AN EXPLORATION OF PATIENT-HELD HEALTH RECORDS FOR IMPROVING HANDOVER COMMUNICATION AND SELF-MANAGEMENT FOR PATIENTS WITH DIABETES AND HYPERTENSION IN OUTPATIENT SETTINGS IN KERALA, INDIA.

BY

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ABSTRACT

High-quality health systems need to optimise healthcare delivery based on the changing health needs of the population. Long-term management of non-communicable diseases (NCDs) requires patients, carers, and health care providers (HCPs) to work together for optimal results. Patient medical information is essential for all HCPs to provide quality care. Additionally, patients and carers need information for self-management. Patient-held records (PHRs) are widely used in low and middle-income countries (LMICs) such as India, to document and hand over medical information to HCPs and other HCPs or patients or carers. A previous clinical handover study in India found that handover communication was poor for patients with NCDs in outpatient settings and suggested a structured PHR for patients with NCDs.

The overall aim of this thesis was to synthesise the evidence base, explore the perceptions of patients, carers and HCPs regarding the use of PHRs and understand the factors that affect the use of PHRs for handover communication, information transfer, and self-management; that can contribute to development or improvement of a future PHR.

In the first results chapter, evidence of the effectiveness and perceived usefulness of PHRs in LMIC is synthesised. Chapter three uses systematic reviews (SR) of PHRs for NCDs and home-based records for maternal and child health records to summarize evidence on PHRs in LMICs. Notably, the above SRs indicate limited studies evaluating PHRs for improving handover communication and self-management. Next chapter details the findings of a qualitative study among patients with diabetes and hypertension, carers, and HCPs from Kerala, India to explore their experiences with current PHRs and reports the similarities and differences in their perspectives on the use and value of current PHRs. Chapter four demonstrates that patients, carers, and HCPs use PHRs in practice; however, their perceived value of PHRs is different. Patients value the PHRs for medication procurement, while carers value them for communication during emergencies with HCPs. However, HCPs perceive PHRs as documents that aid them in clinical decision-making and preventing errors. Patients do not use PHRs for self-management, and HCPs do not use them for communicating self-management information. Chapter five reports patient navigations in the health system, HCP-patient interactions, and lack of agency over illness and overall health as contextual influences that play a role in patients' lack of engagement with PHRs. Chapter six reports a qualitative analysis of HCP data with the theoretical domains framework (TDF) to identify barriers and facilitators for HCPs to use PHRs for maintaining continuity of care in Kerala. Findings indicate that nine domains are likely to influence HCPs' in recording PHRs and communicating with patients and carers in Kerala. Chapter seven presents a plan for co-designing a PHR to be used in Kerala and proposes that an experience-based co-design (EBCD) method may improve user engagement with PHRs.

The thesis findings highlight the complexities and challenges of using PHRs in public health settings in Kerala and indicate suboptimal utilisation of current PHRs for handover communication, information transfer, and self-management. Based on these results, co-designing a PHR is proposed as a potential method to improve handover communication, information transfer, and self-management among patients with diabetes and hypertension in Kerala.

DEDICATION

To my grandparents who believed in me.

To my parents and sisters, whose dedication, love, and support made me who I am.

To my husband and children, whose kindness, patience, and love made completing this thesis a reality.

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AUTHORSHIP STATEMENT

The author (LJ), with guidance from my supervisors, Dr Semira Manaseki-Holland (SMH), Professor Sheila Greenfield (SG), Dr Anna Lavis (AL) and Dr Jeemon Panniyammakal (PJ) conducted the research for this thesis.

Specific contributions to each chapter are detailed below:

Chapter 1 - Background

LJ drafted the chapter. SMH, SG, AL, and PJ reviewed and edited the chapter for content and focus.

Chapter 2 - Methodology and methods

LJ drafted the chapter. SMH, SG, AL and PJ reviewed and edited the chapter for content and focus.

Chapter 3 - Evidence for effectiveness and usefulness of patient-held records in low and middle-income countries; findings from systematic reviews.

Paper 1: A systematic review on the use of patient-held health records in low and middle-income countries.

LJ, PJ, SG and SMH conceived the article. LJ performed the literature search. LJ, Boban Dona (BD), Jose Prinu (JP) collected data from individual studies and interpreted the data. LJ wrote the first draft of the paper. SMH, SG, PJ, AL and CH (Claire Humphries) revised the first and subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

Paper 2: A systematic review of home-based records in maternal and child health for improving informational continuity, health outcomes, and perceived usefulness in low and middle-income countries.

LJ, PJ, SG and SMH conceived the article. LJ performed the literature search. LJ, BD, JP collected data from individual studies and interpreted the data. LJ wrote the first draft of the paper. SMH, SG, PJ, and AL revised the first and subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

Chapter 4 - Similarities and differences between patients’, carers’, and healthcare providers’ use and the perceived value placed on the currently available PHRs in Kerala.

Patients’, carers’ and healthcare providers’ views of patient-held health records in Kerala, India; a qualitative exploratory study.

LJ, AL, SG, PJ and SMH conceived the article. LJ conducted all the semi-structured interviews. LJ and Sujakumari S (SS) transcribed the interviews in English for data analysis. Lekha T R (LTR) reviewed all transcripts for any errors. LJ wrote the first draft of the paper. AL revised the first draft. AL, SG, SMH and PJ revised subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

Chapter 5 - A qualitative analysis of contextual factors that influence patients’ engagement with patient-held records.

LJ, AL, SG, PJ and SMH conceived the article. LJ wrote the first draft of the paper. AL, SG, SMH and PJ revised first and subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

Chapter 6 - Exploring factors affecting health care providers’ behaviours for maintaining continuity of care in Kerala, India; a qualitative analysis using the theoretical domains framework.

LJ, AL, SG, PJ and SMH conceived the article. LJ wrote the first draft of the paper. AL, SG, SMH and PJ revised first and subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

Chapter 7 - A proposed plan for co-designing a patient-held record

LJ drafted the chapter. SMH, SG, AL and PJ reviewed and edited the chapter for content and focus.

Chapter 8 - Conclusion

LJ drafted the chapter. SMH, SG, AL and PJ reviewed and edited the chapter for content and focus.

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LIST OF ABBREVATIONS

CINAHL	Cumulative Index to Nursing and Allie Health Literature
DHS	Department of Health Services
EBCD	Experience-Based Co-design
EHR	Electronic Health Records
EMBASE	Excerpta Medica Database
FHC	Family Health Centre
HIC	High-income Country
HCP	Healthcare Provider
LMIC	Low and Middle-Income Country
MEDLINE	Medical Literature Analysis and Retrieval System Online
MMAT	Mixed-Methods Appraisal Tool
NCD	Non-communicable Disease
NPCDCS	National programme for Prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke
PHR	Patient-held Record
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PROSPERO	Prospective Register of Systematic Reviews
SR	Systematic Review
TDF	Theoretical Domains Framework
WHO	World Health Organization

THESIS FORMAT

This thesis is presented in accordance with the University of Birmingham Alternative Thesis Guidelines, which allow Chapters formatted for submission to peer-reviewed journals and published articles to be included. Some of the work in this thesis has been prepared for submission to peer-reviewed journals (Chapter 5). The final accepted versions of papers in peer-reviewed journals (Chapters 3, 4 and 6) have been included in the thesis. These publications are as follows:

1. **Joseph L**, Lavis A, Greenfield S, Boban D, Humphries C, Jose P, Jeemon P, Manaseki-Holland S. Systematic review on the use of patient-held health records in low-income and middle-income countries. BMJ Open. 2021 Sep 2;11(9): e046965. doi: 10.1136/bmjopen-2020-046965. PMID: 34475153; PMCID: PMC8413937.
2. **Joseph L**, Lavis A, Greenfield S, Boban D, Jose P, Jeemon P, Manaseki-Holland S. A systematic review of home-based records in maternal and child health for improving informational continuity, health outcomes, and perceived usefulness in low and middle-income countries. PLoS One. 2022 Aug 4;17(8): e0267192. doi: 10.1371/journal.pone.0267192. PMID: 35925923; PMCID: PMC9352021.
3. **Joseph L**, Greenfield S, Lavis A, Lekha TR, Panniyammakal J, Manaseki-Holland S. Exploring Factors Affecting Health Care Providers' Behaviors for Maintaining Continuity of Care in Kerala, India; A Qualitative Analysis Using the Theoretical Domains Framework. Front Public Health. 2022 Jul 8; 10:891103. doi: 10.3389/fpubh.2022.891103. PMID: 35875019; PMCID: PMC9304901.
4. **Joseph L,** Greenfield S, Manaseki-Holland S, T R Lekha, S Sujakumari, Panniyammakal J, Lavis A. Patients', carers', and healthcare providers' views of patient-held health records

in Kerala, India: A qualitative exploratory study. Health Expect. 2023 Feb 13. doi: 10.1111/hex.13721. Epub ahead of print. PMID: 36782391.

Please also note that the inclusion of publication and publication-style chapters will result in some duplication, as each chapter will have self-contained components that overlap with parts of other thesis sections. The researcher has initially abbreviated terms upon their first appearance in the text and has consistently continued to use these abbreviations. However, in chapters three, four, five, and six, which follow a published or publication-style paper format, there may be instances of duplicated abbreviations.

Additionally, reference lists are given at the end of each chapter, for both those chapters presented as papers (chapters three, four, five and six) and those presented as traditional thesis chapters (chapters one, two, seven and eight). This is to aid the reader by keeping references with relevant documents and ensuring that formatting is consistent across the thesis.

The full regulations for the University of Birmingham Alternative Thesis Guidelines can be found at:

http://www.birmingham.ac.uk/Documents/university/legal/regulations-part7.pdf
https://intranet.birmingham.ac.uk/as/studentservices/graduateschool/documents/public/rsa/alternative-format-thesis-guidelines.pdf

INTRODUCTION

Introduction

The research within this thesis focuses on the role of patient-held records (PHRs) for improving handover communication, informational continuity and self-management for patients with diabetes and hypertension in Kerala, India. This following section provides the context for the PhD research including researchers' background, the settings and, the justification for research and the aims and research questions.

Context of the PhD research

Clinical handover has been defined as: 'the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or groups of patients, to another person or professional group on a temporary or permanent basis, usually as both verbal and documented information'. This should involve all levels of health care providers (HCPs) who may have information to pass on or those who have a role in the ongoing care. The information exchanged or shared during clinical handover includes at minimum the patient's current health care status, medication and other treatment plans.[2] The most common instances of clinical handover take place during shift- to- shift change of healthcare staff, intra-hospital transfer to another department such as from the emergency department to an intensive care unit, or inter-hospital transfer such as from a secondary care unit to a specialised tertiary care centre. However, clinical handover is also increasingly relevant in outpatient settings. For example, handover may need to occur in an outpatient setting if outpatient investigations are pending or if patients with ongoing medical problems are being advised or likely to re-present for care such as for monitoring the effects on blood pressure or blood sugar after starting a new medication.

Clinical handover encompasses transfer of information and responsibility, while handover communication focuses on the communication aspect.[2] According to the World Health Organization (WHO) Collaborating Centre for Patient Safety Solutions and its International Steering Committee, hand-over communication relates to the process of passing patient-specific health information among HCPs, from one visit to another, or from HCPs to the patient and family for the purpose of ensuring patient care continuity and safety.[3] This definition for handover extends the process of handover communication to patients/families, recognising the importance of involvement of patients in handover.[3] This becomes important in cases where there is no formal handover process in place, and patients/families need to communicate their own medical information to other HCPs.

One element of effective diabetes and hypertension management focuses on the patient's understanding of therapeutic and lifestyle management information received during physician or other HCP-patient interaction that are essential in achieving health outcomes and better adherence to treatment.[4] Clinical outcomes and patient satisfaction have been shown to be improved with better healthcare communication. Since HCPs are the most trusted and often only reliable source of health care information[5], this health care communication for self-management forms an integral part of patient-centred care.[6]

A clinical handover study (2014-2015) done in two Indian states (Himachal Pradesh and Kerala) by researchers at the University of Birmingham, UK, and the Centre for Chronic Disease Control (CCDC), India, investigated the handover process in out-patient care settings for patients with non-communicable diseases (NCDs) in those states. The study found that handover communication was poor and public health systems did not have facility-based medical records and retrieval systems in the outpatient settings for informational continuity. Most information transfer across HCPs and from HCPs to patients occurred using pieces of outpatient notes or prescription papers at clinic visits. Only 24% of such patient-held documents had essential information such as diagnosis, medication management, lifestyle management, and follow-up information. Furthermore, outpatient recall of follow-up and medication information was 55%. The overall outcome was that many patients left the outpatient settings with no clear information on how to effectively manage their condition and engage in self-management activities that can help in preventing further complications.[7] The results were presented at an experts' meeting held in New Delhi, India and it was agreed that a semi-structured patient-held chronic disease booklet would be a potential intervention tool for improving handover communication in outpatient settings.[7] The researchers' background is provided in Box 1.

Researcher background

Box 1

The researcher qualified as a registered nurse from Kerala (a southern state), India, in 2008 and worked for a year in Kerala (2009-2010) as part of a clinical internship. Further, the researcher gained a master's in international healthcare management from the University of Aberdeen, UK, in 2012 and then had a career break to start a family. The researcher returned to work full time in 2016 as a research assistant for a National Institute of Health (NIH) implementation project at the Chronic Centre of Disease Control (CCDC), India, which aimed to reduce cardiovascular risk reduction for pre-diabetic individuals in a worksite environment. The researcher was encouraged by Dr Jeemon Panniyammakal (PhD supervisor in India), to apply for this PhD, which was a follow-on project from the Clinical handover study done in India in 2014-2015 by the supervisors at the University of Birmingham and CCDC, India. The researcher was interested to pursue this research work as it focused on the researcher's native state and wanted to explore research in the public health systems in Kerala that could contribute to quality improvement and management of chronic conditions. The researcher is interested in health systems strengthening, psychosocial aspects of NCDs, patients' and carers' experience of illness, and the management of NCDs.

The researcher received additional training in qualitative research methods at University of Birmingham prior to data collection. In addition, the researcher took one day training in qualitative data analysis at University of Surrey, UK, and use of NVivo for qualitative data management from University of Birmingham.

Kerala

Kerala, the site of this thesis, is a state located in the southern part of India. Tamil Nadu borders it on the south and east, Karnataka on the north, and Lakshadweep Sea on the west. It has a population of over 33 million (according to the 2011 census).[8] It is one of the smallest, most densely populated, and literate states in India. The female-to-male sex ratio is 1084 females per thousand males against 940 females per 1000 males in India.[9] In the 2011 census (the latest available data), the state marks rapid urbanisation of 47.7% from the previous census in 2001. Additionally, there is a very little demarcation between urban and rural areas, the state comprises small and medium towns distributed evenly. [0] Despite slow economic development and low per capita income, Kerala has accomplished successes in human development and health indicators. Kerala is one of the states with the lower infant mortality rates and higher life expectancy. [3] However, Kerala has been experiencing an upward trend in the prevalence of NCDs, particularly cardiovascular diseases (CVD) and their associated risk factors such as hypertension, dyslipidaemia, and diabetes owing to epidemiologic transition. [4]

Initial research plan

As a next step from the clinical handover study in 2014, a PHR for patients with NCDs needed to be developed, tested, and implemented for improving handover communication in the outpatient settings of public health facilities in India. Drawing substantively on the aims and objectives of the PhD studentship, as advertised in 2018, the initial research proposal (as part of the annual PhD student review process) aimed at developing and pilot testing a patient-held health record intervention. A qualitative study using semi-structured interviews with patients with diabetes and hypertension and HCPs was planned to understand their preferences for the type and content of a proposed PHR. Interview topic guides for patients and HCPs were developed to be submitted for ethics review at the CCDC, India. However, the researchers' early fieldwork in Kerala led to changes in the research plan.

In the initial period of the PhD, the researcher engaged with a range of stakeholders from Kerala. The stakeholders included patients visiting family health centres (FHCs), HCPs in the public health system, and Kerala health care administrators. The researcher visited FHCs in Thiruvananthapuram (a district in Kerala) to understand the working of the NCD clinics and the electronic health record implementation progress in 2019. Additionally, the researcher engaged with the team leading electronic health record implementation in Kochi (a district in Kerala) to understand the current purpose of the electronic health records for FHCs and how having electronic health records can improve medical information availability for HCPs. The researcher learned about the availability of the NCD booklet for patients with NCDs in Kerala (Appendix 1a) and the progress of electronic health record implementation in FHCs in Kerala. Based on the findings from the fieldwork, the existence of the NCD booklet, and the progress of electronic health record implementation in Kerala, the researcher discussed with the supervisors the revisions needed for the research proposal. The revised research proposal focused on understanding the use and value of current PHRs within the public health system in Kerala.

The underlying assumptions of this thesis are:

PHRs can be tailored for specific purposes such as being made to inform and involve patients with diabetes and hypertension in their care to aid in self-management, to improve handover communication, and informational continuity of care across health care visits, for HCPs (See Table 1 for key definitions used in the thesis). This thesis explored the context in Kerala for the role of current PHRs for improving handover communication, maintaining informational continuity of care across HCPs and for aiding in patients' self-management. This thesis did not aim to develop a patient-held health record intervention itself but sought to identify the evidence base, understand the context and determinants of the use of PHRs, which can facilitate future PHR development. [5] [6] This thesis will focus on the tracer conditions diabetes mellitus and hypertension for NCDs for feasibility reasons, and these are highly prevalent conditions in India [7] with rising prevalence in South Asia and many other LMICs. [8] [9]

Justification for research

As described above, in the context for this PhD, the previous clinical handover study in 2014 investigated the handover processes in Kerala and Himachal Pradesh and suggested that a semi-structured patient held chronic disease booklet could be an intervention tool for improving handover. Patients and HCPs expressed an interest in having a patient-held booklet in which medical records could be stored, organised, and transported to HCP visits. [7]

The government of India has recently (2016) announced its long-term plans to digitize health records for all citizens.[20] In the first phase, electronic health records are being introduced in seven states, including Himachal Pradesh and Kerala. Kerala is the first Indian state to undergo comprehensive electronic health or e-health systems reforms across all public healthcare facilities.[2] However, these developments are presently in their preliminary stages and will take some time to become integrated enough to effectively facilitate handover communication across primary, secondary, and tertiary levels. Therefore, paper-based PHRs remain in use as the predominant tool for information transfer throughout public healthcare. In addition, the current plans for EHR implementation does not address the issue of integration with private HCPs. Therefore, the issue of informational continuity is not fully tackled with the EHRs. Moreover, usability functions of EHR such as the ease of access of patient information at each HCP visit will play a major factor for their use for clinical decision-making.[22] Whilst having an EHR, is beneficial for retrieval of previous medical information, the information availability for clinical decision-making is based on the quality of information that is being recorded in the first place.[23] [25] Technological advances will not necessarily address issues regarding the quality of information exchanged between HCPs and patients. Therefore, it is necessary to understand the providers' opinions on using current PHRs for handover communication in a context of electronic health record implementation.

There is a gap in our understanding of how currently implemented PHRs are used by patients, carers, and HCPs in India. Little is known about PHRs in LMICs that have been used for information transfer and handover across different HCPs, particularly for chronic NCDs.[26] Therefore, it is vital to identify the types of PHRs used in LMICs and how they are being used, or could be used, for information exchange and communication between HCPs. By doing so, we can better understand the potential benefits and barriers to PHR implementation in LMICs and ultimately improve healthcare delivery and patient outcomes.

As with many healthcare interventions, any benefits may arise due to the tool itself, or due to the wider context, such as through the conversations and thought processes it stimulates and facilitates.[27] It is unclear how patients engage with the current PHRs for handover, information exchange and for self-management. The experiences of patients with diabetes and hypertension regarding PHRs in the current pluralistic health system in Kerala can provide information on how PHRs function as information transfer tools. The Ministry of Health and Family Welfare in India has revealed an interest in developing a mobile application which can act as PHR-based system for the citizens.[28] Kerala state government has also announced its interest in electronic personal health records for patients using the public health facilities.[2] No previous electronic personal health records have been reported to be available in the public health system in India. Previous studies on adoption and use of electronic patient-held records in high income countries (HICs) such as in the UK found that patients perceived them as neither useful nor easy to use and their functionality aligned poorly with their expectations and self-management practices.[29] Therefore having electronic personal health records alone does not empower patients nor is able to improve health literacy. Electronic personal health records should align closely with people's attitudes, self-management practices, identified information needs, and the wider health system's use of these records, without which the risk that these records will be abandoned or not adopted at all is substantial.[30] [3] Additionally, the government health system in Kerala is mostly accessed by the most economic vulnerable patient populations from difficult socio-economic backgrounds.[32] No studies have looked at patient' opinions of using paper-based or electronic forms of PHRs for themselves in India. Therefore, it is necessary to gather the opinions of patients on their views for using PHRs for handover, information transfer across HCPs and for self-management in the public health system context.

Culturally, family members are involved in a person's health care in India.[33] [34] Children or other relatives accompany patients when going for a healthcare check-up. This is extended to family members discussing the healthcare condition of the patients with HCPs and HCPs also discussing important handover information to family members of the patient.[34] Given this background, family members or carers play a significant role in communication with HCPs and hence their experiences with current PHRs need to be explored for insights on the use of PHRs.

Thesis aims and research questions

This thesis focuses on conducting research to fill the gaps in knowledge related to PHRs, which were identified in the previous section. The thesis describes a series of studies that were conducted to address these gaps.

As such, the thesis has the following research questions:

- What are the types of PHRs used in LMICs and what evidence of effectiveness and usefulness for handover in LMICs is available? (Chapter 3)
- How do patients with diabetes and hypertension, carers and HCPs' use current PHRs available in Kerala for handover communication, information transfer and self-management? (Chapter 4)

- Why do patients' with diabetes and hypertension engage (or not) with PHRs for self-management in Kerala? (Chapter 5)
- What are the barriers and facilitators for use of PHRs by HCPs for handover communication and informational continuity across HCPs and patients/families? (Chapter 6)
- What is a potential method for co-designing a PHR to facilitate patient engagement with a PHR within health settings in Kerala, India? (Chapter7)

Thesis aims

The thesis aims to evaluate the evidence from LMICs to support the use of PHRs and to explore the views of patients, carers, and healthcare providers about their current use and the perceived value of PHRs in Kerala, India. Next the aim is to understand why patients engage (or not) with PHRs for self-management and to investigate the factors affecting HCPs' use of PHRs to maintain informational continuity using a theoretical domains framework (TDF). Finally, to propose a way of facilitating patient engagement with PHRs by co-designing a PHR within the public health system in Kerala, India.

Thesis overview

This thesis is organised into eight chapters- background, methods, five findings' chapters, and a discussion and conclusion chapter. Each findings chapter includes a preface linking the chapter's research question to the overall thesis aim; the manuscript title page detailing author contributions for papers submitted (or to be submitted) to journals directly from this thesis; the manuscript; and a chapter summary summarising the essential findings and linking the findings chapters. Chapter four is presented in this thesis first as this better suited the narrative and flow of the thesis, however chapter six was submitted for publication first. As a result, both chapters have detailed methodology section, and all three qualitative chapters (four, five and six) present the same demographic information/results tables for the participants.

Summary

The next chapter details the burden of diabetes and hypertension in India and Kerala, health care programme for diabetes and hypertension available in Kerala and factors affecting long-term management of diabetes and hypertension. It also provides necessary description of how informational continuity and self-management are important in the management of patients with diabetes and hypertension. Finally, a summary of current evidence available from HICs on PHRs is presented.

Table 1. Key definitions of terms in the thesis

Patient-held health records	Patient-held health records refer to any documented patient-held information that include all “key” information necessary for facilitating continuity of care both prior to and during outpatient visits. This includes diagnosis, medication information (i.e., new prescription and/or details regarding current medication), long-term care advice (i.e., how to manage medication and/or other aspects of management/treatment) and follow-up information (i.e., where to go for the next check-up or when to come for next visit).[7]
Handover communication	The process of passing patient-specific medical information from one HCP to another, from one team of HCPs to the next, or from HCPs to the patient and family for the purpose of ensuring patient care continuity and safety. It also relates to the transfer of information from one type of healthcare facility to another, or from the healthcare facility to the patient’s home.[3]
Health care communication	Communication (verbal and documented) that takes place between HCPs and patients during outpatient consultations for caring for themselves in between visits to HCPs.[35]
Information transfer	The process of carrying documented patient-specific health information between healthcare providers, from one visit to another, or from healthcare providers to the patient and family for ensuring patient care continuity.[36]
Informational continuity of care	Informational continuity of care refers specifically to how well a patient's health information is able to 'travel' with him/her throughout the health system, including over time, with the same practitioner and between practitioners in different settings.[37]
Self-management	“The individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition.”[38]

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CHAPTER ONE

BACKGROUND

1.1. Chapter preface

As described in the introduction, this thesis explores the use of PHRs as a medium for handover communication, information transfer, and self-management within a health systems perspective in a LMIC country, India. The purpose of this chapter is to give more details on topics in the Introduction section. In this chapter, the factors affecting the long-term management of diabetes and hypertension, the importance of continuity of care, information transfer, and self-management within the context of long-term management of diabetes and hypertension are presented. Next, a description of current changes in the Kerala health system is provided to understand the electronic health records introduction in the public health system. Further, a background to current evidence on PHRs is presented.

1.2. Non-communicable disease burden in India

Non-communicable diseases (NCDs) continue to be the primary cause of global deaths and are attributed to three-fourths of all mortality events in 2019. Furthermore, the majority of the NCD disease burden lies in LMICs such as India. In India, 5.87 million deaths (60% of total deaths) are attributable to NCDs.[2] Apart from the growing NCD burden, the most concerning issue is the age of onset of NCDs in India. While the average age of onset of NCDs in most HICs is 55 years or older, in India this is 45 years.[3]

1.2.1. Diabetes Mellitus and hypertension risk burden in India

Diabetes and hypertension are the two predominant NCDs widely prevalent in Indian settings.[4] They are among the chief risk factors for coronary artery disease, cerebrovascular disease, and heart failure.[5]

In India, both conditions are common among middle and older-age adults even in rural settings. For example, the overall prevalence of diabetes and hypertension is 11.4% (95% CI, 10.2%-12.5%) and 35.5% (95% CI, 33.8%-37.3%), respectively, which is relatively higher than the overall prevalence of diabetes and hypertension is 7.5% (95% CI, 7.3%-7.7%) and 25.3% (95%

CI, 25.0%-25.6%) in 2018. Further, the burden among those aged more than 40 years, belonging to the poorest wealth quintile in rural areas, 5.9% (95% CI, 5.5%-6.2%) people have diabetes and 30.0% (95% CI, 29.2%-30.7%) have hypertension.[6] This indicates that diabetes and hypertension are not diseases of the rich but equally affect people across the socio-economic gradient. Additionally, hypertension and diabetes co-exist among 40-60 % of people with diabetes.[5] Both conditions require long-term management due to the chronic nature of the condition, to prevent complications. The major complications of uncontrolled diabetes and hypertension are the development of target-organ diseases such as atherosclerosis, kidney failure, retinopathy, and cardiovascular disease (CVD).[5] These target-organ diseases can result in severe mortality and morbidity, as compared to controlled diabetes or hypertension.[5] The latest available evidence on the prevalence of hypertension and diabetes is summarised and presented in Table 1.

Table 1: Most recent prevalence of hypertension and diabetes in India

Year	Description of survey	Results
2018-2019	A large cross-sectional study ICMR-INDIAB[$] covering different states in India with a sample of 113 043 individuals (79 506 from rural areas and 33 537 from urban areas).	The overall weighted prevalence of diabetes was 11·4% (95% CI 10·2–12·5; 10 151 of 107 119 individuals), hypertension 35·5% (33·8–37·3; 35 172 of 111 439 individuals), and dyslipidaemia 81·2% (77·9–84·5; 14 895 of 18 492 of 25 647).[6]
2017-2018	National NCD monitoring survey (NNMS) - is the first comprehensive national survey providing relevant data to assess India's progress towards NCD targets. It is a cross-sectional study done to generate national-level estimates of key NCD indicators. 10659 adults completed the survey	Proportion with raised blood pressure and raised blood glucose is 28.5% (95% CI: 27.0–30.1) and 9.3% (95% CI: 8.3–10.5) respectively.[7]
2015 -2016	The fourth District-Level Household Survey-4 *(DLHS-4 is a district-level survey conducted nationally and covered all 640 districts of India).	Prevalence of hypertension in 25.3% of adults in India.[8] An overall prevalence of 11.3% among 15-54-year-old men and women, which is based on a large population-based sample (n=799,228).[8]
2008-2010 (Phase 1), 2012-2013 (Phase 2) and 2012-2015 (Phase 3)	A large cross-sectional study ICMR-INDIAB covering different states in India with a sample of 57 117 individuals.	The prevalence of diabetes from 15 states in India in which the overall prevalence in the 15 states is 7.3 (95% CI 7·0–7·5).[9]

*In India, the major surveys that provide health information include the National Family Health Survey (NFHS), District Level Household Survey (DLHS) and Annual Health Survey (AHS). NFHS is the equivalent of demographic and health surveys done in many countries around the world; while DLHS focuses on district-level data, particularly on reproductive and child health data and AHS has been conducted in the less developed states of India (Assam, Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Odisha, Rajasthan, Uttar Pradesh and Uttarakhand).

1.3. Long term management of diabetes and hypertension

The management of diabetes and hypertension is complex and requires continuous efforts for achieving controls and targets, which are evidence-based.[0] For this, a health system that can provide care across the care continuum is necessary. The World Health Organization's (WHO) framework for chronic conditions suggests three levels at which action must be taken for managing people with chronic conditions: the micro, meso, and macro levels. The WHO's framework; Innovative Care for the Chronic Conditions (ICCC) describes the expansion of the Chronic Care Model [, 2] to present a structure for organising the health care for chronic conditions in LMICs.[3] Micro-, meso-, and macro- refer to the patient interaction level, the health care organisation and community level, and the health policy level, respectively (Fig 1).[2] Overall, the framework suggests interventions are needed at each of these levels for adequate management of chronic conditions such as diabetes and hypertension.

At the policy level, governments need to make informed decisions for their populations that would address both communicable and NCDs, set standards for quality and incentives in health care.[2] At the meso level, the health care organisation needs to coordinate the delivery and evaluate the quality of the services provided. The health system should be equipped with the provision of early detection (screening), treatment (provision of medicines), and monitoring of patients with diabetes and hypertension which can help in preventing complications.[4] HCPs need to be trained to manage long-term conditions, and guidelines, and treatment protocols need to be developed and implemented for HCPs to follow thus improving health outcomes.[3] At the micro or patient interaction level, the major problems are lack of emphasis on the quality of interactions with HCPs and failure to empower patients to improve health outcomes.[3]

This thesis focuses on the patient-HCP interaction level and the following section provides a summary of current evidence on management of diabetes and hypertension in India.

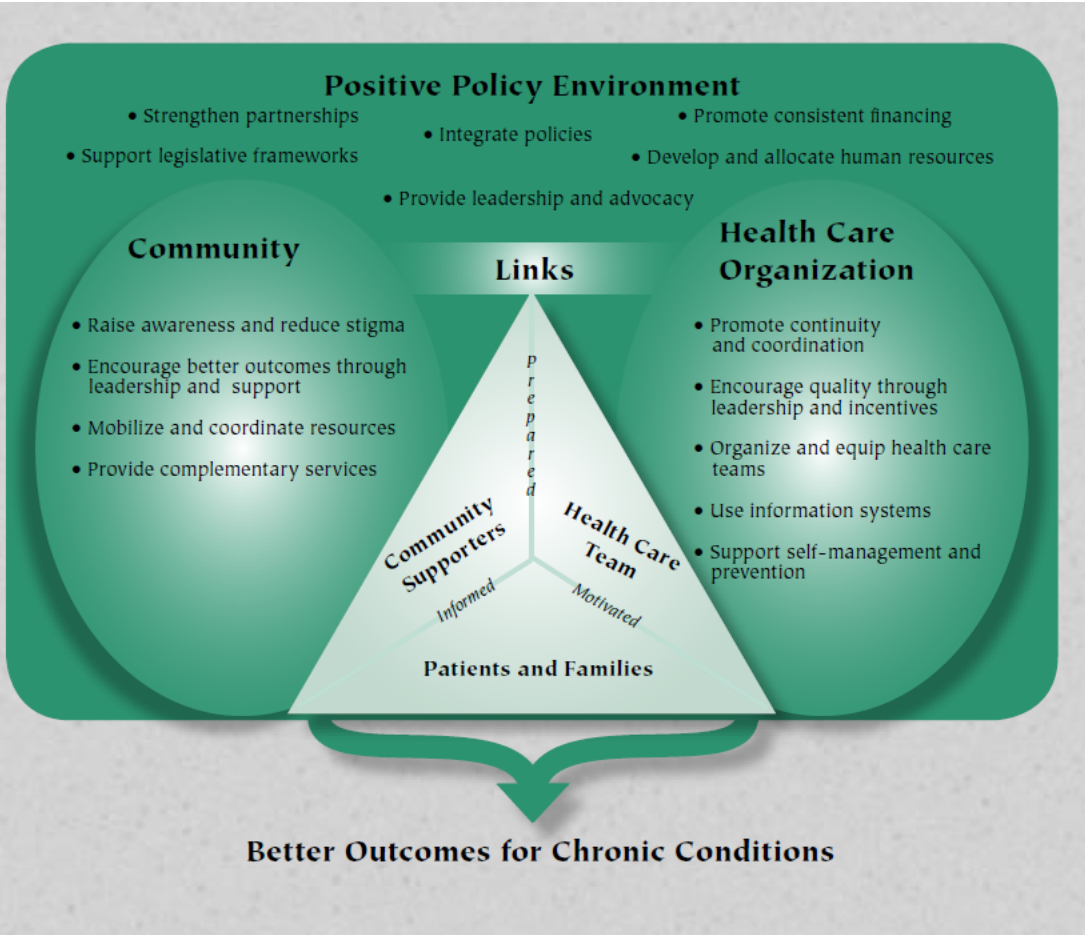

Fig 1 Source: WHO Innovative care for chronic conditions: building blocks for action , [2] (See Appendix 1b for permission to reproduce the figure)

1.3.1. Current evidence on long-term management of diabetes and hypertension from India

In 2008, the government of India launched the National Program for prevention and control of Cancer, Diabetes, Cardiovascular diseases, and Stroke (NPCDCS). The major focus areas were early detection of persons with high levels of risk factors and strengthening the health system to tackle NCDs. [5] Although NPCDCS has managed to improve opportunistic screening, the control rates of diabetes and hypertension are poor. Studies have reported a lack of awareness, treatment availability, lack of adherence, and poor control rates of both diabetes and hypertension. [6] [8] A systematic review in 2014 demonstrated that, of the people who have been diagnosed with hypertension, only 24.9 % in rural and 37.6% in urban areas were on treatment. [9]

Similarly, a nationally representative sample study in India (n=731,864) found that only 13% reported being on anti-hypertensive medications and 8% achieved BP control.[20] In the case of diabetes, with data from 729,829 adults, 3.3% (95% CI, 3.2–3.4%) had diabetes of which only 52.5% (95% CI, 50.6–54.4%) were aware of being diabetic, 40.5% (95% CI, 38.6–42.3%) were on treatment and only 24.8% (95% CI, 23.1–26.4%) had random blood glucose values which reflected the adequate glycaemic control range.[6] The overall prevalence of hypertension and diabetes from a recent survey (2017) in Kerala was 30.4% (95% CI 29.1 to 31.7), and 19.2% (95% CI 18.1 to 20.3) respectively. Further, the control rates of blood pressure and blood glucose were poor with a population level control rate of 12.4% of patients with hypertension and 15.3% of patients with diabetes.[2] This shows that a considerable number of patients are being lost to adequate care from the awareness stage to the control stage of diabetes and hypertension.

At the patient-intervention level, the management of diabetes and hypertension requires adequate communication with doctors and patients and/carers, adherence to pharmacotherapy, and self-management for achieving control. [0 22 23] Other than doctors, HCPs such as nurses and pharmacists can contribute to better public and patient understanding of risk factors, lifestyle modifications, and improved adherence with therapy. [24 25] For effective management of diabetes and hypertension, patients must assume an active role in their health care pathway.[26] HCPs must ensure that patients have adequate information and skills to manage their diabetes and hypertension.[27] For this to occur, patients need a context in which they can freely ask questions, and they need an environment that initiates and supports their self-management behaviours over time. [3] Unfortunately, health care systems in India and other LMICs have failed to create an environment that promotes quality interactions and partnerships with patients, and there is evidence that HCPs do not collaborate with patients on a variety of topics such as communicating patients' preferences for care. [3] One of the major contributing factors is the lack of adequate time spent on consultations in India.[28] Previous studies have shown that HCPs remain the source of trusted health information for patients with diabetes and hypertension in India.[29] [30] Therefore, time constraints, inadequately trained HCPs, lack of awareness or disempowered patients lead to little or no health care communication in outpatient settings. Self-management, medication adherence, current skills, knowledge, or personal responsibilities are rarely discussed in the clinical context. A recent observational study done in Karnataka, India to assess the primary health care system's ability to manage diabetes and hypertension reported several barriers to organising and delivering care. The care processes in these centres were doctor-centred without much participation of other healthcare staff in care for patients with diabetes or hypertension.[3] Additionally, there is little or no electronic health record system for the HCPs, no information or communication regarding patient follow-up and patients' own care at home in between healthcare visits.[3]

In addition to clinical care for patients with diabetes and hypertension, patients have to make changes in their lifestyles, must develop new skills, and must learn to interact with HCPs to manage their chronic conditions. [3] Patients must be supported by HCPs and health care organisations for self-management. [0]

The following section explains the role of continuity of care, information transfer, and self-management within the context of patients with diabetes and hypertension. The importance of handover and healthcare communication has been summarised in the Context for PhD research in the Introduction.

1.3.1.1.Continuity of care

Continuity of care refers to the seamless care over time between care episodes and healthcare settings.[32] Informational continuity is an essential component of continuity of care.

Informational continuity refers to how efficiently patients' health information can travel with them across time, care episodes, care providers and health care facilities.[33 34] Patients' health information includes the patients' experienced symptoms, treatment, management plan, test results, and other relevant details that are usually recorded.[35]

Continuity of care is essential in the management of chronic conditions such as diabetes and hypertension [36 37] to detect early complications and manage complications such as heart attack, stroke, etc. Traditionally, continuity of care has been thought of only as a patient's experience of care with one healthcare provider over time. This is also known as relational continuity of care or care developed with a known provider such as a primary care physician.[34] However, there is another definition of continuity of care that applies to the management of chronic conditions. Continuity of care refers to the seamless care over time between care episodes and health care settings.[32 38] A 2003 review by Haggerty et al described continuity of care as having two core elements; care for an individual patient and care which is provided over time.[34]

The current evidence does not establish a relationship between continuity of care and disease-specific outcomes. However, there is sufficient evidence that better continuity of care is associated with patient satisfaction especially among chronic disease patients.[34] Further, it is known that without clearly documented and easily accessible information about the medical history and demographics from a patient's previous consultations, healthcare is fragmented and unsafe.[39]

For the purpose of this thesis, continuity of care refers to informational continuity and the management continuity that is dependent on the patient's healthcare information. Within this thesis, the emphasis is on improving continuity of care using a PHR rather than examining the relationship between a patient's known provider and providers.

1.3.1.2. The referral system in India and patients' medical information transfer

Health systems with different levels such as primary, secondary, and tertiary care operate effectively within a well-implemented gatekeeping mechanism for a referral.[40] However, even though the Indian public health care system is set up with a referral system, utilisation is often very minimal and established systems differ between each state's health services.[4] Additionally, even though a substantial number of patients in India use private healthcare services, there is no formal integration of care between public or government-run healthcare facilities and private healthcare services. The private sector ranges from single-doctor clinics to corporate hospital chains, which operate independently.[42] Thus, within this pluralistic health system[4] , care for patients with chronic conditions such as diabetes or hypertension becomes difficult. For example, the lack of screening facilities and the asymptomatic nature of increased blood pressure leads to inadequate early detection. This in turn leads patients to develop complications and more often present with an acute CVD such as heart attack or stroke to secondary or tertiary care, which is symptomatic and life-threatening.[43] Since the referral systems are not followed effectively, these patients get treated in tertiary care without being referred back to primary care. Subsequently, the caseload in the outpatient settings in tertiary care centres increases leading to less time for doctors to spend with each patient.

Additionally, patients can choose from various government or private HCPs for their care. This means that the patient can self-refer himself or herself to any HCPs without the knowledge of their public care provider. Hence, documented information transfer both within and between different HCPs is paramount in ensuring continuity of care.[44]. The current formal referral practices range from writing a referral letter with basic information to providers to using telephone or email to other providers regarding their patient.[45] [46] Hence, the patient and their family remain the sole constant throughout the care progression and thus become an important tool in essential information transfer across different health settings.

1.3.1.3. Self-management

Evidence indicates that supporting people to be actively involved in their own care, can improve healthcare outcomes, quality of care, patient experiences, and potentially lead to better healthcare services.[26 47 48] Patient engagement refers to the process of building the capacity of patients, families, carers, and HCPs to support the active involvement of patients in their own care.[49] One of the areas in which patients with diabetes and hypertension need support for active involvement in their care is self-management.[50] According to Barlow et al, self-management refers to an individual's ability to manage their treatment, symptoms, outcomes of health and the needed changes in lifestyle.[5] In this context, there exists a need for efficient communication at two levels, one between the HCPs and another between the HCPs and patient and their carers/family.[5]

The following section provides an overview of the health care delivery system in Kerala, NCD programme and changes in health system within the context of electronic health record implementation in primary care.

1.3.2. Healthcare delivery system in Kerala

India has a federated health care system; which implies both central and state governments have responsibilities towards governance of health care.[53] Further; India has a mixed health-care system, with government run public health care facilities and private health care facilities. However, with the poor regulatory framework, out of pocket payments and market provision of health services dominate as a means of financing health care in the private health sector.[54] The public health-care infrastructure has been developed as a three-tier system (as described in the section, The referral system in India and patients' medical information transfer). At the primary level, there are sub centres and primary health centres. In the secondary level, community health centres and sub-district hospitals are available. Medical colleges and district hospitals function at tertiary levels.[53]

1.3.3. Non-communicable diseases control programme in Kerala

Formal interventions to tackle NCDs at the Kerala state level in the public health system started with the National Rural Health Mission (NRHM) in 2005. The launch of the NPCDCS in 2008 at the national level strengthened the CHCs, district hospitals, and tertiary care centres. However, in Kerala, the state plan fund was utilised to support primary care by focusing on the PHCs and sub-centres. The India Hypertension Control Initiative (IHCI) is a multi-partner initiative that includes the Government of India, Union Ministry of Health and Family Welfare, Indian Council of Medical Research, State governments, and the WHO India that was launched in 2017. IHCI focused on control of NCDs rather than screening.[55]

1.3.4. "Aardram" Mission

One of the four missions announced by the government of Kerala under the 'Nava Kerala Mission' (New Kerala Mission) was related to health care, known as the 'Aardram' mission. The mission's primary objective is to deliver patient-friendly, quality health care services in government-led health care facilities. It focuses on restructuring the existing primary health centres to FHCs, ensuring comprehensive health care services to marginalised populations, and standardising the health services available in primary, secondary, and tertiary health settings.[56]

The upgrade of primary health centres to FHCs is envisaged as a phased series of infrastructural and administrative changes. The activities include infrastructural improvements (buildings, resources for setting up electronic health records), human resource training, and record management through the e-Health system, improved laboratory facilities, and a focus on preventive healthcare service provision.[56] The above has led to provisions of medicines and treatment for patients with diabetes and hypertension in primary care.[57]

One of the elements of the mission is the implementation of "eHealth" technology. The "eHealth" project (2017) is a project funded by the Government of India and the Department of Health and Family Welfare, Government of Kerala, designed to provide citizens of Kerala with a convenient centralized electronic healthcare records system. The eHealth program aims to create longitudinal electronic medical records for the population of Kerala. The project includes a central data server holding health and demographic data. The server is linked to the Health Management Information System projects from all public health institutions in the state of Kerala, right down to the level of sub-centres. The integration improves the use of data and information systems and establishes a centrally managed data source. The system helps citizens to book an appointment and visit any government health facility through this portal. Further, it is intended to enable the citizens to walk into any government health facility without carrying any old consultation papers that are being currently given to patients/carers as a patient-held record of health, medical information.[58] However, the progress of implementation is slow, and the interoperability issues with the private sector persist. Therefore, PHRs are the major form of medical information transfer tool across HCPs and patients/families.

The next section provides an overview of PHRs.

1.4. Patient-held health records

In general, in most health care settings, patients' medical records are stored at the health facility known as facility-based medical records. Sometimes patients are given a copy of their medical records to keep, taking to other health care visits to manage communication with other health care providers.[59] PHRs are formal records that are intended to promote care continuity and contribute to improving quality of care.[60]

Early development of PHRs

Paper-based facility records have been replaced by electronic medical records, which are the digital version of the paper record in most HICs and in several private hospitals in India and Kerala.[6]

PHRs have been implemented due to the difficulty in retrieving medical information notes from the facility-held records.[62] These records have been known as home-based records and were used to record the history of health services received by a patient in LMICs.[63]These have been well established in the case of maternal and child health records. Currently, almost 163 countries have some form of maternal and child health records as PHRs in use.[64] Patients are responsible for keeping the PHRs safely at home and bringing them to each health care visit. [65]

PHRs have been described as shared care records in HICs.[67 68] This is applicable where shared care is seen as a service provided between the primary and secondary care sectors, with general practitioners (GPs) as the fundamental central component.[63] Shared care records have been developed to improve integration between primary and secondary health care services.[68 69] This concept has been successfully used in maternity care by giving maternity notes to pregnant women.[8] Hamilton introduced the 'Co-op (co-operation) card' as early as 1956 in the United Kingdom (UK).[82] The underlying principle of the shared care record is to connect all members of the care team including the patient. When using an electronic format, it provides information access to multiple users, including those in a multi-disciplinary care team that, for instance, consists of HCPs at primary and secondary services (from multiple organisations) as well as the patient themselves.[83] When using a paper-based format, these shared care record cards, were for the transfer of information through a booklet or 'cooperation card', commonly carried by the patient.[84]

Although PHRs were developed for, tracking patient histories and health service use, since patients kept PHRs meant it could be made useful for patients by improving patient engagement with their care.[76] This concept has been utilised in maternal and child health records. PHRs have been used as a tool for imparting health education to a pregnant woman thus improving antenatal appointments, breastfeeding behaviours, improving communication with partners and health care providers.[65 77] Thus PHRs were designed to improve communication between patients and their HCPs and for better involvement of patients in their care.

Therefore, from the above discussion, PHRs have been used as a tool to record the history of health services received by an individual (data recording and storage function), improve information transfer between health care providers, and communication between HCPs to patients (sharing-information function) and to involve a patient in self-management (patient engagement function). Currently, there is no one definition or a standard type of PHRs. There are different types (table 2) and forms (table 3) of PHRs available. Different types of PHRs include either condition specific or person specific and forms include paper-based PHRs or electronic ones that may be portable (such as USBs) or linked to one's electronic medical records.

Table 2: Types of PHRs

Condition-specific	*Person specific*
Predominantly, clinically focused disease-specific records have been used across different conditions. The most common clinically focussed condition-specific record is the patient-held maternal and child record.[65 78] These have been extensively used in both high income and low-income countries, such as the personal child health record (PCHR) or red book in the UK.[79] The other condition-specific PHRs found in the literature are for cancer[74 80 8] , palliative care[82] and other chronic conditions such as DM.[83 84] Other condition-specific patient-held health information is available for use in emergencies such as anaphylaxis[85] and post-splenectomy infection.[86] This type of information tends to be brief, however, as with the full patient-held notes, these shortened personal record systems aim to promote patient participation in care, facilitate early treatment and help avoid hospital admission.[87]	The other kind of patient-held records is clinically focussed whole patient records. These records are not developed for a particular disease condition rather for recording health care encounters made by patients. From a literature search, such paper-based PHRs were in use in Malawi[88] and China.[89]

Table 3: Forms of PHRs

Paper-based	*Electronic*
The most common PHRs are paper-based. Paper-based PHRs can range from simple patient-held 'cards' such as the blue card[90] used in patients with mental health issues to comprehensive handbooks or notebooks to be used by patients' post-stroke.[8] [9]	With technological advancement, facility-based health records have been changed from paper to electronic. Electronic PHRs ranges from tethered personal health records which are linked to patients' electronic health records to stand-alone PHRs, which are not linked with electronic health records.[92] Electronic health record availability led to other forms of personal health records data using storage devices, such as smart cards and USB sticks. Untethered or standalone PHRs' main feature is that the patient-user is the only one permitted to enter, maintain, and self-manage data related to their health conditions.[93] Therefore, PHRs can be electronic records, non-electronic records (paper records), or a mix of electronic and non-electronic records.[94]

PHRs can have different content forms ranging from clinically focussed to person-centred. In practice, the PHRs that are person-centred will have patients' inputs to record the details. Patients can record their personal details, medication details, details of their living will, and the details of all their HCPs such as the Adelaide Palliative card record.[87 93] Clinically focussed records will have patient-encounter related information being documented by HCPs which can be used for further clinical decision-making.[93 94]

Current evidence for PHRs from high-income countries

The researcher did a scoping literature search in MEDLINE using key terms "patient-held records", "patient-held medical records", and "systematic review" to gather the evidence from systematic reviews on PHRs. The search identified five systematic[59 60 88 95 97]reviews for PHRs for chronic conditions, including cancer and mental illnesses. None of the systematic reviews had done a meta-analysis. The evidence from these reviews is summarised in Table 4.

Overall, there is no clear evidence on the effectiveness of PHRs in the management of chronic conditions. However, several studies from the systematic reviews report the usefulness of PHRs for patients and HCPs. One study by Williams et al[74] measured the use of PHRs by HCPs and found that, 93% (69/74) of HCPs felt that they used the PHR for communicating with patients and 94% (70/74) responded that they used it as a tool for communicating with other HCPs. A Dutch trial evaluating a PHR for head and neck cancer, reported that HCPs (n=54) read the PHR. The content most accessed by HCPs was patient information (86%) and oncological case histories (89%), and the patient's notes (85%).[8] The findings from another study show that Although patients and HCPs have positive opinions on having a PHRs, the use of PHRs in practice was very low. For example, the PHR for diabetes patients is used by only 36% (150/418) of trial participants.[74] HCPs also expressed added documentation burden when using PHRs.[74]

Table 4: Evidence from systematic reviews from HIC

Author, year	Condition/Population	Aim of the systematic review	Number of studies	Relevant results	Quality of evidence
Gysels et al[6] , 2007	Cancer	To assess the effectiveness of the PHR in cancer care.	Thirteen studies (7 randomised controlled studies, 3 cross sectional studies, 2 qualitative evaluation and one survey)	This review found that the HCPs used these records to communicate with other HCPs and not with patients. However, no studies in the review objectively measured the information available to each HCPs for making clinical decisions. From this review the benefit of using PHRs for HCPs were to read the notes by other HCPs and for a comprehensive view of patient's condition and benefits for patients were to use it as an aide memoir and take it to consultations with HCPs.	Of the 7 trials, less than half scored half of maximum possible score and of the 6 non-experimental studies, four of them scored highly.
Schoevers et al[95] 2009	Undocumented immigrants	To investigate the potential benefits of a PHR for undocumented immigrants	Seven studies (3 randomised controlled trials, two cluster randomised trials, one cohort study and one qualitative study)	No articles were reported on undocumented immigrants. Results in the review are from patients other than undocumented immigrants. The use and appreciation of the PHRs by HCPs in the studies is lower than the use by patients.	Of the 15 eligible studies, only 7 were included in the review following quality assessment. The included studies were assessed as high quality.
Ko et al[60], 2010	Chronic conditions	To assess whether a PHR enhances clinical care, patient outcomes, or satisfaction in individuals with	Fourteen studies (Five cluster randomised controlled trials one crossover	Reported lack of clear benefits to both patients and HCPs. The review concluded that there is no evidence on PHRs improving patient outcomes such as patient satisfaction, communication or health outcomes.	Low quality of evidence as most of the studies did not meet the methodological quality.

		chronic illnesses compared to standard care.	randomised controlled trial, two cohort studies, one quasi randomised controlled trial and five randomised controlled trials)		
Sartain et al[96], 2015	Various	Systematic review and thematic synthesis of qualitative studies, which investigate the perspective of patients on the effectiveness of the PHR	Ten studies (qualitative evaluations)	Three main themes were summarised. Firstly, the practical benefits of having a PHR such as possessing one's own record, an aide memoire and a tool for sharing information across HCPs. Secondly, the psychological benefits of having a PHR such as being empowered to ask questions, to record own thoughts and feeling in control. Finally, the drawbacks of PHRs such as unwanted responsibility of carrying records.	The reporting quality varied among the ten studies. Nine studies did not mention the research team's experience or training. Only one study explicitly mentioned its qualitative sampling strategy. Eight studies presented major themes, while two provided findings without highlighting themes. Strategies for ensuring reliability were inconsistent, with most lacking details, such as the number of coders. Only four studies

					included participant quotations.
Farrelly et al[87] 2013	Mental illness	To evaluate the effects of personalised, accessible, user-held clinical information for people with a severe mental illness	Four randomised controlled trials	There is no evidence for decrease in hospital admission or encourage people with severe mental illness to attend appointments. Nevertheless, the PHRs intervention is low cost and acceptable to patients and HCPs.	All trials were randomised and described allocation methods well. Due to the intervention's nature, blinding was not possible, but three trials used blinded outcome raters to reduce bias. One study lacked detailed missing data reporting and was unclear. Other studies had low data attrition, evenly spread across intervention arms, and non-intervention-related reasons. None had published protocols.

1.5. Chapter summary

This chapter has explained the background, the extent of hypertension and diabetes burden in Kerala and the current issues with long-term management of patients with diabetes and hypertension. Additionally, it has discussed the role of continuity of care and self-management, provided a brief outline of PHRs and summarised the evidence of PHRs from HICs. Chapter 2 presents an overview of the methodology of the thesis and the multiple-methods used to answer the research questions.

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CHAPTER TWO

METHODOLOGY AND METHODS

2.1. Chapter preface

The overarching research question for the thesis was exploratory[1] rather than to test any priori hypotheses or assumptions. It aimed at understanding how PHRs are used and their value for handover communication, informational continuity, and self-management. As noted earlier, this thesis is comprised of two systematic reviews, a qualitative study with patients, carers, and HCPs, and a proposed plan for co-designing a PHR for improving patient engagement among patients with diabetes and hypertension in Kerala. The two systematic reviews followed PRISMA[2] guidelines The empirical qualitative data are presented in three chapters: a thematic analysis[3 4] of patients', carers' and HCPs' interviews to understand the similarities and differences in how they use and value PHRs; a thematic analysis of patient interviews to understand why patients engage (or not) with PHRs for self-management; and a re-analysis of HCP interviews using the Theoretical Domains Framework (TDF) [5] to identify the barriers and facilitators for using PHRs for recording and maintaining informational continuity of care. Finally, a plan for co-designing a PHR for patients with diabetes and hypertension in Kerala using the Experience-Based Co-Design (EBCD) method to potentially improve patient engagement. Additional specific information on methods, settings, recruitment, and data collection are described in detail in Chapters three to seven. This chapter provides justification regarding the overall research methodology, methods, and study designs, as well as analysis.

2.2. Paradigm

Philosophically, methodology is the paradigm, and assumptions upon which the research is based.[6] Every research is built on a philosophical basis, which is linked to opinions about the methods that should be used in research, what can be understood, who can acquire knowledge, and how knowledge can be obtained.[7] According to Kuhn, the set of assumptions and "way of thinking "or values that are held by researchers is known as a paradigm.[8] In short, a paradigm is an overarching perspective or "world view" that guides the research.[9] [0] An ontology is the philosophical belief system about the nature of the reality and epistemology is the philosophical belief system of how one represents the role of researcher, and the relationship between the researcher and research participants. [7] The decisions made in the process of selection of methodology and methods are based on the researcher's paradigm and epistemological position. [8]Adopting a paradigm helps the researcher clarify their beliefs about the nature of knowledge and enables them to choose the most appropriate methods to answer their research questions.

