Perceived Facilitators and Barriers to Implementing a Technology Supported Primary Care Program for the Management of Type 2 Diabetes and Kidney Disease in India

by

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Helena Legido-Quigley

Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Duke Global Health Institute in the Graduate School of Duke University

2018
ABSTRACT

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Abstract

**Background:** Low-income countries often face the challenge of being incapable to prevent, treat, and manage diseases that are becoming increasingly prevalent over recent years. An example of this is the rise of chronic kidney disease (CKD) primarily due to type 2 diabetes in rural settings in India. Research concerning preventive CKD and diabetes care in India therefore needs to be conducted. Mobile-health has shown to be an effective tool for supplementing the efficiency and outreach of health care in low-income settings.

**Methods:** This study aimed to 1) understand current practices and preparedness of staff related to CKD and diabetes management in rural settings in India 2) identify barriers and facilitators for quality CKD management and care in rural settings 3) assess the perceived usefulness and barriers to the mHealth mobile-clinical decision support system (mCDSS) approach with respect to CKD in limited resource settings. Qualitative in-depth interviews were conducted with 13 stakeholders comprised of health workers, government officials, and patients with CKD and diabetes to accomplish these objectives. Thematic analysis of these interviews yielded four primary themes.

**Results:** These themes consisted of 1) shortages of CKD and diabetes health services 2) low awareness of CKD and diabetes 3) high familiarity with and suggestions for mobile-based device use 4) supported use of Accredited Social Health Activists (ASHA)s for implementation and utilization of a mobile-based device to manage CKD
and diabetes in rural India. Generally, stakeholders reported an insufficiency of health care services to combat CKD and diabetes, as well as reportedly being in favor of a mobile-based device to mitigate this shortage. Stakeholders also underscored the high plausibility of Accredited Social Health Activists (ASHA)s successfully implementing and utilizing the device for CKD and diabetes services.

**Conclusions:** This analysis will inform creation and implementation of this device in order to increase CKD and diabetes health care in rural settings in India. Specifically, components of this device may be created to address opinions reported by stakeholders. For example, an awareness component can be designed for this device to address the reported low awareness for CKD and diabetes. Additionally, a referral system may be incorporated from ASHA to physician to mitigate the high portion of CKD and diabetic patients undiagnosed. Incorporating these components into this device may effectively address the input of stakeholders and work towards increasing CKD and diabetes health care in rural India.
Dedication

This thesis is dedicated to my family, who has been a constant source of support, not only throughout the entire thesis process, but throughout my whole life. I would like to especially dedicate this to my wife, who has been tremendously encouraging both before and throughout my time at Duke.
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I also acknowledge the tremendously important role played by the George Institute for Global Health India concerning this research. Specifically, I would like to thank the Executive Director of the George Institute India, Dr. Vivekanand Jha, as well as the research collaborators, Dr. Oommen John and Abha Tewari, for their informative direction. This thesis would not be possible if not for the roles each of these individuals played in teaching and guiding me.
1. Introduction

1.1 Chronic kidney disease

Chronic kidney disease (CKD), a condition defined by abnormalities of kidney structure or function for >3 months, is one of the steepest rising causes of death globally [1]. CKD may cause renal complications and cardiovascular disease (CVD), as well as progression to end stage kidney disease (ESKD) [2]. Following the Kidney Disease Improving Global Outcomes (KDIGO) classification, CKD is divided into 5 stages [3]. The last stage of CKD, Stage 5, requires life-sustaining and costly renal replacement therapies, including dialysis and transplantation. CKD treatment is exorbitantly expensive for patients in many low- and middle-income countries where the majority of individuals do not have health insurance [4].

A meta-analysis published in 2016, which included over 6 million patients, estimated global CKD prevalence between 11% and 13% of the world’s population [5]. This study also showed global prevalence of CKD stages as follows: Stage 1 = 3.5%; Stage 2 = 3.9%; Stage 3 = 7.6%; Stage 4 = 0.4%; Stage 5 = 0.1% [5]. ESKD is a form of Stage 5 CKD which is defined as needing dialysis or transplantation. Globally, there are far more individuals with earlier stages of CKD than with ESKD [5]. Earlier stages, however, are largely asymptomatic and require screening for detection and treatment. The majority of individuals with CKD live in low- and lower-middle income countries.
India, Central America, and parts of South America have the highest prevalence of CKD globally [6].

Adverse complications of CKD can be prevented by prompt detection and early initiation of therapy [7]. Healthy lifestyle and drug therapy (such as maintaining blood pressure control with blockers of the renin-angiotensin system, glycemic control, and lipid lower medications) are important for prevention of CKD and delaying progression to ESKD. Prevention of CKD is especially important in lower-middle income countries since the financial burden of CKD treatment can be catastrophic for families near the poverty line. Additionally, proper treatment of CKD is often rare in these countries, such as India [8], so prevention is therefore necessitated even more so.

### 1.2 Economic burden of CKD

The World Bank categorizes nations as low, lower-middle, upper-middle, and high income countries using GNI per capita (USD) as the demarcating unit. India is among the lower-middle income countries, categorized by a GNI per capita of 1,006 to 3,955 USD (per year) [9]. 80% of global renal replacement therapy takes place in high income countries (HICs) [10], most likely as a result of these countries having ability to treat CKD patients as opposed to having a higher prevalence of CKD than lower-middle income countries (LMICs). The disparity of the CKD economic impact among HICs and LMICs is also evident in the proportion of health care budgets spent on ESKD. Furthermore, appropriation of health care budgets in LMICs for ESKD is often insufficient. For example, the monthly cost for dialysis in India is approximately 1,200
USD [11]. The 2016 annual Gross National Income (GNI) per capita in India was 1,670 USD [12]. The percentage of people below the poverty line (<1.90 USD per day) in India in 2011 was 21.2% [13]. Thus, the vast majority of patients with ESKD in India stop dialysis within the first 3 months due to cost [10].

Additionally, a 2017 study concluded United States non-dialysis CKD patients spent a higher percentage of their annual income over a two-year period on health care costs than stroke and cancer patients (7.2%, 5.9%, and 5.1%, respectively) [14]. In India, non-ESKD CKD patients with diabetes spend 86 USD per each hospitalization for CKD complications [15].

**1.3 CKD burden in India**

In 2013, prevalence of CKD stages 1, 2, 3, 4 and 5 in India were reported as 7%, 4.3%, 4.3%, 0.8%, and 0.8%, respectively [16]. Table 1 reports the prevalence of CKD averaged from multiple studies, with a mean rate of 11.11% throughout India. Death rates from ESKD in India are higher in older and urban populations, however the total number of deaths by CKD is higher in rural areas [16]. Total urban death percentage increased from 26% in 2001-2003 to 32% in 2010-2013 [16]. The rural Indian CKD death rate from 2010 to 2013 was 68% [12]. This rapid rise in CKD shows no signs of stopping or leveling off. The severity of CKD is widely distributed. Diabetes is more prevalent in renal failure deaths than control deaths [16] and contributes to approximately 30-40% of CKD cases [17].
1.4 CKD risk factors and etiology in India

The major risk factors for CKD – uncontrolled hypertension and diabetes - are widely prevalent in India. Diabetes rates in rural India increased by approximately 200% from 2000 to 2013 and show signs of continuing to rise [18]. Much of the rise in hypertension and diabetes can be attributed to an increase in risk factors including sedentary lifestyle, decreased physical activity level, calorie-dense diets and increased total polyunsaturated fat consumption. The Indian CKD Registry has sought to determine various causes of ESKD. Type 2 diabetes was the primary cause of ESKD, accounting for almost 30% of patients [17]. Additionally, one 2016 study concluded over 50% of Indian subjects with diabetes remained undiagnosed. Poor glucose metabolism was also observed [19]. One possible reason why individuals in this study exhibited impaired glucose response, as well as why diabetes is difficult to control in India, is the high cost of medications and health care. If diabetic patients cannot purchase medication, diabetes will continue to rise in India.

Similar to diabetes, hypertension is also poorly managed in India. Predictors of hypertension in rural India are increased BMI and increasing age [20]. Obesity is also associated with increased risk of hypertension. Additionally, psychosocial stress acts as a predictor for hypertension. These psychological stressors include stress from one’s occupation (work hours, unemployment), loneliness, housing instability, and impaired quality of sleep [21]. 29.8% of individuals in India have hypertension, comprised of 27.6% in rural areas and 33.8% in urban areas [22]. A 2016 study of Kolkata slums
concluded 26% of individuals who were treated for hypertension presented a blood pressure of the “target level” defined as <140/90 mmHg [23]. Similar studies in the Indian states of Kerala, Chennai, Pradesh, and Himachel report higher percentages of control [23], however the definitions used to assess control may vary between studies. These studies and estimates evince the inadequate prevention, treatment, and management for hypertension and diabetes throughout in India. Because hypertension and diabetes are risk factors for CKD, sub-optimal health care for these diseases results in sub-optimal health care of early stages of CKD.

One 2011 study, which included 52,273 patients, concluded CKD is caused by (diabetic nephropathy (31% of study subjects); undetermined etiology (16%); chronic glomerulonephritis (14%); and hypertensive nephrosclerosis (13%) [24]. These results are summarized in Table 1. Similar to diabetes, CKD awareness and detection rates remain poor in India [19], with the vast majority of such patients not having adequate access to quality healthcare.
Table 1: Prevalence and associated costs of CKD and hypertension throughout India

<table>
<thead>
<tr>
<th>CKD Prevalence*</th>
<th>11.11% of persons aged 18 and over</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of Total Deaths Caused by CKD (all ages) [29]</td>
<td>2.39%</td>
</tr>
<tr>
<td>Percent of 2016 of CKD (all stages, DALYs) caused by [29]**</td>
<td>37.58%</td>
</tr>
<tr>
<td>a. Diabetes</td>
<td></td>
</tr>
<tr>
<td>b. Chronic glomerulonephritis</td>
<td>16.10%</td>
</tr>
<tr>
<td>c. Hypertension</td>
<td>17.92%</td>
</tr>
<tr>
<td>d. Other causes</td>
<td>28.40%</td>
</tr>
<tr>
<td>Hypertension PrevalenceA (Urban) [30]</td>
<td>40.80%</td>
</tr>
<tr>
<td>Hypertension PrevalenceA (Rural) [30]</td>
<td>17.90%</td>
</tr>
<tr>
<td>Hypertension Treatment Prevalence (Urban, Rural) [22]B</td>
<td>37.6%, 25.1%</td>
</tr>
<tr>
<td>Average Daily Cost of CKD-diabetes Patient Service Fees [15]***,B</td>
<td>68.25 USD</td>
</tr>
<tr>
<td>Percent of Out-of-Pocket Expenditure on Health Care [31]</td>
<td>69.5%</td>
</tr>
</tbody>
</table>

*Author-calculated average based upon five studies [16, 25, 26, 27, 28]. **Varied Inclusion criteria: Any person over 18 years of age; screened at medical centers across India; urban; semi-urban men. **Author-calculated from totals. 
***Author-calculated from 4-day mean total; CKD stages I-IV. 
A = 2013; B = 2014
1.5 Structure of India’s health care system

The population of India was 1.3 billion people in 2017 [33]. The health care system in India is comprised of three levels [34]. The lowest population level is the sub-center level, in which nurses and midwives typically provide primary health care. This
level serves 3,000 to 5,000 individuals per center. The next most populated level, at 20,000 to 30,000 individuals served, consists of Primary Health Centers (PHCs), in which doctors generally provide care. The top level is comprised of specialized care coming from Community Health Centers, serving 80,000 to 120,000 people [34]. Another important part of health care in India are Accredited Social Health Activists (ASHA)s. ASHAs are young, local females who are intended to serve approximately 1,000 individuals. ASHAs earn payment dependent upon performed services [35]. The sub-center level includes ANMs and female health workers [34], while physicians work at Primary Health Centers and Community Healthcare Centers. Other key roles for combating CKD in India include Primary Care Physicians (PCPs), Nephrologists, Government Officials, Auxiliary Nurse Midwives (ANM)s, and patients. Each of these positions influence CKD prevalence within India. CKD and diabetes patients can be encountered at all three levels of health care.

