Increasing Physician Intention to Address Social Determinants in Primary Health Care:

A qualitative inquiry and pilot RCT in Saudi Arabia

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2 Notes on manuscript-based thesis

The following paragraphs are quoted from the Faculty of Graduate and Postdoctoral Studies at McGill University Manuscript-Based (Article-Based) Theses (updated 2021-04-04).

As an alternative to the traditional thesis format, the thesis research may be presented as a collection of scholarly papers of which the student is the author or co-author; that is, it can include the text of one or more manuscripts, submitted or to be submitted for publication, and/or published articles reformatted according to the requirements described below. Manuscripts for publication are frequently very concise documents. The thesis is expected to be a more detailed, scholarly work than manuscripts for publication in journals. A manuscript-based thesis will be judged by the examiners as a unified, logically coherent document in the same way a traditional thesis is judged. A manuscript-based thesis must: a) be presented with uniform font size, line spacing, and margin sizes (see thesis format); b) conform to all other requirements listed under thesis components above; c) contain additional text that will connect the manuscripts in a logical progression from one chapter to the next, producing a cohesive, unitary focus, and documenting a single program of research - the manuscripts alone do not constitute the thesis; and d) function as an integrated whole.

A Doctoral thesis in this format requires at least three manuscripts, however, prior publication or acceptance for publication of the manuscripts is not a requirement. Publication or acceptance for publication of research results before presentation of the thesis in no way supersedes the University's evaluation and judgment of the work during the thesis examination process (i.e., it does not guarantee that the thesis will be found acceptable for the degree). In the case of multiple-authored articles, the student must be the primary author. Multiple-authored articles cannot be used in more than one thesis. In the case of students who have worked collaboratively on projects, it may be preferable for both students to write a standard format thesis, identifying individual contributions. (See Intellectual Property re: permissions/waivers.)

For this thesis, I have followed the McGill requirements for thesis preparation.

3 Contributions of Authors

Declaration of contribution of co-authors of manuscript contained in this thesis:

Manuscript 1: Exploring social determinants of health in a Saudi primary health care setting: the need for a multidisciplinary approach

Manuscript 2: An online educational intervention to improve primary care physician competencies in addressing social determinants of health in clinical care: Protocol for a pilot cluster randomized controlled trial in Saudi Arabia

Manuscript 3: A simple educational intervention increases physician intention to address social determinants in primary care: A pilot randomized controlled trial in the Kingdom of Saudi Arabia

All three articles report the results of the research project presented in this thesis. The original concept of the research protocol, data collection, analyses and preparation of the first draft of the manuscripts were done by Basmah Almujadidi (the student). The role of the co-authors (Dr. Anne Andermann, Dr. Tibor Schuster, Dr. Gerald Van Gurp, Dr. Aljohara AlQuaiz and Dr. Alayne Adams) was in supervising the preparation of the research protocol, the data collection, advising on the most appropriate data analysis procedures and modifying/reviewing the manuscripts and approving the final version of each manuscript and the final thesis. Manuscript (1) was accepted for publication by the *International Journal for Equity in Health* in February 2022 and was published in March 2022. Manuscript (2) was submitted to *PloS One Journal* and is under review. Manuscript (3) has been submitted to *BMC Primary Care Journal* and is also under review.

4 Thesis Abstract

4.1 English version

Introduction:

Action on the social determinants of health (SDH) in primary health care settings is constrained by practitioner-level (micro), organizational-level (meso), and contextual- or societal-level (macro) factors. The aim of the research undertaken for this doctoral thesis was 1) to better understand the various barriers and enablers for addressing SDH in clinical settings in Saudi Arabia, and 2) to pilot an online educational intervention to improve primary care physician's (PCP) knowledge and behavioral intention to address SDH in clinical care, with a view to promoting more socially accountable care for marginalized patients.

Methods:

We conducted an exploratory sequential mixed method study, with two main phases. First a qualitative phase was used to explore the barriers and enablers to addressing SDH in clinical care from both primary health care physician (PCP) and social worker viewpoints, involving individual in-depth interviews with a purposive sample of 17 PCPs, as well as a focus group with four social workers working in primary care, all recruited from King Khalid University Hospital (KKUH) in Riyadh. Interviews were audio-recorded, translated and analyzed using a deductive-inductive thematic analysis. Next, the quantitative phase consisted of a pilot cluster randomized controlled trial which recruited 100 PCPs across 48 primary care clinics at KKUH to assess the potential impact on physician knowledge, empathy and behavioral intention of implementing an online educational intervention (i.e. the Saudi version of the CLEAR toolkit) to support PCPs in addressing SDH, as compared to routine standard of care.

Results:

According to participants in the qualitative study, financial burdens, challenges in family dynamics, mental health issues and stresses relating to the aging population were common social problems in Saudi primary health care. Study respondents identified multiple factors that hinder action on SDH in primary care that can be categorized into four main themes: 1) lack of physician knowledge or training about addressing SDH in clinical care, 2) organizational barriers such as time constraints, 3) patient cultural norms and expectations, and 4) lack of clarity regarding the physician's scope of practice in managing SDH. Study participants also identified multiple enablers to more socially accountable care including: 1) more education and training, 2) organizational innovations to streamline case finding (e.g. self-completion questionnaires), 3) better interprofessional coordination, and 4) identifying opportunities for broader advocacy and upstream action to improve living conditions for marginalized groups.

Building on the first phase to address several of these barriers and enablers, 86 respondents (RR=86%) participated in the quantitative phase and were randomized to either receive the online educational intervention or continue to offer routine standard of care. At baseline, 98% of PCPs from both the intervention and control groups (n=84/86) were already involved in caring for marginalized and underserved patients (e.g. persons living with a disability, single parents, informal workers, persons with lived experience of poverty), and scored high on the Jefferson empathy scale. However, at 1-year follow-up, intervention group physicians had a higher index of suspicion for often hidden social challenges (e.g. domestic violence, elder maltreatment and neglect), were less likely to prescribe medicines as a "band aid" solution, and were more likely to refer to local social support services, as compared to physicians in the control group (53%, n=17/32 versus 15%, n=5/33; OR=6.35, 95% CI = 1.95 to 20.61).

Conclusion:

This study demonstrates that PCPs, while empathetic and already caring for a wide range of marginalized and underserved patient groups, need more support to address complex social challenges in clinical care. An online educational intervention is a simple, low-cost and easy to scale-up approach to increasing case finding and behavioral intention to refer patients to local support resources, an important indicator of future clinical behavior. Enabling more socially accountable care requires a multipronged approach, including leadership from the Ministry of Health, hospital administrations and medical schools, not only frontline PCPs. Yet, widespread dissemination of clinical support tools to guide PCPs in taking action on SDH in clinical care can provide an important first step to develop broader intersectoral responses and structural changes that prevent health inequities before they become more complex issues presenting to clinical care.

4.2 French version

Introduction

L'action sur les déterminants sociaux de la santé (DSS) dans les cliniques de première ligne est limitée par des facteurs au niveau du clinicien (micro), au niveau organisationnel (méso) et au niveau contextuel ou sociétal (macro). L'objectif de cette étude est 1) de mieux comprendre les différents obstacles et leviers pour aborder les DSS dans les milieux cliniques de première ligne en Arabie saoudite, et 2) de piloter une intervention éducative pour améliorer les connaissances des médecins de première ligne et leur intention de référer leurs patients au soutien social.

Méthodes

Nous avons mené une étude de méthode mixte de type exploratoire séquentielle en deux phases principales. Tout d'abord, une phase qualitative explorait les obstacles et les leviers à la prise en compte des DSS dans les soins cliniques à partir de différents points de vue interprofessionnels, incluant des entretiens individuels approfondis avec un échantillon ciblé de 17 médecins de famille, ainsi qu'un groupe de discussion avec quatre travailleurs sociaux travaillant dans les cliniques de médecine familiale, tous recrutés à l'hôpital universitaire King Khalid (KKUH) de Riyad. Les entretiens ont été enregistrés, traduits en anglais et analysés à l'aide d'une approche thématique « déductive-inductive. » Ensuite, la phase quantitative consistait d'une étude pilote d'un essai contrôlé randomisé en grappes, en recrutant 100 médecins auprès de 48 cliniques de soins primaires au KKUH pour évaluer l'impact potentiel d'une intervention éducative en ligne (c'est-à-dire la version saoudienne du CLEAR toolkit), par rapport aux soins de routine.

Résultats

Selon l'étude qualitative, les difficultés financières, les enjeux familiaux, les problèmes de santé mentale et les problèmes en lien avec le vieillissement de la population étaient des enjeux sociaux courant dans les soins de première ligne saoudiens. Les répondants ont identifié plusieurs

obstacles selon quatre thèmes principaux qui empêchent que ces problèmes soient abordés au niveau des soins primaires: 1) le manque de connaissances, 2) les obstacles organisationnels, 3) les attentes des patients, et 4) le manque de clarté concernant le rôle du médecin. Les répondants ont également identifié plusieurs leviers, notamment : 1) plus de formations, 2) des innovations organisationnelles, 3) une meilleure coordination interprofessionnelle, et 4) plaidoyer pour améliorer les conditions de vie des groupes marginalisés.

S'appuyant sur la première phase pour aborder plusieurs de ces obstacles, 86 répondants (taux de réponse = 86 %) ont participé à la phase quantitative et ont été randomisés pour recevoir l'intervention éducative en ligne ou d'offrir des soins standards. Au départ, les deux groupes avaient un score élevé sur l'échelle d'empathie et 98 % étaient déjà impliqués dans la prise en charge de patients marginalisés (n = 84/86). Cependant, les médecins qui ont reçu l'intervention étaient plus capables à identifier les patients avec des problèmes sociaux souvent cachés (ex. la violence), utilisaient moins souvent des médicaments en guise de « pansement » pour des problèmes sociaux sous-jacents, et référaient plus souvent ces patients aux services de soutien locaux, par rapport au groupe témoin (53%, n = 17/32 versus 15 %, n = 5/33; rapport de cotes = 6,35; IC à 95% = 1,95 à 20,61).

Discussion

Cette étude démontre que les médecins de première ligne sont déjà engagés dans la prise en charge de patients marginalisés et mal desservis, mais ils ont besoin plus de soutien. Une simple formation en ligne est une approche rapide et peu coûteuse pour aider les médecins à mieux identifier les patients avec des défis sociaux, et les référer vers des ressources de soutien locales. Réduire les inégalités sociales de la santé (ISS) nécessite une approche à plusieurs niveaux. Néanmoins, la diffusion à grande échelle d'outils cliniques constitue une première étape en vue de promouvoir des soins socialement responsables, surtout pour les patients marginalisés.

5 Introduction

Health inequities within societies result from the asymmetrical distribution of a variety of factors including income, employment, quality housing, social support, education, poverty, and food security (1). These factors are defined by the World Health Organization (WHO) as social determinants of health (SDH); the social, economic, and political conditions in which a population lives, grows, works, and ages (2, 3). Addressing socioeconomic disparities as such requires multisector action and broad whole-of-society approaches (4, 5).

In the last decade, the relationship between primary health care and social determinants of health has garnered much attention (6, 7). Frontline health workers continuously witness the detrimental impacts of social challenges on their patients' health. There is a growing movement geared toward increasing social accountability in primary health care, as well as enhancing health worker competencies to act on social determinants of health in clinical care (6, 8). Social accountability is the obligation of physicians to address the local priorities of the communities they serve, and more specifically, to better care for and support marginalized populations, assist them in overcoming the social challenges that contribute to poor health, encourage collaboration with communities and policy makers to enable supportive environments that promote health, and create a truly holistic health care system that is responsive to the population's perceived health needs (9).

The gradual adoption of the language of SDH by primary care providers, as indicated within the literature and in professional discourse, reflects acceptance of the idea that social factors influence a patient's presentation to his or her primary care physician and ability to support patients in navigating these challenges can promote improved patient outcomes (6, 9, 10). In 2008, the WHO released a report entitled "*Primary Health Care – Now More Than Ever*" that emphasized the importance of going back to the Alma Ata declaration's definition of primary health care (11, 12). The report urges adoption of a more socially accountable model of health care by taking increased action across a range of social determinants of health and highlights the importance of action at the primary level of entry to care (12). Doing so will lead to a better response to people's needs and improve community health outcomes (6, 7, 9, 10). In 2018, the Astana declaration

renewed its commitment to comprehensive primary health care and emphasized primary health care's critical role in promoting good health, social and economic development to ensure that all patients have an equal right to the highest standard of health care (13).

To support this shift, a worldwide emphasis must be made on the importance of primary health care physicians addressing social determinants of health (12, 14), and the relationship between health care providers and their patient populations. Action can be taken within the primary health care setting at three main level: "in individual doctor-patient relationships (micro), beyond the clinic where interactions occur between physicians and organizations with the communities they serve (meso), and the interactions of societies with their policy makers (macro)", this is the essence of a social accountability care practice (9). Thus, there is a great difference between a narrow view of entry-level health care and the wider perspective of primary health care. Unfortunately, in many countries the balance has skewed towards individualized health care at the expense of population health (14). The Western health system remains resolutely biomedical in its approach to diagnosis and treatment, often slow to adopt the new institutional responsibilities and cultural shifts required to address indirect causes of poor health (4, 14, 15). Recurrent patient visits to primary care clinics suggest that the underlying social causes of disease were not addressed, and patients remain in the same social situations, living conditions, and unhealthy environments (16). There are many perceptions physicians hold about social determinants of health. Some physicians consider issues such as domestic violence, poverty, and unemployment to be beyond their scope (16). Other physicians report being untrained or unqualified to address their patients' social causes of poor health (16).

Addressing patients' social determinants of health is still in the process of being meaningfully embraced in the Middle East (17) and only a small number of articles published in the Eastern Mediterranean region call for adoption of a biopsychosocial approach in medical education and promoting the role of health workers in addressing the social determinants of health more broadly (18-24).

Literature on how primary health care in Saudi Arabia addresses social determinants of health is scant. The Saudi health care system has become one of the most advanced in the Middle East with a strong focus on health promotion. Nevertheless, literature on the integration of social determinants of health in the Saudi primary health care setting remains sparse (25-27). While awareness of challenges of adopting a social determinants approach in primary health care can provide healthcare providers with tools to better support vulnerable patients (5), there is an evidence-practice gap in the existence of locally adapted strategies for addressing complex health and social problems (7, 8). Evidence-based approaches present challenges because of the heterogeneity of Saudi healthcare settings that makes it difficult to identify which intervention is most likely to be effective. Limited understanding of contextual, organizational and individual factors, including behavioral ones can hinder the effectiveness of different western health care interventions. Therefore, there is a palpable need for an examination of physicians' professional behavior to determine if it is aligned with local conditions (28).

5.1 The Saudi Arabian context

Demographically, the kingdom of Saudi Arabia is the second largest Muslim country in the Arabian Peninsula, with its current population of 35.5 million people (29, 30). Riyadh is the capital and largest city in the kingdom with a population of 6 million people (30). The country's largest economic asset is oil production and trade (31) and is thus considered one of the top 20 economies in the world. Saudi Arabia finds itself in a highly transitional period in terms of social reform and economic diversification (31). The current median age in Saudi is 27.5 years of age with a full life expectancy of 75.5 years of age (30). Two thirds of the population are under 35 years old, and 98% of the population are internet users. Adult literacy in Saudi was 97.6% in 2020. The labor participation in 2021 of Saudi males is 66% and women is 32.3%. The Saudi unemployment rate is 12% (32).

Culturally, Saudi Arabia is a mix of Arab traditions and customs with an Islamic worldview (31, 33). The Shariah law governs life such as politics, economics, finances, family, hygiene, and social issues (20, 26, 31, 33). Family and community are vital parts of Saudi society, an individual commonly has an extended support system that includes parents, grandparents, siblings, aunts,

uncles, cousins, and friends (31, 34). Extended family ties are strongly encouraged and maintained. Family is considered an essential part of an individual's identity (20, 26, 31, 33, 34).

5.2 The structure of the health care system

The Saudi Ministry of Health (MoH) is the main government agency responsible for the supervision of health care services and hospitals in both the public and private sectors in the country (26). For many decades, the public sector provided universal health coverage and free of charge health services to the Saudi population and was supplemented financially by the country's oil revenue industry (26, 35). These free and public healthcare provider bodies deliver the primary (healthcare centers), secondary (general hospitals with referrals) and tertiary (with specific tertiary services existing at the third level) healthcare facilities for employees and families (35). Expatriates and their family members working in the public sectors, were also provided with free healthcare, such as the ones working for governmental/teaching hospitals so for example, the Ministry of Defense has hospitals providing treatment free of charge to its employees (35). However, due to changes in the costs of healthcare and a larger shift to sedentary lifestyles, population's demographics, improved life expectancies, changing disease patterns, as well as inadequate management practices in the delivery of health services, a shift to private practice in health care was needed alongside health insurance companies to cover the extra demands and this was mainly for those who wish to pay out of pocket and all those who work in the private sector (36).

5.3 Increasing access to primary health care - past and future

In accordance with the Alma-Ata declaration at the WHO General Assembly in 1978 the Saudi MoH decided to activate and develop the preventive health services by adopting the PHC approach as one of its key health strategies (26, 35). The first step was to establish suitable premises throughout the country. These included former health offices, maternal and child health centers and medical dispensaries. Which were mainly for prenatal care and vaccination programs and showed success in that matter (35).

Saudi Arabia's Vision 2030 was adopted as a roadmap for socioeconomic action in the Kingdom with the objective of transforming the nation. The vision is structured along three core pillars: "a vibrant society", "a thriving economy", and "an ambitious nation" (37). To build the institutional capacity and capabilities needed to achieve Vision 2030, the National Transformation Program 2020 was launched in 2016 across 24 government bodies operating in the economic and development sectors (37). The Saudi Ministry of Health was assigned strategic objectives to meet by 2020 as a response to eight major challenges that were identified in the healthcare system and these include: a growing population, high rates of avoidable injury, inadequate primary care, gaps in quality, variation in provision, access and investment, staff-centric system, significant gaps in workforce capacity and capability, needs to be resource-efficient and financially sustainable (37). To address these challenges, the transformation goals are informed by international frameworks such as the; Model of Care (MoC), a model that promotes public health and focuses on prevention and health awareness, thus the aim is to enhance the healthcare system in three main areas: 1. improving health for all citizens, 2. Improving health care quality and consistency of services, effective, patient-centered, timely and equitable 3. Improve value: by containing costs, improving outcomes, controlling public healthcare expenditure and guiding new investment (37). Plans include increasing the quality of primary health care. One of the objectives is to improve integration and continuity in service provision by strengthening the primary health care system into a full-scale family practice model (37). Saudi Arabia has 2282 public PHC centers, 60% of which are located in the rural outskirts and villages; these centers provide free care to 23 million people (26, 27, 38-40). While the large number of PHC centers is a result of the efforts being made by the Ministry of Health to make PHC accessible to most residents in the country, the total number of physicians working at these is 6107 and only 636 are qualified family physicians (which is about 10% of the total physicians covering PHC centers) (39). Future strategic plans to address the shortage have been made to produce more family physicians such as strengthening the undergraduate and postgraduate training programs in Family Medicine in all aspects (39).

Currently the National Transformation Program has assigned twenty Accountable Care Organizations (ACOs) also known as Health Clusters (this is a defined geographic area that includes primary health care centers and a referring secondary/tertiary hospital) were established

for enhanced governance (37). The surveillance being done in each cluster to ensure an adequate delivery of health care to the community residing in the cluster, is personalized or customized to meet the health needs and supply to each cluster (37). This is done by a population health management team that continuously receives annual reports from the health need assessment surveys (short one and a comprehensive one) whereby health care practitioners, nurses and social workers survey the community in that specific cluster and understand their needs (37).

5.4 Undergraduate and postgraduate medical education

The Bachelor of Medicine and Surgery (MBBS) is a 6-year long program, eligible candidates are high school graduates (based on high-school grades, the national aptitude test, a summative examination in science and an interview). The program is followed by a mandatory 1-year internship. After graduation, a graduate may continue their residency locally or pass a United States medical licensing examination (USMLE) or Medical Council of Canada qualifying exam (MCCQE) and begin the residency journey abroad.

The Family Medicine program is three-years long. Residents must pass the board exam in family medicine to be licensed as "family medicine" consultants. If the MBBS graduate decides not to matriculate into a residency program, they can be licensed by the Saudi Commission for Health Specialties (a regulatory body for all healthcare professionals) to practice as general physicians (GPs). Working institutions differ in their support of GPs. GPs working mostly in the Saudi Ministry of Health clinics, often have 1-2 physicians and often limited nursing or social work support. While family doctors working in larger academic hospital centers have several physicians practicing as a group with ample nursing, social work support and other allied health team members.

In conducting research, it is important to "situate the researcher" and to consider one's own "positionality" in relation to the topic under investigation. I will therefore take this opportunity to discuss my own background in relation to this work, and how I came to choose this research path for my doctoral dissertation. After completing my MBBS degree at King Saud University and a one-year medical internship at King Khaled University Hospital in Riyadh, I was qualified to work in Saudi as a general practitioner, as described above. I found myself looking for ways to make

patients' lives better by really getting to the root of the often indirect and hidden causes of poor health, such as one's social environment. Throughout my internship, I witnessed several scenarios that would have been easily addressed at a primary level of care, had the physician considered a more socially accountable and holistic bio-psycho-social approach to patient management and care. Considering my Saudi background, cultural insight and perspective, and my academic position as a lecturer at the university hospital, I felt compelled to bring what I learned abroad during my postgraduate studies on social determinants of health, back to the way we practice Family Medicine and Primary Health Care in Saudi. I also recognized that coming from the local culture, I can better appreciate the different barriers and challenges that exist, and the need for any approaches to addressing social determinants in clinical care to be tailored to the very particular local context.

This dissertation research therefore sought to better understand the Saudi primary healthcare physician and social worker perspectives on how to take action relative to the social determinants of health within clinical care. The research was informed by the Theory of Planned Behavior and the WHO's Commission on Social Determinants of Health (CSDH) frameworks to have a more well-rounded understanding of the physician's behavior while also putting into context the hospital and healthcare system to which they belong (41, 42). Encouraging primary health care physicians to imagine novel ways for understanding and engaging in health advocacy, creating structural system changes and supportive policy frameworks, enables primary health care physicians to act on the social determinants of health and build alliances with community-based organizations. Moreover, this research will lay the foundations for a future evaluation of a locally adapted educational intervention designed to improve primary healthcare physicians' knowledge, empathy, and behavioral intention to integrate social determinants of health into daily clinical practice, particularly when caring for vulnerable and marginalized patients.

6 Review of the Literature

Although addressing social determinants of health in primary healthcare settings is acknowledged to be critical, how to take action and achieve health equity, as it pertains to social determinants, remains vaguely described in the literature (7-14). In this literature review, the seminal research and international reports that led to today's improved understanding of the social determinants of health is first discussed. Second, definitions and arguments in favor of the role of primary health care in addressing social determinants of health. Third, using the 2008 World Health Organization (WHO) report "Closing the gap in a generation: health equity through action on the social determinants of health" (7), this review discusses the literature addressing social determinants of health in developed Western contexts (e.g., the US, Canada and the UK) (4, 8, 15, 16), and in developing countries belonging to: the Eastern Mediterranean Regional Office (EMRO) region; the Gulf Cooperation Council (GCC) region; as well as in Saudi Arabia (17-27). Finally, an introduction and rationale advocating the use of the Community Links Evidence to Action Research (CLEAR) toolkit, which is a tool designed to address social determinants of health in primary health care settings, such as the Saudi one (43).

6.1 Social determinants of health and health inequities: A global challenge

People's health and disease profiles are usually affected by their socio-cultural, behavioral, economic, healthcare circumstances, and living conditions (1). Today, social disparities result in differences in life expectancy (at birth) between high-income countries and low- and middle-income ones, as well as within countries (44-46). In 2019, the average life expectancy of an individual living in a developed country, such as Canada, was 82.2 years, while in Pakistan it was 65.6 years – a nearly 15-year difference between the countries (47). Within Canada, according to one study, homeless persons have a life expectancy that is 40 years less than that of the average Canadian (48) The variations in life-expectancy between and within countries may be attributed to the social, economic, and political conditions in which a population lives, grows, works, and ages, circumstances the WHO collectively names them as "social determinants of health" (1, 2). Mariana et al. define health inequality as "... any measurable aspect of health that varies across individuals or according to socially relevant groupings" (49). They further differentiate health

inequity as "... an unjust difference in health..." (49). In other words, the existence of preventable health-related differences such as crowded housing and lack of food is unfair. Health inequities within a population result from the asymmetrical distribution of health determinants, including poverty, social support, quality housing, food security, education, employment, and income (3, 44, 45). Social determinants of health and health equity are directly related; addressing social determinants of health will lead to health equity (3, 44, 45).

The Commission on Social Determinants of Health (CSDH) was established by the WHO in 2005 to gather evidence on what can be done to promote action on social determinants of health with the aim of achieving global health equity. Supported by WHO's Eastern Mediterranean Regional Office (EMRO), the CSDH orchestrated a lengthy report in 2008 entitled "Building the knowledge base on the social determinants of health: Review of seven countries in the Eastern Mediterranean Region" which studied Egypt, Iran, Jordan, Morocco, Oman, Pakistan, and the Occupied Palestinian Territories (17). The report identified gender equity and women's empowerment, inadequate healthcare systems and resources, employment conditions, social exclusion, migration, urbanization, environmental conditions, and conflict/post-conflict emergencies as important social challenges, highlighting the need for greater public dialogue and more advocacy to mitigate health inequities in the Middle East region (17).

Importantly, Saudi Arabia was not included in the WHO EMRO report (17). Unlike some countries the report covered, Saudi Arabia shares characteristics of wealthy developed nations including a well-established infrastructure and varied educational opportunities for its healthcare providers that encourage them to improve their knowledge and skills. Yet, similar to the EMRO countries, wealth in Saudi Arabia is highly stratified (26). People belonging to a minimum income class face difficulty gaining access to appropriate healthcare services. Moreover, the population of Saudi Arabia will reach an estimated 39.8 million by 2025, probably compounding reported health inequities and increasing the demand for essential health care services and facilities (26). While the Commission's report "Closing the gap in a generation: health equity through action on the social determinants of health" report suggests strategies for increasing health equity in several

governmental sectors including education, labor, law enforcement and social protection agencies, a strong emphasis was placed on the health sector, particularly on Primary Health Care (PHC) (7). It is also important to consider the definition of the term marginalization which is "a process through which certain population groups experience multiple social determinants concurrently. Thus, limiting their access to health promoting resources, while increasing their risk for poor health" (50). An individual's social position (gender, sexual orientation, race and ethnicity), their social environment and the resources available to prevent or fight disease; education, income and quality of their residential housing, all together produce an individual's health. These complex interactions are the link between marginalization and SDH (50).

6.2 Expanding role of primary health care: How do social determinants of health fit in?

Primary Health Care (PHC) was first defined in the 1978 Alma Ata Declaration, as "essential health care made universally accessible to individuals and families in the community by means acceptable to them and at a cost that the community and country can afford (11). It is also the first level of contact that individuals, the family and community have with the national health system bringing health care as close as possible to where people live and work" (11). Primary Care (PC) and PHC although often used interchangeably, denote different concepts (51, 52). PC is an individual-oriented service that focuses on early diagnosis of illness and effective timely management, and the individual is often held solely accountable for his/her health status and underlying disease, rather than considering the complementary role of their SDH. This reflects a narrow biomedical approach to care (51). PHC, on the other hand, extends more broadly and is drawn from a social model of care that functions on social justice principles, which is based on the understanding that for health to occur, "people's basic needs must first be met and these include shelter, support, safety from violence and affordable food supply" (51).

Evidence shows that healthcare systems with strong PHC services that apply principles of disease prevention and health promotion observe better health outcomes among the populations they serve, compared to health care systems with weaker PHC services (53, 54). For example, Cuba, worked on creating PHC services within their communities, the "polyclinics" program, a neighborhood-based family physician run office/center that offers a wide range of clinical and

preventive services that meet the specific health picture and needs of the individuals and families within the served community, helped give Cubans one of the longest average life expectancies at birth (77.8 years) among developing countries and managed to increase its family physician per patient ratio drastically to about 1:600 (47, 55).

6.3 Primary health care physician's role in addressing social determinants of health

As health workers on the frontlines constantly witness the impact of SDH on their patients' health, incorporating them into the PHC discourse reflects acceptance of the idea that SDH influence a patient's presentation to his or her primary care physician (3, 6). In 2008, the WHO released a report entitled "*Primary Health Care – Now More Than Ever*", that emphasized the importance of the Alma Ata declaration's definition of PHC (11, 12). The report urges adoption of a more socially accountable model of healthcare by taking increased action across a range of SDH and highlights the importance of action at the primary level of entry to care (12). The declaration changes physician's perception about social determinants of health but does very little in preparing them on how to empower individuals and communities in dealing with their social causes of poor health. In addition to content expertise, Primary Health Care physicians must be taught about process thinking. The sociological levels of research can be of use here (9, 10). Micro (the individual), meso (interpersonal), and macro (the society) (9, 10, 56). Doing so, will help physicians understand human behavior at these different levels. Physicians currently might be using an individualized care approach catering to the individual patient, this may be incongruent with social problems patients face (9, 10, 56).

In 2018, the Astana declaration renewed its commitment to comprehensive primary health care and emphasized primary health care's critical role in promoting good health, social and economic development to ensure that all patients have an equal right to the highest standard of health care (8). The Astana declaration recognizes that remaining healthy might be challenging especially to socially vulnerable patients. There is a great difference between a narrow view of entry-level health care and the wider perspective of primary health care. Unfortunately, in many countries the balance has skewed towards individualized health care at the expense of population health (14).

To support this shift, a worldwide emphasis must be put on the importance of PHC physicians addressing SDH (7, 12, 14). In addition to understanding the importance of addressing SDH in primary health care, it is essential to equip the physicians with the essential knowledge and skills underpinned by sociological thinking rather than psychological thinking. This requires a second look into the training of physicians in the area of social determinant of health. Both declarations outline the importance of training; however, it does not articulate how that should be done. Training PHC physicians to be more aware of social issues can benefit both patients and society, though societies face significant barriers and challenges to such intersectional advances (16).