Four commonly described paradigms for academic research are; post-positivism, constructivism, transformative and pragmatism. Post-positivism is an empirical approach rooted in scientific beliefs that aims to explain the world through reductionist and logical principles. It focuses on quantitative research methods and observing objective reality. [2] Constructivism is a qualitative approach that seeks to understand the subjective world of human experience and views social constructs as being shaped by individuals. The transformative paradigm focuses on promoting social justice and empowering marginalized groups. [3] [4] Pragmatism was created as a way to reconcile the differing views of post-positivism and constructivism [5], and it advocates for a flexible approach using mixed and multi-methods. [6]

2.3. Pragmatism

In this thesis, the researcher adopted pragmatism as an interpretative framework and is presented as guiding the multi-methods research[17] because pragmatism is a philosophical perspective that emphasises practicality and usefulness in solving real-world problems. [18] [19]

The researcher's epistemological perspective has changed over the course of the PhD. The researcher began with a relatively positivist perspective, focussing on answering the predetermined research questions and seeking answers about the effectiveness of using PHRs for improving handover, informational continuity, and self-management. The researcher was looking for whether PHRs "work". However, the researcher became more aware of the need to explore the tangible processes user groups (patients, carers, and HCPs) take such as carrying (or not) PHRs to consultations, asking (or not) for PHRs or documenting (or not) in PHRs. If the researcher had to develop or design a PHR for improving the current problems of handover, informational continuity, and self-management, it was necessary to seek alternative designs or practical solutions for current problems faced by the users. The researcher adopted a pragmatist approach. Pragmatism is concerned with action and change. [16] Pragmatism recognises that there are many different ways of understanding the research problem, and that the most effective approach is one that combines multiple methods and perspectives to arrive at practical solutions. [16]

Pragmatism is a relatively newer paradigm, which is concerned with focusing on the appropriateness of research questions than issues of ontology and epistemology and offers the epistemological justification of bringing together multiple perspectives to create a workable solution. [6] The focus in this thesis was on an objective way of data collection and analysis for identifying practical solution for the research questions using varied approaches to look for a solution to the complex research health problem studied. [18 19]

Quality improvement in health research is mostly undertaken to create new knowledge to improve practice. In complex settings such as health care practice, multiple perspectives and experiences may be required to gain knowledge. A pragmatic philosophy was well suited to explore the role of current PHRs in improving handover communication, informational continuity and self-management from patients' carers', and HCPs' perspectives.

While both interpretivism and pragmatism focus on experiences, what differs is the pragmatist adopts a stance that aims for knowledge that is useful in action i.e., why users engage (or not) with PHRs, to use this understanding for creating an improved PHR. Further, pragmatism offered an action-oriented framework for research[20], where the researcher could address the current issues in using PHRs to feed into developing a new improved PHR.

2.4. The rationale for a multi-methods research approach

As mentioned previously, the complexity of the research topic indicated the need to use different methods. Methods used in this thesis were primarily qualitative in nature, although the systematic reviews have quantitative aspects. [2] On the other hand, to be more precise with the use of terminology a multi-methods approach was thought most appropriate for this research compared to mixed-methods, as the latter necessitates the integration of qualitative and quantitative studies. The researcher recognised that integration of quantitative and qualitative data was not necessary for this particular research question, as the aim was not to combine or synthesise the results of different methods, but rather to use multiple methods to gain a deeper understanding of the research problem from different perspectives.

Using a multi-method methodology, the researcher utilised three distinct research methods. Firstly, a multi-methods approach made it possible to examine the research problem from the available evidence from literature using systematic reviews, and from perspectives of patients, carers and HCPs using semi-structured interviews in Kerala. The key criterion for ensuring quality of the selected methods was how rigorously they were conducted within the recognised parameters of each method (explained in the research methods section in Chapter 2).

Secondly, an inductive approach was used with multi-methods that moves from specific observations to broader generalisations, combining different methods of analysis of the same qualitative type.[17] For example; the data collected from HCPs in the Chapter 4 were re-analysed using the TDF to obtain a different perspective on barriers and facilitators for using PHRs. The TDF is a framework that allows researchers to identify factors that influence behaviour and its application in this thesis helped to uncover deeper insights into the challenges and opportunities for HCPs to use PHRs.

Thirdly, a multi-method approach enabled triangulation[22], to broadly explore the phenomenon being researched using different methods. By using triangulation, the researcher can compare and contrast the findings from different sources and methods, identify converging themes, and identify inconsistencies or discrepancies that need to be explored further. In this thesis, triangulation is used to gather information on PHRs through different sources to provide a comprehensive summary of PHRs. The different approaches for obtaining a comprehensive understanding on how PHRs can be used for improving handover communication, informational continuity and self-management were:

a. the systematic reviews enabled gathering evidence on the effectiveness and usefulness of PHRs in improving handover communication, informational continuity and self-management from LMICs.
b. the semi-structured interviews with patients with diabetes and hypertension, carers and HCPs working in public health facilities in Kerala enabled mapping out the complexities of using PHRs as result of studying this from the point of view of more than one user group.
c. the co-design workshops proposed will potentially contribute to developing a PHR that may improve patient engagement with PHRs.

2.5. Research methods

2.5.1. Systematic reviews

Systematic reviews were employed to allow findings from different studies to be synthesised with information on the quality of individual studies [2] Two systematic reviews (Chapter3) were carried out to synthesise the evidence on currently available PHRs in LMICs (Table 1). The systematic review protocol was registered with PROSPERO.[23] A narrative synthesis[24] approach to data analysis was taken owing to heterogeneity and a limited number of studies for a meta-analysis. The Mixed Methods Appraisal Tool (MMAT) [25] tool was used for assessing the quality of included studies.

Of the condition-based PHRs, maternal and child health records or home-based records are the most predominant and well established in LMICs.[26] This systematic review helped to synthesise current evidence on how PHRs may improve handover communication, informational continuity and self-management and the gaps in evidence that may be addressed in future work.

Table 1 Systematic review: methodological considerations and rationale

Systematic review	Relevant information for this thesis	Rationale
Design	Systematic review with narrative synthesis	Both reviews employed a systematic review with narrative synthesis[24], but they did not include meta-analysis. This approach differs from a scoping review[27], which is used when investigating situations where specific, focused research questions are not yet clear for a detailed systematic review. Additionally, systematic reviews without meta-analysis differ from mixed methods systematic reviews[28], which aim to transform either quantitative data into qualitative data or vice versa for synthesis. Notably, systematic reviews typically include quality assessments, which are often absent in scoping reviews.[27]
Research questions	1. What is the current evidence of effectiveness and usefulness of PHRs for handover, information transfer and self-management in the management of NCDs in LMICs? 2. What is the current evidence of effectiveness and usefulness of home-based records for handover, information transfer and self-management in LMICs?	A systematic review was conducted on a topic different from hypertension and diabetes to gather insights from established maternal and child health records. Among condition-based PHRs, maternal and child health records, also known as home-based records (HBRs), are the most prevalent and well-established in LMICs and hence examining its effectiveness and usefulness in improving handover communication, informational continuity and self-management is highly relevant for this thesis.[26] However, it's essential to note that HBRs, although falling under the category of PHRs, differ in certain aspects. Firstly, the use of HBRs is typically limited to the period of pregnancy and childhood, primarily serving as a documentation tool for vaccinations. They do not function as comprehensive longitudinal health records for either the mother or the child. Secondly, although pregnancy and childbirth are critical healthcare events, they do not represent long-term medical conditions requiring ongoing healthcare. Consequently, the systematic review

		will separately address the utility of HBRs for facilitating information exchange among HCPs and for patient self-management. The insights gained from the HBR review can offer valuable information on how HBRs are utilised for information exchange and patient self-management.
Quality assessment	MMAT Tool[25]	For quantitative, qualitative, and cross-sectional studies, all five criteria needed to be met to be classified as 'high quality.' Studies that met three to four criteria were classified as 'medium quality' and studies that met one or two criteria were regarded as 'low quality. While the recommendation for MMAT is not to assign scores to the studies, the classification approach the researcher employed was inspired by the Jadad score[29], which aimed to categorize the studies to facilitate a clearer interpretation of quality of included studies.
Data selection	PRISMA flow diagram	The researcher had completed and written the systematic reviews before the publication of PRISMA 2020.[30] While PRISMA 2020 provides updated guidance for reporting systematic reviews, PRISMA 2009 is still a widely recognised and accepted standard for reporting systematic reviews. The adaptation to PRISMA 2009 flow diagram was made to provide more detailed information on excluded studies at each stage as employed in several previous systematic reviews.[3 ,32]
Data synthesis	Narrative synthesis with a framework to organise the results	1. For the first systematic review, the researcher developed a framework for organising results (Chapter 3, Table 2, Description of result) based on previous studies on PHRs.[33,34] 2. For the second systematic review a framework by Osaki et al[35] (Appendix 3, Table S1: Functions of HBR used for summarising the findings.

2.5.2. Qualitative data

Semi-structured interviews[36] were employed to explore the perspectives of patients, carers, and HCPs on their experiences with PHRs for handover communication, informational continuity, and self-management in Kerala. Interviews were done in two rounds. Initial face-to-face [37]semi-structured interviews with patients were conducted at FHCs (pre-COVID). The data collection was done in two phases and data analysis was iterative. For example, some patients recruited from FHCs, when discussing using PHRs for self-management, would discuss their own feelings and worries about managing their condition. This was explored in further telephone interviews (post-COVID) with other patients.[38]

Sample size

Data saturation serves as a fundamental guiding principle in determining sample sizes for qualitative research.[39] While practical considerations necessitate an initial sample size estimate for ethical approval, the ultimate sample size is contingent upon achieving saturation during the study.[40] In the qualitative study (Chapter 4), data saturation within each group was attained, patients, carers, and healthcare providers, aligning with the three research questions outlined in the introduction. Data saturation denotes the juncture at which researchers possess a comprehensive understanding of the subject matter, leaving no further dimensions or insights of the problem can be found.[40] The details on how data saturation was obtained is explained in Chapter 4.

The researcher interviewed patients first, followed by HCPs and then carers. Patients were interviewed first to get their first-hand experience with PHRs. Since one of the underlying assumptions was regarding PHRs to be made useful for patients for self-management, it was important to understand how patients used current PHRs. The settings, sampling, and recruitment strategies are reported in the Methods sections of Chapters four, five and six.

2.5.3. Analysis of interview transcripts

The researcher independently analysed patients', carers' and HCPs' qualitative interview transcripts using Braun and Clarke's[4] reflexive approach to thematic analysis. Further, the theoretical domains framework (TDF) was used to re-analyse the HCP interview data set. Here the researcher explains the rationale for taking this hybrid approach.

2.5.4. Thematic Analysis

Thematic analysis (TA) is the process of identifying patterns or themes within qualitative data.[4] TA has become an established approach and has been used in applied health research, by both novice and experienced qualitative researchers.[4] Additionally, there have been active discussions and resources available for conducting and teaching TA.[42]

Thematic analysis is an analytic method and not a methodology; hence, TA can be used across different paradigms and forms of qualitative data collection. [43] However, it is not a single method too. According to Clarke et al typology, currently three ways of TA are predominant; coding reliability, reflexive and codebook approaches.[3] The table below summarises the three different TA typology.

The coding reliability approaches focus on the reliability or accuracy when coding the data using a structured codebook. Code-book approach seeks consensus among multiple coders, typically measured using Cohen's Kappa. Themes are developed early in the analytical process either based on theory prior to data collection or following familiarisation with the data. These themes are considered as "domain summaries" or summaries of what participants said in relation to a particular topic or data collection question. Codebook approaches, such as framework analysis or template analysis, lie between coding reliability approaches and the reflexive TA approach. As the name suggests codebook approach uses a structured codebook and view themes as domain summaries, like coding reliability approaches, but prioritise a qualitative philosophy similar to the reflexive approach. Proponents of codebook approaches recognise the interpretive nature of data coding, rather than adopting a positivistic conception of coding reliability. The reflexive approach to TA emphasises the active role of the researcher in knowledge production, with codes representing the researcher's interpretation of patterns of meaning in the dataset. It is understood that no two researchers will intersect the dataset, theoretical assumptions, and analytical skills in the same way. Therefore, reflexive TA discourages attempts to provide "accurate" or "reliable" coding or consensus among multiple coders. Instead, it prioritises the researcher's reflective and thoughtful engagement with the data and the analytic process. Collaboration among multiple coders may be beneficial but should aim to achieve richer interpretations of meaning rather than consensus.[44] [45]

Table 2: Different approaches of TA as described by Braun and Clark

Coding reliability TA approach	Reflexive approach	Structured codebook approach
Coding reliability approaches, such as those adopted by Boyatzis[46], Guest[47], emphasise the measurement of accuracy or reliability when coding data, often involving the use of a structured codebook.	Reflexive approach to TA highlights the researcher's active role in knowledge production. Reflexive TA is considered a reflection of the researcher's interpretive analysis of the data conducted at the intersection of: (1) the dataset; (2) the theoretical assumptions of the analysis, and; (3) the analytical skills/resources of the researcher.	Codebook approaches, such as framework analysis, template analysis or matrix analysis, can be understood to be something of a mid-point between coding reliability approaches and the reflexive approach.
Coding seeks consensus among coders.	Codes are understood to represent the researcher's interpretations of patterns of meaning across the dataset. Hence, it is understood and appreciated that no two researchers will intersect these triple conditions in the same way. As such, there should be no expectation that exactly another may reproduce codes or themes interpreted by one researcher (although, this is of course possible). Multiple coders may, however, be beneficial in a reflexive manner (e.g., to sense-check	Coding is a process of organising the data into these themes (and possible theme refinement during or after coding). Forgoes consensus approach.

	ideas, or to explore multiple assumptions or interpretations of the data).	
Theme development early in the analytic process. Themes can be hypothesised from a theory or familiarisation of the data.	The process of coding (and theme development) is flexible and organic, and very often will evolve throughout the analytical process.	Some or all themes determined in advance or in the early stages of analysis.
Themes are typically “domain summaries” or “summaries of what participants said in relation to a particular topic or data collection question”	Through the reflexive approach, themes are not predefined in order to ‘find’ codes. Rather, themes are produced by organising codes around a relative core commonality, or ‘central organising concept,’ that the researcher interprets from the data.	Like coding reliability approaches, codebook approaches adopt the use of a structured codebook and share the conceptualisation of themes as domain summaries. The codebook is used to map or chart the developing analysis.

2.5.5. Thematic analysis in this research and presentation of themes

The researcher chose TA as the method of data analysis for this study due to the theoretical flexibility required to be able to answer all the research questions and used a reflexive TA approach. Reflexive TA enables focusing on descriptive meaning as expressed by the participants.[48] This is especially useful when exploring an under-researched topic because it encourages the generation of new knowledge and meanings.[4]

The researcher transcribed the patient interview data (n=5). The interview transcripts were re-read for familiarisation and coded line by line. After coding the first three interviews, the coding strategy was discussed with one of the supervisors (AL) to aid in reflexivity. The initial codes were descriptive and based within the data. The rest of the patient interviews were coded using the initial coding strategy while allowing for further inductive codes. The analysis was iterative. Appendix 3 gives a reflexive account of how the researcher analysed patient interviews using thematic analysis. [3 44 45] The reflexive accounts are provided to make the decision-making, reflective, and interpretive processes of analysis more transparent.

In the next phase, HCP data were collected and transcribed. The first three HCPs' interviews were coded line by line to generate the initial codes. The inductive codes from the patient interviews were used as deductive codes for HCP transcripts. However, HCP data were coded independently to allow for generating additional inductive codes from the HCP interview data. A similar approach was taken for coding carer data.

As described above, the patients,' carers,' and HCPs' data were coded separately, and codes were grouped into potential themes separately in Microsoft Excel. The themes and sub-themes specifically about experiences with PHRs from patients, carers, and HCPs were compared and contrasted are presented in Chapter four. For example, the researcher inductively coded HCP interview data and identified their perception of the value of PHRs in terms of clinical decision-making, preventing medication errors, and enhancing patient safety. However, upon comparing and contrasting the experiences with PHRs from patients, caregivers, and HCPs, it became evident that both patients and caregivers did not view PHRs as effective in preventing medication errors or enhancing patient safety. Themes relating to patients,' carers, and HCPs' use of PHRs and value placed on PHRs were organised under three headings; "use of PHRs in practice," "perceived value of PHRs" and "where practice and value conflict."

Next, the researcher focused on themes and sub-themes relating to lack of patients' engagement with PHRs for self-management. Three emergent themes "navigating the care system," "patient and healthcare provider interactions" and "agency over illness and ownership of health" from the patient interviews, which helped to explain the contextual influences on patients' lack of engagement with PHRs, were organised under the following headings: health system factors, patient factors and socio-demographic factors and is presented in Chapter five.

2.5.6. Theoretical domains framework

Healthcare is traditionally a positivist field of enquiry. [49] However, in health systems research, health systems are understood to be social systems, shaped at all levels by human agency and embedded in social and political contexts. [50] Much evidence-based practice fails during the implementation and uptake into routine clinical practice and encounters difficulties in getting embedded in the health system. [5 ,52] One of the reasons is that following evidence-based practice needs behaviour change and behaviour change is often difficult. Several factors can influence the uptake of an evidence-based intervention, and the success of implementation efforts depends on a careful assessment of barriers to and enablers of the behaviour to be improved. [53] Using a theory-based assessment explores the logical identification of such factors, can guide implementation and evaluation design, and may provide the basis for a better understanding of behaviour change processes. However, there are many different theories to choose from, making it difficult to select a specific theory for identifying barriers and enablers. Relying on only one or a few theories may overlook important factors that influence behaviour. To address this problem, the TDF was developed as a comprehensive theoretical framework to guide behaviour change research. [54]

Using reflexive TA, the researcher explored how HCPs describe their use and value of PHR. To further understand the barriers and facilitators for HCPs in recording in PHRs for maintaining informational continuity, the TDF was applied to the HCP interview data. The TDF is an integrative framework[55], which is comprised of 14 domains, integrating constructs from multiple theories (n=33) relating to health behaviour change and can be applied to qualitative data to identify factors affecting behaviour. The TDF is not a specific theory that makes predictions about the relationships between various factors, but rather a conceptual framework for understanding how various cognitive, emotional, social, and environmental factors impact behaviour. It serves as a way to look at these influences and their impact.[5] (The details on how TDF is applied to the HCP interview data in this thesis and is presented in Chapter 6)

2.5.7. Reflexivity

Weekly supervisory meetings with AL (a qualitative expert) were conducted during both the data collection and analysis phases. These meetings provided an opportunity for the researcher, to discuss potential explanations for the collected data. Additionally, monthly meetings were held with AL, SG, SMH, and PJ to discuss the data analysis. Therefore, the analysis was not solely based on the researcher's views, but rather, it took a wider, multi-person approach.[56]

As stated in the introduction, the researcher is a Keralite woman who has lived and received clinical training as a nurse in Kerala. Though, the researcher does not have any work experience within the public health system, the researcher brought an in-depth understanding of social and cultural aspects of treatment seeking, health care system and delivery in Kerala during data collection.

For the one-to-one interviews with HCPs, many of them took the opportunity to ask questions about what the researcher thought about the electronic health record implementation.[57] The researcher had to reiterate and make conscious efforts to keep the interview format and not to share opinions about the electronic health records. However, the researcher had some informal discussions with HCPs regarding the electronic health record implementation in their settings after the interviews.

The researcher believes that being able to understand the treatment seeking practices in Kerala (insider perspective)[58] and as a person without diabetes and hypertension or working experience in public health setting (outsider perspective) gave the researcher better opportunity for staying closer to the data on how PHRs are currently used and the value the users' place on PHRs for handover communication, informational continuity, and self-management.

2.5.8. Plan for improving user engagement by co-designing a PHR

Online searches of relevant literature on strategies for improving patient engagement with health care were done to explore methods for improving patient engagement with PHRs. A critical[59] approach was employed to review the literature to gather and evaluate ideas and make suggestion for a suitable method for improving patient engagement with PHRs. Further the researcher contacted HCPs and patients in family health centres (n=4) in Kerala to gather inputs and gauge willingness for co-design events. However, due to COVID 19 restrictions, the researcher could not organise and execute the co-design project. Therefore, the chapter 7 details the rationale for co-designing a PHR, specifically using the EBCD method. The chapter also discusses practical and ethical considerations and potential challenges that may arise in co-designing a PHR within the health settings in Kerala.

2.6. Chapter summary

This chapter has presented the methodology for this thesis and explained the methods used to explore the research questions. The next chapters discuss the results from the systematic review and each of the studies described above, to explore how current PHRs are used for handover communication, informational continuity and self-management.

The next chapter three will summarise the evidence available from LMICs regarding the effectiveness and usefulness of PHRs.

2.7. References

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CHAPTER THREE

EVIDENCE FOR EFFECTIVENESS AND USEFULNESS OF PATIENT-HELD RECORDS IN LOW AND MIDDLE-INCOME COUNTRIES; FINDINGS FROM SYSTEMATIC REVIEWS OF PHRs

3.1 Chapter Preface

Before conducting the research, it was important to summarise the evidence for PHRs already published in order to help shape the research for this thesis and therefore advance scientific knowledge. To provide a comprehensive examination of the available evidence, this first results chapter presents two SRs, which have been published as separate papers.

Although HBRs are PHRs, they are different in certain ways. Firstly, the use of HBRs is limited to that period of pregnancy or for children acts mainly as a document for vaccination. It does not function as a longitudinal health record for mother or child. Secondly, even though pregnancy and childbirth are critical health care events, these are not long-term diseases, for which health care is needed. Consequently, two systematic reviews will be able to separately address the utility of HBRs for facilitating information exchange among HCPs and for patient self-management. Please see further rationale for HBR review in Box 1.

Therefore, the systematic review of usefulness of HBRs for information exchange across HCPs and patients use of HBRs is presented as a separate review. The learning from the HBR review can inform how HBRs are being used for information exchange and self- management.

Box 1 Rationale for HBR review

Three previous systematic reviews [3] on maternal and child health records did not report on evidence regarding the availability of documented clinical information across visits and healthcare facilities using HBRs in LMICs. Considering that HBRs are widely adopted and often the sole medical records in LMICs, this systematic review aimed to assess the evidence for HBRs in LMICs, focusing on enhancing informational continuity for healthcare providers across visits and facilities and facilitating communication between healthcare providers and women/families.

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Systematic review on the use of patient-held health records in low-income and middle-income countries. BMJ Open. 2021 Sep 2;11(9): e046965. doi: 10.1136/bmjopen-2020-046965. PMID: 34475153; PMCID: PMC8413937.

Joseph L, Lavis A, Greenfield S, Boban D, Jose P, Jeemon P, Manaseki-Holland S. A systematic review of home-based records in maternal and child health for improving informational continuity, health outcomes, and perceived usefulness in low and middle-income countries. PLoS One. 2022 Aug 4;17(8): e0267192. doi: 10.1371/journal.pone.0267192.

Note: The references for this chapter are placed at the end of each systematic review paper. The supplemental materials for paper 1 and 2 have been placed as Appendices four and five. Appendix four includes S1. Search strategy in EMBASE, S2. Table summaries of MMAT quality appraisal assessments for included studies, PRISMA 2009 Checklist.

Appendix five incorporates the following; S1 Table: Functions of home-based records (HBR), S1 Box: Different types of HBRs included in the review, S2 Table: Characteristics of included studies, S3 Table: Results of mixed methods appraisal tool, S4: Systematic review protocol registered in PROSPERO (CRD42019139365), , S6: PRISMA checklist

3.1. Paper 1

Title:

A systematic review on the use of patient-held health records in low and middle-income countries.

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Author contributions

LJ, PJ, SG and SMH conceived the article. LJ performed the literature search. LJ, BD, JP collected data from individual studies and interpreted the data. LJ wrote the first draft of the paper. SMH, SG, PJ, AL and CH revised the first and subsequent drafts. All authors contributed to interpretation of the findings and revised the manuscript for important intellectual content.

3.2. Abstract

Objective

To review the available evidence on the benefit of patient-held records (PHRs), other than maternal and child health records, for improving the availability of medical information for handover communication between healthcare providers (HCPs) and/or between HCPs and patients in low and middle-income countries (LMIC).

Methods

The literature searches were conducted in MEDLINE, EMBASE, CINAHL databases for manuscripts without any restrictions on dates/language. Additionally, articles were located through citation checking using previous systematic reviews and a grey literature search by contacting experts, searching of the World Health Organization (WHO) website and Google Scholar.

Results

Six observational studies in four LMICs met the inclusion criteria. However, no studies reported on health outcomes after using PHRs. Studies in the review reported patients' experience of carrying the records to HCPs (n=3), quality of information available to HCPs (n=1), and the utility of these records to patients (n=6) and HCPs (n=4). Most patients carry PHRs to healthcare visits. One study assessed the completeness of clinical handover information and found that only 41% (161/395) of PHRs were complete with respect to key information on diagnosis, treatment and follow-up. No protocols or guidelines for HCPs were reported for use of PHRs. The HCPs perceived the use of PHRs improved medical information availability from other HCPs. From the patient perspective, PHRs functioned as documented source of information about their own condition.

Conclusion: Limited data on existing PHRs make their benefits for improving health outcomes in LMICs uncertain. This knowledge gap calls for research on understanding the dynamics and outcomes of PHR use by patients and HCPs and in health systems interventions.

Keywords -International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Study design that enabled the accumulation and presentation of current evidence on the use of patient-held health records other than maternal and child health records in low and middle-income countries.
- Thorough literature search of three major electronic databases and reporting as per Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines.
- Inconclusive results due to no evidence from trials.
- Small number of studies and no reporting on health outcomes, making it difficult to determine usefulness for patients with non-communicable diseases.

3.3. Introduction

To meet sustainable development goals and deliver quality care[2], health systems in low- and middle-income countries (LMICs) need to be redesigned and strengthened.[3] In line with this agenda, the World Health Organization (WHO) has formulated a health systems framework that describes six building blocks for health systems; of these, good service delivery comprises the delivery of effective, safe, quality health care and continuity of care is an important characteristic for delivering quality care.[4]

In many LMICs, healthcare delivery is usually organised around acute and single episode care, from different facilities and health care providers (HCP).[5] Such a model of healthcare delivery is inadequate due to increasing non-communicable disease (NCD) burden in LMICs.[6] Continuity of care needed for efficient and effective care, is simply defined as “the seamless provision of healthcare between settings and over time”.[7] Informational continuity represents the cornerstone of continuity of care and is defined as the use of information on past events and personal circumstances to make current care appropriate for each individual.[8] Handover communication not only relates to the process of passing patient-specific health information between HCPs, from one visit to another, but also from HCPs to the patient and family for ensuring patient care-continuity and self-management.[9]

Complete and accurate clinical information about previous management and treatment is necessary for managing all patients but especially patients with chronic conditions due to a need for on-going care from a range of HCPs. [0] Inadequate documented handover for HCPs often results in adverse events [2] or increased in-patient visits [3], repeated tests or examinations leading to costly healthcare, burdensome to patients and a waste of resources. [3] The ability to view patients’ medical records, across healthcare visits and facilities helps to facilitate health information exchange. [4] The absence of out-patient medical records, [5] [6]difficulties in retrieval of facility-based records for out-patient visits, [7] and lack of integrated patient electronic medical records between departments and between health facilities in LMICs contribute to poor informational continuity for HCPs. [8]

A patient-held health record (PHR) can be a viable solution for improving sharing of documented medical information across HCPs. [9] For the purpose of this review, PHRs are formal records given to patients in the form of booklets, which contain patients' medical information. Our hypothesis is that such PHRs with documented medical notes from HCPs can be used as a tool for improving medical information availability for HCPs. [5 20]

Paper-based PHRs are used extensively in maternity care, as home-based records, or maternal and child health handbooks for sharing information across antenatal, labour, and post-natal care by all HCPs even in LMIC settings.[2] Three systematic reviews on maternity and child records indicate that PHRs improve HCP-patient communication and facilitate referrals, and both HCPs and women give positive feedback on their use.[22 25]

There are several systematic reviews [9 26 29] of PHRs for chronic conditions from high income countries (HIC), which evaluated their usefulness in cancer care,[28] and chronic conditions,[26 27] and for people with severe mental illness[29] or undocumented immigrants. [9] These condition-specific PHRs were designed to mainly improve communication between HCP and patients.[28] The reviews found that PHRs may improve a patient's sense of control and empowerment, leading to better involvement in their own care.[28 29]

There is no systematic review of PHRs for conditions other than maternal and child health from LMICs, while there is evidence that generic PHRs do exist in some LMICs.[30] A study in India found that patients were carrying unstructured sheets of paper to out-patient visits and patient-held health booklets were an acceptable and pragmatic intervention to improve information exchange for chronic NCD patients by patients and HCPs. [5]

The current review aimed to investigate the benefits of generic PHRs used in LMICs to ensure the availability of medical information for clinical handover communication and continuity of care between HCPs or outpatient health facility visits, with or without their use for communication between HCPs and patients. This review investigated non-maternal-child health PHRs, designed to record patient histories and healthcare information across a range of conditions and HCPs, including primary and secondary care and not specific to one facility or one speciality.

3.4. Methods

The protocol for this review is registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD42019139365)[3] .

Selection criteria

The published literature was searched for quantitative randomised controlled trials (RCTs), cluster RCTs, quasi-experimental studies, cohort studies, cross sectional and pre-post study designs, qualitative and mixed-method studies. Case reports, commentaries and review articles were excluded studies. The eligibility criteria are provided in Table 1.

Table 1: Inclusion and exclusion criteria

Title	Inclusion criteria	Exclusion criteria
Population	• Participants (patients, carers and/or health care HCPs) from any health background, of 18 years or more, using a PHR were considered. • All healthcare settings within LMICs (as defined by the World Bank 2018)[32] were considered.	• Children and pregnant women • Patients/ carers/HCPs from HIC
Intervention	• Studies which include design, implementation or evaluation of formalised PHRs, with the purpose of improving information exchange and communication between visits to the same facility for HCPs, across different health care facilities (primary to secondary/vice versa), and documented information from HCPs to patients (for patients' own care). • Studies which describe PHRs which are clinically focused and person specific or generic PHRs. Studies which describe condition specific PHRs, they should include NCDs such as Diabetes Mellitus, hypertension, cardiovascular diseases, chronic respiratory diseases or cancer. • PHRs are defined as any formal medical document in the form of a booklet held by patients, which can be used across health care settings or visits, contain patient histories and healthcare information to guide healthcare workers providing care.	• Facility based medical records, which are for HCP use. • Home based records used for maternal and child health care. • Patient-held diaries used for monitoring values such as home-based blood pressure monitoring booklets or patient instructional booklets for example for diabetic foot care, or patient-held records for single communicable disease such as tuberculosis. • Studies that focus on record use for specific and isolated transitions of care, such as hospital shift-change or discharge. Interventions such as a discharge summary or referral letter alone. • Studies that focus on a single function of patient-held medical records such as medication prescriptions, lab results, blood pressure or blood sugar monitoring or out-patient registration papers.

Outcomes	• Outcome relevant to the quality of verbal and/or documented patient-specific information and communication. Standards of information and recording (completeness, accuracy and clarity) of the documented handover information was included. • Patients' and HCPs' views on how PHRs enabled/did not enable communication and documented information exchange was also included. Patients carrying records to consultation, availability of documented medical information for HCPs during consultation was also included. • Patient and HCP satisfaction with PHR, patient centred communication outcomes such as patient satisfaction, recall, understanding and adherence have been included. • Clinical outcomes and adverse events associated with quality of handover communication were also of interest, including (but not limited to) readmissions, diagnostic delays, healthcare utilisation or improved appointment rates, and death. Intermediate outcomes such as blood pressure/blood glucose monitoring, medication management/reconciliation and/or monitoring of lab values were included.	• Descriptive studies which describe the distribution of PHRs without information on outcomes of PHRs.

Legend: PHR=patient-held health record, LMIC=low- and middle-income countries, HIC=high income countries, HCP= health care HCP NCD=non-communicable diseases

Search strategy

The search strategy (Supplementary file 1, S1) was developed for the electronic databases MEDLINE (Ovid) to identify journal articles. The search strategy was made following previous reviews regarding PHRs[26 28] EMBASE (Ovid EMBASE Classic + EMBASE (1947 to present)) and CINAHL (via EBSCO (1980 to present) were searched for studies reporting PHRs in LMICs without a librarian. Additionally, citations were hand searched using relevant systematic reviews [9 28] to locate further relevant studies. Key search terms related to PHRs and LMICs were used to build the search strategy. The search terms used for PHRs were "patient-held book* or handbook* or card", "patient passport", "logbook" and "home based records". Searches in the electronic databases were conducted from database inception until September 2020. No limits on language or publication year were applied during the search. Grey literature search was done by contacting authors of papers, which reported the use of patient-held records, discussion with experts and using the website of World Health Organization (WHO) and google scholar.

Study selection

The search results were uploaded to the reference management software Zotero to remove duplicates. Two reviewers (LJ and DB) independently screened the remaining studies' titles. The initial title screening was broad and retained all studies that referred to PHRs. Two reviewers (LJ and DB) independently screened the abstracts and full texts against the inclusion criteria. Any uncertainty surrounding the inclusion of a study or disagreement following discussions between reviewers were resolved through the assessment of an additional reviewer (SMH).

Data extraction

Two reviewers (DB and PJ) independently extracted data from the included studies. LJ reviewed all the data extraction tables. If there were any discrepancies during this sampling check, discussion took place and for final clarification a third, impartial reviewer (JP or SMH) was consulted.

Data were extracted from published studies using a data extraction form in Microsoft Excel and included details of authors, study settings and country, the objectives and features of the PHR, use of PHRs, and outcomes.

Quality assessment

Quality assessment was done by two reviewers (LJ and DB) using the Mixed Methods Appraisal Tool (MMAT).[33] This provided an overall description of the quality of studies and used descriptors 'low,' 'medium' and 'high' to provide an indication of the quality of the included studies. For quantitative, qualitative, and cross-sectional studies, all five criteria needed to be met to be classified as 'high quality.' Studies that met three to four criteria were classified as 'medium quality' and studies that met one or two criteria were regarded as 'low quality.' For mixed-methods studies, the overall score was dependent on the lowest score of each of the study components (qualitative and quantitative); therefore, scores were determined by the quality of the weakest component. In case of disagreements on quality assessment, the final decision was taken after discussion with an independent third reviewer (JP or SMH).

Data analysis

Given the diversity of populations, settings, the non-uniformity of interventions, and the variations in outcome measures, a statistical meta-analysis was not appropriate. Hence, the review used a narrative synthesis. Papers in the review have been summarised descriptively as follows (Table 2).

Table 2: Description of results

Result	**Description of the result**
Patients carrying the PHRs to HCP visits	Presented as frequencies or number of patients carrying the records to visits or as prevalence of written clinical information availability for HCPs at visits.
HCPs' recording of information and Quality of information recorded	HCPs' recording of information in the PHR is presented as information availability for patients on leaving the facility or patient/HCP self-reported availability of documented information. The quality of information recorded for this review is defined as the completeness of the information on key elements such as diagnosis, medication/treatment details (including lab values) and follow-up information, clarity or legibility of the information recorded, and accuracy of the information being recorded based on treatment guidelines (For example, mismatch of diagnosis and treatment prescribed)/comparison of data with facility-based records. Completeness data are reported as frequencies and stand-alone or comparative data based on key missing components.
Utility of PHR to HCPs and patients	For the review, utility as perceptions of patients and HCPs about using PHRs, satisfaction with use, usability in terms of ease of reading the records, and the functions they serve (for information exchange, clinical information recording at each HCP visit, patient education or as an aide memoire for patients).

Legend: PHR=patient-held health record, HCP=health care HCP

Patient and public involvement

This research was done without patient or public involvement.

Ethics Approval

No ethical approval was needed because data from previous published studies is being used.

3.5. Results

Study selection

The findings of the search strategy are summarized in Fig 1 as a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart.[34] 2286 titles were screened, and 466 abstracts were included. 121 full papers were reviewed, and six studies were included in the final review. The references of included studies were reviewed for potential studies and no new studies were included. We excluded 115 articles because: studies that described PHRs but were not conducted in LMICs (56); studies that described maternal or child health records in LMICs (29); papers that described patient- health education booklet for NCDs (3); studies that described electronic health record implementation (21) and studies that described facility-based records (12).

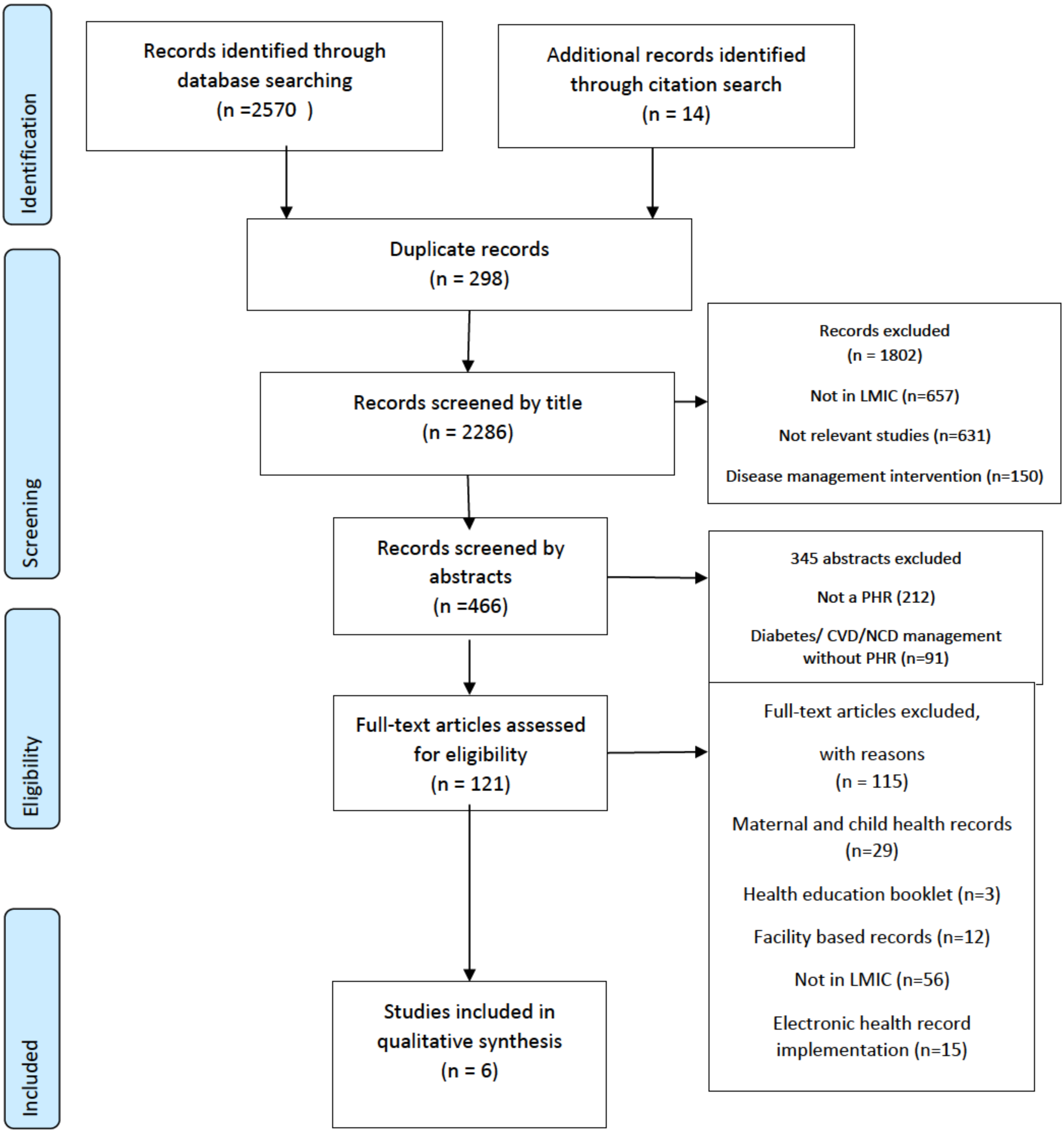

Fig 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram

Characteristics of included studies

Studies were from Zambia (n=1)[35], Lesotho (n=1)[36], South Africa (n=2)[37 38], China (n=1)[39], and Mongolia (n=1)[40] (Table 3). The designs of included studies were mixed methods (n=1)[40], observational (cross-sectional descriptive studies) (n=2)[37 38] and qualitative (n=3)[37 39]. Three studies[36 39 40] evaluated PHRs that were implemented and routinely used by the health department in those countries and one study evaluated PHR using diabetes mellitus and hypertension as tracer conditions for NCDs. All the studies described the use of PHRs in outpatient settings (either primary, secondary or tertiary), while none measured changes in health outcomes following the use of PHRs.

Quality appraisal

Of the six studies included, five were judged to be of 'medium quality' and one was of 'low quality' (Supplementary file1, S2). For the three qualitative studies[37 39], the methods and data collection were appropriate to answer the research question. However, the studies did not mention the use of a specific method of data analysis or provide a rationale for using an analytic method. Therefore, coherence between data sources, collection, analysis and interpretation could not be fully assessed. The single mixed methods study[40] did not adequately explain the method of qualitative data analysis and was marked down on that criterion. Of the two cross-sectional studies, one[35] provided no information on the sampling strategy and hence it was not possible to make judgements on the representativeness of the sample. Further, no information was reported regarding the non-response rate. The other cross-sectional study provided information on sampling strategy, a reasonable description of the target population and response rate. However, the study was marked down due to insufficient information on measurement variables.[36]

Table 3: Characteristics of included studies

Author, year, LMIC	Study design, sample size	Study objective	Settings	Participants	PHR description	Results
Van der Hoek [35], 1995, Zambia	Cross sectional (n=176, n=184)	To describe the views of patients on the newly introduced health passports by health management in Sesheke district, Zambia	Household surveys (n=2), conducted in the catchment areas of one hospital and two health centres.	Patients	Hardcover booklet with 32 pages known as a health passport, size-14.5*10cm, Demographic information on the cover page. Referral letters and discharge letters are replaced with health passports.	68% of the respondents bought a health passport within 4 months of their introduction and 91% within 16 months. 36% (64/176) and 30% (55/184) of the respondents felt that the passports were expensive.
Henbest[36], 1995, Lesotho	Cross sectional (n=878) Patients(n=691) Nurse clinicians (n=74) and doctors(n=104)	To inform the recommendations for the use of PHR in healthcare services in changing Africa, using the PHR in Lesotho.	Healthcare Centres and household survey	Patients, nurses, and doctors	PHR, in the form of a health booklet about the size of a passport (10.5*15cm) with a brightly coloured plasticised cardboard cover. The front cover contains the patient's name, address, date of birth and instruction on the record's use. The back cover has the common symptoms and signs of tuberculosis. The inside printed pages contain forms for recording information such as immunisations, previous significant history drug	89% of patients preferred to have a PHR than a facility-based record. 79% of doctors and 70% of nurses rated the use of PHR as excellent. Doctors and nurses perceived that having a PHR reduces unnecessary repetitions of tests and treatments. They also felt that availability of patient medical information from other HCPs leads to less errors.

					sensitivity and screening activities. There are 16 blank pages for HCP notes. When one record is full, it is stapled to the next record.	
Norden[37],2004 South Africa	Qualitative study Focus group discussions with patients (n=24)	To understand the patients' thoughts on the PHR introduced. It was introduced due to the difficulty in retrieval of medical information at HCP visits from facility-based records.	Primary care clinic	Patients	Pocket size booklet with 10 pages (14*8 cm) Demographic information, problem list and allergies recorded in the first page. Blood pressure, blood glucose, body mass index, peak expiratory flow rates are recorded in the subsequent visits. Prescribed treatment and follow up dates are also documented.	Patients felt that the records function as 'medical identification' and are useful in an emergency, provide important background information, and that they enable continuation of care at other facilities. Patients reported that PHRs could motivate them to act on the advice given, and the records also served as a reminder to take their medication and about the dates of follow-up visits.

Kerry[38] , 2005, South Africa	Quality assurance methods with Focus group discussions (n=13) number of participants not stated	To assess, document and improve the PHR System in the Emtshezi Subdistrict, South Africa.	Health care facilities at sub-district level	Patients, nurses, doctors, administrators and pharmacists	Proposed better PHR: A single booklet PHR for every patient in the district. Size – 10 x 21cm named as Health Book; at least 32 pages for clinical notes; a problem list; pages for laboratory and X-ray results and incorporation of the Health Card for Women, TB Card, and Antenatal Card. The booklet should have a plastic cover.	Patients and HCPs reported that communication of clinical information between health facilities was poor. HCPs described there were difficulties in retrieval of information and recording at hospitals, the current PHRs were unstructured and multiple PHRs were brought by patients. Patients and HCPs felt that having a single, common PHR to be the definitive ambulatory health record for every patient at district level. Feedback from the FGDs were used to design a better PHR.
Chen[39] et al, 2014, China	Qualitative study (semi-structured interviews and observations Doctors (n=4), patients(n=13), family members (n=4)	To examine and explore practices surrounding PHR in a setting where medical records have long been managed by patients: the Chinese healthcare system.	Out-patient departments of hospital.	Patients, family members and doctors	Pocket size book which had chief complaint and history handwritten by the clinician. Diagnosis and prescription are documented on the electronic health system and printouts of the same are provided for the patients.	The findings suggest that through engaging in practices of managing and sharing records, patients were able to obtain familiarity with their own records and to provide necessary assistance to locate information for HCPs to use at the point of care.

						Clinicians felt that a verbal history by the patient was insufficient, as was a history based solely on their own clinic's records.
Ibrahim[40] et al, 2019, Mongolia	Mixed methods, (n=395)	To describe Mongolia's universal patient-held health booklets and their use, explore patients' views on using them and explore training and protocols using tracer conditions diabetes and hypertension.	Out-patient departments of two public hospitals	Patients	Booklet with 40 pages (14.8*21cm). Demographic information on the cover page, history or handover information in subsequent pages.	94% of patients had PHRs with them at OPD visits. Provision of written information for the three categories of key information items (i.e., diagnosis, prescription/management and follow-up information) for the consultation was low at around 37% in the PHR; - 61% had notes related to medication required and 40% contained information about follow-up. Patients (316, 80.0%) reported consulting their PHRs and associated 'documents' at home. They reported using them for understanding their own condition and communicating it to others

Legends: PHR=patient-held health record, HCP=healthcare HCP, FGD=focus group discussion

Synthesis of results from included studies

Overall, the included studies were inadequate to demonstrate a clear benefit of using PHRs to improve information availability to HCPs and patients. However, based on the patients' perspective, PHRs were beneficial to the management of their own care. Further, based on the HCPs' perspective PHRs improved the availability of key clinical information for providing care.

Patients carrying their PHRs

Overall, most patients carried their PHRs to healthcare visits. Of the six studies, two reported data on the prevalence of patients bringing their PHR to subsequent visits. In Mongolia, Ibrahim et al[40] reported that 94% (373/395) of chronic NCD patients brought their PHR to their outpatient visits. This was measured by examining the documents brought to the visit by the patients.

In Lesotho, Henbest et al[36] used a survey with patients and HCPs to report on the practice of carrying records to consultations and HCPs' opinions on the availability of PHRs at consultations. Patients' self-reported practice of carrying PHRs to healthcare consultations was 71% (n=672) and HCPs self-reported the availability of the PHR at visits as 62% (doctors, n=81) and 59% (nurse clinicians, n=68) respectively.

In China, Chen et al [39] used interviews with, and observation of, patients to report patients' perspectives on, and patterns of, carrying records to consultations. They found that the patients with chronic NCDs had different PHRs, according to particular conditions/diseases, and clinics or hospitals. Patients often carried only specific PHRs to consultations based on the condition/HCP/clinic they visit.

HCPs' recording information and the quality of information recorded

The HCPs' recording in PHRs was sub-optimal. Of the six studies, only one (from Mongolia[40]) evaluated HCPs' documenting of information in PHRs and the quality of the information recorded for patients with diabetes and hypertension. The overall written information, across three categories (diagnosis, prescription, and follow-up), within the PHR after the consultation was 37% (n=367). The completeness of PHRs with respect to medication and follow up information were 61% and 40%, respectively. No studies reported the clarity, legibility, or accuracy of the recorded information.

Utility of PHR to HCPs

Generally, HCPs perceived PHRs to be useful in recording patients' medical information. In Mongolia, Ibrahim et al[40] did not formally assess HCPs' perspectives on the use of PHR, but they did find that HCPs in the two public outpatient hospitals wrote in the booklets in spite of also having to enter information in other electronic record systems. Further, more than three-quarters (77.4%, n=106) of patients reported that private HCPs they had visited recorded clinic notes in the PHR.

In Lesotho, Henbest et al[36] described HCPs' satisfaction with using PHRs. This was measured in terms of preference for PHRs, practicality (size, durability, and confidentiality) and comparison with facility-based records (quality of care, access to patient information). Both doctors and nurse clinicians reported a preference for PHRs over facility-based paper records. The HCPs perceived that having a PHR contributed to improving quality of care, by preventing the unnecessary repetition of tests and treatments (86% of nurse clinicians (n=71) and 88% of doctors (n=89)) and that the availability of medical information from other HCP visits helped in the clinical management of patients (78% of nurse clinicians (n=71) and 84% of doctors (n=89)). The qualitative study by Chen et al [39] from China, reported that doctors perceived a patient's verbal history of past medical information as insufficient for providing effective care. Further, access to previous documented clinical information was perceived by doctors as essential to make appropriate clinical decisions. The other two studies[37] [38] did not report the HCPs' perspectives on PHRs.

Protocols and HCP Training

The studies reported very limited protocols and training available for HCPs on the use of PHRs. The study from Mongolia[40] explored the role of protocols and policy directions, with a government order reinforcing the use of PHRs. However, no written guidelines or training materials regarding the use of PHRs or training for clinical handover were reported by HCPs. Another study reported one day training for health workers, with practical instructions on how to use the PHR.[35]

Health outcomes

The included studies do not report measuring changes in health outcomes such as improvement in blood pressure, blood glucose or patients receiving foot examinations or health care advice following the use of PHR.

Utility of PHRs for patients

All included studies reported some use of the information in the PHRs by patients and in general, found that patients regarded PHRs as important documents containing their own medical information. Ibrahim et al[40] described how Mongolian patients (316, 80.0%) consulted their PHRs at home. Patients reported that written information from doctors was important for their own understanding of their condition. Van der Hoek et al[35] reported that some Zambian patients (n=176, 16% (at 6 months) and n=183, 14% (at 18 months)) preferred to keep their records at the clinic itself, due to a fear of damaging the records at home but they did not report whether the patients used the PHRs at home or not. Henbest et al[36] found that most (n=691, 89%) of Lesotho (South African) patients preferred to have a PHR and perceived the record as belonging to them. They reported that having a PHR was important to making information available to the other HCPs they visited. They highlighted that this was very useful in case of travel and emergencies. Norden et al [37] also reported similar findings for South African patients. Patients viewed their PHR as a document containing their own medical information and a tool for continuation of care between HCPs. Additionally, the PHR helped these patients and their families to remember how to manage their own care at home. In their qualitative study, Chen et al [39] found that Chinese patients regarded PHRs as useful. They reported that patients read their documents, organised them chronologically and brought them to each subsequent visit.

3.6. Discussion

Summary of findings

This systematic review identified that there is limited literature from LMICs on the use of PHRs for improving information availability to HCPs and patients for handover communication. This paucity of published research limits our ability to draw conclusions on the benefits or challenges of PHRs in the care of patients with NCDs. Importantly, none of the studies included in the review investigated, reported, or evaluated changes in health outcomes after using PHRs in LMICs. Consistent with studies of maternal and child PHRs[4 43], in general, patients brought their PHRs to each clinical consultation. PHRs being in the form of a booklet in Mongolia and China and attaching medical reports (in the form of papers) to the booklet, both reduced the risk of losing them. Although only one study addressed these, the inadequate completeness of the information documented by HCPs, and a lack of protocols and training on the use of PHRs, are both likely to be prominent issues in all the settings as evidenced by the wider literature on training and protocols for medical records documentation.[44 45] The PHRs were perceived as useful by HCPs for documenting the medical history of patients, thus improving the availability of medical information. From the patient perspective, the PHR functioned as a reminder for medication, improved self-care efficacy and enabled continuity of care by providing relevant clinical information to all HCPs involved in patient care. Consistent findings on the use of PHR in improving self-care for the management of chronic conditions were reported and equally reflected in HIC studies.[27 28]

Implications for research and practice

The findings from the review suggest that PHRs may be particularly useful in health systems where little or no medical record keeping occurs at outpatient level, where record retrieval is difficult, or where multiple HCPs may be involved in a person’s care for chronic conditions. This is especially important in LMICs as most have pluralistic health systems and no ‘gate-keeping,’ so that patients often change their HCPs, or shop around, and receive care at both public and private facilities. [5] [6] [44] Patients’ provision of a verbal medical history as the only means of transferring previous clinical information during HCP visits is, however, insufficient. In LMICs patients’ communication of past medical history may be adversely affected by a lack of health literacy, inability to articulate the clinical procedures received, and a lack of confidence against a background of profound power differentials between patients and HCPs.[47] [49] [50]

A well-completed PHR may in principle improve medical information availability for HCPs. However, no trials, which assessed the availability of medical information for HCPs, were reported from LMICs. In Germany, Straßner et al[50] conducted a trial investigating the utility of PHRs for asylum seekers in reception centres for improving medical information availability for HCPs. The trial found that a PHR for asylum seekers increased the availability of health information for HCPs (aOR 4.22, 95% CI: 2.64 to 6.73), reduced missing information (aOR 0.89, 95% CI: 0.42 to 1.88), and reduced HCP dissatisfaction (aOR 0.43, 95% CI: 0.16 to 1.14) .[5] Previous HIC studies have shown that the use of PHRs for patients with diabetes and hypertension have led to decreases in HbA1c ($p<0.001$)[52] [53], decrease in diastolic blood pressure ($p<0.05$) [5] , and improvement in receiving foot examinations (OR: 1.68; 95% CI 1.12 to 2.50)[53], having physical activity or exercise advised (OR: 1.84; 95% CI 1.16 to 2.92) [53], and monitoring of weight, blood glucose and cholesterol[52]. Similar results may be achieved in LMICs for monitoring blood pressure/glucose/cholesterol, improving foot/eye examination if PHRs are well documented.

Patients, especially those with chronic diseases, usually carry the records they have to HCP visits, especially if they know HCPs will use them. [5] [6] [44] [54] However, in the absence of an organised PHR, patients either bring very little information, such as a prescription alone (common in LMICs), or they bring all the previous pieces of paper that form their home held medical records, making it difficult for HCPs to find the relevant information. [6] Many chronic disease patients have multi-morbidities and often have numerous papers or clinic specific PHRs from the different clinics and hospitals they visit, but they often only carry notes from previous visits to the clinic they are going to visit.[28] Thus, the HCPs do not receive the information about medication and management plans produced by other doctors in other clinics or hospitals. Therefore, it is necessary to develop generic/universal and pragmatic PHRs and create awareness of the importance of using a single generic PHR for all healthcare visits, irrespective of the clinic/hospital, so that all HCPs have the necessary medical information available to make the best clinical decisions.

The WHO recommends that ideally a PHR should be used as complementary to a facility based medical record.[55] Prior reviews from HICs showed that, when HCPs had to enter information in facility-based records (electronic or paper-based) and PHRs, this multiple recording was an unwelcome burden.[56 57] However, documented discharge information for patients /families (e.g., summaries/letters) from HCPs has been found to reduce post-discharge complications[58] and re-admissions,[59] and to improve patient satisfaction[60] and health outcomes.[6] Arguably, it would more efficient and accurate if there were one record system accessible and useful to both patients and HCPs.

Many LMICs are progressing with the implementation of electronic health records, which may enable health systems to overcome difficulties in retrieving information from paper-based facility-based medical records.[62 63] Despite such advancements in technology and information technology capability in some middle-income countries, paper records will remain the prominent form of medical records and are unlikely to be completely replaced by electronic records at least for the near future. Furthermore, the issues of integrating electronic health records across different levels of care in health systems and public-private information exchange are often not addressed in existing health information management systems.[64] Therefore, PHRs having a minimum of data such as diagnosis, medication, lab results and follow-up will enable better information transfer in the health systems transitioning to electronic health records.