1.6 India’s response to CKD

The 4.7% of GDP spent on health care in India [36] is a very small portion compared to the other countries’ health care spending, such as the United States [37]. The National Rural Health Mission (NRHM) was commissioned by the Prime Minister of India in 2005 [38]. NRHM’s objective is to increase GDP spending for rural areas to a minimum of 2.5%, however this still does not include funding for CKD services [38]. This lack of support corresponds to the rapid rise of CKD rates in India. Despite this lack of funding, there has been several initiatives to address the rising rates of CKD in India.
The government has created several programs, including the aforementioned NRHM and the integration of kidney disease management in its 5-year plan cycle [39]. The National Transplant Program is another government intervention still young [40]. Because this plan is still young, India is yet to have an effective program for kidney transplants.

In 2005 and 2008, meetings of the All India Institutes of Medical Sciences, the Indian Council of Medical Research, and the Planning Commission and International Society of Nephrology were held to create prevention of CKD recommendations [8]. The Indian government also undertook an experimental program with the Central Government Health Services to mitigate the financial burden of CKD [8]. In 2005, academic institutions began focusing on ways to improve CKD care in India, as well. Work in both the public and private sector continues to attempt to combat CKD in India.

As of 2009, “the exact burden of CKD in India still remain[ed] undefined” [41]. There are currently no government-mandated preventive programs to screen individuals for CKD in public sector primary health care. Furthermore, the Indian government has not provided any type of subsidized care for CKD patients in the form of medications. Thus, there is failure to implement an action plan in response to the increasing rates of CKD. The government needs to create and build upon effective and immediate initiatives.

The public faces other problems than only a lack of effective government intervention. Public awareness of CKD is low, coupled with a shortage of resources to
combat this disease. This lack of resources results in late diagnoses of CKD, proving difficult to treat and manage [42]. The gap in government operated clinics and hospitals for screening of CKD may be caused by a preference for treating younger patients [43], a demographic in which CKD is not highly prevalent. Another cause of low screening may be the high cost of large-scale testing [44].

Unlike CKD, government programs to manage diabetes are being piloted, such as the National Programme for the Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) [45]. This program was launched throughout 21 states in India in 2010. Diabetes interventions are far more common than CKD programs in India. For example, the Indian 2016 Operational Guidelines for Common Non-Communicable Diseases mandate diabetes and hypertension screening performed annually, yet make no mention of CKD screening [46].

1.7 Engaging mHealth and ASHAs for CKD prevention and management

Globally, rural health care within LMICs often struggles to equal the amount of health care provided in urban areas. This disparity may result from a lack of attraction by health workers to work in rural areas, resulting in low recruitment and retaining of qualified workers. This unattraction is caused by “low wages, poor working conditions, lack of supervision, lack of equipment and infrastructure as well as HIV and AIDS” [47].
This disparity between rural and urban health care occurs in India, as well. 70% of India’s population lives in rural settings [48], necessitating a high portion of health care appropriated in these areas, however this proportionate response does not occur. From 2010-2013, the total number of deaths from CKD in rural India (2,013 deaths) was higher than the total amount in urban areas (930 deaths) [48] and has been increasing over the past two decades. The high amount of deaths caused by CKD in rural areas is not met with a proportionate number of health care workers. For example, in the Indian state of Madhya Pradesh, 80% of physicians from the private sector work in urban settings. [49]

This disparity of health care workers likely contributes to the poorer health observed in rural settings. Indian rural settings suffered an Infant Mortality Rate (IMR) of 62 deaths per 1,000 infants in 2007, while urban setting IMR was substantially less at 39 deaths per 1,000 infants. Furthermore, poor rural health may be exacerbated by almost 70% of Indian hospital space being devoted to urban areas [50], while approximately 70% of Indians live in rural areas [48]. This phenomena is corroborated by the high percentage (74%) of doctors living in urban areas [50]. This severe disparity between urban and rural health care necessitates further investigation into reducing this gap and increasing access to adequate health care for rural individuals in India.

Mobile health (mHealth) has become increasingly more utilized in the previous two decades years. mHealth is defined as “…the use of portable electronic devices with software applications to provide health services and manage patient information” [51].
mHealth has the potential to increase access to adequate health care in rural settings, especially where health care worker shortages exist. mHealth “is emerging as a promising tool to address access, coverage, and equity gaps in LMIC and low-resource settings” and can produce beneficial health outcomes in LMICs [52]. An mHealth analysis of 98 studies using SMS text messaging was comprised of 19 surveillance, 17 patient compliance, 33 prevention, and 28 disease management projects. These primarily HIV/AIDS projects occurred largely in India, Kenya, and South Africa [53].

mHealth is useful among various types of people. A 2017 meta-analysis analyzing 37 studies investigated the effectiveness of mobile health technology creating positive health outcomes in youth. This meta-analysis concluded a small, but positive effect [54]. A common intervention used in mobile-health is SMS text messaging. One systematic review concluded text messaging improved adherence to antiretroviral medication as well as decreased smoking. This study demonstrated the effect mobile-health has on behavioral change [55].

mHealth is also effective for increasing the health of type 2 diabetics. A decade-long meta-analysis reviewing mHealth’s impact on diabetes demonstrated increased glycemic control relative to the standard of care [56]. A separate 2012 study concluded one mobile-health device was associated with a healthier diet and increased exercise [57]. These studies highlight the effectiveness of mHealth on behavioral change for diabetes.
mHealth has not only been utilized for improving diabetic health. In 2014, a mobile-based clinical decision support system (mCDSS) was created to combat CVD in rural areas of India [58]. This mCDSS showed the capacity to increase health care related to CVD [58]. Implementation of this mCDSS may mitigate ubiquities of a lack of rural health care, such as high patient to doctor ratios, low training capability, and poor referral processes. The CVD mCDSS was incorporated into Systematic Medical Appraisal Referral and Treatment in India, also known as SMARTHealth India. The SMARTHealth India function in this study aimed to utilize “(1) a mobile device-based CDSS for CVD risk management, (2) task-[shift] traditional physician roles to NPHWs [nonphysician health care workers], and (3) integration of the overall system within government PHC [Primary Health Care] infrastructure in rural India” [58]. This device was preliminarily successful as it allowed NPHWs to accurately refer a high percentage of individuals who eventually needed blood-pressure lowering medication to physicians [58].

This mCDSS/SMARTHealth India tool’s purpose may be successfully changed to target CKD and subsequently decrease rates of CKD while increasing services in rural India. Additionally, by targeting preventive CKD care instead of ESKD treatment, this study will provide novel insight into mobile-health interventions dealing with earlier stages of CKD. A high amount of CKD intervention research aims to address ESKD and neglects earlier stages of CKD. Studying high quality care for detection and prevention of CKD yields information about treatment of these stages and how to prevent CKD
progressing to ESKD. This emphasis is imperative since CKD treatment is more effective in earlier stages of the disease and therefore is a focus of this research. This research is also important because of the dearth of qualitative research regarding mHealth to combat CKD in rural areas of India or in LMICs.

2. Methods

Overview

This qualitative research is part of a parent study whose objective is to create and validate a mobile technology-aided clinical support (mCDSS) device. This study aims to evaluate the effectiveness of the mCDSS in combination with two other interventions (screening for diabetes plus home health education and training providers) for both management and screening of CKD caused by diabetes in rural settings in India. This primary study was undertaken in order to fill the gap between increasing rates of CKD and diabetes in India and the lack of health care provided for these patients. As previously detailed, rural areas are especially afflicted by high rates of these diseases and face an inadequate health care response, so providing a readily available tool to increase health care may prove beneficial. Implementation of the mCDSS (coupled with other intervention components) may be an effective plan, however possible effectiveness of the mCDSS first needs to be investigated. In order for this effectiveness to be evaluated, qualitative research was conducted.
This qualitative research was guided by three primary objectives. The first objective was to understand current practices and preparedness of staff related to CKD and diabetes and its management in rural settings in India. The type of CKD being investigated in this study is that caused primarily by diabetes. Studying CKD unrelated to diabetes is not an objective of this research. In-depth interviews with stakeholders were intended to provide insight into any gaps in response. Understanding this inadequacy will enable informed creation of the mCDSS to directly address and augment these gaps. The second objective was to identify barriers and facilitators for quality CKD management and care in rural settings. The first objective was intended to assess the gaps in health care, while the second objective was intended to assess how to fill these gaps. Understanding the challenges to CKD and diabetes care will enable creators of the device to address these problems as well as for these problems to be accounted for during the implementation process. For example, if a barrier to proper CKD health care in rural settings reportedly includes low awareness from patients, the mCDSS can be created with an awareness component to address this gap.

The third objective of this research was to assess the perceived usefulness and barriers to the mHealth mCDSS supported care approach with respect to CKD in limited resource settings. This objective focuses on addressing the gaps in the health care system elucidated from the first and second objectives while specifically utilizing the mCDSS. For example, if various stakeholders voiced concern that the device will be too difficult
for health workers to understand, this device can be created to be as user-friendly and simple as possible.

The findings from this qualitative study will complement the parent study, which aims to create a device to be used by ASHAs in rural India to help prevent, manage, and treat CKD and diabetes. The opinions provided by stakeholders in these interviews will guide the mCDSS creation process, such as processes regarding algorithm referrals to be implemented in this device. ASHAs and midwives are the stakeholders most familiar with using mobile-health devices in their work. Their input can guide creation of the device to optimize ease-of-use and to learn about certain features which reportedly would be useful to be included for CKD care delivery.

The physicians to be interviewed (Primary Care Physicians and Nephrologists) give insight into this device by detailing the management of CKD and diabetes as it pertains to rural India, specifically the treatment options available. Government officials may provide useful information by discussing previous interventions undertaken to address non-communicable diseases in India and the advantages and disadvantages of these programs. Understanding these previous programs allows the creation of the device to focus on or avoid facilitators and challenges of these interventions. Interviewing CKD and diabetic patients provides information into awareness and services these patients received about their disease before and after diagnosis. This may inform creation of the device as to what extent to focus on increasing awareness using this device.
2.1 Conceptual framework

A conceptual framework is a defining set of ideas and understandings about the phenomenon being researched [59]. This framework’s intent is to ultimately guide research. The conceptual framework used in this study is a modified version of a framework presented by Kayser et. al in 2015 [60]. Kayser et. al. created a useful conceptual framework for investigating the perceived effectiveness of mHealth technologies.

The conceptual framework used in this study is an adjusted and simplified version of this 5-stage framework, using only certain steps. The first step of this framework involves thinking of possible general purposes for this mCDSS, such as using it to combat CKD. The framework understanding is that this step is important in order to understand the direction of the research. Step 2 includes further thought towards specific uses of this device and the various settings in which this device may be effective. Step 2 is a useful part of the conceptual framework since discerning possible specific uses for the mCDSS will enable interviewers to inquire about these uses to respondents. Steps 1 and 2 were performed by the study staff of physicians and researchers. Step 3 (Step 4 in Kayser’s framework) researches “[d]iscussion and scrutiny of the characteristics arrived at”. The working understanding with this step is that answers received during interviews will be useful for developing the mCDSS, such as addressing certain specific challenges about which respondents spoke. This step occurred during
interviews since respondents provided input into possible uses and implementation methods for the mCDSS.

Lastly, Step 4 (Step 5 in Kayser’s framework) involves using the guidance provided by the respondents to further modify possible uses of the mCDSS. This conceptual framework component presumes that using the respondents’ answers to guide creation of the mCDSS will create an effective device. This step will occur after interview analysis and the subsequent write-up. It is important to note that a conceptual framework should not be confused with procedural research steps. The outlined framework only appears in steps because the conceptual framework guides every step of the analysis.