Several interventions were created to address these issues following the Alma-Ata declaration were in a vertical "top-down" course of action, following deductive epidemiological concepts, this selective approach although feasible, didn't consider the communities needs their choices of action. Doing so, will lead to a better response to people's needs and improve community health outcomes (8, 14).

These principles apply today, however in many countries' implementation is still lagging and health inequities will continue unless specific actions are taken to improve the relationship between health care providers and their patient populations. This could be achievable, as some countries with primary health care inspired by Alma-Ata were able to achieve better health outcomes such as Chili, Cuba, Ethiopia, Nepal, Rwanda and Sri Lanka (14). The reason for success could be cultural as most of them are considered collectivist societies and given that these countries are of low socio-economic level, meaning that specialized medicine might not be an option and this model could work for them and not for others (57).

The Western health system remains resolutely biomedical in its approach to diagnosis and treatment, often slow to adopt the new institutional responsibilities and cultural shifts required to address indirect causes of poor health (4-6, 15, 16). Statistics on recurrent visits to PC clinics remain elevated, suggesting that the underlying social causes of disease were not addressed, and patients remain in the same social situations, living conditions, and unhealthy environments (16).

Thus, the readiness of primary health care physicians to address social determinants of health is essential to the success of multidisciplinary health interventions (58).

6.4 Addressing social determinants of health in high income Western OECD countries

Numerous studies in western contexts address social determinants of health (SDH) in primary health care. These studies include ones that document physicians' perception of addressing SDH, research on community-oriented action, surveillance and screening as well as studies exploring the incorporation of SDH training and education into the health and medical education curricula.

6.4.1 Physicians' perceptions of addressing social determinants of health

There are many perceptions physicians hold about SDH. Some physicians consider issues such as domestic violence, poverty, and unemployment to be beyond their scope (16). Physicians report being untrained or unqualified to address their patients' social causes of poor health (16). In 2011, 87% of American physicians in an online survey were aware of social causes being directly related to poor health, yet only 20% felt comfortable discussing these causes with their patients, citing heavy turnover of patients and lack of manpower (59). The unwillingness of physicians to address SDH may be due to their lack of training and not stemming from stark negligence.

Another perception concerns financial constraints. A similar study in Switzerland showed general practitioners were not concerned with the patient's ability to pay for the consultation fees and did not think it was their role to address issues such as material and social deprivation (60). This is not surprising given that the Swiss healthcare system is government-funded (61). As a result, cost of care is not a prominent issue that Swiss general practitioners deal with. In instances where physicians do take action, a 2005 qualitative study in Belgium explored how general practitioners can assist patients in precarious social situations (62). Interviewed general practitioners gave examples of multiple approaches used to support their marginalized and underserved patients in practice such as, showing more sympathy, reducing the cost, postponing

the payment, waiving fees, arranging coordinated referrals to specialists, and requesting help from other healthcare providers or social caregivers (62). Unlike the Swedish healthcare, in Belgium patients have a variety of healthcare options and insurance; therefore, the inability to pay for health services contributes greatly to how social determinants of health is conceptualized in Belgium (62, 63).

Dealing with a demanding workload influences how physicians perceive SDH. In 2012, the Canadian Medical Association interviewed 32 physicians from various specialties including family medicine; public health, psychiatry, emergency medicine, and pediatrics to explore actions physicians take to help address the social needs of their patients within their practice (64). The most common reported barriers in doing so were time constraints, knowledge deficiencies, lack of skills and training pertinent to socially sensitive situations, and the deficiency in evidence-based research on useful interventions or tools tailored to the needs of practitioners (64). These opinions must be considered in the Canadian context where a shortage of physicians (228 physicians per 100,000 population) puts unreasonable demands and leads to physician burnout (65-67).

Despite the growing movement towards a holistic approach to care, physicians' ways of thinking still draw on a narrow biomedical model (68). A 2014 study found that in 90% of patient encounters, physicians had missed opportunities to empathize and instead focused their time and energy on biomedical inquiry and offering medical explanations (69). In a 2015 study of patient experiences, more than 40% of participants reported their family doctor was unaware of their daily struggles such as having enough food to feed their family, arranging transport to clinic visits, and paying for medications (70). Therefore, it is evident that medical education is still underpinned by a scientific approach to illness and that steps taken towards the adoption of other models and approaches are insufficient, despite the advocacy of holistic approaches by the WHO (7, 12).

6.4.2 Approaches to increase physician action on social determinants of health

Beyond physicians' perceptions, research on actions taken to address social determinants of health began to get implemented. Such initiatives included surveillance and screening, community-oriented action, training and the education of physicians.

6.4.2.1 Surveillance and screening

One way that social determinants of health are addressed is through surveillance and screening of patients in primary health care settings for social causes of poor health. Recently in the United States, Medicare and Medicaid began accepting proposals for projects to identify the outcomes of community screening for social needs with referral to community resources (71). Private organizations including the Robert Wood Johnson Foundation launched campaigns to normalize a socially conscious health care culture (72). Other major foundations such as the National Quality Forum and the Institute of Medicine have called for data collected in the electronic health records systems to include social history questions, both for clinical care as well as surveillance and research purposes (71). Another pilot study at the University of New Mexico created the 'WellRx' instrument to screen 3,000 patients at three different family medicine clinics (73). The 11-question survey asked about housing, income, food insecurity, employment, transportation, and other social domains (73). Many patients had more than one social need, and community health workers used the data to better connect patients with available resources and services in their local area (73). A cluster randomized controlled trial in eight community health centers in Boston, Massachusetts, found that systematic screening for social determinants of health during well-child visits increased physician referrals and family enrollment in supportive agencies, as well as increasing the number of children with access to childcare (74). Similarly, in Canada, at the University of Toronto, Andrew Pinto and colleagues created a 14-item screening tool integrated with the electronic health record system, allowing patients to answer potentially sensitive questions about their social situation in a less pressured and more confidential way. Several jurisdictions in the Toronto area have mandated the use of a modified version of this screening tool for socio-demographic data collection (75).

6.4.2.2 Community action

Another way social determinants of health were addressed was by community-oriented primary care and partnerships with public health and community organizations, aiming to deliver primary care services that improve health and support to defined disadvantaged populations (76). Current literature supports guidance for physicians in promoting broader community action and creating supportive environments for health. In the United States, a study in San Antonio, Texas showed a community-oriented approach in primary care, hiring health promoters acting as 'cultural brokers' between patients and physicians and helping to map out resources in the local community resulted in a 24% decrease in hospital admissions (77). A challenge with this approach is determining who qualifies as a cultural broker. While this solution might have some merit in a Western society, it may not have the same success in a non-western society. In a conservative Arab society, patients are reluctant to share sensitive information regarding social determinants of health to their primary health care physician (23). Including a third party "cultural broker" who belongs to the same community may be considered an intrusive invasion of privacy rather than a gateway to further tailored help.

Another randomized control trial from the UK, involving primary care patients with psychosocial issues, found referral to community-based support groups (e.g. local social group for elderly and womankind) via a liaison organization "the Amalthea Project" reduced patient anxiety and improved overall perception of health in comparison with usual primary care practice (78). Development of such support groups requires a sizable investment in infrastructure, by establishing support organizations, securing necessary funds and identifying needed resources.

6.4.2.3 Training and education

In the United States, training programs including community tours for medical students, to familiarize them with the populations they will serve, have also improved attitudes, skills, and competency in addressing social determinants of health within clinical practice (79-81). Another study demonstrated a video tutorial, on how to screen and refer domestic violence patients, increased pediatric interns' comfort in discussing social determinants of health (80). A similar

observational study found that social history taking and subsequent referrals to community resources improved after an educational intervention in the form of an introductory course in the medical curriculum on social determinants of health. It also increased the intervention group's level of comfort and knowledge on social determinants of health and the locally available community resources (81). In Australia, 'Learning by Doing' approach was part of the New South Wales Health Impact Assessment Project. It includes formal training, access to resources and technical support, and continued building of consensus on the scope of health impact assessment (82).

These modest efforts are sporadic and performed at single institutions. Social determinants of health and how to address them in the clinical setting should be incorporated in the horizontal medical education curriculums, whereby future physicians can appreciate the complex nature of social determinants of health across clinical specialties. Currently, the learning outcomes with regards to social determinants of health are unclear and do not align with the competency-based approach adopted by the Royal College of Physicians and Surgeons (83).

6.5 Addressing social determinants of health in the EMRO Region

Addressing patients' social determinants of health is still in the process of being meaningfully embraced in the Middle East (17) and only a small number of articles published in the Eastern Mediterranean region call for adoption of a biopsychosocial approach in medical education and promoting the role of health workers in addressing the social determinants of health more broadly (18-22). The majority of publications look at social disadvantage in terms of specific areas of focus, such as domestic violence or child abuse (18-22). Although the report specifies women empowerment and gender equity, it does not tell us how to empower them (18). In the EMRO region and GCC regions it would seem that improvement of social determinants of health as a whole hinge on empowering women. For example, women patients and their children may be victims of domestic violence, food insecurity, unemployment, social exclusion, and illiteracy not from lack of resources in the society but because of limited and monitored access to said resources. Given the skewed power structure between men and women, men can influence a family's access to food, healthcare, education, and employment. By addressing the power imbalance, social determinants of health can be addressed in a contextual manner.

As in western contexts, social determinants of health in the EMRO region were studied via Demographic and Health Surveys. The Pan Arab Project for Child Development (PAPCHILD) and national public health expenditure surveys, provide information on child labor and adolescents in Egypt and Morocco (17). Although Egypt has censuses and national surveys, data linking measures of health with measures of social conditions or disadvantages are not available (17). In Morocco, in addition to the PAPCHILD survey, the Pan Arab Family Health Survey (PAPFAM) focuses on maternal and child health, and reproductive health (17). Both surveys focus on prevalence, and neglect the nuances of social determinants of health, which can be addressed through qualitative studies. Undertaking qualitative studies will uncover the common social determinants of health in a context such as Morocco and within the influence of the dynamic interplay between physicians and patients.

In Pakistan and Afghanistan, a systematic review on effective gender-based violence screening tools for use in primary health care settings assessed which tools would be most effective in the local setting and concluded that the Woman Abuse Screening Tool (WAST) or the Ongoing Violence Assessment Tool (OVAT) would be the simplest and most appropriate in this cultural context (84). Another article described the development the Karachi Domestic Violence Screening Scale (KDVSS), a useful tool for helping physicians identify and address physical, psychological, and sexual abuse victims (85). Given the religious similarities, the use of such tools may be of benefit. Therefore, studying their effectiveness in a Saudi context is a logical next step.

6.5.1 Addressing social determinants of health in the GCC Region

Unlike western contexts, the discourse on social determinants of health in primary health care in the Gulf Cooperation Council (GCC) region has been deficient and initiatives such as community action have not been researched or implemented. Some studies conducted in the GCC region (Saudi Arabia, Kuwait, Qatar, Oman, United Arab Emirates and Bahrain) identify their patient's social causes contributing to poor health. However, solutions lag behind because of cultural barriers (19, 20). These cultural barriers can be individual or organizational.

At the individual/physician's level, hurdles faced were similar to those encountered by western physicians. Like western physicians, those practicing in the GCC were aware of social determinants of health, but they lacked the appropriate training to deal with them. In Kuwait, violence against women was identified as one of the main social challenges studied within a primary health care setting. One study examined the knowledge and attitudes of primary health care physicians in screening for domestic violence (20). The researchers found that while 62.5% of primary health care physicians were aware of domestic violence as a health concern, only 34.7% regularly screened for violence among their female patients (20). Alotaby et al. identified potential barriers faced by physicians including insufficient training skills and lack of staff to arrange for actions needed when domestic violence is identified (19). Another study found that over two-thirds learned about domestic violence "on the job" and less than a third of the participating physicians obtained their knowledge and skills in how to manage cases of domestic violence from the scientific literature or from formal education, including medical school, postgraduate training, continuing medical education and conferences (22).

On the other hand, GCC physicians experienced unique personal reservations: Physicians felt embarrassment when addressing social determinants of health, fearing family members reactions (who influence access to care). Some physicians were skeptical of the importance of screening (19). In addition, physicians possess certain opinions and prejudices based on their own upbringing, culture and religious beliefs. These biases are likely to affect their professional behavior including their intention to ask about and address social causes of poor health (19). A noteworthy study on gender issues found female physicians had a higher positive attitude score on screening for and managing situations of domestic violence compared with their male counterparts (18). The contrast between a patient's receptiveness towards male and female physicians is important given the gender dynamics in such a context. Women may perceive other women as belonging to their in-group and would understand their struggle better than male physicians. The collective nature of GCC societies also influences child health. In Bahrain, a cross sectional descriptive study among physicians revealed an acceptable level of awareness of clinical presentation and risk factors of child abuse. Hesitation of reporting child abuse was mainly

attributed to a desire to avoid conflict with the family and to a lack of knowledge on legal reporting mechanisms that would not jeopardize the safety of the child (86).

At an organizational level, health administrators report lack of knowledge on legal action and their limited authority and lack of governing policies as barriers to care (19). The bureaucratic structure of healthcare systems may explain the organizational hindrances faced by health administrators. Additionally, these findings shed light on the influences beyond the clinic and physician's preparedness. Such influences must be taken into consideration when addressing social determinants of health. For example, how will physicians mitigate such organizational hindrances and how will they address SDH beyond the boundaries of their clinics.

6.5.2 Addressing social determinants of health in the Saudi Arabian context

Literature on how primary health care in Saudi Arabia addresses social determinants of health is limited. Social determinants of health are often sensitive topics, and this is a disincentive for physicians inquiring about them, especially in Arab societies that do not naturally foster open conversations and policies addressing social determinants (23). The definition of primary health care (PHC) physician is context dependent. In the Saudi context, PHC physicians are: General Practitioners and Family Medicine physicians or family doctors. The former is an MD graduate with no postgraduate training while the latter is a board-certified practitioner that has undergone a 4-year postgraduate training program (25). Several factors affect the way a consultation takes place in a primary health clinic, these factors could be related to the level of training and background of the physicians.

This atmosphere, compounded by the conservative culture of Saudi Arabia, may also inhibit patients from honestly addressing their situations in current health care environments, an issue that may be improved by the integrative training and practices that focus on physician awareness and action (21). Barriers to health such as poverty, domestic violence, discrimination, and lack of social support may be embarrassing for the patient to discuss and inappropriate topics for physicians to address unless properly broached (21, 23). For example, female Saudi patients

facing issues such as domestic violence may not have access to community services because of cultural restrictions but would benefit from a primary health care center with physicians trained to identify risk factors of domestic abuse (21). Unfortunately, the term "cultural barriers" and "cultural restrictions" are overused in the literature covering social determinant of health without clear and comprehensive explanation of what those terms mean, Moreover, how such barriers manifest themselves in the clinical encounter, and how physicians and patients negotiate treatment in light of them are matters that need to be explored.

A 2015 cross-sectional study of Saudi women attending a primary health care center, in Riyadh, Saudi Arabia identified the common risk factors to domestic violence (younger women, longer duration of marriage, women who have higher educational level than their husbands, inability to bear children, presence of chronic disease in women or husbands, and non-sufficient family income) and the victim's' immediate response to it. The most common reactions to domestic violence were seeking separation (56%) or doing nothing (41%). The author explains that the clinical care provided for patients suffering from domestic violence in primary health care is passive. She strongly recommends providing accessible, effective, and trustful social services to abused women attending primary health care clinics (24).

In line with the Alma Ata Declaration, Saudi Arabia classified the development of PHC as one of the important strategies for providing optimum health care (11, 38). The Saudi Ministry of Health is the main government agency responsible for the supervision of health care services and hospitals in both the public and private sectors in the country. Saudi Arabia has 2282 public primary healthcare centers that provide free care to 23 million people (26, 27, 38-40).

However, several challenges can be identified. The literature on how primary health care in Saudi Arabia addresses social determinants of health remains scant (17, 21, 24). Research efforts, especially those oriented towards action are needed and must be fostered. Indeed, social determinants of health remains a sensitive topic in societies that do not naturally encourage open conversations (23). Consequently, the research gap that remains is not surprising. Another challenge is differentiating the two concepts of PHC and PC. Currently they are used

interchangeably in the EMRO region and particularly in the Saudi literature with no clear demarcation (24, 38, 39, 52). Although in the broader global health context, there is a difference, their interchangeable use may have contributed to the lack of structure and difficulty in implementing primary health care strategies (51, 87).

In addition, social determinants of health in primary health care are addressed separately and the current literature examines one or two social determinants only. This is a gap that will be addressed in this research project. Social determinants of health in primary health care, will be approached in a holistic manner, acknowledging the interconnectedness between the social determinants. Moreover, the bulk of studies is small scale and quantitative utilizing surveys. Although quantitative approaches are highly valuable, they fail to address social determinants of health in a deep manner. A qualitative approach would increase our understanding of such complex interacting social determinants of health.

Beyond the aforementioned challenges, Saudi Arabia is currently investing in improvements in all sectors including the Ministry of Health (37). Plans include increasing the quality of primary health care (37). Saudi Arabia's Vision 2030 was adopted as a roadmap for socioeconomic action in the Kingdom with goals of identifying the general directions, policies, goals, and objectives of the nation (37). To build the institutional capacity and capabilities needed to achieve Vision 2030, the National Transformation Program 2020 was launched in 2016 across 24 government bodies operating in the economic and development sectors. The Ministry of Health was assigned 15 strategic objectives to meet by 2020 (37). One of the objectives is to improve integration and continuity in service provision by strengthening the primary health care system into a full-scale family practice model (37). The Ministry of Human Resources and Social Development is also a key player in the national transformation program, several social safety nets or programs are now underway to support and empower less fortunate individuals by helping with their educational ambitions and there developing competencies and skills to prepare people to enter the labor market and take advantage of existing and future employment opportunities (37). Saudi Arabia is a unique non-Western hybrid as it is considered a high-income country (88), with a GDP of 700 billion US\$ and has the largest economy in the Middle East, Saudi is also a member of the G20, making it a global economic influencer, as a result, it is a key player in determining the future direction of the healthcare sector (the second largest sector globally) (88). Therefore, it is in the interest of the country to adopt effective and efficient healthcare practices that make economic sense both locally and globally.

As outlined previously, there is an immense need for research tackling social determinants of health In PHC settings. This need must be addressed within the context of current reform in government and healthcare systems. The proposed research must take into consideration how a potential change in health care model may influence research findings.

6.6 The role of primary health care in addressing social determinants of health

At the core of the Commission's recommendations is research-generated evidence of effective strategies for combating health inequity through action on the social determinants of health, including via health provider training programs (7). Addressing health equity through a social determinants framework is a longstanding investment requiring gradual and careful development of systems by implementing pilot projects of process and impact evaluation crucial for the future scale up of these projects at the national and international level (89). As a result, a project addressing health determinants in PHC at this point in time is paramount because it may grow parallel to governmental efforts.

Translating evidence-based interventions into routine clinical practice is complex because it requires physician behavioral change (90). Healthcare is delivered in the environment of an encounter between a physician and a patient, making clinical behavior an important proximal indicator of the quality of care their patients receive (91). Several studies have demonstrated that Continuing Medical Education (CME) positively impacts physician performance and patient health outcomes, particularly when this is interactive, involving a myriad of learning resources, is longer, and focusing on outcomes considered important to physicians (92). Thus, for the success of any intervention focusing on changing behavior, an assessment of physician-perceived barriers and of the impact of improved performance in real life scenarios is necessary (93).

6.7 Clinical practice tools on addressing social determinants: The CLEAR toolkit

The Commission's 2008 report identified an urgent need to develop low-cost, accessible training materials such as clinical practice tools and guidelines that can help physicians identify and act on a broad range of social determinants of health in routine clinical care (7).

There has been a great deal of recent literature on different strategies developed and tested to take action on social determinants in clinical care, though these are largely developed and used in western, high-income country contexts. In addition to approaches already mentioned earlier on in this chapter, there has been a growing interest in the development of surveillance and screening tools to identify social determinants in clinical care. For example, in North America, clinical tools have been developed for this purpose such as the HealthBegins screening tool, the Mosaic Medical Patient Navigator tool, the Kaiser Permanente Screening tool called "Your Current Life Situation," the PRAPARE tool (Protocol for Responding to and Assessing Patient Assets, Risks and Experiences) PRAPARE-plus, the Poverty toolkit developed at the University of Toronto, and so on (94). In the UK, New Zealand and recently Australia, social prescribing via "Link Workers" has also garnered much attention as a way of addressing the social determinants of health in clinical care (95).

However, most of these strategies are time-consuming to use and include lengthy checklists that need to be filled out either by healthcare providers or by patients themselves. Some also lack information on the local resources available to support marginalized patients when these social determinants are identified, as many of these tools are used mostly for data collection purposes, rather than for taking action on social determinants directly and assisting patients in clinical care. Therefore, to successfully implement a clinical practice tool with busy health workers in primary care settings, the tool needs to be physician-friendly, and focus on more than a single social determinant, such as income or ethnicity, since very often, many of these determinants cluster together and must therefore be addressed simultaneously (96, 97).

In light of this, in 2010, a group of international researchers created the CLEAR toolkit (43, 97, 98). This is a more multi-dimensional, practitioner-focused clinical decision aid that considers a large number of social determinants simultaneously, as well as being action oriented, by suggestion where clinicians can refer patients for support. It is a simple and easy to navigate tool that can addresses the social determinants of health in clinical care in a four-step approach: a) treating the immediate health problem, b) asking about underlying social problems, c) referrals to local social support services, and d) advocating for more supportive environments (43). Primary health research conducted in Brazil, Bangladesh, Niger, and Pakistan, as well as an extensive review of the scientific literature and multiple rounds of consultations with experts and frontline health workers around the world, was used to create the CLEAR toolkit, which helps frontline health workers assess aspects of patient vulnerability in a culturally appropriate way while concurrently identifying local resources for patients (43). Thus, in 2015, descriptive research adapted and refined the toolkit to local community settings in Montreal, Canada (97). The study found physicians who knew how to ask about social challenges were more likely to report helping their patients work through these issues. Access to a user-friendly, locally adapted directory or referral list that physicians can use can help them better support their patients. The CLEAR toolkit is therefore a practical approach to facilitate the clinical encounter between a physician and a patient relating to social determinants, it has been translated into over a dozen languages, can be easily adapted to local contexts and can be easily shared on mobile applications with its appealing graphics (43,95).

7 Knowledge gaps and study rationale

Despite growing attention given to social determinants of health internationally over several decades, how to take action on social determinants in clinical care is an area that is undergoing rapid development, and there are relatively few intervention studies that clearly demonstrate improved health and social outcomes of one approach over another. The literature review discussed how social determinants of health are currently addressed largely in western, high-income country contexts, but much less is known about non-western, or low- and middle-income country contexts: such as the GCC region within the broader EMRO region.

Primary health care traditionally partners with patients, communities, and public health professionals to address social determinants of health, yet the ability to systematically act on the social determinants of health in PHC settings has been constrained by institutional expectations and responsibilities, as well as the lack of training and role-modelling in medical curricula, and the slow uptake of cultural shifts in medicine that would be required to routinely ask about and address the social causes of poor health in clinical care (4).

Addressing patients' social determinants of health is therefore still in the process of being meaningfully embraced in the Middle East. There is an evidence-practice gap whereby a narrow biomedical approach in primary health care remains despite growing international concern about social determinants of health. Recent non-experimental research in other settings suggests it might be possible to influence frontline health workers' perception and assist them to address social determinants of health as part of routine clinical practice (8, 43). Yet, little formal literature has appeared on the relationship between PHC and SDH in Saudi Arabia, and particularly on intervention research, highlighting the need for more research in this area.

The CLEAR toolkit was identified as an example of an intervention that could be used as a catalyst at the clinical level, as part of a larger medical and systems culture change that is needed, and it complements high-level documents like the Astana and Alma Ata declarations that call for inclusion of social accountability in accreditation standards, clarifying interprofessional roles and responsibilities, and developing incentive systems such as linked remuneration of health workers for specific clinical practices that encourage action on SDOH in clinical care. The CLEAR toolkit can therefore be used as a "prompt" for health workers, signaling that taking action on social determinants is considered part of the primary care role, and encouraging health workers to consider the "whole person" in diagnosis and management – the physical health, the mental health and the social well-being of the patient, but in itself, a simple clinical tool is not the only answer, rather the CLEAR toolkit is part of a larger movement and culture change that is occurring in the field of medicine more broadly.

To date, there have been no empirical studies on changing physician behavior to take action on social determinants of health in Saudi Arabia. Social determinants of health remain closely linked with subtle cultural and social norms, underlining the importance of conducting research in context to foster an in-depth exploration of how these factors play a role in facilitating or hindering behavior change. This study will therefore provide a starting point for developing future streams of research on the social determinants of health in Saudi Arabia, and for identifying prospective training needs and support systems to improve the ability of primary health care physicians to ask about and help patients in navigating their social challenges in the future.

8 Hypothesis and overall aim

The hypothesis underlying this doctoral dissertation research is that increased awareness of the challenges of adopting a social determinants of health approach in primary health care, and knowledge of effective strategies for overcoming these barriers can equip primary health care physicians with the tools and skills necessary to support marginalized patients, enhance collaboration within disparate health and social care systems, and encourage cooperation of local stakeholders in developing evidence-based, and locally-adapted strategies for addressing complex health and social problems (8).

The proposal aimed to examine widely held cultural norms within Saudi Arabia may promote or hinder the willingness of primary health care physicians to take action on the social determinants of health. Preliminary data was gathered to adapt an educational tool that can promote awareness on social determinants of health in a Saudi primary health care setting. With a translated and culturally adapted educational tool, we aimed to assess the educational intervention's feasibility, acceptability and evaluation methods. These findings can then be used in future to design a larger cluster randomized controlled trial in this setting, and also be adapted for use to test similar initiatives in other settings (98).

9 Research Questions and Objectives

9.1 Research Questions

9.1.1 Qualitative research

What are Saudi primary health care providers' (primary health care physicians and clinical social workers) views, current culture of practice and their perceived barriers and facilitators on addressing patients' social causes of poor health in a clinical setting?

9.1.2 Quantitative research

In a population of Saudi primary health care physicians, can a translated and locally adapted educational online intervention improve their knowledge, empathy and behavioral intention to adopt a social determinant of health approach in clinical care?

9.2 Study Objectives

9.2.1 Qualitative study

4) To explore Saudi primary health care physicians' views on addressing their patients' social causes of poor health, current culture of practice where they work, and their perceived barriers and facilitators in asking about and managing their patients' social challenges in clinical care.

b) To explore Saudi social workers views and perceived barriers on addressing patients' social causes of poor health within a primary health care space, identify locally grounded ways of asking about social challenges in the Saudi context, as well as mapping out the network of local support resources available for socially marginalized and underserved patients.

c) To culturally adapt an existing educational online intervention (CLEAR toolkit) and data collection tool (questionnaire) based on the Saudi primary health care providers' feedback.

9.2.2 Quantitative study

To determine the feasibility and acceptability of evaluating an educational online intervention to improve Saudi primary health care physicians' knowledge, empathy and behavioral intention to adopt a social determinant of health approach to clinical care with a view of informing a full-scale cRCT.

9.2.2.1 Feasibility

- Assess feasibility of the intervention (practicality of implementing an online self-administered and physician friendly tool, content and methods of delivery, costs)
- Assess feasibility of the evaluation, study design and procedures (eligibility criteria, randomization and blinding, agreement to randomize, recruitment rate; response rate)

9.2.2.2 Acceptability

- Assess the acceptability of the intervention (primary health care physicians' views of the intervention, examining attrition and adherence)
- Assess the acceptability of the evaluation design and procedures (data collection, timeline)

9.2.2.3 Outcomes

- Document primary outcome measures and likely direction of outcome measures, covariates, variances and intra cluster correlation (ICC) to determine sample sizes in the planning of a subsequent cRCT

10 Conceptual Framework

This implementation and evaluation research is grounded in the specific culture and context of Saudi Arabia's primary health care system (99). Evidence-based practice also requires

behavioral change, presenting a substantial challenge. A systematic, theory-based approach can identify specific elements in changing clinical practice, allowing objective assessment of changing clinician behavior (100). The Theory of Planned Behavior (see **Figure 1**) is a widely used framework to help increase clinician uptake of evidence-based practices. This theory is broken down into non-overlapping and simple psychological/behavioral constructs about what guides human behavior (41), suggesting that attitudes towards the behavior, subjective norms, and perceived behavioral control influence behavioral intention to change and that the latter is a strong predictor of future behavior. Figure 1 illustrates how we used this behavior change model to identify Saudi clinician's perceived barriers and enablers to the integration of a socially conscious approach within primary health care, and to determine the effectiveness of an educational intervention in creating the conditions for widespread change in the culture of practice.

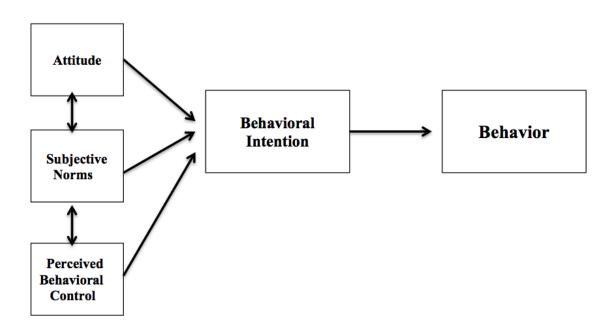


Figure 1. Theory of Planned Behavior (41)

To guide our empirical understanding of social determinants of health in Saudi Arabia and their effects on population health, we adopted the WHO's conceptual framework for action on SDH, which takes note of the specific theories on the social production of health and disease (42).