Strengths and limitations

Our systematic review has several strengths and limitations. The review protocol was registered at PROSPERO, and we followed PRISMA guidelines in our systematic review. A comprehensive search strategy was employed to locate studies from LMICs. Furthermore, our search from the grey literature and discussion with experts in the field helped us to identify generic PHRs from Malawi,[65] Namibia[66] and South Africa.[67]However, these PHRs have not been evaluated systematically, and we have limited information on the usefulness of these records. However, our study also has some limitations. Given the small number of relevant articles, we found very few RCTs on which to base conclusions of robust experimental findings. Scarce data on generic PHRs from LMICs limit our ability to interpret the usefulness of these records in improving health outcomes of patients with NCDs.

3.7. Conclusion

Available data on the use of non-maternity PHR for handover communication between HCPs and HCPs with patients in LMICs are sparse. Existing studies on PHR in LMICs are of medium to low quality, and heterogeneous in terms of study design, population, and context. Further, health outcome assessments after the introduction of PHRs are not available. The available studies show that patients value PHRs for their own use and are likely to carry them to HCPs. HCPs, in turn, consider that PHRs enhance documented information transfer from previous visits specifically when there is difficulty in retrieving past medical information. With LMICs progressing with electronic health record implementation, the role of paper-based PHRs in overcoming issues of integration and for improving adherence to effective self-care needs re-evaluating. Future research should explore minimum information requirements for major conditions, the format, and types of PHRs of most utility to patients and HCPs (electronic or paper-based), and barriers and facilitators to effective use of PHRs across all HCPs for any one patient. Further, the content and HCP training and protocols need to be developed and evaluated for the effective scale-up of interventions to promote the effective use of PHRs for continuity of care and patient self-care.

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Declaration of interest

We declare no competing interest.

Data sharing

No additional data available.

Fig 1. Legends

LMIC=Low- and middle-income countries, CVD=Cardiovascular disease, PHR=Patient-held health record, NCD=non-communicable disease

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3.9. Paper 2

Title:

A systematic review of home-based records in maternal and child health for improving informational continuity, health outcomes, and perceived usefulness in low and middle-income countries

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3.10. Abstract

Background

Evidence shows that a gap in the documentation of patients' past medical history leads to errors in, or duplication of, treatment and is a threat to patient safety. Home-based or patient-held records (HBR) are widely used in low and middle-income countries (LMIC) in maternal and childcare. The aim is to systematically review the evidence on HBRs in LMICs for (1) improving informational continuity for providers and women/families across health care visits and facilities, (2) to describe the perceived usefulness by women/families and healthcare providers, and (3) maternal and child health outcomes of using HBRs for maternal and child health care.

Methods

The protocol was registered in PROSPERO (CRD42019139365). We searched MEDLINE, EMBASE, CINAHL, and Global Index Medicus databases for studies with home-based records from LMICs. Search terms pertained to women or parent-held records and LMICs. Two reviewers assessed studies for inclusion using a priori study selection criteria- studies explaining the use of HBRs in LMIC for maternal and child health care. The included study quality was appraised using the Mixed Methods Appraisal Tool (MMAT). Results from all study designs were summarised narratively.

Results

In total, 41 papers were included in the review from 4514 potential studies. Included studies represented various study designs and 16 countries. The least evaluated function of HBR was information continuity across health care facilities (n=6). Overall, there were limited data on the usefulness of HBRs to providers and mothers/families. Home-based records were mostly available for providers during health care visits. However, the documentation in HBRs varied. The use of HBRs is likely to lead to improved antenatal visits and immunisation uptake, and skilled birth delivery in some settings. Mothers' knowledge of breastfeeding practices and

danger signs in pregnancy improved with the use of HBRs. One randomised trial found the use of HBRs reduced the risk of cognitive development delay in children and another reported on trial lessened the risk of underweight and stunted growth in children.

Conclusion

There is limited literature from LMICs on the usefulness of HBRs and for improving information transfer across healthcare facilities, or their use by women at home. Current HBRs from LMICs are sub-optimally documented leading to poor informational availability that defeats the point of them as a source of information for future providers.

3.11. Introduction

Quality of care is systematically deficient in most low and middle-income countries (LMIC) such that mothers and children receive less than half of the recommended clinical care during antenatal to post-natal and paediatric visits [1]. The World Health Organisation (WHO) has recognised the need for better information systems and documentation to improve outcomes for mothers and children [2]. Delays or errors in decision-making processes due to an inadequate maternity history or case documentation can contribute to complications in pregnancy, especially high-risk pregnancies [3,4]. Pregnancy and childbirth involve several visits to healthcare providers (HCP) for ante-natal care, at the time of delivery, for post-partum care and vaccinations for the new-born [5]. These may involve different HCPs such as community healthcare workers, primary care nurses, general physicians, and obstetricians, and different health care facilities such as clinics or hospitals [6,7]. When clinical handover takes place at these transition points, adequate medical information exchange regarding patients between HCPs and patients/families is necessary for ensuring continuity of care and patient safety [8,9].

A home-based record (HBR) is a patient-held health document used to record the history of health services received by women/children, widely used in LMICs [10]. It can take various forms such as ante-natal records/cards, vaccination cards, or maternal and child handbooks and requires mothers to take the record to each visit to healthcare providers (HCP). In 2018, the WHO recommended the use of an HBR by all pregnant women to improve continuity and quality of care throughout pregnancy to child health care [11]. The primary function of an HBR in this context is to record essential information related to maternal, new-born, and child health (MNCH), including health status, visits to a health care provider, vaccinations received, and the child's growth and development. Additionally, an HBR is intended to be used at home by mothers/caregivers for managing care (looking for danger signs, as a reminder for children's vaccinations, etc.). One of the advantages of having a HBR is that all HCPs will write in the same record, which can help to reduce clinical errors and improve communication between HCPs, especially across different facilities [12]. This documented information is intended to equip all HCPs, especially frontline healthcare workers, with a standardised patient history, to make informed decisions on care and immunisation services [10].

Although HBRs has been used in many LMICs [13,14], the evidence for whether they improve informational continuity for clinicians in those settings has not been reviewed rigorously. Previous systematic reviews [5,12,15,16] have found that mothers and children with records tend to have better clinical outcomes such as improved antenatal care and reduced likelihood of pregnancy complications, and they have shown an increase in mother and child vaccination rates. Another review evaluating the effectiveness of women carrying case notes found no studies reporting the availability of records at the time of delivery [12]. Currently, there is insufficient evidence on the availability of documented clinical information for HCPs (across visits and healthcare facilities) using HBRs in LMICs. Additionally, there is little information on how HBRs are being used in routine practice in LMICs [17]. Given that, HBRs are widely implemented, recommended by WHO and often the only available medical records in LMICs, we aimed to systematically review the evidence of HBRs for women/families in LMICs. Specifically, for improving the informational continuity for HCPs across visits and healthcare facilities and communicating with HCPs and women/families. The findings can further aid in designing appropriate HBRs that can contribute to optimizing implementation of HBRs in LMICs. Further, we summarised the evidence of use and health outcomes of using HBRs by HCPs and women/families.

3.12. Methods

The protocol for this review is registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD42019139365) [18].

Eligibility of studies

Each study had to meet the criteria set out in Table 1 to be included in the review. Eligible study designs include randomised controlled trials, non-randomised trials, cohort studies, cross sectional studies (both analytic and descriptive) and qualitative studies. Studies needed to be done in LMICs as per the World Bank 2018 [19], have an HBR intervention for pregnant women/children such as antenatal records/cards, vaccination cards or maternal and child handbooks (MCH) and at least one measure relating to an outcome of HBR intervention such as availability of HBRs at consultations, improvements in antenatal visits/vaccination rates, etc. published in the English language.

Table 1: Inclusion and exclusion criteria for studies

Characteristics	**Inclusion**	**Exclusion**
Population	Women/parents in LMIC, HCPs in LMICs	Women/parents and HCPs living in HIC
Intervention	Paper-based patient-held record (PHR), also known as home-based records. It can take various forms such as antenatal records/cards, vaccination cards, or maternal and child handbooks (MCH) and requires women/mothers to carry these records to each visit to healthcare providers (HCP).	Facility-based medical records, non-maternal patient-held records.
Outcomes	(a) Informational continuity The availability of patient medical information for HCPs forms the basis of informational continuity. It involves patients carrying records to healthcare visits and HCPs documenting in the records. For this review, the information available in HBRs available at visits for HCPs at antenatal visits, at the time of hospital admission for maternal/childcare, at post-natal healthcare visits, and childcare visits such as vaccination history. It can be presented as frequencies or number of patients carrying the records to visits or as the prevalence of written clinical information availability for HCPs at visits. Views of patients carrying/not carrying HBRs. HCP views on the	Studies which do not provide details on information availability to HCPs/patients and patients/HCPs perceived view of information available in HBR. Studies that report only the distribution and coverage of HBRs.

	availability of HBRs for them to make clinical decisions, record the healthcare services and challenges in using HBRs Data on quality of information recorded and available such as completeness of the records, the accuracy of the information, and clarity or legibility of handwritten information. (b) Perceived usefulness of HBR For the review, usefulness is defined as perceptions of women/family members/HCPs using HBRs, satisfaction with use, usability in terms of ease of reading or recording in the records, and or degree to which an HCP believes that using HBR improves their job, the function PHRs serve for HCPs, and women/families. Health outcomes following the use of HBRs. (c) Maternal, new-born, and child health outcomes as per WHO guidelines such as a change in maternal/neo-natal mortality, behavioural outcomes such as improvement in antenatal visits, improvement in vaccination rates, knowledge, attitude and practice changes.	

Search strategy

We systematically searched the literature using the electronic databases MEDLINE, EMBASE, and CINAHL from database inception to September 2020. Additional database search was done in GIM (Global Index Medicus) from database inception to August 2021 to include studies from LMIC. The reference lists and citations of full-text articles were hand-searched for additional eligible references. The search strategy was developed using search terms about home-based records and country names from the World Bank 2018 [19], by income classification. Search terms included (women-held OR parent-held OR mother OR pregnant women OR caregiver) AND (record OR handbook OR card OR notes) AND a list of LMICs. The search strategy developed for MEDLINE is available in the online supplement (Box 1). Further, we carried out additional searches on the websites of the WHO and the Japan International Co-operation Agency (JICA).

Data extraction

Two reviewers (LJ and BD) extracted data from studies that met eligibility. LJ reviewed all extracted data. The data extracted were the study objective, population, and type of PHR, outcomes assessed, and results. Any disagreements in the data extraction were finalised after discussion with a third reviewer (SMH).

Quality appraisal

For assessing the quality of included studies, the Mixed Methods Appraisal Tool (MMAT) version 2018 [20] was used. We assessed the quality of included studies using, ‘high’, ‘medium’ and ‘low’ descriptors. The studies that met all five criteria for quantitative and qualitative studies based on MMAT, were termed high, while studies that met three or four criteria were deemed to be medium, and finally, studies which met one or two criteria were classified as low. For mixed methods studies, the lowest score of the quantitative or qualitative strand was taken as the overall quality of the study.

Data synthesis

Due to the wide variability of included study designs and outcomes, a meta-analysis was not conducted, and the study findings were summarized narratively. The functions of HBRs in the included studies were summarized by using functions proposed by Osaki et al [21] and Brown et al [17] (Online supplement; Table S1) with elements that define handover communication. Therefore, functions of HBR were classified as

- **A Handover communication and information tool for HCPs-** as a tool for recording health care received by women/children and monitoring by HCPs during clinic visits (primary provider) and across different health care facilities (for referral and transfer of information across HCPs/healthcare facilities).
- **A Handover communication and information tool from HCPs to women/families-**as a tool for receiving own documented medical information of the care received from HCPs, communication on further follow-up, and own care at home.

There are different records such as maternal cards, vaccination cards, maternal and child health handbooks, etc. (Online supplement; Box S1) included in the review and will be referred to as HBRs.

Outcomes

The outcome variables for informational continuity were summarised as availability or patients carrying HBRs to healthcare facilities, patient perception about carrying HBRs, completeness of the HBRs, and views of HCPs about the role of HBRs in improving information availability. The perceived usefulness of HBR variables was patients' and HCPs' satisfaction in using HBR, ease of recording or reading, patients' and HCPs' on how it was important for them, etc. Additionally, outcomes were considered relating to HBR as a handover communication tool between HCPs and mothers/children, such as, maternal and child health outcomes, health service utilisation, improvement in maternal and childcare behaviours such as breastfeeding. Both quantitative and qualitative findings were synthesised under each outcome.

3.13. Results

Study selection

The database searches (MEDLINE, EMBASE, CINAHL, and GIM) found 4964 potential studies of which 470 duplicate studies were removed (Fig 1). Additionally, 20 studies were included from the citation search. In total, 4514 titles were screened for eligible studies. Further, 892 abstracts were assessed for inclusion in the review. Finally, 41 full-text articles (40 studies presented as 41 papers) were included in the review after assessing 147 full papers. We discarded the remaining 106 articles due to the following reasons (a) not being a record for maternal and childcare (n=9) other MCH interventions such as health education classes, training for birth attendants, etc. (n=16), (b) not being used in LMICs (n=57), (c) facility-based health records (n=17) and d) no relevant outcome data (n=7).

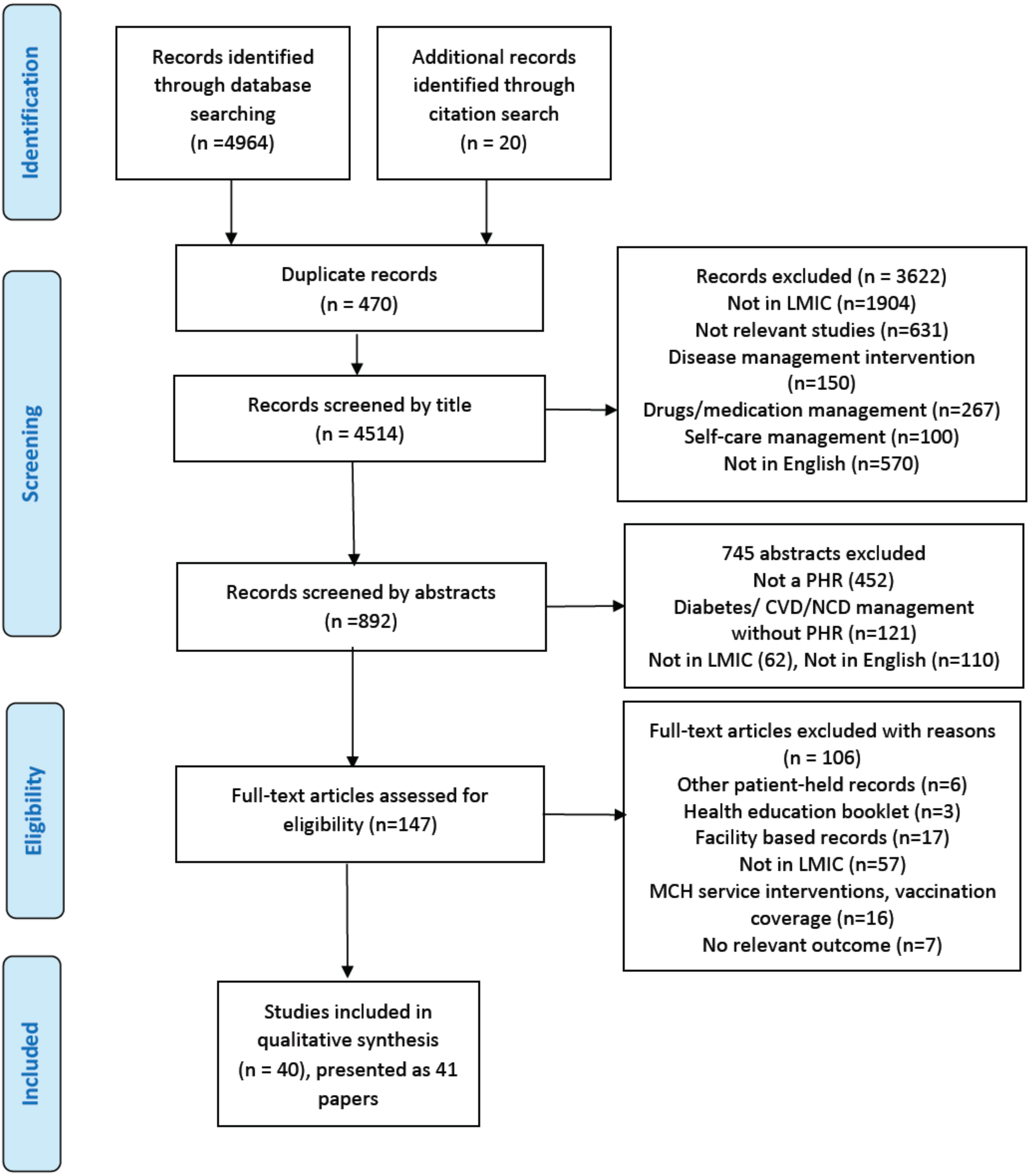

Fig 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram

Characteristics of included studies

In total, 40 studies were included and presented as 41 papers. Two were randomised controlled trials [22,23]; three cluster randomised trials [24-26] and one reporting three-year follow-up results of a cluster randomised trial [27]; eight pre-post studies [28-35]; 25 cross sectional studies [36-60]; two qualitative studies [61,62] and one mixed method study [63]. Sixteen countries; Bangladesh (n=2)[29,60]; Brazil (n=10)[46,50,51,54-58,61,62]; Burkina Faso(n=1)[45]; Burundi (n=1)[31]; Cambodia (n=1)[32]; The Gambia (n=1)[63];Indonesia (n=7)[24,26,35,37,47,48,53]; Kenya (n=3)[40,41,49];Lebanon(n=1)[44]; Malawi(n=1)[59]; Mongolia(n=3)[25,27,36]; Nigeria (n=1)[52];Pakistan(n=2)[22,23]; Palestine(n=2)[30,38]; South Africa (n=4)[33,39,42,43] and Viet Nam(n=1)[28] were represented in the included studies. One study reported the use of MCH handbooks in multiple countries (Egypt, India, Pakistan, Philippines, Senegal, Sri Lanka, Yemen and Zambia) [34]. The study characteristics of included studies are provided in Online supplement (Table S2).

Quality of included studies

Overall, the studies included in the review were moderate to high quality. All randomised controlled trials reported randomisation. However, one cluster-randomised trial did not mention the method of randomisation [26]. The follow-up results of the Mongolian trial [27] reported baseline imbalances between intervention and control groups and differences in follow-up numbers. (Online supplement Table S3). None of the trials (n=5) [22-26] described outcome assessor blinding. Most pre-post studies (n=8) described the measurements and adjusted for confounders (n=4) [30-32,35]. However, the participants' representativeness of the target population could not be ascertained in five studies [29-31,33,34] due to inadequate descriptions of inclusion and exclusion criteria. Overall, twenty cross-sectional descriptive studies described the sampling strategy adequately [36-38,40,43-46,49-60] and 13 studies described the measuring instruments [36-40,42-49]. However, the instrument validity and data relevant to assessing non-response bias were not well described in any included studies.

Qualitative studies [61,62] were of medium to high quality. The mixed methods [63] study did not describe the integration of qualitative and quantitative data.

Summary of results from included studies

The major functions of HBRs, which were evaluated in the included studies, pertained to the recording of health care received by women/children by HCPs and the communication between HCPs and women/family during the health facility visit. In contrast, there were very few studies evaluating referral or information transfer across healthcare facilities/providers. Studies suggested that HBRs could be used to improve handover communication between healthcare visits for HCPs and from HCPs to women/families.

Functions of HBRs

Of the 41 studies, 30 evaluated the HBR as a tool for recording health services given by HCPs (Box 1). Only six studies evaluated the HBRs as a tool for a referral or for information transfer across healthcare facilities and eight reported on HBRs as a tool for communicating between HCPs and women/families.

Box 1 Functions of HBRs evaluated in the included studies

Function of the HBR	Outcomes pertaining to the function	Studies assessing the function
Handover communication and information for HCPs at visits **As a tool for recording healthcare data for HCP**	Availability of HBRs at clinic visits	Tarwa et al 2007, Brown et al, 2018, Vierira et al 2009, Palombo et al, 2014
	Quality of information recorded (HCP capacity)	Harrison et al, 1998, Vierira et al, 2009, Brown et al 2018, Ramraj et al 2018, Naidoo et al 2018, Kabore et al 2020, Camargos et al 2021, Gustaffasson et al 2020, Wallace et al 2019, Abud and Gaiva 2015, Adedire et al 2016, Araujo et al 2017, Amorim et al 2018, Coelho et al 2021
Monitoring by HCPs/tracking vaccination status for immunisation programmes	Healthcare service utilisation and follow-up	Usman et al 2009, Usman et al 2011, Mori et al 2015, Osaki et al 2019, Wallace et al 2019, Kaneko et al 2017, Shah et al 1993, Aiga et al 2016, Hayford et al 2013, Jahn et al 2008, Yanagisawa et al 2015,Bhuiyan et al 2006, Mudany et al 2015, Osaki et al 2013, Kitabayashi et al 2017, Kusumayati and Nakamura 2007, Adedire et al 2016
As a tool for referral and information transfer to other HCPs/healthcare facilities	Availability of HBRs at hospital visits as referral documents.	Gustaffasson et al 2020, Osaki et al 2019, Bhuiyan et al 2006, Shah et al 1993, Gonzalez et al 2019, Camargos et al 2021,
	Quality of information recorded	Gustaffasson et al 2020, Gonzalez et al 2019, Camargos et al 2021
Monitoring by HCPs	Health outcomes	Mori et al 2015, Osaki et al 2019, Dagvadorj et al 2017
Handover communication and information for patients/families **As a tool for communication from HCPs to patients**	Knowledge, attitude and practice	Mori et al 2015, Osaki et al 2019, Aiga et al 2016, Yanagisawa et al 2015, Bhuiyan et al 2006, Hagiwara et al 2013, Kawakatsu et al 2015, Baequni et al 2016

Handover information tool for HCPs

Availability or carrying of HBRs to regular health visits, referrals, or consultations

Seven studies measured the availability of HBRs at health care facilities using direct observation (n=5) [42,46,49,57,58] and women/caregivers' self-reported practice (n=2) [24,29]. The reported availability of HBRs in health care facilities were 56% (156/300), 76% (516/677), 49.4% (727/1471), 60 % (5609/9917), 51% (185/358), 54.6% (100/189) and 83.3% (199/240) respectively.

A Gambian study [63] explored HCPs' views on the availability and use of documented information in the HBRs and showed that the majority of women (235/250, 94%) brought HBRs in the form of government-issued cards to the hospital at delivery. This Gambian study reported facilitators for using HBRs; these were women acting as agents who transport documented information, clear documentation, and having a designated space on the HBR for referrals. The reported barriers were little, or no information being recorded, illegible handwriting, and loss of reports such as lab reports leading to gaps in information in HBRs.

Three studies reported that women/families carried HBRs across healthcare facilities, without measuring the availability at all health care facilities [24,29,34]. In a multi-country study [34] that examined documentation in HBRs at referral centres/hospitals, HCPs did not always write the actions they had taken in the HBRs. However, in the Philippines, the staff were oriented about the use of HBR for referrals and 92.4% (n=66) of HBRs had information documented.

Two studies [42,49] explored women/caregivers' reasons for not carrying HBRs to healthcare. For example, (106/300) [42] and (41/129) [49] participants in South Africa and Kenya participants did not know the importance of HBR in health care visits.

Completeness of relevant fields

Seventeen studies [33,39,43,45,46,49-52,54-60,63] examined the completeness of fields in the HBRs. Completeness was assessed using different measures (Table 2) and the fields in the HBRs were not uniform across all the reported studies. Of the 17 studies, HBRs were least assessed for completion of maternal parameters (n=6) and most assessed for child health parameters (n=15). The reported completeness across different studies and fields in the HBRs varied (Table 3). The most documented information was demographic details and vaccination history [33,39,49]. The least documented information was child's vision problems [49], growth monitoring and vitamin A administration [39,49], maternal HIV status [39] and doctors' notes [33]. (Table 3)

In a study conducted in Burkina Faso [45], comparing recording in HBRs versus facility-based records, 80% (492/615) of HBRs were unrecorded for children who had been vaccinated according to facility-based records. A Gambian study [63] reported that HBRs were incomplete with at least one undocumented category for 80.1% (189/236) of mothers. Further, 26.7% (63/236) noted the 'Estimated Date of Delivery in the HBRs. Of the 94.2% (97/103) of women who brought the HBR to admission for delivery, only 29.9% (29/97) had their status recorded as high-risk on their HBR. A study in Lebanon [44] assessing the legibility of handwriting in HBRs found that one in five cards (90/460) was scored as 'poor'.

Table 2: Completeness of outcome measures and relevant results in the included studies

Author, year	Outcome measure defined	Relevant results
Harrison et al, 1998	Percentage of vaccination status for polio, BCG, DTP, Hepatitis-B vaccine, and Measles, charts completed, and notes from doctors, staff, and mothers.	The South African study in 1998 reported 92.5% (419/453) recording of polio vaccination (most) and the least recorded the form of doctor's notes 11.9% (54/453).
Jahn et al, 2008	BCG Vaccination data	The Malawian study found that vaccination HBRs were available for 63% (3440/5418) children. In the case of BCG data, of the 3487 children under five, 143 documents had no record of BCG (976 children did not have a vaccination card and 2368 cards had documentation of BCG in them).
Vieira et al, 2017	Height and weight of the child	The Brazilian study found that health professionals recorded at least two weight (68.9%) and height (47.3%) measures.
Hayford et al, 2013	Vaccination data from HBR, facility-based records, and maternal recall.	913 children had facility-based vaccination data available; of which 800 children had vaccination HBRs. The measles vaccination coverage based on the mother's recall was 93.4% (853/913) while HBR data showed 87% (790/913).
Palombo et al, 2014	Demographic, anthropometric measurements, vaccination, growth (height and weight), and development data	The Brazilian study reported that the vaccination schedule was completed in 97% (169/185) of the HBR, but only 9% (14/185) and 8% (13/185) of the HBR, respectively, contained growth charts and properly completed developmental milestones.
Abud and Gaiva, 2015	The development curve was considered complete when 2 or more of the items in the handbook had been filled in (out of 4) and growth data was considered complete when the handbook included at least one weight input every three months, with a minimum of 4 records in the first year of life.	The Brazilian study evaluated the child health handbook for completeness of growth and development data. 95.4% of the 929 handbooks had incomplete missing information related to the development and 79.6% (726/950) had missing or incomplete data in the growth chart

Adedire et al, 2016	Vaccination data in HBRs	The Nigerian study evaluated HBRs to assess vaccination coverage found that 57.9 % (275/475) of the children were fully immunised while 42.1 % (200/475) were partially immunised while mothers' recall data found that 74.4 % (558/750) of the children were fully vaccinated, 20.8 % (192/750) were partially vaccinated indicating a poorer recording of vaccination status in HBRs.
Araujo et al, 2017	A score using completed data in growth charts, records of iron and vitamin A supplementation and notes on immunisation schedules.	The study reported adequate data entry in 42% (110/316) HBRs. The least documented data was for iron supplementation and the body mass index-versus-age chart.
Amorim et al, 2018	Completion of fields in HBRs	The study reported 44.5% of the HBR had ≥ 60% of the items completed. The items that should be recorded in maternity wards, birth weight showed the highest proportion of completeness (64.5%); for those that should be filled in PHC/other services, records of vaccines (94.0%) presented the highest completeness in the HBRs.
Brown et al, 2018	Background demographic information, vaccination history, receipt of vitamin A, growth monitoring, early eye or vision screening, and new-born delivery information.	The Kenyan study found that demographic information and vaccination history were recorded in 80% of handbooks. The least documented information was child's vision problems, growth monitoring, and vitamin A, with entries logged in these fields for 33%, 88%, and 60% of records.
Ramraj et al, 2018	A composite measure of completeness by using the following: infant birth weight, BCG immunisation, maternal HIV status, and an indication of maternal syphilis testing.	Another South African study comparing two cross-sectional surveys found an increase in recording of four areas (infant birth weight, BCG immunisation, maternal HIV status, and indication of maternal syphilis testing) from 23.1% (95% CI = 22.2-24.0) in 2011-12 to 43.3% (95% CI = 42.3-44.4) in 2012-13.
Naidoo et al, 2018	HIV-related completeness, sociodemographic completeness, and neonatal completeness	The South African study, which compared completeness in the card vs book, reported the most completed areas as demographic information, the weight of the child, immunisation, and Vitamin A supplementation in 80% of HBRs in the form of a book. The least documented area was HIV- related information; 24% of HBRs did not have any record of the mother's HIV status

Gonzalez et al, 2019	Completion of fields in HBR	The Brazilian study reported a completion pattern in the available HBRs. At least 95% HBRs had the following items completed date of the last consultation visit, maternal height and blood pressure verification, uterine height, foetal heart rate, and the Rh factor; 85% or more: date of the last menstruation, urine test results, and less than 30%: performance of clinical breast examination and cytopathology of the uterine cervix.
Kabore et al, 2020	17 vaccine doses	The Burkina Faso study compared recording in HBRs vs facility-based records using rotavirus and pneumococcal vaccination and found that 80% (492/615) of HBRs were unrecorded for children who had been vaccinated according to facility-based records.
Camargos et al, 2021	Legibility and completeness of sociodemographic, clinical, obstetric, and laboratory data.	The Brazilian study in 2020 evaluated the completeness of ANC records. Clinical parameters such as gestational age 98.4% (388/394) blood pressure 99.4(392/394), fundal height97.7 (385/394), the weight of the mother 98.4% (388/394), etc. were recorded while the least recorded information was on the presence of oedema 44% (174/394). No data was available for centres where care was sought such as the basic reference unit 88% (349/394) maternity unit 76.9% (303/394), and health centre where ANC care82.4% (325/394) was provided. The least recorded data were lab reports.
Gustaffasson et al, 2020	Based on WHO referral criteria-name, age, address, parity, gestational age, complications in the antenatal period, relevant past obstetric complications, treatments applied so far results of those treatments.	The Gambian study reported that HBRs were incomplete with at least one unfilled category 80.1% (189/236). Only 26.7% (63/236) noted the 'Estimated Date of Delivery' in the HBRs. Of the 94.2% (97/103) of high-risk women who brought the HBR to admission for delivery only 29.9% (29/97) had their status recorded as high-risk on their card.
Coelho et al,2021	Completion of development items in the child health handbook	The most recorded item in the handbook was vaccination data 81% (18/22). BMI (Body Mass Index) was not recorded in 72% (16/22) handbooks.

Table 2 legends BCG=Bacillus Calmette–Guérin vaccine, DTP=Diphtheria, tetanus and pertussis vaccine, HBR=home-based records

HCPs' perceptions on the usefulness of HBRs

Five studies [26,30,32-34] explored the usefulness of HBRs in providing health education to women/parents by providers. Two qualitative studies found that HCPs perceived families did not use HBRs for care optimally [61,62]. HCPs reported HBRs as a useful tool for giving them confidence in providing health education [30,32,34] helping them to identify risks [34] and reminding the women/families regarding vaccination [26]. In a South African cross-sectional study [33] assessing the acceptability to nurses of a maternal and child handbook over a card, nurses were satisfied with the health information (95.6%), immunisation information (94.7%), weight charts (89.5%), and notes for both staff (91.3%) and mothers (93.9%) in the handbook.

Health service utilization/uptake of services

The majority of included studies (n=14) evaluated the effects of HBR on healthcare service utilization. The three key areas of measurement of services were vaccinations, antenatal clinic visits, and a skilled birth attendant for delivery. Two trials in Pakistan [21, 22] reported a 31% (adjusted RR = 1.31, 95% CI 1.18–1.46) and 67% (RR = 1.7; 95% CI = 1.4, 2.0) improvement in the 3 ^{d} dose of diphtheria-pertussis-tetanus (DTP) vaccination status for children in the intervention arm with HBR and education in 2009 and 2011 respectively. Another trial in Indonesia [26][69] also reported a 50% improvement in timely vaccination of 3 ^{d} dose of DTP among those with HBR and a reminder sticker for parents.

Five studies demonstrated an improvement in antenatal clinic visits [24,24,28,34,48]. Detailed outcomes are summarised in Table 3. A trial in Mongolia [25] showed that women in the intervention group attended antenatal clinics more than the control group (RR=1.158, 95% CI 0.876–1.532) p=0.30. Another trial in Indonesia [24] found that after using HBR, women were more likely to receive two doses of tetanus immunisation, visit the ante-natal clinic four times, have professional assistance during child delivery and ensure that their children took vitamin A supplements (OR = 2.03, 95% CI: 1.19–3.47). In a repeated cross-sectional study in Indonesia the use of HBR was associated with a 3 times higher probability of using a skilled birth attendant by mother (95% CI 1.031- 9.477) [37]. Further, mothers with HBR were likely to receive more medical tests [38,42], post-natal care [32,35] and health information from HCPs.

Table 3: Impact of HBR on health service outcomes

Outcome measured	Author	Relevant results
Health service utilisation	Usman et al, 2009	Trial in Pakistan reported improvement in the 3rd dose of diphtheria-tetanus-pertussis (DTP) vaccination status for children in the intervention arm with HBR and education. There was a 31% (adjusted RR = 1.31, 95% CI 1.18–1.46) increase in uptake of 3rd dose DTP in 2009.
	Usman et al, 2011	Trial in Pakistan with HBR for vaccination. There was a 67% (RR = 1.7; 95% CI = 1.4, 2.0) increase in uptake of 3rd dose DTP in 2011.
	Wallace et al, 2019	Another trial in Indonesia with HBR and a reminder sticker for parents demonstrated that children in the HBR and sticker group were 50% more likely to receive a third dose of a vaccine containing diphtheria, tetanus, pertussis, hepatitis B, and *Haemophilus influenzae* type b antigens (DTPcv3) within 60 days of DTP1 (RR = 1.46, 95% CI 1.02- 2.09).
	Mori et al, 2015	The trial in Mongolia reported that women in the intervention group attended antenatal clinics more than the control group (RR=1.158, 95% CI 0.876–1.532) p-value= 0.30*.
	Osaki et al, 2019	While the trial in Indonesia found that after using HBR, women were more likely to receive two doses of tetanus immunisation, visit ante-natal clinic four times, professional assistance during child delivery and ensure that their children took vitamin A supplements (OR= 2.03, 95% CI: 1.19–3.47).
	Aiga et al, 2016	Demonstrated a significant increase in the proportion of pregnant women who received at least three antenatal visits to the clinic from 67.5 % (540/800) in pre-intervention to 92.2 % (747/810) in post-intervention (P < 0.001).
	Yanagisawa et al, 2015	The intervention increased ANC attendance (4 times increase), delivery with SBAs (Skilled birth attendants), DID (difference-in-differences) =12.2 (OR=2.613, p<0.01, AOR=1.092) and delivery at a health facility DID= (OR: 2.499, p<0.01, AOR=1.866) even after adjusting for maternal age, education and economic conditions.

	Bhuiyan et al, 2006	Improved antenatal clinic use in the post-HBR group (55.9% vs 35.5%, $p<0.05$)
	Kaneko et al, 2017	Found that after the introduction of an MCH (maternal and child health) handbook post-natal coverage improved from 43.9% in 2013 to 54.2% ($p < 0.05$) in 2014.
	Shah et al, 1993	Use of HBR improved ante-natal and post-natal clinic visits in the Philippines and Zambia, with mothers explaining in focus groups that they felt that their clinic attendance had improved and that they perceived themselves to receive better care.
	Mudany et al, 2015	In Kenya HIV DNA testing in infants rose from 27 000 in 2007 to 55 000 in 2010 to 60 000 in 2012, which represents approximately 60% coverage of estimated HIV-exposed infants.
	Kitabayashi et al, 2017	The Palestinian survey found that mothers with HBR had significantly higher odds of receiving all three medical tests (aOR 1.58; 95% CI 1.287–1.932) and of having been informed about five or more health education topics (aOR 2.10; 95% CI 1.746–2.534) as part of antenatal care, (adjusted for age).
	Osaki et al, 2013	A repeated cross-sectional study reported that using an HBR was associated with a 3 times higher probability that the mother would use a skilled birth attendant (95% CI 1.031- 9.477). Mothers reading most or all of the HBR was found to be associated with mothers receiving ANC at least 4 times (OR=1.736; 95% CI 1.194-2.522) and with their receiving at least two TT (tetanus toxoid) immunisations (OR=1.576; 95% CI 1.146-2.166).
	Kusumayati and Nakamura, 2007	Having HBR was associated with having a delivery assisted by trained personnel [adjusted odds ratio (aOR): 2.12, 95% confidence interval (CI): 1.05 4.25], receiving maternal care (aOR: 3.92, 95% CI: 2.35 6.52), completing 12 doses of child immunisation for seven diseases (aOR: 4.86, 95% CI: 2.37 9.95), and having immunisation before and after childbirth (aOR: 5.40, 95% CI: 2.28 12.76).

Table 3 legends HBR= home-based records, AOR= adjusted odds ratio, OR=odds ratio, HIV=Human Immunodeficiency virus, DNA=deoxyribonucleic acid, *not statistically significant

Maternal, neo-natal, and child health outcomes

In a Mongolian trial [25], complications in maternal health were more likely to be identified, with maternal morbidity during pregnancy at 12.3% in the intervention group compared with 5 .7% in the control group (p-value= 0. 01). However, HBRs had no effects compared to the unspecified pre-existing system in the control group on neonatal death or stillbirths (RR 1·0 95% CI: 0·99–1.01, p = 0.512). In the three-year follow-up results in the Mongolian trial [27] [70], small but significant reduced risk of cognitive development delay in children (OR 0·32, 95% CI 0·14–0.73, p-value = 0.007) was reported. A trial in Indonesia [24] reported lesser risk of underweight children (OR = 0.33, 95% CI: 0.12–0.94; p<0.05) or lesser risk of children with stunted growth (OR = 0.53, 95% CI: 0.30–0.92; p<0.05) for caregivers using HBR.

Handover communication and information tool for women/caregivers

Knowledge, attitude, and practice

Ten studies [24,25,28-30,35,47] evaluated the use of HBR and its effects on knowledge, attitude, and practice outcomes. One study did not report any improvement in knowledge after the use of HBR [47][7] . Individual study results can be found in Table 4. In general, trials (n=2) found an improvement in complementary feeding [24] and the adoption of healthy behaviours by family members of pregnant women [25] after using HBR. Five pre-post studies [28-30,32,35] assessed the knowledge, attitudes, and practices of mothers/caregivers after the introduction of HBR. They showed an improvement in knowledge and practice of breast feeding [28-30,32,35], awareness of danger signs in pregnancy [29,30], and awareness of childhood illness [32].

Table 4: Handover communication tool from HCPs to women/families

Outcomes measured	Studies which measure the outcome	Relevant results
Knowledge, attitude, and practice	Mori et al, 2015	The majority of women did not drink alcohol (7.9% in the intervention group compared with 14.1% in the control group, p=0.161), and approximately half of family members stopped smoking at home (51% in the intervention group compared with 60% in the control group, p=0.048).
	Osaki et al, 2019	Reported an improvement in the initiation of complementary feeding at 6-9 months OR 4.35 (2.85-6.65) p=0.001.
	Aiga et al, 2016	The knowledge and practice of exclusive breastfeeding improved from 66.1 % in pre-intervention to 86.7 % in post-intervention (P < 0.001) and from 18.3 % in pre-intervention to 74.9 % in post-intervention (P < 0.001) respectively.
	Bhuiyan et al, 2006	Reported increased awareness of breastfeeding in the intervention group (28.7% of cases and 4.6% of controls (no p-value)), improved awareness of danger signs of pregnancy (46.9% case and 5% control groups (no p-value)), and knowledge of recommended ante-natal care (78% case and 8.3% control groups, p < 0.05).
	Hagiwara et al, 2013	Reported statistically significant improvement in awareness of breastfeeding for literate women (t-test = 1.85, p ≤ 0.1), awareness of rupture of membranes (t-test = 2.04, p ≤ 0.05) and knowledge of family planning among literate women (t-test = 3.16, p = 0.01).
	Yanagisawa et al, 2015	Evaluated the impact of the handbook by using difference-in-differences (DID) analysis and found that the intervention group had improved awareness of childhood illness (R = 6.2 points for anaemia, 9.9 for parasites, 7.5 for HIV transmission), knowledge of breastfeeding R = 6.2 for early breastfeeding (no p-value) and improved awareness of danger signs of pregnancy.
	Baequni et al, 2016	Overall, compared with the control group, the home-based records group had more knowledge and better practices during pregnancy, delivery, and child health care (e.g., immunisation).
	Kawakatsu et al, 2015	Reported that possession of an HBR was associated with higher health awareness (AOR: 1.41; 95% CI 1.138–1.724; P = 0.002).

	Nasir et al, 2017	Reported that attending mother class using HBR (intervention) significantly increased knowledge of breastfeeding initiation and hepatitis B immunisation (p<0.05). Mothers in the intervention group had the likelihood of practicing good new-born care compared with the control group (odds ratio: 1.812; 95% confidence interval: 1.235–2.660).
	Tjandraprawira et al, 2019	Reported no improvement in knowledge scores for women.

Table 4 legends HBR= home-based records, AOR= adjusted odds ratio, OR=odds ratio

Usefulness of HBRs to mothers/caregivers

Fives studies [28-30,32,36] assessed the utility of HBRs to mothers/caregivers. Mothers could read the contents of HBR [29,36], discuss with husbands/partners [30,32], and record breastfeeding practices in the HBR [28,36]. In Viet Nam [28], it was found that 68.1 % of HBRs (MCH Handbooks) had check-boxes on exclusive breastfeeding ticked by mothers. Focus group discussions with mothers clarified that they carried the records to all healthcare visits but often forgot to record breastfeeding practices in the HBR. In a multi-country study [34], based on focus group discussions, many mothers said that the HBR was a useful "passport" in the referral system because it led to contact with "someone who knows our problem and takes better care of us at the centre".

3.14. Discussion

Summary of findings

We have summarized the available evidence on HBRs from low and middle-income countries for women/families in this systematic review; specifically, to improve the informational continuity for providers and for communication between HCPs and between HCPs and women/families and outcomes of using HBRs. In general, findings suggest HBRs are under-utilized as tools for improving information availability for HCPs across health care facilities in LMICs. Overall, there is sub-optimal recording in HBRs with exception of vaccination data. However, we have shown that HBRs may facilitate improving healthcare services uptakes such as improved antenatal clinic visits, immunisation rates, and a delivery attended by skilled healthcare personnel in LMICs. Further, there was a modest impact on maternal and child health outcomes due to the use of HBRs. The review suggested that HBRs might facilitate the detection of the risk of pregnancy complications by HCPs and have a protective effect on the cognitive development of children, possibly by early detection of developmental delays. Improved awareness of breastfeeding practices and danger signs in pregnancy amongst mothers were reported after using an HBR.

This review found the frequency with which LMIC women/caregivers carry records to healthcare visits varies. However, one of the recent studies [63] reported almost 94% of women had documentation with them at the time of delivery. This finding is consistent with reviews done in high-income countries with most women/caregivers bringing their notes to clinic check-ups [12,15,64]. The retrieval of information from poorly maintained facility-based registers in many LMICs presents an opportunity to use HBRs as a surrogate tool for documented handover information [65]. Women/caregivers who did not carry records to visits were found to be unaware of the importance of having recorded at each visit [49]. However, when HCPs insisted on having the HBR, women/caregivers brought them to visits [26]. Thus, HCPs reminder creates more awareness among women/caregivers of carrying records and thus improve the availability of records at health care visits. Additionally, women carrying HBRs to all visits, irrespective of the reason for the visit, can enable better informational continuity for HCPs, subject to all HCPs being trained to enter minimal data in them.

Although HBRs are intended to be used as complementary documents to facility-based records, the availability of HBRs at healthcare visits enables better clinical decision-making [66]. However, from this review, the overall documentation in the HBRs ranged from 11% to 92%. The least utilized fields were doctors' notes, child growth, and development data, maternal HIV status, and high-risk pregnancy status. However, there are not enough data from these papers to conclude reasons for poor data entry by HCPs. To be useful for all HCPs, HBRs must be completed accurately and capture the necessary clinical information in a standardized manner. The Mongolian trial showed evidence of HBRs facilitating detection of pregnancy complications [25]. However, the limited evidence on medical information availability for HCPs in hospitals or secondary care shows that for HBRs to be useful for handover, referral using HBRs must be an established practice [21]. These results indicate the need for better training for HCPs to ensure better utilization of these records. This could be most useful in pluralistic health systems, where referral pathways are not implemented or adhered to and when patients/families self-refer themselves to different HCPs. Additionally, HBR stock-outs [67] and fragmentation of information due to multiple HBRs per patient [68] act as barriers for recording and maintaining HBRs as an established practice. Therefore, it is necessary to consider the best way to implement such a programme and if there can be a secure system for keeping it going in a way that allows for all to have one HBR and for every HBR to have the full and latest information on it. Otherwise, the cost-effectiveness and benefits of the system are questionable.

The evidence suggests that healthcare utilisation is improved with HBR in LMICs. This result is consistent with previous findings from prior systematic reviews. Magwood et al found that HBRs had statistically significant effects on improving antenatal care attendance; however, the evidence base was small and of low to very low certainty [15]. The mechanism of improvement of healthcare utilization is unclear. This is because the RCTs [22,23] showing improvements in vaccination uptake demonstrated that this was due to HBR intervention and verbal reminders from HCPs. Therefore, whether having the information in the HBR is functioning as a trigger for HCPs to provide verbal reminders and health information, or whether patients' engagement with the records is acting as a reminder, is not well established. This is an important research gap; addressing it will enable alignment of the content of the HBRs to the literacy levels of parents or HCPs and with the function, it serves each user group. Overall, the results obtained (such as improvements in vaccination uptake) from relatively minor studies from specific geographical settings make it difficult to generalize the findings to all regions in LMIC and suggests lower certainty of the outcome.

From the review, HCPs find HBRs useful for health promotion and healthcare communication with women/families. However, limited studies [30,34] reports on HBRs improving the communication of women/caregivers with HCPs. This finding contrasts to studies in HICs, which suggest that HBRs enhance women's feeling of empowerment and thereby enable better communication with HCPs [5,12]. Additionally, there is limited evidence for pregnant women reading and recording data in HBRs from the review. Therefore, further studies, which explore the mechanisms by which behaviour change occurs with HBRs, are necessary to determine the type of health education material in them [17]. However, there is modest evidence of HBRs improving communication with husbands/partners/families. This finding is similar to a qualitative review by Magwood et al, which suggests HBRs improved engagement with care for husbands and families [16]. Therefore, end users' involvement in re-designing HBRs may enable better engagement from women/families (particularly with lower literacy) and providers [69]. A user-centred design could overcome the needs and facilitate a better understanding of the users [17].

Implications for research and practice

Our findings highlight the need for engagement with end users such as frontline workers, health care providers, patients and families while designing an HBR. Additionally, in those LMICs with existing HBRs, implementation evaluations of HBR use and re-formatting or re-designing the content of HBR to meet the needs of end-users will enable better use of HBRs in routine practice. Further research is needed to understand the unused content in HBRs.

Strengths and Limitation

The comprehensive search strategy for, and focused review of, studies in LMICs has helped to understand the usefulness of HBRs in that setting. However, the inclusion of studies in the English language alone may have excluded studies in regional languages. A possible limitation of this review is in the categorisation of the included studies as handover communication for HCPs and patients/families. This is because most studies contain results, which can fit into both categories. For example, the detection of cognitive delay may be due to HCPs recording and monitoring growth and parents being aware of the milestones and communicating this during healthcare visits to HCPs. Therefore, a clear distinction of the function of HBRs for HCPs alone, particularly in the absence of trials focused on the improvement of information available for providers, could not be made, calling for more research to enable an improvement in continuity of information and maternity care. This review has not evaluated the content and design quality of HBRs that may hinder the utility of HBRs for providers. However, in assessing the completion of records, it was found that the fields were different for HBRs from different countries. Therefore, having a minimum criterion, which is necessary for handover across HCPs will enable future studies to assess the quality of documented information. Additionally, this review did not capture the different health education/promotion messages included in each of HBR and its appropriateness, which can affect the MCH outcomes measured.

3.15. Conclusion

Overall, there is a lack of studies from LMICs examining the use of HBRs in improving health outcomes, which is consistent with previous systematic reviews. The findings from the review demonstrate a lack of literature on the availability of HBRs for secondary encounters such as referrals. Our study extends the evidence on current use of HBRs in LMICs for improving informational continuity for HCPs. Although there is a great potential for HBRs to enable information transfer for safe continuity of maternal and childcare, evidence suggests that data completeness in the HBRs is currently suboptimal (except vaccination data) leading to decreased informational continuity for HCPs in LMICs. The review supports the HBR [potentially] being an effective tool for handover communication from HCPs to women/caregivers, in improving utilisation of antenatal visits, immunisations, and skilled birth delivery in LMICs similar to the findings from previous reviews. There is some evidence on improving mothers' knowledge of breastfeeding and identification of danger signs in pregnancy.

Abbreviations

HBR- Home-based records

HCP-Health care providers

LMIC-Low- and middle-income countries

MCH-maternal and child health

Fig 1. Legends

LMIC=Low and middle-income countries, CVD=Cardiovascular disease, PHR=Patient-held health record, NCD=non-communicable disease, MCH=maternal, and child health

3.16. Chapter Summary

This chapter has examined the evidence for PHRs in LMICs using two systematic reviews. The chapter has contributed to the overall aim of thesis in gathering the current evidence of PHRs for handover communication, informational continuity of care and self-management in LMICs. The findings show limited evidence of effectiveness of PHRs for NCDs; there is not enough information to recommend PHRs for improving handover, information transfer or patients' self-management. Further, no studies were reported from India evaluating PHRs for NCDs. Although HBRs are widely implemented, the current evidence does not support their use for handover communication and information transfer owing to sub-optimal recording and use of HBRs. HCPs, mothers and families noted the role of HBRs, and findings report improvement in utilisation of health services such as increase in ante-natal visits. Further, LMIC is a broad term and does not reflect the important differences between the countries included in the classification. One of the key factors that could impact the outcomes of the SRs is the influence of culture. For instance, in the context of an ill individual, cultural norms often involve family participation in decision-making and interactions with HCPs, a practice observed in India and many other South Asian countries.[70,7] The reviews in Chapter 3 highlight that patients find it beneficial to have a PHR for discussing health matters with their family members. Nevertheless, this observation might not apply to countries where individuals generally refrain from sharing details of their illnesses with family members.

This knowledge gap calls for further research on understanding the dynamics and outcomes of PHR use by patients and providers in LMICs. The qualitative research conducted following the systematic reviews aimed to address some of the gap in this literature namely to explore patients', carers and HCPs' experiences with current PHRs for improving handover communication, informational continuity of care and self-management in the public health settings in Kerala, India.

Chapter four describes the qualitative study that explores the experiences with current PHRs for patients with diabetes and hypertension, their carers (family members) and HCPs in Kerala, India. Specifically, the following chapter describes how people actually use PHRs in practice and how patients', carers and HCPs within the health system in Kerala, value PHRs.

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CHAPTER FOUR

SIMILARITIES AND DIFFERENCES BETWEEN PATIENTS', CARERS', AND HEALTHCARE PROVIDERS' USE AND PERCEIVED VALUE OF THE CURRENTLY AVAILABLE PHRS IN KERALA

4.1. Chapter preface

This chapter presents the first of the three results chapters based on the findings of the qualitative study. The qualitative study aimed to fill the gap in the current literature by comparing the experiences, use and perceptions of the value of current patient-held records (PHRs) amongst patients, carers and healthcare providers (HCPs) from Kerala. While existing literature from high-income countries (HICs) has described the use of PHRs by patients, carers, and HCPs, studies found that the perceived purpose of the PHR differed among these groups.

This chapter is reported first in the thesis as it provides a descriptive account of the current use and value of PHRs for patients, carers and HCPs in Kerala. Comparing the perceptions of patients, carers and HCPs provides data on possible divergences and these have implication for using PHRs for handover communication, informational continuity and self-management.

Note: The title of the paper included as chapter 4 reflects the descriptive exploratory qualitative study as a whole, while the chapter title reflects the findings.

This qualitative paper has been published in Health Expectations as below. The final accepted version of the manuscript is included in the thesis chapter. The online supplementary material (Topic guides for patients, carers and HCPs) is provided in the Appendix six.

Joseph L, Greenfield S, Manaseki-Holland S, T R Lekha, S Sujakumari, Panniyammakal J, Lavis A. Patients', carers' and healthcare providers' views of patient-held health records in Kerala, India: A qualitative exploratory study. Health Expect. 2023 Feb 13. doi: 10.1111/hex.13721. Epub ahead of print. PMID: 36782391.

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Title:

Patients', carers' and healthcare providers' views of patient-held health records in Kerala, India; a qualitative exploratory study

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Contributor Statement:

LJ, AL, SG and SMH designed the study. PJ and LJ finalised recruitment strategies. LJ conducted the interviews, LTR and SS supported with transcription and quality of transcripts. LJ analysed the data and drafted the manuscript, with input from AL. All authors critically reviewed the manuscript.

4.2. Abstract

Introduction

Poor medical information transfer across healthcare visits and providers poses a potential threat to patient safety. Patient-held health records (PHR) may be used to facilitate informational continuity, handover communication, and patient self-management. However, there are conflicting opinions on the effectiveness of PHRs, other than in maternal and childcare. Moreover, the experiences of users of PHRs in low and middle-income countries (LMIC) are critical in policy decisions but have rarely been researched.

Aim

This study aimed to explore similarities and differences in the perspectives of patients, carers, and healthcare providers (HCPs) on the current PHRs for diabetes and hypertension in Kerala.

Methods

Qualitative design comprising semi-structured interviews with patients with diabetes/hypertension (n=20), carers (n=15), and healthcare providers (n=17) in Kerala, India. Data was analysed using thematic analysis.

Results

Themes generated regarding the experiences with PHRs from each user group were compared and contrasted. The themes that arose were organised under three headings; use of PHRs in everyday practice; the perceived value of PHR; and where practice and value conflict. We found that in the use of PHRs in everyday practice, multiple PHRs posed challenges for patients carrying records and for HCPs locating relevant information. Most carers carried all patients' past PHRs, while patients made decisions on which PHR to take along based on the purpose of

the healthcare visit. HCPs appreciated having PHRs but documented limited details in them. The perceived value of PHRs by each group for themselves was different. While HCPs placed value on PHRs for enabling better clinical decision-making, preventing errors, and patient safety, patients perceived them as transactional tools for diabetes and hypertension medications; and carers highlighted their value during emergencies.

Conclusion

Our findings suggest users find a variety of values for PHRs. However, these perceived values are different for each user group, suggesting minimal functioning of PHRs for informational continuity, handover communication, and self-management.

Patient and public involvement

Patients and carers were involved during the pilot testing of topic guides, consent, and study information sheets. Patients and carers gave their feedback on the materials to ensure clarity and appropriateness within the context.

4.3. Introduction

Patient-held health records (PHRs) contain patients' medical information documented by healthcare providers (HCP) to reflect the healthcare services received by a patient. PHRs serve as a formal record for information sharing usually carried to health care visits by the patient or carers.[2,3] Usually HCPs document health assessments, treatment plans, and health services received by patients in these records.[4] Despite low levels of evidence of improved maternal and child health outcomes[5], women, carers, and HCPs value MCH records.[6 8] However, there is limited evidence of improvement in health outcomes following the use of PHRs in non-communicable diseases (NCD) in low and middle-income countries (LMICs).[9, 0]

PHRs can be tailored for specific purposes such as to inform and involve patients in their care, and to aid in self-management, to improve handover communication and informational continuity of care across health care visits and HCPs.[2,] The availability of patient medical information for HCPs forms the basis of informational continuity of care. [2] With the increase of NCD burden in LMICs, patients requiring long-term care and repeated encounters with HCPs are increasing. [3] This in turn necessitates informational continuity for patient management and safety. A Mongolian study described the use of a paper-based PHR (booklet), for information transfer across HCPs for patients with NCDs. [4] PHRs also have significance for patients and/carers with chronic NCDs as they need clear direction on optimal self-management. There is limited literature regarding the usefulness of PHRs for patients with NCDs from LMICs. [5]

The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases & Stroke (NPCDCS) in India was introduced in recognition of the growing burden of NCDs. The programme has contributed to an improvement in screening facilities, access to and availability of medications for NCDs. [6] However, there remain considerable gaps in both the patient awareness and patient control of major risk factors for NCDs such as Diabetes Mellitus and Hypertension. [7, 8] Kerala, the site of the current study has been a relatively better-performing state on health indicators such as mortality rates. [9] This state has been experiencing a rapid epidemiologic transition resulting in a huge burden of NCDs.[20] Patients tend to visit different healthcare facilities (public and private) and HCPs leading to fragmentation of medical information transfer across providers. [0,2] There is no paper-based patient-level facility-based records used in outpatient settings in public healthcare facilities in Kerala. A previous study in 2014 in Kerala found that disparate pieces of paper given to patients for patient-held documentation were valued and kept safe by patients and when their use by clinicians was clear to patients, they carried them to all their clinic visits. [22] Additionally, most patients in this study reported having little or no information about self-management of their NCD.[22] After reviewing the results, an experts' meeting suggested having a patient-held health record for patients with NCDs to improve handover communication and informational continuity between providers and patients/carers in Kerala. [22]

Implementation of electronic health records in the public health system has become a priority in India.[23] Within the context of the ongoing implementation of electronic health records in Kerala, it is important to investigate the use and perceived value of PHR for patients, carers, and HCPs.[24] The findings will guide policy decisions as to whether a paper-based PHRs should be continued or replaced by another system. Furthermore, given the prevalence of paper-based PHRs in many LMICs, lessons learnt in one state in India would have implications throughout India and other LMICs.