2.2 Study design and analytical framework

The objectives of this research were studied by qualitative analysis of in-depth stakeholder interviews. The study design included analytical procedures created prior to analysis. This research used Thematic Analysis as the analytical framework to arrive at the main themes. Thematic Analysis is used in qualitative research as a “a method for identifying, analysing and reporting patterns (themes) within data” [61]. Thematic Analysis may be conducted in 6 primary steps [61]: 1) “Familiarising with data” 2) “Generating initial codes” 3) “Searching for themes” 4) “Reviewing themes” 5) “Defining and naming themes” 6) “Producing the report”. Each of these steps were followed in this research. An advantage to using Thematic Analysis is the ability to divide and compartmentalize interviews in order to discern common opinions about
topics. Thematic Analysis can also be used to analyze research from a variety of different settings [61].

One disadvantage of Thematic Analysis previously asserted by researchers is the lack of complexity of this technique. This simplicity may result in an impaired ability to extract relevant themes from interviews and therefore impair further action guided by those themes, including recommendations for creation of a mobile-based device and proper implementation processes. These impairments, however, are not a concern to this research. This lack of concern is because the number of interviews analyzed (13) was low enough that a less-complex analysis was able to be used. This number of interviews provided a variety of informative answers from respondents, but the information provided by respondents was distinct enough to require a less-complex analysis. If a higher amount of interviews were analyzed, a more complex analytical technique may have needed to be utilized in order to analyze the high number and variety of answers and important themes discussed.

The first objective was achieved by interviewing stakeholders familiar with the CKD and diabetes health care system. This includes stakeholders such as Primary Care Physicians, Nephrologists, and Government Officials. First-hand experience of the health care system is helpful in providing informative answers. Interviewing individuals providing health care (physicians, ASHAs) produces insight into the services offered and the quality of these services. Conversely, interviewing patients about these topics may reveal if patients feel the health workers are achieving their goals. Interviewing
both the health care provider and recipient may result in viewpoints from both health care sides concerning this objective.

The second objective also gains varying information from the different perspectives of the stakeholders. An effective intervention will result in increased CKD and diabetes health care across many different rural settings, such as rural villages and Community Health Centres. Therefore, interviewing only one or two cadres of stakeholders is not sufficient for the far-reaching intent of the mCDSS. It is additionally important to interview different types of stakeholders working in different levels of health care, such as ASHAs, Primary Care Physicians, and Nephrologists. This yields an understanding of how to accomplish the second objective across various settings of health care.

The third objective was accomplished by using interview methodology due to the varying familiarity with mobile-based devices among stakeholders. For example, one stakeholder may not be familiar with mHealth while another stakeholder may be very familiar. The input from both stakeholders may differ, but both opinions are useful and informative. Additionally, the open-endedness of interview methodology allowed for not only a non-binary answer, but also an elaboration of the perceived usefulness of the mCDSS device in rural settings.

2.3 Qualitative analysis selection

The open-ended characteristic is a general advantage to conducting interviews since participants may provide useful answers or insight about which the interviewer
did not inquire. Interviews often also serve as more appropriate methods for obtaining data than more closed-response options, such as surveys. This advantage occurs because participants have the opportunity to elaborate upon their response, thus providing answers which would not have been listed on a survey. Interviews also create a dialogue that may produce added insight.

This open-ended methodology results in more opinions and data to be analyzed and therefore provides more useful results to guide further action. Despite these advantages, qualitative analysis is not without it’s drawbacks. Qualitative analysis is often subject to the quality of the questions in the interview guide. If the questions asked during the interview promote comfort, openness, and are asked well the answers will typically be insightful. If the interview questions are asked in a manner which promote narrow answers, this will not produce useful responses.

Additionally, the quality of qualitative analysis is subject to the people being interviewed. If the participants are well-informed, thoughtful, and vocal about their opinions, answers are insightful. If participants are not well-informed about the subject matter or are hesitant to offer their opinion, the answers provided may not be informative or may even be untruthful. Qualitative analysis has both positive and negative characteristics, largely dependent upon who is conducting the interview and who is being interviewed.

CKD in India is also not a highly studied topic and an area to which the Indian government does not allocate many resources. Therefore, a literature search on the
above objectives is not sufficient. In-depth interviews with individuals familiar with the current landscape of CKD and diabetes management in rural India needed to be conducted in order to obtain insight into this setting. The subjective nature of the interview methodology enabled stakeholders to provide contrasting opinions on the same topic, which yielded useful comparisons to inform successful future intervention.

2.4 Creation of interview guides and codes

Interview guides were created jointly by physicians, qualitative researchers, and global health researchers at the George Institute for Global Health India and Duke-National University of Singapore (Duke-NUS). Interview guides were designed in view of the objectives of this study, which were created before the interview guides were prepared. Previous coding in other studies from the study staff guided proper creation of the codes used in this project. The primary goal during the creation of the interview guides and probes was to design them in such a way to prompt stakeholders to provide informative answers while contributing to accomplishing objectives. Interview probes were designed to maximize the amount of information extracted from each interview. Common inquiries ran throughout each interview, however each role (e.g. ASHA, Nephrologist, PCP) had questions asked specific to their specialty.

This researcher’s role in developing the interview probes was to offer input after reviewing the previously created probes. This researcher reviewed the interview guides and provided insight about questions which may be added to produce additional informative answers. Audio recordings and notes were taken during each interview and
reviewed by the same qualitative researcher (from the George Institute for Global Health India) afterwards. The in-depth interviews were recorded and subsequently transcribed into Hindi. The Hindi transcripts were then translated into English, if the interview did not already occur in English. Each interview consisted of questions related to the current status of CKD and diabetes management and treatment in India, use of mobile-health technology to combat CKD, and the role of ASHAs in implementation of this mobile-health technology.

2.5 Analytical coding of interviews

After translation and transcription of interviews, interview analysis utilized codes, which are common topics about which the participants spoke, such as “Perceptions and attitudes towards CKD/DM” and “Work load”. A list of codes used to analyze interviews were created. One set of codes was used for every analysis, regardless of stakeholder role. Another set of codes was created for each specific role and used accordingly. Sub-codes were also created to further coding analysis. The author of this report was the only person who coded the interviews.

Before coding began, codes were created by the author and reviewed by qualitative researchers at The George Institute India and Duke-NUS. Input from these researchers was used to edit the codes and interview codes were subsequently finalized. Each interview line was placed in one or multiple codes. Coding was conducted using NVivo 11™ software. After coding, several themes were extracted. The interview codes can be found in Appendix A. Theoretical saturation was attempted in order to determine
sufficiency of the information produced from these interviews [62]. This coding analysis resulted in common themes which are the primary results of this study.

2.6 Study site and participants

Interview participants were comprised of 13 stakeholders: 4 patients, 2 Auxiliary Nurse Midwives (ANM)s, 2 Accredited Social Health Activists (ASHA)s, 2 Government Officials (1 District Medical Officer and 1 Chief Medical Officer), 1 Nephrologist, and 2 Primary Care Physicians (PCP)s. 6 females and 7 males were interviewed. Participants were purposively sampled. Interviews were conducted in urban areas of Delhi and in the state of Haryana.

2.7 Stakeholder selection

The stakeholders interviewed were specifically selected because of their ability to provide helpful insight into the implementation and utilization of the mCDSS device. The Primary Care Physicians and Nephrologists produced answers chiefly relevant to the exact burden of disease in India and the current status of management and treatment in India for CKD and diabetes. They provided first-hand insight into the efficacy of those treatments as well as suggestions for improvement. Since the mCDSS may be implemented directly into the health care system, interviewing those with such in-depth knowledge of that system is imperative.

ASHAs reported useful information since they are the health care workers who will likely utilize the mCDSS most directly. The ASHAs provided answers regarding the
ability to use the mCDSS, perceived effectiveness of this device, and change in work
load due to this intervention. Government officials, such as District Medical Officers and
Chief Medical Officers, proved insightful regarding government interventions for
combatting CKD and diabetes. The Indian government plays an important role in the
success of health care interventions, so understanding potential ways this device can be
successful from a Government Official’s perspective is useful.

Auxiliary Nurse Midwives provided a first-hand knowledge of the rural health
care environment in India and, like the ASHAs, offered information on the plausibility
of using the mCDSS in these settings. Lastly, it would be unwise to create this mCDSS
without understanding the patients’ perspectives. This device has the end-objective of
benefiting the patients, so understanding the problems they face regarding CKD and
diabetes is imperative to creating a useful device to combat these specific challenges.

2.8 Pre-testing

These interview guides were pre-tested by constant review and editing. Experienced
qualitative researchers were highly involved in this review process. These experts were
trained qualitative researchers from the George Institute of Global Health India and
Duke-NUS. The researchers from the George Institute of Global Health India were the
same researchers who conducted the interviews. Additionally, similar interview guides
used for other studies were reviewed and provided information for the creation of this
study’s guide. Specifically, separate qualitative analysis studies were conducted in
previous years unrelated to this study. The interview guides for these studies guided the
formation for the interview guides for this current project (e.g. similar amount of questions, similar amount of codes).

2.9 Training of staff

Training of staff occurred via collaboration between the study team. After these collaborations, subsequent follow-up questions made certain the study staff fully understood the interview and analysis procedures. The team experts in qualitative analysis ensured the analyst for this study was prepared before analysis began by reviewing and assessing other qualitative analysis performed by this researcher, including work from NVivo 11™. Proper training of the staff ensured interview questions were asked in a specific manner and that interviews were conducted in such a way to yield the most useful results. Additionally, training of staff resulted in proper ethical considerations, such as requiring consent before conducting interviews. Interviews were conducted by two qualitative researchers at The George Institute of Global Health India.

2.10 Interview process

Written consent was obtained by presenting the participants with a written explanation of the study and how the answers they provide may be used. Participants provided their written consent by signing this form. The Consent Form was written in a manner that adequately and clearly presented the information to which the participants were consenting. Prior to beginning this study, ethical approval was obtained from the
Institutional Review Board at the National University of Singapore, as well as the Ethics Committee from the George Institute of Global Health India. Privacy and comfort was ensured as much as possible by interviewing in locations to which the participants agreed. Interviews did not continue if the participant felt uncomfortable and vocalized a desire to stop at any time.

Interviews were conducted using an interview guide, which was comprised of approximately 30 questions. Prior to interviews beginning, the questions in the interview guide were translated into Hindi. The amount of questions varied dependent upon the stakeholder role interviewed. Additional questions were asked if the interviewer needed clarification or further insight into primary interview questions. Interview guides were divided into 3 sections: Existing knowledge and practice on DM/CKD situation in rural setting; Facilitators/barriers for DM/CKD management in rural setting; Perceived usefulness/difficulties for mCDSS approach.

2.11 Analytical framework

Codes were created after study staff discussion about which topics were of interest and after briefly reviewing transcripts to see how participants answered in respect to the objectives. Thematic Analysis reduced the interviews into common themes regarding plausibility and facilitators and barriers to implementation of the mCDSS, which will inform creation and implementation of the mCDSS-SMART Health system. This Thematic Analysis is influenced by each set of interviews from each category and across categories.
Data from the interviews was assessed for quality at each level of analysis. Undetected, inaccurate, or poor interview analysis that is not accounted for may skew interpretation of the interview results. Data quality was assessed by reviewing the variety of responses, elaboration of answers, and repetition of opinions.

Saturation was not reached after analysis of the 13 interviews. Saturation was determined by evaluating if enough varying answers were provided from the analyzed interviews as well as the quality of those answers. Despite saturation not being reached, this study still provided useful conclusions given the exploratory nature of this research. The novelty of this study, being the first of its kind, permitted informative results which will guide further research. It is important to emphasize the exploratory and pilot nature of this study in light of saturation not being reached since the conclusions are not driving specific non-research steps, but instead informing future research which will itself guide action. For example, this study may narrow down certain themes and probes to focus on for future interviews or focus group discussions regarding this research. The results from those studies can then guide action and steps to create a trial intervention.