This framework categorizes the SDH into three distinctive but interlinked classes: (1) structural determinants or social determinants of health inequities i.e. (socioeconomic and political context, socioeconomic position) (2) intermediary determinants i.e. (material circumstances, behaviors and biological factors, psychosocial factors and health system) and (3) cross-cutting determinants such as social cohesion and social capital (see **Figure 2**) (42). The conceptualization of marginalization within the SDH framework allows us to appreciate not only individuals' vulnerabilities but their resilience as well, thus allowing us to explore their experiences in how they cope with stress and adapt to social change (42, 50).

The WHO's conceptual framework on social determinants of health illustrates the complex relationship between the various elements influencing the social, economic and political determinants of health. In regard to structural determinants, individuals within populations are stratified based on income, education, occupation, and gender. Context is in the case paramount as it generates social hierarchies i.e. educational system and maintains them. It is important to mention that the presence of policies or their absence can result in disadvantaged socioeconomic positions. As for intermediary determinant include material circumstances such as housing, psychosocial circumstances such as social support, behavioral and biologic factors such as nutrition and physical activity. What sets CSDH apart from previous frameworks is the conceptualization of the health system as a social determinant of health.

The use of both frameworks described above in the research allowed them to complement each other and look at different levels of barriers when addressing patient's social determinants of health in primary health care. The Theory of Planned Behavior focuses on the physician's perceived barriers as an individual, whereas the WHO's conceptual framework recognizes the organizational and health system structural barriers within primary care practice.

SOCIOECONOMIC AND POLITICAL CONTEXT Governance Socioeconomic Material Circumstances Macroeconomic Position (Living and Working, **Policies** IMPACT ON Conditions, Food **EQUITY IN** Availability, etc.) Social Policies **Social Class** HEALTH Labour Market, Gender Behaviors and AND Housing, Land Ethnicity (racism) **Biological Factors** WELL-BEING

Social Cohesion & Social Capital Psychosocial Factors

INTERMEDIARY DETERMINANTS

SOCIAL DETERMINANTS

OF HEALTH

Health System

Figure 2. Commission on Social Determinants of Health Conceptual Framework (42)

11 Research Methodology

STUCTURAL DETERMINANTS

SOCIAL DETERMINANTS OF

HEALTH INEQUITIES

Public Policies ducation, Health,

Social Protection

Culture and

Societal Values

11.1 Methodological overview and relevance of using a mixed methods approach

Education

Occupation

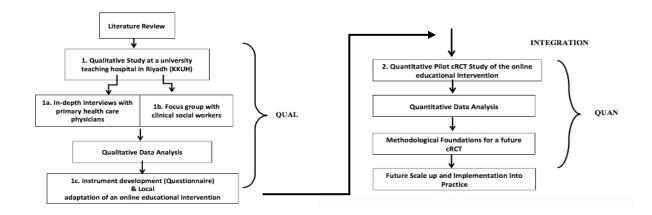
Income

A mixed methods approach was appropriate to address research questions that ask about real-life contextual issues, including cultural influences and perspectives, and thereby drawing strength from each method while minimizing characteristic weaknesses associated with each method alone (99). A sequential exploratory design was specifically chosen because the qualitative scope of this approach served the purpose of complementarity and enabled us to capture a comprehensive picture of the reasons that guide Saudi primary health care providers in asking about and managing patients' social challenges within clinical practice and the cultural and societal factors that influence their practice behavior. This prepared a platform to document the possible need and context for an educational intervention in the following quantitative phase and evaluated whether the proposed intervention would likely work in real-life situations and conditions (101).

The first phase, a qualitative descriptive study, used in-depth interviews with primary health care physicians to understand their current culture of practice and role in addressing patients' social determinants of health and to explore their perceived barriers and facilitators to managing patients' social challenges within established norms of Saudi clinical practice. A focus group study with social workers, who already play active roles in patients' welfare, served to better understand societal key barriers to addressing social determinants of health in a Saudi primary health care setting, to identify standard referral pathways and processes between providers and to map out the network of local support resources available for patients. The qualitative constructs generated from the first phase informed the development of a data collection instrument (i.e. questionnaire) and the local adaptation of an educational intervention, which was also used in the follow-on quantitative study (101, 102).

The second phase involved a pilot cluster randomized controlled trial (cRCT), which we started by testing the feasibility and acceptability methods that can be then used to test the impact of the proposed educational online intervention on primary health care physicians' knowledge, empathy and behavioral intention to routinely ask about and address their patient's social determinants of health in primary health care settings (98). The pilot study will therefore provide the methodological foundations necessary to inform the proper design of a future full-scale cRCT (98) (see **Figure 3**).

Figure 3. Description of Research Methods



11.2 Qualitative phase

A qualitative descriptive approach is the most appropriate methodology for exploring a complex phenomenon about which little is known (103), such as Saudi primary health care physicians' experiences in caring for socially marginalized and underserved patients and how they currently address social determinants in clinical care. To triangulate and develop a more nuanced and multi-faceted understanding of how social issues are addressed in the primary health care space, the qualitative study consisted of two parts that seek to understand the views from two key perspectives: a) in-depth interviews with primary health care physicians, and b) a focus group with clinical social workers working in primary health care and supporting the family medicine unit within a large university teaching hospital (104).

11.2.1 In-depth interviews with primary health care physicians

11.2.1.1 <u>Setting</u>

The study was conducted at King Khalid University Hospital in Riyadh, Saudi Arabia. This public teaching hospital provides primary and secondary care to low- and middle-income patients in the northern part of the city. It includes a large family medicine unit with key collaborators in the Department of Family and Community Medicine who assisted in facilitating this study.

11.2.1.2 Study population

The study population consisted of primary health care physicians working at King Khaled University Hospital. Individual interviews with physicians will help reduce cultural, disciplinary, and gender-related tensions and allow participants to speak freely in a confidential atmosphere conducive to sharing personal information and beliefs that might be repressed in the presence of colleagues. In Saudi, primary health care physicians are considered the frontline health workers, and they are divided into two main categories: Family Medicine Physicians and General Practitioners (39). Family Medicine Physicians are board certified practitioners that have undergone a four-year postgraduate specialty training, during which they learn to manage a wide range of acute and chronic physical health and psychosocial conditions that are prevalent in family practice. Conversely, General Practitioners do not undergo any specialty training after completing their medical studies and tend to work in primary health care outpatient-clinics and walk-in clinics in teaching hospitals such as King Khalid University, as well as non-hospital based local community primary health care centers funded by the Ministry of Health. Both categories of primary health care physicians were included in this study and only junior clinical residents with less than three years of experience were excluded.

11.2.1.3 Sampling and recruitment

A maximum variation purposive sampling approach was used to recruit participants with a wide range of ages (i.e. under 30 years, 30-49 years, 50 years and over), duration of work experience (i.e. still completing training, less than 5 years, 5-19 years, 20 years and more), gender (i.e. male, female) and nationality (i.e. Saudi, non-Saudi) to obtain a wide range of viewpoints (103). By having these different groups in the study sample, we were able to explore whether there are differences between older versus younger generation of health workers, between genders and between Saudi and non-Saudi-trained physicians, as well as to appreciate how language and culture may affect perceptions and actions relating to the social determinants of health in clinical care. Physicians were recruited via email invitations that explain the study's purpose and what participation in the study entails (Appendix 1.1). Mobile text invitations were also sent to all

primary health care physicians working in the Department of Family and Community Medicine at King Khalid University Hospital. Active recruitment stopped when data saturation was reached, where "no new information was observed and no new themes emerged in the data", in total, 17 interviews.

11.2.1.4 Data collection

After receiving confirmation of participation, an interview schedule was organized. Interviews were conducted in person and took place in quiet and confidential settings such as offices or private conference rooms at the hospital. Prior to commencing the interview, informed consent and permission to audio-record was obtained from the participants (Appendix 1.2).

Audio-recording reduced the potential bias resulting from poor notes or gaps in the memory of the interviewer. In addition, the recording helped us to provide a detailed account of the participants responses and a verbatim transcript for analysis. Data was collected using a semi-structured interview guide with open-ended questions informed by the Theory of Planned Behavior (41, 103) and formulated to explore the following constructs: primary health care physician's roles and experiences in providing care to socially vulnerable patients, views on addressing patients' social causes of poor health in their clinics, perceived barriers and facilitators to taking action, and knowledge about the available local resources and support organizations for these patients (Appendix 1.3). The interview guide was first piloted with two local Saudi clinician-researchers and the content was adjusted prior to using the interview guide in the study (105). Individual interviews allowed participants to speak freely in a confidential atmosphere conducive to sharing personal information and beliefs that might be repressed in the presence of colleagues or peers (105). The interviewer facilitated a more active dialogue and allowed room for elaboration by using probes and verbal prompts (105). Interviews lasted on average between 30-40 minutes each.

11.2.1.5 Data analysis

Interview recordings were translated and transcribed verbatim from Arabic to English. The transcripts were analyzed as described by Crabtree and Miller using a thematic analysis approach (106, 107). The data analysis process was done manually without the use of analysis software and entailed preparing the data using individual themes as the unit of analysis and developing categories to create a coding scheme to enable the transparency of variations across the categories. Further analysis techniques included coding the whole corpus of text, reassessing the consistency of the coding, and finally making sense of the themes or categories identified. This helped improve rigor and relevance while helping us understand the social realities of Saudi health care (108).

11.2.2 Focus group with social workers in primary health care settings

11.2.2.1 <u>Setting</u>

As part of the multistage qualitative data collection process, a follow-on focus group was conducted with clinical social workers working at King Khalid University Hospital's primary health care clinics. This allowed us to better understand in-depth, and from an alternate viewpoint, the dynamics within the same clinical practice environment.

11.2.2.2 Study population

Clinical social workers are trained to work with patients in health care settings and are valuable in finding solutions for marginalized and underserved patients they are continuously in contact with, thus bridging the gap between physicians and patients. Social workers are also able to access to data on the referral agencies (NGOs, Ministry of Social Affairs, etc.) available for such patients, facilitating an understanding of the local Saudi framework. This partnership also strengthens the relationship between the public social services and healthcare system, engendering a shared level of responsibility and a more complete approach to care for patients. Focus groups have the potential of producing considerable amount of information in a shorter amount of time (109).

While focus groups are not as confidential as individual in-depth interviews, focus groups and 'formal natural groups' are useful for reflecting the social realities and knowledge (109). Exploring a culturally homogenous group such as social workers at the same teaching hospital allowed a more open dialogue about shared work experiences, content information about the local referral organizations, and suggestions for improvement on service delivery for marginalized and underserved patients (110).

Including their input in our qualitative study helps us better understand social workers' perspectives on addressing the social challenges of patients presenting to primary health care physicians in clinical care. Clinical social workers included in the study, work in the hospital's primary health care clinics and those staffed in other departments of the hospital (e.g. Obstetrics and Gynecology, Oncology, General Surgery), thus embodying diverse viewpoints within the field of social work. Clinical social workers-in-training (interns) and those with less than 2 years of experience were excluded from the study.

11.2.2.3 Sampling and recruitment

Similarly, a maximum variation purposive sampling technique was used to identify a diverse group of clinical social workers with different genders (i.e. male, female), duration of work experience (i.e. less than 5 years, 5-9 years, 10 years and more), and work experience outside the university hospital setting (i.e. university hospital experience only, previous experience in primary health care settings outside the university hospital) to obtain a wide range of viewpoints (109, 111). Email invitation letters were sent that included information about the study's purpose to the head of the Department of Clinical Social Work at King Khalid University Hospital (Appendix 2.1). The assistance of a senior member of the department sought provided a list of contact numbers and emails that were used to assemble a purposeful sample of potential participants to be recruited for the study. Because the university hospital has a total of 37 social workers, we opted to have 4-6 focus groups of 6-12 members in each group (109, 111). However, we only managed to have one focus group of four participants. Stewart and Shamdasani (112) suggest that there are no

general rules as to the number of focus groups in qualitative research and that one focus group may be enough. However, it is often more about data saturation and the range of topics discussed in a group setting (109, 110, 112).

11.2.2.4 Data collection

The focus group was conducted in person and took place at the hospital in one of the offices at the Department of Clinical Social Work. Participants completed the informed consent forms and gave permission for audio recording (Appendix 2.2). A semi-structured focus group interview guide was used to collect participants' input on the following areas: the most common social challenges faced by patients presenting to primary health care clinics, the social workers' perceived barriers to addressing social challenges in a clinical setting and how to overcome them, the current referral process to social work, and the existing network of local community resources for patients with social challenges in Riyadh (Appendix 2.3).

11.2.2.5 Data analysis

The focus group recording was transcribed and translated in a similar approach as described above for Study 1a, involving a thematic analysis with a pre-established deductive frame as well as by an inductive approach (106, 107). The complete dataset was coded to categorize and identify emerging themes, which were then grouped on the basis of similarities, differences, and participants' key phrases (107). We reported the findings by using the themes that emerged from this study which relate to the research questions. The findings of this stage are presented in the "Results" section (Manuscript 1). Establishing trustworthiness in qualitative research is the hallmark of evaluating research findings (113). In a naturalistic paradigm, the researcher wants to demonstrate "truth value" which requires remaining close to the surface of the words and context, allowing the target phenomena to present itself through description rather than through interpretation. Sandelowski confirms that this methodology serves as a great way to explore a complex phenomenon about which little is known, such as Saudi primary care physicians' experience with socially marginalized and underserved patients (103, 113). To support

trustworthiness in this qualitative phase it was important to illustrate the richness of the data and convey it to the reader by an explicit representation of the congruence between the themes identified and the statements made by the participants (114). To ensure rigor, we used the following four criteria to establish trustworthiness in this study (114, 115).

- **1.** *Credibility:* Allowing participants to discuss what they believe is important to maintain credibility and create a sense of partnership when physicians are asked to offer some ideas for improvement. To ensure credibility, member checking was done at the end of the study to confirm the participants findings.
- **2.** *Dependability:* Audit trial and the rich description of the processes and procedures followed to conduct the study provides dependability of the research findings. In addition, the use of overlapping methods, both interviews and focus groups help ensure that the study findings are dependable. Moreover, the researcher conducted multiple discussions with the thesis committee members, who are experts in qualitative research.
- **3.** Confirmability: Steps were taken to ensure as far possible that the findings are the results of what the participants share; that it is their ideas, views and experiences, rather than the researcher's. Therefore, triangulation of data and reflexivity are important methodological aspects of this research project.
- **4.** *Transferability:* Although the notion of transferability is much debated, their remains much effort on the researcher's part, to ensure that the data presented is done in a manner that allows readers to transfer the study method and findings to their own study. Contextual data allows readers to gain a proper understanding of the phenomenon under investigation and to compare the phenomenon described in this study.

To ensure the overall integrity of the study, on-going reflection on the potential biases, maintenance of field notes, member checks to discuss and clarify the researcher's interpretation of the data with participants and peer review of the data (116).

11.2.3 Reflexivity

As an insider researcher, a certain amount trust is present because I identify with the participants' language, culture, shared experiences, and nuanced reactions while also being aware of potential sensitivities. Consequently, I know what to ask and how to ask it thus, encouraging them to be more honest and open with their responses (117, 118). This commonality affords easy access into a population that might otherwise be closed to a non-native researcher who is unfamiliar with the culture (119). Despite the positive effect my position as an insider may have on the participants' responses, caveats such as threats to objectivity and internal bias are possible (120). For example, my familiarity risks participants withholding information they may assume to be obvious to me (121). My own perceptions and biases may lead to an emphasis on commonly shared factors and while overlooking factors that are discrepant (120).

Because these biases may affect the analysis stage of my research, I plan to employ several techniques described in the literature to mitigate any impact. I will continuously and consciously practice self-reflexivity, remaining critical of my positionality and bracketing my own biases and assumptions by keeping a journal/diary, personal log, and audit trial (117, 118). I will also use peer debriefing and triangulation, sharing the data with two other researchers to compare the analysis, ensure a more accurate representation of the themes emerging, and address possible biases (117, 118).

11.3 Mixed methods integration

The combination of findings from the qualitative phase including in-depth interviews with primary health care physicians and focus groups with social workers informed the development of the data collection instrument (questionnaire) and the local adaptation of the educational intervention – the CLEAR toolkit, which was then evaluated in the subsequent quantitative phase. The integration occurred between phase 1 (qualitative phase – instrument development and local adaptation of the intervention) and phase 2 (quantitative phase – pilot testing the locally adapted intervention and instrument), a structure known as integration through *building* in which assessment of the intervention would not be possible without prior adaptation process (101, 122).

11.3.1 Instrument development

Items for inclusion in the questionnaire were built upon the generated themes and qualitative constructs (language used by the primary health care physicians and social workers). Modification of the pool of items on the existing questionnaire was done by using the individual codes within each newly identified theme or domain (not found in the original questionnaire) as the variables, and also by using specific quotes or phrases from the interviews to inform the wording of the new items or questions in the questionnaire (101, 122).

11.3.2 Local adaptation of the educational intervention (The CLEAR toolkit)

Different approaches and strategies are described in the literature for validating and locally adapting a research instrument or intervention. First, to ensure the linguistic translation of the toolkit to an Arabic version that accurately represents the study populations' native tongue and dialect, a linguistic validation process was done and included the following steps: 1) forward translation, 2) reconciliation, 3) backward translation, 4) expert clinician review and 5) cognitive debriefing (i.e. pilot-testing the Saudi version of the toolkit).

Cultural and linguistic adaptation of the toolkit utilized the qualitative findings from the indepth interviews with primary health care physicians and focus groups with social workers. In the generic version of the CLEAR toolkit (see appendix 4.3), "Step 2: Ask" provides examples of questions used to ask patients about their social causes of poor health, each correlating to a specific type of social determinant of health and phrased with trauma-informed approach and consideration of the specific needs and concerns of the patient. Asking questions about sensitive and personal issues differs from one country to the other, and therefore this also needs to be adapted to the local context. For example, the concept of a primary health care physician asking directed questions about social and personal matters that might initially appear to be tangential to one's health is quite uncommon in the Saudi context and can be perceived as unacceptable or fruitless, as the patient might refuse to answer (123). In addition, some words and phrases are not able to be translated

literally, as they need to account for the sociocultural context by identifying the traditional nuances of the Arabic 'Saudi dialect' and the best alternative words and phrases to use in this language (123).

Second, the infographics and other visuals on the original version of the toolkit did not resonate with the local reality (e.g. nurse's uniform) and therefore a visual adaptation was needed to replace the nurse with the hat to how a Saudi female doctor currently looks like in Saudi practice with the lab coat and hijab.

Finally, for the "Step 3: Refer" section in the toolkit, a list of all the local Riyadh support agencies and resources is included to complement each social determinant of health that may be identified during social history-taking, for clinicians to know easily where they can refer to for which issues. In preparing this list of local social referral resources, local contextual insider knowledge was needed to identify these. The local experts included the Saudi social workers working in the Department of Family Medicine and therefore the list of resources of the Saudi version of the CLEAR toolkit now reflects the current Saudi setting and referral processes that match the available social service and support organizations in Riyadh (see appendix 4.4).

11.4 Quantitative phase

11.4.1 Study objectives

To determine the feasibility and acceptability of evaluating an educational online intervention to improve Saudi primary health care physicians' knowledge, empathy and behavioral intention to adopt a social determinant of health approach to clinical care with a view to informing a full-scale cRCT.

1) **Feasibility**: a) Assess feasibility of the intervention (practicality of implementing an online self- educational and physician friendly tool, content and methods of delivery, costs), b)

Assess feasibility of the evaluation, study design and procedures (eligibility criteria, randomization and blinding, consent process, questionnaire response rate).

- 2) **Acceptability**: a) Assess acceptability of the intervention (primary health care physicians' views of the intervention), b) Assess the acceptability of the evaluation, study design and procedures (data collection, study timeline).
- 3) **Outcomes**: a) Document primary outcome measure and b) likely direction of outcome measures, covariates, variances and intra cluster correlation (ICC) to determine sample sizes in the planning of a subsequent cRCT.

11.4.2 Study rationale

In this phase, a pilot cRCT study will be used to assess the methodological foundations necessary for the proper design of a full scale cRCT, by testing the feasibility, acceptability and evaluation methods that can be then used to test the impact of the proposed educational intervention and inform a consecutive full-scale cRCT, ultimately enhancing the cRCT's methodological rigor and scientific value (124-128).

11.4.3 Equipoise

Participants reluctance to take part in an cRCT may indicate lack of equipoise regarding the benefits and risks of the intervention (98). Equipoise of the CLEAR intervention rests on the possibility that physicians exposed to the toolkit make better use of the social services that address social determinants of health, thus providing more holistic and probably more effective care from their clinical setting.

11.4.4 Study design

Parallel group cluster randomized controlled trial, with workplace as the unit of allocation, intervention and analysis (129). A special concern is the contrast between cluster analysis and individual analysis, to understand the nature of the clustering in this sort of educational intervention. I anticipate that, beyond the usual concerns of clustering reducing the measured variance (similar people might work in the same environment), I will find an informative clustering related to the educational intervention. If people working in the same center talk with one another about the educational intervention, which I expect is likely, this "contamination" could increase the educational effect. This would be crucial information in structuring a larger scale intervention trial or, indeed, rolling out the intervention on a large scale (130).

11.4.5 Participants and setting

11.4.5.1 Number of participants

Of 435 primary health care centers in and around the greater Riyadh area (29), 96 centers are in two large health care facilities. King Khalid University Hospital (KKUH) has 48 clinics and the Ministry of Health another 48 clinics. In KKUH centers, the number of physicians per clinic will vary from 3 to 10; the number of physicians in Ministry of Health clinics only ranges between 1 and 3. The pilot trial will include all physicians in all 96 centers in these two facilities, with no subsampling. This will cover a significant proportion of Riyadh, serving a wide variety of patients including those with greater marginalization and lower socio-economic status.

11.4.5.2 <u>Setting</u>

This study will be done in Riyadh, Saudi Arabia, includes a wide range of primary health care practice types, from large university academic centers to single-physician primary health care practices funded by the Ministry of Health.

11.4.5.3 Eligibility criteria

The pilot study will include both Saudi and non-Saudi trained primary health care physicians of both sexes, who are either Family Medicine Physicians (FM) or General Practitioners (GP) and are clinically active, serving patient within Riyadh and registered at the Saudi Committee for Health Specialties. Primary health care centers excluded from this study are those located outside Riyadh city where local support organizations and community referrals are not within reach for patients in need.

11.4.6 Recruitment strategy

To increase the number of physicians participating in the study, there will be two main strategies used: 1) promotion of participation in the study by high-level administrators and the department's manager at KKUH, where a standard invitation will be sent out to attend a presentation at the grand rounds describing the study's purpose and what it entails, will encourage primary health care physicians to take part in the study. 2) For the Ministry of Health-funded centers, I will communicate with the Deputy Manager of the Primary Health Care Department at the Ministry, who will then send formal invitations to primary health care physicians to take part in the study. As incentive for department physicians to participate in the study and to complete the questionnaires, the department managers will inform them about the opportunity to obtain Continuing Medical Education (CME) credits. Based on these strategies of recruitment, potentially participating primary health care centers and affiliated physicians will be identified. Each physician listed by the manager as a potential participant, will receive either an email with the questionnaire plus the educational intervention (i.e. the intervention group), or will receive an email with only the questionnaire (i.e. the control group). The allocation ratio to control and intervention arm will be 1:1. The randomization procedure is described separately in this document.

11.4.7 Consent process

Due to the nature of a cluster randomized trial, consent has to be obtained at two levels: first at the managing administrative level (cluster / center level) and second at the individual participant (within cluster / physician level). To obtain the first level of consent, the emails sent to the department or center manager will contain detailed information and explanation about the purpose and scope of the study along with an electronic consent form confirming participation of the center in the study. The managers will be informed that allocation of the study intervention will be based on a randomization. Neither managers nor participating physicians will be aware of the study arm they are allocated to. The manager's consent will provide permission to contact a list of selected physicians to invite to participate in the study. The consent will be obtained through viewing and digitally confirming the agreement by selecting the respective response option: agree / disagree via mouse click or keyboard entry. To ensure that each agreement or disagreement retrieved will be linked to the correct study site, the electronic consent forms will contain pseudo codes that securely store the site and manager name in the study database (e.g. Survey Monkey or REDcap). If consent has been obtained from a site, the manager will be contacted again to provide a list of selected physicians. These physicians will receive an email inviting them to participate in the study and informing them about the nature of the intervention they were allocated to. The physicians then are asked to provide digital consent to become eligible study participants. Similar to the managers' consent forms, pseudo codes attached to the physician's consent forms will securely register the site and physician name in the study database.

11.4.8 Educational intervention "The Saudi CLEAR toolkit"

A one-page Riyadh-specific insert within the two-page leaflet of the locally adapted Arabic-translation of the CLEAR toolkit will reflect the culture of practice and local terminology in Saudi Arabia and include the appropriate list of local referral agencies and organizations. This tool, which is a simplified, easy to navigate four-step approach (treat, ask, refer and advocate), will function to guide primary health care physicians in Riyadh to first treat any underlying medical illnesses and symptoms, second how to ask about nine common social determinants of health and

address their patients' social determinants of health and refer them to the corresponding support organizations and resources available. Finally, the tool gives tips on how physicians can advocate for more supportive environments and get involved with leaders and local community members.

11.4.9 Outcome assessments and data collection tool (study questionnaire)

The three primary outcomes are knowledge, empathy and behavioral intention relevant to addressing social determinants of health in clinical practice.

11.4.9.1 Physician knowledge

Lack of knowledge is frequently cited as a barrier for physicians taking action on social determinants in clinical care (131). This includes lack of knowledge regarding existing local resources for referring patients, and how to navigate socially sensitive clinical care situations (132). Clinical vignettes will be used to measure primary health care physician's knowledge and ability to manage complex health and social issues within a clinical context.

11.4.9.2 Physician empathy

Physician empathy involves the ability to understand the patient's inner experience or perspectives to provide compassionate care by "standing in the patient's shoes," which has been shown to improve patient satisfaction, compliance, and clinical outcomes (133, 134). Simply enquiring about sensitive issues in an empathetic fashion "makes patients more forthcoming about their symptoms and concerns yielding more accurate diagnoses and better care and leads to therapeutic interactions that directly affect patient recovery (135). Empathy also creates beneficial effects on physician well-being and has been linked to lower burnout and higher levels of clinical competence (69). In this study, I will use of the Jefferson Scale of Physician Empathy (Health Professional Version) to measure physician empathy (136).

11.4.9.3 Physician's intention to change

Following the original theory of planned behavior (41), to predict physician behavioral intention when addressing their patients' social challenges, we need to know the following: 1)

Attitude: whether a physician is in favor of addressing their patients' social challenges, 2) Subjective Norm: their views of whether others think they should address patients' social challenges within clinical practice, and 3) Perceived Behavioral Control: how much control the physician believe they have on addressing their patients' social challenges. These three underlying constructs help to predict a physician's intention to address social determinants of health in his or her clinical practice which is a direct indicator of their future behavior (i.e. whether they will actually do so in future clinical practice). To measure behavioral intention and its three-predictor variables (i.e. Attitude, Subjective Norms, Perceived Behavioral Control), I will use the Theory of Planned Behavior Questionnaire, which has a brief-form with a subset of items sufficient for the purpose of this study (137).

11.4.10 Data collection tool (study questionnaire)

An emailed self-administered questionnaire will include four main components with a total of 50 items, mostly based on validated measures and scales found in the literature for our chosen outcome measures.

11.4.10.1 Clinical vignettes

Combining traditional survey and experimental methods, vignettes can offer aspects of both the high internal validity of experiments and the high external validity of survey research to disentangle multiple predictors of clinician behavior (138). Vignettes have often been used to assess opinions or preferences across various countries, health care systems and specialties and thus can be used as valid tool to reflect what physicians do in "real-world" complex situations with their patients by measuring key aspects of the decision-making process (139). Two clinical vignettes describe realistic clinical situations so that physicians can assess identical scenarios. The response option is usually in multiple-choice format. Since this could overestimate physician's performance, I will add open-ended responses. Thus, I have created a combination of multiple-choice and open-ended response formats for these clinical vignettes (140).

11.4.10.2 The Jefferson Empathy Scale

This is a validated psychometric tool commonly used to measure empathy among physicians of various clinical specialties that can be adapted to different contexts and has already been translated to Arabic (133, 136, 141). The scale consists of 20 Likert-type items answered on a 7- or 5-point scale (1=strongly disagree, 7=strongly agree).

11.4.10.3 The Theory of Planned Behavior Questionnaire

Behavioral intention will be measured using three Likert-type items on generalized intention answered on a 7-point scale (1=strongly disagree, 7=strongly agree). Three questions measure Attitude using a 7- point scale with the use of 4 opposite adjectives of evaluation (e.g. good practice vs. bad practice, harmful vs. beneficial, pleasant vs. unpleasant, the wrong thing to do vs. the right thing to do). Three items are also allocated for each of the two other predictor variables Subjective Norms and Perceived Behavioral Control and are answered on a 7-point scale (1=strongly disagree, 7=strongly agree). Together, this results in a total of 12 items adopted from the short form of the Theory of Planned Behavior Questionnaire (137).

11.4.10.4 Respondent demographics and clinical practice parameters

The questionnaire will also include Saudi-specific questions informed by the qualitative study, and four demographic items on physician's age, gender, nationality and years of practice. Finally, the questionnaire will also include some practice-related questions such as the type and size of practice (community vs. hospital based), number of primary health care physicians, and the availability of a social worker on site.

11.4.11 Method of delivery

Personalized emails to the eligible participants will be sent out after I obtain an encrypted web-link from the independent statistician to be inserted in the respective email. This web-link

will refer to either the educational intervention and questionnaires for either the control or intervention arm. The control group will receive questionnaires at baseline (time of response after randomization) and at one-month follow up. The group randomized to intervention will receive baseline questionnaires and then at one-month follow up will receive the web link that includes both the educational intervention and questionnaires. The primary contrast will be between intervention and control centers at the second-time point.