Studies from HIC have reported on the patients' carers,' and HCPs' perspectives on PHRs. A few qualitative studies have shown that patients valued having PHRs as a record of their condition. Other practical benefits of PHRs described by patients include the role as an aide-memoire, as a tool for communicating with HCPs, and in improving self-management.[9,] However, studies also have shown that when the intended purpose of the PHR is unclear to the users, then the value of

PHRs is diminished for the users. Patients reported that when not having clarity on whose (patients'/HCPs') responsibility it is to record in PHRs or what the importance of information for patients/HCPs for self-management or continuity of care is, PHRs are used sub-optimally. HCPs' experiences in using PHRs from studies done in HIC show that most HCPs appreciate the benefits of PHRs in improving the availability of medical information, however, the recording of PHRs and the use of PHRs by HCPs were low.[25 27]

On reviewing the literature, it is apparent that the experiences of the users of PHRs for chronic conditions from LMICs have received little attention. Improving patient and carer involvement in care is a potential approach to improve information transfer across different health settings and self-management as well as a seamless continuity of care. It is therefore important to understand how patients, carers, and HCPs routinely use PHRs, or what value each group places on them if any. It is known that the benefits of a tool can arise due to the tool itself or due to its interaction with the wider context such as the conversations around it.[28]

Against this background, the qualitative study described here aimed to address a gap in the literature; the use and value of PHRs for patients' carers' and HCPs from LMIC. The study's purpose was to explore similarities and differences in the perspectives of patients, carers, and healthcare providers on their perspectives of PHRs in Kerala. Three research questions were identified:

1. How do patients, carers, and HCPs use current PHRs in Kerala, India?
2. What value do patients, carers, and HCPs place on PHRs for themselves?
3. What are the users' perspectives on current PHRs' value for information transfer, handover communication, and self-management?

4.4. Methods

Study design

This is an exploratory[29] descriptive[30] qualitative study with data collected through semi-structured interviews conducted with patients, carers, and HCPs in outpatient settings in Kerala, India. We recruited patients with diabetes and/ hypertension as a tracer condition for NCDs.

Settings

We conducted the study in Kerala from February to November 2020 in primary care settings (family health centres) in the public health system.

In 2017, the Government of Kerala initiated the "*Aardram Mission*" to transform and mobilize the State's public healthcare system to meet the current health challenges. One of the objectives of the "*Aardram Mission*" is the decentralisation of healthcare from the secondary and tertiary levels to primary care-led services and the initiation of population-level activities to address the impact of NCDs, especially hypertension and diabetes.[3 ,32] Primary Health Centres have been upgraded to family health centres (FHCs) with additional HCPs. [3,3] FHCs have provision for treating patients with diabetes mellitus and hypertension under NPCDCS [6]. Under this programme, free or subsidized medicines are available for NCDs such as diabetes, hypertension, cardiovascular and respiratory diseases in the public health facilities. Medicines for patients with diabetes and hypertension are dispensed monthly after consultation with the doctor at the PHC or FHCs. Currently, patient-level electronic health records and health information systems are being installed in public healthcare facilities in Kerala. [3] The electronic health records are longitudinal medical records that contain medical and demographic information about a patient, currently accessible to HCPs (public health facilities) only in Kerala. [33] Given the plethora of types of private and public providers un-connected to each other, current electronic records planned in India for the public healthcare system do not solve the information exchange problem.

Both public and private sectors provide NCD services and can be described as follows. In the public health system, diabetes and hypertension services are provided at primary health centres (PHC) or family health centres (FHC). If specialist care is needed, patients are referred to NCD clinics at community health centres or district hospitals. In the private sector, general practitioners, and health clinics (without in-patient facilities) operate at the primary care level, and medium to large hospitals (both inpatient and outpatient facilities) operate at secondary and tertiary levels. Generally, public healthcare facilities are free of cost or charge minimally, while private health care facilities need patients/carers to pay for the health care services unless their insurance would pay.[2] Few publicly financed health insurance schemes are designed to entitle poor and other vulnerable households to choose cashless healthcare from a pool of empanelled private or public providers. One such scheme for low salaried employees from the organised sector is the Employees State Insurance Scheme (ESIS). Culturally, carers or family members are involved in a person's healthcare in India. Patients' spouses, children, or other relatives accompany them when going for a healthcare check-up or in the case of an emergency visit to a hospital. Carers discuss the healthcare condition of the patients with HCPs and HCPs discuss with patients and carers. In public health facilities, most patients or carers are given formal PHRs in which HCPs enter information to reflect the health care services received by a patient.[2] These patient-held documents take different forms such as OP (outpatient) tickets, diagnostic and lab reports, notebooks, or patient passbooks or booklets. (Table 1).

Study participants, sampling, and recruitment

Three groups of participants were identified for the study: patients with diabetes and hypertension, carers, and HCPs. In the pre-COVID phase, the study was conducted at two FHCs in the Alappuzha district, Kerala, which is one of the first districts where the NPCDCS was implemented in 2015. The COVID-19 lockdown and travel restrictions in Kerala, from March 2020, made onsite face-to-face interviews[34] challenging. Therefore, from March 2020 to November 2020, telephone interviews were conducted with eligible participants from other districts (Trivandrum, Ernakulam, Malappuram, and Wayanad) to capture views from a wider geographical area within Kerala.[35].

Three recruitment strategies were used for identifying participants for the study (Fig 1). Firstly, nurses informed eligible patients and carers attending the outpatient clinics of FHCs about the research study. Interested patients and carers meeting eligibility were interviewed. Purposive sampling[36] was used to identify eligible participants based on the following inclusion criteria; adult (18 years and above) patients and their carers with diabetes/hypertension or both, seeking care from public healthcare facilities or both public and private healthcare facilities. Secondly, patients, carers, and HCPs were recruited through convenience sampling[37], identified by members of the research team in Kerala through another pre-diabetes project in a worksite (Latex factory) in Trivandrum district. The convenience and purposive sampling were combined to ensure the participation of patients and carers from low socio-economic groups (patients' and carers' self-reported status of employment, education, housing, and possession of ration card*) (this is an identification card used by the public distribution system to identify families below the poverty line) using public and private health care facilities in the study. Thirdly, purposive sampling was employed to recruit HCPs working in public healthcare facilities in a range of districts, rural and urban locations and experience with electronic health records, and snowball sampling[38] was used as a strategy to recruit more HCPs, by asking HCPs at the end of interviews to recommend other HCPs.

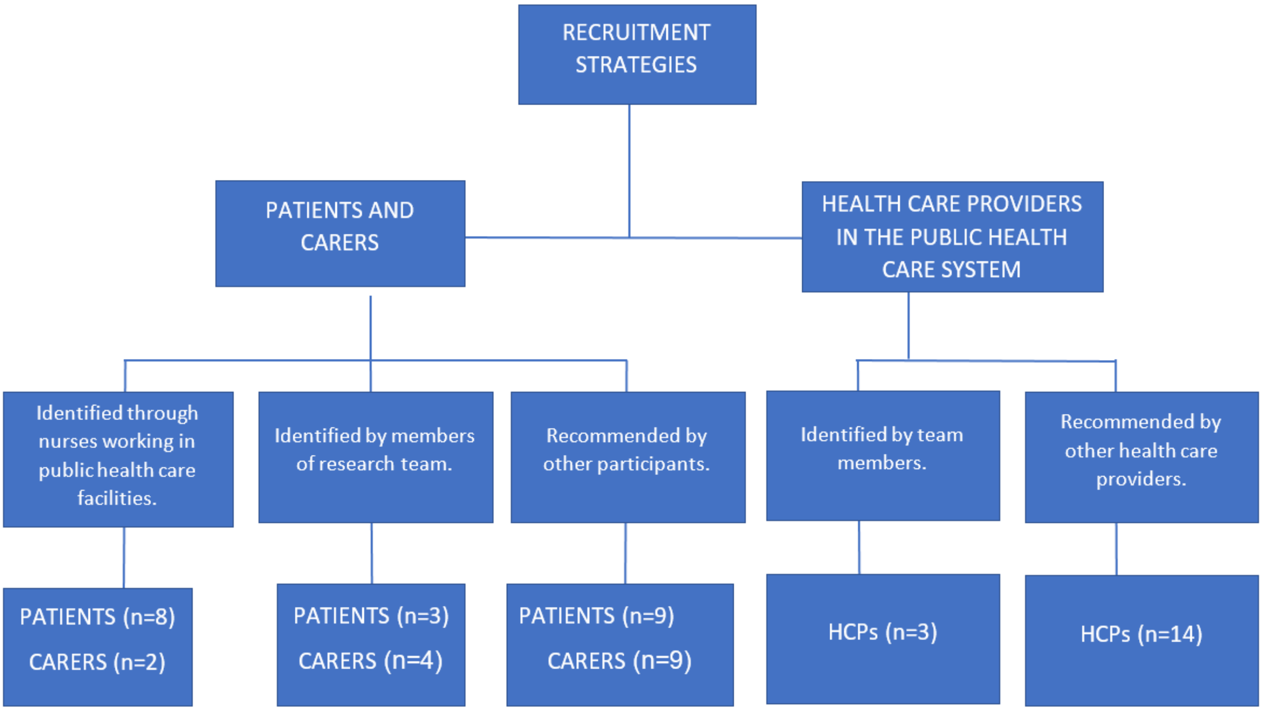


Fig 1 Diagrammatic representation of recruitment for the study.

Data collection

Semi-structured interviews[34] took place both face-to-face (n= 12) and by telephone (n=40). The first author conducted all interviews in Malayalam using topic guides (Supplementary file: S1). These were piloted with two patients with diabetes and hypertension, one carer and one HCP respectively before data collection to ensure clarity. The patient and carer topic guide included open-ended questions regarding healthcare visits to HCPs, diabetes and hypertension management at home, use of PHRs for information exchange, communication, and self-management. Patients and carers were interviewed separately. The HCP topic guide slightly differed to capture the context and organisation of care for patients with diabetes and hypertension and existing systems for information exchange (PHR and electronic health records).

Face-to-face interviews with patients, carers, and HCPs took place in an available quiet room at FHC. Telephone interviews were conducted at a convenient time for participants. All interviews were audio-recorded and lasted between 15 and 60 minutes. The first author translated and transcribed the first five interviews from each group into English. A trained research assistant translated and transcribed the rest of the interviews into English. A local researcher (Postdoctoral Fellow in Sociology) who was familiar with the study settings and fluent in Malayalam and English, checked for any translation and transcription errors in all the transcripts. Data collection continued until data saturation was reached within each of the groups.[39] The interviews for each group (patients, carers, and health care providers) were done sequentially. Data saturation is the point at which the researchers fully understand issues and when no further dimensions or insights into issues can be found. [39] Achieving data saturation ensured that the findings were grounded in the experiences of key participant groups. Firstly, patient interviews were done, and data collection was stopped when no new information regarding PHRs was obtained. For example, the data on "how patients' carried their PHRs" were explored until explanations for whether patients carry records or not, whether their behaviour differs in carrying PHRs for diabetes and hypertension and other conditions, the reasons for why they carry them (or not) were obtained until no new information was added in the next interview. Healthcare provider (HCP) interviews were done until no new information on recording and use of PHRs for communication, informational continuity and self-management were obtained. For example, how HCPs recorded in the PHRs, the reasons for documenting or not documenting in PHRs were explored until no new data was obtained.

Data analysis

We used an iterative thematic approach[40 42] to analysis, which focused on analysing interviews in their entirety and identifying themes related to patients,' carers,' and HCPs' experiences of using PHRs. A predominantly inductive approach to coding was followed. First author coded three interviews from each group (patients, carers, and HCPs), initially. Corresponding author then reviewed the transcripts and the generated codes. The first author coded the full dataset manually. The patients,' carers,' and HCPs' data had been coded separately and codes were grouped into potential themes in Microsoft Excel. Potential themes were discussed and agreed upon with the team members. Not all the themes from the interview transcripts of patients, carers, and HCPs are reported in this paper (will be published later). The themes and sub-themes specifically about experiences with PHRs from patients, carers, and HCPs were compared and contrasted and this focused analysis is reported in this paper. The results are organised under three headings (use of PHR in everyday practice, perceived value, and where practice and value conflict) (Fig 2).

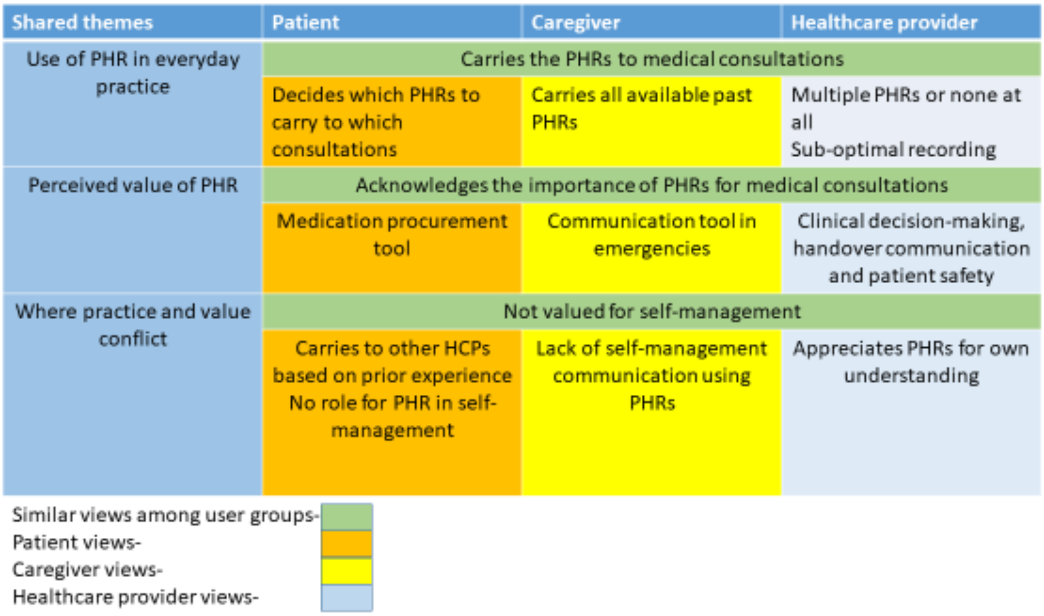
Ethics

Ethical approval for the qualitative study (Appendix 2) was received from the Centre for Chronic Disease Control, New Delhi [CCDC IEC 05 2019] and the University of Birmingham [ERN 18-1933].

4.5. Findings

The characteristics of patients, carers, and HCPs interviewed (n= 52) are summarised in Table 2. The 20 patients were aged between 41-70 years and eight of them had both diabetes and hypertension. Most of them were unemployed (n=4) or engaged in minimum-wage employment (n=11). Carers were aged between 28-56 years, ten of them had parents/in-laws with diabetes/hypertension, and others were spouses of patients with diabetes and/hypertension. HCPs included doctors (n=13) and nurses (n=4) in the public health care system. Their work experience ranged from less than a year to 20 years. Numerical pseudonyms are used when presenting quotes to ensure confidentiality.

The first heading, "Use of PHR in everyday practice," describes how each group engaged with the PHR in practice. The second heading, "Perceived value of PHR" centres on how each user group's practices guided the value they placed on PHRs. Specifically, this section demonstrates how previous healthcare visits influenced each user groups' perceptions. The third heading, "Where practice and value conflict" explores how the practices and perceived values related to the PHR differ both within and between groups. Under perceived value three sub-themes - clinical decision-making, handover communication, and patient safety, medication procurement and emergency use, reflecting the perceived value of PHRs for each group, i.e., HCPs, patients with diabetes and/hypertension and carers. The sub-themes are illustrated in Fig 2. Illustrative quotes are presented in Table 3.



Shared themes	Patient	Caregiver	Healthcare provider
Use of PHR in everyday practice	Carries the PHRs to medical consultations		
	Decides which PHRs to carry to which consultations	Carries all available past PHRs	Multiple PHRs or none at all Sub-optimal recording
Perceived value of PHR	Acknowledges the importance of PHRs for medical consultations		
	Medication procurement tool	Communication tool in emergencies	Clinical decision-making, handover communication and patient safety
Where practice and value conflict	Not valued for self-management		
	Carries to other HCPs based on prior experience No role for PHR in self-management	Lack of self-management communication using PHRs	Appreciates PHRs for own understanding

Similar views among user groups- 🟩
Patient views- 🟧
Caregiver views- 🟨
Healthcare provider views- 🟦

Fig 2 Conceptualisations of patient-held records by participant groups

Use of PHR in everyday practice

HCPs varied in their responses when describing how they used PHRs for documenting consultations and the extent of their information recording. Most HCPs described looking at PHRs if the patients bring them to consultations. HCPs requested and insisted on PHRs from patients with diabetes/hypertension, particularly for their monthly consultation. (Quote 1)

Some HCPs described spending time, especially when the patient (diabetic/hypertensive) is using their healthcare facility for the first time, collecting a detailed health history and documenting this in the PHR for future use. However, HCPs felt that their subsequent recording in PHRs was inadequate. HCPs reported finding sub-optimal recording in PHRs when patients come for monthly consultations. Most HCPs cited a heavy patient load in outpatient settings as the reason for their own perceived inadequate documentation. However, one HCP cited other reasons for inadequate documentation by other HCPs such as the absence of monitoring of HCP documentation, and a greater patient load on junior HCPs. (Quote 2)

Although HCPs described how patients did not always carry PHRs, all the patients participating in this study described carrying PHRs to FHC/public health care facilities when they visit health centres for monthly medication for diabetes or hypertension. Patients framed the process of carrying the books or records to the monthly consultations for diabetes or hypertension as their responsibility. However, it was also clear that they do not always carry all PHRs to other health care consultations. (Quote 3)

Against this background, HCPs discussed how having lots of different PHRs makes it difficult to locate the information needed or to take time to find it. (Quote 4)

In contrast to patients' decision-making regarding which PHRs to carry, carers in the study described either carrying all the past PHRs themselves or encouraging the patient to do so for consultations. Carers felt that because the person they were caring for had multiple PHRs, they felt unqualified to choose which record to carry. Their views also included HCPs needing the medical information in the PHRs. One carer noted that she filed all her parents' PHRs chronologically and found that it was a great help in subsequent visits to HCPs. (Quote 5)

In everyday practice, thus, patients said they brought diabetes/hypertension-specific PHRs to diabetes/hypertension appointments but did not carry them to other healthcare visits. In contrast, carers did not make such decisions and tended to carry all records to health care visits. HCPs requested PHRs from patients with diabetes/hypertension when they visit them for the first time and monthly diabetes/hypertension consultations. However, according to HCPs, recording in PHRs varies and is sub-optimal. As such, although each group of participants appeared to at least partially engage with PHRs in practice, albeit in different ways.

Perceived value of PHR for themselves

The perceived value of PHR by the users was based on their own PHR practices. These practices are attributed to the purpose it serves for each group

Clinical decision-making, handover communication, and patient safety

HCPs regarded PHRs as an important tool for clinical decision-making. HCPs described feeling more confident in managing those patients who had brought their PHR, due to having their medical history available in the PHR for review. HCPs thereby emphasised the value of having documented evidence of previous management and for preventing the creation of future gaps in information. HCPs felt having documented information is particularly important when the patient is unable to communicate accurate details of their medicines. They also explained their lack of trust in the information communicated by patients as they felt that this might be affected by the recall. (Quote 6)

Three HCPs explained that when they encounter patients without a PHR or with missing information on past medications, they consider them as new patients. Thus, they begin the treatment with patients' current issues. (Quote 7)

HCPs reported that the value of PHRs lies in preventing medication errors and, thus, emphasized their importance in ensuring informational continuity and patient safety. (Quote 8)

Neither patients nor carers mentioned preventing medication errors or patient safety issues as motivating their carrying of PHRs to appointments.

Medication procurement

For patients, the perceived value of their diabetes and/hypertension PHRs lay in medication procurement/medication re-fills. The value, therefore, was underpinned by the need to gain access to long-term free medications. (Quote 9)

According to the patients, the staff at healthcare facilities advised them to carry the PHR when they visit the doctor to collect their medications. (Quote 10) Some HCPs described how PHRs could act as a way of tracking medication procurement by patients. However, in contrast to the patients or carers, this was not the primary utility of PHRs described by the HCPs.

Emergency use

Carers play an important role in patients' care in Kerala, particularly in emergencies. They said they would often replace ambulance-based emergency medical systems and transport patients to hospitals in emergencies.

In contrast to patients and HCPs, carers framed the value of PHRs in terms of their use during emergencies. Not all carers in this study said they accompanied patients to every HCP visit. Irrespective of that, all carers found it difficult giving accurate descriptions of a patient's up-to-date medical information, including medications. Carers described carrying PHRs when they take patients to casualty or in cases when patients cannot explain their condition to HCPs. (Quote 11)

Where practice and value conflict

Under this heading, the participants' views on areas in which PHRs are being used in practice, but where they do not always identify the value of PHR for themselves, and also where the booklets' use differs from that which is intended is summarised.

Patients said they carried PHRs to health care consultations even when they could not find value in this for themselves. Patients confirmed carrying them to health care visits when they had experienced HCPs requesting PHR. (Quote 12)

As described above, most patients considered the PHR important for medication procurement, and only very few patients described referring to PHRs as a reminder of their own daily medication intake. This is maybe one of the possible reasons that these PHRs are not communicated by HCPs as a self-management tool to the patients and patients perceive PHRs as tools for the HCPs. (Quote 13)

HCPs reported that they did not use PHRs (even the ones with additional health information such as a menu plan) to direct patients and carers for follow-up or self-management at home. In addition, some HCPs referred to the implementation of electronic health records in the public health system, which would help patients, as patients' not needing to carry any papers to healthcare visits. Some HCPs did not see the value of PHRs for patients/family members themselves, as they placed emphasis instead on information transfer across healthcare visits. (Quote 14)

Patients and HCPs had different views on medication information recall and therefore they differed in describing the value of PHRs for communicating about medicines. Some patients reported that most HCPs only asked if they had a condition such as diabetes or hypertension and if they are taking medication for them when going to healthcare visits other than for diabetes/hypertension so they did not think they would need to carry PHRs for DM/hypertension to other visits. (Quote 15)

Patients were asked whether they looked at their own lab results from the PHRs and most responded that they do not. Some patients reflected that their results were discussed with them by HCPs. For example, one patient described having a conversation with the nurses when they check blood pressure values in the PHR and whether the values were "normal". Patients preferred having a conversation with HCPs rather than using their current PHRs for self-monitoring. (Quote 16)

Some patients said they find PHRs a source of medical information for carers. Most patients reported discussing the reports of diagnostic tests/lab tests with their carers. Similarly, most carers placed value on the medical information in PHRs, which enabled them to understand what happened at the doctor's appointment when they were not accompanying the patient. Even though patients appeared not to read or find value in using PHR for monitoring care, they did find some value in PHRs providing an opportunity for family members to discuss their health condition. (Quote 17)

4.6. Discussion

This qualitative study explored similarities and differences in patient, carer, and HCP perspectives on using PHRs for managing diabetes and hypertension in Kerala. These are vital actors in the management of patients with chronic diseases in India and most LMICs and together can ensure the provision of a seamless, long-term continuity of care to enable better health outcomes for the patients. Patients and carers reported carrying PHRs to consultations, but patients made decisions on which PHRs to carry, based on the purpose of the health care visit. HCPs felt that their own documentation in records was inadequate due to the heavy patient load. Each of the user groups was seen to place a different value on the PHR, based on their own conceptualisation of its importance for themselves. HCPs perceived PHRs as valuable for preventing medication errors and improving informational continuity and patient safety. Patients perceived PHRs to be valuable for them in procuring medicines for their conditions. Finally, carers perceived PHRs to be important for them in communicating patients' medical information to HCPs during emergencies. Therefore, patients and HCPs did not view current PHRs as a tool for self-management. Carers felt that PHRs provide information for communication and self-management at home. This is because the relationship between use in everyday practice and the value each group places on PHR is complex.

Overall, our findings indicate that among our study participants, PHRs were being used mostly as information transfer tools across healthcare visits to the same provider for diabetes/hypertension consultations. However, owing to different values placed by patients and HCPs on PHRs and a lack of awareness of the use of PHRs by providers, the information carried by patients may not be comprehensive. Due to the divergent values of the different user groups, there are differences in use and lost opportunities for optimal use of PHRs that could lead to improved patient care and health outcomes.

Comparison with existing literature

Previous studies of maternal PHRs from HIC reported improved communication between women and HCPs and improved involvement of women in their care.[43] However, communication among the community and hospital HCPs has not improved using PHRs.[44] Women from HICs and LMICs valued having their own medical information.[6, 43] However, there is limited literature from LMICs on PHRs for diabetes and hypertension. [5] Our study goes beyond previous research by exploring disconnects between HCP's, patients', and carers' current use and value of PHRs and how they influence handover communication, information transfer, and self-management in Kerala. A mixed-methods study done in Ireland to evaluate the use of PHRs in palliative care found that families used and valued PHRs more than patients or HCPs.[45] While patients could find the value in using PHRs for communicating with families and HCPs, they did not use them in practice. The HCPs did not feel PHRs helped much in facilitating decisions or communicating with patients, families, and HCPs.[45] Understanding disconnects in use and value of PHRs could therefore inform modifications to PHRs and develop support interventions that could enhance their use.

Patient safety

In our study, HCPs felt that the medical information in PHRs is valuable for clinical decision-making, the prevention of medication errors, and thus for enhancing patient safety. The providers' views of value, which are based on providing appropriate care are consistent with previous literature.46 However, in our study HCPs did not use PHRs for communicating with patients nor emphasized the importance of patients taking the PHRs to all HCPs, irrespective of the health care facility. Additionally, patients and carers with previous experience with HCPs requesting PHRs in the past tended to say they take them to their subsequent consultations. However, not taking into account the potential for preventing medication errors or patient safety, patients carried records based on the purpose of their healthcare appointments. These findings are similar to a study done in the UK, which found that patients and carers were unaware of the purpose and value of carrying medication lists to consultations to enhance medication safety.[47] This finding highlights the need for support interventions such as creating awareness regarding the purpose of PHRs to all stakeholders irrespective of health settings.

Informational continuity

Our study findings suggest that although patients viewed PHRs for diabetes and/hypertension primarily for medication procurement, they took the PHRs to other provider consultations. A qualitative study from Australia reported difference in patient perception with long-term conditions in carrying PHRs to HCPs. Patients who actively participated in their health felt they would take PHRs to their providers. However, patients who were more passive in making decisions about health did not feel the need to carry their information in PHRs to their HCPs.[48] Specifically, patients with previous experience with HCPs requesting PHRs in the past said they carried them to their subsequent consultations just that the HCP may ask for them again as they did in a previous visit. This shows that patients carrying records may not be an act of being empowered as suggested by previous literature[48,49], rather the behaviour is a result of the external motivation provided by thinking that HCPs have asked them for the records in the past and hence may ask again. This finding does not imply that extrinsic motivation is of a lower utility to the use of PHR in practice by patients than intrinsic motivation. Locke and Schattke argue that external motivation can be viewed as a means to an end or doing something for future value.[50] Similarly in this study patients carried PHRs to other consultations due to the external motivation provided by HCPs requesting PHRs, even when patients did not themselves consider their PHR necessary for communicating with HCPs. This finding points towards a reinforcing role for HCPs in improving patients and carers' carrying PHRs to health care visits and particularly important in health systems with minimal facility-based records and lack of integrated electronic records.

Multiple PHRs led patients to make decisions on which PHR to take to the consultations, leading to sub-optimal information transfer. Multiple PHRs posed difficulty in informational continuity for providers, as they may not have up-to-date information on all medications/diagnostic tests or other pertinent medical information that aid in preventing medication errors/duplication of tests. Therefore, our findings suggest an increasing risk for patient safety, especially for patients with multiple morbidities who are increasing in prevalence in Kerala[5] and similar LMIC settings.[52]

Communication

Our findings show that the value carers placed on PHRs were different from that of patients. Most previous studies from HIC combine patients' and carers' views of the acceptability and usefulness of PHR together. [,47] However, in this study it was illustrated that there was a different primary value of PHR for carers. Carers valued PHRs for its importance in communicating patients' conditions and medications during an emergency referral to health centres when the carers need to act promptly and appropriately, often without the information known only to the patient themselves. Carers or family members in similar settings who are involved in patients' healthcare may find PHRs valuable.[53]

Patient engagement with PHRs

This study showed that most patients reported not reading or looking at the PHR themselves. One possible explanation the low levels of patients' engagement with their own PHRs is that patients view PHRs as documents for HCPs. Previous literature has shown that most patients in Kerala believe that HCPs act in the patient's best interest. [3] Thus, there is an accepted notion that the documents written by HCPs need to be kept safe when instructed to do so since the doctor may ask for it next time. Additionally, since the patients are not given any instructions for how to use the PHRs for self-management, and effort is not made to write notes in a way that is useful to patients so that generally they cannot read or appreciate the information in their own PHRs. This problem is particularly acute for patients with lower levels of education who may find it even more difficult to read and understand HCPs' notes or instructions in PHRs. The potential implications of these findings are significant for Kerala as well as LMICs, given that chronic disease patients have to be able to manage their own care if they are to avoid emergency crises, long-term complications, and ultimately to take the overall pressure on the healthcare services needed to manage these patients. There is evidence that if the patients are relying on verbal information alone, the comprehension and retention of information by patients is less than that written for them to take home, and without PHRs carers may also not be able to explain follow-up or self-management needs to patients or communicate with future HCPs.[54 56] Additionally, for the patient's own use, previous studies from HIC have found that a lack of timely information regarding patient medical information such as treatment details, can increase the probability of adverse events.[57 59]

Implications for practice and research

Our findings indicate a need for the healthcare systems to consider the use of universal [4] or standard PHR[60] in continuity of care across multiple providers systems, for the prevention of medication errors and improving patient safety and for carers to support the patients during emergency acute crises. If PHRs are to contribute to handover, informational continuity and self-management, policy makers and implementers need to recognise the potential divergences of use and value of PHRs to patients, carers, and HCPs. Further, HCPs need training, implementation protocols, and monitoring and supervision for better use of PHRs for improving continuity of care. Additionally, designing easy-to-use formats and creating awareness for the patients and carers to bring the PHRs during every visit to any provider may enable better information transfer across providers. Furthermore, empowering patients and carers to communicate with HCPs regarding recording notes in PHRs may ensure better handover communication.

Similar research on how different stakeholders use and value PHRs can help to reaffirm the areas in which PHRs may be developed. PHRs may be valuable for information transfer across multiple provider systems, for the prevention of medication errors, to improve patient safety, and for carers to support patients during a health emergency. PHRs are potentially a low-cost intervention that could have a significant impact on safer and more efficient healthcare for chronic NCD patients, irrespective of any electronic record system currently envisaged in India or elsewhere. Future research should go beyond the findings of this study to examine in more depth HCPs' perceptions about the role of PHRs in self-management of patients with diabetes and hypertension.

Strengths and limitations

The use of qualitative methodology has revealed several key issues reflected in the user groups' use and perceived value of PHRs for handover communication. This is the first study to explore, compare and contrast the views of users of PHRs in Kerala. The study's credibility was strengthened using data triangulation[6] , through interviews with patients, carers, and HCPs. Our study findings present views of patients, and carers from lower socio-economic strata visiting mostly public health facilities. Therefore, the results may be transferable to other low socio-economic groups in other LMICs. The number of interviews conducted resulted in data saturation [62]being achieved for each individual group.

Due to the varied nature of PHRs used by participants in the study, the findings cannot give insights into whether a treatment prescription is valued more than a comprehensive patient-held notebook for its users. Further, the findings from the study do not show any difference for less literate patients' value for illustrated PHRs. Previous reports from maternal and child health have shown that graphically illustrated PHRs are valued more by less literate mothers. Moreover, previous studies from HIC show regardless of the type of PHR, proper use by HCPs and patients is more important for preventing medication errors.[47] A reflexive approach was taken to consider the influence of LJ who has had clinical training from Kerala. The multi-disciplinary research team trained in anthropology, medical sociology, and clinical backgrounds contributed to the analysis and interpretation of the findings to minimise bias.

Conclusion

We argue that any healthcare tool will perform differently in a complex health care system. Hence the success of maternal and child health records such as vaccination cards for information storage and transfer may not be achieved with a PHR for diabetes and/hypertension in a pluralistic health system. Our exploration of the use and the perceived value placed on PHRs found that currently the PHR served each group differently who then placed a different value on PHRs. The utilitarian focus of the health system and HCPs in Kerala may lead to more disparity in health information transfer, and a more costly healthcare system as patient safety is compromised in the short-run and complications and multi-morbidities rise in the long-term.

Quality of care improvement by better information transfer and patient safety should be a focus for managing people with NCDs in LMICs. Better healthcare governance for preventing fragmentation of care across private and public health care facilities and loss of information transfer needs to be prioritized. The current pattern of use of PHRs among participants in this study does not provide informational continuity across all HCPs. PHRs may be utilised as an adjunct to electronic health records. Further research is needed to understand better the type and content of PHR for people with long-term conditions, and support interventions to ensure information exchange between HCPs in public and private health systems, and the efficient use of hard-copy PHR along with electronic records or development of an easily and universally accessible electronic PHR. A co-design approach involving meaningful consultation with patients, carers, and HCPs for using PHRs could be a possible way to increase the engagement of patients.

Data availability statement

Data are available on request from the authors: The anonymised interview transcripts that support the findings of this study are available from the corresponding author upon request.

Authorship Contribution statement

LJ, SG, SMH, PJ and AL contributed to the study conception and design. LJ and AL designed data collection tools. SMH, SG, AL, and PJ provided guidance in the overall design and delivery of the research. LJ collected the data. LJ, SS, and LTR prepared the data and data analysis was performed by LJ and AL. The first draft of the manuscript was written by LJ and all authors contributed to critical revisions of the manuscript. All authors read and approved the final manuscript.

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Figure legends

Figure 1 HCP=health care providers

Figure 2 HCP=health care providers, PHR=patient-held health records

Table 1 Patient-held health records available with patients in this study sample

Patient-held records used in out-patient settings in this sample of patients from Kerala	
Notebook	A plain notebook which is usually used for patients with chronic conditions such as Diabetes Mellitus (DM) or hypertension, mostly in the public health care facility for HCPs to document their notes, medicines, etc.
Non-communicable disease (NCD) Booklet or patient-passbook from the Family Health Centre	Printed NCD booklets distributed from the public health care settings. These booklets have additional information for patients such as the diet plan, recommended physical activity, and health promotion messages to refrain from smoking.
Medical Prescription and lab tests	Most HCPs in outpatient settings (both public and private) give patients a written or printed copy of their medication prescription. This usually contains the patient's demographic information, diagnosis, and medication. Lab test results such as blood glucose results.
OP sheets/out-patient ticket or sheets	Patients visiting public health hospitals or health centres receive an OP ticket that is used by the HCP to write their notes (provisional diagnosis), medications, and diabetes for the patient.
Diabetes booklet from a specialised Diabetes centre (private)	A patient-held booklet with the doctor's notes, prescriptions, and additional health care information for patients from a private specialty centre.

OP=outpatient, HCP=health care providers, NCD= non-communicable disease

Table 2: Study sample characteristics

Patient Identification	Age	Marital status	Literacy	Education	Occupation	Gender	Chronic NCD
IDI 1	70	married	Literate	8th standard (secondary)	Housewife	Female	Diabetes, Hypertension
IDI 2	55	married	Literate	4th standard (lower primary)	*Thozhilorup- (a government sponsored minimum wage unskilled work for rural women)	Female	Diabetes, Hypertension
IDI 3	64	married	Literate	5th standard (upper primary)	Manual labourer in the past	Male	Diabetes, Hypertension and Cardiovascular disease
IDI 4	48	married	Literate	6th standard, (upper primary)	Thozhilorup- (a government sponsored minimum wage unskilled work for rural women)	Female	Diabetes, Hypertension
IDI 5	42	married	Literate	4th standard (lower-primary)	Skilled worker	Female	Diabetes, Hypertension
IDI 6	51	married	Literate	10th standard (secondary)	Housewife	Female	Diabetes
IDI 7	52	married	Literate	3rd standard lower-primary)	Housewife	Female	Diabetes, Hypertension and Cardiovascular disease
IDI 8	68	Married	Literate	3rd standard lower-primary)	Housewife	Female	Diabetes and hypertension
TP 1	54	Widow	Literate	Secondary education	Skilled worker	Female	Hypertension
TP 2	42	Married	Literate	Degree	Technical worker	Male	Diabetes Mellitus
TP 3	53	Married	Literate	Secondary education	Skilled worker	Female	Diabetes Mellitus
TP 4	52	Married	Literate	Secondary education	Skilled worker	Female	Diabetes Mellitus

TP 5	64	Married	Literate	Completed secondary education	Skilled worker	Male	Diabetes Mellitus
TP6	43	Married	Literate	Completed secondary education	Skilled worker	Female	Diabetes Mellitus
TP 7	46	Married	Literate	Completed secondary education	Technical worker	Female	Hypertension
TP 8	57	Married	Literate	Degree	Administrative worker	Female	Hypertension
TP 9	62	Married	Literate	Diploma	Retired (Healthcare professional)	Female	Diabetes
TP 10	63	Married	Literate	Degree	Retired (Education/teacher)	Male	Diabetes and Hypertension
TP 11	41	Married	Literate	Degree	Administrative worker	Male	Hypertension
TP 12	56	Married	Literate	Completed secondary education	Shop owner	Male	Diabetes
Carer 1	42	Married	Literate	Degree	Managerial worker	Male	Mother with Diabetes
Carer 2	41	Married	Literate	PhD	Managerial worker	Female	Parents with hypertension and cardiovascular disease (CVD)
Carer 3	32	Married	Literate	Masters	Administrative worker (Research)	Female	Mother-in-law with Diabetes, liver cirrhosis and cancer.
Carer 4	31	Married	Literate	Masters	Healthcare professional (Research)	Female	Father with Diabetes
Carer 5	32	Divorced	Literate	Plus, two	Skilled worker	Female	Father and mother with Diabetes CVD
Carer 6	48	Married	Literate	3rd standard	Skilled worker	Female	FIL and MIL with Diabetes and Hypertension
Carer 7	52	Married	Literate	8th standard	Unskilled worker	Female	Husband with diabetes
Carer 8	32	Married	Literate	Degree	Administrative worker	Female	Father
Carer 9	48	Married	Literate	12th (secondary school)	Housewife	Female	Husband with Hypertension and CVD

Carer 10	56	married	Literate	Tenth standard	Unskilled worker	Female	Husband
Carer 11	45	Married	Literate	12th (secondary school)	Skilled worker	Female	Mother-in-law with Diabetes
Carer 12	28	Single	Literate	Tenth standard	Skilled worker	Male	Father
Carer 13	32	Married	Literate	Tenth standard	Skilled worker	Male	Mother
Carer 14	56	married	Literate	12th (secondary school)	Skilled worker	Male	Husband
Carer 15	47	Married	Literate	12th (secondary school)	Housewife	Female	wife

Healthcare providers

Identification	**Gender**	**Qualification**	**Job designation**	**Years of experience**
HCP1	Male	Graduate in Medicine	Doctor in PHC	1 year and 5 months
HCP2	Female	Graduate in Nursing	Staff nurse in PHC under NUHM	2 years
HCP3	Female	Diploma in Nursing	Staff nurse in PHC	3 years
HCP 4	Female	Postgraduate in Medicine	Doctor in CHC	12 years
HCP5	Female	Postgraduate in Medicine	Doctor in FHC	less than a year
HCP 6	Female	Postgraduate in Medicine	Doctor in FHC	15 years
HCP 7	Female	Postgraduate in Medicine	Doctor in administrative cadre	6 years
HCP 8	Female	Diploma in Nursing	Staff nurse in FHC	4 years
HCP 9	Female	Diploma in Nursing	Staff nurse in PHC	4 years
HCP 10	Female	Graduate in Medicine	Assistant Surgeon	10 years
HCP 11	Male	Graduate in Medicine	Doctor in PHC	3 years
HCP 12	Male	Postgraduate in Medicine	Doctor in administrative cadre	less than a year
HCP 13	Female	Graduate in Medicine	Medical Officer in hospital	20 years
HCP 14	Male	Graduate in Medicine	Doctor in FHC	8 years
HCP 15	Male	Postgraduate in Medicine	Doctor in TH hospital	6 years
HCP 16	Female	Postgraduate in Medicine	Doctor in administrative cadre	3 years
HCP 17	Male	Graduate in Medicine	Doctor in FHC	2 years

PHC=primary health centre, FHC=family health centre, CHC=community health centre, NUHM=National Urban Health Mission, TH=Taluk Hospital

Table 3 Themes and quotes

Theme	**Illustrative quotes**
	We ask them to bring the notebook for next month's visit. We make sure that they carry them here (health centre) for monthly medication. Quote 1, HCP 14
Use of PHR in everyday practice	There is like a huge number (of people) in primary care, the dire need is to cater to them and finish the consultations soon. Then these issues as some doctors who work really hard will continue their work, but some people are there don't work at all. Therefore, like some sort of hierarchy, which makes some work more, and they may have difficulty to give more care to patients. Then, there is no method anywhere, to improve the staffs those who work less. Even if they do not document well, there is no checks or penalty. In this situation, everywhere there is an issue like workload. It is only because of the difference in work not due to overwork. There are some systems where human resources are less, which is another issue. Quote 2, HCP 12, doctor with administrative and clinical responsibilities
	If I come for fever or something like that, I will not bring this book [notebook]. I will get the medicines written on the prescription paper ("cheetu"). This book (notebook) is only for things like sugar [local term for diabetes]. Everyone has to bring a book to get medicines [diabetes/hypertension medicines]. Quote 3 (IDI 6, Female, 42 years)
	But not everyone (patients) will carry records all time. There may be many papers also at times. Imagine having a long queue of patients outside your room and then someone brings in many papers, it will take time to go through them. I think for new patients we will have to sit through and check them, but with regular patients, it may be one or two here and there. Quote 4 HCP 1
	If somebody asks for some record for a check-up, I have to search everywhere unless it is not arranged properly or kept in chronological order. If it is arranged in a file, my husband or mother-in-law can take it in my absence. Like for my mother-in-law, before we visited the Hepatologist, I arranged her records according to the date to understand the progress. Everything was available and it saved me a lot of going back and forth with records. However, I may not be always there in my home, and I can tell them through the phone that I

	arranged it as on date. That much specific it is and so it helps me or others, each time with all the visits to doctors. Quote 5, Carer 3, 32years, Female
Perceived value of PHR for themselves	But some patients may come without a prescription and tell three tablets for blood pressure, four tablets for some other problem, three yellow tablets, or round tablets. They are the more problematic persons for us. It becomes difficult then, they are having medicines for BP, but we don't know which one and we may have to insist them to go and bring the papers. For them, it is their medicine, they probably don't realise that many tablets are round. Quote 6, HCP 6, doctor in FHC
	In situations, where a patient doesn't know the name of the drug or do not know if they have been taking medicines for BP, even if they say they are saying they take medicine and they don't know the name or dose or not have any documents like a past prescription, we consider him /her as a new patient. Quote 7, HCP 12, Dr in FHC
	Once a COPD (Chronic Obstructive Pulmonary Disease) patient came to FHC, we were not aware that he had this condition (COPD). The patient did not mention it nor did have any records with him. We (the doctor) prescribed him a particular antihypertensive. Later we understood he is a COPD patient. Then he came onto the next visit, with the prescription of a pulmonologist and we changed the anti-hypertensive for him. So now, the whole treatment was affected. Quote 8, HCP 5
	At first, because the private hospital is nearby, and I regularly visit the doctor there for my pressure (local term for hypertension). Since I came to diagnosed, I had pressure I have been taking medicines from the same doctor, but it was expensive. Then I came here (FHC), mainly because this FHC has started giving medicines for pressure free. So, I bring the book to show here and get the medicines. Quote 9, IDI6, Female, 51years
	I was in the hospital for 30 days…. I used to go there (hospital) for my treatment sometimes, but it takes one whole day, travelling, and the queue and then somehow when we see the doctor, we just want them to write the medicines and go back. So then, I came here (FHC) and they gave me a book, wrote my details in them, and told me to bring it every time when I come here for medicines. Quote 10, IDI2,55 years, Female

	It’s better to have records with us, without records we won’t have proof to tell or to show. In my case with our parents' means, they won’t be remembering about their conditions [when visiting casualty]; they will be in a different emotion or situation when they reach hospital, so they won’t be able to communicate it properly. Quote 11, Carer 2, 40years, Female
Where practice and value conflict	Yes, I do carry the paper. Mainly for the eye doctor to see how much is my” sugar” [local term for blood glucose value and diabetes]. They usually ask for that. They will ask you what the previous value was or when was your last check-up, things like that. Quote 12, IDI 6, Female, 42 years
	I thought that this is for them (healthcare providers) to write (“ezuthi pathipikuga”). Quote 13, IDI 2, Female, 55 years
	Everyone knows there is very rush in the primary health centre (PHC). Initially, it will take more time, once the database (electronic health record) is fully activated, it will be very easy. Only at the pharmacy do they (patients/carers) get a printout, for the remaining [places] everywhere it is paperless. So, patients need not carry any papers after eHealth is completed. Quote 14, HCP7, doctor in administration
	No, they don’t ask like the names of medicines and for any papers for diabetes. They will just ask if I am taking any medicines regularly and then I tell them that I take medicines for pressure and cholesterol. Then they will say that is ok. Sometimes they will ask for medicine, but I can’t say that always. Mostly they don’t ask. Quote 15, TP
	I ask the nurse when they check and write the BP in the book, like if it is normal. I don’t look at the values but hearing from them if it is normal, I am ok. Quote 16, IDI 5, Female, 51 years
	Yes, she (daughter-in-law) checks the test result also checks the medicines provided in the slip or the book. I mean she knows my medicines. Like if it is changed, increased, or decreased and she will tell me that it is decreased or not. Quote 17, IDI 5, Female, 51 years

4.7. Chapter Summary

This chapter has addressed the second research question on how patients, carers and HCPs use current PHRs for handover, informational continuity and self-management in Kerala. This chapter presented the results of comparing the current use and value of PHRs among patients, carers and HCPs. The findings suggest that while all user groups use and value PHRs, there are differences in how they perceive their use and value.

For instance, patients do not carry all PHRs to HCP visits and HCPs reported sub-optimal recording in PHRs. Each user group placed a different value on PHRs. Patients value PHRs as transactional tools for their medicines, carers value PHRs for communication with HCPs in emergencies and HCPs value PHRs for clinical decision-making and prevention of errors. Divergences in the use and perceived value of PHRs implies sub-optimal effectiveness and usefulness of PHRs for handover communication, informational continuity of care and self-management in Kerala. This is because for PHRs to function effectively as tools for handover communication and information transfer, both patients and HCPs must value PHRs for the same, as PHRs contain patient medical information, which is a source of reliable information for HCPs to make clinical decisions. However, if patients do not see the value of PHRs for HCPs, they may not carry the relevant PHRs. To improve the effectiveness and usefulness of PHRs, both patients and HCPs must recognize the importance of PHRs for handover information and ensure that they are carried and recorded by HCPs in all healthcare visits.

Additionally, both patients and HCPs do not value PHRs for communicating regarding self-management. HCPs in this study reported not using PHRs for communicating self-management activities with patients and patients did not use nor placed any value on PHRs for their self-management. Both parties do not value PHRs for self-management, which leads to limited use of PHRs for self-management among the participants interviewed.

Chapter four has therefore shown that patients do not engage with PHRs for self-management, but did not provide an in-depth explanation of why patients do not engage with PHRs. The next chapter uses the patient interview data to explore in detail the reasons for why patients do not engage with current PHRs for their self-management. By doing so, the next chapter builds on the findings of this chapter and provides a deeper understanding of the challenges and barriers that prevent patients from engaging with PHRs for their self-management.

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CHAPTER FIVE

A QUALITATIVE ANALYSIS OF CONTEXTUAL FACTORS THAT INFLUENCE PATIENTS' ENGAGEMENT WITH PATIENT-HELD RECORDS.

5.1. Chapter Preface

Chapter three highlighted the gap in evidence from the literature regarding using PHRs for self-management of NCDs in LMICs. No studies reported use of PHRs for self-management from India. Findings from Chapter four suggested that the patients interviewed for this study in Kerala viewed PHRs as transactional tools that help them procure medicines, and they did not see a role for current PHRs in their own medication management at home or self-management.

In order to establish why these patients did not engage with PHRs for self-management, this chapter reports the findings from the patient interviews on the factors that influence their lack of engagement with PHRs for self-management. This chapter is aligned with the thesis's overall aim to understand the determinants of the use of PHRs for self-management in public health settings in Kerala, which may facilitate the future development of supportive interventions for patients' engagement with PHRs.

This chapter has been written in paper format for submission to a peer-reviewed journal.

Title:

A qualitative analysis of contextual factors that influence patients’ engagement with patient-held records.

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5.2. Abstract

Background

How and/or whether patients engage with patient held records, and what influences this, is an under-researched topic. In tandem, patients' self-management is an important but complex part of healthcare. In some settings such as Kerala, India patients are given medical advice during consultations and/or documented medical information in patient-held records (PHR) for the purposes of self-management. However, to date, the role of contextual factors such as health system factors in influencing self-management and the role, if any, played by PHRs is unknown.

Methods

As a part of a qualitative study with patients, carers and health care providers (HCP) exploring their experiences with current PHRs, 20 qualitative interviews with patients with diabetes and/or hypertension from three different districts of Kerala, India were analysed using thematic analysis.

Results

Three key contextual factors influenced patients' lack of engagement with PHRs for self-management in Kerala: health-system factors, patient-level factors and socio-economic factors, including environmental factors. Firstly, patients described visiting different health care providers in their care pathway for diabetes/hypertension due to the pluralistic health system. This led to different advice being given, alongside multiple PHRs, which influenced how patients viewed self-management instructions and PHRs. Secondly, during consultations with HCPs, providers document patient information rather than being used to communicate or recommend the use of PHRs for self-management used PHRs. Consequently, patients perceived PHRs as documents for HCPs rather than as a tool for self-management. Thirdly, patients' socio-economic and cultural contexts influence their self-management and hence limited engagement with PHR

for self-management. Most patients with lower education and lower ability to pay reported performing only minimal self-management activities such as going to follow-up visits, buying long-term medicines and salt restriction. Women with lower education found it difficult to manage self-management activities, specifically physical activity, between work and household chores.

Conclusion

Overall, the lack of patient engagement with PHRs for self-management in Kerala is a result of the complex interplay of health-system, patient-level, and socio-economic factors. These findings emphasize the need for locally adapted support interventions for using PHRs for self-management that are reflective of patients' contexts. There is a need to acknowledge that many self-management activities may be difficult to follow with issues such as lower ability to pay and lack of space and time for physical activities. This has implications for developing interventions for self-management and for patient engagement with PHRs in Kerala and similar LMIC settings. Therefore, a co-designed PHR for patients with diabetes and hypertension may help to identify priority self-management areas for patients and improve patient engagement with PHRs and overall healthcare.

5.3. Introduction

Long-term conditions such as diabetes or hypertension necessitate patients having to adapt to living with and managing their health condition. Models of managing long term conditions such as the Chronic Care Model (1) and the Innovative Care for Chronic Conditions Model of the World Health Organization (WHO)(2) focus on the need for long-term relationships between healthcare providers (HCPs) and patients and/or their families for self-management support. (3-5) Studies have reported that patients with diabetes and/or hypertension in India do not have regular support from the health system in managing their care. (6-8) Kerala, the location of the present study, has an increasing burden of diabetes and hypertension (9). This increase has prompted an attention on the part of government led public health systems towards improved screening, the delivery of adequate health education to patients, and the availability of medications for diabetes and hypertension in public health care facilities.(10) However, self-management support is minimal in the public health system; and operates on providing information on, and an awareness of, risk factors of non-communicable diseases and patients receiving verbal instructions and patient-held records (PHRs) during consultations. Current self-management support in the National Non-Communicable Disease programme is also focused on improving information and awareness through printed information, education, and communication materials such as posters, leaflets, or booklets.(11) Humphries et al described in their clinical handover study in Kerala and Himachal Pradesh States, how HCPs provided patients and/or carers with patients' medical information in the form of PHRs.(12) Although these records contained patients' medical information such as their blood pressure or blood glucose levels, many patients and carers left the outpatient settings without clear information on or understanding of how to bring about any changes to the patient's self-management.(12)

Numerous factors influence the process of self-management, both internal and external to the patient. Broadly, these factors can be divided into patient level, family, environmental, condition-related, structural and health system factors. (13, 14) One part of developing self-management support interventions such as PHRs that can potentially engage patients and carers lies in better understanding contextual influences. (15)

Studying context is increasingly accepted as a vital aspect of health systems research. (16) Additionally, implementing and embedding self-management support tools into regular clinical practice in public health systems is dependent on contextual factors. (17, 18) One way to understand the influence of contextual factors is to explore how patients in their everyday lives practise self-management, and how they currently use PHRs for themselves.

We undertook an exploratory (19) descriptive (20) qualitative study with data collected through semi-structured interviews conducted with patients with diabetes and/or hypertension, carers, and HCPs regarding each group's experiences with PHRs in outpatient settings in Kerala, India. The study found that the patients interviewed did not engage with current PHRs for self-management in diabetes and hypertension (21). A previous framework (22) for developing maternal and child health records suggests tailoring the content of PHRs based on the function and anticipated capacity of the users. Efforts to strengthen the capacity of users generally focus on improving the content and functionality of PHRs (23). However, due to the long-term nature and complexity of self-management for patients with diabetes and hypertension, we anticipated that improving notes alone might not improve uptake of PHRs for self-management. It is; instead, key to understand why patients may not engage with PHRs for self-management. This paper therefore presents an analysis of what factors influence the lack of engagement with PHRs for self-management amongst patients with diabetes and/or hypertension in our study.

5.4. Methods

Study design, setting and recruitment.

The details of the qualitative study exploring the role of PHRs in the care of patients with diabetes and/hypertension in Kerala among patients, carers and HCPs have been published elsewhere (21). For this paper, we reanalysed the 20 patient interview data to explore why patients do not engage with PHRs for self-management.

Briefly, the qualitative study was carried out in Kerala from February to November 2020 in primary care settings. A total of 52 participants were recruited; 20 patients with diabetes and/hypertension, 15 family members and 17 HCPs were interviewed. Patients were eligible to participate in the study if they were more than 18 years of age, with a diagnosis of diabetes or hypertension for which they were undergoing medical treatment. Purposive sampling (24) was used to ensure we recruited participants seeking care from a range of health settings (public, private) and participants belonging to low socio-economic groups for the study. We employed two strategies for recruiting participants. In the pre-COVID phase (February 2020), nurses at FHCs informed patients about the research study and LJ conducted face to face interviews with interested patients after obtaining consent. During the COVID phase (March-November 2020), convenience sampling (25) identified patients from public and private healthcare facilities who were interviewed via telephone, using a topic guide. Topics included participants' accounts of the process of being diagnosed with diabetes/hypertension, accounts of subsequent treatment; the experience with PHRs, communication with HCPs, and accounts of self-management. All patient interviews were done in Malayalam and translated into English. A postdoctoral fellow (LTR) checked all the transcripts for any errors. Additional demographic details were collected verbally, to describe the study sample and contextualise participants' reported experiences.