This exploratory study methodology has its advantages, but also has limitations. The analysis used in this study extracted important themes from all 13 interviews, however there was not a sub-group comparison analysis conducted. Comparing themes between sub-groups may provide insight into the potentially varying opinions on topics between cadres. This limitation may be addressed in further research, in which sub-group analysis can be performed. If this study was not exploratory, then the lack of saturation may be a limitation, as well. Because of the exploratory nature of this study,
however, reaching saturation is not completely necessary, as results from this study can still guide future research on this topic. Furthermore, the generalizability of this research methodology may be limited in scope and one need be cautious in applying this research to other settings. For example, because of the exploratory nature of this study, the results may not be generalizable to other countries or diseases. Future research guided by this study, however, will be more generalizable and may inform research in other countries and about other diseases.

3. Results

Overview

The analysis of 13 in-depth stakeholder interviews yielded four primary themes. These four themes are 1) a shortage of CKD and diabetes health services 2) low awareness of CKD and diabetes 3) high familiarity with and suggestions for mobile-based device use 4) supported use of ASHAs for implementation and utilization of a mobile-based device to manage CKD and diabetes. These themes helped achieve the three objections of this study. Stakeholders generally iterated that a mobile-based device may be effective in filling the reported gap for underserved populations attempting to manage CKD. ASHA involvement was said to be imperative for proper utilization of this mobile-based device. Uses for this device were mentioned, such as increasing awareness and creating a bio-database. Barriers for utilization of this device included both logistical (poor internet, absence of a Smartphone) and social challenges (patients expecting ASHAs to make less mistakes since they would have more resources).
### Table 2: Characteristics of interviewed stakeholders

<table>
<thead>
<tr>
<th>Role</th>
<th>Number Interviewed</th>
<th>Gender and Age (M=Male; F=Female)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auxiliary Stakeholder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>2</td>
<td>45F, 34F</td>
</tr>
<tr>
<td>Midwife (ANM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accredited Social Health Activist (ASHA)</td>
<td>2</td>
<td>42F, 49F</td>
</tr>
<tr>
<td>Government Official (District Medical Officer and Chief)</td>
<td>2</td>
<td>49M (DMO), 40M (CMO)</td>
</tr>
<tr>
<td>Medical Officer</td>
<td>Nephrologist</td>
<td>1</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
<td>---</td>
</tr>
<tr>
<td>Primary Care</td>
<td>Physician</td>
<td>2</td>
</tr>
<tr>
<td>(PCP)</td>
<td>Patient</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>6 Females, 7 Males</td>
</tr>
</tbody>
</table>
Table 3: Supporting Quotes for Themes

<table>
<thead>
<tr>
<th>Themes</th>
<th>Supporting Quotes from Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Shortage of CKD and Diabetes Health</td>
<td>“…we do not have any established program to manage CKD patients or even collect data. In the absence of a renal registry, the exact disease burden of CKD/ESRD in the Indian population cannot be assessed accurately. Data is not available for diabetes, but according to me, diabetes is the disease which is not properly screened.”</td>
</tr>
</tbody>
</table>

-Nephrologist, Male
2. Low Awareness of CKD and Diabetes

“...you will be surprised to see even on the first screening the blood sugar is 340 [milligrams per deciliter], so till now the patient has been roaming around with 340 and 350 random blood sugar....So, still that awareness is very low”

-Government Official, Male

3. High Familiarity with and Suggestions for Mobile-Based Device Use

“I think it’s feasible! Now if you visit any of the PHCs, all the PHC staff—most of them [have] smart phones. India has come [to] that stage. So, if you have a mobile app or some software in the computer and you train them how to use that, it will be really helpful”

-Government Official, Male
“It will be beneficial as it will have all the biodata of the patient. It will show when the patient took the medicine, which medicine he had taken, when the treatment had started…Records of patients can be made which can be told to the doctor. It will save time also.”

-ASHA, Female**

4. Supported Use of ASHAs for Implementation and Utilization of a Mobile-Based Device to Manage CKD and Diabetes

“ASHAs are [the] key person of rural population…if we want to know about a child in the village…we ask the ASHA worker for that because the ASHA worker knows about every child in their village. She knows about every patient and knows what problem is going on with them.”

-Primary Care Physician, Male
“…without technology it will become vast and too hectic for everyone…if the technology is there then everything happens quickly”

-Primary Care Physician, Female

*These words are direct quotes from the stakeholders and are largely representative of the other stakeholders’ opinions from the same role, unless stated otherwise. **This female’s comment is her idea of what should be included in the mCDSS. The features listed in this comment were not listed by the study staff and may or may not be in the mCDSS.

### 3.1 Shortage of CKD and diabetes health services

Generally, every stakeholder reported a shortage of CKD and diabetes services. Stakeholders iterated that this shortage included staff shortages and was seen in rural areas. There was a highlighted lack of services more so for CKD treatment than for diabetes. While not every stakeholder reported a shortage for diabetes services, several respondents did say there was inadequate screening for diabetes within their community. One patient elaborated on the connection between a lack of proper diabetes screening and staff shortages when this individual told of having to wait for a long period of time for their diabetes screening because of a staff scarcity. While waiting, this patient said they felt poorly because of the fasting required beforehand. Very few respondents mentioned having adequate CKD health services in the communities.
3.1.1 Lack of CKD services and diabetes screening

Physician respondents reported referring CKD patients who visit the rural clinic to a General Hospital because the rural clinics are not capable of offering adequate services to CKD patients. Respondents also mentioned a lack of services at Primary Health Centers (PHCs), including PHCs in rural areas. Diabetes management services were generally reported as sufficient by respondents, but screening services were reported as insufficient. Respondents described a large gap between the adequacy of diabetes care compared to the inadequacy of CKD care. One Primary Care Physician (PCP) mentioned the inability for rural services to treat CKD patients.

“If rural areas are taken, then we refer patients of chronic kidney disease. We do not keep them with us here.”

-Primary Care Physician, Female

A different Primacy Care Physician highlighted the contrast in PHCs’ ability to treat and manage diabetes compared to CKD.
“Related to diabetes management, we have things like the lab facilities, blood sugar test, and random blood sugar, only sugar is checked. For ANC [antenatal care], urine and albumin are tested.”

“We have no facility for chronic kidney disease at PHC level.”

-Primary Care Physician, Female

The relatively adequate management of diabetes was a common sub-theme throughout interviews. For example, glucose-tests were reported as free in PHCs. Additionally, diabetes management outreach was told to be far-reaching. One PCP mentioned realizing diabetes (or “sugar”, as most respondents referred to diabetes as) became a problem in their area and subsequent “camps in villages” and organizations were created to manage diabetes and increase awareness.

“…glucometers are carried and awareness is spread for hypertension and diabetes. Outreach camps are organized and we spread awareness in school also.”

-Primary Care Physician, Female

Despite these screening interventions, respondents still maintained diabetes screening services were not adequate and underscored an overwhelming under-detection of diabetes. Stakeholders also continued to iterate the lack of CKD health
services. One Nephrologist detailed this lack of CKD services, the consequences of this scarcity, and the lack of diabetes screenings as follows.

“...we do not have any established program to manage CKD patients or even collect data. In the absence of a renal registry, the exact disease burden of CKD/ESRD in the Indian population cannot be assessed accurately. Data is not available for the diabetes, but according to me, diabetes is the disease which is not properly screened.”

-Nephrologist, Male

This Nephrologist also detailed the severely low awareness by diabetic patients about their disease state.

“[A] significant amount of people [are] diabetic, but they don’t know that they are diabetic. They come to know only when they manifest some form of complications. Major chunks, about 90%, are still hidden. Lot[s] of people are dying, but we are short of resources.”

-Nephrologist, Male

One District Medical Officer simply stated “They don’t know what type of disease they have”, regarding the uncertainty of individuals’ own disease states. Even if a patient knows he or she has a disease, they are unaware of the potential treatment options, as detailed by one ASHA.
They do not know that they have sugar [diabetes], even if they get to know it, they don’t feel like [visiting] a doctor for treatment. They are not aware that if they get it checked, it can be treated.”

-AHSA, Female

3.1.2 Shortages of staff

Various respondents reported a shortage of staff related to treating and managing diabetes and CKD. Two PCPs said there were no Nephrologists where they worked. One PCP reiterated the challenge of a “manpower shortage”. This PCP detailed a staff shortage related to follow-up difficulties, screening of CKD and diabetes, and PHC services. The PCP stated “there is a manpower shortage, all the time”. Shortages of staff reportedly affect diabetic patients’ feeling of well-being, as well. One diabetic patient described the physiological consequence of having to wait for a diabetes screening due to a shortage of staff.

“Patients [have] empty stomach[s] from the morning, like I have to come from here only 2 minutes route, but someone coming from outside [with an] empty stomach has to wait for so long till his number arrives and till that time the patient becomes very hungry. [Diabetic] patient’s appetite is also increased and [secondly the] patient can go for one test only, either empty stomach or after eating food.”

-Patient, Male
This same patient reported crowding occurring due to a lack of staffing. One PCP detailed the double burden of a shortage of staff coupled with a busy schedule.

“...I am there at [PHC], I am alone, I have to manage here...ANM [Auxiliary Nurse Midwife] also has everything now, they have to see all the diseases, they have to see birth [to] death also...So they are overburdened and same we have manpower shortage, but still we are working.”

-Primary Care Physician, Female

These viewpoints provided insight into the first objective concerning “preparedness of staff” as well as a component of the second objective, specifically “barriers...for quality CKD management and care”. Regarding these objectives, staff was reported as unprepared by stakeholders because of the shortages mentioned. Additionally, the shortage of staff, CKD, and diabetes services may be a barrier to delivering proper CKD and diabetes health care in these settings.

Stakeholders reported a lack of CKD and diabetes health services, however barriers to adequate care need to be investigated from an individual level, as well. While it is important understand the service inadequacies, understanding the individual inadequacies to combating CKD also serves as informative. Examples of possible individual insufficiencies include a lack of motivation to receive treatment, low awareness of CKD, and low medication-plan adherence. Proper interventions can only
be created after insight regarding both service-level and individual-level inadequacies is gained.

3.2 Low awareness of CKD and diabetes

A generally low awareness of CKD and diabetes was mentioned by several stakeholders. Awareness in this sense refers to individuals understanding that CKD and diabetes are diseases they may be susceptible to or have. Several respondents described the ramifications of this low awareness and how to combat this.

3.2.1 Consequences of low awareness of CKD and diabetes

One stakeholder mentioned how a lack of awareness of CKD and diabetes can lead to a decreased chance of receiving screening. Likewise, a Nephrologist explained even more severe complications stemming from a lack of awareness.

“Most patients come to realize they have ESKD when it is too late, there are no mechanisms for early identification, referral.”

-Nephrologist, Male

CKD is not the only disease reportedly affected by low awareness and the subsequent undiagnosed state. One Government Official detailed the negative consequences of a patient with untreated diabetes caused by low awareness and the importance of diagnosis.
“…you will be surprised to see even on the first screening the blood sugar is 340 [milligrams per deciliter], so till now the patient has been roaming around with 340 and 350 random blood sugar….So, still that awareness is very low”

-Government Official, Male

A Nephrologist reported one of the “main issues” causing a late realization by patients of their CKD state as a “lack of awareness among the people and even doctors”.

Health professionals are “not screening for kidney disease among those with diabetes.”

(Nephrologist, Male) A Government Official also explained how not only low awareness of diabetes and CKD was present, but also low awareness regarding treatment for these diseases. This Official also detailed how proper intervention may increase awareness for diabetes.

“Now they have awareness, as initially we had to ask them to go for a [diabetes] test.

Nowadays, patient himself says that my joins are [in pain], then it may be because of [diabetes], we say that it is a good thing screening will be done…So one can say that there is awareness”

-Primary Care Physician, Female

This Primary Care Physician’s statement iterates that these individuals are aware of diabetes, which is a notion not many other stakeholders shared. One ANM, however, reported that patients are aware of diabetes, but are not aware of CKD. These outlying
comments suggest that a small portion of people are aware of diabetes and that individuals are even less aware of CKD. Patients were not the only demographic reported to be inadequately aware of CKD. ASHAs and physicians were reported to…

“have little bit [of] knowledge in kidney disease because they do not know much beyond the urea, creatinine, because the reason behind is that once the kidney disease has been diagnosed, we refer them.”