11.4.12 Randomization and blinding

Randomization will occur at the level of primary health care practices using an allocation ratio (intervention to control) of 1:1 (129). As the practice type (KKUH vs. Ministry of Health), the national status (Saudi vs. non-Saudi), training background (FM vs. GP) and sex of the physician are deemed important outcome predictors, randomization will be stratified by these variables ensuring a balanced distribution of these factors across the study's intervention and control arm. An independent statistician will perform randomization using appropriate software (e.g. SAS, STATA, SPSS), following operating procedures that ensure the generation of an unpredictable allocation sequence and concealment of this sequence from the investigators prior to allocating health centers to the respective study arms. The investigator, who is sending out personalized emails to the eligible participants, will obtain an encrypted web-link from the independent statistician to be inserted in the respective email. This web-link will refer to either the educational content and surveys for either the control or intervention arm.

11.4.13 Study Timeline

The pilot study will take around a three-month period between gathering baseline data and delivery of the intervention the following month.

11.4.14 Assessment of survey response and mitigation strategies

Response rates will provide an indication of acceptability of the instrument and its applicability. Participants who do not complete the survey will receive reminder emails after 3, 7

and 21 days. To assess self-selection bias, I will compare late with early responders particularly with respect to familiarity with social determinants approaches. After 21 days, I will contact a random sample of non-responders by telephone in both intervention and control groups and conduct a brief 15 min semi-structured phone interview in an effort to understand how different they are from those who responded. Since answers in an interview will not be directly comparable with responses in the self-administered questionnaire, I will also do semi-structured interviews with the same number of early respondents (142). The interview guide will further discuss the perceived barriers and facilitators influencing the acceptability of the toolkit, physicians' understanding of it, and their interests in (and motivations for) practice change, and recommendations for improving clinical uptake of the toolkit.

11.4.15 Statistical methods

11.4.15.1 Participant flow and descriptive statistics

A flow chart following CONSORT guidelines illustrates the centers recruited to the study (see Figure 3) (143). I will also document how many individual physicians responded, how many physicians were excluded from the sample, and why, with the final number of physicians who responded in the control arm and the intervention arm at baseline and follow-up. I plan to calculate descriptive statistics for baseline and follow-up variables by center including means, standard deviations, quantiles and frequency distributions. Descriptive statistics will also be used to calculate the various scores (knowledge, empathy and behavioral intention) and their individual change (follow up vs. baseline). Baseline variables of individual respondents will include age, sex, national status, training background and type of practice. Variables measured both at baseline and follow up include scores on clinical vignettes, the Jefferson empathy scale and theory of planned behavior questionnaire.

11.4.15.2 Effect estimation

I will estimate data dispersion, effect sizes and intra-class correlation of responses to inform sampling, size determinations and inclusion criteria for a future full-scale randomized trial

(129). In order to consider the clustered nature of the data and allocation of the interventions, I will employ linear mixed effect models to obtain proper standard errors for effect estimates and to examine whether the clustering is informative (possible spill-over of educational initiative) (144).

11.4.15.3 <u>Scoring</u>

As validated scales for the measures of empathy and behavioral intention will be used, the analysis will involve predefined scoring. I will send respondents' answers on the Jefferson Empathy Scale to the Thomas Jefferson Center for Research in Medical Education & Health Care. The reports on the scores will be sent back and will include descriptive statistics of scores including mean, standard deviation, range, mode and quartiles for the entire sample, a histogram showing distribution of empathy scores for the entire sample, and gender/specialty comparison by total empathy scores. For the behavioral intention, analysis will follow the standard approach to scoring for the Theory of Planned Behavior Scale (137), as described elsewhere and summarized in Table 1. Once scoring is complete, I will analyze the data to determine the difference between intervention and control groups, with calculation of 95% confidence intervals, for the outcome measures.

Table 1. Scoring key for Theory of Planned Behavior Scale

Question Numbers on the Survey	Response Format	Construct Measured	Items requiring reverse scoring	Items requiring internal consistency analysis
12 a, b, c, d	1 to 7	Attitude	12b and 12d	12a to 12d (after recoding)
13 a, b, c	1 to 7	Subjective Norms	13a	13a (after recoding), 13b, 13c
13 d, e, f	1 to 7	Generalized Intention	13d	13 d, 13e and 13f
13g, 13h, 14	1 to 7	Perceived Behavioral Control	14	13g, 13h and14 (after recoding)
15	0 to 10	Intention Performance	n/a	n/a

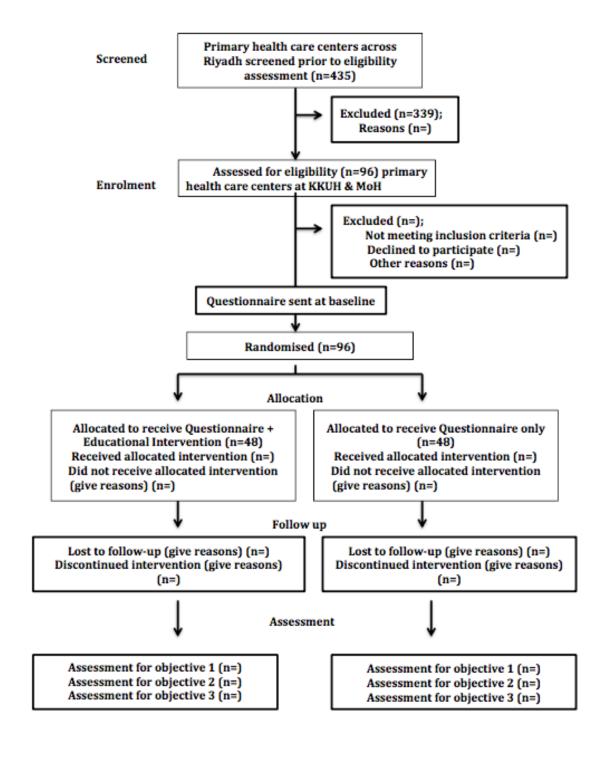
11.4.15.4 <u>Missing data</u>

Nearly all interventions experience missing data. Self-selection (decision not to participate or not to answer certain questions) is a concern, given the interest required to complete the educational intervention. Those who opt not to do the intervention or to respond to all the questions may be less interested in social determinants, thus increasing the measured effect by limiting measurement to those who are more interested. If follow-up telephone contact finds informative differences between responders and non-responders, a sensitivity analysis will examine the likely implications of this bias for the principal analysis (145).

11.4.15.5 <u>Implications for health services</u>

Increased physician awareness of social determinants can lead to better use of available social services and support networks by those who need them most, thus mitigating some of the worst consequences of social determinants. Further, the low costs of doing this – a free online educational initiative that takes an hour of physician time -- compares favourably with immediate and long-term gains.

Figure 4. Study diagram and flowchart (143)



11.5 Ethical considerations

Agreement to participate was first sought from the higher management level of each clinic; individual participants in the clinic only needed to consent to the completion of a questionnaire specific to the intervention status of their cluster. St Mary's Hospital Research Centre in Montreal, Canada (a McGill University-affiliated teaching hospital and research center), King Khalid University Hospital, and the Ministry of Health in Riyadh, Saudi Arabia reviewed this study protocol, consent forms, and any subsequent modifications. Prior to the commencement of the study, a letter of protocol approval was obtained by all affiliations. There were no financial disclosures or conflicts of interest for any of the investigators on this study.

Autonomy

Participants were informed in the invitation email as well as the beginning of the interview or focus group that their autonomy is of the utmost importance. If they choose not to answer a certain question, they are more than welcome to refrain from answering. Participants were also able to withdraw from a study after the interview is conducted with no harm to themselves.

Confidentiality

Participants information was anonymized, and personal information was only available to the researcher. Data is kept in a secure place using a password protected hard disk.

12 Results

The results for each of our research objectives are presented as manuscripts prepared based on the data analysis from this project.

12.1 Exploring Social Determinants of Health in a Saudi Primary Health Care Setting: The Need for a Multidisciplinary Approach (Manuscript 1)

12.1.1 PREFACE

Addressing social determinants of health in a primary health care setting is poorly explored in the Saudi literature. An exploratory qualitative study was therefore conducted at a large university hospital in Riyadh that included 17 in-depth interviews with primary care physicians and a focus group with social workers. Appendix 16.3 and 16.6 includes the interview and focus group guides used in this study. Our analysis thematically synthesized primary health care physicians' perceptions of addressing social determinants of health in primary health care, their perceived barriers and enablers to doing so within their routine clinical practice. As part of my doctoral work, I conducted these interviews and focus groups, led the analysis and interpretation of the findings, as well as the write up of the initial draft of this manuscript with regular input from my supervisor and committee members. This manuscript was accepted for publication by the *International Journal for Equity in Health* in February 2022 and was published in March 2022. The qualitative findings of this study were the basic groundwork needed to understand the culture of practice in Saudi and further explore the needs of primary health care physicians in addressing their patients' social challenges within their clinical practice. The constructs helped design the data collection tool and educational intervention used in the following two manuscripts (2 & 3) in this thesis.

Title: Exploring Social Determinants of Health in a Saudi Primary Health Care Setting: The Need for a Multidisciplinary Approach

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This manuscript has been accepted at the *International Journal for Equity in Health* on February 3rd, 2022.

Keywords: Frontline health workers, primary healthcare physicians, social determinants of health, underserved patients, social accountability, qualitative research.

12.1.2 ABSTRACT

Background: Action on social determinants of health (SDH) in primary health care settings is constrained by practitioners, organizational, and contextual factors. The aim of this study is to identify barriers and enablers for addressing SDH in clinical settings in Saudi Arabia, taking into consideration the influence of local cultural and social norms, to improve care and support for marginalized and underserved patients.

Methods: We conducted a qualitative study involving individual in-depth interviews with a sample of 17 primary health care physicians purposefully selected based on the inclusion criteria, as well as a focus group with four social workers, all recruited from King Khalid University Hospital (KKUH) in Riyadh, Saudi Arabia. All interviews were audio-recorded, translated from Arabic to English, transcribed verbatim, and analyzed using thematic analysis following a deductive-inductive approach.

Results: According to study participants, financial burdens, challenges in familial dynamics, mental health issues and aging population difficulties were common social problems in Saudi primary health care. Action on SDH in primary care was hindered by 1) lack of physician knowledge or training; 2) organizational barriers including time constraints, patient referral/follow up; 3) patient cultural norms and 4) lack of awareness of physician's role in managing SDH. Enablers to more socially accountable care suggested by participants includes: 1) more education and training on addressing SDH in clinical care; 2) organizational innovations to streamline identification of SDH during patient encounters (e.g. case finding questionnaire completed in waiting room); 3) better interprofessional coordination and clarification of roles (e.g. when to refer to social work, what support is provided by physicians); 4) identifying opportunities for broader advocacy to improve living conditions for marginalized groups.

Conclusion: Enabling more socially accountable care requires a multipronged approach including leadership from the Ministry of Health, hospital administrations and medical schools. In particular, there is a need for: 1) training physicians to help patients in navigating social challenges; 2) improving clinical/administrative interprofessional teams, 3) mobilizing local communities in addressing social challenges; and 4) advocating for intersectoral action to prevent health inequities before they become more complex issues presenting to clinical care.

12.1.3 BACKGROUND

In recent decades, the relationship between primary health care (PHC) and the social determinants of health (SDH) has garnered increasing attention (1, 2). Although frontline health

workers continue to witness the detrimental impacts of social challenges on their patients' health, a growing movement is advocating for increased social accountability in primary health care, and investments in clinical competencies to act on SDH (1, 3).

According to the World Health Organization (WHO), social determinants of health (SDH) are defined as "the conditions in which people are born, grow, live, work and age; these circumstances are shaped by the distribution of money, power and resources at global, national and local levels" (2, 4).

Gradually incorporating SDH into the PHC discourse reflects acceptance of the idea that social factors influence a patient's presentation to his or her primary care physician and the ability to support patients in navigating these challenges can promote improved patient outcomes (1, 5, 6).

In 2008, the World Health Organization (WHO) released a report entitled "*Primary Health Care – Now More Than Ever*" that emphasized the importance of going back to the Alma Ata declaration's definition of primary health care (7, 8). The report urges adoption of a more socially accountable model of health care by taking increased action across a range of SDH and highlights the importance of action at the primary level of entry to care (8). Doing so will lead to a better response to people's needs and improve community health outcomes (1, 2).

Health systems are often slow to adopt such changes (9-11). Recurrent visits to primary care clinics suggest that the underlying social causes of disease were frequently not addressed, and patients remain in the same social situations, living conditions, and unhealthy environments (9). Some physicians consider issues such as domestic violence, poverty, and unemployment to be beyond their scope (9). Other physicians report being untrained or unqualified to address their patients' social causes of poor health (9).

Addressing patients' social determinants of health is still in the process of being meaningfully embraced in the Middle East (12) and only a small number of articles published in

the Eastern Mediterranean region call for adoption of a biopsychosocial approach in medical education and promoting the role of health workers in addressing the SDH more broadly (13-17).

The Saudi health care system has become one of the most advanced in the Middle East with a strong focus on health promotion (18, 19). Nevertheless, literature on the integration of SDH in the Saudi primary health care setting remains sparse and little is published on levers for addressing SDH in clinical practice and improving support for marginalized patients (20).

Marginalization is "a process through which certain population groups experience multiple social determinants concurrently. Thus, limiting their access to health promoting resources, while increasing their risk for poor health" (21). An individual's social position (gender, sexual orientation, race and ethnicity), their social environment and the resources available to prevent or fight disease; education, income and quality of their residential housing, all together produce an individual's health. These complex interactions are the link between marginalization and SDH (21). It is therefore our aim to report qualitative findings from a mixed methods study in Riyadh, that addresses this gap. Our study aims to explore the views of primary health care physicians in Saudi Arabia about addressing SDH in clinical practice, describe their current culture of practice regarding SDH and identify perceived barriers and enablers in asking and managing patient social challenges in clinical care.

Conceptual Framework:

To guide our empirical understanding of social determinants of health in Saudi Arabia and their effects on population health, we adopted the WHO's conceptual framework for action on SDH, which takes note of the specific theories on the social production of health and disease (22). This framework categorizes the SDH into three distinctive but interlinked classes: (1) structural determinants or social determinants of health inequities, (2) intermediary determinants, and (3) cross-cutting determinants such as social cohesion and social capital (22). The conceptualization of marginalization within the SDH framework allows us to appreciate not only individuals' vulnerabilities but their resilience as well, thus allowing us to explore their experiences in how they cope with stress and adapt to social change (21, 22).

12.1.4 METHODS

Study Design

We used a qualitative descriptive approach within a naturalistic inquiry paradigm to explore the complex phenomenon of the barriers and enablers to addressing SDH in clinical care (23). In depth interviews were used to explore Saudi primary health care physicians' perspectives on caring for underserved and marginalized patients which is crucial in understanding the local setting and Saudi primary health care context (24). In addition, triangulation with a focus group involving clinical social workers based at the same clinical site provided a nuanced and multifaceted understanding of how social issues are addressed in the primary health care space. While physicians provided immediate clinical care in a primary health care practice that often includes discovery of SDH, it still requires further exploration and management, and this unique care is provided by a clinical social worker. Exploring a culturally homogenous group such as social workers at the same teaching hospital allows a more open dialogue about shared work experiences, content information about the local referral organizations, and suggestions for improvement on service delivery for vulnerable patients thus reflecting the social realities and knowledge (25, 26).

Setting

The kingdom of Saudi Arabia is the second largest Muslim country in the Arabian Peninsula, with its current population of 35.5 million people (27, 28). Riyadh is the capital and largest city in the kingdom with a population of 6 million people (28). The current median age in Saudi Arabia is 27.5 years of age with a full life expectancy of 75.5 years of age (28). The country's largest economic asset is oil production and trade (29). Saudi Arabia finds itself in a highly transitional period in terms of social reform and economic reevaluation (29). Saudi Arabia's culture is a mix of Arab traditions and customs with an Islamic worldview (24, 29). The Shariah law governs life such as politics, economics, finances, family, hygiene, and social issues (14, 19, 24, 29). Family is a vital part of Saudi society, an individual commonly has an extended support system that includes parents, grandparents, siblings, aunts, uncles and cousins (29, 30). Extended

family ties are strongly encouraged and maintained. Family is considered an essential part of an individual's identity (14, 19, 24, 29,30).

This study was conducted at King Khaled University Hospital (KKUH) in Riyadh, Saudi Arabia, a public teaching hospital that provides primary and secondary care to low- and middle-income patients in the Northern part of the city. It includes a large family medicine unit with key academic collaborators in the Department of Family and Community Medicine.

Sampling and Recruitment

a. In-depth Interviews with Primary Health Care Physicians

A maximum variation purposive sampling technique was used to select the 17 physician participants with different duration of work experience (i.e. 5 with less than 10-year experience, 5 with 10-15 years of experience, and 7 with over 15-year experience), gender (i.e. 10 male, 7 female) and nationality (i.e. 12 Saudi, 7 non-Saudi) to obtain a wide range of viewpoints (23). Primary health care physicians were recruited via email invitations that explained the study's purpose and what participation in the study entails. A mobile text invite was also sent to all primary health care physicians working in the Department of Family and Community Medicine at KKUH. Active recruitment stopped when data saturation was reached, where "no new information or themes are observed in the data" (31) in the total 17 interviews (23).

Prior to commencing each interview, an informed consent and permission to audio-record from the participant was discussed and signed. Interviews were conducted in both English and Arabic, based on the participants preference, and they each lasted on average 30-40 minutes.

b. Focus Group with Social Workers

As part of the multistage qualitative data collection process, a follow-on focus group was conducted with 4 clinical social workers working at KKUH primary health care clinics. This allowed a more in-depth understanding from an additional viewpoint of the dynamics within the same clinical practice environment. A maximum variation purposive sampling technique was

similarly used for the focus group to identify a diverse group of clinical social workers to obtain a wide range of viewpoints (32). An email invitation letter was sent which includes information about the study's purpose to the head of the Department of Clinical Social Work at KKUH. Active recruitment stopped when data saturation was reached (26).

Data Collection and Analysis

Data was collected using semi-structured interview guides with open-ended questions informed by the Theory of Planned Behavior (23, 33). The Theory of Planned Behavior is a widely used framework to help increase clinician uptake of evidence-based practices. This theory is broken down into psychological/behavioral constructs about what guides human behavior (33), suggesting that attitudes towards the behavior, subjective norms, and perceived behavioral control influence behavioral intention to change and that the latter is a strong predictor of future behavior (33). Interviews explored perceived barriers and facilitators to taking action within established norms of Saudi clinical practice, and knowledge about the available local resources and support organizations for these patients. The interview guide was piloted with two local clinician-researchers and the content was adjusted prior to using the guide in the study (34).

All interview and focus group recordings were transcribed and translated verbatim from Arabic to English. A second translator was recruited to review the transcripts for accuracy. Transcripts were then analyzed using a thematic content analysis approach as described by Crabtree and Miller (35, 36). A pre-established deductive coding frame was used as well as an inductive approach to categorize and identify emerging themes (35). The deductive frame centered around five predetermined questions: 1) the most common social challenges faced by patients presenting to Saudi primary health care clinics, 2) approaches to asking about social challenges in a sensitive way, 3) the perceived barriers to addressing social challenges in a clinical setting, and 4) opportunities and enablers that can be used to overcome these barriers and promote more socially accountable care.

Textual data were coded to categorize and identify emerging themes that were then grouped on the basis of similarities, differences, and participants' key phrases (35). Data coding was done

by two independent researchers (BA and AA), the codes and categories identified by the two were compared and any disagreement was resolved. The data analysis process was done manually without the use of analysis software and lasted about three months. Further analysis techniques included: coding the whole corpus of text, reassessing the consistency of the coding, and finally making sense of the themes or categories identified. This helped improve relevance while helping understand the social realities of Saudi health care (37). To ensure rigor, it was important to illustrate the richness of the data and convey it to the reader by an explicit representation of the congruence between the themes identified and the statements made by the participants (38), we used the following four criteria (credibility, dependability, confirmability, transferability) to establish trustworthiness in this study (38, 39).

12.1.5 RESULTS

Study findings are presented in terms of four key themes emerging from analysis: 1) kinds of challenges faced by marginalized patients presenting to primary care; 2) physician approaches to addressing social challenges; 3) barriers to taking action on SDH, and 4) opportunities for promoting social accountability in clinical care.

1. Types of marginalized patients presenting to primary care:

The most common social challenges among patients presenting to Saudi primary care clinics were related to financial constraints, family dynamics, mental health challenges and difficulties related to old age. As described by a Saudi male consultant in family medicine with 30 years of experience:

"What makes my patients vulnerable in our clinic is multifactorial. Some of them are vulnerable because of social disadvantages which include poverty, low income, low social support from the family or from the community in general. Other than social, it could be psychological: many have depression or anxiety which sometimes leads to more severe disability."

In terms of patients' *financial issues*, participants discussed low-income including unemployment affecting patients' ability to afford medication and access means of transportation to attend appointments at their clinic. In her 10 years of practice, a Saudi female family consultant said: "financial difficulties are unfortunately the major social cause of poor health among my patients," and particularly for women. A Saudi female family consultant and assistant professor who trains and teaches residents and medical students shared an example:

"A patient who is a widow ... (who) is responsible for her children and grandchildren...starts sobbing during the consultation, and you find out her financial status is so awful that she sells her own stuff to spend on her kids."

She explained that these stressors can manifest as somatic symptoms that can be misdiagnosed as physical illnesses, describing a patient who often complained of tension headaches and Irritable Bowel Syndrome symptoms.

With respect to *family dynamics*, patients may face domestic abuse or violence, marital dispute and divorce, spousal neglect, and lack of family support. A Saudi female family consultant and assistant professor, who has been working for KKUH for almost four years gives an example:

"The other common problem is family abuse. I can tell you hundreds of stories about it, and the most recent is a widow who had a son and four daughters who were abusing her. They tried to kick her out of the house and threatened her."

Regarding *mental health issues*, participants said that patients, in particular those who don't realize they may be suffering from depression and anxiety, present with a somatization disorder and with psychosomatic complaints. Sometimes these mental health issues stem from a specific situation the patient is experiencing and are consequences of the financial and family dynamic challenges as the following quotations illustrate:

"I once had a schoolteacher who kept coming with symptoms of depression and low mood such as headaches, fatigue, and insomnia. I found out later on that she was a second wife and had to take care of her husband's children from his first in addition to her hectic work schedule." F Saudi 17/7 003

Finally, regarding *old age difficulties*, participants described their elderly patients as often having common chronic diseases such as diabetes and hypertension, however it was not the main challenge these patients were having. Many respondents described the impact of social isolation on the elderly and the compounded health-related consequences due to their loneliness. For example, one male doctor described a patient who is "lonely to the extent that he comes to the hospital by himself in a taxi because none of his sons were available to bring him to the appointment." M Saudi 28/6 001

2. Physician's approaches to asking about social challenges:

The majority of study respondents claimed that understanding their patient's social history is part of their role as primary health care practitioners and family consultants, and an essential aspect of effective treatment: "I ask them directly...we need to ask, we have to solve the case, the puzzle. Because we have to find out if it's really an organic problem or something else." M_Saudi_23/6_007. A similar sentiment was expressed by a female doctor who saw it a necessary part of patient history taking: "I honestly ask all of the patients as soon as I have doubts... Even if it takes an hour, because you might be really saving him or her in this session... so, it is essential to ask, not a duty. It is something beyond duty to ask." F_Saudi_17/7_001

Several respondents provided insight regarding how to initiate these conversations such as asking patients for permission to broach a topic: "I need to ask you about a sensitive topic, would you mind that? If you don't mind, we need to get into your situation at home." M_NonSaudi_28/6_002. A direct approach was also described:

"Sometimes patients want you to ask, so I ask.... How do I ask? Directly to the bottom line! Aunt, how is your financial condition? How is your relationship with your husband? Are you children

treating you well? In a nice way using colloquial language, I try to use some words from their dialect. Or try to be close to her understanding and make the questions more friendly." F_Saudi_17/7_001

While aware of the importance of asking the patients about their social challenges, a minority of respondents expressed hesitancy in intervening on these issues: "I learned the hard way when I moved here not to intervene in these sensitive issues... If you sense something is wrong, you have to ask, but here the society and community is really reserved...It's better off not to ask in the first place." F_NonSaudi_17/7_004

3. Physician's perceived barriers to taking action on SDH and socially accountable care:

Although primary care physicians in Saudi report caring for a wide range of patients experiencing various forms of social adversity, they report many barriers to asking about and addressing these challenges in clinical practice. These barriers were categorized starting with factors related to both the physician and patient, up to a broader community-societal level (see Table 1).

a. Micro-level physician-patient factors

A number of micro-level factor hindered efforts to address SDH in the clinical encounter. Among these was a prevailing biomedical bias in the medical profession. While some participants perceived the field of family medicine and primary care as being holistic and requiring a biopsychosocial approach other were disinclined to take action on SDH during their clinical encounter with a patient. A young male Saudi family physician explained why some of his peers feel reluctance:

"They don't want to hold the responsibility, but rather refer to the social worker or the police... some are refusing to take the case, and make the real job, the job a primary care physician should do." M_Saudi_23/6_007

Lack of physician knowledge and training on how to address SDH was another factor hindering action. Participants felt they didn't have enough information and guidance on how to address their patient's social challenges. As one female practitioner remarked: "Unfortunately, due to our lack of knowledge in this area, we tend to focus more on the physical and organic symptoms and neglect the underlying social issues." F Saudi 23/6 003

Most participants were not adequately educated on the role of a social worker within their clinical setting and were not aware of the diverse set of services, resources and local support organizations they are capable of providing for the patients: "I don't know what the social office actually does. Other than giving financial support, we don't know what they offer our patients." M NonSaudi 28/6 002

Finally, patient-related barriers include patients' refusal to answer questions regarding their social challenges or to allow physicians to take action. As explained by a female Saudi primary care physician: "The patient refuses most of the time to acknowledge the fact that their medical symptoms might be stemming from non-medical and non-organic reasons." F Saudi 23/6 003

Patients' reluctance to openly discuss their social struggles was explained by their lack of knowledge about the scope of care a family doctor is capable of providing. As the same physician explained: "The people here in our community are used to -- when they go to the primary care centers-- the doctors just listen to the complaint and they immediately prescribe medication." F_Saudi_23/6_003

Patients' resistance to answer questions or allow physicians to take action are due to several factors including fear of being exposed to other family members, and community stigma. To illustrate, one participant said: "Especially in our community, patients are really shy about these issues...There's a lot of resistance due to the stigma and fear of being labelled as mentally ill and getting addicted to antidepressants." F Saudi 23/06 003

Despite the large number of domestic abuse cases seen at the primary care clinics, and reticence in discussing these issues openly, physicians are often faced with situations of patient hesitancy. A Saudi female physician explained that many female patients refuse to get referred to official bodies of authority handling family violence. As another female doctor elaborated: "There is a lot of resistance from the patient. Most of the time it is out of fear of the husband and fear of getting divorced and the husband taking custody of the kids by law."

A physician's inability to communicate with patients and understand their concerns was a common barrier reported by participants. Information can be disregarded, lost or misunderstood in the consultation due to different cultural backgrounds, languages or dialects. One Saudi male physician who worked in three different regions explained: "The new foreign doctors have to adapt to our community, so there is a lot of misinterpretation and a lot of communication errors (....) Even though you're a Saudi and working in a Saudi city, if I went to one of the villages of the south region or southwest, I'd be totally lost because they have their own type of phrases." M_Saudi_23/6_007

b. Meso-level organizational factors and Interprofessional relationships

A second category of barriers were management-related such as time constrains, difficulties with patient follow up and disconnect between the primary care department and the social workers.

Regarding clinic time constraints, participants expressed that given their caseload and frequent overscheduling, appointments were not long enough to adequately address the SDH a patient may be facing: "For a single doctor at the clinic, it is too much... and we cannot do this for everybody." Poor patient follow-up is also a constraint. For example, the KKUH appointment system is organized such a way that patients may not always see the same physician. This hinders continuity of care and follow up which are essential to wholistic care.

Lack of communication between social work and primary care departments at the hospital was also reported as hindering SDH referral. One female Saudi family physician with 7 years of

experience described "... miscommunication and disconnect between our department here and the social workers" (F_Saudi_23/6_003), while her counterpart social worker confirmed her account..." (there is) no connection with the social worker. Our connection is just with paper, unfortunately." (M_Saudi_26/6_005). Social workers were also concerned about the division of tasks between physicians and themselves, including role boundaries, as one of the female social workers expressed here "You are asking the doctor to play two roles here. That will require so much time in his clinic." F Saudi SW 001

c. Macro-level societal factors

A third category of factors hindering the referral of patients with SDH issues concerned the disconnect between the primary care clinic and community-based support agencies and other resources. Although some participants only knew about a few local support agencies and organizations from personal encounters or advertisements, the majority of them did not. Those who did know about these resources continued to mention how difficult it was to reach them and have direct access when needed. This was a common finding expressed by participants across all demographics as stated; "I don't know about any organization outside the hospital that I can refer my patients to." M_Saudi_26/6_005

4. Opportunities for promoting social accountability in clinical care:

A number of recommendations to help overcome barriers in managing SDH among socially marginalized patient populations were suggested by participants.

a. Micro-level opportunities for promoting social care:

A key entry point for promoting social care through graduate and postgraduate education and training. A Saudi assistant professor and family medicine consultant emphasized the importance of including a chapter in the medical school curriculum at all levels that specifies the relationship between SDH and poor health. "The curriculum has no information about the social aspect or social work in detail, it just briefly mentions the biopsychosocial history taking" F_Saudi_26/6_006

Physician workshops and seminars were also suggested. Developed with the guidance of social workers, these events would be designed to train physicians on how to better address patients with social challenges, the standardized hospital process and steps needed to refer and support these patients, in addition to introducing the physicians to the various local resources and organizations available. Physicians are motivated to learn as illustrated by the following quote:

"I would love to attend some sort of physician workshop or even have a presentation about this issue and the available organizations" (F_NonSaudi_17/7_004), "We, as doctors, need to educate and accustom ourselves. Even if nobody shared the information [to follow-up regarding a referred patient], we are supposed to take the first step and go and ask the social workers ourselves." F_Saudi_17/7_001

It was further recommended that education about SDH be extended to patients. In addition to increasing patient awareness about the scope of family medicine and primary health care services, physicians should stress to patients that opening up and disclosing information regarding one's social challenges, is integral part of treatment: "I think we need to educate the patients that non-clinical data is very important." M_Saudi_26/6_005

b. Meso-level opportunities for promoting social care:

At the organizational level, recommendations included nurses for screening & triaging patients to allow for longer appointments when necessary: "a screening service for social problems, and some sort of a triage for different types of patients." (F Saudi 17/7 003) could be implemented.