Data analysis

The analysis for this paper is as follows. The line-by-line coded patient interview data were grouped under potential themes. Potential themes and sub-themes relating to reasons for not using PHRs for self-management were re-grouped together and discussed with the second author (AL). From this, we were able to identify the contextual influences for patients' lack of engagement with PHRs for self-management. The themes that were identified during this process were then organised under three main contextual factors: health-system factors, patient-level factors, and socio-economic factors. (Table 1: Organising headings and explanation)

Table 1: Organising headings and explanation

Organising headings	Emergent theme	Explanation
Health system level factors	"Navigating the care system"	The theme that shows the influences of the pluralistic health system, how that leads to possession of multiple PHRs and how that shapes patients' views of PHRs
Patient-level	"Patient and healthcare provider interactions"	This theme details patients' perceptions and experiences of PHRs for HCPs' records. Patients have formed their views on PHRs based on their interactions with various HCPs, different PHRs they have gathered through their illness journey, selectively engaging with self-management practices suggesting that the theme relate to aspects that patients can potentially influence through their attitudes and behaviours.
Socio-economic	"Agency over illness and ownership of health"	The theme details structural factors, such as financial context and the challenges of managing health in conjunction with employment Given that they are structural, patients may have limited ability to change or influence these socio-economic factors, making them broader contextual elements that affect healthcare experiences

Ethics

Ethical approval for the overall qualitative study (21) was received from the Centre for Chronic Disease Control, New Delhi [CCDC_IEC_05_2019] and the University of Birmingham [ERN_18-1933].

5.5. Results

Participant characteristics are summarised in Table 2 (reproduced from the qualitative study reported elsewhere (21)). Twenty females (n=14) and males (n=6) were interviewed. Participants were married/widowed and literate. The participants' formal education levels varied and six of them had only primary education. Of the 20 patients, ten reported to have a Below Poverty Line (BPL) card indicating lower levels of economic condition.

Table 2: Patient characteristics

Patient Identification	Age	Marital status	Literacy	Education	Occupation	Gender	House	Ration card	Chronic NCD
IDI 1	70	Married	Literate	8th standard (secondary)	Housewife	Female	Own	BPL	Diabetes, Hypertension
IDI 2	55	Married	Literate	4th standard (lower-primary)	Factory worker	Female	Rent	BPL	Diabetes, Hypertension
IDI 3	64	Married	Literate	5th standard (upper primary)	Manual labourer in the past	Male	Own	BPL	Diabetes, Hypertension and Cardiovascular disease
IDI 4	48	Married	Literate	6th standard, (upper primary)	Thozhilorup-a government sponsored minimum wage unskilled work for rural women)	Female	Own	BPL	Diabetes, Hypertension
IDI 5	42	Married	Literate	4thstandard (lower-primary)	cook	Female	Own	BPL	Diabetes, Hypertension
IDI 6	51	Married	Literate	10th standard (secondary)	housewife	Female	Own	APL	Diabetes
IDI 7	52	Married	Literate	3rd standard lower-primary)	housewife	Female	Rent	BPL	Diabetes, Hypertension and Cardiovascular disease
IDI 8	68	Widow	Literate	3rd standard lower-primary)	housewife	Female	Rent	BPL	Diabetes and hypertension
TP 1	54	Widow	Literate	Secondary education	Packaging section	Female	Rent	BPL	Hypertension
TP 2	42	Married	Literate	Degree	Electrical technician	Male	Own	APL	Diabetes Mellitus

TP 3	53	Married	Literate	Secondary education	Packaging section	Female	Rent	BPL	Diabetes Mellitus
TP 4	52	Married	Literate	Secondary education	Packaging section	Female	Rent	BPL	Diabetes Mellitus
TP 5	64	Married	Literate	Completed secondary education	Security	Male	Rent	APL	Diabetes Mellitus
TP6	43	Married	Literate	Completed secondary education	Packaging section	Female	Own	APL	Diabetes Mellitus
TP 7	46	Married	Literate	Completed secondary education	Quality check	Female	Own	APL	Hypertension
TP 8	57	Married	Literate	Degree	HR officer	Female	Own	APL	Hypertension
TP 9	62	Married	Literate	Diploma	Retired Nurse	Female	Own	APL	Diabetes Mellitus
TP 10	63	Married	Literate	Degree	Retired Assistant Professor	Male	Own	APL	Diabetes and Hypertension
TP 11	41	Married	Literate	Degree	Accounts Executive	Male	Own	APL	Hypertension
TP 12	56	Married	Literate	Completed secondary education	Grocery shop owner	Male	Own	APL	Diabetes Mellitus

BPL=Below poverty line, APL=Above poverty line

We now discuss the contextual influences influencing patients' engagement with PHRs for self-management, arranged into three sections. (Fig 1). Firstly, ***navigating the care system*** illustrates the ways in which patients' navigations of a pluralistic healthcare system influence how they currently use and view PHRs, and the place of these in self-management. Secondly, ***patient and healthcare provider interactions*** explore how interactions with HCPs (during consultations) influence their views and use of PHRs for self-management. Thirdly, ***agency over illness and ownership of health*** demonstrates how wider socio-economic and structural contexts can curtail patients' agency over their self-management, and thereby influence their use of PHRs. Illustrative quotes for these themes are presented in Table 3.

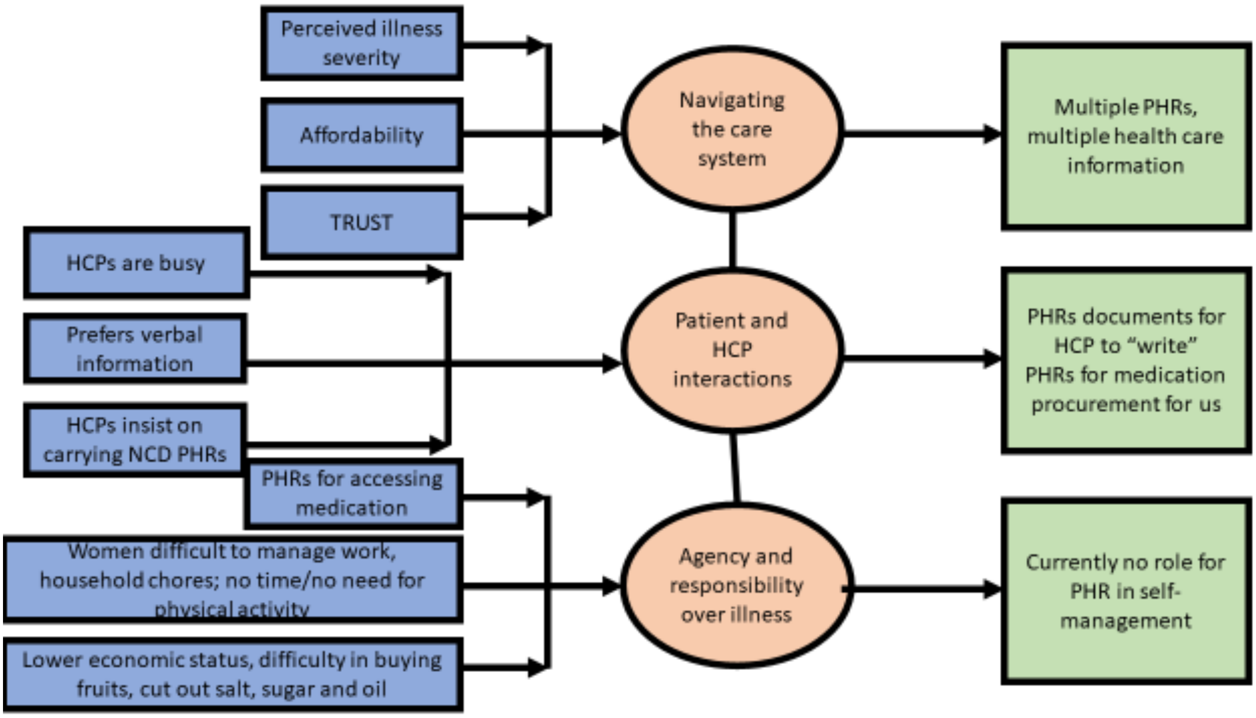

Fig 1: Contextual influences on patients' lack of engagement with PHR for self-management. The central circles represent the three contextual influences on patients' engagement with PHRs from the interview data; the blue boxes indicate the reasons illustrated by the patient data for lack of engagements with PHRs and the green boxes refer to how each of the contextual influence possibly led to patients' lack of engagement with PHRs.

Navigating the care system

It was clear from the semi-structured interviews that patients do much work to manage their care pathway due to the need to navigate the pluralistic structure of the healthcare system. Patients reported receiving PHRs from the different healthcare facilities they visited. "I have three books from medical colleges and a lot of papers from other doctors," is how one patient explained having multiple PHRs. This navigation of the health system was particularly highlighted by participants' descriptions of how they had received their diagnosis of diabetes and hypertension from HCPs. (q1) Many participants recounted having received their initial diagnosis at one facility and subsequently deciding to continue treatment at either a different public or a private health care facility. Participants described changing facilities because the diagnosis of diabetes or hypertension may have occurred opportunistically when patients visited HCPs for other ailments. (q2) Due to the absence of a strict gatekeeping mechanism in primary care, patients can choose any healthcare facility for their care. In this study, participants often chose a health care facility based on their perceptions of the severity of their health condition. Thus, the process of seeking care often involves seeking a second opinion from other HCPs (private or public). Participants reported that these HCPs were recommended by friends or family or through a referral from another HCP (q 3). Another critical factor for navigations reported by participants was financial constraints. They prioritise the affordability of long-term medications for diabetes and hypertension and choose which health care facility to go to accordingly. (q4)

Trust

It was clear from the interviews that when patients have more than one condition, they usually go to other HCPs or specialists in hospitals rather than primary care doctors. They reasoned that based on the perceived severity of the condition, the care they received during the acute phase in the hospital, and the increased trust placed in private or public hospitals, they should continue treatment with the specialists in the hospitals. For example, one participant recounted being treated at a private hospital for stroke and described that he now trusted the HCPs at this private hospital more than other HCPs to take care of his stroke management (q 6).

A few patients mentioned not trusting the medicines available in the public health facilities. They felt that private HCPs prescribe "better medicines" that work for them. (q7)

In summary, participants frequently changed their HCPs and healthcare facilities during the care pathway, navigating the pluralistically structured health system.

Patients change HCPs due to the varying degree of trust they place in HCPs in public and private healthcare systems, the perceived severity of their healthcare issues, and the affordability of treatment. The process of seeking care from different HCPs was described as helping the patient confirm the diagnosis and decide what kind of medicine they want to take or whether they wish to completely stop the medication, as they have to take them long term. Since different healthcare facilities and HCPs can result in further medical advice and multiple PHRs, patients make decisions regarding which documents to carry across providers (q8). These navigations are crucial to the question of how patients engage with PHRs because different healthcare facilities give patients different records (q5) and different HCPs provide different medical advice. Therefore, this navigation of the healthcare system early on in their illness journey influenced patients' subsequent self-management and underpinned their lack of engagement with the multiple PHRs.

Patient and healthcare provider interactions

Patients’ and HCPs’ interactions during consultations influence patients’ views of *who* PHRs are for - their own self-management or for HCPs – thereby also shaping their lack of engagement with the records. Participants reported being aware of the need for both medication and follow-up visits, as doctors had told them of these during the consultation; they reported that HCPs explained they need to bring PHRs when coming to public health centres for their diabetes/hypertension appointments. (q 9)

Medication procurement (PHRs for themselves)

Most patients returned to primary care (public health centres), or ESI (Employees' State Insurance) clinics for treatment for diabetes and/or hypertension while continuing their treatment for other conditions at hospitals. Participants said that they came for monthly healthcare visits to meet the HCP, refill the prescription, and buy the medicines for another month as they have been instructed to by the public health facilities (q 10). Participants reported that health centre staff informed them to bring PHRs when coming for monthly medication procurement from public health centres. Most patients in this study described PHRs as a tool for enabling them to get medicines from the public health centres, as described in this quote “That book is for here (family health centre). So, I bring it here to get the medicines, that is all. I don't take it anywhere else or look at it." IDI 1

Documentation

Additionally, it was clear from our interviews that most participants viewed PHRs as primarily for HCPs to document in during the consultation. The consultation process described in quote 11 illustrates the interactions between patients and doctors.

Most participants in this study recounted not asking for any medical information from HCPs. They said they did not ask for any explanation of any changes in their test values or in medicines. They did not consult PHRs for their blood pressure or blood sugar values. Some of the reasons highlighted by patients for not asking for explanations or asking for information from HCPs were their own time constraints, the perceived workload of the doctors, and a perceived lack of control over the results. (q 12) They also described how they received information from their carers who looked at the PHRs at home and explained if the medicines were changed or if the values were "high" (q13). These accounts illustrate that participants viewed PHRs as documents *for* doctors, not for themselves. (q 14).

This finding contrasts with one patient who sought treatment at a specialised diabetes centre, where HCPs (q 15) used the PHR with additional information to provide self-management support.

In summary, from the perspective of the patients interviewed, PHRs emerge as documents for HCPs to write in during consultations, rather than for themselves. Patients therefore did not see PHRs as tools for self-management, and hence they did not engage with them for this. They did, however, see them, as transactional tools that help them in medication procurement, and that aligns with the finding that many participants felt that taking medicines for diabetes and hypertension is often the only essential self-management activity.

Agency over illness and ownership of health

This theme describes the socio-economic and cultural contexts that influence and constraints patients' self-management activities, and in turn contribute to their lack of engagement with PHRs for self-management. Although patients valued PHRs primarily for obtaining access to medications, they did not consult their PHR for their daily drug intake. In addition, whilst some participants reported adhering to the prescribed dose and frequency, most said they adjust their medications without medical direction. For example, one patient described that they may not take a dose if they feel their blood pressure is low or they may increase the dose of the drug themselves based on their symptoms. (q 13)

Some participants further explained how they had stopped allopathic medicines and started non-allopathic treatments such as Ayurveda or Homeopathic treatment. * (Refer Box 1 for description of Ayurveda) Patients reported opting for Ayurveda or Homeopathic remedies for diabetes and hypertension when accessing primary health centres was challenging. Further, this choice is influenced by fears of allopathic medication side effects, financial constraints, allopathic medicines not working for them and reluctance to start insulin. (q 14) A few patients mentioned other reasons such as difficulties in storing insulin (lack of a refrigerator), lack of skills in administering insulin or lack of family support to remind or administer insulin.

Most participants with primary level education reported that they had not read the PHRs themselves. (q 15) They reported that they relied on verbal information given by HCPs during consultations or if they have carers or other relatives with education to explain their medical information in the PHRs such as changes in dose of the medicine.

Most participants reported making the monthly visit to public healthcare facilities for follow-up visits. They described needing to make necessary arrangements at work and home before visiting the public health centre. Some participants mentioned the health care facilities being far away, difficulties in visiting every month, and the time taken at each of the visits make going for follow-up a difficult task. (q 16)

When explaining how they had changed or how they managed their diet, participants mostly recounted focusing on restricting salt or sugar at medical direction. Participants also explained making a shift from eating rice to having chapattis. Most participants did not recount increasing vegetable or fruit intake. (q 17) A few participants, particularly those with financial difficulties, expressed an inability to buy fruits as they were costlier and hence unaffordable. (q 18)

However, crucially, in the case of physical activity, most participants said they either did not have time or did not feel the need for this. Some felt that their work or/and household chores gave them physical activity. It is important to note here that the majority of participants in our dataset were women and they explained how they have to go to work and manage their household chores.

There is a further important aspect that these discussions of a lack of physical activity highlight. Participants explained how they felt helpless in controlling their condition. This had led them to control their diet, by decreasing or cutting salt, sugar, or oil as this was accessible for them, and by adjusting their medications as noted above. Each of these actions denoted an exercising of agency against a wider background of a lack of agency over their overall health and therefore PHR was limited to its use in medication procurement. (q 19)

A few women participants, particularly those who reported financial difficulties, discussed how they were stressed about carrying on with their daily lives. They explained that they try to follow advice received on diet but felt that despite their efforts could not make sense of why the disease was not being controlled despite their efforts. (q 20)

However, it is important to note demographic differences played into the sense of ownership that participants felt they had over their health. Those with more education (secondary level or more), seeking care from private health facilities explained that they could manage their condition well. They were keen to utilise the facilities available to them at their workplace or could afford to go to a gym. (q 21)

In summary, female participants, particularly those with primary education and low economic conditions struggled with balancing their work and household chores, and self-management needs to be seen against this background. They seemed   to attend follow-up visits with HCPs and manage to access free/affordable medications from public health centres. However, they seemed to be minimally adhering to self-management activities such as diet or physical activity as verbally informed by HCPs. As these self-management activities are constrained, patients do engage with self-management and hence do not see PHRs as a useful tool for engaging in self-management practices.

Box 1: Description of Ayurveda

Ayurveda, which means 'Science of Life,' derives its name from the Sanskrit words 'Ayur,' meaning life, and 'Veda,' meaning knowledge and takes an integrated view of the interactions among the physical, mental, spiritual, and social aspects of human life. India has a tradition of using Ayurvedic medicines and has established a government department for complementary and alternative medicine (CAM) known as 'AYUSH' (Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy).[2]

In the public healthcare system, qualified and registered Ayurvedic practitioners are stationed in selected primary care facilities in Kerala and other states in India.[2,3] They administer a programme named "Jeevani" specifically designed to cater to patients with diabetes.[4]

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Table 3: Themes and illustrative quotes

Themes	Illustrative quotations
Navigating the care system This theme highlights the pluralistic health system context in which patients seek care for their condition, gather information on self-management, how these factors seem to influence and underpin their use of PHRs	I used to go to XX. That's a sub-centre. Now they changed something I don't know. When we went to get medicines, they informed to us that since we are from XX (place), now we have to get medicines from here (family health centre). I don't know why. Then as it was difficult to travel from my place to here (family health centre), I started to go for Homeopathic medicine alone. The doctor from Homeo (homeopathic medicine) said once you start having medicines for pressure (hypertension) you cannot stop immediately and so that is why we came here today. **Q1** IDI 4, 48 years, Female
	The first time, I was going for a job with "thozillurap*". At that time one day, I had a wound when I stepped on a stick. I immediately washed my leg clean. I had no problem for two days. After that, my leg was swollen. Then I went to XX health centre, and they checked my sugar. I was told that I had sugar, I never had it before. That is how I knew. Then I went to the hospital, as I thought it was better. That time it was Dr S at the hospital. He was a good doctor. Part of my feet, under my feet was swollen. It had become "septic". He cut the edges of the wound and took out the pus and they covered it well. I was in the hospital for 30 days. They controlled my diet and regulated my pressure. I used to go there for my treatment sometimes, but it takes one whole day, travelling, and the queue and then somehow when we see the doctor, we just want them to write the medicines and go back. **Q2,** IDI 2,55 years, Female
	I did not get any doctor's reference. My husband's friend told us about that centre is particularly the good treatment over there. It is like a centre for Diabetes. Sometimes we need to see whether the other doctors also say the same things about my condition. **Q3,** TP3
	I have stopped medicines in the past, that time I could not buy medicines every time. This is like we have to take medicines continuously. Once I had severe headache and the doctor scolded me for not taking medicines. I told him I cannot buy from this hospital; it is costly. So, he told me to go to the FHC and then I came here to it free. **Q4** IDI 2, 55 years, Female

	After 5 years I changed from there (X hospital) and came here (FHC). I cannot buy medicines for long time; I don't have money to do that…. I do not have earnings, my husband died, and I stay alone with my mother-in-law. Q 5, IDI 8, Female
	I have like three books from X, Y college [tertiary public hospital] and here [FHC]). I carry them to each of these places when I have to see doctors. **Q5** IDI 7, Female, 52
Trust This sub-theme suggests the contextual influence of patients' trust for HCPs/healthcare facilities and its possible impact on how trust seems to influence their health care decisions and how they view PHRs.	Yes, I have shown it to Medical College [tertiary public hospital]. I actually did my scans and all check-ups from the medical college. I have got someone who knows me in this hospital [private]l. This relative recommended I take medical care from this hospital. So, I went to see this neurosurgeon doctor [in the private hospital]. This doctor has actually worked in another Indo-American hospital, so I felt more trust in this doctor. **Q6** (IDI 3-Male, 64years).
	Now I am not going to the PHC for getting the treatment. The medicines I took from there (PHC) did not help me. Now, I am going to ABC (a private tertiary hospital). There is another doctor there who I consult. I take medicines for both sugar and thyroid from there. **Q7** TP4, Female, 43 years
	Sometimes I take the OP ticket (a single sheet of paper, which serves as the request slip for lab investigations, lab and blood results will be documented on it, prescriptions and doctor's notes) with me or sometimes the prescriptions so I show them that. Doctor will look at that (prescription) and will write anything necessary into that book. **Q8** TP 1, Female
Patient and healthcare provider interactions This theme explores how HCP consultations appear to influence patients' views of current PHRs for themselves and for HCPs.	I come to FHC every month because doctors and nurses have told me to that I have to take BP medicines regularly and cannot be missed. **Q 9,** (IDI 3-Male, 64years).
	When I first came here, they asked me to get a notebook for writing my details. The girl in the pharmacy wrote everything (my details) and then I saw the doctor and the pharmacy girl gave me medicines. She asked me to bring the book every time when I come here for medicines. So, I bring the book for getting medicines.

	Q 10(IDI 3, 64 years, married, Literate 5th standard (upper primary), Manual labourer in the past, Male, Diabetes, Hypertension and Cardiovascular disease)
	That book is for here (family health centre). So, I bring it here to get the medicines, that is all. I don't take it anywhere else or look at it. IDI 1
	Usually, when I go for getting my medicines, the doctor will ask if there are any problems. I will tell him like if my leg hurts or any other issue. He will ask if I was having pickles or poppadum's if the BP is high. He will be writing in the notebook and tell that he has written medicines or if there are some tests to be done. **Q 11,** IDI 8
	There is a long queue in the clinic, doctor will be busy and if I start asking this and. that they will get angry, not just them people waiting outside also will be irritated, there is a long queue everyone wants to see the doctor and buy medicines and go. Q12
	My son's wife has two sisters who are both, working as a nurse, so they check my pressure and check this book (notebook for FHC) and slip (out-patient slip-on which doctors' write their notes) and say that I am having high pressure. They also scold me for having everything (food), but it's been years I have not been using poppadum and pickle. **Q12** (IDI 1, Female,70 years)
	That book is for here (family health centre). So, I bring it here to get the medicines. **Q** 13 IDI 1, Female,70 years)
	The book, I thought was good. It had a lot of information on diet and exercise. In addition, the doctor gave me a lot of information or something more like counselling. He said that medicines are important for me to achieve control and keep track of sugar. I need to exercise also regularly. At least one hour of exercise every day will help me to keep sugar in control. **Q 14** TP6, 43 years, Female, Literate, packing section in factory
Agency over illness and ownership of health This theme demonstrates how wider socio-economic and cultural contexts can curtail patients' agency over their self-management and thus seems to influence the lack of engagement with current PHRs for self-management	For a long time, I followed as per their direction to take medicines, but I realized the half dose might not work for me. Therefore, gradually I increased the dose to one. If any issues happen, then I will consult a doctor and change the combination of medicines. **Q 15** TP 9

	About sugar, it became reduced (the blood sugar value), so I stopped taking medicines from ESI. In addition, I thought when we take medicine continuously something else may happen as some kind of side effect for English medicine (a local term for allopathic medicines). That is why I stopped the medicine and went to Homeopathy. **Q 16** TP 2
	You know my dear I have a small job. I work in XX Fisheries. It is near XX, it is like an exporting company. I go there to work on sorting and packing. I have night duty today. Usually, it is shifting duty for me. Therefore, when I have day duty or morning shift I cannot come or attend anything in FHC. Today I came for getting my medicines I should have been sleeping. By 4 pm the bus will come, and I can get on it and go for my shift. **Q 17** (IDI 2, 55 years, married Literate 4th standard (lower-primary) women) Female, Diabetes, Hypertension)
	R: yes, slips (out-patient on which doctor's write notes) are with me I don't know how to read them, my son's wife knows so she checks this. I: Could you tell me what she checks? R: yes, she checks the test result also checks the medicines provided in the slip or in the book. I mean she knows my medicines. Like if it is changed or increased or decreased and she will tell me what to do. **Q 18** (IDI 4, Female, 48 years)
	I was once told by a doctor to have fruits in my diet. But I will not be able to buy them. **Q 19**, IDI 8
	There is no particular reason or one thing, maybe thinking about my children may be about my grandchildren especially when you are in a family you will have different reasons to get "tensed" like money or something. Sometimes my sugar just goes down and sometimes it goes up. Then there are times when I cannot even move; if some change comes then I can't do anything. **Q 20,** IDI 7
	Surely, that depends on our attitude and so on. If I have any concern about my health, or myself that I know how to control my diet and understand how to take proper exercise especially after that worksite health programme, I know where to go and get help and support. There is no need to think like that I am helpless or not in control of my health. **Q 21** TP 8

5.6. Discussion

Main findings

This paper has reported a qualitative analysis of what influences a lack of engagement with PHRs for self-management among patients with diabetes and hypertension in Kerala, India. We were able to identify three key contextual influences: patients' navigations of the pluralistic health system; patients' and HCPs' interactions during consultations; and a lack of agency and health ownership amongst patients, which have been categorized into health-system, patient, and socio-economic levels.

Participants' care-seeking practices for managing diabetes and hypertension resulted in possessing multiple PHRs from different HCPs and healthcare facilities. Participants had received doctors' verbal instructions during consultations on the importance of taking medication and coming for follow-up and, thereafter, perceived PHRs primarily for themselves largely as transactional tools to buy medicine. As such, they did not see a role for PHRs in their self-management other than for accessing medications. Although this is a significant component in self-management(29,30), the patients in our study did not engage with the PHRs for any other self-management activity.

Secondly, the interactions with HCPs in different facilities during the course of navigating the pluralistic care system led participants to view the current value of PHRs as being for HCPs as tools for documenting information in the consultation.

Thirdly, the analysis highlighted the difficulties experienced by patients in engaging in self-management for diabetes and hypertension due to difficulties posed by work or financial constraints. Patients' views of self-management activities as difficult or not needed signified a wider lack of agency over health due to work or economic constraints. Most women participants, in particular, found it challenging to engage in physical activity amidst work and household chores especially for those with primary education. Patients with lower economic status also reported difficulties in buying fruits and focused on cutting out sugar, salt, and oil from their diet to manage their condition. These curtailments of their agency to manage their health led, in turn, to a lesser engagement of patients with PHRs for self-management.

Healthcare system factors

Patients moving between different HCPs in their care for NCDs have been reported in previous studies focusing on managing patients with NCDs in India. (7, 31-33) However, the potential influence of these practices on patients' engagement with PHRs for self-management have not been previously studied in India. This study highlights the problems for patients navigating between multiple HCPs leading to multiple PHRs, which makes it difficult to follow one PHR for self-management among patients with diabetes and hypertension in Kerala.

In our analysis, we found that patients chose healthcare facilities based on their trust in providers, their perceptions of the severity of illness, and their confidence in the healthcare received at hospital, and the cost of long-term medicines. In Cambodia, health-seeking behaviour was determined by the trust in and relationship with HCPs. (34) This analysis makes a contribution regarding how individual trust in the health system may be affected by factors other than the relationship with HCPs alone and how patients prefer communicating with HCPs than engaging with PHRs for self-management in Kerala.

Some of the reasons reported by patients for their navigations across different HCPs reinforce findings from previous studies. Some participants also were apprehensive about the perceived quality of medicines from the public health care system. This lack of trust in the medicines distributed through the public health system has been reported in studies from Kerala and other states in India. (35,36)

Additionally, the current HCP-patient interactions and communications during consultations seem to contribute to a lack of ownership of PHRs by patients. Previous studies have reported the limited time and communication in consultations for patients with diabetes and hypertension in India. (7, 12) However, this analysis contributes further to how these patient-provider interactions influence patients' view of PHRs and how they may contribute to lack of ownership of PHRs for self-management by patients in Kerala.

Overall, the above health system level contextual influences do not create an enabling environment for patients to engage with PHRs.

Patient-level factors

The current HCP-patient interactions and communications during consultations in this study seem to contribute to a lack of ownership of PHRs by patients. Previous studies have reported the limited time and communication in consultations for patients with diabetes and hypertension in India. (7, 12) However, this analysis contributes further to how these patient-provider interactions influence patients' view of PHRs and how they may contribute to lack of ownership of PHRs for self-management by patients in Kerala.

This study found that patients with diabetes and hypertension interviewed in Kerala do not engage with PHRs for self-management, as patients reported undertaking minimal self-management practices. This study corroborates the findings that self-management is a complex (37) and dynamic process. (30) Our study has shown that the patients may show self-management behaviours such as buying medications monthly yet not follow the doctors' advice on daily medication intake, fruit intake or physical activity recommendations. Previous research studies from Kerala have shown similar findings such as lack of adherence to medications and self-management activities,(35) constraints to exercise(31, 38) and dietary modifications limited to the restriction of salt, sugar, or oil.(39, 40) To date, national NCD programmes are limited to screening, maintenance of a supply of medication and providing health-promoting messages.(41) This study shows that the patients were aware of the importance of taking long-term medications and have received healthcare information on diet through various health care consultations. However, over time, patients noted their limited agency over following recommended activities related to diet/physical activity they can undertake. We found that patients' own medication intake was varied, and they reported changing the dose without medical advice. Against this background, the ways in which patients varied their medication intake, as noted above could be an attempt by patients to regain agency, managing their own medicines based on their symptoms they experienced such as attributing increased fatigue to lowering of blood pressure and subsequently changing the dose of medication. Therefore, it seems that the health-promoting messages in the current PHRs may not be useful for the patients we interviewed in Kerala. Additionally patient preference for verbally communicating with HCPs regarding their condition, suggests communication and monitoring by HCPs could be beneficial for them. Support for self-management using nurses or pharmacists may be more appropriate owing to time constraints for doctors in resource-limited settings. (42-44)

Socio-economic and environmental factors

Factors such as having a lower education, physically demanding work and lower income also posed difficulties in self-management as reported by participants in this study. Patients performed limited self-management tasks such as going to monthly follow-up health care visits, buying medicines, and reducing salt, sugar, or oil from their diet; but did not follow any other self-management activities. These findings indicate several factors that curtail participants' health agency, and thus self-management. Women with lower education and income struggled to incorporate physical activity or manage to go to health care visits between work and household chores. Additionally, patients in this study perceived their physical activity as adequate due to household chores or their jobs. Previous studies in Kerala and India have shown that any physical activity done was related to occupation and that people engage in very little spare-time physical activity. (45,46) However, almost all patients in this study explained managing their diet by reducing sugar and salt. Previous studies have shown that women with lower education and lesser income were susceptible to poor management of lifestyle factors and chronic diseases in Kerala. (47-49) The employed participants in this study explained not having adequate time for dedicated exercise. Incorporating workplace diabetes/hypertension management programmes can provide support for self-management by creating a healthier environment. (50, 51) These findings point to the ways in which broader factors such as social, cultural, and economic structures influence both engagement with PHR and, in turn, self-management. As seen in this study, the verbal information given by HCPs alone may not be sufficient for patients to engage in self-management activities. Peer-led support in terms of patients inspiring one another to take actions for living with diabetes and hypertension may be explored for stress and coping with the condition. (52)

Previous literature has shown that PHRs do not always get used or are embedded in the clinical settings by patients or HCPs. (53-55) One possible explanation is that PHRs do not get used when the purpose of the PHR is not clear to all users. (56) Osaki et al (22) suggested that developing a home-based record (PHRs for mothers and children) should be based on a function-capacity framework. The framework showed that an increasing number and complexity of functions (for recording by HCPs, for reading by mothers/families, for recording by mothers/family) in a home-based record requires greater capacity among its users (mothers/family members and HCPs). Our findings suggests that contextual factors influence the lack of engagement with PHRs for self-management. However, patients in this study viewed PHRs as documents for HCPs. Therefore, further research should take into account the above considerations by health care administrators on making practical decisions on what kind of function a PHR should perform and the type of content it should contain. This may be achieved by involving end-users of PHRs such as patients, carers, and front-line HCPs in developing the PHR.

Strengths and Limitations

As far as the authors are aware, this is the first study to qualitatively analyse the contextual influences on patients' lack of engagement with PHRs for self-management in Kerala. We offer a perspective on how contextual factors affects patients' lack of engagement with PHRs for self-management, rather than focusing on the content of the PHRs and how it contributes to patient disengagement. Although the topic guide did not specifically explore contextual factors' influence on patients' lack of engagement with PHRs, the topic guide was designed to explore reasons for why patients did not engage with PHRs for self-management. Hence, the identified contextual influences could be potentially reflective of why patients' do not engage with PHRs for self-management in similar settings. A potential limitation is that while patients have reported reducing salt, sugar or oil, the patients were not observed making these changes in their diet.

Implications for practice

A method for collaborating on interventions for self-management (57) that acknowledges self-management as a continuous process requiring the involvement of patients, caregivers, and healthcare providers could enhance engagement. Within the background of electronic health record implementation in Kerala and India paper-based PHRs may become redundant. This could potentially create a more digital divide and loss of agency for patients from a lower educational background. (58)

In order to improve patients' engagement with PHRs further support interventions such as training for HCPs to guide patients to these resources and for reinforcing medication adherence information may be needed. However, as seen in this study, the verbal information given by HCPs alone may not be sufficient for patients to engage in self-management activities. Peer-led support in terms of patients inspiring one another to take actions for living with diabetes and hypertension may be explored for stress and coping with the condition. (41)

The themes from this study could be further explored in empirical studies to identify areas for developing appropriate interventions for self-management. Additionally, a theory-driven approach to explore the health system-level trust may derive further insights into interactions between patients' perception and practices, and wider structural contexts and how these might impact patients' engagement with their care. This study suggests self-management support for realising the necessary lifestyle changes, medication adherence, and managing emotional changes need to be developed in consideration with the wider structural contexts that influence patients' agency to self-manage and have ownership over their health. This would require governments to look beyond providing information and education regarding lifestyle risk factors that targets patients' behaviour through PHRs or other information and education materials alone. Further research needs to be done into what interventions could support self-management amongst people with diabetes and hypertension within the public health system and the inter-sectoral agencies such as the public distribution system that influences the availability of food groups for people with low-socio economic status in Kerala.

5.7. Conclusion

Patients' engagement with PHRs in this study was limited to re-filling monthly medications for diabetes and /hypertension from health centres. Patients did not engage with PHRs for monitoring their care or medication management at home. This study highlights the urgent need for supportive contexts in which people can not only engage with PHRs for self-management, but also access the ability and resources needed to bring about actual improvements to their health. Patients' experiences suggests that patients with diabetes and hypertension need trusting relationships and face-to-face communication with HCPs for developing skills and adherence to self-management. Hence, the development of a PHR for improving self-management for patients with diabetes and hypertension must consider co-designing with patients, carers and HCPs for better patient engagement. Future research must explore the content and support needed throughout the course of the disease for PHRs to be useful in self-management.

5.8. Chapter Summary

This chapter has explored why patients interviewed do not engage with PHRs for self-management in Kerala. The findings suggest patients are influenced by the complex pluralistic health system that leads them to be in possession of multiple PHRs and advice from different HCPs. Patients reported making these navigations in the health system to due to trust they place in HCPs from hospitals to manage their conditions such as cardiovascular disease or stroke. They also seemed to return to primary care for the treatment of diabetes and hypertension due to the affordability of medicines from the FHCs. Patient and HCP interactions during consultations led them to perceive PHRs as tools for documentation for HCPs. This chapter highlighted the difficulties experienced by patients in engaging in self-management for diabetes and hypertension due to difficulties posed by work or financial constraints and hence patients' engagement with PHRs was low. Because of this analysis, the reasons for patients' lack of engagement with PHRs for self-management have been explored.

This chapter contributes to the aim of the thesis in understanding the factors determining the use of PHRs for self-management by patients. The next chapter further analyses the barriers and facilitators for HCPs to use PHRs for maintaining informational continuity using the TDF.[59]

5.9. References

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CHAPTER SIX

EXPLORING FACTORS AFFECTING HEALTH CARE PROVIDERS' BEHAVIOURS FOR MAINTAINING CONTINUITY OF CARE IN KERALA, INDIA; A QUALITATIVE ANALYSIS USING THE THEORETICAL DOMAINS FRAMEWORK.

6.1. Chapter preface

The previous chapter highlighted the contextual factors that influence why patients do not engage with current PHRs for self-management in Kerala. This chapter presents findings from applying the TDF to the interview data from HCPs collected in the qualitative study outlined in Chapter four in order to, highlight the perceived barriers and facilitators for recording and maintaining PHRs for informational continuity.

As detailed in the background chapter (Chapter One), currently electronic health records are being implemented in the public health settings in Kerala.[2] This chapter contributes to the overall aim of the thesis by offering an understanding of the determinants of use of current PHRs by HCPs within the context of introduction of electronic health records in family health centres (FHCs). It specifically contributes to understanding of the barriers and facilitators for HCPs in using PHRs for improving informational and management continuity of care within the context of managing patients with diabetes and hypertension in low- and middle-income countries (LMICs).

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Joseph L, Greenfield S, Lavis A, Lekha TR, Panniyammakal J, Manaseki-Holland S. Exploring Factors Affecting Health Care Providers' Behaviors for Maintaining Continuity of Care in Kerala, India; A Qualitative Analysis Using the Theoretical Domains Framework. Front Public Health. 2022 Jul 8; 10:891103. doi: 10.3389/fpubh.2022.891103.

Title:

Exploring factors affecting health care providers' behaviours for maintaining continuity of care in Kerala, India; a qualitative analysis using the theoretical domains framework.

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Author Contributions

LJ designed the study with the support of SG, SM-H, AL, and JP. SG, SM-H, AL, and JP supervised the project. TL worked with LJ as second qualitative coder. LJ prepared the first draft. All authors gave critical feedback on the manuscript, contributed to the article and approved the submitted version

6.2. Abstract

Introduction

Access to patients documented medical information is necessary for building the informational continuity across different healthcare providers (HCPs), particularly for patients with non-communicable diseases (NCDs). Patient-held health records (PHRs) such as NCD notebooks have important documented medical information, which can contribute to informational continuity in the outpatient settings for patients with diabetes and hypertension in Kerala. We aimed to use the theoretical domains framework (TDF) to identify the perceived HCP factors influencing informational and management continuity for patients with diabetes and hypertension in relation to PHRs

Methods

We re-analysed semi-structured interview data for 17 HCPs with experience in the NCD programme in public health facilities in Kerala from a previous study, using the TDF. The previous study explored patients, carers and HCPs experiences using PHRs such as NCD notebooks in the management of diabetes and hypertension. Interview transcripts were deductively coded based on a coding framework based on the 14 domains of TDF. Specific beliefs were generated from the data grouped into the domains.

Results

Data were coded into the 14 domains of TDF and generated 33 specific beliefs regarding maintaining informational and management continuity of care. Seven domains were judged to be acting as facilitators for recording in PHRs and maintaining continuity. The two domains “memory, attention and decision process” and “environmental context and resources” depicted the barriers identified by HCPs for informational continuity of care.

Conclusion

In this exploration of recording and communicating patients' medical information in PHRs for patients with diabetes and hypertension, HCPs attributions of sub-optimal recording were used to identify domains that may be targeted for further development of supporting intervention. Overall, nine domains were likely to impact the barriers and facilitators for HCPs in recording in PHRs and communicating: subsequently maintaining informational and management continuity of care. This study showed that many underlying beliefs regarding informational continuity of care were based on HCPs' experiences with patient behaviours. Further research is needed for developing the content and appropriate support interventions for using PHRs to maintain informational continuity.

6.3. Introduction

Continuity of care is essential to provide quality care to patients with diabetes and hypertension.(1) Continuity of care refers to the seamless care over time between care episodes and across health care settings. (2) Informational continuity is an essential component of continuity of care. Informational continuity refers to how efficiently patients' health information can travel with them across time, care episodes, and health care facilities.(3, 4) Patients' health information can includes the patients' symptoms, treatment, management plan, test results, and other relevant details that are usually recorded.(5) Having patient-level electronic or paper-based health records, which can be shared with all involved health care providers (HCPs), is ideal for developing informational continuity.(6) However, most low and middle income countries (LMICs) such as India have little or no patient-level paper-based or electronic health records available in the public health system.(7) Health care in India is provided by public and private healthcare facilities. Patients tend to self-refer themselves to several doctors for their care for their condition/conditions. Therefore, in most cases patients/carers need to act as carriers of medical information and communicate with HCPs to ensure continuity of care. Without access to clearly documented and accessible health information regarding the patient, HCPs cannot provide safe and quality care over time. Furthermore, without past medical information or a shared management plan, medical management continuity for patients with diabetes and hypertension is hindered.(3, 8) Due to the long-term nature of diabetes and hypertension, the nature of care needs is also varied over time, and hence information transfer and handover communication across visits and providers becomes essential.(9) For example, with time a patient on oral diabetic medicine may need to change to insulin injection to maintain his/her blood glucose under control. The information needed for a patient and HCP when using oral medication and when on insulin injection are different. Factors hindering continuity of care include lack of readily available facility-based records, HCPs not recording the information, poor retention of verbal communication between HCPs and patients/carers, patients not being able to communicate essential details. (7)

HCPs working in public health facilities in India are often overburdened with the workload. (10) However, very few studies are conducted from the HCPs' perspective on current challenges for managing care for patients with diabetes and hypertension from Kerala. (11, 12). Kerala is a south Indian state with a high burden of non-communicable diseases (NCD) particularly diabetes and hypertension.(13) Patient-held health records have been recommended as a part of NPCDCS (National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke)to record and monitor health status of patients with diabetes and hypertension.(15) The government of Kerala under the Aardram Mission aimed to transform existing primary care health centres to focal point of primary care by adding various services for patients with NCDs. HCPs can potentially use current patient-held health records for communication and maintaining continuity of care in the outpatient settings of public health settings in Kerala. However, based on a previous clinical handover study done in 2014, Himachal Pradesh and Kerala, HCPs' documentation in PHRs is sub-optimal. (7) We explored the experiences of HCPs with PHRs in public health settings in Kerala using semi-structured interviews, as a part of larger qualitative study with patients and carers (under review in a journal, unpublished, own work). We found generalised awareness regarding the need for past medical information to manage patients with diabetes and hypertension. The recording in PHRs were sub-optimal and HCPs identified difficulties in locating information from multiple PHRs with patients. Therefore, to assist the development of appropriate supporting interventions to improve informational continuity of care, applying theory may offer new insights.(16) The Theoretical Domains Framework (TDF) is an integrative framework that synthesises many behaviour change theories, which can help explain issues relating to the implementation of best practice evidence in healthcare settings.(17) The TDF helps combine and simplify data and theories relating to a specific behaviour into a set of theoretical domains.(17) The revised version of the TDF contains 14 theoretical domains (Table 1) that can be applied to a range of behavioural problems (17, 18). We aimed to use the TDF to act as a step to identify factors relating to establishing and maintaining informational and management continuity and map them to behavioural domains so that further research can be directed to develop support interventions in Kerala.

6.4. Method

Design

We re-analysed data from a previous study using the TDF (18). Semi-structured interviews with 17 HCPs working in public health care facilities with experience of NCD programme (Table S1) in Kerala were included. The data selected for this analysis were part of a qualitative study with patients, carers, and HCPs to explore their experiences with patient-held health records in Kerala. A paper-based patient-held health record (PHR) was developed as a clinically focused and primarily for HCPs to record clinical information. The PHR also contained additional information for patients, such as a generic diet plan for patients with diabetes and hypertension. However, owing to stock-outs, HCPs advised patients with diabetes and hypertension to buy themselves a notebook, which was used as PHR to be carried to public health facilities. Prescription pads or outpatient sheets were available in the government facilities. However, the state guidelines for management of diabetes and hypertension recommend the use of NCD PHR for tracking patient visits to primary health centres.

Settings

We re-analysed the data collected from HCPs working in public health settings in Kerala. The semi-structured interview data was collected from February to November 2020. In the pre-COVID phase, HCP data was collected at two FHCs in the Alappuzha district, Kerala, which is one of the first districts in which the NPCDCS was implemented in 2015. During COVID phase (March 2020 to November 2020), telephonic interviews were conducted with eligible HCPs working in public health facilities from other districts (Trivandrum, Ernakulam, Malappuram, and Wayanad).

Sampling and recruitment of HCPs

A purposive sampling (19) to ensure that HCPs with following experience were recruited; caring for patients with diabetes and hypertension working in public health facilities; work experience at FHCs with electronic health records under Mission Aardram. Convenience (20) and snowball sampling (21) were used to identify HCPs managing patients with diabetes and hypertension. Members of the research team contacted HCPs working in family health centres/primary health centres. Eligible and interested HCPs were given further information regarding study details by LJ.

Data collection

Data collection took place between February to November 2020. Semi-structured interviews were conducted face-to-face or telephonically based on HCPs' preferences. Face-to-face interviews were conducted in the doctors' room in FHC. The study investigator used a topic guide for the interviews (Supplementary Table S2). All interviews were done by LJ in Malayalam or English, or a mixture of both, based on interviewee preference. LJ was not previously known to HCPs. Interviews lasted 30 to 60 minutes and were audio-recorded. The audio recordings were transcribed to English and were checked by LTR against the audio, who was familiar with the clinical settings and Malayalam language.

The topic guide was developed and piloted before data collection to ensure the clarity of questions. The topic guide was informed by previous literature on handover communication and informational continuity and the working of health systems in Kerala. It included open questions regarding roles, responsibilities, and clinical practices of HCPs in managing care for patients with diabetes and hypertension, barriers to maintaining continuity of care, experiences with electronic health records and patient-held health records, and challenges in managing patients with diabetes and hypertension.

Data analysis

The data analysis followed the processes described by previous qualitative studies, which used the TDF. (22-25) A deductive approach to content analysis (26) using the 14 TDF domains as the coding categories was done. Initially, LJ coded three transcripts at the domain level and developed a coding guideline (18) (Supplementary Table S3). The interview transcripts were coded line by line deductively against the TDF framework. SG and AL reviewed the coding guidelines and accuracy of the coding of three transcripts. Two researchers (LJ and LTR) independently coded the data manually in the next phase and met after coding five transcripts and then the remaining transcripts to discuss any variations. Any variations were discussed and resolved. Interview data could be placed in more than one domain.

After all interview transcripts were coded deductively within the domain level, Microsoft Excel was used to organize the coded data. LJ then generated data-driven statements relating to specific beliefs within each domain. Grouping statements by participants identified specific beliefs or sub-themes. The frequency of each belief (to represent the number of participants who mentioned the belief) was counted across all interviews. Domains were judged as likely to be relevant as barriers or facilitators if they fulfilled the following criteria; more than two HCPs mentioning the factor, high frequency of specific beliefs in a domain, presence of conflicting beliefs or strong beliefs that may influence maintaining informational continuity of care.

6.5. Results

Of 17 HCPs interviewed, 13 were doctors, and four were nurses working in the public health facilities in Kerala. Respondents came from rural and urban public health care facilities with and without electronic health records implemented in their current workplace. All HCPs reported being responsible for care for patients with diabetes and hypertension in the outpatient settings (Table 1).

Summary of domains

Content analysis resulted in charting the interview data into all 14 domains of TDF (Table 2). The most frequently mapped domain was knowledge, and the least mapped domain was behavioural regulation. 33 specific beliefs were identified from the HCP interviews.

Each mapped domain is summarised below with an illustrative quote. Additional quotes are presented in supplementary file (Table S4).

Knowledge

Most HCPs reported being aware of the booklet for patients with diabetes and hypertension issued as part of the NCD programme. They explained the reasons for booklets not being used in every health centre due to lack of availability or stock-outs. Some HCPs reported that they did not receive any booklet for their centre, and they had started asking patients to buy a notebook when they came to the health centre for their diabetes and hypertension consultations. The reasons given by HCPs for maintaining a patient-held health record in the form of a notebook included the need for clinical information of patients, documenting medication prescriptions helps to track the patients to see if they have been regularly collecting medicines and to track the blood pressure or blood sugar values of patients.

We give medicines, especially medicines, for patients with NCDs for 15 days, and then they have to come. You see there are no facility-based records. We do have some registers, but it will be very difficult to track who came, when, and such details. So, if they bring the notebook, we can know. As a doctor, I think the notebook will give us a chance to monitor blood pressure and blood sugar. We are using a glucometer now as our lab technician is on leave, but still, we record it, and we can know if they had high BP previously. HCP 1

All HCPs demonstrated awareness of patients' past PHRs and explained that patients might not carry PHRs to health care appointments.

Yes. I have had experiences of patients' not bringing any records. It is in the past. In some situations, the patient may not be aware of the name of drugs or their own prior BP level. Few patients are there who come without knowing anything. Out of 50, only 1 or 2 are like that. Not 50; out of 100, one or two are like that. HCP 16

Skills

Most HCPs reported receiving some training on treatment guidelines for managing patients with diabetes and hypertension. HCPs reported not receiving any training for documentation in the PHRs from their current workplace. However, two doctors said that they received an orientation from the senior medical officer, who explained what types of records need to be maintained. Most doctors felt that they had picked up the content of documentation from their years of medical training and their workplace practices.

No, these are the things (asking for PHRs/recording in them) we pick up in the workplace; there is no specific training as such for recording in PHR. HCP 11

A few HCPs reported spending time communicating with the patient regarding managing their care when they are diagnosed with diabetes or hypertension. Both nurses and doctors shared the opinion that they communicate with patients to bring their NCD book when they come for renewing prescriptions.

First of all, we inform the patients to bring a 200-page notebook. In the patient's book, address and code number will be there in front page. Inside pages, we mention the date and Doctor's write the prescribed medicines and to know are there any repetition or duplication of medicines. We tell them to bring it every time they come for buying medicines. HCP 3

Most HCPs discussed that the training for electronic health records was important and useful. They reported that the focus was on setting up and having a mechanism for electronic health records to be incorporated into the consultations. However, a few HCPs discussed how some HCPs might be less skilled in entering the information in the electronic health record.

Those with little computer knowledge or experience have difficulty in typing. It may be difficult for doctors who are older as they have followed a pattern and have built a system around themselves *to work. They have their own traditional style, which they may not change. However, that can also be solved if we can get a data entry staff. HCP 15*

Social/professional role and identity

Healthcare providers, particularly doctors, saw themselves as responsible for documentation and maintaining records to prevent errors.

If there is a notebook in our public health system, we doctors treat it as a record; we know we are in charge of recording the details of the consultation. HCP 6

Participants who were doctors felt that they took extra efforts to maintain informational continuity by deciding to document in both electronic and patient-held records.

We (doctors) continue to use the notebook. If we consult a patient this month, it may be some other doctor who deals with the patient on the next visit. There is still a chance to forget entering some details in the electronic health records. All (doctors) are new to this new system, and we may miss entering certain details. Most NCD (non-communicable disease) patients will bring the book (PHR), and we ask them to show it at consultations. Since we have only started the electronic ones (records), not all the past details may be fully entered into the system. Hence, it is good that we can refer to the notebook (PHR), so we maintain both currently. -HCP 5

Beliefs about capabilities

In general, HCPs expressed confidence in documenting relevant information in PHRs and maintaining informational continuity. However, some HCPs reported difficulties in documenting in detail when the patient load is high in outpatient settings.

While most HCPs reported documenting in PHRs for informational continuity, some HCPs felt they had to prioritize documentation over communicating with patients in a busy outpatient setting.

Sometimes in an OP, we will have a long queue, and then some emergency patients will arrive. I will have to go and attend; then, when I come back, I will be looking to finish off the OP patients. On top of that, we have many registers to maintain, so we will be writing in that than what we tell the patient. HCP 4

Other factors that influenced HCPs' capabilities included confidence in other team members such as field workers (junior public health nurses and ASHAs) to follow-up patients with diabetes and hypertension to prevent dropping out from care.

Generally, most people have interest to avail treatment for NCD from us. JPHN and ASHA workers have a good role in follow up care. Follow up is done correctly and continuously for the already existing patients. HCP 14

HCPs also noted confidence in patient behaviour to return to their health care facilities that HCPs perceived to be contributing to informational and management continuity of care.

I have been practising here for around two years. I know the existing NCD patients. So, I will know if the patient is new or not. Most of our regular patients will come here and will bring their notebooks. If they have increased blood pressure or blood sugar in this visit, we may have to make judgements about changing the dose of medicines. HCP 16

Optimism

Most HCPs believed that patients would bring documents to consultations, particularly for diabetes or hypertension appointments. They also felt that if patient details are recorded well, there is potential for electronic health records to maintain informational continuity. However, some HCPs had mixed feelings about relying on electronic health records alone to maintain informational continuity. They pointed out that patients need to bring their unique identification card or phone number to retrieve patient information. Additional issues such as power failures or inadequate documentation were reported.

Ideally, if everyone (HCPs) records the details properly in the case sheet in the electronic record, this will work. There will be information available for doctors in the next visit. But then we should be able to record, and the patient should bring their unique ID (identification card), or else it will not be useful. HCP 6

Beliefs about consequences

Almost all HCPs spoke about the negative effects of not having adequate patient information. These included the potential for error, delays in arriving at proper treatment, and requesting additional follow-up. Some HCPs highlighted how having a PHR with recorded information is helpful for clinical decision-making.

The advantages are that I will get to know the patient's condition for a longer time, and accordingly, I can change the medication increase or decrease, or if they are not responding to medication, then I can guide them to go to some MD specialist who knows better, who is better experienced and who can prescribe them better. HCP 13

Most HCPs felt that they had experienced not having enough patient information during the consultation. Most HCPs reported that patients were familiar with carrying PHRs to diabetes and hypertension consultation, so they continue to write in them.

We are still writing in the notebooks during consultation. Now we are typing the details in the electronic records and writing in the book so that if one fails, the other works. HCP 10

Reinforcement

Some HCPs held the enabling belief that regular patients brought PHRs to consultation and hence recorded in them as they felt satisfied in providing safe care.

Most people who take treatment from us will continue to do so. They will be regular in bringing the papers, they will inform us if they have taken other treatment from outside, so it will be easier to write their records and treat them. HCP 13

Some HCPs reported that they recorded key information from patients' past PHRs in the notebook for diabetes/hypertension to make their work later on easier.

As doctors, I feel we will always be comfortable with patients who regularly come to get treatment from us because we know them, we have recorded the details we need. I think it is good and easy for doctors and patients. HCP 6

Intentions

Intentions are conscious decisions to perform a behaviour. Most HCPs made a conscious decision to record in PHRs to prevent information loss. HCPs using electronic health records also reported deciding to record in PHRs and electronic records to maximise the possibility of information availability.

I think that there is a possibility for power issues, or somehow the details were not recorded in the electronic record, so I will make it a point to write in the notebook. HCP 14

Ideally, we should not be using OP tickets now. But we do it as the patient has to bring the unique health ID the next time they come. The card can be read, and the details will be available to us. Now it is our headache when they missit,it, or they do not care about it. Again, the information is lost so we give them the OP tickets with prescriptions so that they will bring at least these. HCP 17

We are still writing in the notebooks during consultation. Now we are typing the details in the electronic records and writing in the book, so that if one fails the other works. HCP 10

Goals

Goals related to recording in the PHRs for informational and management continuity were described by HCPs as availability of relevant patient information for themselves. However, this task was not prioritized when the aim was to attend to all patients waiting in the outpatient clinic. Most HCPs referred to documenting in PHRs for them to have information on the patient's previous medicines to prevent medication errors.

Some HCPs inferred that there is an emphasis on recording information regarding medication for informational continuity rather than on test results.

Yes, there is a focus on documenting the medicines majorly and maybe the BP readings. There are some deficiencies in recording from the doctors' side, but this is mainly due to the volume of work. They (other HCPs) have to cater to a large number of patients, around 150-200 in their OP. So, the recording will be very much based on what they would need next time. HCP 12

Memory, attention, and decision processes

Most HCPs believed that when there is a huge patient load in outpatient settings, they find it difficult to locate the necessary information from patients' multiple PHRs.

But not everyone (patients) will carry records all time. There may be many papers also at times. Imagine having a long queue of patients outside your room, and then someone brings in many papers; it will take time to go through them to find what we need. It will interrupt the process of consultation. I think for new patients, we will have to sit through and check them, but with regular patients, it may be one or two here and there. HCP 1

A few HCPs felt that they had to record crucial information such as the medication information (change the dose or medicine) and were found to have disregarded communicating test results to the patients.