-Primary Health Care Physician, Female

3.2.2 Methods for increasing awareness

Many respondents offered insight for increasing awareness of diabetes and CKD. One PCP explained what a previous diabetes awareness intervention included and the results of this intervention.

“…we had counseled them for diabetes, we had taken classes for them for 1 week, then after that they had understood everything.”

-Primary Health Care Physician, Female

In addition to teaching 1-week long classes, outreach camps were suggested by a PCP to increase awareness of diabetes. Additional methods described by stakeholders to increase awareness included providing “printed pamphlets” and increasing awareness
during medical visits and Anganwadi (rural care centres for children and mothers) meeting.

“During an Anganwadi meeting, pregnant women and old ladies can be told”

-ASHA, Female

Meetings for programs specifically for pregnant women or elderly ladies were suggested as another place to increase awareness. One of the most informative respondents concerning awareness detailed their current program to increase awareness and screening. This plan involved partnering with Anganwadi centres and schools to conduct screenings there. This stakeholder also suggested a “media campaign”, as well as combining diabetes and non-communicable disease (NCD) awareness with other IEC (Information, Education, and communication) programs.

Primary Care Physicians reported that diabetes awareness was present, although low. Government Officials highlighted the fact that a lack of awareness results in a lack of awareness about treatment, while Nephrologists reported individuals not seeking treatment till their CKD was too far advanced for reversible treatment. Patients mentioned a desire for awareness to be spread. These results contributed to accomplishing the second objective of learning about “barriers...for quality CKD management and care”. The reported low awareness represents the low education concerning CKD and diabetes, while this highlighted lack of awareness may prove to be
a barrier to effective CKD and diabetes management in rural health care settings in India.

Both themes discussed thus far have detailed the lack of services at the health systems level and individual level. Additional needed information concerns stakeholders’ viewpoints about effective interventions for combatting these inadequacies. Likewise, it is imperative to assess the plausibility of implementing certain interventions for combatting CKD, such as an mCDSS. The success of an mCDSS may largely be contingent upon familiarity of the health worker with the device before implementation. The first two themes presented the problem of inadequate CKD services and awareness, while the following two themes outline a possible solution.

3.3 High familiarity with and suggestions for mobile-based device use

Respondents widely reported being well-versed in mobile device use and pointed out the far-reaching effects mobile devices provide. A large portion of respondents iterated that cell phones were widely used around India. Access to internet was reported as high, however the quality of that internet was reported as low at times. ASHAs and one ANM reported using mHealth in the form of tablets. While knowledge of mobile-based devices was high, knowledge of any current mobile-based devices specifically to manage CKD was low.
3.3.1 Plausibility of mobile-device use to manage CKD

Most respondents said a mobile-based device to manage CKD was plausible.

One reason for this belief was cited as the familiarity with mobile-based devices, as illustrated in the following quote.

“I think it’s feasible! Now if you visit any of the PHCs, all the PHC staff—most of them [have] smart phones. India has come [to] that stage. So, if you have a mobile app or some software in the computer and you train them how to use that, it will be really helpful”

-Government Official, Male

Likewise, ASHAs were reportedly familiar with mobile-based devices. In addition to ASHAs, one of the two ANMs said she used tablets in her work. The other ANM mentioned not using any mobile device.

 “…now every ASHA is using mobile [or a tablet], so there is no problem in it.”

-Primary Health Care Physician, Female

One PCP clearly iterated support of using this mobile-based device and echoing the general sentiment of other stakeholders by stating...
“nowadays, everyone has Smartphone, ANM also has [them], the tablet has also been given to the ANM. So, the app’s idea is right.”

-Primary Care Physician, Female

### 3.3.2 Suggestions for mobile-device use

Potential perceived benefits from the respondents’ views for a mobile-based device to manage CKD varied widely. One ASHA described a potential benefit being a way to expedite the process of helping someone obtain emergency care. Another ASHA described the perceived benefits of a database for patients’ health information.

“It will be beneficial as it will have all the biodata of the patient. It will show when the patient took the medicine, which medicine he had taken, when the treatment had started…Records of patients can be made which can be told to the doctor. It will save time also.”

-ASHA, Female

Other potential advantages for a mobile-based device reported by stakeholders included SMS text reminders for follow-up appointments, an increase in access to medicine, a streamlined process of providing data to clinicians, and tracking patient medication intake. One Nephrologist added…
“Training would be a key component to improve the screening for kidney disease and providing training at District Hospitals to physicians to be able to detect, manage, and appropriate referral. [This] is an important component of the approach to CKD burden management.”

-Nephrologist, Male

One respondent described the ability for the mobile-based device to be useful in locating disease prevalence geographically and understanding disease distribution from this mapping. When asked about the benefits of using a tablet in an ASHAs work, one ASHA responded as follows.

“The advantage will be that if there is an immediate emergency, then we can send the message directly. The doctor will also be alert, then it will be beneficial for the survival of a patient, as if someone is having seizures and we press a button and send a message that the condition of the patient is bad, take him away from here, so much benefit will be there.”

-ASHA, Female

One ASHA reported not using tablets in her work, however she did describe the perceived benefits of using tablets.

### 3.3.3 Challenges to mobile-based device use

While respondents provided many benefits of a mobile-based device, they also provided possible challenges to it’s successful implementation. One patient voiced their
concern about the inability for whomever is using the mobile-based device to understand how to use it.

“…[the mobile-based device] should be used, but it is a village area [where] maximum people are not literate. The person who has knowledge can use it and the person who does not have knowledge—for them it is useless. Anyone who does not know how to use a Smartphone—for them it is not beneficial!”

-Patient, Male

One PCP underscored a primary concern of slow internet. This PCP described this potential problem as the only possible issue and as “the biggest challenge of the rural area”. While one ANM mentioned not using mobile-based devices in their work, a Government Official iterated that Primary Health Centre employees used mobile-based devices. Nephrologists suggested this device could be used for screening purposes.

These reports contributed to components of all three objectives. Understanding the use of mobile-based devices in India aids in understanding “current practices” of diabetes and CKD management of the first objective. Obtaining perceptions about the plausibility and perceived effectiveness of mobile-based devices is insightful respective to possible “facilitators for quality CKD management and care in rural settings” of the second objective. Lastly, understanding the use and familiarity of mobile-based devices in health care settings is relevant to the third objective since understanding mobile-
based device use in Indian health care provides insight into “perceived usefulness and barriers to the mHealth mCDSS supported care approach”.

As detailed, the mCDSS was reported to be seen as potentially effective for combatting the inadequacies described in the first two themes. Solely having an effective device, however, is not sufficient for ensuring this device reaches its objective. If this device has been designed well, but cannot be implemented into the health care system effectively, the device may not serve its purpose. An effective system needs to be used to implement this device.

3.4 Supported use of ASHAs for implementation and utilization of a mobile-based Device

Every stakeholder with whom equipping ASHAs with the mobile-based devices was discussed iterated this would be beneficial. Insight was provided regarding how to most effectively utilize ASHAs, how to motivate them to add this device to their work, and how these ASHAs would deal with the increased work load. The importance of ASHAs’ current work was underscored by one respondent.

“…for doing any such program, ASHAs are the backbone.”

-Government Official, Male

One PCP emphasized that “ASHAs are the key person of the rural population.” Many stakeholders reported that the importance of ASHAs was due to the connection the
ASHA has with the population. ASHAs were described as knowing most of their community by face and name.

“...if we want to know about a child in the village...we ask the ASHA worker for that because the ASHA worker knows about every child in their village. She knows about every patient and knows what problem is going on with them.”

-Primary Care Physician, Female

One ANM iterated the influence ASHAs have in the community by saying...

“Any program or anything happens, they are involved. They are known by name and face wise also, that they are their ASHA workers, so they listen to them.”

-Auxilliary Nurse Midwife, Female

### 3.4.1 Increase of Work Load

The increased work load from adding the mobile-based device to ASHAs’ responsibilities was reported as not a high concern. One ANM placed herself in the role of the ASHAs working with the mobile-based devices and felt there would be “no issue with increase in work” and stated “We have to do work.”

One ASHA reported that “The work will increase!”, however she mentioned possibly decreasing the work load by using the mobile-based device where patients are
gathered, like an “Anganwadi meeting”. A Government Official provided detailed insight into the work load of ASHAs, as well as the necessity for them to be involved in certain programs.

“I don’t think ASHAs will be burdened except those ASHAs who are working for more than 20,000 [people in the] population. They are very busy. Apart from the communicable diseases, ASHAs should also be involved in the non communicable diseases. So, for every program to be successful, ASHAs should be a part of it.”

-Government Official, Male

3.4.2 Utilization of Mobile-Based Device by ASHAs

While an increased ASHA work load was not reported as a main concern, several stakeholders did provide insight into effectively incorporating this mobile-based device into ASHAs’ roles. One idea offered was to provide incentives to ASHAs for adding this to their work. The PCP described the reasoning behind this idea as follows.

“By receiving incentives, they feel motivated that they are getting and more often they will send patients for follow-up [if] they will receive incentive…This thing influences them a lot.”

-Primary Care Physician, Female
This PCP also stated the incentive plan was beneficial because of the absence of salaries for ASHAs. The same PCP emphasized why use of the mobile-based device would be advantageous.

“…without technology it will become vast and too hectic for everyone…if the technology is there then everything happens quickly”

-Primary Care Physician, Female

One stakeholder said that this device will be used effectively by ASHAs if it is “[kept] simple and short.” This stakeholders added advice to “Make it easy for them”.

Challenges to effective utilization of this mobile-based device by ASHAs were reported as the previously detailed poor internet connection, however one ASHA added a social component challenge, as well. This ASHA told how patients would feel that ASHAs should make less mistakes because they have more resources after being given a mobile-based device.

“And if there is any error in any treatment, people will say that you have tablets, but they have not even been treated”

-ASHA, Female
ANMs reported ASHAs as influential within the community, while Government Officials and Primary Care Physicians also highlighted the importance of ASHAs. Patients reported an idea of utilizing ASHAs to increase awareness, while the Nephrologist interviewed did not speak about the topic of ASHAs using the mobile-based device. Similar to the previous theme, this theme contributes to all three objectives. Understanding the use of ASHAs in the community and their perceived usefulness for implementing and using the mCDSS provides insight into “understanding current practices” of the first objective, identifying potential “facilitators for quality CKD management” of the second objective, and into potential usefulness of the mCDSS of the third objective.

The third and fourth theme have provided insight into solutions for the inadequacies addressed in the first two themes. Stakeholders reported a lack of adequate CKD and diabetes services, as well as low awareness of CKD and diabetes. These challenges may be effectively addressed by the creation of the mCDSS and implementation of this device with ASHAs. Overall, all four themes will work together to guide creation of the mCDSS in order to improve CKD and diabetes-caused CKD in rural areas in India.
4. Discussion

Overview

Our qualitative study is the first of its nature in India and in an LMIC. This study was conducted in order to learn directly from individuals about CKD and diabetes awareness, current practices to manage these diseases, and the possibility of creating and implementing a mobile-based device that will supplement these practices. Participants described the current practices, facilitators and barriers to seeking quality CKD care, and potential usefulness of using an mCDSS for CKD service delivery in rural India. Our research’s intent is to aid in reducing the gap in services for CKD and diabetes management in rural India. This gap contributes to increased rates of CKD and diabetes in these areas. Both government intervention and the private sector have not been able to significantly decrease the rates of CKD and diabetes in rural India. Therefore, creative interventions, such as mobile-health programs, are needed to supplement this lack of effective health care.

4.1 Summary of results

The answers provided by stakeholders were informative and insightful. The resulting quotes gathered from interviews worked together to produce a general idea of opinions and input toward CKD in India and using a mobile-based device to combat it. These useful answers culminated in the themes and sub-themes presented in this section. Data collected from interviews is subject to the participants’ answers, regardless
if the answers are or are not informative. Fortunately, the answers provided by participants were useful and the resulting extracted themes were consequently informative.

