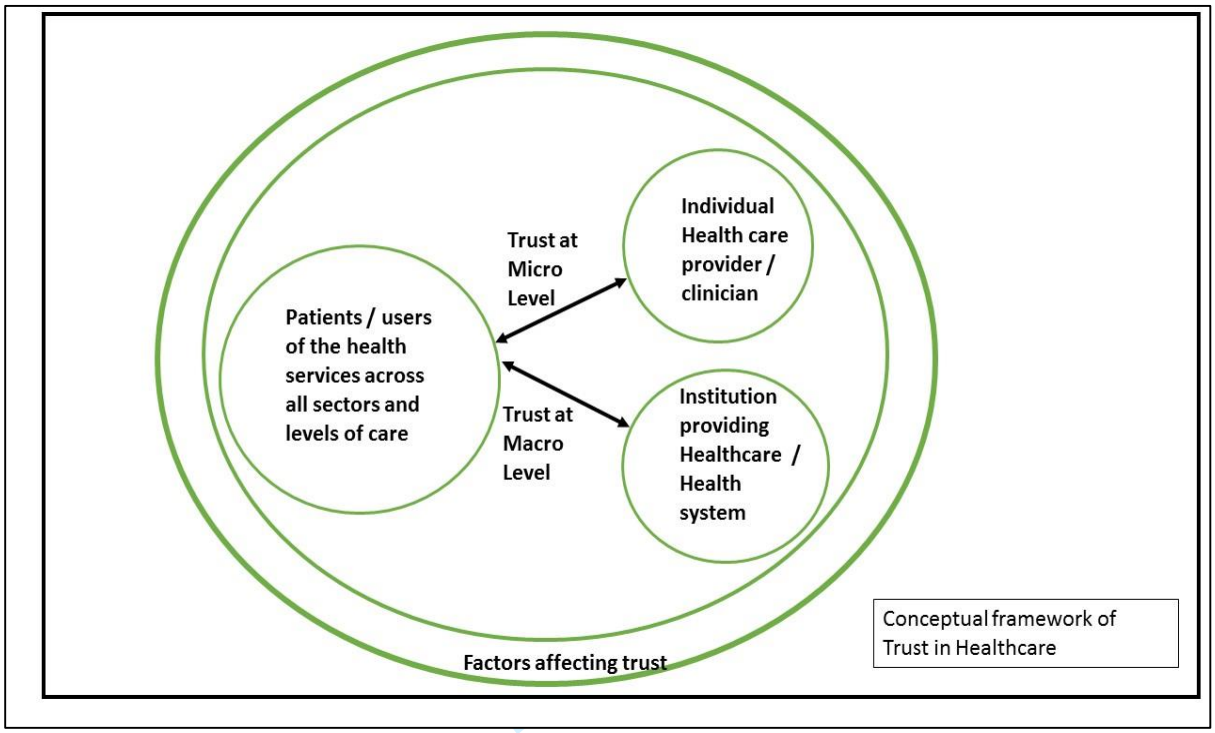
Figures

Figure 1: Conceptual Framework for Trust in Healthcare

Figure 1: Conceptual Framework of Trust in Healthcare.



PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Scoping review protocol – refer Title on page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	No
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Refer page 1 of manuscript for complete list of authors and contributions.
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Refer page 1of manuscript for complete list of authors and contributions. Guarantor of the review is the main author and the university.
Amendments	4	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	It is an amendment after peer review comments. List of changes is attached in Appendix 1 – feedback on editor's and peer reviewer's comments.
Support:			
Sources	5a	Indicate sources of financial or other support for the review	No financial support is available at present.
Sponsor	5b	Provide name for the review funder and/or sponsor	The International Medical University, Kuala Lumpur Malaysia is the institutional review board for the ethics approval.
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	There are no sources or organisations as funder or sponsors at present. The university is the Institutional Review Board for Ethics approval. The process of application for ethics approval is being initiated. Funding is being applied for from the Institutional Review Board.
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical

			education will create an emerging practitioner who will be more aligned to the patients' needs.
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Participants – patients, users /clients of health care and healthcare providers or practitioners Interventions- Tools used to measure trust in health care Comparators- Measures or standards for trust in health care that have been defined or stated elsewhere Outcomes - To get information on the nature and level of trust between patients, clients and healthcare providers; To identify the tools used to measure trust in healthcare; To make recommendations if appropriate for policy changes or changes to healthcare practice; To make recommendations if appropriate for improvements or innovations in medical education Please refer to page 5 of manuscript for aims of the scoping review.
METHODS			
Eligibility criteria	8	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	Please refer to page 7 of the manuscript - study selection process - eligibility criteria
Information sources	9	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	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies - information sources Planned dates of coverage is between 2007 to 2017 The study is planned to be conducted during the period from October 2019 – September 2020.
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies- information sources & search strategy: The following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms will be as both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results will be downloaded, imported and stored into a

			"Refworks" folder specifically created for reference management.
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Please refer to page 6 & 7 of the manuscript – study data items and data abstraction process. All data will be kept confidential. A master index of all studies reviewed will be maintained
Selection process	11b	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)	Please refer to page 6 and 7 of the manscript – study selection process: Stage 3: Study selection – Study selection process First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*. In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed. Eligibility criteria: Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between health-care providers and patients or users of health services. We will include studies that fulfil the following criteria:

			(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between health-care providers and patients or users of health services. (2) The study took place in a health care setting. (3) The study was published or reported in the English Language. (4) The study was published in journals, reports or in conference proceedings as literature. (5) The study measured interpersonal trust (e.g. trust in the nurse, physician, GP) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire. (6) The study looked at factors affecting trust in health care between patients, clients and the healthcare provider or practitioner. Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram (2009) will be used as a guide to record the review process.
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	All data extraction will be done by 2 reviewers and then consensus obtained. Piloting forms will be done independently and then consensus obtained. Data from investigators will be obtained and confirmed through email communication.
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Please refer to page 7 & 8 of the manuscript –data collection
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Please refer to page 7 & 8 of the manuscript –data items and data abstraction process - To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following: 1. Author 2. Publication year 3. Source origin/country of origin 4. Aims / purpose of the study