I have thought about it. Most of the time in the OP, I may not get time to teach them about diet and physical activities. We just check the blood values and blood pressure, and we change the dosage of medicine based on that. We may not even talk about the importance of blood values. This is what happens mostly during consultation time. HCP 5

Environmental context and resources

Almost all HCPs reported the high patient load in outpatient settings. HCPs discussed contextual factors that contribute to the potential loss of information and their own sub-optimal recording.

One of the most discussed factors causing sub-optimal recording was the patient load during specific NCD days.

There is like a huge number (of people) in primary care; the dire need is to cater to them and finish the consultations. HCP 12

Another factor discussed by HCPs is the distraction caused by long queues and time pressures experienced by them to complete the consultations.

The NCD days are hectic and noisy too. The pharmacy will also have a difficult time. We used to consult around 200 patients on NCD day. So, there is not much to guess how much we can enter. It is not whether we know how to record, which I believe most of us can do but practically whether it is possible to write detailed notes. HCP 6

A few HCPs felt that since there is no mechanism in place for auditing the patient-held records, which could possibly be a reason for sub-optimal recording.

Social influences

Some participants discussed the influence other people had on their recording and usage of PHR. A few HCPs described how senior doctors influenced their pattern of recording. Senior colleagues were perceived to provide information on content as well as the norms of recording behaviours in the health system.

I have studied in a Government Medical College. During my training period, I have learned to document whenever we submit the records in different specialties from the seniors. We tend to do as they say to us. Even between departments, there will be some variations in what we record. We will usually follow what has been done before. HCP 12

Emotion

Only a few HCPs expressed their difficulty in providing care for patients who do not bring their records, and this leaves them frustrated as they will have to insist the patients go back and take their records or refuse medications.

But some patients may come without a prescription and tell three tablets for blood pressure, four tablets for some other problem, three yellow tablets, or round tablets. They are the more problematic persons for us. It becomes difficult then, they have medicines for BP, but we do not know which one, and we may have to insist them to go and bring the papers. For them, it is their medicine; they probably do not realise that many tablets are round. HCP 6, doctor in FHC

Behavioural regulation

Only a few HCPs suggested having formats or templates for recording relevant information can help with easier documentation.

I think having some template will be useful. See most of the NCD patients will have some standard medicines, so having them printed out in the booklet and in the EHR will definitely help with recording. HCP 10

One HCP highlighted the lack of supervisory checks for PHRs may be a potential reason for sub-optimal documentation.

Barriers and enablers identified within relevant domains

The domains relevant for factors influencing continuity of care are summarised in Fig 1. The most frequently perceived enablers for recording in PHRs and maintaining continuity of care treatment fell into the following domains: “knowledge,” “skills,” “social or professional role and identity,” “beliefs about capabilities,” “intentions,” “goals” and “optimism.” All participants indicated that patient behaviours in carrying records act as a barrier to informational continuity (“beliefs about consequences”). The most frequently perceived barriers for recording in PHRs and maintaining informational continuity fell into the following domains “memory, attention and decision processes” “environmental context and resources” domain; these were in relation to limited resources or capacity and the challenges presented by the health system leading to perceived barriers to capabilities and skills.

6.6. Discussion

This study aimed to use TDF to identify the factors influencing the establishment and maintenance of informational and management continuity for patients with diabetes and hypertension. This was done using capturing perspectives of health care providers working in public (government) health facilities providing care for patients with diabetes and hypertension in Kerala. The data were mapped into the 14 domains of the TDF. We identified most frequently perceived enablers for recording in PHRs and maintaining continuity of care treatment fell into the domains of knowledge, skills and professional role and identity. Whilst some other domains such as beliefs about capabilities, intentions, goals, and optimism had some specific beliefs which suggests being a facilitator for informational continuity. The most frequently perceived barriers were in the mostly in two domains. The domains were “memory, attention and decision processes,” “environmental context and resource” domains.

Facilitators

This study showed that knowledge and skill are interlinked for maintaining informational continuity and subsequent management continuity using PHRs. For example, knowledge of the availability of PHRs for patients with diabetes and hypertension prompted HCPs to record in them. HCPs were aware of the working of the public health system and the need for maintaining PHRs due to the absence of facility-based records or perceived difficulties in the retrieval of information from electronic health records. Furthermore, doctors identified their role in documenting in PHRs and maintaining informational continuity for themselves. Even though the TDF does not discuss the relationship between domains, this study suggests a link between the professional identity and confidence of doctors in recording in PHRs. Similar findings, which linked knowledge, and skills domains have been reported for prescribing behaviours among trainee doctors. (27)

Barriers

Most of the barriers to continuity of care were attributed to beliefs about consequences and capabilities due to patients' behaviour. One of the reasons for this attribution to patients' behaviour as HCPs are reliant on patients/carers to bring their past records, communicate their health information to maintain informational continuity of care. Additionally, these findings highlight whether it is possible to rely on clinicians alone to critically evaluate their behaviours, which may threaten the continuity of care. Similar findings have been reported when using the TDF for identifying barriers and facilitators to prescribing behaviours. Studies have reported that clinicians may attribute the deviations in clinical behaviours to other external factors such as environmental factors or issues with lack of resources. (23, 27) The above suggests that there may be a need for using cultural models that consider organisational culture as important influence in health improvement and may explain the variations in HCPs' clinical practices. (28,29) Although HCPs did not identify a lack of training for documentation in PHRs that may be a barrier to adequate documentation in the PHRs. Additionally, a few beliefs may contribute to being barriers to maintaining informational continuity. HCPs believed that patients who have come to seek treatment in public health settings would continue to do so. However prior studies from India have shown that patients have a tendency to “shopping” for care across HCPs. (7, 11, 12, 30) Along with this, the overall goal for recording in PHRs for HCPs in this study is focussed on having information for themselves. These beliefs could be a possible reason for not communicating the importance of PHRs for all HCPs to patients and carers.

The findings from the study indicate domains such as belief about consequences, reinforcement and optimism have specific beliefs associated with anticipated and experienced patient behaviour such as bringing records or communicating with HCPs. In the domain reinforcement, HCPs reported that patients who regularly come to their health facility for appointments brought previous PHRs. Previous studies have suggested that informational continuity of care is built over time. (3, 4) For informational continuity to be achieved patients/carers also need communicate their symptoms, and other relevant information to HCPs that could be recorded. HCPs within this study have reported multiple factors that may contribute to be a barrier or an enabler. Some factors contribute to a number of domains. For example, patient behaviour of bringing multiple records impacted on belief about consequences, belief about capabilities and memory attention and decision-making.

Role of electronic health records and NCD notebook in continuity of care

Overall HCPs had mixed opinions regarding electronic health records and their role in maintaining informational continuity. Some HCPs felt that if electronic health records are being used widely in the health system and regularly documented well, they have a potential for improving informational availability. Only one HCP felt that using PHRs along with electronic health records would add to documentation burden. Most HCPs felt since they are familiar with recording in PHRs such as NCD notebooks, having both forms of documentation would ensure a better chance of maintaining continuity of care. HCPs regarded patient held NCD notebooks as records and reported on using them for the information recorded. These findings are similar to other LMICs, which have been using paper as documentation interface. (31, 32) Further research in having both paper-based PHRs and electronic health records for improving quality of care is needed in these settings. (33) Further research is needed to map the intervention content for any behaviour change intervention for HCPs that should include basic training sessions. (34)

Strengths and limitations

This study used qualitative methods to explore HCPs' practices of recording in PHRs regarding the management of patients with diabetes and hypertension and to use the TDF to explore factors affecting informational and subsequent management continuity of care. Incorporating the TDF ensured the data was coded and analysed using a recognised framework that can help in future intervention development processes. However, further research should also incorporate the interactive nature of the communication process and the development of informational continuity. This will give insights into healthcare providers' and patients' power dynamics and relationships.

There are a few limitations of this study. The interview guide was not developed using the TDF framework and hence could have overlooked some domains, which could have been potentially relevant. For example, only a few HCPs mentioned influences of senior doctors on their recording behaviour. This social influence of senior doctors and other health care workers have been previously reported with blood transfusion practices (25), prescribing behaviours of trainee doctors (27) and nurses (23). However, not using the TDF to develop the interview guide gave the advantage of capturing contextual information that could potentially explain interviewees' behaviours.

6.7. Conclusion

Using theory, we identified a range of determinants for HCPs in recording in PHRs and maintaining continuity of care. We identified the high workload, influence of patient behaviours and interruptions in outpatient settings that act as barriers to enact the behaviours. This led HCPs to prioritize recording sub-optimally. We offer new insights into the intentions and goals of HCPs when using PHRs; the recording in PHRs is to maintain informational continuity for HCPs. Therefore, comprehensive recording in medical records, which can enable informational continuity for all future HCPs should be one areas of targeted intervention. Next, communicating with patients/carers the importance of carrying documented medical information, and use of PHRs for patients or carers to interact with all HCPs should be targeted for intervention development. This study suggests that knowledge, skill, and professional identities are associated with positive HCPs' behaviours relating to maintaining continuity of care. Further research is needed to map the intervention content for any behaviour change intervention for HCPs and it should consider the existence of electronic as well as paper-based PHRs.

6.8. Chapter Summary

This last chapter based on the data from the qualitative study in this thesis has examined HCPs' perceptions of factors for recording and maintaining informational continuity of care with current PHRs. The analysis used the TDF [7, 8] to explore barriers and facilitators for maintaining informational and management continuity of care in among HCPs interviewed working in public health settings in Kerala. As detailed in chapter one, the overall aim for this thesis was to gather the evidence base, understand the current use of PHRs and the determinants affecting the use of PHRs for handover communication, informational continuity, and self-management.

The findings suggest the high workload, influence of patient behaviours and interruptions in outpatient settings act as barriers for recording in PHRs. The analysis showed that the intentions and goals of HCPs when using PHRs was recording in PHRs is to maintain informational continuity for HCPs. Therefore, on the basis of the findings from the preceding chapters current PHRs are being used, but with varied value to patients, carers, and HCPs. Importantly, this analysis highlights the need to address the barriers faced by HCPs in maintaining informational continuity using PHRs in Kerala to improve the effectiveness of informational and management continuity of care, which in turn could lead to better control of diabetes and hypertension.

In addition, Chapter four highlighted the divergences in patients', carers, and HCPs' use and value of PHRs. It pointed to the ways in which PHRs are not being used for self-management by patients and how HCPs also do not use PHRs for communicating with patients regarding self-management. This suggests that co-designing a PHR with patients, carers and HCPs in Kerala could provide an opportunity to improve patient engagement with PHRs

The following chapter thereby builds on the findings from chapters four, five and six to propose a plan for co-developing a PHR in Kerala.

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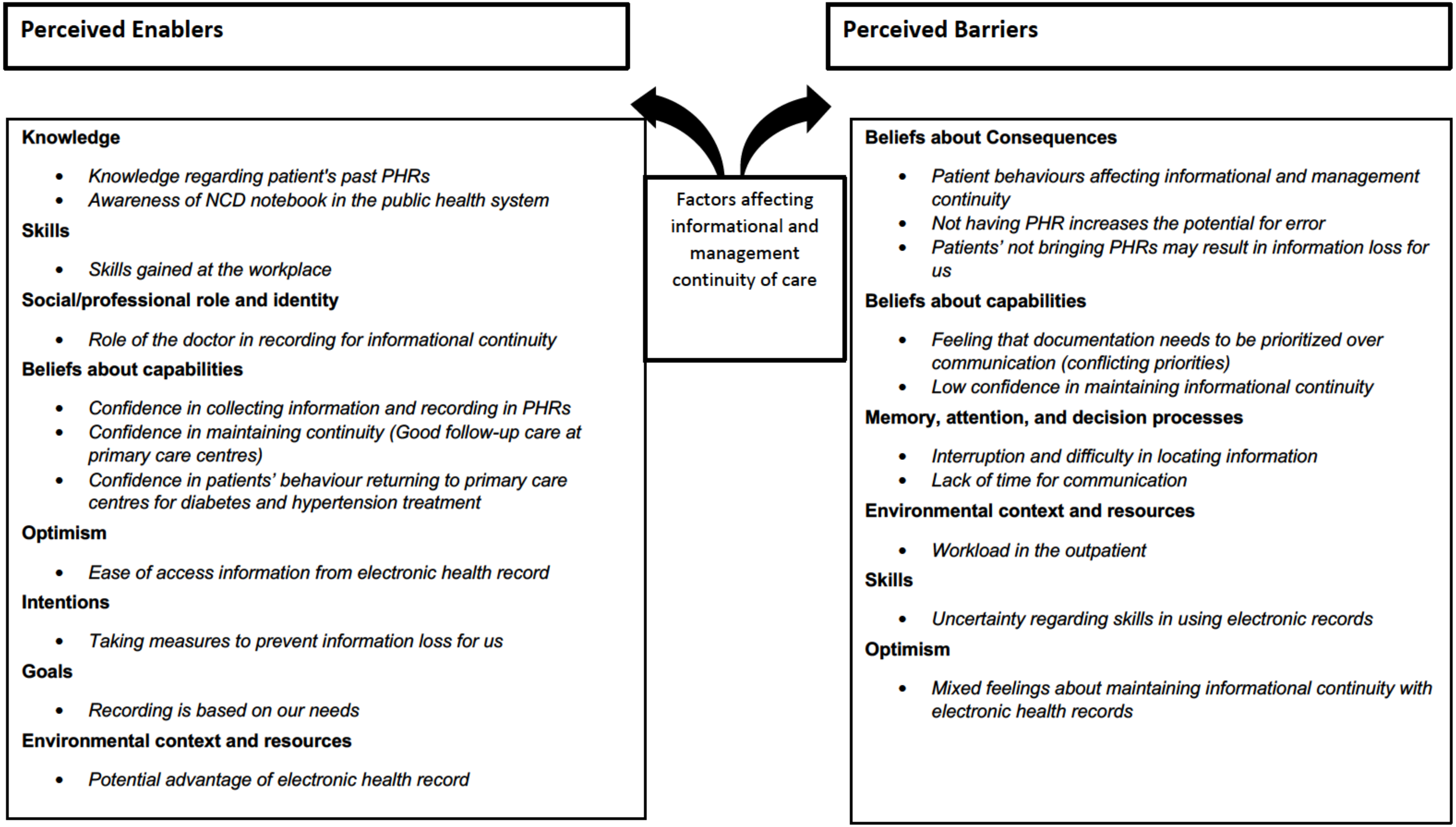


Perceived Enablers

Knowledge

- *Knowledge regarding patient's past PHRs*
- *Awareness of NCD notebook in the public health system*

Skills

- *Skills gained at the workplace*

Social/professional role and identity

- *Role of the doctor in recording for informational continuity*

Beliefs about capabilities

- *Confidence in collecting information and recording in PHRs*
- *Confidence in maintaining continuity (Good follow-up care at primary care centres)*
- *Confidence in patients' behaviour returning to primary care centres for diabetes and hypertension treatment*

Optimism

- *Ease of access information from electronic health record*

Intentions

- *Taking measures to prevent information loss for us*

Goals

- *Recording is based on our needs*

Environmental context and resources

- *Potential advantage of electronic health record*

Factors affecting informational and management continuity of care

Perceived Barriers

Beliefs about Consequences

- *Patient behaviours affecting informational and management continuity*
- *Not having PHR increases the potential for error*
- *Patients' not bringing PHRs may result in information loss for us*

Beliefs about capabilities

- *Feeling that documentation needs to be prioritized over communication (conflicting priorities)*
- *Low confidence in maintaining informational continuity*

Memory, attention, and decision processes

- *Interruption and difficulty in locating information*
- *Lack of time for communication*

Environmental context and resources

- *Workload in the outpatient*

Skills

- *Uncertainty regarding skills in using electronic records*

Optimism

- *Mixed feelings about maintaining informational continuity with electronic health records*

Fig 1 Factors affecting informational and management continuity of care

Table 1: Demographic details

ID number	**Age**	**Gender**	**Qualification**	**Job position**	**Clinical /Administrative role**	**Years of experience**	**Experience with electronic health record**
HCP1	29	Male	Graduate	Doctor in PHC	Clinical	1 year and 5 months	No
HCP2	32	Female	Graduate	Staff nurse in PHC	Clinical	2 years	No
HCP3	28	Female	Post Graduate Diploma	Staff nurse in PHC	Clinical	3 years	No
HCP 4	34	Female	Postgraduate	Doctor in CHC	Clinical	12 years	No

HCP5	35	Female	Postgraduate	Doctor in FHC	Clinical	less than a year	Yes
HCP 6	50	Female	Postgraduate	Doctor in FHC	Clinical	20 years	Yes
HCP 7	38	Female	Postgraduate	Assistant Surgeon (FHC)	Administration	6 years	Yes
HCP 8	33	Female	Graduate	Staff nurse in FHC	Clinical	4 years	Yes
HCP 9	33	Female	Graduate	Staff nurse in PHC	Clinical	4 years	No
HCP 10	46	Female	Graduate	Assistant Surgeon (FHC)	Clinical	10 years	Yes
HCP 11	37	Male	Graduate	Doctor at PHC	Clinical	3 years	No

HCP 12	34	Male	Postgraduate	District Surveillance officer	Administration	less than a year	No
HCP 13	53	Female	Graduate	Medical Officer at Hospital	Clinical	20 years	No
HCP 14	40	Male	Postgraduate	Assistant Surgeon (FHC)	Clinical	8years	Yes
HCP 15	42	Male	Postgraduate	Doctor at TQ Hospital	Clinical	6 years	No
HCP 16	37	Female	Postgraduate	District Surveillance officer	Administration	3 years	No
HCP 17	32	Male	Graduate	Doctor at FHC	Clinical	2 years	Yes

PHC=primary health centre, CHC=community health centre, FHC=family health centre, NCD=non-communicable disease

Table 2: Content analysis

Domains/Categories	**Factors affecting handover communication, informational and subsequent management continuity (sub-categories/specific beliefs)**	**Frequency count (out of 17)**
1. Knowledge	Knowledge regarding patient's past PHRs	17
	Awareness that patients may not carry records	15
	Awareness of NCD notebook in the public health system	17
	Awareness of patients returning to primary care centres for diabetes and hypertension treatment	8
2. Skills	Skills gained at the workplace	10
	Documenting skills	6
	Communicating with patients	3
	Uncertainty regarding skills in using electronic records	5
3. Social/professional role and identity	Role of the doctor in recording for informational continuity	13

	Nurses recognising the role of a doctor in recording	3
4. Beliefs about capabilities	Low confidence in maintaining informational continuity	10
	Feeling that documentation needs to be prioritized over communication (conflicting priorities)	9
	Confidence in patients' behaviour returning to primary care centres for diabetes and hypertension treatment	8
	Confidence in maintaining continuity (Good follow-up care at primary care centres)	7
	Confidence in collecting information and recording in PHRs	6
5. Optimism	Optimistic about patients bringing documents	11
	Mixed feelings about maintaining informational continuity with electronic health records	8
	Ease of access information from electronic health record	7
6. Beliefs about Consequences	Patient behaviours affecting informational and management continuity	16
	Patients’ not bringing PHRs may result in information loss for us	10

	Not having PHR increases the potential for error	8
7. Reinforcement	Regular patients bring PHRs	7
8. Intentions	Taking measures to prevent information loss for us (HCPs)	15
9. Goals	Recording is based on HCP needs	12
10. Memory, attention, and decision processes	Lack of time for communication	7
	Interruption and difficulty in locating information	11
11. Environmental context and resources	Workload in the outpatient	17
	Potential advantage of electronic health record	9
	Workplace issues	4
12. Emotion	Treating patients who do not bring records is frustrating	3
13. Social influences	Encouraged to record in PHRs by senior colleagues	3
14. Behavioural regulation	Formats can help with recording	2
	Lack of supervision	1

CHAPTER SEVEN

A PROPOSED PLAN FOR CO-DESIGNING A PATIENT-HELD RECORD

7.1. Chapter preface

This chapter aims to propose a plan for co-designing a PHR for improving patients' engagement with PHRs in Kerala. Due to the COVID-19 pandemic and travel restrictions, the intended plan for co-designing a PHR could not be carried out. Hence, this chapter provides the rationale for co-designing a PHR for improving patient engagement and the practical and ethical aspects that need to be considered for a co-design project in Kerala.

The chapter begins by introducing patient engagement in health care and providing a brief explanation of co-design in health care. It then presents the rationale for co-designing a PHR to improve patient engagement with PHRs. This is followed by discussion of why EBCD [1] may be a suitable method for improving patient engagement with PHRs by co-designing a PHR in the FHCs in Kerala. Next, the description of plans for the EBCD, including recruitment, events and venue are detailed and finally some of the challenges for co-designing a PHR in Kerala are discussed.

Prior to the proposed co-design work, a body of research had been undertaken to understand how patients, carers and HCPs use and value PHRs and factors affecting PHRs use for handover, information transfer and self-management. Patients, carers and HCPs use and value PHRs for medication procurement, emergency communication and/or informational continuity and patient safety differently (Chapter four). However, patients did not engage with PHRs for self-management and HCPs did not use PHRs for communicating with patients and carers. Further, chapters five and six explored the reasons for patients and HCPs not being able to engage with PHRs. Factors such as navigating the pluralistic health system, interactions between patients and HCPs and patients' socio-economic status influence their lack of engagement with PHRs for self-management as detailed in Chapter five. Additionally, chapter six identified the domains “memory, attention and decision process" and "environmental context and resources" as barriers for recording in PHRs. Therefore, the current use of PHRs for handover communication, informational continuity and self-management is poor among the interviewed participants in Kerala. Hence, it is important to consider methods that capture experiences of the end-users of PHRs for developing a new PHR or improving the existing PHR.

Perspectives of end users are helpful in designing useful and valuable PHRs as the users feel that their needs and perspectives are being heard and considered and are more likely to use the tool and to provide feedback that can help to improve its use and value. Moreover, patients, carers and HCPs in a few FHCs expressed an interest in developing or improving the current PHRs. Thus, this chapter outlines a proposal for co-designing a PHR suited to users' needs and the practical aspects to be considered for co-design workshops in Kerala and is written as a potential suggestion that may be undertaken by the researcher or other researchers in future.

7.2. Introduction

In the 2020s, person-centred care is acknowledged as a central pillar of high-quality healthcare[2], and part of the World Health Organization's (WHO) global health strategy.[3] The global mandate for community participation or public involvement in healthcare was advocated by the WHO as a critical feature for health system strengthening as early as 1978 in the Alma Ata declaration of "Health for All." [4] There has been a renewed focus on community participation in health care and service design within sustainable development goals and the WHO's proposal of developing people-centred health systems.[5] WHO defined community engagement more broadly as a process by which partnership is established between the government and local communities in the planning, implementation and utilisation of health-related activities.[6] Hence community engagement or participation is an umbrella term[7] and is used to describe a wide variety of approaches that includes inclusion in health programme delivery, decentralisation and planning in primary health care and knowledge co-production in the LMICs. [8] Further, approaches that improve community engagement and participation are identified as key for implementing preventive and control of chronic non-communicable diseases in LMICs. [10] However, how these can be translated into meaningful involvement for people and communities is not well documented.

The significance of involving patients in their healthcare has gained recognition from healthcare providers, patient advocates, researchers, and policymakers as they realize that the actions patients take, or fail to take, play a crucial role in effectively preventing and managing illnesses. [2] Evidence suggests engaged patients have better health outcomes and lower acute hospitalisations. [3] [5]Various reasons have been cited for the importance of patient engagement, including viewing it as a patient's right to be involved in decisions that affect their health, and as a way to improve healthcare outcomes and reduce costs. [6] [8] Recently, Carman et al defined patient engagement as a partnership between patients, families, and healthcare providers at various levels, from direct care to policy-making, to improve healthcare outcomes. They described a continuum of engagement activities, ranging from information sharing to shared authority and co-leadership of improvement efforts. [6]

Several chronic care management models such as chronic care model emphasise the need for patient engagement in chronic conditions. [9] [2] Engagement strategies from HICs used in the management of chronic conditions include self-management support interventions such as collaborating with nurse or diabetic educator for glucose monitoring and medication management.[22] [23] Other interventions include improving HCPs' communication with patients and patients' access to electronic medical records.[24] [25] However, to-date most interventions incorporated by health system for patients with diabetes and hypertension in India are limited to creating health awareness by community health workers and ensuring provision of medicines.[26] Further, interventions need to be well accepted and tailored to the needs of the patients and HCPs for better uptake. Collaborating with end-users and non-academic stakeholders during the development of interventions is one way to achieve patient centred interventions, and it is commonly referred to as co-design.[27]

In the literature, involving stakeholders in the development of interventions or public health initiatives is referred to using various terms such as co-design, co-production, co-creation, participatory action research, or user-centred design.[28] Although different authors often use these terms interchangeably, they all refer to similar approaches to engaging stakeholders.[27]

7.3. Co-Design

The foundational studies by Ostrom et al[29 30] in 1973 and 1978 highlighted the importance of citizens' involvement in the "co-delivery" of public services, and in health care services, it signifies that health care services are "co-produced" between patients, carers, family and health care providers.[31] Subsequent work by Ostrom et al in 1996 demonstrated citizens could also fulfil the role of designers of public services.[32] Co-design refers to an intentional and voluntary process aimed at enhancing the capacity of public service delivery systems and improving the design and implementation of such services.[33] The approach has its origins from the participatory design movement in Scandinavia in the 70s[34] and through several developments such as user-centred design and/human centred design to designing for health care. [33 35]

Co-design consists of people with the relevant skills and experience coming together to create a tangible ‘product’ such as training materials, information booklets, a new service, organisational policies, and service specifications.[36] Co-design is participatory in nature and aims to create solutions by joint working between stakeholders that goes beyond basic consultation or observation.[37 38] Research has indicated that interventions that are co-designed have been associated with higher levels of acceptance, uptake, and long-term adherence among end-users, as well as greater satisfaction with the intervention and improved health outcomes.[27 39 40] For instance, community-based participatory studies in India have demonstrated reduction in fasting blood glucose levels and blood pressure among participanrs.[4] [42] Therefore, by involving users in the design process, co-design methods could increase engagement with a health tool or service.[43] Further, when end users are involved there is a possibility of better tailored solutions that address the need of that specific population and better satisfaction with the designed product that could improve adoption.[44 45]

7.4. Rationale for co-designing a PHR for improving user engagement

As described in the context for the PhD in the introduction, patients and HCPs were interested in having a PHR for improving handover. Further, from chapters four to six, the current use of PHRs is inadequate in addressing the complex needs of patients with diabetes or hypertension and the challenges faced by HCPs in using them. Patients, carers, and HCPs could come together in a co-design process to create a PHR that addresses the needs for self-management, handover, and informational continuity. Previous community-led initiatives in Kerala are shown in Box 1.

Box 1: Previous community-led initiatives in Kerala

- The Kerala state government implemented a decentralised mechanism for managing primary care services in the public health system in 1997.[46] Through an initiative called the People's Campaign for Decentralized Planning, the local self-governments or *panchayats* were given budgetary as well as governance responsibilities and support for managing public health facilities. [47 48] The local self-governments are in a position to identify felt needs of their community, people, assess the strength of local resources, make feasible development schemes, prioritize these schemes and integrate them into a local plan document and thus enable better localized health care services. [46 48] The latest available evidence shows that primary health centres that receive active support from the local self-governments do perform better. However, the support and involvement of local self-governments vary greatly across different health centres in Kerala.[49]
- Another significant involvement of communities came about within the realm of palliative care. Neighbourhood Network in Palliative Care (NNPC) started out as a local NGO (Pain and Palliative Care Society) initiative in Northern Kerala in 1993.[50] Under NNPC community volunteers and trained HCPs work together to provide care for long-term terminally ill patients. The volunteers are trained to identify problems of the chronically ill and bed-ridden patients in their area and to intervene appropriately. The underlying concept of the programme is to empower the local communities to look after the chronically ill patients in their community.[5] [52] With the success in Northern Kerala, the NNPC received support from the Kerala government and currently around 230 clinics are providing community-based palliative services across the 14 districts in Kerala.[52]

Despite the above examples, there are very few community-led initiatives to tackle non- NCD or improve health services for patients with NCDs in Kerala. A community-based diabetes trial described an intervention to reduce lifestyle risk factors by peer educators[53] and another community-based participatory research on promoting smoke free homes reported a reduction in smoking at home by men. [54]Routine community level initiatives for NCDs by Kerala government health services are limited to creation of awareness regarding lifestyle risk factors for NCDs by community health workers or ASHAs.[55] However, there is limited information on community-level initiatives or health service led activities for improving patient and carer involvement in the management of NCDs.

With the history of decentralisation and planning of health services at the local self-government level and commitment of citizen volunteers to previous community-led initiatives in Kerala, co-designing a PHR for patients with long-term conditions such as diabetes and hypertension may create better patient engagement with PHRs and thus involve them better in their management.

Co- design emphasizes the concept that people with lived experience, should be central to decision-making of services that they are part of.[56]Further, co-design for healthcare involves engagement with, and empowerment of, those HCPs and patients with lived experience. Therefore Experienced-Based Co-Design (EBCD) a specific co-design method, would be suitable for the development of a prototype of a PHR as it focuses on patients' experiences.

7.5. Experience-based co-design (EBCD)

Originally, the EBCD approach involves six defined stages (Table 1) and is typically undertaken over a period of 9-12 months for improvement of health service design.[57] The six stages can be grouped into an exploratory phase and co-design phase. The exploratory phase focuses on gathering user experience, emphasizes collaboration between different stakeholders, and focuses on patients' experience and the co-design phase is focussed on service users actively and directly participating in specific parts of, or the whole design process itself.[58] [59]

EBCD has been recently applied in the development phase of health system research projects to prioritize the problems experienced by patients.[37] Previous authors have reported adapting EBCD to different circumstances.[60]A review has described the various ways of adapting EBCD such as discarding the observation phase/review event, adapting the use of video narratives and changing the small group workshop with HCPs.[6] However, the importance of retaining patient interviews and interaction between patients and HCPs is re-iterated when adapting EBCD. [6]
The focus on accelerated EBCD is shortening the "discovery" or exploratory phase. To identify priorities in the discovery phase, pre-collected audio or video interviews are analysed for "touch points". [6]

Table 1 Stages of EBCD[59]

Stage	Description
Stage 1	Establishing the governance and project management arrangements.
Stage 2	Gathering staff experiences through interviews as well as observation of services.
Stage 3	Collecting experiences of service users through narrative interviews that are filmed.
Stage 4	A co-design event brings together the participants to identify emotionally significant points or 'touchpoints' where service users come into contact with services and to develop a set of key priorities to address
Stage 5	Small groups with staff and participants are created to work together to co-design improvements
Stage 6	A celebration event is held to reflect on what has been achieved and to prioritize areas for further consideration

This chapter describes the proposal for the co-design of a PHR to improve user engagement with PHRs for improving handover, informational continuity and self-management in Kerala.

7.6. Methods

Study design

The PHR would be developed using an accelerated form of Experienced-Based Co-Design (AEBCD) to shorten the exploratory phase.[60] As previously mentioned, the EBCD process typically takes 9-12 months to complete its original six steps. However, due to the different settings in Kerala and possible delays in recruiting participants, especially HCPs and administrators who are under time pressures due to post pandemic health system issues, an accelerated format may provide additional time to plan and conduct events and enable project completion within 12 months.

Instead of observing clinical areas and conducting interviews to gather experience data, this planned co-design process would use the data on patient, carer, and HCPs experiences of PHRs collected in Chapter four and the findings from Chapters five and six for co-design events. Two separate patient and carer meetings would be conducted to identify touch points for patients and carers. Traditionally, the nature of relationships between HCPs and patients/carers are hierarchical. Struggles and tension amongst participants have been reported, in previous papers[62 63] often due to power issues. Therefore, having separate workshops may enable patient participants to share their experiences freely.

Next, a joint co-design event with patients, carers, HCPs, state-level managers and local self-government representatives would be conducted for discussion on how to improve PHR for using PHRs for handover communication, informational continuity of care and self-management.

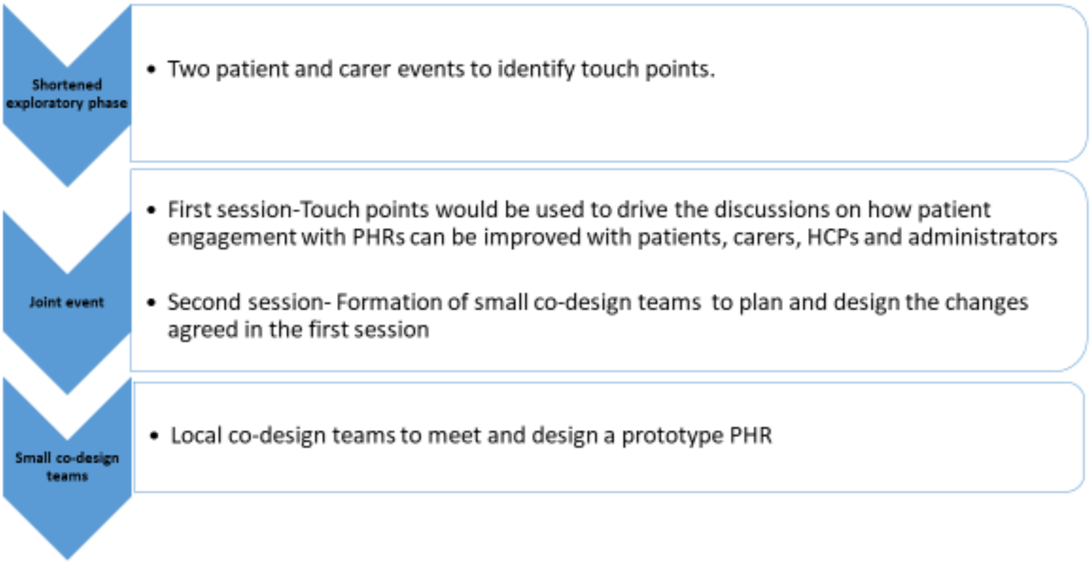
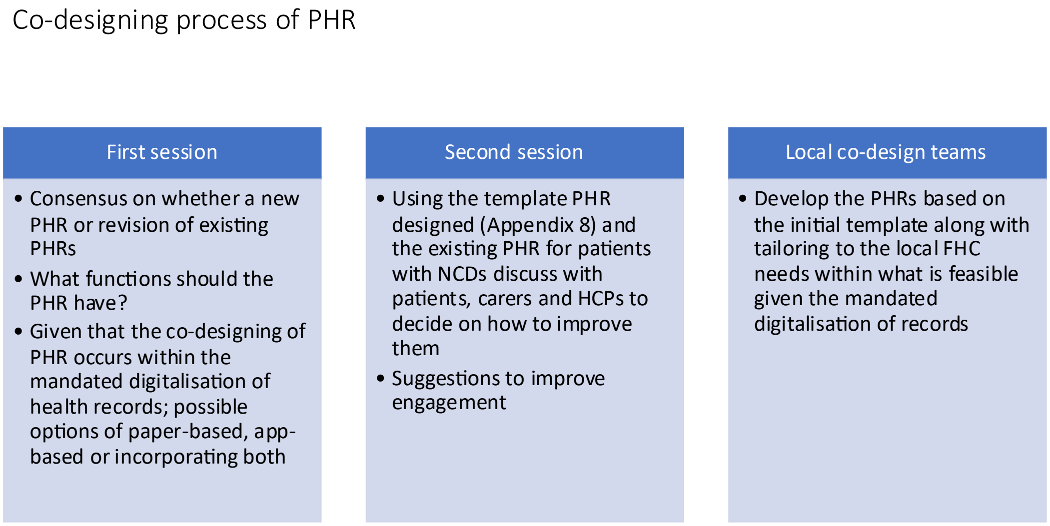


Fig 1 Steps for the proposed adapted EBCD method

The joint event would be done as two sessions. In the first session, presentation of identified touch points by facilitators and the findings from chapters four to six would be used to drive the discussion on how to improve PHRs for self-management, informational continuity and handover. This session would also be utilised to discuss whether a new PHR is needed or revise the existing PHR; what functions should the PHR carry out and template of the PHR. In the second sessions, co-design groups are created to plan how an improved PHR would be designed. The researcher has developed a template PHR for guiding the co-design of PHR with patients, carers and HCPs. The template PHR (Appendix 8) was developed using previous PHRs and discussion with supervisors. Local co-design groups would meet over two months and finalise a prototype PHR.

The planned process is illustrated in Figure 2.



Co-designing process of PHR

First session

- Consensus on whether a new PHR or revision of existing PHRs
- What functions should the PHR have?
- Given that the co-designing of PHR occurs within the mandated digitalisation of health records; possible options of paper-based, app-based or incorporating both

Second session

- Using the template PHR designed (Appendix 8) and the existing PHR for patients with NCDs discuss with patients, carers and HCPs to decide on how to improve them
- Suggestions to improve engagement

Local co-design teams

- Develop the PHRs based on the initial template along with tailoring to the local FHC needs within what is feasible given the mandated digitalisation of records

Fig 2 Overall tentative plan for the co-design of a PHR

In the context of mandated digitalization of health records, co-designing a PHR offers several possible options: paper-based, app-based, or a combination of both. These options entail distinct advantages and challenges. Paper-based PHRs provide a tangible format that some patients may prefer, but they require manual record keeping and lack the convenience of digital access. App-based PHRs offer the benefits of real-time data updates and accessibility via smartphones but may exclude individuals with limited tech access. Combining both approaches allows patients to choose their preferred method while ensuring digital integration for healthcare providers. The choice should align with the diverse needs of patients, balancing accessibility and convenience with the imperative of digital health record mandates.

7.6.1. Participant population

Patient participants would be eligible if they would have had the experience of seeking care from FHCs for diabetes, hypertension, or both. At least one or two patient participants must have had the experience of seeking care from an FHC with electronic health records implemented. As the electronic health implementation is ongoing in FHCs, having patient participants who have experienced using PHRs from FHCs with electronic health records would provide valuable insights into their experience and the potential benefits or challenges. Participants would have had the experience of using a PHR and be literate in Malayalam (the local language). Besides these considerations, patients who are too sick to participate (decided by patients /carers) would not be eligible since patients need to travel to the venue. Along with patient participants, carers would be eligible as they are considered to be a part of the patient's health care journey. Therefore, carers with experience in caring for patients with diabetes, hypertension, or both would be recruited. In addition, carers with experience in accompanying patients to secondary or tertiary levels would be recruited as they would have experience of interacting with multiple HCPs and PHRs.

State-level health managers would be recruited for the joint workshops. HCPs such as medical officers (doctors at family health centres) and nurses would be recruited for co-designing events as they are potential users of PHRs. Pharmacists were also considered to be participants in the co-design process, as they would have a chance to interact with patients and their PHRs. However, pharmacists' experiences were not captured as part of the qualitative study in Chapter four.

7.6.2. Plans for recruitment

Patients and carers would be recruited in the following ways. Firstly, the researcher approached a few FHCs in January 2021 to gauge their interest in participating in a co-design process. In FHCs where staff and patients/carers expressed an interest, the researcher would place an advertisement at the FHC itself. Secondly, patients and carers would be recruited from a pool of participants who have had experience in being part of community-based health research projects in Kerala. Thirdly, information regarding participating in the co-design process would be disseminated using "ayal kootams" (local women self-help groups) and involving representatives of local self-government (panchayats). The use of local women self-help groups would ensure participation from lower socio-economic backgrounds.

HCPs and state-level managers would be recruited in the following ways. HCPs would be given an invitation at the FHCs. Secondly, HCPs that participated in the qualitative study described in Chapter four would be recruited. Finally, the snowball method[40] would be used, by which recruited participants would be asked to suggest other colleagues or to refer the advertisement to others.

7.6.3. Using local narratives for a state-level co-design workshop

The EBCD method in the literature has been described as useful for identifying priorities and co-designing a service at an institutional or local level. However, this has been identified as time and resource intensive.[60] The qualitative study in Chapter four identified the perceived value of current PHRs for handover communication, informational continuity, and self-management for patients, carers, and HCPs for diabetes and hypertension. Although the results of the qualitative study in Chapter four may not be generalizable to all patients and carers attending public health facilities in Kerala, they can be used as “touch points” for patients and carers to share their stories. These touch points can be used as triggers for a facilitated group discussion with patients and carers. Additionally, the researcher hypothesised that using local narratives from patients and carers for local improvement alone could make health care staff at local FHCs feel defensive. There is a possibility that HCPs may feel blamed for the lack of resources or shortcomings of the health system and HCPs alone may not be able to sort out these issues themselves. Further, HCPs may feel defensive that their positive efforts are not being valued and only shortcomings are highlighted. This could also prevent patients and carers from narrating their experiences completely due to the fear of anticipated issues in their further care.[44] Another reason for considering a state-level co-design is the existence of a traditional and “top-down “health system structure in Kerala's public health system settings.[64] Therefore, state-level health care managers and local self-government representatives need to be involved in making the coproduction process credible for all participants involved.

7.6.4. Venue

Patients and carers telling their stories and experiences could provide a different perspective than the usual conversations in a health care consultation. However, when the settings are hospital, health care settings, patients and carers may not feel comfortable in responding well.[65] [66] Therefore, a neutral location such as community halls, or local wedding halls were considered for the event.

7.7. Reflection on challenges

Joint working is one of the core principles of EBCD, which focuses on working with the patients rather than for patients. [59] One of the factors that may hinder joint or collaborative working is the existing positions of power held by HCPs. [67] [68] There is well-documented imbalance of power between patients and HCPs and this has highlighted to act as a barrier to involvement activities and thus hindering collaborative working. [5] The researcher has therefore considered planning workshops with patients separately for patients to share their experiences. A previous study using the EBCD method reported that the *patient-only* events enabled the participants to be comfortable within the group and to discuss the experiences.[69] The ethos of respecting and valuing the knowledge of all those working together on the developing the PHR would be stated explicitly in each event. Additionally, the facilitators would present the findings from the patient and carer meetings. Therefore, co-designing a PHR with academic researchers, patients/carers, HCPs and other relevant stakeholders such as health care administrative workers etc. could potentially contribute to developing a PHR to improve patient involvement and subsequently improve quality of care.

One of the possible key challenges of conducting EBCD in Kerala is the competing values and conflicting interests of different stakeholders.[70] [7] Patients, families and carers, HCPs, and administrators may have different priorities and agendas, which can create tensions and conflicts. For example, patients and families may prioritize tailored information in PHR and verbal communication with HCPs, while HCPs and administrators may prioritize efficiency. Information asymmetry among the service users and service providers is one of the known reasons for the conflicting priorities.[72] Adding to this, the societal hierarchies and the high esteem conveyed upon medical staff can present additional ethical challenges for co-design such as acknowledging HCPs views even when their participation is low. [73] Patients may feel intimidated by the expertise and experience of their HCP counterparts, leading them to believe that they have less to contribute to the design process.[69] To address this challenge, it is important to create a safe and inclusive environment for patients to share their thoughts and ideas which is proposed through the *patient only* events. These events can be an opportunity to provide clear explanations of any medical concepts and the processes of EBCD. Further, facilitators can help to ensure that all voices are heard and that the discussion stays focused on the goals of the co-design process in the joint EBCD event.

A significant difficulty is effectively handling the expectations of different user groups, especially patients and carers.[57 69 74] It is crucial to establish clear expectations at the outset of what outcomes participants can anticipate reducing the possibility of dissatisfaction or feeling taken advantage of, particularly when collaborating with patients who have limited resources.

Finally, some patients/public may prefer not to engage with coproduction. Patients/citizens should not feel obliged or coerced to participate in workshops.[75] On the other hand, representativeness of the patient group may be a challenge. Therefore, researchers need to reflect on this aspect while recruiting patients, carers, and other members of public for a co-design workshop.

Previous literature from HICs have identified the following barriers for successful EBCD: lack of resources, lack of training for facilitators, poor managerial support, and high staff turnover, barriers for recruiting vulnerable patients and the retention of these group until the end of the EBCD process. [70] All of these barriers are potentially applicable for running an EBCD project in Kerala.

7.8. Conclusion

This is the first project to propose an EBCD approach to co-design a PHR in the public health settings in Kerala and thus contributes to the emerging literature about best practice for involving patients in co-design activities. In this proposed study, a modified approach to using local narratives for a state-level co-design workshop is suggested to improve acceptability of the process.

7.9. Chapter Summary

This chapter has explored the proposed development of a PHR using the EBCD method by incorporating the qualitative findings from Chapters four, five and six into the co-design of the PHR. It has highlighted some of the practical considerations and challenges for carrying out the EBCD workshops. The chapter highlights how the EBCD method would need to be adapted to develop a PHR in Keralite settings and consequently use co-design as a possible way to improve engagement with PHRs India and other similar LMIC settings. This chapter therefore contributes to the overall aim of thesis by exploring ways to improve patients' engagement with PHRs for self-management in Kerala.

The following chapter will summarise the findings and wider policy implications of the entire thesis, discuss the strengths and limitations of the thesis as a whole, and highlight opportunities for future research.

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CHAPTER EIGHT

DISCUSSION AND CONCLUSION

8.1 Chapter preface

Chapter eight re-visits the thesis aims, and research questions and summarises the principal findings of the research work. This is followed by a discussion of the limitations of the thesis (strengths and limitations of each study have been described in the relevant chapters), implications, and future research recommendations.

8.2 Introduction

India has a high prevalence of hypertension (207 million individuals) and diabetes (74 million individuals). [2] Due to inadequate awareness, treatment, and control there are greater risks of vascular and renal complications among Indians.[3 6] A recent study in Kerala identified poor blood pressure control among diabetic patients, necessitating improved control.[7] Previous research in India found ineffective handover communication for NCD patients and proposed using structured PHRs for better information transfer.[8 9] PHRs are often used in LMICs like India to document and share medical information between patients, carers, and HCPs for optimal care and self-management. However, there is limited evidence on the use of current PHRs from Kerala for handover, information transfer, and self-management.

8.3 Aims

This thesis aimed to evaluate the current evidence to support the use of PHRs from LMICs and to explore the views of patients, carers, and health care HCPs regarding the use of current PHRs for handover, informational continuity, and self-management. Next, it aimed to understand why patients engage (or not) with PHRs for self-management and to identify the barriers and facilitators for HCPs in recording in PHRs using the TDF [0], and to propose a method to co-design a PHR which may enhance patient engagement with the PHR. The thesis aims were met through multiple studies (rationale presented in Chapter 2) which were developed to answer the following research questions:

- What are the types of PHRs used in LMICs and what evidence of effectiveness and usefulness for handover in LMICs is available? (Chapter 3)
- How are patients, carers, and healthcare providers in Kerala, India using currently available PHRs? (Chapter 4)
- Why do patients engage (or not) with current PHRs? (Chapter 5)
- What are the barriers and facilitators for using PHRs by HCPs for handover communication and informational continuity across HCPs and patients/families? (Chapter 6)
- What is a potential method for co-designing a PHR to facilitate patient engagement with PHRs within health settings in Kerala, India? (Chapter7)

Chapter one provided the background, the rationale for the thesis was presented in the Introduction and Chapter two described the methodology used in the thesis. Chapter three summarised the evidence on PHRs in LMICs using two systematic reviews. Chapter four explored and compared the experiences of patients, carers, and HCPs with current PHRs in Kerala, India, analysing the current use of PHRs by each group and the value they placed on these. Chapter five presented an analysis of why patients do not engage with current PHRs for self-management. Chapter six then used the TDF to understand the barriers and facilitators to the use of PHRs by HCPs for handover communication and informational continuity of care. Chapter seven proposed Experience-Based Co-Design method to co-design a PHR for patients with diabetes and/or hypertension in Kerala for improving patient engagement and reflected on the practical and ethical considerations of using the EBCD method.

8.4 Summary of findings

The research in this thesis presents several novel additions to the existing knowledge base about PHRs, with a focus on the public health settings in Kerala context. Each qualitative analysis employed represented the first time it has been used with patients, carers and HCPs (Chapters four, five and six) in Kerala. Further, this thesis presents the complexities and challenges of using PHRs in practice for handover, informational continuity and self-management.

The systematic reviews found limited evidence on effectiveness of PHRs to improve handover communication and self-management in LMICs. However, HCPs, patients, and carers value maternal and child health PHRs. From the qualitative study, patients value PHRs for medication procurement, carers value PHRs for communication with HCPs in emergencies and HCPs value PHRs for clinical decision-making and prevention of errors among those interviewed in Kerala. Limited patient engagement with PHRs for self-management was attributed to patients' navigations of pluralistic health system, their interactions with HCPs and their wider socio-economic conditions answered why patients do not engage with current PHRs for self-management. The factors affecting HCPs' use of PHRs to maintain informational continuity were identified using TDF and facilitators fell into the following domains: "knowledge," "skills," "social or professional role and identity," "beliefs about capabilities," "intentions," "goals" and "optimism." Barriers mostly were described by two domains "memory, attention and decision processes" and "environmental context and resources" domain. About the final research question, co-designing a PHR using the experience-based co-design method was proposed for improving patient engagement with PHRs by providing justifications and attention to practical and ethical concerns.

The key findings will be discussed below as they relate to each research question. These findings are compared with existing literature and are located and contextualised within the existing knowledge base in the following paragraphs.

8.4.1 What are the types of PHRs used in low- and middle-income countries (LMICs) and what evidence of effectiveness and usefulness for handover in LMICs is available?

Chapter three was designed to answer the first research question. The first systematic review synthesised the evidence on PHRs for NCDs, using narrative synthesis. The key finding was the inclusion of only six studies in the review, highlighting the scarcity of research evaluating PHRs for chronic conditions like diabetes or hypertension. Furthermore, no RCTs were identified that assessed the effectiveness of PHRs for NCDs in improving health outcomes or other related processes in LMICs.

Among the selected studies, it was noted that patients often carried PHRs to healthcare appointments. However, the findings revealed suboptimal record-keeping by HCPs in PHRs. HCPs acknowledged that access to patients' medical information from other HCPs through PHRs reduced errors. Patients perceived PHRs as a form of 'medical identification' and found them valuable in emergencies, as they provided essential background information and facilitated continuity of care across different healthcare facilities. A significant gap in the literature was the lack of exploration into the experiences of carers using PHRs in LMICs. These findings must be understood in the context of the rising burden of chronic conditions like diabetes and hypertension in India and other LMICs. Current strategies for managing NCDs in these regions primarily focus on screening, ensuring medication accessibility, and promoting healthcare access.

The systematic review on HBRs in maternal and child health included 41 research papers. Key findings highlighted that HBRs were predominantly available for healthcare providers during medical visits. However, the extent of documentation in HBRs varied. The utilisation of HBRs resulted in improved attendance at antenatal visits, increased immunization rates, and a higher likelihood of skilled birth deliveries. Mothers' knowledge of breastfeeding practices and pregnancy danger signs also improved with HBR use. HCPs perceived HBRs as helpful for health education, vaccination reminders, and access to previous vaccination records. However, some

HCPs felt that mothers and families did not utilize the information within HBRs at home. Mothers believed they could read and discuss HBR information with their families but often failed to record it. Qualitative studies from India were notably absent from the review, underscoring the need for further exploration into the use and reasons for the use or non-use of current PHRs.

8.4.2 How are patients, carers and healthcare providers in Kerala, India using currently available PHRs? (Chapter 4)

This qualitative study was designed to address the second research question and contributed to the existing literature by offering a comparative analysis of the current use and perceived value of PHRs among patients, carers, and HCPs in Kerala. Data was collected through one-on-one semi-structured interviews with individuals living with diabetes and hypertension, their carers, and HCPs. The interview data were transcribed and subjected to thematic analysis. Chapter four of the study presented and compared themes related to practical use and perceived value of PHRs, yielding three key findings:

Firstly, the presence of multiple PHRs carried by patients posed challenges for both patients and HCPs. Secondly, each group perceived the value of PHRs differently: HCPs valued them for clinical decision-making and patient safety, patients for medication management, and caregivers for emergency situations. Lastly, PHRs were not used for self-management by patients or HCPs, with HCPs documenting minimal information within them. Patients did not view PHRs as valuable for information transfer but carried them to consultations when requested by HCPs.

Notably, the experiences of carers using PHRs, especially non-maternal PHRs, had been previously absent in LMIC literature. The findings suggest that while PHRs have the potential to enhance healthcare delivery, significant challenges exist, including the use of multiple PHRs, limited documentation by HCPs, and varying perceptions of their value among stakeholders. Suboptimal recording by HCPs in PHRs, as reported in this study, has also been observed in previous research in India and other LMICs, which raises patient safety concerns due to the need for past medical information in clinical management.

Chapter four revealed that both patients and HCPs do not use nor value PHRs for communicating self-management practices, highlighting potential communication failures in self-management in Kerala, ultimately affecting patient outcomes and overall satisfaction with care. These differences in PHR use and value among patients, carers, and HCPs have implications for handover communication, informational continuity, and self-management in the long-term management of diabetes and hypertension in Kerala. This underscores the need for co-designing PHRs and developing support interventions that align with the perceived value of PHRs for different user groups, considering the absence of comprehensive electronic health records in most LMICs.

8.4.3 Why do patients engage (or not) with PHRs for self-management (Chapter 5)

For answering the third -research question, the themes and sub-themes from the patient interview data pertaining to the reasons for patients’ lack of engagement with PHRs were grouped. The themes generated were mapped as contextual factors at the levels of health system, patient-level, and socio-economic factors.

Chapter five of the thesis presented three significant findings regarding patients with diabetes and hypertension. Firstly, patients navigate the health system based on factors such as trust in HCPs, perceived illness severity, and medication affordability, resulting in multiple PHRs that affect their engagement with PHRs for self-management. Secondly, patients perceive PHRs as transactional tools for medication procurement and documentation for HCPs, preferring verbal communication with HCPs during consultations. Thirdly, patients' socio-economic and cultural backgrounds influence their engagement with self-management activities, with those with lower education and financial resources performing minimal self-management activities. Women with lower education face additional challenges in managing physical activity between work and household chores, affecting their engagement with PHRs for self-management.

The chapter underscored the need to improve the self-management support offered to patients with diabetes and/or hypertension by addressing the wider socio-cultural factors curtailing patients' agency. This may involve developing culturally appropriate interventions that target patients' knowledge, attitudes, and beliefs about their health condition, as well as addressing structural barriers such as poverty. Contextual factors such as the health system factors, and patient-level factors contribute to limited engagement with PHRs for self-management (chapter 5) and are often overlooked in the literature. The issues of patient engagement with PHRs or limited uses of PHRs have been attributed to lower literacy of the patients/carers/families. As such, the importance of using pictures, and patient-friendly language and thus largely improving the content of PHRs have been the focus of developing or improving PHRs [7] [8]. However, this study suggests that additional support interventions that consider the contextual factors may be needed for using PHRs effectively for self-management.

8.4.4 What are the barriers and facilitators for using PHRs by HCPs for handover communication and informational continuity across HCPs and patients/families? (Chapter 6)

While the previous chapter had examined the contextual factors that appear to influence patients' engagement with PHRs, this chapter explored factors that may influence HCPs' use of PHRs for continuity of care and handover communication.

Three key findings were identified: Overall, seven domains were identified as facilitators for HCPs using PHRs to establish and maintain informational continuity and subsequent management continuity for patients with diabetes and hypertension. Of which, the knowledge of the availability of PHRs for patients with diabetes and hypertension encouraged HCPs to record them. HCPs' knowledge and awareness of the working conditions of the public health system, their previous experiences with lack of information due to the absence of facility-based records, or perceived difficulties in retrieving information from electronic health records. The most frequently perceived barriers were the most in the two domains. The domains were "memory, attention and decision processes," "environmental context and resource" domains. Other barriers to continuity of care were attributed to beliefs about consequences and capabilities due to patients' behaviour. Overall, HCPs had mixed views regarding electronic health records and their role in maintaining informational continuity in public health settings. Some HCPs felt that if electronic health records are being used widely in the health system and regularly documented well, they could improve informational availability for HCPs.

The study examined the use of PHRs in the context of electronic health record implementation and analysed the barriers and facilitators for recording and maintaining PHRs for continuity of care using the TDF. This approach helped to identify important domains for further intervention development. The findings emphasise the need for healthcare providers to be trained on the use and benefits of PHRs to increase their uptake and utilisation.