Improving the communication between the primary health care and the social work departments was also considered integral to creating a stronger, more functional bond that would be beneficial for both departments and, ultimately, for patient care and support. Suggestions included greater collaboration by dedicating a specific social worker to handle primary health care

department patients or by localizing SW offices in close proximity to the PHC department. One primary care clinician noted that having a dedicated social worker for each clinic would be ideal, while another suggested: "... if they had an office next to our clinic...you save time for both the doctor and social workers because the help is a teamwork, which is what a primary care clinic should be, to support each other for the benefit of the patient." M_Saudi_23/6_001

Key to effective SDH care is a multidisciplinary primary care team with a clear referral strategy. Included on this interprofessional team is a dedicated social worker, thus fostering greater integration between clinical and social work departments and enabling a well-articulated referral system that allows for direct communication, feedback and follow-up between social worker, clinician and patient. As part of this referral process, it is critical that the physician understand "what the social worker is going to do with the patient, so it can be explained ahead to the patients." F Saudi 17/7 002

c. Macro-level opportunities for promoting social care

In terms of macro-level opportunities for promoting social care, a central action is to identify and publicly advertise local resources and organizations for patients' social aid and support. Public awareness of available services, local organizations and support agencies should be displayed in hospital hallways, waiting areas and even shopping malls to "stimulate interest in people" F Saudi 17/7_001

Table 1. Saudi physician's perceived barriers and enablers to socially accountable care

Physician's perceived barriers to socially accountable care

1. Micro-level physician- patient factors

- -Biomedical bias
- -Lack of physician knowledge or training
- -Patient's refusal, cultural beliefs and expectations

2. Meso-level organizational factors and Interprofessional relationships

- -Clinic structure
- -Time constraints and difficulties to follow up
- Disconnect between primary care physicians and social workers

3. Macro-level societal factors

-Disconnect between the primary care clinic and the outside community hinders referral of patients to local support agencies

Physician's perceived enablers to socially accountable care

1. Micro-level opportunities for promoting social care

- -Graduate & postgraduate education/training
- -Physician workshops & seminars
- -Educating patient communities on SDH

2. Meso-level opportunities for promoting social care

- -Use of nurses for screening & triaging patients to minimize consultation time
- -Foster stronger integration between PHCs and social work departments
- -Multidisciplinary primary care team with a clear referral strategy

3. Macro- Level opportunities for promoting social care

-Identify & publicly advertise local resources and organizations for patients' social aid and support

12.1.6 DISCUSSION

Although the term "Social Determinants of Health" was unfamiliar to many of the primary care providers in the study, it was generally understood that to effectively identify and address a patient's health needs, it is often necessary to "dig in their social history" and in some cases, uncover their "hidden agenda". This stance towards SDH in clinical care corresponds well with findings from a Canadian study involving physicians who had previously practiced in the Middle

East (40). While a conceptual understanding of being a socially accountable health practitioner exists in the Arab world, the construct of SDH is relatively new. This could explain why many publications in Gulf Cooperation Council (GCC) countries focus on specific areas of social disadvantage (e.g., violence or child abuse), versus a wholistic social determinants approach (13-17, 40). This could be related first component of the WHO's conceptual framework for action on SDH, the socioeconomic position of the patient as a structural social determinant of health (22).

Like other studies in the Middle East (40), our research found that in Saudi primary care clinics, physicians often see many patients struggling with issues relating to poverty, exposure to family violence, mental health challenges and frailty in old age. Forms of marginalization found in the Saudi patient population presenting to primary care are comparable to those seen in a Canadian Family Medicine center in Montreal serving a large population of immigrants and refugees (41). Among these were patients with mental health problems, people living in poverty, single parents, substance abuse, isolated seniors and victims of abuse and neglect (41). These findings elude to social vulnerability possibly being a global issue that may require a universal framework of action focused on the social determinants of health such as the WHO's conceptual framework for action on SDH to deepen our understanding of the type of change needed to address these challenges (21, 22).

A first step in taking action on the social determinants of health is to "ask" about them. However, inquiries about a patient's social struggles and life challenges requires a relationship between provider and patient that is built on trust. Primary health care practitioners in our study perceived that asking questions about a patient's social history is an integral part of their role. Some were confident enough to ask directly or probe indirectly, while others found it difficult and challenging, fearful of being intrusive and offending their patients. Several barriers were noted that align with the social accountability framework (5, 6, 42). Starting from the micro or individual level, many physicians considered issues such as marital problems, domestic violence, poverty, and unemployment to be beyond the scope of the biomedical model in which they have been trained. At the meso level of community level, social issues are not always acknowledged or discussed due to sociocultural barriers, further complicating the process of providing care. Finally,

at the macro level, inadequate advocacy for or policy attention to the social determinants of health are apparent. Clearly, further efforts at the meso and macro levels are necessary to support physicians at the micro level.

Physicians also reported being untrained or unqualified to address their patients' social causes of poor health, emphasizing gaps in knowledge including understanding the role of the social worker on site in their hospital, being familiar with available resources, and knowing which organizations and support agencies to refer patients to. This is consistent with the current literature and the hurdles faced were similar to those encountered by western physicians, who also lacked the appropriate training to deal with SDH (15, 40, 41). There is also fear of retribution for getting involved in sensitive areas. In a study in Bahrain, hesitation in reporting child abuse in clinical practice, was mainly attributed to a desire to avoid conflict with the family and lack of knowledge about legal reporting mechanisms (43).

Hesitation, however, was not confined to healthcare providers. Several physicians' described scenarios in which patients refused to answer sensitive questions or failed to connect their social and health concerns. For example, a patients' level of education and understanding of how social stressors can lead to poor health might delay their visit to a primary care physician, resist questions relating to their social struggles or refuse to accept help even if they disclosed. Another factor influencing patients' decisions about their health is stigma, and fear of being exposed as someone needed psychosocial or other forms of social or economic assistance. This is supported by the work of Hofstede on collectivist cultures (44), in which individuals give precedence to the welfare of the group rather than the individual. Against this backdrop, patients may not want to bring harm to their families, even if the price is their own wellbeing.

Beyond issues related to the awareness, comfort and competency of health workers to address SDH, there are organizational and interprofessional barriers at the meso-level. Organizational barriers include those related to clinic processes and structures i.e. consultation time constraints, clinical workload and difficulty following up with patients. For example, a demanding workload influences how physicians perceive SDH and whether they have the time

and energy to address them. The development of policies and procedures, the work life balance for practitioners is necessary. The lack of policies contributes to the structural determinants of health as described in the WHO's conceptual framework for action on SDH (22). This is also issue in the western contexts, where the most common reported barriers to addressing SDH included time constraints, knowledge deficiencies, lack of skills and training pertinent to socially sensitive situations, and deficits in evidence-based research on useful interventions or tools on SDH what are tailored to the needs of practitioners (45). In 2011, in an online survey, 87% of American physicians reported being aware that social factors impact health, yet only 20% felt comfortable discussing these issues with their patients, citing heavy turnover of patients and lack of manpower (46).

The disconnect between social workers and primary care physicians is an example of interprofessional barriers to addressing SDH at the meso level. Barriers perceived by social workers mainly related to a lack of communication and collaboration with physicians with respect to patient management. Social workers felt that lack of knowledge about their role and scope of services delayed the required referral process to their department. However, less clear is the division of tasks between both departments. Social workers believed patients were more comfortable disclosing sensitive matters away from the clinic. From the physician's perspective, close proximity between the primary care clinics and the social workers office was seen as desirable but potentially threatening to social workers who may fear role encroachment (47). Of note, while the hospital where the study was conducted (KKUH) has a social worker on staff, the majority of primary care clinics and centers belonging to the Ministry of Health do not. Therefore, it is important to train doctors to address social determinants of health in the absence of social workers.

Finally, at the macro-level, societal factors hindering primary care physician's action on SDH in clinical care are related to the disconnect between clinic and community. An often-repeated barrier by participants in the study was a lack of knowledge about available resources for vulnerable and marginalized patients, how they might be accessed and once accessed, how to ensure that appropriate help and support are provided.

Suggestions for improvement and opportunities to enable physicians to more effectively address SDH align with the social accountability framework and must address micro, meso and macro levels of change (5, 6, 42, 48). At the micro level, recommendations include increasing education about SDH starting with curriculum for medical students and providing graduate and postgraduate training on the actions and approaches for dealing with SDH in clinical care. Workshops and presentations for physicians and consultants on new developments in SDH approaches and their efficiency in clinical care are also recommended.

Family medicine and primary health care physicians could also benefit from training on Trauma-informed care which emphasizes the relationship between physician and patient as a key component of care and strengthens their connection to their patient. The Trauma-informed care approach guides physicians who might be unsure of how to approach some difficult and sensitive topics that are central to a person's health. Physicians are susceptible to society's collective denial of child abuse and neglect. Physicians are morally called on to provide compassionate and healing care to the survivors of such trauma. Given that adverse childhood experiences (ACEs) can be a root cause of many illnesses clinicians encounter on a daily basis, trauma-informed care can improve patient healing and outcomes, and lead to greater professional satisfaction (49). This approach can be further supported by educating patient communities on SDH and how doctors can address these issues within their clinical practice.

At the meso-level of action, one recommendation from primary health care physicians was greater reliance on nurses for screening and triaging patients, with the goal of freeing up consultation time for SDH assessment and referral (50). This would also serve to strengthen the connection between primary care physicians and social workers, contribute towards the development of a socially accountable, productive and multidisciplinary team of health workers capable of enacting effective SDH referrals.

At the macro-level of action, participants stressed the need for better media coverage and campaigns to identify available resources, support organizations and local agencies for addressing

all kinds of social determinants of health. This effort could be supported by ongoing efforts of the Ministry of Health and Ministry of Human Resources and Social Development to implement the Saudi government's new direction and vision towards a more efficient and accessible primary health care network.

Study Limitations:

A major limitation of the study was its predominant focus on government teaching hospitals, and medical doctors and the implications of both for the transferability of research findings. Other non-academic hospitals also run by the Ministry of Health serve more diverse and socially vulnerable populations but were not included in the study as they lacked social worker services. A related limitation was difficulty recruiting social workers into the study, with participation limited to a 4-person focus group of social workers. Nevertheless, valuable insights were produced regarding shared work experiences, local referral organizations, and suggestions for improvement on service delivery for vulnerable patients [49]. In addition, the study sample did not include the perspectives of patients themselves, which would offer an important opportunity to further triangulate findings about the value integrating a social determinants approach. Finally, valuable insight would have been gained had we focused on how the participants spoke about their experiences in addition to what they said. Doing so would deepen our understanding of our participants' experiences and help us avoid reproducing marginalization.

Conclusions:

Results from this study emphasize an important new direction for primary health care research and advocacy in Saudi Arabia. In particular, they provide fresh perspectives on how primary health care physicians can more effectively address SDH within the clinical setting, and beyond as advocates for system and policy change that recognizes SDH and supports linkages between health services and community-based organizations. Further, critical knowledge gaps are identified that will guide health education policy and the scale-up of social accountability

approaches to undergraduate, post-graduate, and continuing medical education in Saudi Arabia

and throughout the Middle East.

Study results also underline the need for greater interprofessional cooperation between

physician and clinical social workers, who are trained to address the social challenges of their

patients and to provide them with the support they need. Social workers have a wealth of

knowledge and experience in availing support resources in the community and are well placed to

assist family physicians in taking action on social determinants. At the same time, sensitivity to

role encroachment, and conflict minimization should be exercised.

Finally, primary care physicians in Saudi Arabia understand the importance of addressing

their patient's social causes of poor health but require an enabling policy environment that values

a social determinants approach and supports them in overcoming barriers in routine clinical

practice. In this regard, investments in operationalizing a social accountability approach are needed

which are compatible with the government's commitment to achieve sustainable development

goals (SDGs) focused on the social determinants of health. The effectiveness of primary

healthcare systems will be enhanced if they support partnership between primary care physicians

and community-based services given that so much of health lies beyond medical care.

List of Abbreviations:

SDH: Social Determinants of Health

KKUH: King Khaled University Hospital

PHC: Primary Health Care

WHO: World Health Organization

GCC: Gulf Cooperation Council

ACEs: Adverse Childhood Experiences

SDGs: Sustainable Development Goals

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Declarations:

Ethics approval and consent to participate: IRB approval was sought from the following

research ethics committees and review boards: St Mary's Hospital Research Centre in Montreal,

Canada (a McGill University-affiliated teaching hospital and research center); King Khalid

University Hospital in Riyadh, Saudi Arabia. Canadian and Saudi-based collaborators ensured the

quality and integrity of this research and seek informed consent from all participants as well as

ensuring the confidentiality of the data collected.

Consent for publication: Not applicable

Availability of data and materials: The data from this study will not be made publicly available

as it contains personal identifiable data.

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Authors contribution: B. Almujadidi contributed to the conception of the study design,

developed the data collection materials, conducted the recruitment, data collection, analysis and

drafted the initial manuscript. A. Andermann participated in the data analysis. A. Alquaiz

contributed with the participant recruitment and data collection. A. Andermann and A. Adams

critically revised and edited drafts of the manuscript. All authors gave their final approval on the

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12.2 An Online Educational Intervention to Improve Primary Care Physician Competencies in Addressing Social Determinants of Health in Clinical Care: Protocol for a Pilot Cluster Randomized Controlled Trial in Saudi Arabia (Manuscript 2)

12.2.1 PREFACE

One of the main barriers perceived by Saudi primary care physicians in the previous manuscript was their lack of knowledge and training when it comes to addressing their patients' social determinants of health (SDH). A growing number of multi-lingual clinical practice tools, such as the CLEAR toolkit (appendix 16.11), can guide physicians in asking about SDH and knowing where to refer marginalized patients for support. By integrating and using the qualitative constructs and findings from Manuscript 1 and locally adapting this tool to the culture of practice in Saudi, we were able to create a Saudi version of CLEAR (see appendix 16.12).

The focus of this manuscript was then to create a pilot RCT protocol that can therefore assess the feasibility and acceptability of this educational intervention in improving primary care physician knowledge, empathy and behavioral intention to address SDH in clinical care. An electronic self-administered questionnaire was also designed based on validated scales and measures to collect the data from the study participants (appendix 16.10). This type of study allows one to understand the research environment prior to conducting a full-scale RCT, thus exploring a variety of challenges that could arise within the pilot study and could be better addressed in the future which will be further discussed in the following manuscript (3).

Title: An Online Educational Intervention to Improve Primary Care Physician Competencies in Addressing Social Determinants of Health in Clinical Care: Protocol for a Pilot Cluster Randomized Controlled Trial in Saudi Arabia

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Keywords: Social determinants of health, primary health care physicians, clinical tools, pilot cluster randomized controlled trials, feasibility and acceptability studies, educational intervention, physician behavior, physician empathy, marginalized patients.

Competing interests & Funding: The authors declare that they have no competing interests, and no financial disclosures were involved in the study.

Availability of data and materials: The data from this study will not be made publicly available as it contains personal identifiable information.

12.2.2 ABSTRACT

Background: There is an increasing body of literature on how primary healthcare physicians can

address social determinants of health (SDH) in routine practice. A growing number of clinical

practice tools, such as the CLEAR toolkit, guide physicians in asking about SDH and knowing

where to refer marginalized patients for support. There is an evidence gap whether such tools

successfully influence physicians to take action on SDH. The objective of this study is therefore

to assess the feasibility and acceptability of a cluster randomized controlled trial of an online

educational intervention for improving primary care physician knowledge, empathy and

behavioral intention to address SDH in clinical care.

Methods: A pilot feasibility parallel group randomized controlled trial will be carried out with the

primary care practice as the unit of allocation to compare the online educational intervention with

the standard of care. The study will be conducted in Riyadh, Saudi Arabia, where 96 primary care

practices will be randomized to receive the online educational intervention, consisting of a locally

adapted Arabic translation of the CLEAR toolkit. Study participants will receive an electronic self-

completion questionnaire with a total of 48 items based on validated measures and

scales. Descriptive statistics will be calculated at baseline and one-year follow-up. Recruitment

challenges, data dispersion, effect sizes, and intra-class correlation of responses will inform the

planning of a future full-scale RCT.

Discussion: Literature on training health workers to address the SDH in clinical care includes few

randomized controlled trials. This pilot study will assess the feasibility and acceptability of an

online, culturally adapted, educational intervention that will guide physicians in adopting an SDH

approach in clinical care. Results of this pilot will provide an indication of the direction of impact

on physician knowledge, empathy, and behavioral intention, which are antecedents to better caring

for marginalized and underserved patients.

Trial Registration: ISRCTN14600984, Date: 13/01/2021

https://doi.org/10.1186/ISRCTN14600984

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12.2.3 BACKGROUND

Social determinants of health (SDH) are defined by the World Health Organization as the social, economic, and political conditions in which a population lives, grows, works, and ages (1, 2). Addressing socioeconomic disparity requires a range of "upstream approaches" including intersectoral action, health in all policies and broad whole-of-society approaches (3-5). Yet, the final report of the World Health Organization's Commission on Social Determinants of Health also recognized the importance of incorporating SDH considerations into health provider training programs, including developing low-cost, accessible training materials such as clinical practice tools and guidelines that can help primary health care (PHC) physicians identify and act on a broad range of SDH considerations (2, 6, 7). Developing locally adapted strategies to overcome institutional barriers is important to better support the complex physical health, mental health and social needs of marginalized and underserved populations (4, 7-9).

Frontline health workers witness daily the physical and mental health impacts of the social challenges that their patients face. In spite of the many calls for greater social accountability in PHC (6, 8), evidence on the effectiveness of trainings for frontline physicians to help address SDH in clinical practice remains sparse, relying mostly on observational studies or expert opinion rather than methodologically sound and adequately powered clinical trials. Identifying strategies for changing clinical practice requires understanding how to create physician behavioral change (10). Healthcare is delivered in the environment of an encounter between a physician and a patient, making behavioral intention an important proximal indicator of the care that patients will receive (11). Several studies have demonstrated that Continuing Medical Education (CME) positively impacts physician performance and patient health outcomes, particularly when behavior change interventions are interactive, involve a variety of learning methods, focus on outcomes considered important to physicians and include indicators that capture the impact of improved performance in real life scenarios (12, 13).

Most clinical practice tools or other educational interventions relating to SDH focus only on a single social determinant such as income or ethnicity (15, 16), whereas social challenges tend

to be multiple and inter-related. In 2010, an international group of researchers, clinicians and knowledge users created the CLEAR (Community Links Evidence to Action Research) toolkit based on formative health research across a range of countries (Brazil, Bangladesh, Niger, and Pakistan), as well as an extensive review of the scientific literature and consultations with experts and frontline health workers around the world (8, 16, 17). This clinical decision aid guides frontline health workers to address SDH in clinical care by assessing social challenges in a culturally appropriate way (e.g. exposure to violence, housing instability, food insecurity, lack of childcare, etc.) and concurrently identifying local resources that can respond to identified needs (8). In 2015, descriptive research adapted and refined the toolkit for use in Montreal, Canada (16). The study found that physicians who knew how to ask about social challenges were more likely to report helping their patients work through these issues. Access to a user-friendly, locally adapted directory or referral list was particularly helpful in supporting physicians when suggesting support resources to patients.

The Saudi health care system, while one of the most advanced in the Middle East with a strong focus on health promotion, is very different from other contexts with a large heterogeneity of healthcare settings (e.g. large, well-resourced academic settings versus single-provider community-based settings) which make it difficult to identify which interventions are most likely to be effective for all primary care practices (18, 19). Thus far, the literature on the integration of SDH in the Saudi primary health care setting remains sparse, and an assessment of the effectiveness of Western health care interventions transposed and implemented in the Saudi health system requires a careful examination of the contextual factors (20-22).

Due to the lack of empirical studies on how to incorporate SDH into Saudi Arabia's primary care system, a pilot study was developed to determine the feasibility and acceptability of an educational online intervention (i.e. the Saudi version of the CLEAR toolkit) to improve physician knowledge, empathy and behavioral intention to adopt a SDH approach in primary health care, with a view to informing a full-scale cluster randomized controlled trial (cRCT). By assessing many intervention parameters (including content, delivery, acceptability), as well as study feasibility (e.g. inclusion criteria, randomization and blinding, consent process, response

rate), the pilot will assess the magnitude and direction of several candidate outcome measures, including estimating variance parameters and intra cluster correlation (ICC) coefficients to determine required sample sizes for the planning of a subsequent large scale cRCT. This pilot study will therefore provide an important starting point for future research on SDH in Saudi Arabia and can be adapted to other country contexts to improve the ability of PHC workers to ask about and help patients navigate social challenges in the future, to enable the future scale up of SDH health system reforms at national and international levels (14).

12.2.4 METHODS

Trial Design and Study Setting

This pilot study will be a parallel group cluster randomized controlled clinical trial, with the workplace (i.e. the primary care practice) as the unit of allocation, intervention, and analysis (23). This study will be conducted in Riyadh, Saudi Arabia in 96 primary care centers that are associated with a large university academic center and the Ministry of Health. A cluster analysis is used here to understand the nature of clustering in this sort of educational intervention. We anticipate that, beyond the usual concerns of clustering reducing the measured variance (similar people might work in the same environment), we will find informative clustering related to the educational intervention. If people working in the same center talk with one another about the educational intervention, which we expect is likely, this "contamination" could increase the educational effect. This would be important information in designing a larger scale intervention trial or rolling out the intervention on a large scale (24).

Study Participants, Eligibility Criteria and Sample Size Calculation

Of 435 primary health care centers in and around the greater Riyadh area (25), 96 centers are associated with two large health care facilities, one university-affiliated hospital and one government-led primary health care services network. King Khalid University Hospital (KKUH) has 48 clinics, and the Ministry of Health primary health care services network has another 48 clinics. In KKUH centers, the number of physicians per clinic varies from 3 to 10, while the

number of physicians in Ministry of Health clinics ranges between 1 to 3 physicians. The pilot trial includes all 288 physicians in all 96 centers with no subsampling to estimate variances and clustering effects to inform a full trial. The pilot study will include both Saudi and non-Saudi trained primary health care physicians serving patients within Riyadh. Primary health care centers excluded from this study are those located outside Riyadh city where local support organizations and community referrals are not within reach for patients in need. The sample size was calculated using Raosoft (sample size calculator). Expected number of physicians were 1000, expected response distribution was set as 50%, and the margin of error was kept as 5%. The sample size estimated is 278±10.

Educational Intervention

A locally adapted Arabic-translation of the CLEAR toolkit will reflect the culture of practice and local terminology in Saudi Arabia and include a list of local referral agencies and organizations to guide primary health care physicians to ask about nine common SDH (i.e. employment, child care, education, nutrition, housing, domestic violence, child maltreatment, discrimination, isolation), and refer their patients to corresponding support organizations and local community resources. There is also guidance on advocacy for structural change to create more supportive environments by getting involved with leaders and local community members to prevent adversity before patients present to the health system with more complex health and social challenges.

Data Collection of Primary and Secondary Outcome Measures

The primary outcome measure of this study will be physician behavioral intention to address SDH in clinical care, and the secondary outcome measures are physician knowledge and empathy. Finally, demographics questions will include items on physician's age, gender, nationality, years of practice, type and size of practice, and the availability of a social worker on site, for a total of 48 items, mostly based on validated measures and scales.

The primary outcome will be measured using 12 items from the short form of the Theory of Planned Behavior Questionnaire (26, 27), where behavioral intention depends on three

underlying constructs: 1) *Attitude* (e.g. whether physicians are in favor of addressing their patients' social challenges), 2) *Subjective Norms* (e.g. whether physicians believe that others around them think this is considered good vs bad practice, harmful vs. beneficial, the wrong thing to do vs. the right thing to do), and 3) *Perceived Behavioral Control* (e.g. whether physicians believe they have the agency and ability to address their patients' social challenges). These constructs are measured using a 7-point scale (1=strongly disagree, 7=strongly agree). Behavioral intention is then a direct indicator of future behavior (i.e. physicians with behavioral intention are very likely to do this in future clinical practice).

The secondary outcome measure of physician knowledge will be assessed using clinical vignettes to determine the physician's knowledge in how to ask about SDH in clinical care, knowledge of existing local referral resources, and knowledge of how to manage complex and socially sensitive issues within a clinical context, which are often cited as physician barriers to addressing SDH (28, 29). Vignettes combine the high internal validity of experiments and the high external validity of survey research to disentangle multiple predictors of clinician behavior (35), and thus can be used as valid tools to reflect what physicians would do in "real-world" complex situations (36).

The secondary outcome measure of physician empathy has been shown in previous studies to improve patient satisfaction (30, 31), create stronger therapeutic alliances (32) and is also linked to lower levels of professional burnout (33). This will be measured using 20 items answered on a 7- or 5-point Likert scale (1=strongly disagree, 7=strongly agree) as part of a validated psychometric tool known as the Jefferson Scale of Physician Empathy (Health Professional Version) that has already been translated to Arabic among many other languages (34, 38, 39).

IRB approvals, data security and informed consent

Institutional review board (IRB) approvals for this protocol were received from St Mary's Hospital Research Centre in Montreal, Canada (SMHC-13-14), a McGill University-affiliated teaching hospital and research center, and by King Saud University Medical City (Ref.No.16/0320/IRB), and King Fahad Medical City (18-227E) IRBS in Riyadh, Saudi

Arabia. Participant data will be password protected and accessible only to authorized personnel only (i.e. principal investigators) to fulfil their duties within the scope of the study.

Due to the nature of a cluster randomized controlled trial, consent will be obtained at two levels, first at the managing administrative level (cluster / center level) and second at the individual participant level (within cluster / physician level). To obtain the first level of consent, meetings will be held with the department or center manager providing detailed information about the study (i.e. study objectives, random allocation, blinding, intervention, data collection, etc.). The manager's consent provides permission to contact a list of eligible physicians to invite them to participate in the study.

The second level of consent will involve an information session for participants to describe the study, ethical considerations and data protection measures (e.g. voluntary participation, ability to stop at any time, confidentiality of data, person to contact if in need of support, etc.). Next, written digital consent will be obtained through viewing informed consent information sent along with the questionnaire and asking participants whether they agree to participate in the study by selecting: "agree / disagree to participate" via mouse click or keyboard entry.

Randomization and Blinding

Randomization will occur at the level of primary health care practices using an allocation ratio (intervention to control) of 1:1 (23). An independent statistician will perform randomization using a computerized random number generator. This will ensure the generation of an unpredictable allocation sequence and concealment of this sequence from the investigators prior to allocating health centers to the respective study arms.

Recruitment Strategy

To increase the number of physicians participating in the study, four main strategies will be used: 1) High-level administrators and the department's manager at KKUH will be asked to promote the study by issuing an invitation to a grand rounds presentation describing the study's purpose, the informed consent information, and an explanation of what is involved for primary

health care physicians who choose to participate (e.g. baseline and follow-up questionnaire); 2) Each eligible participant will then receive a personalized email with the invitation to participate as an encrypted web-link from an independent statistician that assigns them to either the control or intervention arm, as well as the informed consent information, and a link to the baseline questionnaire to complete online, 3) continuing medical education credits for completing the study will be used as an incentive to participate, and 4) non-responders will in addition receive 3 rounds of reminder messages after 3, 7 and 21 days sent by WhatsApp to increase enrollment. After 21 days, we will contact a random sample of non-responders by telephone in both intervention and control groups and conduct a brief 15-minute semi-structured phone interview in an effort to understand how different they are from those who responded (40).

Timing of enrollment, intervention and data collection

The eligibility screen will be carried out with the KKUH Department manager prior to the study commencement, and informed consent will be provided orally during the grand rounds information session and again in written form along with the recruitment email.

At t₁, the baseline questionnaire will collect demographic data (e.g. age, gender, training, practice type, etc.) as well as measurement of primary and secondary outcomes, and 12 months later, at t₂ participants allocated to the intervention arm will receive the online educational intervention, and both study arms will be sent the follow-up questionnaire measuring change in primary and secondary outcomes. As with the baseline questionnaire, non-responders to the follow-up questionnaire will be sent reminders by WhatsApp after 3, 7 and 21 days to increase response rates and reduce losses to follow-up. A summary of the schedule of enrolment, interventions and assessment procedures is outlined in Fig 1, following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) recommendations (44).

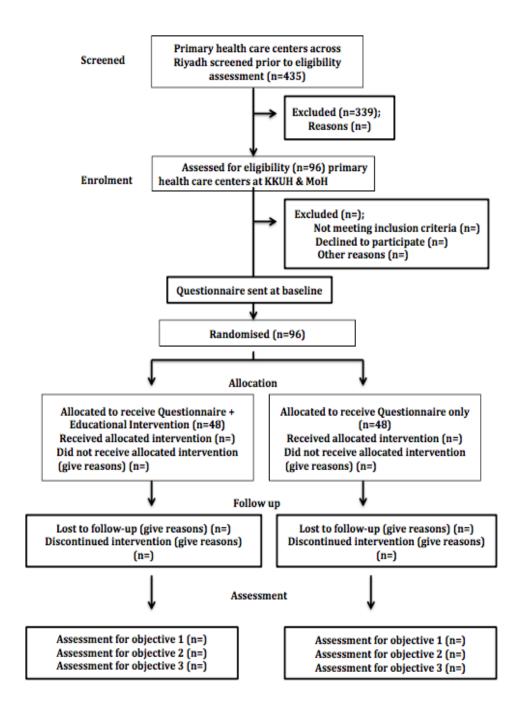
Figure 1. Spirit flow diagram: Schedule of enrolment, interventions and assessment

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	-tı	0	tı	t2	ts	t4		tx
ENROLMENT:								
Eligibility screen	x							
Informed consent	X							
Randomized		x						
Allocation		A						
INTERVENTIONS:								
Educational Online				x				
Intervention								
ASSESSMENTS:								
Baseline			x					
variables*								
Intention to change			X	X				X
Knowledge and			x	x				x
empathy			^	^				^

^{*} age, gender, training, practice type, etc.