			5. Research / Study design 6. Methodology 7. Population characteristics (e.g., number of participants, country, physician specialty, 8. Nature of Healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector. 9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment) 10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources), 11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and 12. Any factors reported to be associated with hospital physician engagement - demographics, - characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment) - work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance 13. Key findings that relate to the review questions
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Assessment of risk of bias will focus primarily on the design and conduct of studies. Sponsor bias which may influence the reporting of analyses and results will be looked out for. In data synthesis, this information will be deliberated based on eligibility criteria and consensus obtained. The planned method of using two reviewers to assess each study for eligibility is expected to reduce errors and bias.
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	The results of the extracted data will be analysed using descriptive statistics (e.g. percentage) to provide summary characteristics of the studies
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from	The planned summary measures are analysis including descriptive numerical summary analysis and qualitative thematic analysis. The results including the outputs will be

		studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	discussed in relation to the study purpose and implications for future research, practice and policy *Currently there is no plan to combine data from studies as this is not a meta-analysis*.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Nil planned
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Plan to use GRADE to assess the evidence where applicable.

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

A study of the nature and level of trust in healthcare between patients and providers, its dimensions and determinants: a scoping review protocol.

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Manuscript ID	bmjopen-2018-028061.R2
Article Type:	Protocol
Date Submitted by the Author:	13-Sep-2019
Complete List of Authors:	Rasiah, Supathiratheavy; INTERNATIONAL MEDICAL UNIVERSITY , Community Medicine ; International Medical University School of Medicine, COMMUNITY MEDICINE Jaafar , Safurah ; INTERNATIONAL MEDICAL UNIVERSITY , Community Medicine Yusof, Safiah ; INTERNATIONAL MEDICAL UNIVERSITY , Nutrition and Dietetics Ponnudurai, Gnanajothy; INTERNATIONAL MEDICAL UNIVERSITY , Human Biology Chung , Katrina; INTERNATIONAL MEDICAL UNIVERSITY , Pathology Amirthalingam , Sasikala ; INTERNATIONAL MEDICAL UNIVERSITY , Family Medicine
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health, Health policy
Keywords:	trust in healthcare, scoping review protocol, nature of trust, Level of trust

A study of the nature and level of trust in healthcare between patients and providers, its dimensions and determinants: a scoping review protocol.

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2. Dr Teguh Haryo Sasongko Associate Professor Human biology, School of Medicine International Medical University, Kuala Lumpur, Malaysia who assisted in the final review of the paper.

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ABSTRACT

Introduction

This scoping review aims to systematically search the literature to identify the nature and or level of trust between the patient, the users of health services (clients) and the individual healthcare providers, across public and private healthcare sectors, at all levels of care from primary to tertiary care. It also aims to identify the factors that influence trust between patients and healthcare providers and to identify the tools used to measure trust in healthcare.

Methods and Analysis

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's scoping review methodology, and Levac et al's methodological enhancement.

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded, imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted. A consultation exercise with stakeholders may be incorporated as a knowledge translation component of the scoping study methodology.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board of the International Medical University. The university will use the findings of this research to improve the understanding of trust in healthcare in its endeavour to improve health services delivery and in its teaching and learning curriculum. Dissemination of the results of the scoping review will be made through peer reviewed publications, research reports and presentations at conferences and seminars.

Key words: Nature and level of Trust in healthcare, scoping review protocol

Article summary

Strengths and limitations of this study

Strengths:

- This study seeks to identify the level and nature of trust in healthcare between patients, clients and specific individual healthcare providers.
- It will review the literature across all levels of care from primary care to tertiary care, and in the private and public sector.
- It also seeks to identify the factors that influence trust and the tools used to measure trust in healthcare.

Limitations

- The study reviews articles published only in English and over a period of 10 years between January 2007 – December 2017.
- The scoping review will not encompass trust between patients, clients of health services and the organisations or institutions involved in providing health services or the health system.

1. INTRODUCTION

Context of Healthcare provision

The provision of healthcare occurs in a setting characterised by uncertainty and an element of risk as to the competence and intentions of the healthcare practitioner[1]. Traditionally it has been widely accepted that the users or consumers of the service (i.e. the patients, and, the clients who come for health promotion and preventive healthcare services) trust the judgement, knowledge and expertise of the health professional to provide a competent service[2]. The effective delivery of healthcare requires both the supply of healthcare as well as the acceptance and use of services by the patient and clients. Patient/provider interaction is at the heart of healthcare provision[2]. The nature and environment of healthcare provision occurs on a relational basis – relationships between the providers and users of the service which consequentially impact upon health outcomes and wellness.

Trust and its importance in healthcare

Trust is a relational notion between people, people and organisations, and, people and events[3]. Patient's trust in the physician can be defined as a collection of expectations that the patients have from their doctor[4]. It can also be defined as a feeling of reassurance or confidence in the doctor[5]. It is an unwritten agreement between two or more parties for each party to perform a set of agreed upon activities without "fear of change from any party"[6]. This is especially true in relationships that result from a lack of choice or occur in a context of asymmetry, such as that between the healthcare provider and patient. Thus, trust is a set of expectations that the healthcare provider will do the best for the patient, and with good will, recognising the patient's vulnerability. Trust facilitates cooperation between people (known to each other and/or strangers) that is catalysed, facilitated and sustained by trust[7]. Trust is fundamental to effective interpersonal relations and community living[7]. It forms a fundamental basis in the provision of healthcare.