8.4.5 What is a potential method for co-designing a PHR to facilitate user engagement with PHRs within health settings in Kerala, India? (Chapter7)

Given that patients, carers, and HCPs hold differing value for PHRs based on their experiences with PHR, if the PHRs are co-designed by incorporating each stakeholder group’s views, PHRs have a better chance of being adopted. This chapter proposed a plan for co-designing a PHR using EBCD method, aiming to contribute to improved patient and HCP engagement with PHRs. The chapter explored the practical and ethical considerations such as using local narratives for a state-level co-design, venue and recruitment of patients and carers. The proposed plan considered the possibility of hierarchical nature of HCPs and hence initial separate workshops with patients and carers were proposed. Co-designing a PHR using the EBCD method has the potential to improve patient and HCP engagement with PHRs and improve the management of chronic conditions such as diabetes and hypertension.

8.5 Strengths and Limitations

The strengths and limitations of the individual studies have been discussed within each chapter, this section will briefly discuss the overall strengths and limitations of this thesis and the results within the thesis should be interpreted with the context of the strengths and limitations.

The systematic review (Chapter 3) provided a comprehensive summary of the literature regarding the effectiveness and usefulness of PHRs in LMICs and marks the first time that such a review has been undertaken. Two systematic reviews enabled to summarise and focus the evidence on PHRs for NCDs and PHRs for maternal and child health care. Multiple databases were included in the search strategy to reduce the omission of eligible studies. The findings of systematic reviews (Chapter 3) were reported following the PRISMA guidelines. [9] Limited studies were included in the systematic review on PHRs for NCDs and therefore the practical utility of the research is limited. Further, a possible limitation is the lack of search in the national databases in LMICs.

The study reported in Chapter four is the first study to qualitatively explore patients', carers and HCPs experiences with current PHRs in Kerala, India. In addition, the use of three diverse sources of information (patients with diabetes and hypertension, carers, and HCPs) allowed for each of their perspectives on current PHRs (Chapter 4) and achieved data saturation for each group. [20] Achieving data saturation ensured that the findings were grounded in the experiences of key participant groups. The evidence this thesis present adds a compelling and current perspective from patients, carers and HCPs to the existing evidence base of user experiences with PHRs.

From a qualitative research viewpoint, data triangulation further enhanced the perspectives from data.[20] Data from different sources aid in understanding the phenomenon more comprehensively, rather than as an indicator for validity.[2] Within this thesis, understanding comprehensively and not validating the information means that the researcher have not assumed patients' interview accounts (Chapter 4) are to be believed over HCPs accounts and vice versa, rather patients, carers and HCPs' experiences are needed to understand their current use and value of PHRs.

Only the researcher coded transcripts for Chapter four and five, however analysis and interpretation of data were discussed with a multi-disciplinary supervisory team with expertise in anthropology, medical sociology, clinical epidemiology, and experience with health systems in Kerala. Further, in chapter six, the credibility of data analysis was enhanced by multi-analyst triangulation.[22] and also adds to the limited number of studies utilising TDF from LMICs.

One of limitations of this thesis is that it has focused on public health settings alone, while a considerable volume of health care is provided by private health settings in Kerala, India and other similar LMICs. However, the patients were drawn from those seeking care from the public health care settings and those seeking care from both private and public health settings. As such, they are representative of the patterns of care seeking by patients with diabetes and hypertension in Kerala. Further it is important to consider that patients who had been diagnosed with diabetes and/ hypertension and sought treatment are included and hence this study would have not captured those people who had access issues to health care settings.

The qualitative study in Chapter four had more women than men and most of the respondents were over 45 years of age. This may have limited the exploration of views of young men. However, it must be noted that most patients were recruited at the health centres or based on which healthcare facility they access care for diabetes and hypertension. There is evidence from previous studies that more women seek care than men in Kerala do.[7 23]

The qualitative study had patients with diabetes and hypertension as tracer conditions for NCDs, while patients with other NCDs such as chronic obstructive pulmonary diseases or cancers may have different views on PHRs.

Also, in chapter six, the researcher does not claim to have reached data saturation[20] in relation to domains of the TDF. The topic guides for semi-structured interviews with HCPs were not based on the domains of TDF. However, the purpose of the use of TDF for reanalysis of HCP interview data was to provide different insights into the barriers and facilitators for HCPs in recording, updating and maintaining the PHRs for informational continuity.

Finally, the co-design workshops could not be done owing to COVID 19 and subsequent lock down in Kerala.

8.6 Implications of findings for policy and practice

As explained in Chapter one (section 1.3 Long-term management of diabetes and hypertension), this thesis focused on the patient and HCP interaction level or micro level of the WHO's framework for chronic conditions. [2] Overall, the findings show how PHRs are used in current practice and the factors affecting their use for handover communication, informational continuity, and self-management for patients with diabetes and hypertension in Kerala, India. This section looks what are the consequences of the research findings of the thesis for health care practices.

Multiple PHRs contribute to discontinuities in informational transfer and handover communication across HCPs, patients with diabetes and hypertension, and carers in Kerala.

The results from Chapters three and four, further support the idea of having a single or universal PHR as suggested by a study conducted in Mongolia [24] for information transfer across different health settings for patients with long-term conditions such as diabetes. However, with the implementation of electronic health records for patients in the public health settings in Kerala paper-based PHRs may become redundant. Accompanied by national level efforts for digitalisation of health care (Ayushman Bharat Digital Mission), there are significant changes in how medical information of patients may be stored and transferred across HCPs. [25] One such change proposed by the Indian government is creating and using a universal health identification number (currently known as the ABHA number). [26] Creating unique identifiers for patients potentially enables storing and sharing patients' medical records with all HCPs that patients visit. [26] Additionally, the Indian government also has released standards of electronic health records which mandates the use of content exchange summaries that enable sharing of medical information when patient moves from one healthcare facility to other. [27] Despite the promising digital innovations, there is still a lack of evidence of adequate health information exchange and handover communication between healthcare facilities in Kerala and other LMIC settings.

HCPs report sub-optimal recording in PHRs; thus, inadequate informational and management continuity for managing patients with diabetes and hypertension.

Within the limited number of studies included in the systematic reviews (Chapter 3), the completeness of the PHRs were varied and sub-optimal in most cases (exception of vaccination data). The qualitative study (Chapter 4) reported that HCPs stated that the recording in PHRs were sub-optimal. HCPs explained that they try to document information when the patient is new in their facility. However, HCPs noted that the subsequent recordings might not be as comprehensive.

Regarding the barriers associated with using PHR for informational and subsequent management continuity for patients with diabetes and hypertension, two domains of the TDF were found influential (Chapter 6). The two domains "memory, attention and decision process" and "environmental context and resources" depicted the barriers identified by HCPs for informational continuity of care. HCPs reported a lack of time to communicate with patients in the outpatient settings due to the increased workload. They also highlighted difficulties in locating the information from multiple PHRs brought to the healthcare appointment by patients. Previous studies from India have highlighted similar constraints due to workload and lack of time. The critical implication of the finding that HCPs do not have enough time with each patient is that patients with diabetes and hypertension may not receive adequate education and support for self-management at home. As described in Chapter one (Section: 1.3 Long-term management of diabetes and hypertension), adequate communication with HCPs is needed for adherence to medicines and self-management.

While the efforts for digitalisation of health records have discussed the increasing availability of medical records for patients, HCPs, and interoperability issues, there are insufficient efforts to ensure information is recorded. As seen in Chapter six, the barriers to recording in a PHR are not addressed by creating opportunities for recording medical information digitally. Furthermore, there is a need for the health care staff to be trained in compliance of standards for recording in digital health records. [26] Additionally, guidelines and protocols must be developed for recording and utilising the information in health records. In the absence of guidelines and training for recording a minimum information in digital health records, the issues of disruption to information transfer and handover communication will persist.

The importance of the thesis findings lies in the fact that the thesis explored **patients, carers, and HCPs' experiences of using PHRs and the value they place on PHRs**, which was the first of its kind within Kerala. Some of the longstanding issues with handover communication, informational continuity of care and self-management could be resolved if the work commenced in the study is continued, leading to a generalisability potentially, nationally and in similar health care settings in India and other LMICs. Thus, this thesis adds to the growing body of literature that describes the critical role of patients and carers in making healthcare infrastructures work globally. Patients and carers are essential and often central to maintaining informational continuity and handover communication, as they need to bring past PHRs and communicate with HCPs regarding their health information for optimal care. Patients and carers need to play an active role in the management of long-term conditions such as diabetes and hypertension.

Patients' and/carers' active involvement with care is necessary as they need to engage with their HCPs and care for preventing complications.

Role of culture and literacy

Limited data on existing PHRs make their benefits for improving health outcomes in LMICs uncertain. Further, the impact of the findings (Chapters 4-6) may be significantly influenced by culture. For example, cultural differences in communication styles and hierarchies in healthcare settings can affect how patients interact with HCPs and how they view tools like PHRs in different LMICs. [28,29]Cultural variations in health literacy levels can impact how patients and carers understand and engage with PHRs. Some cultures such as in China and India may prioritize traditional or alternative medicine practices potentially affecting the perceived utility of PHRs.[28] [30] China has a history of traditional medicine, including practices like acupuncture and herbal remedies and many Chinese individuals may integrate Traditional Chinese Medicine (TCM) alongside Western medicine. In this context, the perceived value of PHRs may vary. Some patients may prioritize TCM records over Western medical records in their PHRs, while others may see PHRs as a tool to track both.[3]

One implication of the finding is that literacy levels could have introduced differences in reading and comprehension levels among participants. However, since most participants in this study (Chapter 5) were literate, the reasons they provided for their lack of engagement with PHRs for self-management appear to extend beyond issues of literacy as self-management suggestions were printed in the local language in the PHRs.

Although participants may be literate, this does not necessarily reflect their health literacy. Furthermore, the medical information recorded by HCPs may be in a format that is primarily designed for communication between HCPs, potentially making it less accessible to patients. Therefore, while literacy is an important factor to consider, the barriers to effective engagement with PHRs may encompass broader issues related format of medical information, having multiple PHRs making it difficult to engage, their own perceptions of PHRs being tool for HCPs and not themselves and broader structural factors, which could impact participants' abilities to manage their health effectively.

8.7 Future research

The research within this thesis has added to the relative dearth of literature on PHRs from LMICs and particularly understanding about PHRs use and value in India, thus contributing to knowledge. Given the increasing NCD burden in India and other LMICs and therefore the importance of handover communication and informational continuity for safety and quality patient care, there is a pressing need for further research to guide the development and implementation of PHRs. strategies. The following areas have been identified by the thesis as areas that need to be addressed in future to improve the use of PHRs for handover, information transfer and self-management.

1. Evaluation of current PHRs and their effectiveness in handover, informational continuity, and self-management in similar LMICs.

   Chapter three identified the dearth of literature on PHRs from LMICs. There is evidence of PHRs being used in many LMICs such as Malawi[32] Namibia[33]; however, they have not been evaluated. It would be useful to evaluate their effectiveness and usefulness particularly with the influx of digitalisation of healthcare in LMICs. Paper records will remain the main form of medical records and are unlikely to be replaced entirely by electronic records, at least soon in many LMICs. [34]
2. Factors affecting patient engagement with PHRs for self-management in other chronic conditions in Kerala, India and similar LMICs

   In the qualitative study (Chapters 4 and 5) study participants were limited to patients with diabetes and hypertension. However, some patients have had past histories of cardiovascular diseases, and their experiences included interactions with more HCPs.

Therefore, further qualitative work may be done within different NCDs such as chronic obstructive pulmonary diseases, cancer, and other chronic multi-morbid patients, to further develop and strengthen the generalisability of the factors affecting patients' engagement with PHRs for self-management identified in this thesis. This would allow for the development of clearer functions for PHR, which truly incorporates, and value the perspectives of all relevant stakeholders.

3. This thesis did not consider the perspectives of higher-level managers such as NCD nodal officers or health administrators, policy makers in Kerala. A previous study on implementation issues for HBRs included key informants with expertise in running maternal, neonatal and child health programmes, reported implementation level barriers.[35] Future work could consider exploring implementation issues as well as role of PHRs with the health care managers for their views on how PHRs can be useful (or not) within the electronic health records implementation in India.
4. Barriers and facilitators for HCPs' use of PHRs in Kerala

   As stated in the limitations, the interview guide for HCPs' interview was not developed based on the TDF. There is a possibility for other domains to be important. A quantitative survey using the TDF among HCPs in both public and private settings, and across primary, secondary, and tertiary levels may be done for further generalisability of the domains identified from Chapter six. Additionally, further research could allow for understanding the intervention content for any behaviour change intervention for HCPs in Kerala.
5. Co-designing a PHR

   Future research should consider co-designing a PHR with stakeholder groups in Kerala. Given the various digital health innovations, proposed and planned changes in electronic health record implementation and potential of mobile app based PHRs; co-designing will enable gathering patients and carers' preferences and may contribute to improved user engagement for PHRs in Kerala. A co-designed PHR, which is context specific, could serve as a model for PHR to be used in India and similar settings in LMICs. Further, the co-designed PHR should be implemented and evaluated to understand the effectiveness of PHRs for handover communication, informational continuity, and self-management.

6. Understanding the role of paper-based and app-based PHRs within the context of electronic health record implementation. Further investigation of preferences for paper-based or app-based PHRs could be an interesting area of study. This would allow for exploration of how different types of PHRs could function within the context of digitalisation of health care.

8.8 Conclusion

The existing literature describes that patient-held records are tools intended to improve handover, informational continuity, and self-management. However, this thesis reveals that among the patients, carers, and HCPs interviewed from Kerala, each group value PHRs differently. This perspective sheds light on how different value placed on PHRs by each user group contributes to the reasons for the sub-optimal use of PHRs in practice for handover, information transfer and self-management in the public settings in Kerala.

Notably, this study is the first to comprehensively explore the experiences of patients, carers, and HCPs with PHRs in Kerala, India. Further, the findings of this thesis confirm that patients and carers carry PHRs to HCP visits in Kerala. The findings provide important evidence on the contextual barriers among patients interviewed for engaging with PHRs for self-management. These findings have important implications for LMICs like India, where the prevalence of multiple long-term conditions is increasing. Patients with multiple –long term conditions have complex health histories and multiple medications and therefore face significant challenges in communicating their medical history with multiple HCPs, managing their care effectively, making it crucial to develop interventions that empower patients, carers, and HCPs to use PHRs effectively. By the end of this thesis, the complexity and challenges of using PHRs for handover, information transfer and self-management has been documented and analysed using an evidence-based approach.

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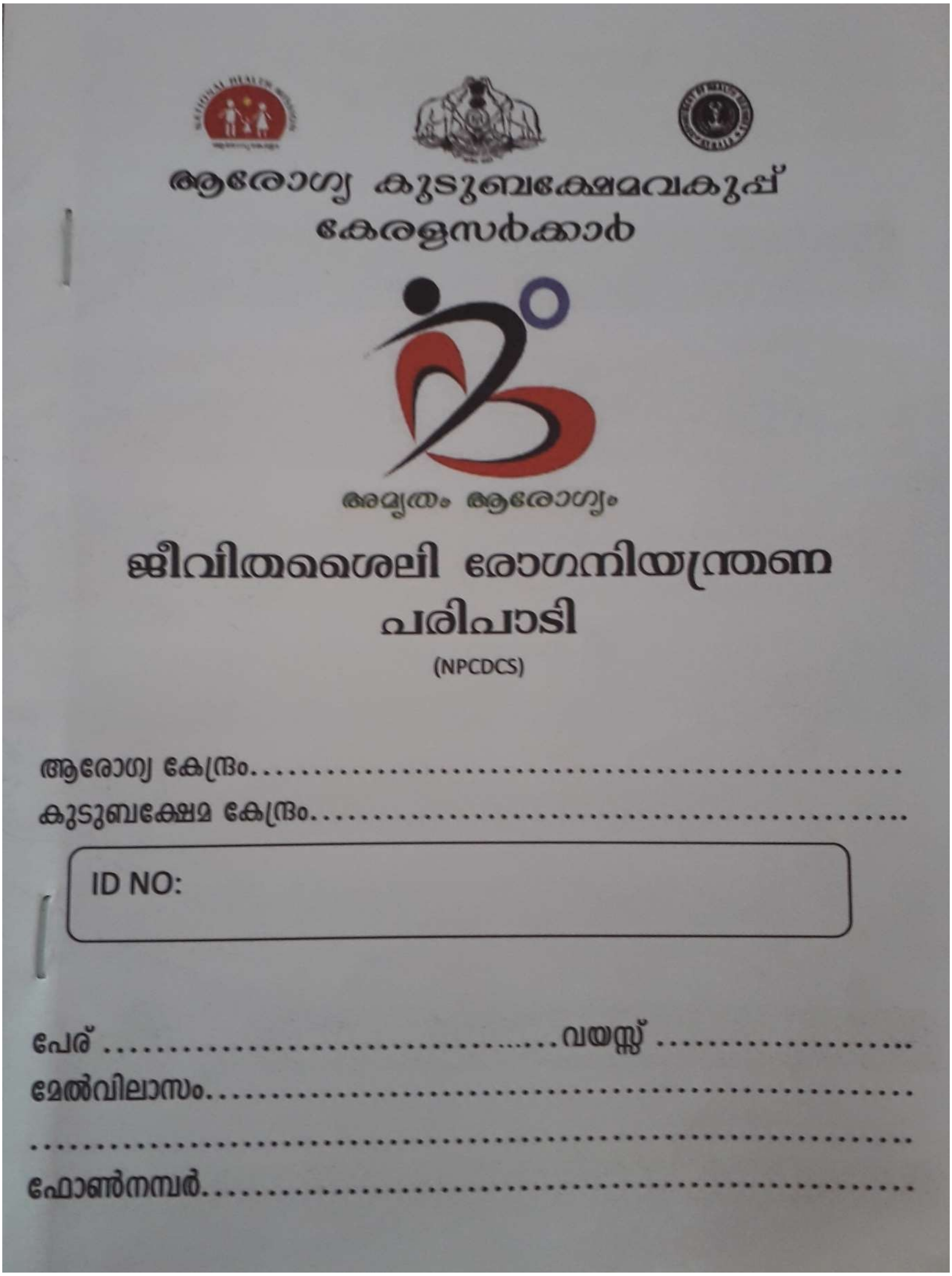
Appendices

Appendix 1 a: Patient-held booklet for NCD patients available in the public health system

Note: Patients did not have to pay for the NCD PHR. Patients need to pay Rs 5 as registration/consultation fee. Payment at the family health centres were not highlighted by patients nor HCPs. The notebook was instead of the NCD PHR. There were periods of stock-outs for NCD PHRs, during which the HCPs asked patients to buy a general notebook to be used instead of the NCD PHRs



ആരോഗ്യ കുടുംബക്ഷേമവകുപ്പ്
കേരളസർക്കാർ

അമൃതം ആരോഗ്യം

ജീവിതശൈലി രോഗനിയന്ത്രണ പരിപാടി

(NPCDCS)

ആരോഗ്യ കേന്ദ്രം...

കുടുംബക്ഷേമ കേന്ദ്രം..

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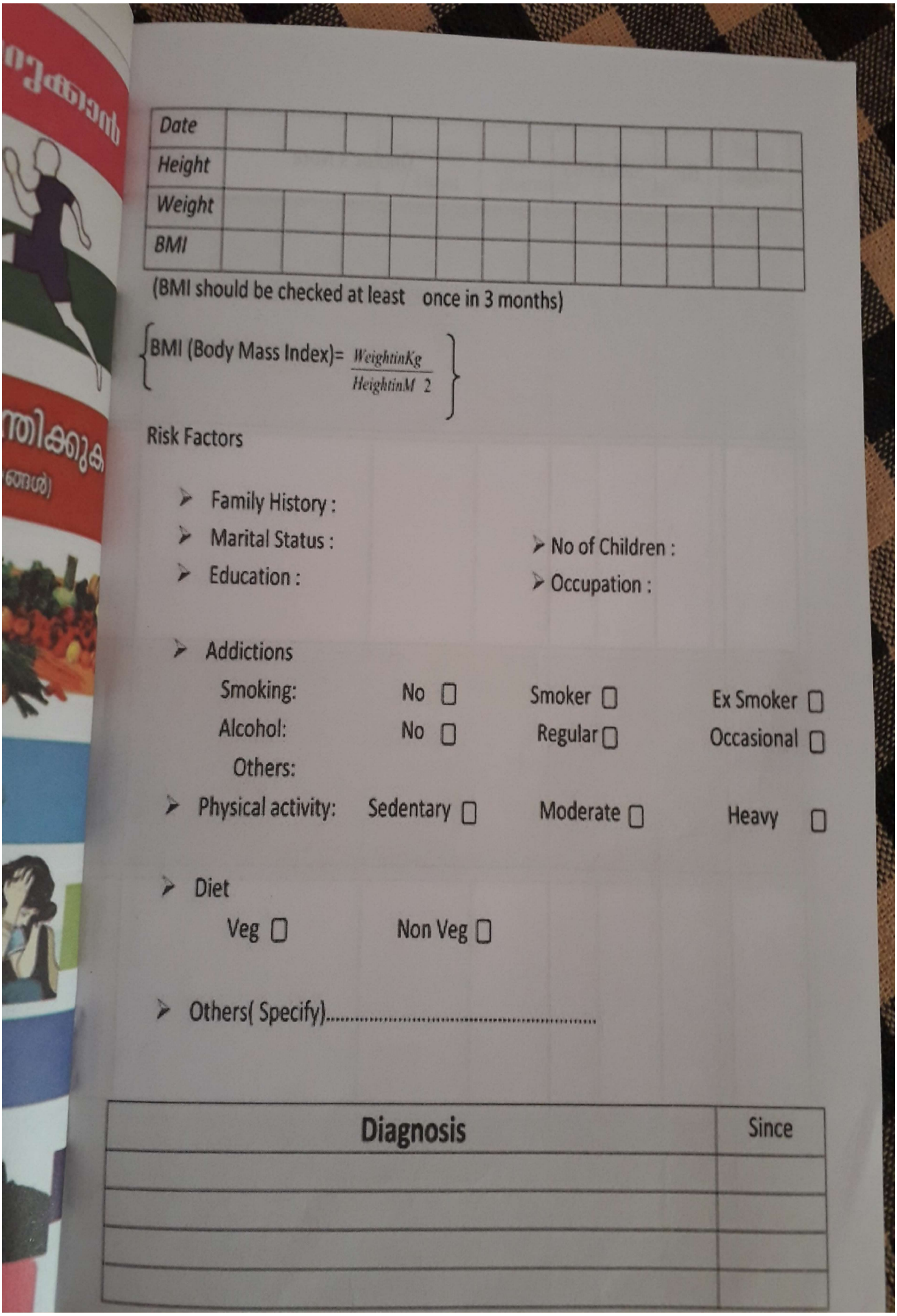


Date												
Height												
Weight												
BMI												

(BMI should be checked at least once in 3 months)

{BMI (Body Mass Index)= $\frac{\text{WeightinKg}}{\text{HeightinM}\ 2}$ }

Risk Factors

- Family History :
- Marital Status :
- Education :
- No of Children :
- Occupation :

- Addictions

Smoking: No ☐ Smoker ☐ Ex Smoker ☐

Alcohol: No ☐ Regular ☐ Occasional ☐

Others:

- Physical activity: Sedentary ☐ Moderate ☐ Heavy ☐

- Diet

Veg ☐ Non Veg ☐

- Others(Specify)..

Diagnosis	Since

ജീവിതശൈലി രോഗങ്ങളെ ചെറു

പ്രവർത്തന നിരതരായിരിക്കുക

കൊഴുപ്പുള്ള ആഹാരങ്ങൾ നിയന്ത്രി

(മാംസാഹാരങ്ങൾ, എണ്ണ, തേങ്ങ, ബേക്കറിസാധനങ്ങ

പച്ചക്കറികളും പഴങ്ങളും കൂടുതൽ ഉപയോഗിക്കുക

ശരീരഭാരം നിയന്ത്രിക്കുക

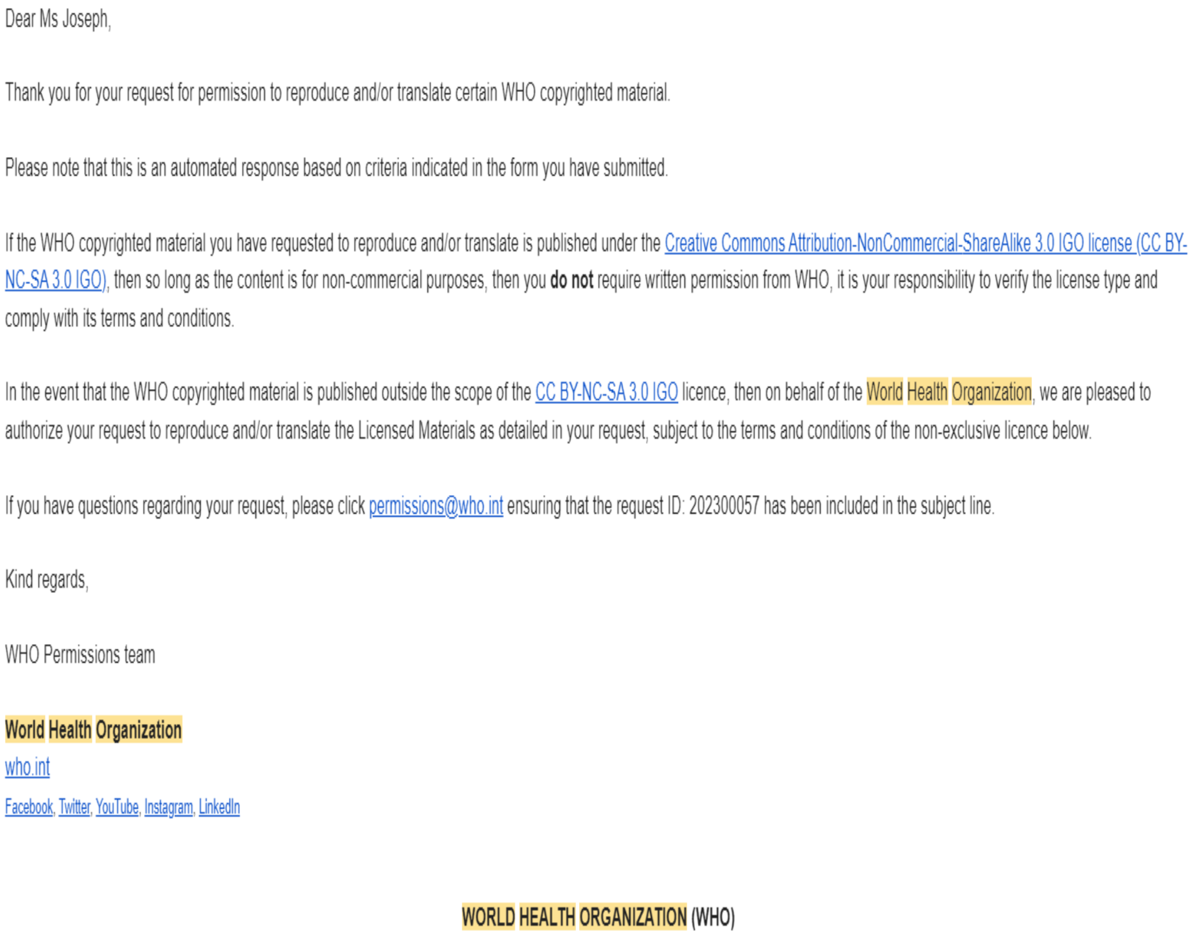
മാനസിക സമ്മർദ്ദം കുറക്കുക

പുകവലി ഉപേക്ഷിക്കുക

മദ്യത്തിന്റെ ഉപയോഗം കുറയ്ക്കുക

ദിനചര്യയിലെ ഈ ശ്രദ്ധ രോഗത്തെ പ്രതിരോധിക്കുന്നു

Appendix 1 b: Permission for using WHO's Innovation for Chronic Conditions framework



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WORLD HEALTH ORGANIZATION (WHO)

Appendix 2 Ethics approval

Note: LJ was working with CCDC; while starting the PhD, she applied for ethics clearance at CCDC. Once she got the approval, this was submitted at University of Birmingham's ethics committee, which granted an expedited approval in lieu of CCDC's ethics clearance. Further, LJ did not have any formal studentship arrangements with the local institute in Kerala, only local supervisory arrangements that did not qualify LJ for applying ethics approval from the local institute.

CENTRE FOR CHRONIC DISEASE CONTROL

Independent Ethics Committee (IEC)

Organization No: IORG0005264 **IRB No : IRB00006330**
Expires on : MAR/02/2023 **Expires on: MAR/02/2023**

Protection of Human Subjects
IEC Certification/Declaration of Exemption

1. Request Type ☐ ORIGINAL ☒ CONTINUATION ☐ EXEMPTION	2. Type of Mechanism ☐ GRANT ☐ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☒ OTHER	3. Name of Funding Agency and, if known, Application or Proposal Identification No. **Self-funded PhD**

4. Title of Application or Activity **Amendment 1: New Title "An exploration of patient held health information for improving clinical handover and patient centred care for patients with diabetes and hypertension in out-patient settings in India"** **Previous approved study title "Development of a universal patient held health booklet intervention for improving continuity of care and people centred health service for diabetic and cardiovascular patients in India"** **Project Code: [CCDC_IEC_05_2019]**	5. Principal Investigator: **Linju Maria Joseph, Centre for Chronic Disease Control** 6. Key Personnel: **Linju Maria Joseph**

7. **List of documents submitted for review :**

1) Covering Letter
2) Study proposal version 2, dated 02.02.2020
3) Project Summary
4) Summary of changes from previous approved version
5) Participant Information Sheet and Informed Consent form dated version 2, dated 17.02.2020 (English)
6) Interview guides version 2, dated 03.01.2020 (English)
7) Survey questionnaire version 1, dated 03.01.2020 (English)

8. Certification of IRB Review

☒ This activity has been reviewed and approved by the IEC in accordance with the Indian Council for Medical Research (ICMR) Guidelines and other GCP recommendations.

by: ☒ Full IEC Review [05/MARCH/2020] or ☐ Expedited Review [DD/MONTH/YEAR]

☐ This activity contains multiple projects, some of which have not been reviewed. The IEC has granted approval on condition that all projects covered by the Indian Council of Medical Research Guidelines will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

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C-1/52, 2nd Floor, Safdarjung Development Area, New Delhi-110016, India
Tel: +91-11-46082601, 41618456 | E-mail: ccdc@ccdcindia.org

A Scientific and Industrial Research Organisation, recognised by Department of Scientific & Industrial Research, Government of India.
A Centre of Excellence in Clinical Research, recognized by Clinical Development Service Agency, Department of Biotechnology, Government of India.

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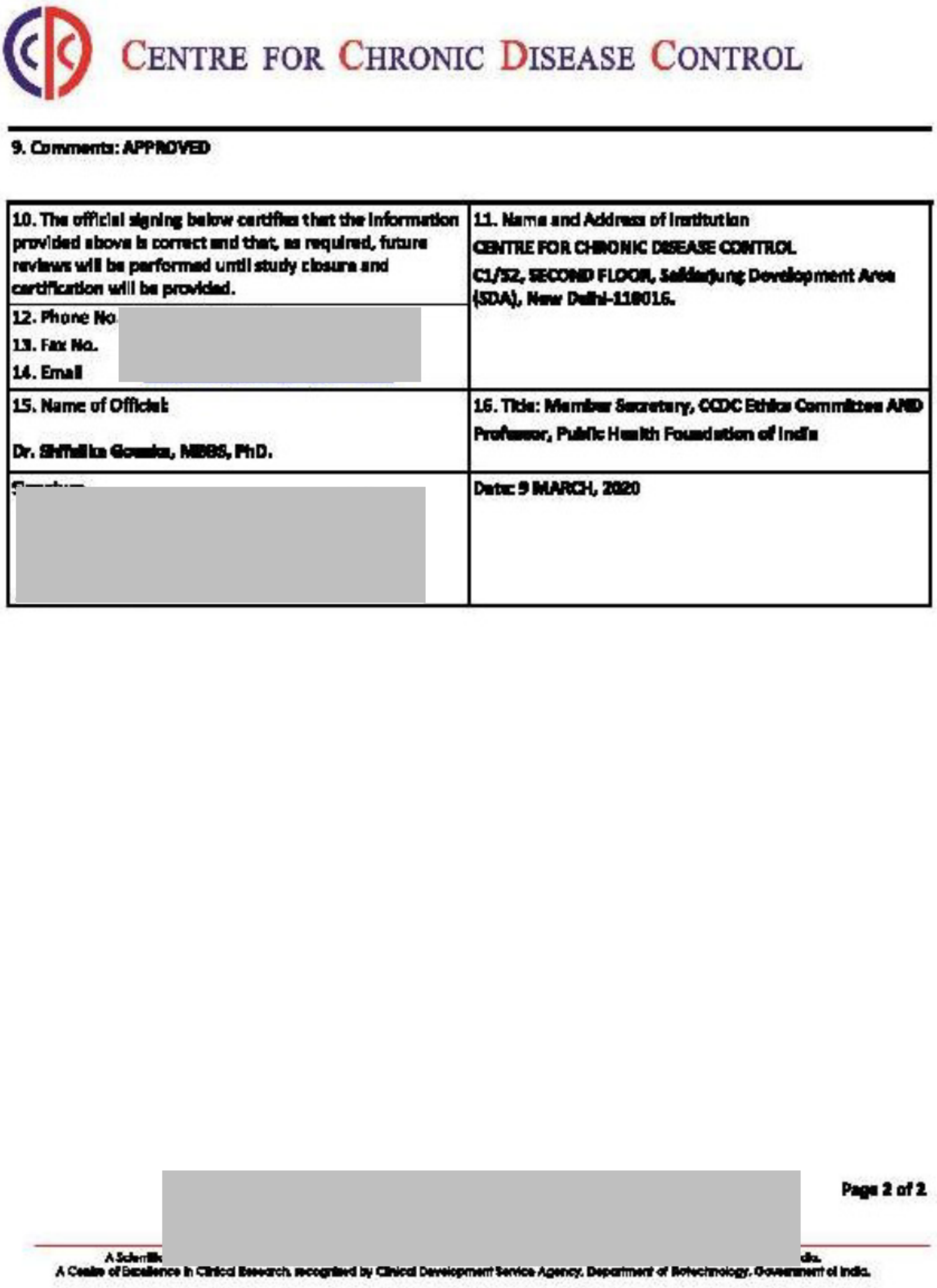

CENTRE FOR CHRONIC DISEASE CONTROL

9. Comments: APPROVED

10. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	11. Name and Address of Institution CENTRE FOR CHRONIC DISEASE CONTROL C1/52, SECOND FLOOR, Safdarjung Development Area (SDA), New Delhi-110016.
12. Phone No. [redacted] 13. Fax No. 14. Email	
15. Name of Official: Dr. Shifalika Goenka, MBBS, PhD.	16. Title: Member Secretary, CCDC Ethics Committee AND Professor, Public Health Foundation of India
[redacted]	Date: 9 MARCH, 2020

Page 2 of 2

A Scienti [redacted] dia.
A Centre of Excellence in Clinical Research, recognized by Clinical Development Service Agency, Department of Biotechnology, Government of India.

Appendix 3 - Analysis of patient interviews; personal reflective account

Reflective notes after first five patient interviews

The purpose of the qualitative interviews were- to understand how patients currently use the PHR/any patient-held information for themselves(For example for prescriptions to be used in pharmacies, for second opinions), what they understand about the need for HCPs on this information with them (knowledge of handover), their current practice of using patient held information (how they organise it or do they, how they use it, how they take /don't take it to HCP visits, how they keep it safe-attitude), how they take information to multiple providers and ask

/Request information or do they request information.

Since these are reflective notes, I decided to use first-person rather than third-person reporting acknowledging the active role of the researcher in the interpretative process in the qualitative study.

Patients understand the processes in the public health system. They seem to know what type of records they get from HCPs such as OP tickets. Patients' knowledge of bringing notes back for OP consultations currently seems to be because they would not get medicines otherwise. Patients currently seem unaware of the need for doctors (for other conditions) of the previous notes from other doctors. Sometimes patients report bringing the notes if it is their first visit. Attitudes or values are different. Some of them keep every record, and some do not.

The overall goal of a good thematic analysis is to identify patterns in the data that are important and interesting and talk about the issue under research. This is not to summarise the data alone but interprets and makes sense of it. A common pitfall is using the main interview questions as the themes (Clarke & Braun, 2013).

Familiarisation

I transcribed the first five interviews in English and another research assistant in English transcribed another two interviews. The process of transcription and reading of the transcripts provided insight into the data and was an important part of preliminary data analysis. Critically, I regularly discussed all aspects of the project with my supervisor (AL). The supervision allowed for discussion in areas that I had not initially engaged in.

Generating initial codes

Initially, I had thought of using NVivo software for coding and managing the interview transcripts. However, I felt it was better to use Word documents for coding as I did the initial transcriptions (n=3) in Word documents. Using the Word document, I was able to code line by line. The code and the interview data were copied into Microsoft Excel for better organisation. By code, I meant any meaningful piece of conversation was given a label. At this point, I felt I was using primarily inductive codes (codes from the data). For example, "carrying records to HCPs" was coded from initial transcripts (Illustrative quote- I bring this book here for the doctor to write. IDI 1, female, 70 years). Spending time with the data by line-by-line coding helped me familiarisation the data.

The first three interviews were coded initially. These codes were discussed with one of the supervisors (AL), in terms of why these were interpreted as meaningful.

The analytic process was iterative. The interviews were done after initial codes explored the ideas of carrying records between HCPs and processes of going to different HCPs in depth. After completing

the rest of the patient interviews (n=15) the rest of the interview data was coded. Additional codes were added through this process. Although I had not adopted a conceptual or theoretical framework for coding, I felt that there were some influences from the literature. Additionally, the critical discussion with my supervisor allowed me to develop ideas around the function of PHRs for patients themselves and HCPs.

Search for potential themes

A theme is a pattern that captures something significant or interesting about the data and/or research question. I examined the codes and some of them clearly fitted together into a theme. For example, several codes related to participants' descriptions of family members being involved in their care and their perceptions of how family members help with interpreting the information in PHRs. These were grouped into an initial theme called family members' role concerning PHRs.

Table 1 contains the initial themes and codes. The initial themes were more descriptive. By the end of these steps, most codes were grouped under a theme. In this stage, the discussions with supervisors led to thinking beyond how patients perceived the function of PHRs to thinking about what drives them to value PHRs for themselves.

Reviewing themes

All coded data is added to the themes for review in this step. I used Microsoft Excel and compiled all the interview data about the theme on one Excel sheet. This helped me to review the theme and data. I reviewed the data for two things; first, if the data supported the theme next, how the theme fits with the entire data set. This point formed patterns of how patients carried records to HCPs and how they did not engage with PHRs for self-management. Now I started thinking beyond the type and function of PHRs to look at the data for the shared meaning of why patients do not engage with PHRs for self-management. This led me to think about the central concept that makes people not engage with PHRs other than their reading ability.

Table 1 Initial themes and codes

Organising themes	**Descriptive and analytical codes**
Process-Patients carrying medication papers	Carrying records to HCPs
	Need PHR for getting medicine
	Patient's value of their own medical information
	Not carrying the booklet/notebook to other consultations
	No need for past documents
	Reasons for carrying records
Communication with HCPs	Patient and HCP communication (Patient's description of how they explain their condition (any difficulties associated with them).
	HCP verbal instructions
	HCP verbal communication regarding results
	HCPs requesting documented records
	HCPs not requesting medical information
	Do not look at records
Responsibility for health (ownership)	Follow-up visits to HCPs
	Long term medication
	Own understanding of taking medicines
	Dietary management
	Complying with physical activity recommendations by HCPs
	Attitudes towards physical activity
	Concerns of why DM/HTN is not controlled
Role of family with respect to PHRs	Family involvement with patient-held notes
	Family asking PHRs
	Family reading and communicating
Difficulties in managing care (Contexts)	Affordability (medicines, diet)
	Stopping medicines without HCP advice
	Reluctance to start insulin
	Need to make adjustments to come for appointment/FHC
	Travel/access to care
	Balancing work and disease management
	Household work and physical activity
Navigating the care system (health system context)	Initial diagnosis
	Having multiple note book/booklet
	Other diagnosis along with DM and hypertension
	Continuing treatment at a different HCP/facility
	Keeping past records safe

	Not reading/looking at PHRs
Moving between HCPs	Someone recommended
	Second opinion from other HCPs
	Alternate system of medicine
Contexts	Public health system
	Buying medicines from outside public system/other systems
	When interacting with HCPs
	At home

Table 2

Potential themes	Codes	Description of code	Quotes
Tool for procuring medicines How do patients conceptualise PHR functions for themselves? Or the **importance/perceived value** they give them for themselves (participants views on the booklet/patient-held documents such as notebook, booklet, prescriptions, and lab results and its functions)	Need PHR for getting medicine	Participants' description of what the PHR atFHC functions for them.	That book is for here (family health centre). So, I brought it hereto get the medicines. (*IDI 1, 70 years, married Literate-8th standard (secondary) Housewife Female, Diabetes, Hypertension)* R: That (notebook in FHC). When I first came here, they askedme to get a notebook for writing my details. The girl in the pharmacy wrote everything and gave me medicines. She asked me to bring the book every time I come here for medicine. So, I brought the book for getting medicine. (IDI 3, 64years, married, Literate 5th standard (upper primary), Manual labourer in the past, Male, Diabetes, Hypertension and Cardiovascular disease)

Tool for documentation “write” How do patients conceptualise the need for PHR for HCP?	HCPs requesting documented records	Patients reporting on HCPs requesting documented information, perceptions ofHCPs needing the information	Yes, I do carry the paper. Mainly for the doctor to see how much sugar is. They usually ask for that. They will ask youwhat the previous value was or when was your last check-up. Doctor had told me that since I had sugar, I may have some eye problems too. So, she asked me to go and get myself checked for eyes. (IDI 6, Female, 42 years)

Defining and naming themes

The aim of this final stage in the analytic process is to synthesise and to develop a way of presenting and explaining the analysis. This is the final refinement of the themes, and the aim is to ‘. Identify the‘essence’ of what each theme is about.’ (Braun & Clarke, 2006, p.92). In this analysis, why patients don't engage with PHRs was conceptualised using patients’ data, with emphasis on their contextual influences. The three themes were organised as contexts influencing patients’ engagement with PHRs.

Navigating the care system	This theme highlights the context in which patients seek care for their condition, gather information on self-management, the factorsthat underpin their use and view of PHRs.
Trust	This sub-theme reflects why patients go to different HCPs for their care and how this mayhave an influence on how they information for self-management and PHRs.
Patient and healthcare provider interactions	This theme explores patients’ experiences andviews of current PHRs focusing on individual HCP consultations and patients’ home settings.
Agency over illness and ownership of health	This theme demonstrates how wider socio-economic structural contexts can curtail patients’ agency over their self-management.

Appendix 4: Paper 1 supplementary files

S1. Table summaries of MMAT quality appraisal assessments for included studies

Author, year, LMIC	Type of study	4.1. Is the sampling strategy relevant to address the research question?	4.2. Is the sample representative of the target population?	4.3. Are the measurements appropriate?	4.4. Is the risk of nonresponse bias low?	4.5. Is the statistical analysis appropriate to answer the research question?	Score (Out of 5)
Van der Hoek [23], 1995, Zambia	Quantitative descriptive	Can't tell	Can't tell	Yes	No	Yes	2
Henbest[24], 1995, Lesotho	Quantitative descriptive	Yes	Yes	Can't tell	Yes	Yes	4
		1.1. Is the qualitative approach appropriate to answer the research question?	1.2. Are the qualitative data collection methods adequate to address the research question?	1.3. Are the findings adequately derived from the data?	1.4. Is the interpretation of results sufficiently substantiated by data?	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?	
Norden[25],2004 South Africa	Qualitative	Yes	Yes	Can't tell	Yes	Can't tell	3 (Very little detail on coding and data analysis)
Kerry[26] , 2005, South Africa	Qualitative	Yes	Yes	Can't tell	Yes	Can't tell	3 (Very little detail on coding and data analysis)
Chen[27] et al,	Qualitative	Yes	Yes	Yes	Yes	Can't tell	4

2014,China							
		4.1. Is the sampling strategy relevant to address the research question?	4.2. Is the sample representative of the target population?	4.3. Are the measurements appropriate?	4.4. Is the risk of nonresponse bias low?	4.5. Is the statistical analysis appropriate to answer the research question?	Score (Out of 5)
Ibrahim[28] et al, 2019, Mongolia	Quantitative descriptive	Yes	Yes	Yes	Yes	Yes	5 (Has description of non-responders and confounders)
		1.1. Is the qualitative approach appropriate to answer the research question?	1.2. Are the qualitative data collection methods adequate to address the research question?	1.3. Are the findings adequately derived from the data?	1.4. Is the interpretation of results sufficiently substantiated by data?	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?	
	Qualitative	Yes	Yes	Can't tell	Yes	Can't tell	3 (Very little detail on coding and data analysis)
		5.1. Is there an adequate rationale for using a mixed methods design to address the	5.2. Are the different components of the study effectively integrated to answer the research question?	5.3. Are the outputs of the integration of qualitative and quantitative components adequatel	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the	

		research question?		y interpreted?		methods involved?	
	Mixed methods	Yes	Can’t tell	Yes	Can’t tell	Yes	3(Integration may have occurred in the interpretation of results-It is unclear, cannot tell if there is divergent findings)

Appendix 5: Paper 2 supplementary files

Table S1: Functions of home-based records (HBR) as described by Osaki et al and Brown et al[2]

Osaki et al	Brown et al [2]	Handover communication function for the review
Data recording and storage (serve as the reliable documented source of individuals' health data)	Tool for documenting vaccinations and other primary care services, particularly during childhood but increasingly across the life course, in a standardized manner.	Handover communication across healthcare visits
Monitoring and referral in HBRs enable healthcare workers, correctly and efficiently track the personal health data and treatment histories of clients.	When appropriately completed and referenced, HBRs provide necessary information for frontline clinical decision-making that may ultimately improve continuity of care.	Handover communication across health care providers (HCP).
	HBRs complement facility-based record systems and serve as a verified surrogate in the absence of functioning facility-based record systems.	Handover communication across healthcare visits and HCPs.
Behaviour change communication (particularly for integrated handbooks)	HBRs help stimulates demand for vaccination services by raising caregivers' awareness of the benefits of vaccines, the recommended vaccination schedule, and the date of the child's next vaccination visit.	Handover communication from HCPs to women/families.
	HBRs serve as a prompt to initiate a discussion between health care workers and caregivers about the importance of immunisation during a health encounter at a facility or an outreach session.	Handover communication from HCPs to women/families.

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[1] Osaki K, Aiga H. Adapting home-based records for maternal and child health to users' capacities. Bull World Health Organ. 2019 Apr 1;97(4):296-305. doi: 10.2471/BLT.18.216119. Epub 2019 Feb 14. PMID: 30940987; PMCID: PMC6438250.

[2] Brown DW, Bosch-Capblanch X, Shimp L. Where Do We Go From Here? Defining an Agenda for Home-Based Records Research and Action Considering the 2018 WHO Guidelines. Glob Health Sci Pract. 2019 Mar 29;7(1):6-11. doi: 10.9745/GHSP-D-18-00431. PMID: 30877139; PMCID: PMC6538131.

Continuous self-monitoring by mothers and caregivers to recognize and address health risks via self-care or self-referral to a higher or lower level of health facility		Handover communication from women/families to HCPs.
Table S1 legends; HBR=home-based records, HCP=healthcare providers		

Box S1 Different types of HBRs included in the review

1. Antenatal records or women-held records- women are given their own case notes to carry during pregnancy.
2. Vaccination cards- Parent or caregiver held vaccination cards for children.
3. Child Health Records- Parent or caregiver held records including growth and development information and vaccination information
4. Maternal and child health handbook- Parent or caregiver held handbooks with both maternal and child health information

Table S2: Characteristics of included studies

Author, published year	Country	Study type	Objective of study	Type of HBR	Population	Outcomes measured	Relevant Results
Aiga et al, 2016	Viet Nam	Pre-post survey and qualitative focus group discussions	To determine pre-post intervention of HBR, levels of pregnant women's knowledge, attitude, and practices (KAP) towards their antenatal care service utilisation and exclusive breastfeeding practices.	The standardised MCH Handbook was composed of a recording section and guidance section for respective maternal and child health stages, i.e. pregnancy, delivery, postnatal, new-born, and childhood.	Mothers who received the MCH handbook within the first implementation phase.	The knowledge, attitudes, and practice of mothers about antenatal care, breastfeeding practices, and use of the MCH handbook.	The proportion of pregnant women who made three or more antenatal care visits significantly increased from 67.5 % (pre-intervention) to 92.2 % (post-intervention) (P < 0.001).
Abud and Gaíva, 2015	Brazil	Cross-sectional	To analyse the input of growth and development data in the Child Health Handbook.	Child Health Handbook	Mothers or guardians of the children	Completeness of growth and development data in child health handbook	Of the analysed handbooks, 95.4% of the development data and 79.6% of the data in the growth charts were incomplete.
Amorim et al, 2018	Brazil	Cross-sectional study	To describe the filling process of the Child	Child Health Record (CHR)	Children (3-5 years) resident	Frequency of filling of each CHR field	A total of 44.5% of the CHR had ≥ 60% of the

			Health Record (CHR) in health care services		in Belo Horizonte who carried the 6th Edition of the CHR (2009)	and the CHR frequency with filling percentage of < 60%, ≥ 60%, ≥ 70%, 80%, and ≥ 90%, an association between the percentage of fields' filling to be registered at birth or in the PHC/other services, comparison of the number of fields in the CHR completed	items completed. The CHR with ≥ 60% and ≥ 70% filling in the registration fields in the PHC/other services were significantly higher when the CHR also showed a higher percentage of filling (≥ 60%) of the registering fields in the maternity ward. This difference was not observed for the largest percentage of fields in the PHC/other services (80 and 90%), by the small number of CHR.
Andrade et al, 2014	Brazil	A qualitative study with a phenomenological approach	To understand the experiences of health professionals in primary care with the Child Health Booklet in child health care.	Child Health Booklet	Health professionals (doctors and nurses)	Experience with the booklet in child health care and filling out of the booklet	The understanding of the booklet of child health as a means of monitoring the growth of children and their vaccination status was the only conception present in the speech of all professionals and even for some, this understanding turned out to be the only value of the booklet in their health practices with the child.

Araujo et al, 2017	Brazil	Cross-sectional	To evaluate the use of child health surveillance tools (by health professionals) especially focusing on growth.	Child Health Handbook	Mothers or guardians of the children	Growth charts, records of iron and vitamin A supplementation, and notes on immunisation schedules registered in the instrument were analysed.	All the factors studied showed high frequencies of limited data entry, ranging from 41.1% for the weight-versus- age chart to 95.3% for the body mass index-versus-age chart. Higher frequency of inadequate data entry was found among children aged 25 months and over and among those living in areas of these municipalities with minimal numbers of professionals in the healthcare teams.
Baequni et al, 2016	Indonesia	Cross-sectional (Secondary data analysis) Data included Indonesia Demographic and Health Surveys (IDHS)	To analyse the effects of home-based records on pregnancy, delivery, and child health care in Indonesia	Maternal and Child Health Handbook (MCHHB)	Women who had children under 5 years old	The effects of home-based records on pregnancy, delivery, and child health care	The home-based records group had more knowledge and better practices during pregnancy, delivery, and child health care (e.g., immunisation). The home-based records group knew how to solve the problems of complications during pregnancy and used skilled birth attendants for delivery. This study also found that husbands in the home-based

							records group were involved in discussing the delivery location, finding transportation, and identifying a blood donor.
Bhuiyan et al, 2006	Bangladesh	Pre-post study	To develop MCH handbook and to assess its effect on mother's knowledge, practice and utilization of MCH services.	MCH handbook	Pregnant mothers Health care providers	Data to develop the content of the handbook was gathered through focus group discussion with mothers and health care providers. Mothers' knowledge, attitude and practice regarding MCH services were collected through pre-post surveys.	There has been satisfactory improvement of knowledge regarding antenatal care, danger signs, breastfeeding and vaccination among case group after intervention of MCH handbook.
Brown D W et al, 2018	Kenya	Mixed methods-Cross-sectional survey with open-ended questions	To describe HBR ownership and report on the utilization of selected recording areas in HBRs Kenya.	Child HBR/integrated MCH book	The caregivers of children aged 0±23 months exiting selected health facilities and healthcare workers.	The caregivers were asked several questions related to how they obtained and used their child's HBR. The HBRs were checked for their completeness.	One-third (n = 41) of those without an HBR in hand at the visit noted that they did not know the importance of bringing the document with them. Roughly two-thirds (n = 443) of caregivers noted they were asked by clinic staff to see the HBR during the clinic visit. Across the 516 reviewed HBRs,

							recording areas were most commonly identified for the child's demographic information (80% of HBRs) and vaccination history (82%) with the information marked in>90% records.
Camargos et al, 2021	Brazil	Cross-sectional	To evaluate the antenatal care (ANC) home-based records of puerperal women attended in public and private maternity hospitals.	ANC Mother HBRs	Puerperal women.	Records were assessed regarding completeness, legibility, and completeness of sociodemographic, clinical, obstetric, and laboratory data.	88.5% of the cards had no record of the name of the primary care unit of reference, 76.9% of the maternity of reference, and 82.4% of the ANC institution. Evaluation of oedema, use of ferrous sulphate and folic acid were not registered in 55%, 91.1%, and 92.6% of the cards, respectively. The absence of records in the weight chart was identified in 86.8% of the cards, and in the uterine height chart, 79.7%.

Coelho et al, 2021	Brazil	Cross-sectional	To identify parents' knowledge about the Child Health Handbook, map the completion of the booklet by professionals, and correlate the completion of the booklet with the guidance of parents by health professionals.	Child Health Handbook	Mothers or guardians of the children	Completeness and parents' knowledge.	The most recorded item in the handbook was vaccination data 81% (18/22). BMI has not been recorded in 72% (16/22) handbooks.
Dagvadorj et al, 2017	Mongolia	Follow up cluster RCT	To assess the effectiveness of the handbooks on child development in Mongolia.	MCH Handbook	Women living in the Bulgan province of Mongolia who gave birth between March and August 2010 participated in the study and the three-year follow-up if they still lived in the area.	The primary study outcome was a risk of developmental delay as assessed by the Mongolian Rapid Baby Scale.	In Mongolia, a 3-year follow-up showed a reduced risk of cognitive development delay in children (OR 0·32, 95% CI:0·14–0·73, p-value = 0.007)
Adedire et al, 2016	Nigeria	Cross-sectional study	To assess immunisation coverage rates and to identify the factors associated with vaccination status of children 12–23 months in a rural district in south-western Nigeria.	Vaccination cards	Mothers	Vaccination status of the children	Of the 750 children, 475 possessed vaccination cards, indicating a vaccination card retention rate of 63.3 %. Using mothers' recall, 558 (74.4 %) of the children were fully vaccinated, 192 (20.8 %)

							were partially-vaccinated, and 36 (4.8 %) were non-vaccinated. However, based on immunisation cards, 275 (57.9 %) of the children were fully immunised while 200 (42.1 %) were partially immunised.
Gustaffsson et al, 2020	The Gambia	Mixed-methods study	To assess the number, type, content quality, and completeness of women-held documents on admission to maternity units in The Gambia. To explore context-specific barriers and facilitators to effective use of women-held documents in maternity units by health professionals and maternity staff, especially for women admitted with high-risk pregnancies or deliveries.	Maternity cards	In-patient women aged 16 and over three maternity hospital departments in the Greater Banjul.	Characterised the nature and quality of documents; including the number of each type of document, whether individual criteria were met, and how many women carried documents that met the minimum criteria.	Of the women admitted, all but 10/250 (4%) brought either a maternity card or a structured referral sheet. Women were less likely to have documents complete if they were illiterate and had not attended three maternity appointments. During qualitative interviews, three themes were identified: women as agents for transporting information and documents (e.g. remembering to bring maternity cards); the role of individual healthcare professionals' actions (e.g. legibility of handwriting); system and organisational culture (e.g.

							standardised referral guidelines).
Hagiwara et al, 2013	Palestine	Pre-post study	To examine the effect of the MCH handbook on women's knowledge and behaviour.	MCH Handbook	Women who used the MCH centres and healthcare workers of those centres	Knowledge, attitude, and practice related to MCH. User satisfaction and barriers to use of MCH handbooks.	Knowledge related to MCH such as the importance of exclusive breastfeeding and how to cope with the risks of rupture of membranes during pregnancy increased among MCH handbook users, especially among less-educated women. The MCH handbook may be an effective tool for communication with health providers and husbands, for both highly educated and less-educated women during their first pregnancy.
Harrison et al, 1998	South Africa	Cross-sectional	To determine the relevance of the road to health book along with the road to health card.	Road to health book	Nurses and mothers who used the RTH books.	The use of and comments on the RTH book by nurses and mothers were based on analysis of the questionnaires.	Most (81.6%) preferred the RTH book to the Road-to-Health card. It was sturdy (95.6%), had a satisfactory layout (87.5%), and provided useful information for health personnel (71.9%)
Hayford et al, 2013	Bangladesh	Cross-sectional	To compare measles vaccination coverage estimates from surveys	Vaccination card	Mothers	Six indicators of measles vaccination history were	913 children had facility or clinic-based vaccination data

			(vaccination card/card plus history), clinic records, and immune markers in oral fluid and blood.			ascertained for each child: 1) maternal report 2) card record of vaccination 3) 'card + history'; 4) EPI record of vaccination in clinic books; 5) protective levels of measles IgG antibodies in oral fluid and 6) protective levels of measles IgG antibodies in the blood.	available; of which 800 children had vaccination HBRs. The measles vaccination coverage based on the mother's recall was 93.4% (853/913) while HBR data showed 87% (790/913).
Hikita et al, 2018	Mongolia	Cross-sectional	To investigate the use of an MCH handbook, and related factors, in Mongolia.	MCH Handbook	Women living in Bulgan Province, Mongolia, with children born between January and December 2010 (and who thus would be 3 years old in 2013) were selected as participants for the study.	Mothers' utilisation of the MCH handbook was defined based on questions for reading and recording of details in the handbook.	88.1% of users reported having read the handbook. In this study, two-thirds of participants who had received an explanation on how to use the MCH handbook reported having made a record in it, whereas only one-third of those who had not been taught how to use it reported having made a record in it. This suggests that receiving an explanation from medical personnel is

							important for women to use the handbook.
Jahn et al, 2008	Malawi	Cross-sectional	To assess factors related to recorded vaccine uptake, which may confound the evaluation of vaccine impact.	Parent held health documents	Mother	Vaccination coverage by age	Of 5418 children, vaccination documents were available for review for 3440 (63%). Documents were missing for 37% and exact birth dates for 29% of the 5418 under 5-year-olds in this population. The BCG vaccination data, of the 3487 children under five, 2368 cards had documentation of BCG in them.
Kaneko et al, 2017	Burundi	Pre-post study	To assess the effectiveness of the MCH handbook for increasing notification of birth at health facilities and post-natal care (PNC) uptake.	MCH Handbook	Mothers having infants aged less than six weeks	Socio-demographic status, delivery place by a type of health facility, the proportion of mothers having the MCH handbook, having received notification of birth at a health facility, having delivery mode records, having accurate birth weight data by recall or records, and receiving guidance on PNC.	95.1% of mothers had an MCH handbook post-study. The observed in the proportion of mothers receiving notification of birth at health facilities, from 4.6% to 61.0% (95% confidence interval [CI : 55.9%–66.2%), and the proportion of mothers receiving guidance on PNC, from 35.9% to 64.2% (95% CI: 59.2%–69.3%).