In total, the data collection phase will last about 12 months between the initial gathering of baseline data, the delivery of the educational intervention and collecting the final data from the follow-up questionnaires. We will document the number of physician responses, how many physicians were excluded from the sample, and why, and the final number who responded in the control arm and the intervention arm at baseline and follow-up using CONSORT guidelines (Fig 2).

Figure 2. Study Diagram and Flowchart (41)



Statistical Methods, Missing Data and Data Analysis

Descriptive statistics will be calculated for baseline demographics comparing those in the intervention arm and those in the control arm to ensure adequacy of randomization in eliminating potential sources of residual confounding.

As validated scales for the measures of behavioral intention and empathy will be used, the analysis will involve predefined scoring. For the behavioral intention, analysis will follow the standard approach to scoring for the Theory of Planned Behavior Scale (27), as described elsewhere and summarized in Table 1 (supporting information). Data from the Jefferson Empathy Scale will be sent to the Thomas Jefferson Center for Research in Medical Education & Health Care for scoring.

Once scoring is complete, we will analyze the data to determine the difference between intervention and control groups, with calculation of 95% confidence intervals, for the primary and secondary outcome measures. In light of the clustered nature of the data and allocation of the interventions, we will employ linear mixed effect models to obtain proper standard errors for effect estimates and to examine whether the clustering is informative (possible spill-over of educational initiative) (42). Intra-class correlation of responses will inform sampling, size determinations and inclusion criteria for a future full-scale randomized trial (24).

Missing data is a common issue in trials. Those who opt not to respond to all the questions may be less interested in social determinants, thus increasing the measured effect by limiting measurement to those who are more interested. If follow-up telephone contact finds informative differences between responders and non-responders, a sensitivity analysis will examine the likely implications of this bias for the principal analysis (43).

12.2.5 DISCUSSION

This pilot cluster RCT protocol is an important contribution to a growing area of research inquiry on the role of physicians, and the health system more broadly, in addressing SDH. Equipoise of the educational intervention rests on the possibility that physicians exposed to the toolkit make better use of the local community supports and social services that address SDH, thus providing more holistic and effective care. Yet there is a possibility that the intervention will have no effect or even unintended negative consequences (e.g. spouse may respond poorly if marital discord revealed in the clinical encounter, individual with unsafe work conditions may lose job if confronts employer, etc.). Thus, the importance of conducting empirical research to document and address these important issues.

Study Limitations

Primary health care physicians are typically busy and participation rates in research are often low. To overcome these barriers, this research has built-in incentives to increase the participation of primary health care physicians. These include a letter from high-level administrators to promote participation, offering continuing medical education credits for their completed questionnaires, and sending multiple reminders to enhance compliance (12). To overcome the barrier of physicians not reading their emails, and therefore not participating in the research, the invitation message will also be sent using new technologies that are widely used by younger generations such as "iChat" and "WhatsApp". To ensure that the participants in the intervention group read the educational materials prior to completing the questionnaire, the link to the questionnaire will be embedded in the educational materials, and therefore to access this link, the physician needs to open the educational materials, click the link, complete the questionnaire and only then will access to continuing medical education credits be enabled.

The challenges of conducting research in a setting with few academic incentive structures and complex social constructs are limitations that may influence the quality of the data obtained. We expect a possible selection bias, as the physicians contacted are not a random sample of their respective population. This selection bias could affect the measured impact of the intervention,

perhaps over-estimating the potential impact. We propose to address this by contacting a random sample of non-responding physicians, to compare their responses with those who did respond to e-mail reminders. A sensitivity analysis will also test the likely size of this bias, to inform future studies geared to measure the impact of similar educational initiatives.

Implications for policy and practice

Addressing health equity through a SDH framework requires sustained investments and supportive systems. The proposed pilot study will offer timely insight on how to assess the impact of interventions addressing SDH in clinical care. The results will be of interest to primary health care physicians, social workers, health educators and health policy makers. Using a cluster randomized controlled trial design, the pilot will inform the design of a larger formal evaluation of the educational value of the Saudi version of the CLEAR toolkit by assessing its feasibility, acceptability and informing decisions regarding sample size and primary outcome measures.

Finally, it will generate useful preliminary evidence on the potential impact of the intervention on physician knowledge, empathy, and behavioral intention to adopt a social determinants approach to clinical care among the intervention group as compared to the control group. The pandemic has clearly shown the urgency and importance of reducing health inequities. This protocol provides opportunities for countries to adapt and translate these interventions and data collection tools for use in clinical care contexts internationally to better identify training needs and support systems to improve the ability of primary health care physicians to ask about and help their patients in navigating physical health, mental health and social challenges. Data generated in this way can be used by Ministries of Health and medical education institutions to create local evidence for informing policy decisions in support of local health system strengthening.

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12.3 A Simple Educational Intervention Increases Physician Intention to Address Social Determinants in Primary Care: A Pilot Randomized Controlled Trial in the Kingdom of Saudi Arabia (Manuscript 3)

12.3.1 PREFACE

This manuscript reports the results of the pilot cRCT study previously detailed in Manuscript 2. This pilot study recruited 48 primary care clinics that included 100 primary care physicians working in a large university hospital. This sample was randomized by clinic and measured at baseline and one-year follow up for primary outcome measures (i.e. intention to change their practice) and secondary outcome measures (i.e. knowledge and empathy), that were chosen based on the qualitative study (Manuscript 1) to be the most appropriate indicators of physician's experience when addressing their patients social determinants of health in clinical care. Despite the small sample size, the findings of this manuscript met our research objectives and demonstrates the potential impact of the online educational intervention by increasing the index of suspicion to improve case finding of often hidden and underreported social challenges in clinical care, as well as promoting physician intention to refer their patients to local social support services, an important predictor of physician behavior in practice.

Title: A Simple Educational Intervention Increases Physician Intention to Address Social Determinants in Primary Care: A Pilot Randomized Controlled Trial in the Kingdom of Saudi Arabia

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Keywords: Social determinants of health, primary health care physicians, clinical tools, pilot cluster randomized controlled trials, feasibility and acceptability studies, educational online intervention, physician behavior, physician empathy, physician knowledge

12.3.2 ABSTRACT

Background: There is an increasing body of literature on approaches that primary care physicians (PCPs) can use to incorporate social determinants of health (SDH) considerations as part of their routine clinical practice. However, relatively few of these approaches have been rigorously evaluated using experimental study designs. This study therefore aims to assess the feasibility of a cluster randomized controlled trial designed to measure the effectiveness of an online educational intervention on improving PCPs knowledge, empathy and behavioral intention to address SDH in clinical care.

Methods: We conducted a pilot cluster randomized controlled trial in 48 primary care clinics from a large university academic center in the Kingdom of Saudi Arabia to determine the effect of an online educational intervention on how to address SDH in clinical care (i.e. a locally adapted Arabic translation of the CLEAR toolkit), as compared to standard clinical practice. PCPs from both the intervention and control clinical practices (i.e. the clinic being the unit of allocation) received a questionnaire at baseline and at one-year follow-up. Data analysis involved calculating differences in primary and secondary outcomes measures (i.e. physician behavioral intention, knowledge and empathy) between the intervention and control groups.

Results: While physicians in both the intervention and control groups scored high on the empathy scale in terms of caring for their patients, the intervention group physicians had a higher index of suspicion for often hidden social challenges, such as intimate partner violence. The intervention group physicians were also less likely to prescribe medicines as a "band aid" solution for complex social issues, though these differences with the control group physicians were approaching, but did not reach, statistical significance. However, the intervention group physicians were over 6 times more likely to recommend referring their patients with underlying social challenges to local support services as compared to physicians in the control group (OR=6.35, 95%CI= 1.95-20.61).

Conclusion: While this pilot RCT had a small sample size and limited statistical power, it nonetheless demonstrated clinically important findings for promoting more socially accountable

care. The locally adaptable online educational intervention is easy to disseminate widely by email

or text message and takes little time to read, yet it has been shown to have a potential for clinically

meaningful impact on the primary outcome measure of the study, by increasing the index of

suspicion to improve case finding of often hidden and underreported social challenges in clinical

care, as well as promoting physician intention to refer to local social support services, an important

predictor of physician behavior in practice.

Trial Registration: BMC ISRCTN14600984

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12.3.3 BACKGROUND

Promoting population health and reducing health inequities through action on the social determinants of health (SDH) requires both large-scale, "top-down" intersectoral action and health in all policy approaches, as well as "bottom-up," locally responsive community-based approaches, which includes addressing the social determinants in primary health care (PHC) and providing more socially accountable care (1, 2). While there is a growing interest in the expanding social role of clinical care (1, 3-5), how to take action on the SDH in the clinical domain remains illdefined with relatively little empirical evidence to guide practice. Most of the existing clinical practice tools focus on a single social determinant such as housing, income, language barriers or exposure to violence (6, 7), even though there is a clear understanding that these factors are often multiple, co-existing and intersectional. There is growing recognition, particularly with the inequities brought to light by the recent pandemic, of the need to promote greater whole-personcare to address the physical health, mental health and social well-being of patients. Low-cost, easily accessible training materials such as clinical practice tools and guidelines are needed to help primary health care physicians to identify and act on a broad range of SDH in clinical care and to help patients in navigating the available local support resources within health and social care systems, as well as in local communities (1).

One such clinical practice tool is the CLEAR toolkit which was developed to assist frontline physicians, nurses and other allied health workers in addressing the social causes of poor health, and better support disadvantaged and marginalized patients in their local context (8).

Frontline health workers face many barriers in carrying out such work, including insufficient training in social history taking, uncertainty about how to address SDH in clinical practice, and a lack of knowledge of local referral resources, yet it has been shown that health workers with specific ways of asking patients about their social challenges were more likely to report having helped their patients as compared with those who did not know how to ask (93.8% vs 52.9%; p = 0.003) (7). The CLEAR toolkit is a short and easy-to-read resource that synthesizes best practices on addressing social determinants in clinical care (3), has been translated into 17

languages, can be easily adapted to local contexts and is available free of charge for download online (9).

However, translating evidence-based interventions into routine clinical practice is complex because it requires physician behavioral change (10). Healthcare is delivered in the clinical environment at the interface of an encounter between a physician and a patient, making physician clinical behavior, and behavioral intention, an important proximal indicator of the quality of care their patients receive (11). For the success of any intervention focused on changing behavior, an assessment of physician-perceived barriers and of the impact of improved performance in real life scenarios is necessary (12). As well, taking action on SDH in PHC settings has been constrained by organizational factors (13), and therefore greater institutional responsibilities and cultural shifts in clinical practice norms are also required to address the social causes of poor health (14).

There is an important window of opportunity in Saudi Arabia to introduce new clinical approaches as part of broader initiatives for strengthening the primary health care system in the next few years (15-17). While a biomedical approach remains the current standard of care in PHC across much of the Middle East, there is growing awareness of the importance of SDH (18), and frontline health workers are increasingly open to new approaches, particularly if online educational interventions and supports through Internet websites or social media can be used to more easily, rapidly and conveniently convey new information and approaches (19), and ultimately provide better care for patients (19-21).

The aim of this study is therefore to determine the feasibility and acceptability of a pilot experimental study design for evaluating an online educational intervention to improve the knowledge, empathy, and behavioral intention of primary health care physicians in adopting a SDH approach in routine clinical care with a view to informing a full-scale cluster randomized controlled trial (cRCT).

12.3.4 METHODS

Study Design

As part of a larger exploratory sequential mixed methods study design, we conducted a feasibility-pilot study of a two-arm, parallel group cluster randomized controlled trial (22, 23) comparing the use of a brief, online educational intervention to support primary health care physicians in addressing SDH in clinical practice, to routine standard of care. The protocol for this trial and CONSORT checklist is available as appendices in the supporting materials.

Study Setting, Participants and Sample Size

We conducted the pilot cRCT in 48 primary care centers affiliated with King Khalid University Hospital (KKUH), with the primary care practice as the unit of allocation, intervention, and analysis. KKUH is a public teaching hospital that provides primary and secondary care to low-and middle-income patients in the Northern part of the city. Primary health care centers excluded from this study are those located outside Riyadh city where local support organizations and community referrals are not within reach for patients in need. Study participants included all Saudi and non-Saudi trained primary health care physicians who are either licensed as Family Medicine Physicians (FM) or General Practitioners (GP) and are working clinically in one of the 48 primary care clinics at KKUH (i.e. 48 clusters with no subsampling), comprising 100 physicians in total.

Educational Intervention and Local Adaptation

The online educational intervention was an Arabic translation and local Riyadh adaptation of the CLEAR toolkit which guides frontline health workers in a) treating the immediate health problem, b) asking about underlying social problems, c) referring to local social support services, and d) advocating for more supportive environments (9). This educational intervention was adapted to the Saudi context using the CLEAR toolkit trainer's manual, which assists health system administrators in a) adapting the toolkit to their local language and culture (including local referral resources, sensitive and culturally-appropriate ways of asking about social history, etc.), b) educating frontline health workers, c) measuring the impact of using this approach to address SDH

in clinical care, and d) scaling-up the use of this approach more widely across the health system (24). The locally adapted toolkit is available as an appendix in the supporting materials.

Study Primary and Secondary Outcomes and Data Collection Tools

The primary outcome measure of this study is physician behavioral intention to address SDH in clinical care measured using 12 items from the short form of the Theory of Planned Behavior Questionnaire (25, 26). The secondary outcome measures are physician knowledge and empathy measured using clinical vignettes to assess how physicians would respond in "real-world" complex situations, and the Jefferson Scale of Physician Empathy (Health Professional Version), a validated psychometric tool that has already been translated into Arabic among many other languages (27). The study questionnaire therefore included four main components: 1) study participant demographics and clinical practice characteristics, 2) clinical vignettes to assess knowledge and attitudes, 3) the Jefferson Empathy Scale to measure physician empathy, and 4) the Theory of Planned Behavior Questionnaire to assess intention to change clinical behaviors, such as referral practices. In total, the questionnaire contained 48 items based on validated measures and scales from the scientific literature.

IRB Approval and Informed Consent

Institutional review board (IRB) approvals for this protocol were obtained prior to study commencement from St Mary's Hospital Research Centre in Montreal, Canada, a McGill University-affiliated teaching hospital and research center, and by King Saud University Medical City in Riyadh, Saudi Arabia. Due to the nature of a cluster randomized controlled trial, consent was obtained at two levels, first at the managing administrative level (cluster / primary care center level) via meetings to describe the study objectives and methods, and second at the individual participant level (within cluster / physician level) via digital consent embedded in the study questionnaire and asking participants whether they agree to participate in the study by selecting: "agree / disagree to participate" via mouse click or keyboard entry. Participation in the study was voluntary and data confidentiality was ensured by anonymizing data collected and stored. There were no adverse events reported in carrying out this study.

Study Recruitment and Randomization

In total 100 primary care physicians across the 48 primary care clinics at KKUH were invited to participate in this study (**Fig. 1**). Primary care physicians working for the same primary health care clinic were randomized and allocated to receive either the educational online intervention to support action on social determinants in clinical care (Intervention Group Clinics) or to be part of the usual standard of care group with no additional educational support (Control Group Clinics). Study recruitment proceeded via the head of the Family Medicine Department at KKUH and the local managers of the primary health care clinics, who assisted in identifying physicians. All physicians across the 48 primary care clinics received an initial email explaining the nature of the study and providing informed consent information. An independent statistician performed randomization using a computerized random number generator. This ensured the generation of an unpredictable allocation sequence and concealment of this sequence from the investigators prior to allocating physicians to the respective study arms.

Data Collection, Incentives and Reminders

Due to prevalent use of cell phone technology, and to increase the likelihood of a higher study response rate among physicians who are known to be a harder-to-reach study population, the lead researcher created two WhatsApp groups (for the intervention and control groups) and invited each participant via their cell phone number to their respective group. At baseline, the lead researcher sent each group a small introduction about the study objectives and a google form link to the baseline questionnaire. At 12 months follow-up, the questionnaire link sent to the intervention group included an embedded version of online educational intervention (i.e. participants needed to read the intervention to complete the questionnaire), whereas the control group received a link to the same questionnaire but without the online educational intervention. Continuing medical education credits for completing the study were used as an incentive to participate, and non-responders also received reminder messages WhatsApp after 3, 7 and 21 days sent by to increase enrollment. Questionnaire data from the google forms link was downloaded and imported to data analysis software.

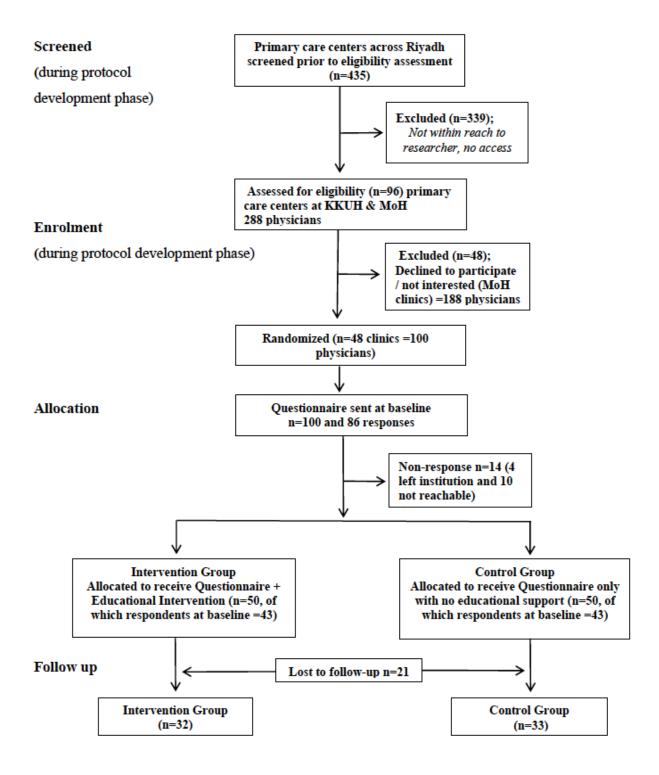
Statistical Analysis

Descriptive statistics were calculated at baseline using SPSS software, and statistical analyses were conducted comparing intervention and control groups at follow-up using an intention to treat analysis. Responses to the questionnaire involving 5-point or 7-point Likert scales were collapsed into binary categories, and cross tabulated by intervention group to assess hypothesized differences in primary and secondary outcomes (i.e. behavioral intention, knowledge and empathy in relation to addressing underlying SDH of patients in clinical care) between intervention and control groups.

12.3.5 RESULTS

A total of 86 primary care physicians (43 in the intervention group and 43 in the control group) completed the baseline questionnaire (response rate = 86%), and over three-quarters of these physicians also completed the 12-month follow-up questionnaire (65 physicians, of which 32 in the intervention group and 33 in the control group), with the remaining 24% lost to follow-up (n=21/86) (**Figure 1**).

Fig. 1. Participant Flowchart (CONSORT) (28)



Description of study participants in intervention and control groups

Following randomization, and in spite of non-responses and losses to follow-up over the course of the study, study respondents in the intervention and control groups were comparable with regard to demographic and clinical practice parameters including age, gender, nationality, duration of clinical practice, designation, or type of clinic (**Table 1**).

Table 1. Comparison of demographic and clinical practice parameters

		Control Group n (%) total n = 33	Intervention Group n (%) total n = 32	
Gender	Male	19 (58)	16 (50)	
	Female	14 (42)	16 (50)	
Age (years)	20-39	15 (46)	12 (38)	
	≥40	18 (56)	20 (62)	
Nationality	Saudi	16 (49)	20 (63)	
	Non-Saudi	17 (52)	12 (38)	
Duration in	0-9	10 (30)	8 (25)	
practice (years)	≥10	23 (70)	24 (75)	
Designation	Resident/Registrar	15 (46)	10 (31)	
	Consultant	18 (55)	22 (69)	
Clinic type (multiple response)	Primary care	17 (52)	14 (44)	
	Family med clinic	25 (76)	24 (75)	
	VIP/Other clinic	19 (58)	21 (66)	
Clinic size (number	1-9	8(25)	3 (50)	
of physicians)	≥10	27 (81)	29 (52)	
Clinic employs	Yes	15 (46)	17 (54)	
social worker(s)	No	10 (30)	13 (41)	
	I don't know	8 (24)	4 (13)	

Physicians caring for marginalized and underserved patients

At baseline, almost all study participants reported caring for marginalized or underserved patient groups (n=84/86, 98%). The majority were involved in caring for persons with mental health problems (n=71/84, 85%), persons living with a disability (n=58/84, 69%), and parents of children who are living with a disability (n=64/84, 76.2%). About half of respondents also reported caring for single parents (n=40/84, 48%), informal workers (n=41/84, 49%), and persons with lived experience of poverty (n=39/84, 46%) (**Figure 2**).

Almost all participants considered it their role as primary care physicians to ask patients about their underlying social challenges (n=82/86, 95%, 95% CI= 89-99%). Respondents consider that their colleagues should also be asking about social challenges with their patients (n=73/86, 86%, 95% CI=75-91%), and if they were the patient, they would want to be asked about this by their doctor (n=66/86, 76%, 95% CI=67-85%).

At baseline, almost three-quarters of respondents reported that they have never seen a training document that helps a physician address the social causes of poor health in a clinical setting. However, most participants reported having specific ways of asking patients about potentially sensitive topics such as poverty or family violence (n=63/86, 73%) and helping their patients in accessing care and support (n=62/86, 72%).

Person with mental health problems 85% Parents with physically or mentally disabled children 76% Disabled/ handicapped patients **69%** Informal workers (e.g. domestic servants, drivers, etc.) 49% Single parents 48 % People living in poverty Person with substance/drug abuse problems or addictions 45 % Victims of verbal or physical abuse and neglect Isolated seniors 30 % People suffering from food insecurity 18 % Newly arrived immigrants and refugees 12 % Young children from disadvantaged households 11 % persons experiencing homelessness 10 20 30 40 50 60 70 80 90

Fig. 2. Caring for marginalized and underserved patients in Saudi primary care

Even high levels of physician empathy are not sufficient for addressing SDH in clinical care

While there were no clinically relevant differences between the intervention and control groups in terms of empathy towards their patients experiencing social challenges, with both groups expressing a very high degree of empathy, there were differences that emerged between the intervention and control groups relating to whether physicians were attuned to the underlying social challenges their patients may be facing and their willingness to address these challenges in a more direct way rather than prescribing medicines or using other measures as "band-aid solutions."

An index of suspicion is important to identify underlying social challenges in clinical care

In the follow-up questionnaire, participants were asked to complete a couple of clinical vignettes to assess their approach to addressing SDH in clinical care. In one of the vignettes, physicians are asked to identify the most likely diagnosis for a 22-year-old female patient who comes to the clinic with her husband. In this vignette, the husband mentions to the physician that his wife has been having difficulties sleeping, complaining of headaches and a lack of appetite. When the physician talks to the patient and asks her directly about her symptoms, the patient is very quiet and only gives short answers and the husband refuses the physical examination. After

reading this vignette, the respondents in the intervention group were somewhat more likely to have a raised index of suspicion for potential underlying social challenges, such as domestic violence (n=21/32, 66%, 95% CI=46-81%) as compared to the control group (n=16/33, 48%, 95% CI= 30-66%).

Avoiding "band-aid solutions" and addressing social challenges in a more direct way

In the same clinical vignette, physicians in the intervention group were less likely to simply prescribe patients anti-depressants or pain medication as a "band-aid solution" for underlying social challenges (n=19/32, 59%) as compared to the control group (n=16/33, 48%). Physicians in the intervention group were more likely to report that they would address patients' social causes of poor health within the clinical encounter (n=21/32, 66%), during each consultation (n=18/32, 56%) and also whenever their patient expresses a desire to do so (n=26/32, 81%).

Intention to refer patients to local support services is an indicator of future action on SDH

Over one third of physicians in the intervention group reported that they would act as role models in advocating for more supportive environments for their patients (n=13/32, 41%) as compared to less than a quarter of physicians in the control group (n=8/33, 24%). Importantly, however, after receiving the online educational intervention, almost half of the physicians in the intervention group reported that they would refer their patients with underlying social challenges to local support services (n=17/32, 53%), as compared to only one sixth of the physicians in the control group (n=5/33, 15%). This corresponds to 6-fold increased odds of referring to social support services in the intervention group as compared to the control group (OR = 6.35, 95% CI = 1.95 to 20.61, RR = 3.5, 95% CI = 1.46 to 8.37).

12.3.6 DISCUSSION

This pilot cluster randomized controlled trial has shown that primary health care physicians are already engaged in caring for a wide range of marginalized and underserved patient groups,

and they are generally empathetic towards the social challenges that these patients are facing (29). Yet these high levels of empathy that were shared between both the intervention and the control group physicians, were not sufficient to ensure the necessary physician knowledge and behavioral intention to address SDH in clinical care.

Even though this pilot study had a small sample size of under 100 physicians across 48 primary care clinics, and therefore relatively low statistical power, it has nonetheless succeeded in demonstrating that a brief, online educational intervention on how to address the SDH in clinical care settings, such as social history taking and referral to local support resources, can significantly influence physician behavioral intention in the intervention group to change their clinical practice, and increases the likelihood of physicians reporting that they intend to refer their patients to local support resources, which is an important indicator of future clinical behavior (30-34). This finding is even more important in terms of predicting intervention effectiveness because in real-life conditions, since a very low-level intervention such as this, which simply involved texting health workers a link to a simple, locally adapted online educational tool that they can open and read on their cell phones in 10-15 minutes, is sufficient to impact the primary outcome of the study, namely changing clinical practice and referral behaviors. In absolute terms, over one third of physicians in the intervention group reported intention to refer to local social supports as compared with the baseline in the control group (i.e. an additional 12 physicians out of 32 reported that they would refer their patients to local social support services for a total of 17 physicians out of 32 in the intervention group, compared to only 5 physicians out of 33 in the control group. In relative terms, physicians in the intervention group are over 6 times more likely to take action on SDH in clinical care and refer their patients to local supports (OR = 6.35, 95% CI = 1.95-20.61).

There were also several other associations that were not sufficiently powered to demonstrate statistical significance but are also clinically relevant. For instance, physicians in the intervention group were also more likely to have a higher index of suspicion to identify presenting social challenges, such as domestic violence, thereby providing more socially accountable and whole person care that addresses physical health, mental health and social challenges (34, 35). The physicians in the intervention group also prioritized managing these social challenges more

directly, for example, by referring patients to social support, and were less likely to try to prescribe medicines such as anti-depressants or pain medications as "band-aid" solutions for complex social challenges or focusing only on physical health issues and not addressing the underlying social issues. These differences could be explained by the greater reported confidence of intervention group physicians in addressing their patient's social challenges within the patient encounter, as compared with control group physicians providing usual standard of care (36).

Our findings are consistent with a growing number of research studies supporting the positive impact of educational interventions in increasing the awareness and knowledge of primary health care physicians regarding the identification and management of social challenges in clinical care (37). Despite growing international recognition of the importance of addressing SDH, adopting SDH approaches in clinical care is still gaining traction (38-40). In addition to the CLEAR Toolkit that was the basis for the intervention in this study, there is a growing number of other clinical tools that are also starting to emerge, such as the Health Begins "Get Ready, Get Set, Go Upstream" Tool (38) or the Poverty Toolkit (41). This study demonstrates the importance of such clinical tools in influencing physician behavioral intention and in providing more socially accountable care to better support patients facing social challenges or undergoing difficult life transitions (30).

Our study highlights the importance of rigorous implementation and evaluation research in assessing the outcomes of such clinical decision aids and educational interventions to be able to advocate for more widespread dissemination in clinical care settings (42), to translate research findings into policy development and changes in clinical practice that can lead to more wholistic care and improved health and social outcomes (43). A previous scoping review has shown that interventions to promote action on SDH in clinical care require uptake and support from organizational leadership to enable more widespread dissemination and a broader shift in clinical culture and practices that can reduce barriers to access for socioeconomically disadvantaged and marginalized populations and improve outcomes on a wider scale (44).

Study strengths and limitations

One of the main strengths of this pilot cRCT was the very high response rate especially for busy health workers who are known to be a difficult-to-reach study population often lacking time to engage in research. Using online technologies to assist in recruitment and data collection as well as providing repeat electronic reminders direct to the physician's cell phone (i.e. sending WhatsApp messages to physicians as reminders) was extremely effective in reaching out to the study population, and this is a trend that is increasingly being used in research (45). Moreover, the design of the intervention also served to reduce barriers to utilization, being free, available online, translated into the local dialect, visually accessible infographics to better reflect the clinical reality, adapted and tailored to provide culturally relevant information and locally relevant resources (rather than broad generalities that does not resonate with local clinical realities), and also information that is presented in a condensed and easy to read format that is rapid to use (taking 15-20 minutes of the physician's time) and includes graphic design and imagery which is familiar and intuitive. Of course, as this was a pilot study, the main study limitations are the small sample size and limited statistical power (46).

Implications for policy and practice

An online educational intervention promoting action on the SDH in clinical care has been shown to sensitize primary care physicians to practice more "whole person care" by asking patients about underlying social challenges and greatly increases the likelihood that physicians will help connect patients in need to local social supports and resources. These findings are particularly relevant in light of the recent pandemic where disruptions have created numerous challenges for people across the whole of society, and particularly for groups who were already marginalized and underserved even prior to the pandemic.

Of course, there remains an important need for broader societal policies to help prevent health disparities through targeted government investments and supportive systems such as quality childcare, employment opportunities and social safety nets, yet at the frontline of care, primary health care physicians are important allies in supporting patients already experiencing marginalization and ensuring that they receive adequate support.