Trust between the patient and the healthcare provider *(doctors, nurses, physiotherapists/occupational therapists)* is important in doctor-patient interaction and rapport. It influences patient management outcomes, especially in the treatment of long term illness, as well as influences outcomes of health promotion and prevention initiatives. A trusting relationship between provider and patient can have a direct therapeutic effect[8]. Trust relations can be distinguished at the micro and macro levels. At the micro level, Trust can be interpersonal trust – which is that trust between the individual patient or individual client and the individual clinician, or between two clinicians; organisational or institutional trust is that between the clinician and the manager of the organisation. Trust at the macro level includes trust between patients, the public and the organisation or institution. This study will focus on interpersonal trust between the patient or client and the individual healthcare provider.

Trust is typically associated with high quality communication and interaction, which facilitates disclosure by the patient, enables the practitioner to encourage necessary behaviour changes and may permit the patient greater autonomy in decision-making about treatment[9].

Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical education will create an emerging practitioner who will be more aligned to the patients' needs.

Erosion of trust in health care

Critical incidents and sentinel events have contributed to erosion of the patients' trust in healthcare, the institutions and health systems[10]. The changing socio-political environment in healthcare, the impact of the era of information technology, and, the fact that patients have become increasingly empowered to make informed decisions, have influenced the nature of trust in health[11].

The aim of this scoping review is

1. To systematically search the literature to identify the nature and or level of trust between the patient, the users of health services and the individual healthcare providers, across public and private healthcare sectors, at all levels of care from primary through secondary to tertiary care.

2. To identify the factors that influence trust between patients and healthcare providers or practitioners, at all levels of care from primary through to tertiary level of care, and across all sectors- public and private.

3. To identify the tools used to measure trust in healthcare between patients, clients and providers of healthcare.

Conceptual framework

Figure 1 depicts the conceptual framework for trust in healthcare. The study will explore the nature and the level of trust at the micro-level between patients and users of health services and the individual healthcare provider. The study will also explore the factors that influence trust, between patients and healthcare providers.

2. METHODS

Commissioning Agency

This study is commissioned by the International Medical University, Kuala Lumpur Malaysia. The university has identified research on "Trust in Healthcare" as one of its research thrust areas in its journey towards becoming the centre for research on trust in healthcare.

Study design

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's[12] scoping review methodology, and Levac et al's [13] methodological enhancement. This framework identifies six stages in undertaking a scoping review: (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting the data; (5) collating, summarising and reporting the results. The PRISMA checklist and the PRISMA 2009 flow Diagram will be used as a checklist in designing, reviewing, and reporting this scoping review.

Stage 1: Identifying the research question

The research questions are:

i. What is the nature and or level of trust between the patient, the users of health services (clients) and the individual healthcare providers (interpersonal trust) across public and private health care sectors, at all levels of care from primary through secondary to tertiary care?
ii. What are the factors that influence trust between patients, users of health services and providers of healthcare?
iii. What are the tools used to measure trust in healthcare at the interpersonal level?

Stage 2: Identifying relevant studies

The scoping review will be as comprehensive as possible in identifying primary studies and reviews answering the research questions. The research will be restricted to publications in English between the time period of January 2007-December 2017 and adhere to the eligibility criteria. A preliminary search was conducted between 7 December 2017 – 14 December 2017.

Information sources and search strategy:

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded and imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

A variety of grey literature will also be searched through the websites of relevant agencies such as the National Institutes of Health, National Institute of Clinical Excellence, and Agency for Healthcare Research and Quality, to identify studies, reports and conference abstracts of relevance to the research questions of this review. We will also conduct a targeted search of the grey literature in local, provincial, national and international organisations' websites and related health or scientific organisations. Supplementary articles may be obtained by contacting field experts and searching references of relevant articles.

Stage 3: Study selection –

Study selection process

First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*.

In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed.

Eligibility criteria:

Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between healthcare providers and patients or users of health services. We will include studies that fulfil the following criteria:

(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between healthcare providers and patients or users of health services.
(2) The study took place in a healthcare setting.
(3) The study was published or reported in the English Language.
(4) The study was published in journals, reports or in conference proceedings as literature.
(5) The study measured interpersonal trust (e.g. trust in the nurse, physician, healthcare practitioner) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire.
(6) The study looked at factors affecting trust in healthcare between patients, clients and the healthcare provider or practitioner.

Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded.

Stage 4: Data collection –

Data items and data abstraction process

A data extraction form will be created by the research team. This form will be reviewed and pretested by all reviewers before implementation to ensure that it captures the information accurately. All reviewers will be trained and be given an exercise using a random sample of articles to be included in the study. The data extraction form will also be piloted on a sample of five articles by the reviewers involved in the scoping study. The aim is to assess for completeness and ease of use. The percentage of agreement between reviewers will also be measured with a target of at least 80 percent agreement.
To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following:

1. Author
2. Publication year
3. Source origin/country of origin
4. Aims / purpose of the study
5. Research / Study design
6. Methodology
7. Population characteristics (e.g., number of participants, country, physician specialty,
8. Nature of healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector,

9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment),
10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources),
11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and
12. Any factors reported to be associated with hospital physician engagement

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- work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment)
- work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance

13. Key findings that relate to the review questions.

The information extracted will then be summarised and tabulated in an *Excel file*. Each article will be assigned to 2 reviewers. The reviewers will work independently to extract the data; the data extracted by the pair of reviewers will be compared, and any discrepancies will be further discussed to ensure consistency between the reviewers. Conflicts will be discussed between the reviewers and consensus obtained. If there is difficulty in reaching a consensus, a third reviewer's opinion will be obtained. This process is undertaken so as to ensure accurate and reliable data collection.

Stage 5: Data summary and synthesis of results

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. The collection of studies will be also examined for heterogeneity. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted; it allows clear identification of themes arising from the data, facilitating prioritization, higher order abstraction and theory development. The findings will be analysed (including descriptive numerical summary analysis and qualitative thematic analysis), reported and discussed.

Stage 6: Consultation

A consultation exercise with stakeholders will be incorporated as a knowledge translation component of the scoping study methodology.

Patient and Public involvement:

Patients and public were not involved in the development of this scoping review protocol.