Four key themes emerged from analysis of interviews through which the study objectives were achieved. The primary themes consisted of 1) a shortage of CKD and diabetes services 2) low awareness of CKD and diabetes 3) familiarity with and use for mobile-based devices in health care 4) implementation of a mobile-based health care device through ASHAs. Generally, stakeholders reported a shortage of services designated for CKD and diabetes, inadequate CKD screenings, low awareness of CKD and diabetes, favorability towards using mHealth to manage these diseases and towards ASHAs being the implementing health care worker. These conclusions were arrived at from analysis using Thematic analysis. Codes were created for overall analysis and role-specific analysis. Transcripts were divided into these codes which resulted in the extraction of the four primary themes. This analysis and the conclusions made from it will contribute to the creation and implementation of the mCDSS to aid in the prevention, treatment, and management of CKD and diabetes in rural India.

The first theme concerns the shortage of CKD and diabetes health care services as reported by stakeholders. This lack of services was first reported in 2006 [63]. This corroborating 2006 report insisted there is “hardly any state-funded medical treatment and medical insurance facilities for patients with CKD and ESRD in India.” The Physician responsible for this document also detailed that “screening for and early
detection of CKD, particularly in high-risk patients with hypertension and diabetes, remain grossly inadequate” [63]. In response to the need for increased diabetes care, India has recently mandated ANMs screen for diabetes and hypertension, as previously mentioned [46]. While this is a useful measure, this mandate is only applicable to certain districts and similar efforts are yet to be created for CKD itself. A key observation of our study are stakeholders’ views that screening alone will not be sufficient and training of providers in management of CKD and diabetes is equally important.

This first theme contributes to accomplishing the first and second objectives. Understanding of current practices, a component of the first objective, was achieved by reports of a lack of adequate CKD and diabetes care services in the stakeholders’ settings. Specifics of these services were provided by stakeholders and contributed to the understanding of current practices. For example, one specific was that while both CKD and diabetes services are lacking, CKD services are lacking more than diabetes services. One respondent connected the lack of services to a shortage of staff. Learning about staff shortages contributed to the first and second objectives since this is related to the “preparedness of staff” and “barriers…for quality CKD management and care”. A scarcity of staff acts as a barrier to proper CKD and diabetes health care, as evinced by one stakeholder. Understanding barriers to adequate CKD and diabetes services enables creation of programs which specifically address these challenges.

Continued research into this theme should be conducted. The stakeholders reported various services related to both CKD and diabetes that were inadequate.
Interviewing a larger sample size and additional roles of stakeholders may produce insight into other specific services related to CKD and diabetes that are lacking. For example, stakeholders reported screening for CKD was inadequate, but insight regarding the adequacy of medication provisions for CKD, accuracy of diagnoses, and other various services needs to be ascertained. Understanding the majority of CKD services that are inadequate will appropriately guide future action, while only discerning a small portion of inadequate services will limit the impact of further research.

The second theme extracted from interview analysis reported low public awareness about CKD and diabetes. These reports parallel a similar study investigating awareness of CKD and it’s risk factors among 12 LMICs. This study determined 6% of individuals with CKD were aware of their disease and 31% of diabetics were unaware of theirs [64]. In our study, awareness of diabetes was higher than awareness of CKD, but both were reported as low throughout the interviews. This theme primarily addresses the second objective, since low awareness acts as a barrier for adequate CKD care in rural areas. Knowledge of barriers to proper CKD and diabetes care will enable future plans to specifically address these barriers. Stakeholders discussed ideas for increasing awareness and also detailed previous initiatives to increase awareness for diabetes. These initiatives included teaching 1-week long classes to increase diabetes awareness and were reported to be effective. Transferring these lessons in order to increase awareness for CKD in India may prove effective.
Similar to the first theme, this theme also necessitates further research. It was highly reported there was a very low awareness of the individuals’ disease states of CKD and diabetes, however reasons behind this low awareness were not provided. Research investigating the factors behind this lack of awareness need to be investigated in order to provide insight into effective interventions. Understanding factors contributing to this low awareness, such as a lack of public health education, will enable an intervention to be created targeting these factors and in turn, increasing awareness. For example, if individuals with CKD and diabetes are not aware of their disease state because they are not aware of the signs and symptoms of CKD and diabetes, public health campaigns can educate the population about these indicators, which may increase awareness of disease states.

The third theme concluded concerned familiarity with mobile-based devices for health care, as well as suggestions for using a similar device. Stakeholders widely reported being familiar with these devices. Several respondents even mentioned using them in their daily work. Suggestions for using a mobile-based device included health-related reminders via SMS text messaging and a bio-data bank. mHealth is used in various lower-middle income countries [53], in addition to India. Research on integrating an mCDSS device in India has shown promising results [58]. Additionally, the third theme addresses the “perceived usefulness” of a health-related mobile-based device. The suggestions for use of this mobile-based device specifically address
“perceived” usefulness of the third objective. Respondents not only perceived this device as being useful, but also expanded upon possible ways to use this device.

The fourth theme concerned using ASHAs to implement and continue to use the mobile-based device. Many stakeholders emphasized the important role ASHAs play in communities and favored using ASHAs as the mechanism by which to introduce the device into the rural setting. Stakeholders did not predict an issue of ASHAs having too much of a work load with this added responsibility. Interestingly, respondents from one study reported monetary incentives would decrease motivation for ASHAs, which is contrary to what one respondent reported in our study.

ASHAs have shown to have success in implementing a new program, such as the mCDSS [35]. This study investigated the success with which ASHAs implemented a new maternal health program in rural India. Respondents reported this program most likely increasing awareness and changing behavior towards maternal care. In addition to this research concluding ASHAs being influential in implementing a health program in rural India, the support iterated by stakeholders highlights the need for ASHAs to be involved in any health intervention. While ASHAs may be useful in implementing the mCDSS, they may be also be effectively utilized in other interventions. For example, screening of CKD was reported as inadequate by respondents, so ASHAs may be used to increase CKD screening. ASHAs’ familiarity with the people whom they serve, coupled with signs and comorbidities, allows for ASHAs to effectively determine those who necessitate CKD screening. Furthermore, given ASHAs’ usual responsibilities,
screening for CKD would be an additional responsibility ASHAs would be able to incorporate into their practice.

It is important to understand if adding CKD screening to ASHA responsibilities would overburden ASHAs and in turn decrease the quality of their already existing duties. As previously stated, stakeholders generally reported adding the use of the mCDSS to ASHAs’ current duties would not overburden them. Because of this viewpoint, it is reasonable to surmise that adding the role of screening for CKD will not overburden ASHAs in their current capacity. If this additional role does prove to be burdensome, the screening mechanism may possibly be changed to a more limited but manageable capacity, such as a simplified checklist which would indicate if the patient needed to be screened for CKD.

This fourth theme accomplishes the second and third objectives. Understanding the role ASHAs play in the success of rural health care contributes to finding “facilitators” to adequate CKD care, which is a component of the second objective. It is evident ASHAs have the potential to be facilitators for any intervention attempting to improve rural health care in India. Additionally, this theme provides information for the third objective in elucidating “perceived usefulness and barriers” to implementing the mCDSS. Stakeholders reported ASHAs as a useful means of implementation, however barriers to this implementation were discussed as well, such as the logistical challenge of poor internet connection.
4.2 Comparison to similar research

Regarding research similar to this study’s, there is a dearth of literature published investigating the facilitators and barriers to implementing a mobile-based health device to combat CKD in rural India. Furthermore, there is a shortage of research specifically assessing pre-dialysis CKD interventions. The primary source of literature related to this topic focuses on qualitative research concerning those with ESKD. Research on perceptions about diabetes and hypertension in Asia are more prevalent than research solely on CKD. There is also a scarcity of in-depth information on facilitators and barriers to care of patients with earlier stages of CKD. One study, however, showed a low perception of chronic kidney disease from patients in an urban Taiwan setting [65], offering similar results to the low awareness observed in this study despite the difference in urban and rural settings.

Contradictory are the results of a study conducted on Bangladeshis living in Britain. These Bangladeshis did not show a significant lack of awareness about type 2 diabetes [66], unlike the results from our study. This British study reported the Islamic leaders among who these Bangladeshis follow were supportive of health education. This difference in proactivity between leaders in India and from Bangladesh may account for this increased awareness. Other, non-qualitative studies have also shown a lack of services for chronic kidney disease care in India [46], corroborating the results of our study. In regard to qualitative research concerning hypertension in Asia, Pakistani respondents iterated the “[p]hysician’s attitude, patient’s past experiences, and
knowledge related to hypertension” played key roles in determining hypertension medication-taking habits [67].

4.3 Potential success of intervention

In light of similar research, there is a high probability our study’s objective of implementing an mCDSS to aid in preventing, treating, and managing CKD and diabetes in rural India will be successful. One reason to predict our study’s success is that mobile-health has proved effective for improving health outcomes in lower-middle income countries, such as India [53]. Additionally, as previously mentioned, a very similar trial used an mCDSS tool to combat cardiovascular disease in India [58]. This trial is a useful comparison for this study. This trial resulted 78% of patients referred by Non-Professional Health Workers needing hypertension treatment. This trial however, did report rates under 50% regarding doctor visits and follow-up appointments [58]. Additionally, interventions aiming to improve CKD outcomes have shown to be successful. Effective programs targeting CKD have been created in Taiwan and Australia [68]. The success of these programs, along with the promising outcomes of the mCDSS tool for CVD and mHealth in general suggest our mCDSS multicomponent intervention will be successful for improving CKD and diabetes-related health outcomes.

It is important to not only focus on the possible success of the mobile-based device, but also the success of other plausible interventions, as well. While the mobile-based device may be an effective tool to supplement the CKD health care infrastructure in rural India, interventions such as public health campaigns and equipping ASHAs
with the ability to screen for CKD may be an equally or more effective facilitator to improving health outcomes related to CKD. Solely focusing on mobile-based device interventions may neglect the utilization of other useful interventions. The mobile-based device may also be a part of these other interventions. For example, a mobile-based device may be used to help ASHAs screen for CKD or to aid in AHSAs providing public health education classes to increase awareness about CKD. Additionally, more research is needed regarding the other possible mechanisms to improve CKD health services in rural India, as the implementation of a mobile-based device may not be the only or most effective tool to implement.

4.4 Strengths and limitations of research

Strengths of our study include the open-ended characteristic of interview methodology, the opportunity for a heterogeneity of answers, and the variety of stakeholders interviewed. The open-ended quality of interviews lends itself to obtaining more information upon which further action can be based. This provides a higher degree of useful insight than other binary procedures, such as closed-ended surveys. The different answers provided by the stakeholders also produced a wide range of useful data. For example, if every stakeholder provided the same answer for a question, the information extracted from this answer would be limited as opposed to if stakeholders provided various different answers. The variety of answers was made possible largely due to the variety of stakeholders interviewed, which was another strength of our study.
One weaknesses of our study is the subjectivity of interviews. While the subjectivity of interviews is a strength of this study, it also acts as a weakness. In quantitative studies, the results may be considered more definitive than a qualitative study whose results are based in the subjective analysis of interviews. Objectivity tends to lend itself to the scientific method more so than qualitative analysis, however this is why several qualitative experts contributed to this study. Another weakness of our study is the informed inputs from stakeholders are only postulations about the outcome of this mobile-health intervention and not certainties. Therefore, a weakness is that it is research with a large component based upon having stakeholders hypothesize about future interventions. This weakness is part of qualitative analysis, however it does not significantly impact the quality of results from this study.

**4.5 Recommendations for further action**

The insight provided from the interviewed stakeholders is informative and insightful. The objective of the interview analysis is to help inform the creation process of the mobile-based device. The input from the interviews provides useful information to shape this process. One of the primary themes of this study is the low awareness of CKD and diabetes in India. One possible way to increase awareness is through awareness campaigns. These campaigns may use media messages, commercials, billboard advertisements, and public health flyers to make people aware of CKD and diabetes and the associated risk factors. Additionally, health care workers such as physicians and ASHAs can be used to increase awareness and teach individuals about
prevention and management techniques for CKD and diabetes. For example, a Physician or ASHA may give a one-minute lesson on what CKD and diabetes are and how to determine if you have them at appointments with patients.