Online educational interventions that are locally adapted and adequately tailored to clinical realities, such as the one used in this study, are very inexpensive and easily deployed using new digital technologies, and this initial research has shown promising results that such interventions can help health workers learn how to ask about social precarity in a sensitive and culturally adapted way, and increase their likelihood of referring patients to local supports. It is therefore particularly timely for such interventions to be scaled-up more widely across health systems, and to take advantage of these opportunities to conduct larger-scale implementation and evaluation research to continue to gather high quality data on intervention effectiveness and measure the impact on population health and equity outcomes.

Competing interests: The authors declare that they have no competing interests. Moreover, the content of this manuscript has not been published nor submitted for publication elsewhere.

Authors' contribution: B. Almujadidi, A. Andermann and T. Schuster contributed to the conception of the study design and developed the data collection materials. B. Almujadidi and A. Alquaiz conducted the recruitment and data collection. B. Almujadidi, A. Andermann and T. Schuster participated in the data analysis. B. Almujadidi drafted the initial manuscript, which A. Andermann critically revised and edited. All authors gave their final approval on the final version of the manuscript and agreed to be accountable for all aspects of the work.

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13 Thesis Discussion & Conclusions

To develop a more nuanced and multi-faceted understanding of how social issues are addressed in the primary health care space and to understand the current culture of practice and the role of physicians in addressing their patients' social determinants of health (SDH) challenges within established norms of Saudi clinical practice, a mixed methods exploratory sequential design study was selected as the most appropriate approach. First, a descriptive qualitative study that included in-depth interviews with 17 primary health care physicians and a focus group with four social workers within a large university teaching hospital was carried out. Then, these qualitative findings informed the development of the data collection instrument (i.e. questionnaire) for the quantitative phase as well as informing the local adaptation of the educational online intervention (i.e. the Saudi adaptation of the CLEAR toolkit), which were then both used in the subsequent quantitative pilot cluster RCT study.

Although the findings of both phases could not be generalized to all practicing primary care physicians in the Kingdom of Saudi Arabia, the integration of these findings explored the current reality and shed light on a topic not often explicitly discussed, namely, how to address social determinants in clinical care. The type of integration in this mixed methods study occurred between the two phases, which is described as integration through "building" in which assessment of the intervention would not be possible without a prior adaptation process (122). The qualitative findings portrayed a comprehensive understanding of what the participants perceived as obstacles and barriers to their taking action on SDH, allowing the following quantitative phase to be more customized to their needs. Additionally, items/domains on the questionnaire were built using the qualitative constructs used by the participants in the study. Local adaptation of the CLEAR toolkit was also developed by utilizing the qualitative findings. This allowed us to focus on the common types of social determinants of health seen in the Saudi primary care setting, as well as translating the questions into Arabic while also accounting for the sociocultural context and identifying the traditional Saudi nuances, even the imagery was adapted to show a female health worker wearing a hijab (123). The adaptation to the local context also included the types of social causes of poor

health presenting to primary health care clinics in Riyadh, and a list of referral resources was created to include the local support agencies and resources available for patients in Riyadh.

Our qualitative and quantitative results suggest that, while a conceptual understanding of being a socially accountable health practitioner exists in the Arab world, the construct of SDH is relatively new. A topic that is all too often broached with reticence because of its sensitivity, is a disincentive for physicians inquiring about these factors, especially in societies that do not naturally foster open conversations and policies addressing SDH. This atmosphere, compounded by the conservative culture of Saudi Arabia, may also inhibit patients from addressing their situations in current health care environments candidly (130). Barriers to health such as poverty, domestic violence, discrimination, and lack of social support may be embarrassing for the patient to discuss and inappropriate for physicians to address unless properly broached (98, 130). Primary health care practitioners in our study perceived that asking questions about a patient's social history is an integral part of their role, demonstrating that a level of empathy and recognition of their patients' non-verbal cues is inherently present. However, inquiries about a patient's social struggles and life challenges requires a relationship between provider and patient that is built on trust. Some participants reported they were confident enough to ask directly or probe indirectly, while others found it difficult and challenging, fearful of being intrusive and offending their patients. This hesitation seems to occur in western context too, in 2011, in an online survey, 87% of American physicians reported being aware that social factors impact health, yet only 20% felt comfortable discussing these issues with their patients (146).

The initial qualitative findings revealed four key themes: 1) kinds of challenges faced by marginalized patients presenting to primary care; 2) physician approaches to addressing social challenges; 3) barriers to taking action on SDH, and 4) opportunities for promoting social accountability in clinical care.

Like other studies in the Middle East (147), our research found that in Saudi primary care clinics, physicians often see many patients struggling with issues relating to poverty, exposure to family violence, mental health challenges and frailty in old age. Forms of marginalization found

in the Saudi patient population presenting to primary care are comparable to those seen in a Canadian Family Medicine center in Montreal serving a large population of immigrants and refugees (97). Among these were patients with mental health problems, people living in poverty, single parents, substance abuse, isolated seniors and victims of abuse and neglect (97). These findings allude to social vulnerability possibly being a global issue that may require a universal framework of action focused on the social determinants of health such as the WHO's conceptual framework for action on SDH to deepen our understanding of the type of change needed to address these challenges (42, 50).

Several barriers to taking action on SDH were noted that align with the social accountability framework (9, 10, 56). Starting from the micro or individual level, many physicians considered issues such as marital problems, domestic violence, poverty, and unemployment to be beyond the scope of the biomedical model in which they have been trained. Physicians reported being untrained or unqualified to address their patients' social causes of poor health, emphasizing gaps in knowledge including understanding the role of the social worker on site in their hospital, being familiar with available resources, and knowing which organizations and support agencies to refer patients to. This is consistent with the current literature and the hurdles faced were similar to those encountered by western physicians, who also lacked the appropriate training to deal with SDH (9, 10, 19, 56, 97, 147).

Beyond issues related to the awareness, comfort and competency of health workers to address SDH, there are organizational and interprofessional barriers at the meso-level. Organizational barriers include those related to clinic processes and structures i.e. consultation time constraints, clinical workload and difficulty following up with patients. For example, a demanding workload influences how physicians perceive SDH and whether they have the time and energy to address them. The development of policies and procedures, the work life balance for practitioners is necessary. The lack of policies contributes to the structural determinants of health as described in the WHO's conceptual framework for action on SDH (42). This is also issue in the western contexts, where the most common reported barriers to addressing SDH included time constraints, knowledge deficiencies, lack of skills and training pertinent to socially sensitive

situations, and deficits in evidence-based research on useful interventions or tools on SDH what are tailored to the needs of practitioners (64).

Finally, at the macro level, inadequate advocacy for or policy attention to the social determinants of health are apparent. Societal factors hindering primary care physician's action on SDH in clinical care are related to the disconnect between clinic and community. An often-repeated barrier by participants in the study was a lack of knowledge about available resources for marginalized and underserved patients, how these resources might be accessed and once accessed, how to ensure that appropriate help and support are provided.

Suggestions for improvement and opportunities to enable physicians to more effectively address SDH similarly align with the social accountability framework and must address micro, meso and macro levels of change (9, 10, 56, 148). At the micro level, recommendations include increasing education about SDH starting with curriculum for medical students and providing graduate and postgraduate training on the actions and approaches for dealing with SDH in clinical care. Workshops and presentations for physicians and consultants on new developments in SDH approaches and their efficiency in clinical care are also recommended. At the meso-level of action, one recommendation from primary health care physicians was greater reliance on nurses for screening and triaging patients, with the goal of freeing up consultation time for SDH assessment and referral (149). This would also serve to strengthen the connection between primary care physicians and social workers, contribute towards the development of a socially accountable, productive and multidisciplinary team of health workers capable of enacting effective SDH referrals. At the macro-level of action, participants stressed the need for better media coverage and campaigns to identify available resources, support organizations and local agencies for addressing all kinds of social determinants of health.

Evidence-based approaches present challenges because of the heterogeneity in Saudi healthcare settings which make it difficult to identify which intervention is most likely to be effective. However, the qualitative findings helped in the understanding of contextual, organizational, individual, and behavioral factors that probably helped in the effectiveness of a

western health care interventions such as CLEAR (134). The following pilot RCT study displayed similar results to those in our qualitative study. Saudi primary care physicians working at KKUH care for a wide range of marginalized and underserved patients and believe that it is their role to ask their patients about social challenges. Lack of knowledge was one of the main barriers to taking action on SDH as perceived by the participants in our qualitative study. The pilot study's educational intervention "the Saudi CLEAR toolkit," despite its minimal online exposure, was believed to affect the intervention group's index of suspicion for social challenges, such as domestic violence, and prioritized managing these social challenges, for example, by referring an elderly patient experiencing poverty to social support.

Participants were more likely to refer patients to local support services and less likely to prescribe medications as a 'band-aid' solution to underlying social challenges. These results are promising because they give us an idea of the physician's inclination to evolve in their dealing with SDH in a primary health care setting. This willingness to grow is the starting point of a transformative change in primary health care. Although the setting examined was well-sourced and heterogenous thus limiting the generalizability of the study findings.

13.1 Research strengths and limitations

To the best of our knowledge, this pilot study remains to be one of the first trials in the Eastern Mediterranean region and in Saudi Arabia to explore the impact of a locally adapted educational intervention (the Saudi version of the CLEAR toolkit) in addressing SDH in clinical care. Thus, identifying prospective training needs and support systems to improve the ability of PCPs to ask about and help patients in navigating their social challenges. Further, the low costs of doing this – a free online educational initiative that did not take more than 10-20 minutes of a physician's time to read through compares favourably with immediate and long-term gains. Another key strength of this study was the delivery channel and data collection method leveraged. Given the challenge of soliciting input from the sample population, text messages were tested and proven to be the most effective and time-efficient channel of engagement. This resulted in a good

response rate among busy healthcare providers by using online technologies such as "WhatsApp" to assist in recruitment, distributing the study intervention and data collection.

Several limitations need to be considered when interpreting findings of the study. First, a selection bias in both qualitative and quantitative studies. Primary care physicians and social workers that agreed to take part in key informant interviews and focus group, neither of which involves random samples of the respective populations, probably reflect the more socially aware and more interested segments of their profession. Those with very conservative social views or extremely biomedical perspectives of the physician's role would be less likely to participate. This selection bias probably affected the measured impact of the work, specifically in the case of the pilot cRCT. Moreover, participants of both studies were from a single region in Saudi Arabia (Riyadh area), findings might be somewhat different in the other 12 regions. Therefore, how this represented the diversity of primary care physicians practicing in Saudi Arabia remains uncovered. However, this is the case for most qualitative studies, their findings are context dependent, rather than statistically generalizable.

Second, the entire study predominantly focused on a single government teaching hospital, and medical doctors and the implications of both for the external validity and transferability of research findings is another major limitation. Other non-academic hospitals run by the Ministry of Health serve a more diverse and socially vulnerable populations but were not included in the study as they lacked social worker services. A related limitation was difficulty recruiting social workers into the study, with participation limited to a 4-person focus group of social workers. Nevertheless, valuable insights were produced regarding shared work experiences, local referral organizations, and suggestions for improvement on service delivery for vulnerable patients.

The third limitation is that the study sample did not include the perspectives of patients themselves, which would offer an important opportunity to further triangulate findings about the value integrating a social determinants approach. Additionally, valuable insight would have been gained had we focused on how the participants spoke about their experiences in addition to what

they said. Doing so would deepen our understanding of our participants' experiences and help us avoid reproducing marginalization.

The fourth limitation, most notably, was the underpowered nature of the pilot study (150). A more in-depth and highly powered study is required to detect significant differences in behavior between the control group and intervention group since control group already exhibited some interest in addressing the social determinants of health. Nonetheless, there were clinically significant differences identified in this study, that were approaching statistical significance, and likely would be statistically significant in a properly powered study.

A fifth limitation is related to the sample size of the pilot study, which could explain why the associations were not significant. Firstly, our sample size was too small to detect the difference. Second, the two groups were perhaps homogeneous in their characteristics, as a result, the sampling may have selection bias (151). A more heterogeneous group should be compared in the future (e.g. Family medicine vs. specialists). However, our intentions were not to assess associations as we did not have a large enough sample from the start for a multivariate analysis and was mainly a tool validation and feasibility assessment. Further studies with a larger sample size are warranted to confirm and quantify the effectiveness.

13.2 Conclusions

Results from this study emphasize an important new direction for primary health care research and advocacy in Saudi Arabia. In particular, they provide fresh perspectives on how primary health care physicians can more effectively address SDH within the clinical setting, and beyond as advocates for system and policy change that recognizes SDH and supports linkages between health services and community-based organizations. The study's online educational intervention is important for primary care physicians to start sensitizing their responsibility to address their patients' health harming social conditions. The simplicity and user-friendly toolkit; a social intervention rightly situated in a primary health care setting that is easy to initiate and maintain, thus improving the quality of care provided to those most in need of our attention. Any primary care provider can engage in some degree of social intervention. Primary care-based

interventions such as the one used in our pilot study, targeting individual level determinants of health, was accessible to a small group of practices and primary care providers within an academic setting. Our study was done on small scale to inform future larger-scale research that will need to implement interdisciplinary health care resources and partnerships within health teams that will address equity. As such, critical knowledge gaps are identified that will guide health education policy and the scale-up of social accountability approaches to undergraduate, post-graduate, and continuing medical education in Saudi Arabia and throughout the Middle East. The extent and success of such online educational interventions depends on the intent to prioritize them, dedication of resources, and engagement with community partners which is parallel to the country's 2030 vision. As many Saudi medical schools have already incorporated more holistic teachings of the bio-psycho-social model and its relevance for medical practice. Pre-clinical years have courses that are public health oriented such as: Evidence-based Medicine, Epidemiology and Community Medicine & Health Sciences. While in their medical years, medical students now learn more about social determinants of health and approaches to primary care in clinical blocks such as their clerkship Family Medicine rotation. So, it would be easy to introduce even more content, such as the Saudi adaptation of the CLEAR toolkit, into the current curriculum.

Finally, primary care physicians in Saudi Arabia understand the importance of addressing their patient's social causes of poor health but require an enabling policy environment that values a social determinants approach and supports them in overcoming barriers in routine clinical practice. In this regard, investments in operationalizing a social accountability approach are needed which are compatible with the government's commitment to achieve sustainable development goals (SDGs) focused on the social determinants of health. The effectiveness of primary healthcare systems will be enhanced if they support partnership between primary care physicians and community-based services given that so much of health lies beyond medical care.

13.3 Knowledge translation

The research proposed is fairly new to the Saudi Arabian context and the use of a Western model may make the use of an end-of-project approach to knowledge translation more useful than an integrated one. Moreover, a fully integrated model of knowledge translation (KT) would require

the participation of all stakeholders, but in this project, although patient is an important stakeholder of this research, their perspective wasn't included. Finally, given that the project is not at an implementation and decision-making stage, it would be more suitable to engage through publication in peer review journals and receiving feedback from the professional community before engaging at a wider level.

13.3.1 Knowledge translation goals

The KT goals include increasing knowledge and awareness on the importance of addressing social determinants of health in a primary healthcare setting, how to take action and support socially vulnerable patients. Understanding the physicians' perceived barriers related to behavior and attitude can help strengthen their social history taking skills and ultimately improve the quality of primary health care practice and patients' health outcomes. The research findings and proposed educational toolkit (a four-step physician's guide on how to address social determinants of health in a clinical setting) will encourage creating structural system change and supportive policy frameworks that enable primary health care physicians to act on the social determinants of health and build alliances with community-based organizations.

13.3.2 Knowledge users

The KT users are primary health care practitioners in academic and non-academic institutions, Family Medicine residency program directors, healthcare social workers in academic and non-academic institutions. This group of stakeholders directly deal with patients and the evidence of knowledge gaps on how to address social determinants of health in their practice will improve physician agency and help scale-up teaching social accountability approaches to undergraduate, post-graduate, and continuing medical education courses in Saudi Arabia. Social workers are able to access data on the referral agencies (NGOs, Ministry of Human Resources and Social Development) available for the vulnerable patients, which allows an understanding of the local Saudi context and how to address these social challenges within this framework.

13.3.3 Target audiences

Other potentially relevant target audiences include health care administrators and managers in hospitals and clinics, health care policy makers in the Ministry of Health in Saudi Arabia. This group of stakeholders are in administrative and governance roles in healthcare systems and will be organizational assets by granting permission to work in and access hospitals and clinics and encourage the use of new educational interventions. Lastly, health policymakers can help create or streamline regulations, procedures, and guidelines that support our goals, providing workshops and training for healthcare professionals. Reducing the patient turn-over rate at primary care clinics by addressing the underlying causes of illness, makes clinics more efficient, better organized, and much more patient-oriented. This also allows the hospital administrators to formulate a better budget, understand which area the funds should be allocated, and help create a more intersectoral environment.

13.3.4 Knowledge translation tools and strategies

Diffusion: Presentations of research findings as posters and oral presentations at global health, international primary health care, and social accountability conferences (e.g., Family Medicine Forum, NAPCRG, WONCA, World Summit on Social Accountability, Canadian Conference on Global Health, Consortium of Universities for Global Health Annual Conference), in addition to presenting at university research seminars, public health conferences, and journal clubs at King Saud University, Princess Nourah bint Abdulrahman University and King Saud bin Abdulaziz University for Health Sciences.

Dissemination: presentations and workshops delivered over the span of a year to primary health care physicians at several university hospitals in Riyadh and summary briefings to the chief director of primary health care programs under the Ministry of Health in Saudi to promote scaling-up of this approach of patient care, and also to garner interest in continuing future research about addressing social determinants of health in primary health care. In addition, a suggested policy brief for the Saudi Commission for Health Specialties for a broader dissemination of this model of

educational intervention that could help in building national guidelines and medical education accreditation that support a culture change in favor of a socially conscious approach to primary health care. Work with health education specialists at university hospitals to create a Saudi version physician guideline for toolkit utilization including paper brochures and mobile applications for ease and convenience.

13.3.5 Knowledge translation tailoring

The CLEAR toolkit is evidence based but needs tailoring to the Saudi Arabian context. Only through knowledge translation will we have feedback on the utility of the toolkit and its benefit to the Saudi primary health care population. Patient perspective: the knowledge translation plan does not take into consideration the patient perspective because the research itself does not. Based on scholarly feedback, future iterations of the knowledge translation plan may include the development of specific messages for patients and their dissemination amongst patient groups.

13.3.6 Knowledge translation evaluation

Evaluation is necessary to assess whether and how the KT goals outlined above are met. Reach indicators determine the number of distributed and downloaded clinical decisions aids (i.e. the CLEAR toolkit), and policy document referencing. Use indicators determine whether target audiences are using the knowledge in graduate and postgraduate medical training (i.e. how to use the toolkit in primary health care practice and using the manuscripts as reading material in graduate curriculum). Partnership/collaboration indicators, for instance, would involve determining whether stakeholders' distribution of research findings to partners such as the Ministry of Health, Ministry of Human Resources and Social Development. Hospitals and clinics collaborating with local community resources and support organizations that help socially marginalized and underserved patients.

14 Contribution of Research Findings to Family Medicine and Primary Care

This thesis contributes to the growing area of research on reducing health inequities, and to my knowledge, it will be the first time that an educational intervention will be implemented in the Arab World to improve physician knowledge and skills in addressing the social determinants of health within a clinical context.

This research will bring a fresh perspective on assessing the impact of interventions addressing social determinants of health in clinical care. The results will be of interest to primary health care physicians, social workers, health educators, health policy makers, as well as knowledge translation researchers and behavioral scientists interested in the determinants of behavior and behavior change. This study will provide new evidence on barriers that Saudi Arabian primary health care physicians face in navigating patients' social determinants of health and will be the first pilot trial in the Eastern Mediterranean region to explore the feasibility of an impact assessment of an educational intervention to assist frontline health workers in better caring for the "whole person" during routine clinical care.

This evidence of physician knowledge gaps and the assessment of educational approaches to improving physician agency will help to guide health education policy and scale-up social accountability approaches to undergraduate, post-graduate, and continuing medical education in Saudi Arabia and throughout the Middle East.

This research explores complex issues of inter-professional cooperation, local and language adaptations of an existing educational package, providing lessons for theoretical and methodological developments in implementation science and evaluation research. Moreover, it provides new directions in primary health care research, providing primary health care physicians with the opportunity to imagine novel ways for understanding and engaging in health advocacy, creating structural system changes and supportive policy frameworks that enable primary health care physicians to take action on the social determinants of health and build alliances with

community-based organizations.

This study supports the National Transformation Program adopted and implemented through Saudi Vision 2030. That is, this study provides evidence that interventions should not be limited to behavior change at the individual level but also at the governance level, by restructuring primary health care centers within the health clusters. Data via their current health needs surveillance can then be used to create specific contracts with the desired organizations licensed by the Saudi Ministry of Human Resource and Social Development, depending on which common social challenges exist within community in each health cluster. Implementation of such policies is a challenging future prospect as this will require streamlining the data collection process at the cluster level and integrating it with current policies. Thus, knowledge produced by this study can serve as a fulcrum for the population health management teams by liaising with social work entities, capacity building for health practitioners to better address their patient community's social determinants of health and working synergistically with the population health teams at the Saudi Ministry of Health.

Moreover, a clear definition of who is considered marginalized in the country is still in process. This thesis can therefore help advance the reflection needed to enable policies to identify and provide access to better adapted services and more socially accountable care for marginalized groups with the Ministry of Health-led services, and for several other ministries and governmental municipalities to work together in tandem and focus on these population groups to better address their healthcare needs and help to reduce health inequities.

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16 Appendices

16.1 Email invitations for physicians to participate in in-depth interviews

Dear colleague,

I hope this email finds you well.

As you know, there is growing evidence that people in lower socioeconomic groups have more health problems and die earlier than the richest and most educated segments of society. The purpose of this research is dedicated to examining Saudi primary care physicians' views on social determinants of health, describing their understanding in the linkage between primary health care and social determinants of health in the Saudi Arabian context, uncovering examples of social determinants of health in Saudi primary care practices, understanding how physicians address social determinants of health, and discovering their challenges, and their suggested opportunities for improvement.

This research study is seeking approval from The St Mary's Hospital Research Ethics Committee, Montreal, Canada and King Khalid University Hospital, Family and Community Medicine Department, Riyadh, Saudi Arabia.

I therefore hope that you can participate, as your input is very valuable to us.

Thank you in advance for your time.

Yours sincerely,

Dr. Anne Andermann & Basmah Almujadidi

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16.2 Consent forms for in-depth interviews with primary health care physicians

Research Title: Addressing Social Determinants Of Health In A Saudi Primary Care Setting.

Brief Description of the Research Project: This research study is dedicated to examining Saudi primary care physicians' views on social determinants of health, describing their understanding in the linkage between primary health care and social determinants of health in the Saudi Arabian context, uncovering examples of social determinants of health in Saudi primary care practices, understanding how these physicians address social determinants of health, and discovering their challenges, and their suggested opportunities for improvement.

Contact Details of Principal investigators (PIs):

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University: McGill University, Montreal, Canada

Contact Details of Graduate Student:

Name: Basmah Almujadidi Occupation: PhD student

Email: basmah.almujadidi@mail.mcgill.ca University: McGill University, Montreal, Canada

Hello. My name is Basmah Almujadidi and I am currently a PhD student supervised by Dr. Anne Andermann at McGill University. The purpose of this research is to learn about how primary care physicians can better support their patients in dealing with various social challenges. This proposal was granted approval from and the St Mary's Research Ethics Committee.

If you choose to participate in this research study, it would involve participating in an in-depth interview lasting for 40-45 minutes. During the interview, you will be asked questions about your views on the common challenges faced by patients presenting to your practice and how you envision yourself addressing these issues.

Your answers to these questions will be tape recorded to keep a record of what you said in your own words. If you do not want to be **tape recorded**, you can say so and we will not record you, and take written notes instead. All paper records and tape recordings of the interviews will be kept in a safe and secure place for five years. After 5 years, all research materials will be destroyed.

Neither your name nor information that could identify you personally will be used in the data analysis and publication / presentation of this study. Your identity will be kept **completely confidential** by the following method: You will be assigned a number and your name will not be recorded.

The research is intended to benefit patients who are dealing with various social challenges, but there is no direct benefit to you from participating in this research. Your participation in this study is completely voluntary. You may refuse to participate or withdraw your consent or discontinue your

participation in the study at any time without penalty or loss of benefits or rights to which you might otherwise be entitled. You can also refuse to answer any questions that make you feel uncomfortable.

If you have any concerns after participating in the research you can contact **Basmah Almujadidi**, King Saud University Hospital- College Of Medicine, Family and Community Medicine Department, Demonstrator and research coordinator, +966503442596 Email: basmah.almujadidi@mail.mcgill.ca. You are welcome to ask questions at any time.

Name	(first,		last)
I agree to participate in this study	Yes	No	
I agree to my interview being audio-taped	Yes	No	
Signature of participant:		Date:	

There are 2 copies of the consent form, one copy is for you.

16.3 Interview guide for primary health care physicians

[Prior to starting, complete the consent form for each participant] Thank you for having signed the consent form and agreeing to participate in the interview. Do you have any questions? [Pause] Okay then, I will now turn on the audio recorder and we will begin.

- 1. What has been your role in providing medical treatment or other forms of care to particularly vulnerable or disadvantaged patients?
- 2. Have you ever asked patients about potentially sensitive topics such as poverty, food insecurity, family violence, structural racism and so forth? If no, why not? If yes, how do you ask?
- 3. How do you intervene if a patient mentions a social challenge?
 - Has it been helpful? Please explain.
- 4. If a patient needed additional support for a social challenge they are dealing with, where would you refer them?
- 5. Tell me about any local resources or support organizations you know of?
 - a. Have these resources been helpful? Please explain.
- 6. In your opinion, is it the role of primary care physicians to ask their patients about and try to help address the social causes of poor health? Please explain.
- 7. Can you describe the barriers to taking action on the social determinants of health and what more should be done in the future to help patients address these social challenges within the primary care space?
- 8. We are conducting a second phase of this project that would entail a randomized control trail (RCT), would you be interested in participating in that phase too?

The interview is now over. Thank you so much for your time. Do you have any additional comments that you would like to add?

16.4 Email invitations for social workers to participate in a focus group

Dear colleague,

I hope this email finds you well.

Clinical social workers are trained to address the social challenges of their patients and to provide them with the support they need. Recently, there has been an increasing body of literature on actions that primary care physicians can also use to act on the social determinants of health as part of routine primary care practice. The purpose of this research is dedicated to exploring Saudi social workers' perspectives on primary care physicians also asking about and addressing the social challenges of their patients in primary care practice, and understanding how social workers can facilitate (or hinder) this involvement.

This research study is seeking approval from The St Mary's Hospital Research Ethics Committee, Montreal, Canada and King Khalid University Hospital, Family and Community Medicine Department, Riyadh, Saudi Arabia.

I therefore hope that you can participate, as your input is very valuable to us.

Thank you in advance for your time.

Yours sincerely,

Dr. Anne Andermann & Basmah Almujadidi

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16.5 Consent forms for focus group with social workers

Research Title: Addressing Social Determinants Of Health In A Saudi Primary Care Setting.

Brief Description of the Research Project: This research study is dedicated to exploring Saudi social workers' perspectives on primary care physicians also asking about and addressing the social challenges of their patients in primary care practice, and understanding how social workers can facilitate (or hinder) this involvement.

Contact Details of Principal investigators (PIs):

Name: Dr. Anne Andermann Occupation: Physician

Email: anne.andermann@mail.mcgill.ca

University: McGill University, Montreal, Canada

Contact Details of Graduate Student:

Name: Basmah Almujadidi Occupation: PhD student

Email: basmah.almujadidi@mail.mcgill.ca
University: McGill University, Montreal, Canada

Hello. My name is Basmah Almujadidi and I am currently a PhD student supervised by Dr. Anne Andermann at McGill University. The purpose of this research is to learn about how social workers can better support primary care physicians in dealing with their patients' various social challenges. This proposal was granted approval from and the St Mary's Research Ethics Committee.

If you choose to participate in this research study, it would involve participating in a focus group meeting lasting for 40-45 minutes. During the interview, you will be asked questions about your views on the common challenges faced by patients presenting to your practice and how you envision yourself addressing these issues.

Your answers to these questions will be tape recorded to keep a record of what you said in your own words. If you do not want to be **tape recorded**, you can say so and we will not record you, and take written notes instead. All paper records and tape recordings of the interviews will be kept in a safe and secure place for five years. After 5 years, all research materials will be destroyed.

Neither your name nor information that could identify you personally will be used in the data analysis and publication / presentation of this study. Your identity will be kept **completely confidential** by the following method: You will be assigned a number and your name will not be recorded.

The research is intended to benefit patients who are dealing with various social challenges, but there is no direct benefit to you from participating in this research. Your participation in this study is completely voluntary. You may refuse to participate or withdraw your consent or discontinue your participation in the study at any time without penalty or loss of benefits or rights to which you might otherwise be entitled. You can also refuse to answer any questions that make you feel uncomfortable.

If you have any concerns after participating in the research you can contact **Basmah Almujadidi**, King Saud University Hospital- College Of Medicine, Family and Community Medicine Department, Demonstrator and research coordinator, +966503442596 Email: basmah.almujadidi@mail.mcgill.ca. You are welcome to ask questions at any time.

Name (first, last):			
I agree to participate in this study	Yes	No	
I agree to my interview being audio-taped	Yes	No	
Signature of participant:	Da	ite:	

There are 2 copies of the consent form, one copy is for you

16.6 Focus group guide for social workers

Focus Group Guide for Social Workers

[Prior to starting, complete the consent form for each participant] Thank you for having signed the consent form and agreeing to participate in this focus group. Do you have any questions? [Pause] Okay then, I will now turn on the audio recorder and we will begin.