Data Management: All data will be kept confidential and a master index of all studies reviewed will be maintained.

3. DISCUSSION

Implications

The findings will be discussed as they relate to the study purpose and implications for future research, practice and policy. The International Medical University will use the findings of this scoping review research to improve the understanding of trust in healthcare, in its endeavour to improve health services delivery by its faculty in its healthcare clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence based decisions to focus resources and research as well as help to advance the science in this area.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board of the International Medical University. Dissemination of the scoping review findings will be done through peer reviewed publications, research reports and conference / seminar presentations.

A. CONTRIBUTORSHIP:

Supathiratheavy Rasiah[1] – main author, conceived the project, developed the conceptual framework for the study, analysed the preliminary data and wrote the manuscript, and also independent reviewer in the preliminary review.

Safurah Ja'afar[1], - contributed in writing the manuscript and was one of the independent reviewers in the preliminary review.

Safiah Yusof[2], contributed in performing the search working with the librarian to search for and compile the list of relevant journal articles and store in the specific "Refworks" folder.

Gnanajothy Ponnudurai[1] – contributed in writing the manuscript.

Chung Pooi Yin Katrina[1] – contributed in writing the manuscript.

Sasikala Devi Amirthalingam [1] – contributed in writing the manuscript.

All authors read and approved the final version of the manuscript.

B. COMPETING INTERESTS: NONE DECLARED.

C. FUNDING: None to report.

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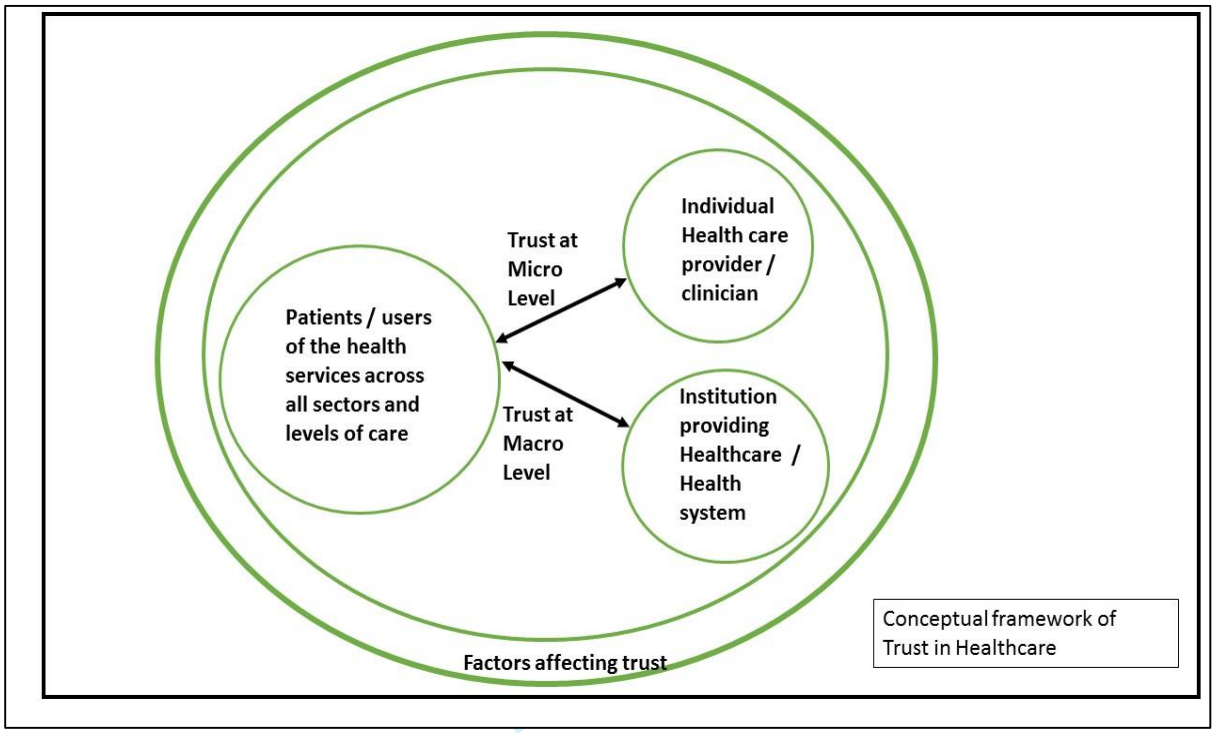
Figures

Figure 1: Conceptual Framework for Trust in Healthcare

Figure 1: Conceptual Framework of Trust in Healthcare.



PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Scoping review protocol – refer Title on page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	No
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Refer page 1 of manuscript for complete list of authors and contributions.
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Refer page 1of manuscript for complete list of authors and contributions. Guarantor of the review is the main author and the university.
Amendments	4	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	It is an amendment after peer review comments. List of changes is attached in Appendix 1 – feedback on editor's and peer reviewer's comments.
Support:			
Sources	5a	Indicate sources of financial or other support for the review	No financial support is available at present.
Sponsor	5b	Provide name for the review funder and/or sponsor	The International Medical University, Kuala Lumpur Malaysia is the institutional review board for the ethics approval.
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	There are no sources or organisations as funder or sponsors at present. The university is the Institutional Review Board for Ethics approval. The process of application for ethics approval is being initiated. Funding is being applied for from the Institutional Review Board.
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical

			education will create an emerging practitioner who will be more aligned to the patients' needs.
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Participants – patients, users /clients of health care and healthcare providers or practitioners Interventions- Tools used to measure trust in health care Comparators- Measures or standards for trust in health care that have been defined or stated elsewhere Outcomes - To get information on the nature and level of trust between patients, clients and healthcare providers; To identify the tools used to measure trust in healthcare; To make recommendations if appropriate for policy changes or changes to healthcare practice; To make recommendations if appropriate for improvements or innovations in medical education Please refer to page 5 of manuscript for aims of the scoping review.
METHODS			
Eligibility criteria	8	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	Please refer to page 7 of the manuscript - study selection process - eligibility criteria
Information sources	9	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	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies - information sources Planned dates of coverage is between 2007 to 2017 The study is planned to be conducted during the period from October 2019 – September 2020.
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies- information sources & search strategy: The following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms will be as both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results will be downloaded, imported and stored into a