Similar to India, Brazil has recently faced an increase in prevalence of a disease, albeit infectious in etiology. This disease is called the Zika virus. In order to spread awareness about this virus, 220,000 troops of Brazil’s army traveled to houses throughout Brazil to tell them about the Zika virus [69]. Given the magnitude of the prevalence and the explosive anticipated rise in numbers, India may benefit from such a large-scale, media-covered campaign for CKD and diabetes awareness. As mentioned, the Indian government has mandated diabetes screening in certain districts. Scaling up this program would increase diabetes screening and would also ensure rural areas are not neglected. This program, as well as the other outlined interventions, require funding. Funding for these awareness and screening interventions should come from a multitude of sources. India’s GDP is significantly lower than many other countries, so the government may not have the capacity to fund these public health operations.

Crowdfunding, a mechanism by which funding is raised from various smaller scale donations, may be an effective alternative to government funding. These donations can come from the government itself, but also from non-profit organizations, non-governmental organizations, international organizations, and wealthy donors who are invested in public health. An additional idea to increase awareness, promote screening, and work toward improved health outcomes is the emphasis on various disease-days.
For example, World Kidney Day will be on March 8th in 2018. This day can be used to increase awareness about CKD throughout India. World Diabetes Day will be on November 4th in 2018. An emphasis on these two days in India may prove an effective measure for improving related health outcomes.

Additionally, public health interventions often fail because of a lack of pre-existing infrastructure in which to integrate. For example, an intervention which aims to increase access to medication in rural areas may have little success if there is no medication dispersal system already in place, such as a pharmacy system. One recommendation to ensure success of our intervention is the integration of this mCDSS into the current ASHA system of India. Using ASHAs to implement the mCDSS, along with other components of the parent study, will use the success of this pre-existing system. This integration will provide a useful infrastructure to integrate the mCDSS in. It will also not require a new infrastructure to be created. Stakeholders reported high predicted success of this integration, which supports this idea even more so.

5. Conclusion

This research has the potential to inform creation of a mobile-based device which may augment the gap observed in rural CKD health care in India. Stakeholders iterated the lack of CKD and diabetes health services in India. Stakeholders also reported favorability for the use of a mobile-based device to provide additional resources for
CKD in these settings. This research is novel since there is currently little research on mHealth in LMICs for combatting CKD. It is imperative that an effective intervention is implemented into the rural health care system of India to combat CKD, given the increasing rates of this disease.

Using a mobile-based device, such as an mCDSS, to help prevent, treat, and manage CKD in rural India may prove highly effective. Stakeholders reported ASHAs being an integral part of the health care community. Given this role, ASHAs have the potential to utilize the mCDSS in an effective manner. Using a pre-existing infrastructure allows for the mCDSS to be incorporated into a far-reaching health care component (ASHAs) and also prohibits the need for a new infrastructure to be created. While the mCDSS may be useful in combating CKD in rural India, other facilitators still need to be investigated to supplement the current CKD health care system. These interventions, in addition to the mCDSS, may result in improved health outcomes for individuals with CKD in rural India through proper prevention, treatment, and management of CKD.
Appendix A

Codebook: SMART-Kidney Interview Analysis Codes

Overall Codes

1) CKD/DM within population
   a. Perceptions and attitudes towards CKD/DM
   b. Population most affected
   c. Burden of disease
   d. Knowledge about CKD/DM
   e. Patient-doctor interactions concerning CKD/DM

2) ASHA Use
   a. Work load
   b. Current ASHA roles for CKD/DM
   c. Potentially useful ASHA roles for CKD/DM

3) Mobile health intervention efficacy
   a. Benefits
   b. Challenges
   c. Plausibility
   d. Perceived usefulness

4) Suggestions for effective intervention
   a. Personnel
   b. Specific actions
   c. Actions to avoid
   d. Collaboration with other health care services

5) Awareness/understanding on mobile-based application
   a. Familiarity with mobile-based applications
   b. In what way they have used mobile-based applications before
   c. How to increase mobile-based application awareness and understanding
   d. Complications faced when using mobile-based applications

Government Official (CMO)/District Medical Officer Codes

1) Burden of CKD/DM on population
   a. Risk factors
   b. Population most affected
   c. Financial burden
   d. Familial component

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2) Current interventions to control CKD/DM
   a. Government interventions
   b. NGO interventions
   c. Research conducted
   d. Efficacy of interventions

3) Efficacy of mobile health interventions
   a. Challenges
   b. Benefits
   c. Perceived usefulness
   d. Precedent

4) ASHA use
   a. Business of ASHAs
   b. Ability for ASHAs to take on more roles
   c. Effectiveness of ASHAs
   d. Increase access to health care using ASHAs
   e. Drawbacks of using ASHAs

5) Suggestions for effective intervention
   a. Increasing efficacy
   b. Solving complications
   c. Increasing access to health care
   d. Increasing app usability

ASHA Codes

1) ASHA Roles
   a. Work load
   b. Education about diabetes from ASHAs
   c. ASHA responsibilities
   d. Diagnosis of diabetes

2) Knowledge/understanding about diabetes
   a. Lack of knowledge
   b. Interventions to increase understanding
   c. Knowing if they (the patient) has diabetes

3) Attitudes towards diabetes
   a. Scared after diagnosis
   b. Financial stress
   c. Familial aspect

4) Usefulness of mobile device
   a. Benefits
b. Challenges  
c. Suggestions  
d. Plausibility

Primary Health Care (PHC) Physician Codes

1) PCP Roles  
a. Working at a PHC  
b. Who the PHC serves  
c. DM/CKD services at the PHC

2) DM/CKD treatment  
a. Dealings with DM/CKD patients  
b. Prevalence of DM/CKD patients  
c. Education for DM/CKD patients  
d. Number of nephrologists available

3) Challenges to serving DM/CKD patients  
a. Distance/travel  
b. Helpful potential provisions  
c. Patient monetary challenges

4) ASHA roles  
a. Duties  
b. Perceived usefulness  
c. Workload (before and after intervention)  
d. Incentives

5) Usefulness of mobile technology  
a. Benefits  
b. Challenges  
c. Perceived usefulness of the application  
d. Implementation within PHCs  
e. Suggestions

ANM Codes

1) Responsibilities  
a. Pregnant mother services  
b. DM/CKD services  
c. Potential additional DM/CKD services  
d. Training

2) Work load  
a. Increase of work load
b. Time
   c. Managing work load
3) Usefulness of mobile device
   a. Benefits
   b. Challenges
   c. Suggestions for effective use

Patient Codes

1) Personal life
   a. Job
   b. Where they live
   c. Family life
2) Health History
   a. Diabetes history
   b. Renal health complications
   c. Hypertension history
3) Seeking Health Care
   a. What kind of doctor they typically see
   b. How often they meet with the doctor
   c. Experiences at the doctor

Nephrologist Codes

1) Interaction with patients
   a. Awareness of CKD
   b. Prevalence of CKD in their practice
2) Useful interventions
   a. How to increase awareness of CKD
   b. Increased training for health care workers
3) Use of technology
   a. Helpfulness
   b. Barriers to implementation
Appendix B

Interview Guides

Stakeholder: High Level Government Officials

*Existing knowledge & practices on NCD, diabetes, and CKD in India*

1. **What are the efforts from the government for NCD?**
   a. Is there a separate DM/CKD control program?
   b. Where do DM/CKD fit in with the efforts of the government?
   c. How have efforts been rolled out in the country with respect to DM and CKD?
   d. Have you perceived CKD as a serious health issue in India? If yes or no, why?

2. **What health service standards are currently established and agreed upon by the Ministry of Health (MOH) for the treatment of DM/CKD, if any?**
   a. If any, how are these monitored/audited? How much are these standards adhered to? If they are not monitored/adhered to, why not?

3. **Is there a written practice/service improvement strategy for DM/CKD care?**
   a. If yes, how well are these strategies implemented? What mechanisms are there to monitor the implementation? If they are not monitored/implemented well, why not?
   b. How are clinical standards for DM/CKD care are reviewed and updated/revised as necessary? How frequently are standards reviewed? Who reviews these standards?

*Facilitators of quality DM/CKD management*

1. According to you, what do you think is the political commitment for providing quality diabetes/CKD care to the rural population?
2. What do you think will enable better provision of quality DM/CKD management? Which one is the most important? Why?
3. What do you think about integrating DM/CKD screening & referral into the work practices of ASHA? Why do you think it is helpful or not?
4. What do you think about integrating DM/CKD home health education (HHE) into the work practices of ASHA? Why do you think it is helpful or not?

*Barriers for quality DM/CKD management*

5. What are the main challenges for quality DM/CKD management in India and particularly in the rural areas?
   a. Which of them according to you is most important? Why?
   b. How do you think you can overcome the problem?
c. Why do you think that could be easy or difficult?

Perceived usefulness/ difficulties to mCDSS approach for DM/CKD

6. Are you aware about the mobile health (mHealth) approach to managing chronic disease?
   a. Do you think, this can be helpful in DM/CKD?
   b. Do you think it will help DM/CKD management in rural areas?

7. Do you think a diabetes and CKD management program using mCDSS-SMART health will be helpful in rural communities? Why or why not?
   a. What will be the benefits?
   b. What will be the challenges?
   c. What do you think will be the difficulties encountered during such a mCDSS DM CKD management program? Why do you think so? How can we solve this at the planning stage? How can we scale up the program?

8. Do you think that there will be challenges for integration into the Primary Health Centre (PHC) system? If yes, what challenges? If no, why not?

9. Do you think there will be challenges for scalability of such a program? If yes, what challenges? If no, why not?

10. Do you think there will be challenges for financial sustainability of such a program in general? If yes, what challenges? If no, why not?

11. Do you think there will be challenges with such a program in terms of procurement of medication and supplies? If yes, what challenges? If no, why not?
Stakeholder: District level government officers

Existing knowledge & practices on NCD (DM/CKD) in India

1. What are the efforts from the government for NCD?
   a. Is there a separate DM/CKD control program?
   b. How has it been rolled out in the country with respect to DM and CKD?
   c. Have you perceived CKD as a serious health issue in India? If yes or no, why?

2. What health service standards are currently established and agreed upon by the MOH for the treatment of DM/CKD, if any?
   a. How are these monitored/audited?
   b. How much are these standards adhered to?
   c. If they are not monitored/adhered to, why not?

3. Is there a written practice/service improvement strategy for DM/CKD care?
   a. How well are these strategies implemented?
   b. What mechanisms are there to monitor the implementation?
   c. If they are not monitored/implemented well, why not?
   d. How are clinical standards for DM/CKD care are reviewed and updated/revised as necessary? How frequently are standards reviewed? Who reviews these standards?

Facilitators of quality DM/CKD management

4. How is the overall health delivery for providing quality DM/CKD care to the rural population?

5. What do you think will enable better provision of quality DM/CKD management? Which one is the most important? Why?

6. What do you think about integrating DM/CKD screening & referral into the work practices of ASHA? Why do you think it is helpful or not?

7. What do you think about integrating DM/CKD HHE into the work practices of ASHA? Why do you think it is helpful or not?

8. How will the financial incentives for ASHAs be managed and taken care of?

9. What is the current nutrition advice being disseminated to patients? Has the nutrition advice been updated within the past several years to fit the growing knowledge concerning DM prevention? Why do you think this nutrition advice is helpful or not?

Barriers for quality DM/CKD management

10. What are the main challenges for quality DM/CKD management in India and particularly in the rural areas?
   a. Which of them according to you is most important? Why?
   b. How do you think you can overcome the problem?
c. Why do you think that could be easy or difficult?

11. What do you think about adding new staff and reorganizing services for CKD delivery?
   Sub-question: How do you feel about the use of non-professional health workers? Are the educated enough to perform their job well? How do physicians typically view them?

Perceived usefulness/difficulties to mCDSS approach for DM/CKD

12. Are you aware about mHealth approach to managing chronic disease?
   a. What do you know about it? Do you think, this can be helpful in DM/CKD?
   b. Do you think it will help DM/CKD management in rural areas?