- 1. In your experience, what are the most common social challenges faced by patients in a primary care setting?
- 2. How do you ask patients about potentially sensitive social challenges such as poverty, food insecurity, domestic violence and so forth?
- 3. Can you describe the standard process of patient's referral from a primary care clinic?
- 4. What are the local resources or support organizations in the local geographic area of Riyadh that are particularly helpful for each of the social challenges that you mentioned previously?
- 5. What could help us overcome some of the barriers to addressing patients' social challenges in a clinical setting?

The focus group is now over. Thank you so much for your time. Do you have any additional comments that you would like to add?

16.7 The Jefferson Empathy Scale "HP" Version

- 1. An important component of the relationship with my patients is my understanding of the emotional status of the patients and their families
- 2. I try to understand what is going on in my patients' minds by paying attention to their nonverbal cues and body language
- 3. I believe that empathy is an important therapeutic factor in medical treatment
- 4. Empathy is a therapeutic skill without which my success as a physician would be limited
- My understanding of my patients' feelings gives them a sense of validation that is therapeutic in its own right
- 6. My patients feel better when I understand their feelings
- I consider understanding my patients' body language as important as verbal communication in physician-patient relationships
- 8. I try to imagine myself in my patients' shoes when providing care to them
- 9. I have a good sense of humor, which I think contributes to a better clinical outcome
- 10. I try to think like my patients in order to render better care
- 11. Patients' illnesses can be cured only by medical treatment; therefore, affectional ties to my patients cannot have a significant place in my endeavor
- 12. Attentiveness to my patients' personal experiences is irrelevant to treatment effectiveness
- 13. I try not to pay attention to my patients' emotions in interviewing and history taking
- 14. I believe that emotion has no place in the treatment of medical illness
- 15. I do not allow myself to be touched by intense emotional relationships among my patients and their family members
- 16. My understanding of how my patients and their families feel is an irrelevant factor in medical treatment
- 17. I do not enjoy reading nonmedical literature or experiencing the arts
- 18. I consider asking patients about what is happening in their lives an unimportant factor in understanding their physical complaints.
- 19. It is difficult for me to view things from my patients' perspectives
- 20. Because people are different, it is almost impossible for me to see things from my patients' perspectives

16.8 The Theory of Planned Behaviour questionnaire

Items on the Questionnaire	Outcome Measures
Overall I think that addressing patient's social or personal problems within a Primary care setting is	Attitude
To what extent do you agree or disagree with the following statements?	Subjective Norms
People who are important to me think that I should NOT address patients' social causes of poor health in a primary care clinic I feel under social pressure to address my patients' social challenges within my clinic It is expected of me that I address these patients' social causes of poor health within my clinic	
I expect to address my patients' social challenges in each consultation I want to address my patients social challenges in each consultation I intend to address my patients' social challenges in each consultation	Generalized Intention
I am confident that I can address my patients' social challenges in the consultation if I want to Whether I address my patients' social challenges in the consultation is entirely up to me For me to address my patients social challenges in the consultation is	Perceived Behavioral Control
Out of the next 10 patients you see with a social problem, for how many would you expect to address these problems?	Intention Performance

16.9 Email invitation to participate in the pilot RCT study

Dear colleague,

I hope this email finds you well. We would like to invite you to participate in a pilot study on primary care physicians in Riyadh. The purpose of the study is to better understand how to better help patients deal with complex health and social challenges in a Saudi clinical context. Your participation will consist in answering a short online survey that will take approximately 10 to 15 minutes to complete and you will obtain CME credits upon completion of two surveys sent at separate times.

Your participation is completely voluntary and all of your responses will be kept confidential. You may withdraw your consent and discontinue participation at any time. Data will be stored for a period of 10 years. We realize that some of the questions are of a personal nature and assure you that the strictest confidentiality will be maintained. This study has received ethical clearance from the research committee at St Mary's Hospital Research Centre in Montreal, Canada (a McGill University-affiliated teaching hospital and research center), King Khalid University Hospital, and the Ministry of Health in Riyadh, Saudi Arabia.

For any questions about the study, please contact the study coordinator, Dr. Basmah Almujadidi (basmah.almujadidi@mail.mcgill.ca).

You can access the survey by clicking on the link below:

[LINK ATTACHED]

Thank you in advance for your time and cooperation.

Yours sincerely,

Dr. Anne Andermann & Basmah Almujadidi

Anne Andermann, MD, MPhil, DPhil, CCFP, FRCPC
Medical Specialist – Public Health and Preventive Medicine
First Nations and Inuit Health Branch, Health Canada
Public Health Department, Cree Board of Health and Social Services of James Bay
Family Medicine Centre, St Mary's Hospital
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Website: http://www.mcgill.ca/familymed/research/faculty/

Basmah Almujadidi, MBBS, MPH Phd Candidate -Department of Family Medicine McGill University basmah.almujadidi@mail.mcgill.ca

Primary Health Care Physicians Awareness of Addressing Social Determinants of Health in Clinical Care in Saudi Arabia: An Online Survey

As part of an ongoing PhD thesis from McGill university in Montreal, Canada and in collaboration with King Saud university, we kindly invite you to participate in the following online survey. The results will help us quantify the current status of primary healthcare physicians attitudes towards addressing their patients' social determinants of health in clinical practice.

*	Required
1.	Consent/Agreement *
	Check all that apply.
	I agree to participate in this study and for the researcher to use my responses anonymously as data I disagree
Ski	ip to question 2
S	ection 1: Background Information
2.	1. Are you: *
	Check all that apply.
	Male
	Female

3.	2. How old are you? *
	Check all that apply.
	(20-29 years) (30-39 years) (40-49 years) (>50 years)
4.	3. What is your nationality? *
	Check all that apply.
	Saudi Syrian Jordanian Egyptian
	Sudanese
	Indian
	Pakistani Omani
	Yemeni
	Other:
S	ection 2: Practice Information
5.	4. How many years have you been a practicing physician? *
	Check all that apply.
	(0-4 years)
	(5-9 years)
	(10+ years)

6.	5. Are you a: *
	Check all that apply.
	Resident Registrar Senior Registrar Consultant
7.	6. In which clinic do you work in at King Khaled University Hospital (KKUH)? *
	Check all that apply. Primary care clinics Family medicine clinics Employment clinics VIP clinics Satelitle clinics Other:
8.	7. How many primary health care physicians work at your facility? * Check all that apply. 1-2 3-9 >10 physicians
9.	8. Are there one or more social workers working in your clinic? * Check all that apply. Yes No I dont know

Section 2: Physician's Experience Caring for Vulnerable Patients

10.	9. Have you ever been involved in caring for any of the following patient populations? Please tick all that apply *
	Check all that apply.
	People living in poverty
	People suffering from food insecurity
	☐ Isolated seniors
	Single parents
	Young children from disadvantaged households
	Victims of verbal or physical abuse and neglect
	Person with mental health problems
	Person with substance/drug abuse problems or addictions
	Homeless persons
	Newly arrived immigrants and refugees
	Informal workers (e.g. domestic servants, drivers, etc.)
	Disabled/ handicapped patients
	Parents with physically or mentally disabled children
	Other:
11.	10. Do you have specific ways of asking patients about potentially sensitive topics such as
	poverty, family violence, spousal abuse, drug addiction and so forth? *
	Check all that apply.
	Yes
	□ No
	Unsure

12.	11.In caring for patients who are vulnerable was there anything you said or did that you considered particularly helpful for these patients? *
	Check all that apply.
	☐ Yes ☐ No
	Unsure
13.	12. Have you ever seen a training document that helps a physician address the social causes poor health in a clinical setting? *
	Check all that apply.
	☐ Yes ☐ No
14.	13. Which of the following is the least favorable strategy for supporting marginalized and vulnerable patients in primary health care? Please tick all apply *
	Check all that apply.
	Asking about underlying social problems in a sensitive way Referral to local social support services
	Setting yourself as an example and advocating for a more supportive environment for those patients Prescribing patients antidepressant and pain medication
	ction 3: Each question in this section refers to addressing your patients' social challenges
VVII	ann your on no

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	1	2	3	4	5	6	7				
Harmful								Bene	ficial		
*											
Mark only	one ova	Ι.									
			1	2	3	4	5	6	7		
The wron	ng thing t	o do								The rig	ght thing to d
* Mark only	one ova										
	one ova	<i>l.</i>	2	3	4	5	6	7			
* Mark only Good pra			2	3	4	5	6	7	Bad pr	actice	
Mark only			2	3	4	5	6	7	Bad pr	actice	
Mark only			2	3	4	5	6	7	Bad pr	actice	
Mark only Good pra	octice (1	2	3	4	5	6	7	Bad pr	actice	

19. 15. To what extent do you agree or disagree with the following statements? -Kindly scroll to 1 right to view all the answer columns *

Mark only one oval per row.

	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree Nor Disagree	Somewhat Agree	Agree	Strong Agree
People who are important to me think that I should NOT address patients' social causes of poor health in a primary health care clinic							
I feel under social pressure to address my patients' social challenges within my clinic							
It is expected of me that I address these patients' social causes of poor health within my clinic							
I expect to address my patients' social challenges in each consultation							
I want to address my patients' social challenges in each consultation							
I intend to address my patients' social							

challenges in eac consultation	ch					
I am confident th I can address my patients' social challenges in the consultation if I want to						(
Whether I addres my patients' soci challenges in the consultation is entirely up to me	al					(
16. For me to ad	dress my p	patients' soc	ial challenges	in the cons	ultation is: *	
16. For me to ad Mark only one ova 1 2	l.	patients' soc 4 5	ial challenges 6 7	in the cons	ultation is: *	
Mark only one ova	l.			in the cons	ultation is: *	
Mark only one ova	3 ext 10 patie	4 5	6 7	Difficult		u e
Mark only one oval 1 2 Easy 17. Out of the ne	3 ext 10 patie	4 5	6 7	Difficult		u ex
1 2 Easy 17. Out of the new to address these	ext 10 paties e problems	4 5	6 7	Difficult		u ex

Section 4: What would you do in this situation?

22.	18. An 80-year-old male patient knows appointment very late and looking of slippers were detached. When you down, you asked again and this time had missed the bus that usually brint taxi. His wife died and his son abanchimself financially. As his primary he management in this situation? - Ranwould do first, with 1 being most im	distressed, his casked the patie e you held his hags him to the hadoned him a fewealth care physicals the following	clothes went why went why wend, the nospital, and went went actions and actions a	ere dirty vas he late patient fi and he die go and he at would l according	and the s e, he was nally resp dn't have e is barel oe the mo	etraps on his quiet and lo conded sayi money to to y able to su ost appropr op 3 that yo	ooke ing I ake ppo riate
	Check all that apply.	1	2	3	4	5	

	1	2	3	4	5
Refer to ophthalmology					
Ordering HgA1c					
Call the patients son or family members					
Refer the patient to a social worker for financial aid and transportation fees					
Refer the patient to a local support agency for patients with type 2 diabetes					

23.	19. A 22-year-old female patient comes to your clinic with her husband, he told you she has
	been having difficulties sleeping, complaining of headaches and lack of appetite. She is very
	quiet and only gives short answers when asked about her symptoms. She is veiled and her fa
	is covered, you can barely see her facial expressions. You ask to perform a physical exam and
	the husband refuses and demands you to just give her some pain medications. As her prima
	health care physician, what do you think is the main explanation for the patient's symptoms?

24. 20. To what extent do you agree or disagree with the following statements? *

Mark only one oval per row.

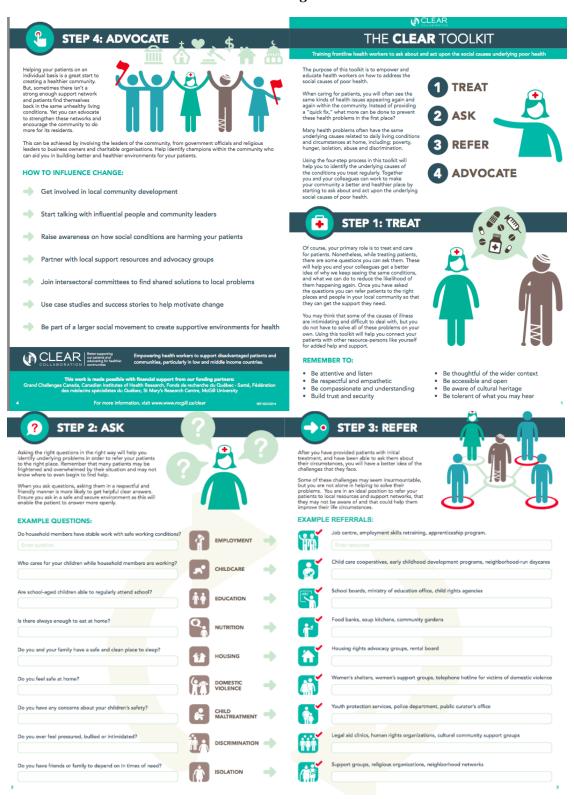
	strongly disagree	disagree	neither agree nor disagree	agree	strongl agree
An important component of the relationship with my patients is my understanding of the emotional status of the patients and their families					
I try to understand what is going on in my patients' minds by paying attention to their nonverbal cues and body language					
I believe that empathy is an important therapeutic factor in medical treatment					
Empathy is a therapeutic skill without which my success as a physician would be limited					
My understanding of my patients' feelings gives them a sense of validation that is therapeutic in its own right					
My patients feel better when I understand their feelings					
I consider understanding my patients' body language as important as verbal communication in physician- patient relationships					
I try to imagine myself in my patients' shoes when providing care to them					
I try to think like my patients in order to render better care					

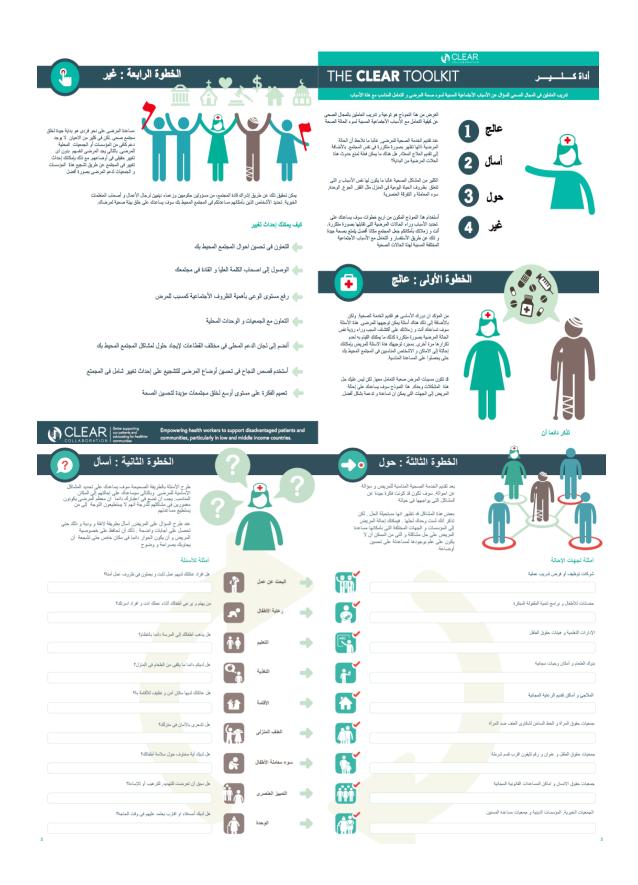
Patients' illnesses can be cured

only by medical treatment; therefore, affectional ties to my patients cannot have a significant place in my endeavor			
Attentiveness to my patients' personal experiences is irrelevant to treatment effectiveness			
I try not to pay attention to my patients' emotions in interviewing and history taking			
I believe that emotion has no place in the treatment of medical illness			
I do not allow myself to be touched by intense emotional relationships among my patients and their family members			
My understanding of how my patients and their families feel is an irrelevant factor in medical treatment			
I do not enjoy reading nonmedical literature or experiencing the arts			
I consider asking patients about what is happening in their lives an unimportant factor in understanding their physical complaints			
It is difficult for me to view things from my patients' perspectives			
Because people are different, it is almost impossible for me to see things from my patients' perspectives			

25.	21. Do you consider it the role of a primary health care physician to ask about theunderlying social challenges of their patients? *
	Check all that apply.
	Yes
	☐ No ☐ Unsure
26.	22. Would you recommend other primary health care physician to ask about the underlying social challenges of their patients? *
	Check all that apply.
	Yes
	☐ No ☐ Unsure
27.	23. If you were the patient, would you prefer that your family physician ask about your social challenges ? *
	Check all that apply.
	Yes
	☐ No ☐ Unsure
28.	24. Do you have any further comments or suggestions? *

16.11 Online educational intervention in English and in Arabic





16.12 The Saudi adaptation of the CLEAR Toolkit used in the pilot RCT

CLEAR

THE **CLEAR** TOOLKIT

تتريب العاملين في الخط الأمامي من المجال الصحي على الاستفسار عن الأسباب الاجتماعية المؤدية لسوء صحة المرضى وطُرق التعامل معها.

- الغرض من هذه الأداة هو تمكين وتتقيف العاملين في المجال الصحى عن كيفية التعامل مع الأسباب الاجتماعية المؤدية لسوء الحالة الصحية.



- عند تقديم الخدمة الصحية المرضى، غالبًا ما ناتحظ أن الحالات الصحية المرضية ذاتها تظهر بصورة متكررة في نفس المجتمع. بالإضافة إلى تقديم العلاج المعتاد، هل هناك ما يُمكن عمله لمنع حدوث هذه الحالات المرضية من الأصل؟
 - الكثير من المشاكل الصحية غالبًا ما تكون خلفها نفس الأسباب، والتي نتعلق بظروف الحياة اليوهية.
- اتباع خطوات هذه الأداة الأربع سوف يساعدك على تحديد الأسباب المحيطة بالحالات المرضية التي تقابلها بصورة متكررة. انت وزمانتك بإمكانكم جعل المجتمع مكانا أفضل يتمتع بصحة جيدة وذلك عن طريق الاستفسار والتعامل مع الأسباب الاجتماعية المختلفة



السببة لهذه الحالات الصحية.

الخطوة الأولى: عَالَج

من المؤكد أن دورك الأساسي هو معالجة المرضى و الاهتمام بهم. ولكن بالإضافة إلى ذلك هذاك أسئلة يمكن توجيهها المرضى.

هذه الأسئلة سوف تساعتك أنت وزمختك على اكتشاف المبب وراء

تكرار نفس الحالة العرضية وطرق تفادى حدوثها مره أخرى.

بعُجرد توجيهك هذه الأسئلة للعريض بإمكانك إحالته للأماكن والأشخاص العناسين في العجتمع المحيط بك حتى يحصلوا على المساعدة الملائمة

قد تعقد أن التعامل مع مسببات العرض الاجتماعية صعب ولكن ليس عليك حل هذه العشكانت وحدك. هذه الأداة سوف تُساعدك على إحالة العريض إلى الجهات العنخصصة التي يُعكن أن تساعده وتدعمه بشكل أفضل

تذكر دائما أن:

- تكون أسته عجيد.
- تكون مُتعاطف مع المريض وتعامله بإحترام.
 - تكون رؤوف وأتفهم.
 - تفوز بثقة العريض و تشعره بالأمان.

- تكون متواجد و نو تتفكير منفتح .
- تضع في اعتبارك العادات والتقاليد المحلية.
- تكون متسامحا في ما قد تسمعه من المريض.





الخطوة الرابعة: ادعم

تُعتبر مساعدة المرضى على نحو فردي بداية جيدة لخلق مجتمع صحي. ولكن في كثير من الأحيان لا يوجد دعم كافي من المؤسسات أو الجمعيات المحلية للمرضي.



وبالتالي يجد المرضى أنفسهم بدون أي تغيير حقيقي في أوضاعهم. ومع ذلك بإمكانك إحداث تغيير في المجتمع عن طريق تشجيع هذه المؤسسات والجمعيات لدعم المرضى بصورة أفضل. يمكن تحقيق ذلك عن طريق إشراك قادة المجتمع من مسؤولين حكوميين ورجال دين ورجال أعمال وأصحاب المنظمات الخيرية وتحديد أشخاص بإمكانهم مساعدتك على خلق بيئة أفضل وصحية لمرضاك.

يمكنك إحداث تغيير من خلال:

- المشاركة في تحسين أحوال المجتمع المحيط بك.
 - التحدث مع أصحاب النفوذ وقادة المجتمع.
- 🦾 رفع مستوى الوعى بأهمية الظروف الاجتماعية كسبب للمرض.
 - التعاون مع الجمعيات والمؤسسات المحلية.
- 🥌 الانضمام إلى لجان الدعم المحلية في مختلف القطاعات لإيجاد حلول لمشاكل المجتمع.
 - 🧅 استخدام قصص النجاح لتشجيع المرضى على إحداث تغيير في المجتمع.
 - 🛑 تعميم الفكرة على مستوى أوسع لخلق مجتمعات داعمة لتحسين الصحة.



Empowering health workers to support disadvantaged patients and communities, particularly in low and middle income countries.

This work is made possible with financial support from our funding partners: Grand Challenges Canada, Canadian Institutes of Health Research, Fonds de recherche du Québec - Santé, Fédération des médecins spécialistes du Québec, St Mary's Research Centre, McGill University

16.13 Saudi IRB approval for phase 1 qualitative study – interviews and focus group

Kingdom of Saud King Saud Univer P.O.Box 7805 Riy Tel: +966 11 4670	rsity(034) adh 1172 011	المملكة العربية السعودية جامعة الملك سعود (634) ص.ب ه-۷۸ الرياض ۱۱۵۷ هاتف: ۱ ۱۵۷۷ الـ۹۲۹		جامعــة الملكسعود		
Fax: +966 11 4671 http://medicalcity.ks		فاکس : ۱۱۶۱۷۱۹۹۲ ا ۲۲۹+		King Saud University		
250		Call Fall		دينة الطبية الجامعية		
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	26.05.2016 (1 Ref. No. 16/0					
	To:	Dr. Basmah Almujadidi				
	10.	Department of Family and Cor	mmunity Medicine			
		King Saud University College of				
		King Saud University Medical				
		Email: basmah.almujadidi@m	ail.mcgill.ca			
	Cc:	Dr. Anne Andermann				
		Dr. Aljohara Alquaiz	1			
		Co-investigator				
	Subject:	Research Project No. E-16-197	5			
	Project Title:	"Addressing the Social Deter				
		Care Setting in Saudi Arabia: A	Preliminary Qualitative St	udy"		
	Done Dr. Base	male Almoria didi				
	Dear Dr. Basi	mah Almujadidi,				
	I am pleased	eased to inform you that your above-mentioned research project was				
		the Institutional Review Board approved. Work on this project		an 1437). The		
	We wish you success in your research and request you to keep the IRB informed					
		ogress and final outcome of th				
	the project related to thi	number shown above in any is study.	future correspondence of	or follow-ups		
	If you have ar	ny question, please feel free to	contact me.			
	Thank you!					
			علاقيات العز	1/26		
	Sincerely you	ire /	13/12/3	100		
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	Prof. Khalid N		Datitutional R	evi		
	MBBS, MSc, F					
		stitutional Review Board				
		niversity College of Medicine		[0.9]		
	King Saud Un	niversity Medical City				
		5 Riyadh 11472 K.S.A.				

16.14 St. Mary's IRB approval for phase 1 qualitative study – in-depth interviews

Centre de recherche de St. Mary

June 21, 2016

Dr. Anne Andermann Principal Investigator Research Associate St. Mary's Research Center

Re: Amendment # 7 approval for Protocol: SMHC# 13-14

Entitled: "CLEARtoolkit pilot study: Helping health workers address the social causes of poor health."

Principal Investigator: Dr. Anne Andermann

Sponsor: FRSQ

Dear Dr. Andermann,

This is to confirm receipt of your amendment received <u>June 17, 2016 f</u>or the above-mentioned protocol. Please be advised that the Chair of the Research Bhics Committee (REC) provided expedited approval for your amendment on <u>June 17, 2016</u>. The amendment will be recorded at the <u>July 13, 2016</u> meeting of the St. Mary's Research Bhics Committee.

Approved documents:

Protocol for QLEAR Toolkit, Saudi Arabia version, dated: March 22, 2016

Should you have any questions or require additional information, please do not hesitate to contact me at (514) 345-3511, ext. 3698.

Thank you for your attention to this matter,

Tierry Morel-Laforce Senior Ethics Officer

Bureau d'examen de la recherche / Research Review Office

Pavillon Hayes / Hayes Pavillon

Bureau / Suite 4710

Tél / Tel..: 514 – 345 3511 # 3698 tierry.morel.laforœ.chsm@ssss.gouv.qc.ca

CC Ms. Tal Cantor, Research Coordinator, SMHC

3830, avenue Lacombe, Pavillon Hayes, bureau 4720 Montréal (Québec) H3T 1M5 Téléphone : 514 345-3511 poste 5060 Télécopieur : 514 734-2662 www.dusss-ouestmtl.gouv.qc.ca

16.15 St. Mary's IRB approval for phase 1 qualitative study – focus group

Québec

Centre de recherche de St. Mary

December 22, 2016

Dr. Anne Andermann Principal Investigator Research Associate St. Mary's Hospital Center

Amendment # 8 approval for Protocol: SMHC # 13-14

Entitled: "CLEAR toolkit: Helping health workers address social causes of poor health."

Principal Investigator: Dr. Anne Andermann

Sponsor: Fonds de recherche du Québec – Santé (FRQS)

Dear Dr. Andermann,

This is to confirm receipt of your amendment received December 6, 2016 for the above-mentioned protocol. Please be advised that the Chair of the Research Ethics Committee (REC) provided expedited approval for your amendment on December 7, 2016. The amendment will be recorded at the January 11, 2017 meeting of the St. Mary's Research Ethics Committee.

Approved documents:

Letter received December 6, 2016 requesting an amendment to conduct a "Cognitive mapping approach", involving follow-on focus groups with health workers, social works and representative from local community support groups.

Should you have any questions or require additional information, please do not hesitate to contact me at (514) 345-3511, ext. 3698.

Thank you for your attention to this matter,

Rebecca MacDonald, MA

Agente principale à l'éthique / Senior Ethics Officer Bureau d'examen de la recherche / Research Review Office Pavillon Hayes / Hayes Pavillon Bureau / Suite 4710 Tél / Tel..: 514 - 345 3511 #3698

stmary.cer-rec.comtl@ssss.gouv.qc.ca

CC: Basmah Almujadidi, Research Coordinator

3830, avenue Lacombe, Pavillon Hayes, bureau 4710 Montréal(Québec)H3T 1M5 Téléphone : 514 345-3511 poste 3698 Télécopieur : 514 734-2652 www.ciusss-ouestmtl.gouv.qc.ca

16.16 Saudi IRB approval for phase 2 quantitative study - pilot RCT

Kingdom of Saudi Arabia Ministry of Health King Fahad Medical City (162)



المملكة العربية السعودية وزارة الصحة مدينة الملك فهد الطبية (١٦٢)

IRB Registration Number with KACST, KSA:
IRB Registration Number with OHRP/NIH, USA:
Approval Number Federal Wide Assurance NIH, USA:

H-01-R-012 IRB00010471 FWA00018774

May 8, 2018
IRB Log Number: 18-227E
Department: External
Category of Approval: EXEMPT

Dear Basmah Almujadidi,

I am pleased to inform you that your submission dated May 2, 2018 for the study titled 'Primary Health Care Physicians Awareness of Addressing Social Determinants of Health in Clinical Care in Saudi Arabia: A Qualitative Inquiry and Pilot RCT' was reviewed and was approved according to ICH GCP guidelines. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

If you have any further questions feel free to contact me.

Sincerely yours,

Prof. Omar H. Kasule
Chairman, Institutional Review Board (IRB)
King Fahad Medical City, Riyadh, KSA
Tel: +966 1 288 9999 Ext. 26913
E-mail: okasule@kfmc.med.sa

According of 8 MAY 2018;

16.17 St. Mary's IRB approval for phase 2 quantitative study - pilot RCT

Centre intégré universitaire de santé et de services sociaux de l'Ouest-del'Île-de-Montréal



Centre de recherche de St. Mary

May 31, 2018

BY E-MAIL ONLY

Dr. Anne Andermann Principal Investigator Research Associate St. Mary's Hospital Center

RE: Approval of amendment #8.1 of protocol : SMHC-13-14

Entitled "CLEAR toolkit: Helping health workers address social causes of poor health."

Principal Investigator : Dr. Anne Andermann Co-Investigator: Dr. BAsmah Almujadidi

Sponsored by : Fonds de recherche du Québec - Santé (FRQS)

Dear Dr. Andermann,

This is to confirm receipt of your amendment received May 24, 2018 for the above-mentioned protocol. Please be advised that the Chair of the Research Ethics Committee (REC) provided expedited approval for your amendment on May 24, 2018. The amendment will be recorded at the June 13, 2018 meeting of the St. Mary's Research Ethics Committee.

Approved documents:

- Form E: Immediate reporting & amendment form, received: May 24, 2018.
- Research Ethics approval, King Fahad Medical City, dated: May 8, 2018.
- Research Ethics amendment approval, King Saud University, dated: May 10, 2018.
- Research Ethics renewal, King Saud University, dated: May 10, 2018.
- Cover letter, dated: May 22, 2018.

Please note that this letter is to acknowledge that amendments were made to the Saudi Arabia component of this study and that our Research Ethics Committee did not review the complete amended protocol. Since appropriate local IRB approval was obtained, it is not necessary for us to approve the revised protocol.

Should you have any questions or require additional information, please do not hesitate to contact me at (514) 345-3511, ext. 3698.

Thank you for your attention to this matter,

Rebecca MacDonald, MA

Agente de planification, programmation et recherche - CER du Centre Hospitalier de St. Mary Direction des affaires universitaires, enseignement et recherche Centre intégré universitaire de santé et de services sociaux de l'Ouest-de-l'Île-de-Montréal Centre Hospitalier de St. Mary

encl: Approved Form E

CC: Dr. Basmah Almujadidi, Co-Investigators

3830, avenue Lacombe, Pavillon Hayes, bureau 4710 Montréal(Québec)H37 1 M5 Téléphone : 514 345-3511 poste 3698 Télécopieur : 514 734-2652 www.ciusss-ouestmtl.gouv.qc.ca