			"Refworks" folder specifically created for reference management.
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Please refer to page 6 & 7 of the manuscript – study data items and data abstraction process. All data will be kept confidential. A master index of all studies reviewed will be maintained
Selection process	11b	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)	Please refer to page 6 and 7 of the manscript – study selection process: Stage 3: Study selection – Study selection process First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*. In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed. Eligibility criteria: Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between health-care providers and patients or users of health services. We will include studies that fulfil the following criteria:

			(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between health-care providers and patients or users of health services. (2) The study took place in a health care setting. (3) The study was published or reported in the English Language. (4) The study was published in journals, reports or in conference proceedings as literature. (5) The study measured interpersonal trust (e.g. trust in the nurse, physician, GP) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire. (6) The study looked at factors affecting trust in health care between patients, clients and the healthcare provider or practitioner. Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram (2009) will be used as a guide to record the review process.
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	All data extraction will be done by 2 reviewers and then consensus obtained. Piloting forms will be done independently and then consensus obtained. Data from investigators will be obtained and confirmed through email communication.
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Please refer to page 7 & 8 of the manuscript –data collection
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Please refer to page 7 & 8 of the manuscript –data items and data abstraction process - To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following: 1. Author 2. Publication year 3. Source origin/country of origin 4. Aims / purpose of the study

			5. Research / Study design 6. Methodology 7. Population characteristics (e.g., number of participants, country, physician specialty, 8. Nature of Healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector. 9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment) 10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources), 11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and 12. Any factors reported to be associated with hospital physician engagement - demographics, - characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment) - work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance 13. Key findings that relate to the review questions
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Assessment of risk of bias will focus primarily on the design and conduct of studies. Sponsor bias which may influence the reporting of analyses and results will be looked out for. In data synthesis, this information will be deliberated based on eligibility criteria and consensus obtained. The planned method of using two reviewers to assess each study for eligibility is expected to reduce errors and bias.
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	The results of the extracted data will be analysed using descriptive statistics (e.g. percentage) to provide summary characteristics of the studies
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from	The planned summary measures are analysis including descriptive numerical summary analysis and qualitative thematic analysis. The results including the outputs will be

		studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	discussed in relation to the study purpose and implications for future research, practice and policy *Currently there is no plan to combine data from studies as this is not a meta-analysis*.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Nil planned
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Plan to use GRADE to assess the evidence where applicable.

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

A study of the nature and level of trust between patients and healthcare providers, its dimensions and determinants: a scoping review protocol.

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Manuscript ID	bmjopen-2018-028061.R3
Article Type:	Protocol
Date Submitted by the Author:	13-Nov-2019
Complete List of Authors:	Rasiah, Supathiratheavy; INTERNATIONAL MEDICAL UNIVERSITY , Community Medicine ; International Medical University School of Medicine, COMMUNITY MEDICINE Jaafar , Safurah ; INTERNATIONAL MEDICAL UNIVERSITY , Community Medicine Yusof, Safiah ; INTERNATIONAL MEDICAL UNIVERSITY , Nutrition and Dietetics Ponnudurai, Gnanajothy; INTERNATIONAL MEDICAL UNIVERSITY , Human Biology Chung , Katrina; INTERNATIONAL MEDICAL UNIVERSITY , Pathology Amirthalingam , Sasikala ; INTERNATIONAL MEDICAL UNIVERSITY , Family Medicine
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Public health, Health policy
Keywords:	trust in healthcare, scoping review protocol, nature of trust, Level of trust

A study of the nature and level of trust between patients and healthcare providers, its dimensions and determinants: a scoping review protocol.

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2. Dr Teguh Haryo Sasongko Associate Professor Human biology, School of Medicine International Medical University, Kuala Lumpur, Malaysia who assisted in the final review of the paper.

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ABSTRACT

Introduction

Introduction

The aim of this scoping review is to systematically search the literature to identify the nature and or level of trust between the patient, the users of health services (e.g. clients seeking health promotion and preventive healthcare services)–and the individual healthcare providers (doctors, nurses and physiotherapists/ occupational therapists), across public and private health care sectors, at all levels of care from primary through secondary to tertiary care. It also aims to identify the factors that influence trust between patients, users of health services (clients) and providers of healthcare at all levels of care from primary care to tertiary care, and across all health sectors (public and private). The study will also identify the tools used to measure trust in healthcare provider.

Methods and Analysis

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's scoping review methodology, and Levac et al's methodological enhancement.

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded, imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. The collection of studies will be also examined for heterogeneity. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted; it allows clear identification of themes arising from the data, facilitating prioritization, higher order abstraction and theory development. A consultation exercise with stakeholders may be incorporated as a knowledge translation component of the scoping study methodology.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board. The International Medical University will use the findings of this scoping review research to improve the understanding of trust in health care, in its endeavour to improve health services delivery in its health care clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence based decisions to focus resources and research as well as help to advance the science in this area. Dissemination of the results of the scoping review will be made through peer reviewed publications, research reports and presentations at conferences and seminars.

Key words: level of Trust in healthcare, scoping review protocol

Article summary

Strengths and limitations of this study

Strengths:

- This study seeks to identify the level and nature of trust in healthcare between patients, users of health services and specific individual healthcare providers, e.g. physicians, surgeons, nurses, community health workers, physiotherapists and occupational therapists, and pharmacists.
- It will review the literature across all levels of care from primary care to tertiary care, and in the private and public sector.
- It also seeks to identify the factors that influence trust and the tools used to measure trust in healthcare providers.