13. Do you think a diabetes and CKD management program using mCDSS-SMART health will be helpful in rural communities?
   a. What will be the benefits?
   b. What will be the challenges? Why or why not?

14. What do you think will be the difficulties encountered during such a mCDSS DM/CKD management program? Why do you think so?
   a. How can we solve this at the planning stage?
   b. How can we scale up the program?

15. How do you think such a program will impact the current level of care in the PHC?

16. Do you think that there will be challenges for scalability of such a program at the district level? If yes, what challenges? If no, why not?

17. Do you think that there will be challenges for financial sustainability of such a program in general and at the district level? If yes, what challenges? If no, why not?

18. Do you think that there will be challenges during such a program in terms of medication, supplies and procurement? If yes, what challenges? If no, why not?
### Stakeholder: Nephrologists

#### Existing knowledge & practices on DM/CKD in rural settings
1. What are the current standards of care for NCD like DM/CKD from your perspective?
   a. Any preventive efforts are available?
   b. What are they?
2. Could you describe your current work practice?
3. How do you currently manage patients with CKD? (To ask specifically for the following areas: Measuring BP/providing lifestyle advice/prescribing therapy/self-management for DM and anti-hypertensive used/increasing adherence/referring patients)
4. What are the current referral practices for sending patients? How are the patients with DM/CKD referred to you i.e. the mechanism of referral? Sub-question: What is the approximate rate of people who receive a follow-up that actually end up going to the doctor to which they’re referred? If they do not go, do they go to an alternate doctor or not go at all?
5. What are your thoughts on referring patients to nephrologists based on estimated kidney failure risk? How high should risk of kidney failure be before referral to a nephrologist?

#### Facilitators and barriers for quality DM/CKD management in rural settings
6. What do you think will be the factors that will encourage better DM/CKD management in rural areas? Which one is the most important? Why?
7. What do you think about integrating DM/CKD screening & referral into the work practices of ASHA? Why do you think it is helpful or not?
8. What do you think about integrating DM/CKD HHE into the work practices of ASHA? Why do you think it is helpful or not?
9. In general, do you feel there is a need to change how DM/CKD is currently managed in your district (includes prevention, screening, diagnosis and treatment)? If yes, why? If no, why?
   a. E.g. high disease rates, low levels of education, inadequate care currently, etc.
   b. E.g. other competing healthcare priorities
10. What are the main challenges for DM/CKD management in your district/area?
    a. How do you think you can overcome the problem?
    b. What according to you is difficult? Why?
    c. Why do you think that could be easy or difficult?
Perceived usefulness/ difficulties to mCDSS approach for DM/CKD

11. Are you aware about using mobile technology approach to managing chronic disease?
   a. What do you know about it?
   b. Do you think, this can be helpful in DM/CKD

12. Have you heard about clinical decision support system (CDSS)?
   a. What do you know about it?
   b. Do you think it will help DM/CKD management in the PHC?

13. CDSS will be based on an algorithm for management of diabetic CKD. What do you think is important in the CKD management algorithm?
   a. What medications need to be included for treating CKD patients in the rural areas?

14. Do you think a diabetes and CKD management program using mCDSS-SMART health will be helpful?
   a. What will be the good aspects of decision support for DM/CKD management?
   b. What will be the challenges?
   c. Why or why not?

15. What do you think about involving the PHC doctors in delivering care for CKD in the rural areas?
Stakeholder: Primary Care Physicians

Existing knowledge & practices on DM/CKD management in rural settings
1. What are your current duties as a PHC doctor?
   E.g. disease areas, extent of care provided
2. What are the work practices of PHC doctors in relation to DM/CKD management?
   a. How do you manage DM/CKD patients?
   b. Does management include health education and self-management? If yes, what components?
   E.g. diagnosis, work-up, treatment, follow-up and referral to specialists
3. What is your current attitude of PHC doctors toward DM/CKD management?
   (E.g. important/not important part of practice, common/uncommon in daily practice).
4. Do you get some training in managing DM/CKD management? Where and how is the training? Any refresher?
   What is the current nutrition advice being disseminated to patients? Has the nutrition advice been updated within the past several years to fit the growing knowledge concerning DM prevention? Why do you think this nutrition advice is helpful or not?
5. What is the mechanism of referral to the next level of care (nephrologists) for DM/CKD complications?
   a. Are there specialists available to treat DM/CKD complications in the district?
   b. How the follow up of these patients is done?

Facilitators/barriers for quality DM/CKD management in rural settings
6. What do you think will be the factors that will encourage better DM/CKD management in rural areas? Which one is the most important? Why?
7. What do you think about integrating DM/CKD screening & referral into the work practices of ASHA? Why do you think it is helpful or not?
8. What do you think about integrating DM/CKD HHE into the work practices of ASHA? Why do you think it is helpful or not?
9. In general, do you feel there is a need to change how DM/CKD is currently managed in your district (includes prevention, screening, diagnosis and treatment)?
   If yes, why? If no, why?
   a. E.g. high disease rates, low levels of education, inadequate care currently, etc.
   b. E.g. other competing healthcare priorities
10. What are the main challenges for DM/CKD management in your district? (E.g. system of diagnosis, treatment, continuing care, and referral; existing level of knowledge among ASHA, providers and specialists)
   a. Which of them according to you is most important? Why?
   b. How do you think you can overcome the problem?
   c. Why do you think that could be easy or difficult?
11. Do you think that DM/CKD management will this impact other services provided by the PHC doctors? If yes, why? If no, why not?

Perceived usefulness/ difficulties to mCDSS approach for DM/CKD

12. Are you aware about using mobile technology approach to managing chronic disease?
   a. What do you know about it?
   b. Do you think, this can be helpful in DM/CKD
13. Have you heard about clinical decision support system (CDSS)? What do you know about it? Do you think it will help DM/CKD management in the PHC?
14. Do you think diabetes and CKD management program with aid of a mobile tablet device will be helpful to PHC doctors?
   a. What do you think of its use?
   b. Do you understand it will be a challenge?
   c. Why or why not?
15. What do you think will be the difficulties encountered during such a mCDSS DM/CKD management program in rural areas?
   a. Which component will be challenging to implement? Why?
   b. How can we overcome this/suggestions?
16. What will be the challenges for integration into the PHC system?
Stakeholder: ASHAs

Existing knowledge & practices on DM/CKD situation in rural settings
1. In general, what are the main duties/priorities of accredited social healthcare activists (ASHAs) currently? (related/unrelated to chronic disease management)
   • E.g. which disease areas, educational topics, etc.
2. What are the current work practices of ASHA in relation to DM/CKD management in the community?
3. What are the current attitudes/levels of knowledge of ASHA on DM/CKD management? (E.g. important/not important part of practice, common/uncommon in daily practice), (E.g. aware/not aware, interested/not interested)
   • Do you feel these current attitudes/levels are able to be changed, or are they so entrenched in the culture that it would be hard to change them?

Facilitators/barriers for quality DM/CKD management in rural settings
4. What do you think of home diabetes/CKD screening in your village? Will it be useful? If yes or no, why?
5. What do you think of home diabetes/CKD home health education in your village? Will it be useful? If yes or no, why?
   What kind of education do you feel would be most valuable?
6. How will providing the proposed 1) home-based DM screening and 2) home health education for DM/CKD change your day-to-day practice at work?
7. What will be the difficulties you will face with regards to time and incentive during the home based screening and education sessions into your current work schedule?
8. What could help you to successfully incorporate the DM screening and HHE into your work duties?
9. Do you think this work will impact other services? What are your plans to ensure that other services are not impacted?

Perceived usefulness/ difficulties to mCDSS approach for DM/CKD
10. Are you aware of mobile health way of managing chronic diseases?
    a. What do you know about it?
    b. Do you think, this can be helpful in management of DM/CKD
11. Have you heard about clinical decision support system (CDSS)? What do you know about it?
12. The ASHA will use the tablet with alerts and scripts available for screening, referral and home health education. Do you know how to use tablet devices and mobile devices?
a. What will be the good aspects of using tablets in your activities?
b. Do you think there will challenges? Why or why not?

13. **What do you feel will be the usefulness of such mCDSS system from your view?**
   a. Do you think a diabetes and CKD management program using mCDSS-SMART health will be helpful?
   b. What will be the good aspects of decision support for DM/CKD management?
   c. What will be the challenges? Why or why not?

14. **What will be the challenges or difficulties encountered in such a DM/CKD program?**
**Stakeholders: Patients (DM/CKD)**

*Existing knowledge & practices on DM/CKD situation in rural setting*

1. Can you describe how your doctor has been checking you for diabetes/CKD in your village?
   a. How often do you check your blood sugar/BP levels?
   b. Do you have your blood sugar or kidney function tests measured regularly?
   c. Where and who checks your blood sugar, BP levels (e.g., at the clinic, doctor, other health care professional)?

2. **What does your doctor tell you or discuss about your diabetes/CKD during the clinic visits?**
   a. Does the provider explain whether your blood sugar, BP is high or normal?
   b. Does the provider explain the reasons for starting or changing medications for sugar/blood pressure?
   c. Are the side effects of medicines explained to you?

3. **What do you find to be easy/difficult about managing your DM/CKD?**
   a. How have the health care providers made it easier or helped you to manage your DM/CKD?

4. **What do you think could be improved in terms of the care you receive for your DM/CKD?**
   a. Related/unrelated to healthcare providers, e.g., cost of medication/treatment Do you think providers could be trained to help patients manage their diabetes/CKD better?

*Facilitators/barriers for DM/CKD management in rural setting*

5. **What services do ASHAs currently provide your household?**
   a. How often do they visit your household?
   b. When they visit your household, what do they talk to you about? (E.g., which disease areas, health topics, etc.)
   c. What activities do they do when they visit your household? E.g., education, treatment, screening, etc.?

6. **(Refer to question 5) In the above areas you have described, how useful do you find the services provided by the ASHAs?**
   a. What are the most useful things the ASHAs have done for your family?
   b. Who in your household meets with the ASHAs? (E.g., everybody, only the head of the household, only the adults, etc.)
   c. How has your household benefitted from the ASHA visits?
   d. If the ASHA visits have not been very useful, why have they not benefitted your family so much?
7. What other things do you think the ASHA could do for your family that would improve your family’s health?
   a. Which other health areas would you like the ASHA help or educate your household about?

8. Have you, or any member of your household, ever had your blood glucose and/or BP and/or kidney function checked?
   a. If yes, when and where did you/household member get it checked? Who checked the blood sugar/BP/kidney function? How often was blood sugar/BP/kidney function checked?
   b. If not, have you thought about getting your blood sugar/BP/kidney function checked, and why? If you have thought about it, why have you not gotten your blood sugar/BP checked? If you have not thought about it, why have you not thought about it? (e.g. not aware, no access, etc.)

9. Do you think it would be beneficial for you if ASHAs were to check your blood sugar/BP/kidney function for screening for diabetes/CKD in your home? Why or why not?

10. Do you think it would be beneficial for you if ASHA were to give you diabetes related health education (and CKD health education) in your home? Why or why not?
   a. Do you think other services provided by ASHAs will be impacted by such care?

11. Do you have access to medications for diabetes/CKD? If yes, where do you have access to these medications?

12. Do you have access to doctors who can treat you for chronic kidney disease in your village or district? If yes, where do you have access?

13. Do you think diabetes/CKD services at the PHC will have an impact on other services provided at the PHC? Why or why not?

Perceived usefulness/difficulties for mCDSS approach

14. What do you think about mobile technology based health screening and education for diabetes/CKD? Why or Why not?

15. What do you think of a program based on mobile technology for DM/CKD?

16. Do you think it would be beneficial if you were given SMS to remind you about the follow up doctor visit for tests and review? Why or why not?

17. What do you feel will be the usefulness of such mCDSS system from your view?
   a. Do you think a diabetes and CKD management program using mCDSS-SMART health will be helpful?
   b. What will be the good aspects of decision support for DM/CKD management?
18. What will be the challenges or difficulties encountered with such a program? Why or why not?
References