Limitations

- The study reviews articles published only in English and over a period of 10 years between January 2007 – December 2017.
- The scoping review will not include trust in provision of health services by dentists, allied health professionals such as phlebotomists, medical laboratory scientists, dieticians and social workers, and in the area of mental health, and trust at the macro level or health systems level, so as to be focussed in the scope covered.

1. INTRODUCTION

Context of Healthcare provision

The provision of healthcare occurs in a setting characterised by uncertainty and an element of risk as to the competence and intentions of the healthcare providers[1]. Traditionally it has been widely accepted that the users or consumers of the service (i.e. the patients, and the clients who come for health promotion and preventive healthcare services) trust the judgement, knowledge and expertise of the health professional to provide a competent service[2]. The effective delivery of healthcare requires both the supply of healthcare as well as the acceptance and use of services by the patient and clients. Patient/provider interaction is at the heart of healthcare provision[2]. The nature and environment of healthcare provision occurs on a relational basis – relationships between the providers and users of the service which consequentially impact upon health outcomes and wellness.

Trust and its importance in healthcare

Trust is a relational notion between people, people and organisations, and, people and events[3]. Patient's trust in the physician can be defined as a collection of expectations that the patients have from their doctor[4]. It can also be defined as a feeling of reassurance or confidence in the doctor[5]. It is an unwritten agreement between two or more parties for each party to perform a set of agreed upon activities without "fear of change from any party"[6]. This is especially true in relationships that result from a lack of choice or occur in a context of asymmetry, such as that between the healthcare provider and patient. Thus trust is a set of expectations that the healthcare provider will do the best for the patient, and with good will, recognising the patient's vulnerability. Trust facilitates cooperation between people (known to each other and/or strangers) that is catalysed, facilitated and sustained by trust[7]. Trust is fundamental to effective interpersonal relations and community living[7]. It forms a fundamental basis in the provision of healthcare.

Trust between the patient and the healthcare provider *(doctors, nurses, physiotherapists/occupational therapists)* is important in provider-patient interaction and rapport. It influences patient management outcomes, especially in the treatment of long term illness, as well as influences outcomes of health promotion and prevention initiatives. A trusting relationship between healthcare provider and patient can have a direct therapeutic effect[8]. Trust relations can be distinguished at the micro and macro levels. At the micro level, Trust can be interpersonal trust – which is that trust between the individual patient or individual client and the individual clinician, or between two clinicians; organisational or institutional trust is that between the clinician and the manager of the organisation. Trust at the macro level includes trust between patients, the public and the organisation or institution. This study will focus on interpersonal trust between the patient or client and the individual healthcare provider.

Trust is typically associated with high quality communication and interaction, which facilitates disclosure by the patient, enables the practitioner to encourage necessary behaviour changes and may permit the patient greater autonomy in decision-making about treatment[9].

Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst providers. Transferring this knowledge to medical education will create an emerging practitioner who will be more aligned to the patients' needs.

Erosion of trust in health care

Critical incidents and sentinel events have contributed to erosion of the patients' trust in healthcare, the institutions and health systems[10]. The changing socio-political environment in healthcare, the impact of the era of information technology, and, the fact that patients have become increasingly empowered to make informed decisions, have influenced the nature of trust in the healthcare provider [11].

The aim of this scoping review is

1. To systematically search the literature to identify the nature and or level of trust between the patient, the users of health services and the individual healthcare providers, across public and private healthcare sectors, at all levels of care from primary through secondary to tertiary care.

2. To identify the factors that influence trust between patients and healthcare providers, at all levels of care from primary through to tertiary level of care, and across all sectors- public and private.

3. To identify the tools used to measure trust in healthcare between patients, clients and providers of healthcare.

Conceptual framework

Figure 1 depicts the conceptual framework for trust in health care. The study will explore the nature and or the level of trust at the micro-level between patients and users of health services and the individual healthcare provider. The study will also explore the factors that influence trust, between patients and healthcare providers.

2. METHODS

Commissioning Agency

This study is commissioned by the International Medical University, Kuala Lumpur Malaysia. The university has identified research on "Trust in Healthcare" as one of its research thrust areas in its journey towards becoming the centre for research on trust in healthcare.

Study design

The scoping review will be conducted based on the methodology developed by Arksey and O'Malley's[12] scoping review methodology, and Levac et al's [13] methodological enhancement. This framework identifies six stages in undertaking a scoping review: (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting the data; (5) collating, summarising and reporting the results. The PRISMA checklist and the PRISMA 2009 flow Diagram will be used as a checklist in designing, reviewing, and reporting this scoping review.

Stage 1: Identifying the research question

The research questions are:

i. What is the nature and or level of trust between the patient, the users of health services (clients) and the individual healthcare providers (interpersonal trust) across public and private healthcare sectors, at all levels of care from primary through secondary to tertiary care?
ii. What are the factors that influence trust between patients, users of health services and providers of healthcare?
iii. What are the tools used to measure trust in healthcare at the interpersonal level?

Stage 2: Identifying relevant studies

The scoping review will be as comprehensive as possible in identifying primary studies and reviews answering the research questions. The research will be restricted to publications in English between the time period of January 2007- December 2017 and adhere to the eligibility criteria. A preliminary search was conducted between 7 December 2017 – 14 December 2017.

Information sources and search strategy:

An experienced information specialist (HM) searched the following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms were both keywords in the title and or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results were downloaded and imported and stored into a "Refworks" folder specifically created for reference management. The preliminary search was conducted between 7th December 2017 and 14th December 2017.

A variety of grey literature will also be searched through the websites of relevant agencies such as the National Institutes of Health, National Institute of Clinical Excellence, and Agency for Healthcare Research and Quality, to identify studies, reports and conference abstracts of relevance to the research questions of this review. We will also conduct a targeted search of the grey literature in local, provincial, national and international organisations' websites and related health or scientific organisations. Supplementary articles may be obtained by contacting field experts and searching references of relevant articles.

Stage 3: Study selection –

Study selection process

First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare providers". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*.

In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed.

Eligibility criteria:

Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between healthcare providers and patients or users of health services. We will include studies that fulfil the following criteria:

(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between healthcare providers and patients or users of health services.
(2) The study took place in a healthcare setting.
(3) The study was published or reported in the English Language.
(4) The study was published in journals, reports or in conference proceedings as literature.
(5) The study measured interpersonal trust (e.g. trust in the nurse, physician, healthcare provider) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire.
(6) The study looked at factors affecting trust in healthcare between patients, clients and the healthcare provider.

Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded.

Stage 4: Data collection –

Data items and data abstraction process

A data extraction form will be created by the research team. This form will be reviewed and pretested by all reviewers before implementation to ensure that it captures the information accurately. All reviewers will be trained and be given an exercise using a random sample of articles to be included in the study. The data extraction form will also be piloted on a sample of five articles by the reviewers involved in the scoping study. The aim is to assess for completeness and ease of use. The percentage of agreement between reviewers will also be measured with a target of at least 80 percent agreement.
To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following:

1. Author
2. Publication year
3. Source origin/country of origin
4. Aims / purpose of the study
5. Research / Study design
6. Methodology
7. Population characteristics (e.g., number of participants, country, physician specialty,
8. Nature of Healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector,
9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment),

10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources),
11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and
12. Any factors reported to be associated with hospital physician engagement

- demographics,
- characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment)
- work environment (e.g., organisational support, quality of work-life and perceptions of safety),
- work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance

13. Key findings that relate to the review questions

The information extracted will then be summarised and tabulated in an *Excel file*. Each article will be assigned to 2 reviewers. The reviewers will work independently to extract the data; the data extracted by the pair of reviewers will be compared, and any discrepancies will be further discussed to ensure consistency between the reviewers. Conflicts will be discussed between the reviewers and consensus obtained. If there is difficulty in reaching a consensus, a third reviewer's opinion will be obtained. This process is undertaken so as to ensure accurate and reliable data collection.

Stage 5: Data summary and synthesis of results

Quantitative methods using content analysis will be used to categorise study findings on factors associated with trust between patients, clients and healthcare providers. The collection of studies will be also examined for heterogeneity. Qualitative analysis on peer reviewed articles of qualitative interviews and focus group discussion will be conducted; it allows clear identification of themes arising from the data, facilitating prioritization, higher order abstraction and theory development. The findings will be analysed (including descriptive numerical summary analysis and qualitative thematic analysis), reported and discussed.

In reviewing the instruments used to measure trust, they will be evaluated for validity and reliability, as well as to understand the domains which are measured, and how the domains are measured.

Stage 6: Consultation

A consultation exercise with stakeholders will be incorporated as a knowledge translation component of the scoping study methodology.

Patient and Public involvement:

Patients and public were not involved in the development of this scoping review protocol.

Data Management All data will be kept confidential and a master index of all studies reviewed will be maintained.

3. DISCUSSION

Implications

The findings will be discussed as they relate to the study purpose and implications for future research, practice and policy. The International Medical University will use the findings of this scoping review research to improve the understanding of trust in health care, in its endeavour to improve health services delivery by its faculty in its healthcare clinics and hospitals, and in its teaching and learning curriculum. The findings will also help faculty make evidence-based decisions to focus resources and research as well as help to advance the science in this area.

Ethics and Dissemination

Ethical approval will be obtained for the research project from the Institutional Review Board of the International Medical University. Dissemination of the scoping review findings will be done through peer reviewed publications, research reports and conference / seminar presentations.

A. CONTRIBUTORSHIP:

Supathiratheavy Rasiah[1] – main author, conceived the project, developed the conceptual framework for the study, analysed the preliminary data and wrote the manuscript, and also independent reviewer in the preliminary review.
Safurah Ja'afar[1], - contributed in writing the manuscript and was one of the independent reviewers in the preliminary review.
Safiah Yusof[2], contributed in performing the search working with the librarian to search for and compile the list of relevant journal articles and store in the specific "Refworks" folder.
Gnanajothy Ponnudurai[1] – contributed in writing the manuscript.
Chung Pooi Yin Katrina[1] – contributed in writing the manuscript.
Sasikala Devi Amirthalingam [1] – contributed in writing the manuscript.

All authors read and approved the final version of the manuscript.

B. COMPETING INTERESTS: "NONE DECLARED"

C. FUNDING: None to report.

Caption for Figure 1: Conceptual Framework of Trust in Healthcare

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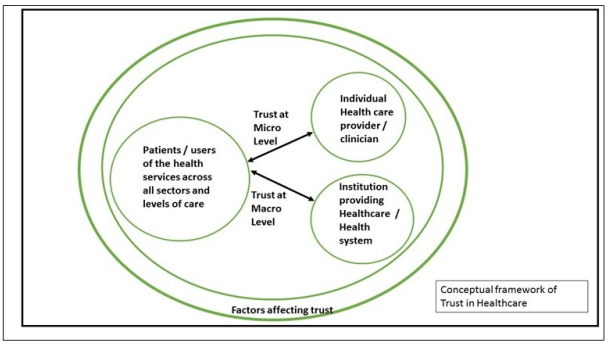

Figure 1 : Conceptual Framework of Trust in Healthcare

Figure 1: Conceptual Framework of Trust in Healthcare

338x190mm (96 x 96 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Scoping review protocol – refer Title on page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	No
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Refer page 1 of manuscript for complete list of authors and contributions.
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Refer page 1of manuscript for complete list of authors and contributions. Guarantor of the review is the main author and the university.
Amendments	4	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	It is an amendment after peer review comments. List of changes is attached in Appendix 1 – feedback on editor's and peer reviewer's comments.
Support:			
Sources	5a	Indicate sources of financial or other support for the review	No financial support is available at present.
Sponsor	5b	Provide name for the review funder and/or sponsor	The International Medical University, Kuala Lumpur Malaysia is the institutional review board for the ethics approval.
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	There are no sources or organisations as funder or sponsors at present. The university is the Institutional Review Board for Ethics approval. The process of application for ethics approval is being initiated. Funding is being applied for from the Institutional Review Board.
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Understanding the issues that influence a person's trust in the healthcare provider will assist in drawing up suitable operating policies in the delivery of healthcare, as well as influence healthcare practices and behaviours amongst practitioners. Transferring this knowledge to medical

			education will create an emerging practitioner who will be more aligned to the patients' needs.
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Participants – patients, users /clients of health care and healthcare providers or practitioners Interventions- Tools used to measure trust in health care Comparators- Measures or standards for trust in health care that have been defined or stated elsewhere Outcomes - To get information on the nature and level of trust between patients, clients and healthcare providers; To identify the tools used to measure trust in healthcare; To make recommendations if appropriate for policy changes or changes to healthcare practice; To make recommendations if appropriate for improvements or innovations in medical education Please refer to page 5 of manuscript for aims of the scoping review.
METHODS			
Eligibility criteria	8	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	Please refer to page 7 of the manuscript - study selection process - eligibility criteria
Information sources	9	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	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies - information sources Planned dates of coverage is between 2007 to 2017 The study is planned to be conducted during the period from October 2019 – September 2020.
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Please refer to page 6 of manuscript – Stage 2 identifying relevant studies- information sources & search strategy: The following databases MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search terms will be as both keywords in the title and /or abstract and subject headings (eg, MeSH, EMTREE) as appropriate. Search results will be downloaded, imported and stored into a

			"Refworks" folder specifically created for reference management.
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Please refer to page 6 & 7 of the manuscript – study data items and data abstraction process. All data will be kept confidential. A master index of all studies reviewed will be maintained
Selection process	11b	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)	Please refer to page 6 and 7 of the manscript – study selection process: Stage 3: Study selection – Study selection process First step: Study selection will be initiated using screening procedures to pull together only potentially eligible studies for the scoping review. It involves two steps of screening. The first step will be to go through all the collected titles and abstracts by two independent reviewers. All retrieved citations are subjected to a set of minimum inclusion criteria. These criteria were tested a priori on a sample of abstracts to ensure that they are robust to capture articles that may relate to "Nature and Levels of Trust in Healthcare". Any discrepancies will be resolved either through consensus or, if needed, involvement of a third reviewer. Finally articles that are selected as deemed relevant by either or both of the reviewers will be included in the full-text review in the Second Step Screening. *The online or e-learning articles are not included in the study selection for inclusion*. In the second step, both the reviewers will be assigned to the same articles and assess them in full-text. Any disagreement between the reviewers will be resolved through discussion with a third reviewer, and thus facilitating consensus for final inclusion. An inter-rater reliability calculation may be done if needed. Eligibility criteria: Titles and abstracts of articles which directly matched the identified keywords from year 2007 to 2017 will be filtered for relevance to nature and level of trust between health-care providers and patients or users of health services. We will include studies that fulfil the following criteria:

			(1) The study reported qualitative and or quantitative data on the nature of trust or levels of trust between health-care providers and patients or users of health services. (2) The study took place in a health care setting. (3) The study was published or reported in the English Language. (4) The study was published in journals, reports or in conference proceedings as literature. (5) The study measured interpersonal trust (e.g. trust in the nurse, physician, GP) with a valid, reliable instrument and used an established trust questionnaire (i.e. included a reference to a published article which used the respective trust questionnaire or used a validated questionnaire. (6) The study looked at factors affecting trust in health care between patients, clients and the healthcare provider or practitioner. Studies using invalidated instruments, single item questionnaires, or those measuring trust in non-health related environment will be excluded. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram (2009) will be used as a guide to record the review process.
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	All data extraction will be done by 2 reviewers and then consensus obtained. Piloting forms will be done independently and then consensus obtained. Data from investigators will be obtained and confirmed through email communication.
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Please refer to page 7 & 8 of the manuscript –data collection
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Please refer to page 7 & 8 of the manuscript –data items and data abstraction process - To ensure study relevance, the various study characteristics are listed below and, this includes but is not limited to the following: 1. Author 2. Publication year 3. Source origin/country of origin 4. Aims / purpose of the study

			5. Research / Study design 6. Methodology 7. Population characteristics (e.g., number of participants, country, physician specialty, 8. Nature of Healthcare settings – hospital, and clinic types, unit/department, primary care/secondary care / tertiary care, public or private sector. 9. Description of quality indicators including definition, numerator, dominator, psychometrics of the indicators (face validity, reliability, construct validity, risk adjustment) 10. Intervention characteristics (e.g., Concept, duration, engagement strategy, timing, required resources), 11. Tools used to measure level of trust, physician engagement, intervention results (e.g., barriers, facilitators, outcomes) and 12. Any factors reported to be associated with hospital physician engagement - demographics, - characteristics in the work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work attitudes (e.g., physician work engagement, job satisfaction, commitment and empowerment) - work environment (e.g., organisational support, quality of work-life and perceptions of safety), - work outcomes (e.g., patient experience, safety, quality of care, individual and organisational performance 13. Key findings that relate to the review questions
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Assessment of risk of bias will focus primarily on the design and conduct of studies. Sponsor bias which may influence the reporting of analyses and results will be looked out for. In data synthesis, this information will be deliberated based on eligibility criteria and consensus obtained. The planned method of using two reviewers to assess each study for eligibility is expected to reduce errors and bias.
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	The results of the extracted data will be analysed using descriptive statistics (e.g. percentage) to provide summary characteristics of the studies
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from	The planned summary measures are analysis including descriptive numerical summary analysis and qualitative thematic analysis. The results including the outputs will be

		studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	discussed in relation to the study purpose and implications for future research, practice and policy *Currently there is no plan to combine data from studies as this is not a meta-analysis*.
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Nil planned
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Plan to use GRADE to assess the evidence where applicable.

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.