Kabore et al, 2020	Burkina Faso	Cross-sectional	To assess the characteristics of HBRs and FBRs, their completion by vaccination providers, and their usefulness in estimating vaccine coverage (VC)	Vaccination HBR	Caregivers of children aged 0 to 23 months	Characteristics and completion patterns of HBR, concordance of HBRs and FBRs to determine their reliability as data sources in estimating vaccine coverage	Half (50.6%) of HBRs were non-standard. About two-thirds (64.6%) of caregivers were concerned with discordant information. Multivariate logistic regression model showed that standard HBR was protectively associated with discordant information (OR = 0.46, 95% CI: 0.26–0.81, p = 0.010).
Kawakatsu et al, 2015	Kenya	Cross-sectional	To clarify the effectiveness of and identify the factors related to possession of an MCH handbook among parents in rural Western Kenya using propensity score matching (PSM)."	MCH Handbook	Mothers with children aged 12-24 months.	Vaccination status, health-seeking behaviour for fever, diarrhoea, maternal health knowledge.	MCH handbook was an effective tool for improving both health knowledge and health-seeking behaviour in Kenya.
Kitabayashi et al, 2017	Palestine	Cross-sectional (secondary data)	To assess associations between MCH handbook ownership and receipt of selected content of antenatal care services in Palestine	MCH handbook in Palestine was a 60-page booklet written in Arabic, which consisted of a medical record section and a health	Anonymous data set of the Palestinian Family Survey 2010 -data of 2026 women who had live births within the past 12 months.	sociodemographic characteristics, history of pregnancies and deliveries, mortality and morbidity of women and their children, MCH services, family planning, and	Handbook users had significantly higher odds of receiving all three kinds of medical tests and receiving information on five or more health education topics as part of antenatal care.

				education section.		attitudes towards reproductive health.	
Kusumayati and Nakamura, 2007	Indonesia	Cross-sectional	To assess the effects of utilization of the MCH handbook in Western Sumatra on the utilization of maternal health services.	MCH Handbook	Mothers who were pregnant or had children under three years of age.	Utilization of MCH handbook, utilization of MCH services.	MCHH utilization was associated with a higher likelihood of mothers utilizing ANC, TT (tetanus toxoid) immunisation, and family planning services and planned use of skilled birth attendance.
Mansour et al, 2019	Lebanon	Cross-sectional (secondary data)	To assess the quality of the picture and content of the HBR itself against a pre-defined set of criteria. To compare the data found in vaccination HBRs to assess measures of vaccination status agreement between caregiver recall and HBR.	Vaccination HBR	500 pictures of HBRs, 9315 caregivers of Lebanese and Syrian children	Picture and design quality of HBR, agreement of vaccination status between caregivers' recall, and vaccination home-based record per vaccine dose.	Out of 9315 surveyed caregivers of Lebanese and Syrian children, 8407 (90.3%) caregivers reported that the child ever had received an HBR, yet only 5713 (61.4%) of them were able to present vaccination cards. For 3375 (36.2%) children, only caregivers' recall was available to assess the vaccination status of the child. Only 227 children (2.4%) had never received any vaccination and did not have any available record.

Mudany et al, 2015	Kenya	Cross-sectional	To assess the uptake of the mother-child health booklet by assessing the number of PCR tests done for infant HIV diagnosis and the number of MCH clinics that offered to test.	The booklet contained information on the HIV status of the mother, drugs used in pregnancy, infant and young child nutrition, immunisation records, WHO growth monitoring charts, and required actions in maternal-child emergencies. The first part of this booklet had maternal medical information during pregnancy, delivery, and the postpartum period, with the mother's HIV status and antenatal profile.	Not reported	HIV testing in infants	Most health workers reported that the booklet made it easy for them to identify HIV-exposed infants. During the pilot period, the number of infants tested for HIV DNA increased in Nyanza from 9966 to 13 379, a 34% increase compared with a 9% overall increment in the remaining seven provinces where the booklet was not introduced.

Mori et al, 2015	Mongolia	Cluster randomised trial	To assess the effectiveness of the Maternal and Child Health (MCH) handbook in Mongolia To increase antenatal clinic attendance, and to enhance health-seeking behaviours and other health outcomes.	Maternal and Child Health handbook containing a log for recording information on maternal health and personal information, course of pregnancy, delivery and postpartum health, weight during and after pregnancy, dental health, parenting classes, child development milestones from the ages of 0–6 years, immunisation and illnesses, and height and weight charts for children.	Pregnant women and their infants living in the Bulgan province of Mongolia between May 2009 and September 2010.	Antenatal clinic attendance, health-seeking behaviours, client-provider communication, maternal physical and mental health, neonatal health, and healthy behaviour	The intervention group (253 women) attended antenatal clinics on average 6.9 times, while the control group (248 women) attended 6.2 times. Socioeconomic status affected the frequency of clinic attendance: women of higher socioeconomic status visited antenatal clinics more often. Pregnancy complications were more likely to be detected among women using the handbook.
Nasir et al, 2017	Indonesia	Pre-post interventional study	To examine the effect of mother class using HBR on knowledge and practice of new-born care among mothers in the community setting.	Maternal and Child Health Handbook (MCHHB)	Mothers	Six composite outcome variables were set up: skilled birth attendance; hepatitis B immunisation, cord	Mother class has significantly improved mothers' knowledge and practice on new-born care. Mothers might get information on new-

						care, thermal protection, eye care, breastfeeding initiation. The composite variables were then categorized as a binary outcome.	born care during antenatal care visits at the health facilities as part of usual MCH services, but this study showed that giving knowledge about new-born care through mother class has helped the mothers to be more knowledgeable and do the good practices. Therefore, providing mother class in the community could be a method that teaches mothers how to engage in appropriate health behaviour for their babies and themselves.
Naidoo H et al, 2018	South Africa	Cross-sectional	To assess the extent to which healthcare personnel, complete HIV-related, sociodemographic, neonatal, growth, and immunisation information in the RTHC and/or RTHB.	Road-to-Health Booklet (RTHB), or the older, less detailed, Road-to- Health Card/Chart (RTHC).	Children aged less than two years attending the paediatric departments	HIV testing, sociodemographic and neonatal completeness	24% of all RTHBs had no record of maternal HIV status and 67% of RTHBs from documented HIV-exposed infants had no record of maternal ART duration. Neonatal information completeness was similar between RTHBs and RTHCs.

Osaki et al, 2019	Indonesia	Cluster randomised trial	To assess the effect of MCH handbook use in rural Java, where service coverage was comparatively low.	Maternal and Child Health Handbook	Pregnant women attending the health centres.	Maternal immunisation, antenatal clinic appointments, vitamin A intake, feeding practices, child growth, and development.	Respondents in the intervention area received consecutive MCH services including two doses of tetanus toxoid injections and antenatal care four times or more during pregnancy, professional assistance during child delivery, and vitamin A supplements administration to their children, after adjustment for confounding variables and cluster effects (OR =2.03, 95% CI: 1.19–3.47). In the intervention area, home care (continued breastfeeding; introducing complementary feeding; proper feeding order; varied foods feeding; self-feeding training; and care for cough), perceived support by husbands, and lower underweight rates and stunting rates among children were observed

Osaki et al, 2013	Indonesia	Cross-sectional	To identify the roles of home-based records both before and after childbirth, especially in provinces where the MCH handbook (MCHHB) was extensively promoted, by examining their association with MNCH service uptake	MCH handbook	Using nationally representative data sets, the Indonesia Demographic and Health Surveys (IDHSs) from 1997, 2002, 2003, and 2007. The IDHS identifies respondents' ownership of home-based records before and after childbirth.		Provincial data from 2007 showed that handbook ownership was associated with having delivery assisted by trained personnel [adjusted odds ratio (aOR): 2.12, 95% confidence interval (CI): 1.054.25 , receiving maternal care (aOR: 3.92, 95% CI: 2.356.52), completing 12 doses of child immunisation for seven diseases (aOR: 4.86, 95% CI: 2.379.95), and having immunisation before and after childbirth (aOR: 5.40, 95% CI: 2.2812.76), whereas national data showed that service utilisation was associated with ownership of both records compared with owning a single record or none.
Ramraj T et al, 2018	South Africa	Cross-sectional	To assess the completeness of patient-held infant Road to Health Booklets (RTHBs), amongst HIV exposed and unexposed infants during	Road-to-Health Booklet (RTHB),	Infants aged 4-8 weeks who were receiving their six-week immunisation on the day of	Completeness of the RTHB - that should have been completed at birth, namely; infant birth weight, BCG	Overall, recording of all four indicators increased from 23.1% (95% confidence interval (CI) = 22.2-24.0) in 2011-12

			the first two years after the RTHB was launched country-wide in South Africa		visit and who did not need emergency care	immunisation, maternal HIV status, and an indication of whether maternal syphilis testing was done.	to 43.3% (95% CI = 42.3-44.4) in 2012-13.
Silva et al, 2015	Brazil	Qualitative study	To analyse the use of child health records by families, based on the perceptions of health professionals, in pursuit of new support for integrated health care for children.	Child Health Record	Family and mothers	The use of child health records by families.	The study showed that HCPs believe health records are an instrument of communication and education for families. There is a concern about instructing mothers and families about the importance of keeping track of their children's health, in addition to the purpose, content and relevance of health records. Professionals also believed that, despite the guidance provided, families seldom use this instrument. The study participants also recognized the right of families to demand the recording of data in records; this attitude showed that families are interested in their

							children's health, and also assists in the work of professionals.
Shah et al, 1993	(Egypt, India, Pakistan, Philippines, Senegal, Sri Lanka, Yemen and Zambia)	Pre-post surveys	To evaluate the function of the HBMR (a home-based maternal record) following a set of WHO guidelines.	Home-based maternal record (HBMR)	Mothers and a range of HCPs including community health workers, skilled birth attendants, nurses, and physicians	Use of HBMR, Identification of risk conditions, and referral care	Substantial improvement in maternal and neonatal care, and continuity of care in areas using HBMR. (Examples: Philippines 91–100% vs. 36.6–51.9%; Zambia 93.5% vs. 49.8%). Records adapted to the local situation. Improvement was noted in maternal knowledge for self-care.
Palombo et al, 2014	Brazil	Cross-sectional	To evaluate the use and records of the Child Health Handbook (CHH), especially	Child Health Handbook	Mother and child pairs	The use of the CHH was evaluated with the following questions: Did the mother have the	Fifty-one percent of the mothers were carrying the CHH at the time of the interview, similar to the proportion of mothers who were

						CHH at the time of the interview?	instructed to bring the CHH to health appointments. Annotations in the CHH during the visits were reported by 49%. The vaccination schedule was completed in 97% of the CHH, but only 9% and 8% of the CHH, respectively, contained growth charts and properly completed developmental milestones.
Tarwa et al, 2007	South Africa	Quantitative descriptive study	To assess whether the Road to Health Card (RTHC)s are completed and interpreted adequately at primary, secondary, and tertiary care levels in South Africa.	Road to Health Card (RTHC)	Caregivers who accompanied children younger than five years of age.	Information on whether the RTHC had been brought along and, reasons for not bringing.	The RTHC was not brought to 48% of the consultations. Of these respondents, about 72% thought that bringing along the RTHC was not necessary. Health workers seldom asked to see the RTHC in the primary and secondary care settings, but 50% of them did so at Hospital (p = 0,002).
Tjandraprawira et al, 2018	Indonesia	Cross-sectional study	To investigate its role in increasing awareness of Indonesian women about the various obstetric	Mother and Child Health (MCH) handbook	Recently delivered postpartum women treated in the maternity ward of	The average score among ≥ 50% MCHH readers Average score among < 50% MCHH readers	The MCH handbook did not hold a significant role in effecting this finding (p-value 0.295). No significant influence in improving maternal

			danger signs and the entailing complication.		Majalengka General District Hospital.	Average questionnaire score	knowledge levels around pregnancy and the associated obstetric danger signs.
Gonzalez et al, 2019	Brazil	Cross-sectional study	To measure the prevalence of acquiring and evaluating the level of completion of the pregnant women's medical booklet on the occasion of childbirth in Rio Grande, Brazil	Pregnant women's medical booklet	All the parturient living in the urban and rural areas in Rio Grande	The prevalence of the outcome and the frequency of completion of the information registered in the pregnant woman's medical booklet among the surveys were compared	Out of 10,242 pregnant women in this study 54.8% (95% CI 53.8%-55.7%) had their pregnant woman's medical booklet with them at the time of admission. The completion pattern of the pregnant woman's medical booklet is divided into three groups, namely: with at least 95%: date of the last consultation visit, maternal height and blood pressure verification, uterine height, cardio-fetal heart rate, and the Rh factor; 85% or more: date of the last menstruation, qualitative urine test, VDRL (Venereal disease research laboratory test) and HIV; and less than 30%: performance of clinical breast examination and cytopathology of the

							uterine cervix. The use of the pregnant woman's medical booklet and its completion were lower than expected on several items.
Usman et al, 2009	Pakistan	RCT	To assess the effect of a redesigned immunisation card and centre-based education on mothers on DTP3 completion.	Redesigned immunisation card	Children visiting the selected EPI centres for DTP1 and residing in the same area for the last 6 months.	Immunisation status of 3-dose DTP vaccination.	A significant increase of 31% (adjusted RR = 1.31, 95% CI = 1.18–1.46) in DTP3 completion was estimated in the group that received both redesigned cards and centre-based education compared with the standard care group.
Usman et al, 2011	Pakistan	RCT	To assess the effects of providing substantially redesigned immunisation cards, centre-based education, or both interventions together on DTP3 completion at six rural Expanded Programme on Immunisation (EPI) centres in Pakistan.	Redesigned immunisation card	Children visiting the selected EPI centres for DTP1 and residing in the same area for the last 6 months.	The immunisation status of 3-dose DTP vaccination.	39% of children in standard care group completed DTP3. Compared to this, a significantly higher proportion of children completed DTP3 in redesigned card group (66%) (Crude Risk Ratio [RR = 1.7; 95% CI = 1.5, 2.0), centre-based education group (61%) (RR = 1.5; 95% CI = 1.3, 1.8), and combined intervention group (67%) (RR = 1.7; 95% CI = 1.4, 2.0).

Vieira et al, 2017	Brazil	Cross-sectional study	To investigate the factors associated with mothers reading the Child Health Handbook (CHH) and health professionals completing this instrument, in Feira de Santana, Bahia, 2009.	Child Health Handbook	Children under one year of age up to the day of the survey, from the municipality of Feira de Santana, who attended the vaccination units accompanied by their respective mothers and/or caregiver.	Mother reading the CHH and health professionals completing weight and height measures.	The prevalence of reading, weight, and height was, respectively, 81.1%, 68.9%, and 47.3%. Mothers with a higher level of education had a greater chance of reading the CHH.
Wallace et al, 2019	Indonesia	Cluster RCT	To estimate the effect of low-cost parental reminder interventions using HBRs on completion and timeliness of the 3-dose DTP cv series.	Child's HBR (vaccination reminder)	All children who received DTPcv1 in a study health facility in January 2016 and had the vaccination recorded on the facility vaccination register	The primary outcome was the receipt of the third dose of diphtheria-tetanus-pertussis-containing vaccine (DTPcv3) within 7 months and the secondary outcome was the receipt of a timely DTPcv3 dose.	In intention-to-treat analysis, neither intervention group had significantly different DTPcv3 coverage compared with the control group (RR = 0.94, 95% confidence interval [CI 0.87; 1.02 for HBR-only group; RR = 0.97, 95% CI 0.90; 1.04 for HBR + sticker group) by study end. However, children in the HBR + sticker group were 50% more likely to have received a DTPcv3 vaccination (RR = 1.46, 95% CI 1.02, 2.09) within 60 days of

							DTPcv1 vaccination, compared with children in the control group.
Yanagisawa et al, 2015	Cambodia	Pre-post study	To assess the effectiveness of the MCH handbook in Cambodia	MCH Handbook	Women who had given birth 1 year before the survey lived in an intervention or control area.	Maternal behaviours include antenatal attendance, deliveries attended by SBAs, and deliveries at health facilities). Secondary outcomes included maternal knowledge of danger signs during pregnancy and delivery, prevention of anaemia, prevention of intestinal parasites, mother-to-child HIV transmission, early breastfeeding practice and child immunisation	The intervention increased ANC attendance, delivery with SBAs and delivery at a health facility, even after adjusting for maternal age, education and economic conditions.

HBR=home-based records, MCH=maternal and child health, SBA=skilled birth attendant, ANC=antenatal care, cRCT=cluster randomised controlled trial, HIV=Human Immunodeficiency virus,

Table S3: Results of Mixed Methods Appraisal Tool

Author, year	RANDOMIZED CONTROLLED TRIALS					
	Is randomization appropriately performed?	Are the groups comparable at baseline?	Are there complete outcome data?	Are outcome assessors blinded to the intervention provided?	Did the participants adhere to the assigned intervention?	Score
Usman, 2009	Yes (computer generated list)	Yes	Yes	No	Yes	4
Usman,2011	Yes (computer generated list)	Yes	Yes	No	Yes	4
Dagvadorj, 2017	Yes (shuffled, sealed envelopes)	Yes	No	No	Yes	3
Mori, 2015	Yes (shuffled, sealed envelopes)	Yes	Yes	No	Yes	4
Osaki ,2019	Yes (Lottery method)	Yes	No	No	Yes	3
Wallace, 2019	Can't tell	Yes	Yes	No	Yes	3
	NON-RANDOMIZED STUDIES					
	Are the participants representative of the target population?	Are measurements appropriate regarding both the outcome and intervention (or exposure)?	Are there complete outcome data?	Are the confounders accounted for in the design and analysis?	During the study period, is the intervention administered (or exposure occurred) as intended?	
Aiga et al, 2016	Yes	Yes	Yes	No	Yes	4
Hagiwara et al, 2008	No	Yes	Yes	Yes	Yes	4

Kaneko et al, 2017	Can't tell	Yes	Yes	Yes	Yes	4
Shah et al, 1998	No	Yes	No	No	Can't tell	1
Yanagisawa et al, 2015	Yes	Yes	Yes	Yes	Yes	5
Bhuiyan et al, 2006	Can't tell (no sampling frame description)	Yes	Yes	No	Yes	3
Nasir et al, 2017	Yes	Yes	Yes	Yes	Can’t tell	4
Harrison et al, 1998	Can't tell	Yes	Yes	No	Yes	3
	QUANTITATIVE DESCRIPTIVE STUDIES					
	Is the sampling strategy relevant to address the research question?	Is the sample representative of the target population?	Are the measurements appropriate?	Is the risk of nonresponse bias low?	Is the statistical analysis appropriate to answer the research question?	
Kusumayati and Nakamura, 2007	Can't tell	Can't tell	Yes	Can't tell	Yes	2
Tarwa et al, 2007	Can't tell	No	Yes	Can't tell	Yes	2
Mudany et al, 2015	No	Can't tell	Can't tell	Can't tell	Yes	1
Jahn et al, 2008	Yes	Yes	Yes	Yes	Yes	5
Hayford et al 2013	Yes	Yes	Yes	No	Yes	4
Vieira et al,2017	Yes	No	Yes	Can't tell	Yes	3
Hikita et al, 2018	Yes	Yes	Yes	Yes	Yes	5
Palombo et al, 2014	Yes	Yes	Yes	No	Yes	4
Kitabayashi et al, 2017	Yes	Yes	Yes	Can't tell	Yes	4
Osaki et al, 2013	Yes	Yes	Yes	Can't tell	Yes	4

Kawakatsu et al, 2015	Yes	Yes	Yes	Can't tell	Yes	4
Baequni et al, 2016	Yes	Can’t tell	Yes	Can’t tell	Yes	3
Brown et al, 2018	Yes	Yes	Yes	Can't tell	Yes	4
Ramraj et al, 2018	Yes	Yes	Yes	Can't tell	Yes	4
Naidoo et al,2018	No	Yes	Yes	Can't tell	Yes	3
Tjandraprawira et al, 2018	No	No	Yes	Can't tell	Yes	2
Kabore et al, 2020	Yes	No	Yes	Yes	Yes	4
Abud and Gaiva, 2015	Yes	Yes	Yes	Can’t tell	Yes	4
Camargos et al, 2021	Yes	No	Yes	Can’t tell	Yes	3
Coehlo et al, 2021	Yes	No	Yes	Can’t tell	Yes	3
Araujo et al, 2017	Yes	No	Yes	Yes	Yes	4
Amorim et al, 2018	Yes	Yes	Yes	Can’t tell	Yes	4
Gonzalez et al, 2019	Yes	Yes	Yes	Can’t tell	Yes	4
Adedire et al, 2016	Yes	Yes	Yes	Yes	Yes	5
Mansour et al, 2019	Yes	Yes (Only one district out of 26 excluded with proper justification)	Yes	Yes	Yes	5
	QUALITATIVE STUDIES					
	Is the qualitative approach appropriate to answer the research question?	Are the qualitative data collection methods adequate to address the research question?	Are the findings adequately derived from the data?	Is the interpretation of results sufficiently substantiated by data?	Is there coherence between qualitative data sources, collection, analysis and interpretation?	

Andrade et al, 2014	Yes	Yes (exploratory, descriptive)	Yes	Can't tell	Can't tell	3
Silva et al, 2015	Yes	Yes	Yes	Yes	Yes	5
	MIXED METHODS STUDIES					
	Is there an adequate rationale for using a mixed methods design to address the research question?	Are the different components of the study effectively integrated to answer the research question?	Are the outputs of the integration of qualitative and quantitative components adequately interpreted?	Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?	
Gustaffson et al, 2020	Yes	Yes	Can't tell (Not clear from the paper)	No	Yes	3

S4: Systematic review protocol registered in PROSPERO (CRD42019139365)

Patient-held records in low- and middle-income countries (LMICs): a systematic review

Review question

To explore the literature around patient-held records in low- and middle-income countries.

In particular, we wish to answer the following question:

Can patient-held record use in LMICs improve clinical handover, patient-centred care, and self-care management?

In addition, we wish to:

1. Summarize the evidence on patient-held records in improving clinical handover, patient-centred care, and self-care management.

2. Investigate user perceptions of patient-held record use.

Searches

The search strategy will be developed for electronic databases such as MEDLINE (Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R) (1946 to present)), EMBASE (Ovid EMBASE Classic + EMBASE (1947 to present)); and CINAHL (via EBSCO (1980 to present)).

Also, a lateral search using any relevant systematic reviews to locate additional relevant studies will be carried out.

In addition, the grey literature search will also be searched to identify documents relating to available guidance on patient-held records (OpenGrey).

Key search terms will be related to “patient held records” and “low-middle income countries”.

The searches in the electronic databases will be carried out from their respective inception dates to November 2018.

No limits will be imposed on language or publication year during the searches, although studies published in languages other than English will not be included.

Additional search strategy information can be found in the attached PDF document (link provided below).

Types of study to be included

All study designs will be included: intervention studies with patient-held records vs no records or usual care, non-intervention studies including information on handover communication, and qualitative studies on the perceptions of users.

Inclusion criteria:

1. Any patient-held health information, which provides a continued record of care, which has been designed for use by both healthcare providers and patients. 2. Studies including paper-based records (which will be classed as hand-held). If electronic, the records will be accessible by hospital clinicians, patients, and community clinicians.

3. Studies that have reported the use of patient-held records for the transfer or exchange of information across care transitions.

Exclusion criteria:

1. Any paper or electronic record that is a hospital-based medical chart, or facility-based medical record.

2. Studies, which have reported on the tools specific to one or more transitions of, care (i.e. hospital shift-change, referral, transfer, or discharge) such as discharge summaries or referral letters. 3. Patient diaries and mobile health interventions that involve text messages will not be considered to be eligible interventions.

Condition or domain being studied

Patient-held records in low- and middle-income countries. All disease conditions will be included, provided the associated intervention involves the use of patient-held records.

Participants/population

Participants (patients, carers, and healthcare workers) of any age and sex from low- and middle-income countries (as defined by the World Bank in 2018).

Intervention(s), exposure(s)

Any intervention that uses patient-held records. Examples of patient-held records include: maternal and child health cards, diabetes passports, chronic disease booklets, person-specific patient-held handbooks, etc.

For the purposes of this systematic review, patient-held records are defined as continued care records (with health information recorded by health care providers) handed over to the custody of the person, which contributes to handover communication and continuity of care.

Comparator(s)/control

None.

Context

Main outcome(s)

Patient-held records in low- and middle-income countries (LMICs).

Measurements and reports of the process or clinical outcomes will be considered, as follows:

Process outcomes relating to handovers (the record being a continued record) such as the number of completed entries in the patient-held record, or appointment-keeping, legibility, or accuracy of the information recorded.

Relevant clinical outcomes highlight an improvement in patient care continuity.

Patient- and health care provider-reported outcomes of satisfaction with the care or the care continuity.

Additional outcomes will include factors (e.g., barriers, facilitators, etc.) that are reported as affecting the use of patient-held records.

Measures of effect Not applicable.

Additional outcome(s)

Additional information on the development of the patient-held record, if reported.

Measures of effect No time limitations.

Data extraction (selection and coding)

Two reviewers (LJ and DB) from the studies retrieved during the searches will select eligible studies.

The initial title and abstract selection will be broad, with studies mentioning patient-held records being retained, to facilitate further reference searching for additional papers.

Following this, the full texts of the retained literature will be sought, and those that can be accessed will be screened against the aforementioned inclusion criteria.

If there is a degree of uncertainty surrounding the inclusion of a study or any disagreement following discussions, an additional reviewer (JP) will be available to provide a conclusive assessment.

Data extraction will be split between available members of the research team (DB, PJ, LAJ), with LJ randomly sampling 10% of all studies to ensure reliability in the process. If there are any discrepancies during this sampling check, discussions will take place, and if a resolution cannot be reached, then a third impartial reviewer (JP or SMH) will be called upon for a final decision. LJ will be responsible for organising the data and will check for data entry discrepancies.

An electronic data extraction form has been drafted in Excel, piloted, and is ready for final use.

The data to be extracted will include details of the studies (authors, settings, year), the features of the patient-held records, the aims and objectives of the studies, study designs, the information recorded and communicated by the studies, the outcome measures relating to handover, patient-centred care, self-management, the clinical outcomes, the user perceptions of the patient-held records, and the findings from the studies.

Risk of bias (quality) assessment

The quality assessment will be carried out by two reviewers (LJ and DB). Given the mixed-methods nature of this review, the Mixed Method Appraisal Tool (MMAT) will be used, which is a reliable instrument that has been used for several mixed-methods systematic reviews covering literature across the high-, middle- and low-income countries.

Strategy for data synthesis

The review will be summarised descriptively. A meta-analysis will not be carried out as a large degree of heterogeneity is expected in the different types of patient-held records for different diseases, and the different tools for evaluation.

First, a preliminary synthesis of the included studies will be undertaken by listing and presenting the results in tabular form.

S5: Example search strategy in EMBASE

Patient-held records

1. (exp medical records/or exp medical records, problem-oriented/or exp medical records systems, computerized/or exp nursing records/or (((medical or health) and record*).mp. or (case note* or case record*).mp.) or (record* or book* or handbook* or card*).mp AND ((held adj3 (patient or parent or person or woman or man or family or consumer)).mp. or (carried adj3 (patient or parent or person or woman or man or family or client or consumer)).mp.)) OR ((log-book* or logbook*).mp. or home based record*.mp. or passport*.mp. or personal health record*.mp.)
2. ((patient-held or patient-held or home based or home-based or personal child or "mother and child" or "maternal and child" or mother-child) adj2 (record* or book* or handbook* or card*)).mp
3. ((patient access or personal or patient-held) adj2(record*or portal * or health record* or information* or prescription* or electronic record*)).mp
4. 1 or 2 or 3

Low-and Middle-income countries

5. exp developing country/ or exp medically underserved/ or developing countr$.mp. or medically underserved area$1.mp. or low income countr$.mp. or middle income country.mp. or low resource.mp. or resource poor.mp. or global.mp. or exp Africa/ or exp "South and Central America"/or exp asia/ or exp Caribbean islands/ or exp pacific islands/ or exp eastern Europe/ or exp Indian Ocean/or south america$1.mp. or Africa$1.mp. or Caribbean.mp. or central America$1.mp. or south America$1.mp. or eastern Europe$1.mp. or pacific island$.mp. or Indian ocean island$.mp. or asia.mp. or Afghan$.mp. or Bangladesh$1.mp. or Benin$.mp. or Burkina Faso.mp. or Burkinabe.mp. or Burundi$.mp. or Cambodia$1.mp. or Central African.mp. or Chad$.mp. or Comor$.mp. or Congo$.mp. or Eritrea$1.mp. or Ethiopia$1.mp. or Gambia$1.mp. or Guinea$1.mp. or Haiti$.mp. or Kenya$1.mp. or Korea$1.mp. or exp North Korea/ or Kyrgyz$.mp. or Liberia$1.mp. or Madagascar.mp. or Malagasy.mp. or Malawi$.mp. or mali$.mp. or mozambi$.mp. or Myanmar$.mp. or Nepal$.mp. or Niger$.mp. or Rwanda$1.mp. or Sierra Leone$.mp. or Somalia$1.mp. or Tajik$.mp. or Tanzania$1.mp. or Togo$.mp. or Uganda$1.mp. or Zimbabwe$.mp. or Angola$1.mp. or Armenia$1.mp. or Beliz$.mp. or Bhutan$.mp. or Bolivia$1.mp. or Cameroon$.mp. or Cape Verde$.mp. or Congo$.mp. or "Côte d'Ivoire".mp. or Ivory Coast.mp. or Ivorian.mp. or Djibouti.mp. or Egypt$.mp. or El Salvador.mp. or Salvadoran.mp. or Fiji$.mp. or Georgia$1.mp. or Ghana$.mp. or Guatemala$1.mp. or Guyan$.mp. or Hondura$.mp. or Indonesia$1.mp. or India$1.mp. or Iraq$1.mp. or Kiribati.mp. or Kosov$.mp. or Lao$.mp. or Lesotho.mp.

or Marshall Islands.mp. or Marshallese.mp. or Mauritania$1.mp. or Micronesia$1.mp. or Moldov$.mp. or Mongolia$1.mp. or Morocc$.mp. or Nicaragua$1.mp. or Nigeria$1.mp. or Pakistan$1.mp. or Papua New Guinea$1.mp. or Paraguay$.mp. or Philippines.mp. or Filipino.mp. or Samoa$1.mp. or sao tome$.mp. or Senegal$.mp. or Solomon Island$.mp. or sri lanka$1.mp. or Sudan$.mp. or Swazi$.mp. or Syria$1.mp. or Timor$.mp. or Tonga$1.mp. or Turkmen$.mp. or Tuvalu$.mp. or Ukrain$.mp. or Uzbek$.mp. or Vanuat$1.mp. or Vietnam$.mp. or West Bank.mp. or Gaza.mp. or Yemen$.mp. or Zambia$1.mp. or Albania$1.mp. or Algeria$1.mp. or "Antigua and Barbuda".mp. or antiguan.mp. or barbudan.mp. or Azerbaijan$1.mp. or Belarus$.mp. or Bosnia$1.mp. or Botswana.mp. or Brazil$.mp. or Bulgaria$1.mp. or Chile$.mp. or China.mp. or Chinese.mp. or Colombia$1.mp. or Costa Rica$1.mp. or Cuba$1.mp. or Dominica$1.mp. or Ecuador$.mp. or Gabon$.mp. or Grenad$.mp. or Iran$.mp. or Jamaica$1.mp. or Jordan$.mp. or Kazakhstan$1.mp. or Latvia$1.mp. or Leban$.mp. or Libya$1.mp. or Lithuania$1.mp. or Macedonia$1.mp. or Malaysia$1.mp. or Maldiv$.mp. or mauriti$.mp. or Mexic$.mp. or Montenegr$.mp. or Namibia$1.mp. or Palau$.mp. or Panama$.mp. or Peru$.mp. or Romania$1.mp. or Russia$1.mp. or Serbia$1.mp. or Seychell$.mp. or South Africa$1.mp. or Saint Kitts.mp. or Saint Lucia.mp. or Saint Vincent.mp. or Suriname$1.mp. or Thai$.mp. or Tunisia$1.mp. or Turk$.mp. or Uruguay$.mp. or Venezuela$1.mp

6. 4 and 5

S6: PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1, Title page
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2, Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5,7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7,8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	9
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary file, S5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	10,11

Appendix 6: Paper 3 supplementary files

S1 Interview guides

Patient topic guide

- Could you please tell me why you have come to primary care today?
  Your symptoms, treatment and effects of your condition on daily life
- Could you please tell me about how you came to know about your condition ("sugar/pressure")?
  How did you seek care?
- Could you tell me about your current treatment?
  Number of doctors involved, health care facilities, current medicines, the process of getting treatment, meeting doctors, taking blood pressure/blood sugar at facilities
- What information regarding your condition have you received from health care providers (HCP)?
  About the condition, treatment, diet/physical activity advices verbal and documented
- How do you feel about managing your condition?
  At home, involvement of family members, communication with HCPs, getting medicines, getting tests
- Could you please tell me how you manage your health care visits?
  Do you go to other HCPs for sugar and pressure?
- In your opinion, do you think HCPs need information from regarding your past medical conditions?
  Yes/No; then why?
- Could you tell me how you manage the papers you get from your doctors?
  Storing, carrying across health care visits in the same facility, carrying to different HCPs and health care facilities, use at home, show to family members, do you look at what HCPs have documented?
- How do you feel about using the papers given to you for managing your care?
  Does the papers from HCPs hold any value for you or not and why
  Can you think of any factors which helps you to use the papers/booklet?
- Could you tell me if you are able to use the information in the booklet such as previous blood pressure values or medication prescription to manage your condition in anyways?
  Communicating with doctors/nurses at primary centres or other health care facilities, look at the blood pressure/blood sugar values to see if they are improving or not, use it for managing medicines, communicating with family members

Carer topic guide

- Could you please tell me about how your family member came to know about their condition ("sugar/pressure")?
- Could you tell me about their current treatment?
  Number of doctors involved, health care facilities, current medicines, the process of getting treatment, meeting doctors, taking blood pressure/blood sugar at facilities
- What information regarding their condition have you received from health care providers (HCP) when you have accompanied them?
  About the condition, treatment, diet/physical activity advice verbal and documented
- Could you please tell me how you manage your family members' health care visits?

Do you accompany them? Do you ask details about the communication with HCPs? Do you encourage them go to other HCPs for sugar and pressure?

- In your opinion, do you think HCPs need information from regarding your family members' past medical conditions?
  Yes/No; then why? One or more examples when you needed the papers for HCPs
- Could you tell me how you help your family member manage the papers from doctors?
  Storing, carrying across health care visits in the same facility, carrying to different HCPs and health care facilities, use at home, do you look at what HCPs have documented?
- How do you feel about having the papers given to you/family member for managing care?
  Does the papers from HCPs hold any value for you or not and why
  Can you think of any factors which helps you to use the papers/booklet?
- Could you tell me if you are able to use the information in the booklet such as previous blood pressure values or medication prescription to manage your family members' condition in anyways?
  Communicating with doctors/nurses at primary centres or other health care facilities, look at the blood pressure/blood sugar values to see if they are improving or not, use it for managing medicines, communicating with family members

Healthcare provider topic guide

- Could you please walk me through your typical day like in FHC (or PHC/CHC/hospital)?
- Could you please tell me about how you manage patients with diabetes and hypertension in your centre?
- Could you please tell me if people mention access as an issue for their care?
- Could you tell me in your opinion issues relating to management of patients with diabetes and hypertension in your centre?
- Have you got a chance to look at patient's lab reports?
- Could you please tell me what kind of notes patients bring to consultation?
- How do you currently manage any records brought by patients to FHC?
  Could you please tell me what do you normally do with other OP sheets/ reports brought by patients?
- What written documentation do you provide the patients with diabetes and hypertension and other NCD patients?
  Any advice regarding how to use these documents for themselves, other HCPs
- In your opinion, do patients take this book/papers to other providers?
- What do you think about not having documented patient's health information from other providers?
  One or more examples when you needed the papers from other HCPs, how did you manage without past information?
- In your experience and opinion can patients explain what has happened in the previous doctor visit?
- In your experience how do you provide information on caring for themselves to patients/carers?
  Verbal information, booklet/recorded information
- Could you please describe your experience with recording in electronic health records?
  What was the best thing about it? What was the most difficult? How does it affect information retrieval and handover communication? What are your thoughts on electronic health records current implementation?

Appendix 7: Paper 4 supplemental files

Table S1 Overview of non-communicable disease programme

India

The Government of India launched the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2008 and later merged into the National Health Mission (NHM) in 2013 to integrate the NCD-related programme activities such as health promotion, early diagnosis, treatment, and referral. The federal structure of the Indian health system mandates shared responsibility of health by states and central government. The national policies set the directions and allocate funds for the programmes, while the states are responsible for establishing and maintaining the public health infrastructure and health care activities.

Kerala

In Kerala, NCD programme activities included early detection, treatment, and referral facilities at the primary and secondary public health facilities. Public health centres (PHC) provided care at the primary level and community health centres and district hospitals at the secondary level. Patients with diabetes and hypertension could access treatment and follow-up care at PHCs. A paper-based patient-held health record (PHR) was developed as a clinically focused and primarily for HCPs to record clinical information. The PHR also contained additional information for patients, such as a generic diet plan for patients with diabetes and hypertension. However, owing to stock-outs, HCPs advised patients with diabetes and hypertension to buy themselves a notebook, which was used as PHR to be carried to public health facilities. Along with this, both national and state governments have pledged to deliver comprehensive primary health care services to the entire population. The government of Kerala has begun a programme to upgrade and transform all primary health centres in states as part of the Mission Aardram programme and renamed these facilities as Family Health Centres (FHC). These facilities focus on upgrading the infrastructure, establishing electronic health records, and providing more doctors and staff in closer collaboration with elected rural governments (panchayat) members.

Table S3 Coding Framework

Domain (definition)	Constructs	Description relevant to the study
1. Knowledge (An awareness of the existence of something)	Knowledge (including knowledge of condition/scientific rationale) Procedural knowledge Knowledge of task environment	Awareness of the availability of PHRs for patients with diabetes/hypertension. Awareness of using PHRs for informational continuity for providers and patients. Procedural knowledge on using PHR for recording health care given and health care information regarding patient. Awareness of health education available in the PHR.
2. Skills (An ability or proficiency acquired through practice)	Skills Skills development Competence Ability Interpersonal skills Practice Skill assessment	Recording skill-without errors Requesting PHR Using PHRs to explain own care management
3. Social/professional role and identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	Professional identity Professional role Social identity Identity Professional boundaries Professional confidence Group identity Leadership Organisational commitment	Doctors stating recording (maintain records for informational continuity) as their responsibility or as a recognised practice. Other statements reflecting the role of doctors/nurses in communicating the care plan with patients/family, preventing medication errors, being efficient with time and resources and patient safety. Role of other health care providers such as nurses or pharmacists in recording, preventing errors, communicating with patients/families.
4. Beliefs about capabilities (Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use)	Self-confidence Perceived competence Self-efficacy Perceived behavioural control Beliefs Self-esteem Empowerment Professional confidence	How HCPs are able to ask, record and maintain informational continuity using PHRs.

5. Optimism (The confidence that things will happen for the best or that desired goals will be attained)	Optimism Pessimism Unrealistic optimism Identity	Statements reflecting how the use of PHRs can improve informational continuity for HCPs, how electronic health records can contribute to informational continuity.
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	Beliefs Outcome expectancies Characteristics of outcome expectancies Anticipated regret Consequents	Perceptions about outcomes, advantages and disadvantages of using PHR for informational continuity for HCPs and patients.
7. Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	Rewards (proximal/distal, valued/not valued, probable/improbable) Incentives Punishment Consequents Reinforcement Contingencies Sanctions	Increasing, or decreasing, the probability of using PHRs for patients with diabetes/hypertension due to a relationship between consequents and using PHR; constructs of associative learning (e.g. motivated to record in PHR due to repeated positive experiences).
8. Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	Stability of intentions Stages of change model Trans-theoretical model and stages of change	A conscious decision to perform a behaviour (requesting PHR from patients with diabetes/hypertension, recording in PHRs and explaining own health care management at home to patients using PHR).
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	Goals (distal/proximal) Goal priority Goal/target setting Goals (autonomous/controlled) Action planning Implementation intention	Priorities, importance or commitment to providing informational continuity using PHRs to other providers, discussion of informational continuity and own care management for patients with diabetes and hypertension.

10. Memory, attention and decision processes (The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	Memory Attention Attention control Decision making Cognitive overload/tiredness	The processes involved, and the factors taken into account (e.g. patient circumstances), when making the decision about recording (eliciting previous medical history and reminding patients regarding health care activities at home.
11. Environmental context and resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour)	Environmental stressors Resources/material resources Organisational culture/climate Salient events/critical incidents Person × environment interaction Barriers and facilitators	Any circumstance of doctors' situation or environment that encourages or discourages providing appropriate care for patients with diabetes/hypertension using PHR (including people and organisational factors e.g. resources, client circumstances).
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	Social pressure Social norms Group conformity Social comparisons Group norms Social support Power Intergroup conflict Alienation Group identity Modelling	External pressure from other people that influence the decision to record/use PHR e.g. encouragement from patients or colleagues, request from patients/caregivers for documented medical information regarding their condition
13. Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts	Fear Anxiety Affect Stress Depression Positive/negative affect Burn-out	Emotions are feelings about providing care for patients with diabetes/hypertension and using PHRs (e.g. fear, anxiety, stress).

to deal with a personally significant matter or event)		
14. Behavioural regulation (Anything aimed at managing or changing objectively observed or measured actions)	Self-monitoring Breaking habit Action planning	Behavioural regulation refers to ways of doing things, at an individual or environmental level, that relate to pursuing and achieving desired goals (e.g., using PHR for patients with diabetes and hypertension to maintain informational continuity).

Table S4 Additional illustrative quotes based on domains

Domain	**Sub-themes**	**Interview data**
Knowledge	Knowledge regarding patient's past PHRs	They will bring some records. Some patients pin the whole OP sheets as a bulk. HCP 3
		Yes, patients bring old medical records. HCP 17
	Awareness that patients may not carry records	Usually, patients will come with OP sheets but if they have miss placed or lost it that, they will come for another OP sheet. HCP 16
		In some situations, patients may not bring any records nor do they know their medicines name or past blood pressure levels. HCP 15
	Awareness of NCD notebook in the public health system	We have an NCD book for people with diabetes/hypertension and they bring the book with them for each visit. HCP 14
		Now that eHealth is implemented, there is a lot less paperwork. Because once we give the token to the patient at the registration, the same details (demographic) will be available until pharmacy. Although we cannot follow that always. In the case of NCD patients, they will have a notebook or for older citizens, they have another one (booklet). For them we still use them. We will write the token number inside the book so that the doctor can write it in the book. HCP 8
	Awareness of patients returning to primary care centres for diabetes and hypertension treatment	Most like around 80% of NCD patients come to FHC for buying their repeat medicines. Others come if they experience any difficult or they feel like they need to check their blood values (such as Fasting Blood Glucose). HCP 10
Skills	Skills gained at workplace	No these are the things (asking for PHRs/recording in them) we pick up in the work place, there is no specific training as such for recording in PHR. HCP 11
		No training as such we have seniors do the things and we do the same thing. HCP 13
		We used to consult around 200 patients on NCD day. Therefore, there is not much to guess how much we can enter. It is not whether we know how to record, which I believe most of us can do but practically whether it is possible write detailed notes. HCP 6
	Communicating with patients	When a patient is initially diagnosed with diabetes, I tell them to take their medicines regularly, control their diet and walk for at least 30 minutes. HCP 4
		I will tell the patients like I find that you are improving with medicine as I see all the records so I let them know I will reduce the dose of medicine. HCP 13
		In case of old age people, they may have their book or else we suggest the patients to bring any type of book. If we simply issue a number, they may miss it to bring next time. So, we usually advise them to buy a book and we enter the identification number on it. We tell them to bring it to health centre when they come to buy medicines for diabetes or hypertension. HCP 8

		During their (patients') first visit itself, we tell them to bring a notebook, Aadhar, ration card and phone number. We record their details and tell them to bring notebook the next time. Later they bring the notebook for every subsequent visit. In case, if they have any difficulties, we advise them to come after 1 week. HCP 9
	Training for electronic records	They have trained us. Initially Dr X who taught us regarding the electronic system. Later department posted some candidates to provide such training. There were 2 permanent staff for more than 2 weeks with us, up to last December to January. However, during lockdown they have withdrawn one candidate. HCP 8
		Usually, patients with NCD have continuous medications. There is no option in the electronic records to repeat them. Every time we need to type it, it is difficult but I am sure with practice it should be better. HCP 10
	Uncertainty regarding skills in using electronic records	Those with little computer knowledge or experience have difficulty in typing. It may be difficult for doctors who are older as they have followed a pattern and have built a system around themselves to work. They have their own traditional style, which they may not change. However, that can also be solved if we can get a data entry staff. HCP 15
		Practically what happens is patients take one registration and get the card and unique ID. But they will not bring it the next time. So, what is the point in having the electronic record, if each time we are having to issue temporary IDs, then there is no information being entered in the system, then how will we get the information next time? HCP 6
Social/professional role and identity	The role of the doctor in recording for informational continuity	If there is a notebook in our public health system, we doctors treat it as a record; we know we are in-charge of recording the details of the consultation. –HCP 6
		We (doctors) continue to use the notebook. If we consult a patient this month, it may be some other doctor who deals with the patient on the next visit. There is still a chance to forget entering some details in the electronic health records. All (doctors) are new to this new system and we may miss entering certain details. Most NCD patients will bring the book and we ask them to show it at consultations. Since we have started the electronic ones, not all the past details may be fully entered into the system. Hence, it is good that we can refer to the notebook so we maintain both currently. -HCP 5
	Nurses' recognising doctors' role in recording in PHR	Doctors usually write the medicines and the blood reports. We check BP and GRBS every month. In addition, HbA1c every three months. Doctors write these details in patient's notebook and we will copy them in the treatment card kept at the PHC. If there is any change in medicines doctors will write, it and they will also add the review date in the treatment card. HCP 2
		In the patient's book, address and code number will be there in front page. Inside pages, we mention the date and Doctor's write the prescribed medicines and check for any repetition or duplication of medicines. HCP 3

Beliefs about capabilities	Confidence of collecting information and recording in PHRs	So if it is a new patient, I will ask for detailed past medical history and document it in the notebook and initiate treatment based on his blood pressure/sugar values. HCP 15
		It is not whether we know how to record, which I believe most of us can do but practically whether it is possible write detailed notes. HCP 6
	Feeling that documentation needs to be prioritized over communication (conflicting priorities)	Sometimes in an OP, we will have a long queue and then some emergency patient will arrive. I will have to go and attend, and then when I come back, I will be looking to finish off the OP patients. On top of that, we have many registers to maintain, so we will be writing in that than what we tell the patient. HCP 2
	Minimal information recorded	Usually, we write the basic patient details in the OP ticket, but if the patient does not bring it, then it is not of much use. HCP 10
	Low confidence in maintaining informational continuity	When there is a lot of patients in the OP, the documentation will get affected. I will be focusing on writing the medicines at least, or if they are same from last time, will document “repeat all”. HCP 10
	Confidence in maintaining continuity (Good follow-up care at primary care centres)	Most people who have taken treatment from us will avail treatment for NCDs from us. Our Junior Public Health Nurses (JPHN) and Accredited Social Health Activist (ASHA)s play an important role in following people up and ensuring that they continue their treatment here (PHC). HCP 15
	Confidence in patients’ behaviour returning to primary care centres for diabetes and hypertension treatment	I have been practising here for around 2 years. I know the existing NCD patients. So I will know if the patient is new or not. Most of our regular patients will come here and will bring their notebook. If they have increased blood pressure or blood sugar in this visit we may have to make judgements about changing the dose of medicines. HCP 15
Optimism	Ease of access information from electronic health record	After using electronic health records, it is easy to get patients’ history. Particularly we can know the medicines they take. Once we enter the details doctors can view the details in the subsequent visits. HCP 10
	Mixed feelings about maintaining informational continuity with electronic health records	Ideally if everyone records the details properly in the case sheet in the electronic record this will work. There will be information available for doctors in the next visit. Then we should be able to record and the patient should bring their unique ID (identification card), or else it will not be useful. HCP 6
	Optimistic about patients bringing documents	Patients bring their notebooks or any documents they get from other doctors. We consider the documents, which patients bring as authentic. Besides these are the best available option or the only option. HCP 13
		They always carry the book to hospital on each visit. HCP 3
Beliefs about Consequences	Patient behaviours affecting informational and management continuity	I feel from patients’ perspective they are getting free treatment and medicines and follow up from PHCs. Sometimes there will be an interruption to treatment. In case a pregnant mother was taking, medicines from this PHC might go to her house for delivery and then there will be definitely issues with information being transferred. They may eventually reach back the system for treatment but not

		sure when they will be back, or whether they continued their treatment, for all these information we have to depend on the patients. HCP 15
		It is not that we do not get medical information from patients. Sometimes the information may not be clear. This where I have found it most difficult. They will verbally inform us they are hypertensive and the BP values may suggest that. Then they will say I am taking a 500 mg tablet. In such cases, I ask them to get the papers from home. HCP 6
	Not having PHR increases potential for error	But some patients may come without a prescription and tell three tablets for blood pressure, four tablets for some other problem, three yellow tablets, or round tablets. They are the more problematic persons for us. It becomes difficult then, they are having medicines for BP but we don’t know which one and we may have to insist them to go and bring the papers. For them, it is their medicine, they probably don’t realise that many tablets are round. HCP 6, doctor in FHC
		Once a COPD (Chronic Obstructive Pulmonary Disease) patient came to FHC, we were not aware that he had this condition (COPD). The patient did not mention it nor did have any records with him. We (the doctor) prescribed him a particular antihypertensive. Later we understood he is a COPD patient. Then he came onto the next visit, with the prescription of a pulmonologist and we changed the anti-hypertensive for him. So now, the whole treatment was affected. HCP 5
		In case of diabetic patients, we refer them to GH if they have any renal issues. We get their creatinine tested and refer them. However, when they come back to us, they insist on taking their previous medicines. When they do not bring back the notes, they got at the hospital it is difficult for us to know what has happened at the hospital. HCP 10
Reinforcement	Regular patients bring PHRs	Most people who take treatment from us will continue to do so. They will be regular in bringing the papers, they will inform us if they have taken other treatment from outside, so it will be easier to write their records and treat them. HCP 13
		Mostly, our regular patients inform us they went for treatment in other hospital in the previous month and will bring the records to show the doctor. HCP 3
		Once a COPD (Chronic Obstructive Pulmonary Disease) patient came to FHC, we were not aware that he had this condition (COPD). The patient did not mention it nor did have any records with him. We (the doctor) prescribed him a particular antihypertensive. Later we understood he is a COPD patient. Then he came onto the next visit, with the prescription of a pulmonologist and we changed the anti-hypertensive for him. So now, the whole treatment was affected. HCP 5
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Goals	Recording is based on our needs	Yes, there is a focus on documenting majorly the medicines and may be the BP readings. There are some deficiencies in recording from the doctors' side but this is mainly due to the volume of work. They have to cater to a large number of patients around 150-200 in their OP. So the recording will be very much based on what they would need next time. HCP 12

		The documenting becomes very much what we need the next time. Most patients who take treatment from here will come back here. HCP 14
Memory, attention and decision processes	Lack of time for communication	I have thought about it. Most of the time in the OP, I may not get time to teach them about diet and physical activities. We just check the blood values and blood pressure and we change the dosage of medicine based on that. We may not even tell about the importance of the blood values. This is what happens mostly during consultation time. HCP 5
		I try to make it a point to communicate with new patients regarding how to manage but sometimes there is a rush and I will not have enough time with patients. HCP 1
	Interruption and difficulty in locating information	But not everyone (patients) will carry records all time. There may be many papers also at times. Imagine having a long queue of patients outside your room and then someone brings in many papers; it will take time to go through them to find what we need. It will interrupt the process of consultation. I think for new patients we will have to sit through and check them, but with regular patients it maybe one or two here and there. HCP 1
		They (patients) have documents, which contain details like medicines, investigations, RBS value and BP value alone. No doctors will get enough time to write all stories during busy OP's. Some time they may not write diagnosis also. If they consult in a big private hospital, they may enter the detailed diagnosis but in small PHC's diagnosis is like hypertension or type 2 diabetes. There will not be any detailed diagnosis or family medical history because they will not get time. There is no point in discussing that. In a single NCD day, there may be around 150-200 patients at a time. We used to consult 200 to 220 patients that is one doctor in a single day. Therefore, there is not much to guess how many records can we enter? It is not about whether they know which they know but practically will not be able to write detailed notes. HCP 6
		After a referral to GH (general hospital), three things can happen. Mostly people will return to us with the OP ticket or sheet; others come and verbally report what happened at the consultation at GH. The last category never will come back. HCP 10
Environmental context and resources	Workload in the outpatient	Sure, we do enter some family history but can't do it all time because of heavy workload and rush in the morning and evening O.P is peak time and almost 250 patient daily. HCP 8
		There is like a huge number (of people) in primary care, the dire need is to cater to them and finish the consultations. HCP 12
		But not everyone (patients) will carry records all time. There may be many papers also at times. Imagine having a long queue of patients outside your room and then someone brings in many papers, it will take time to go through them to find what we need. It will interrupt the process of consultation. I think for new patients we will have to sit through and check them, but with regular patients it maybe one or two here and there. HCP 1
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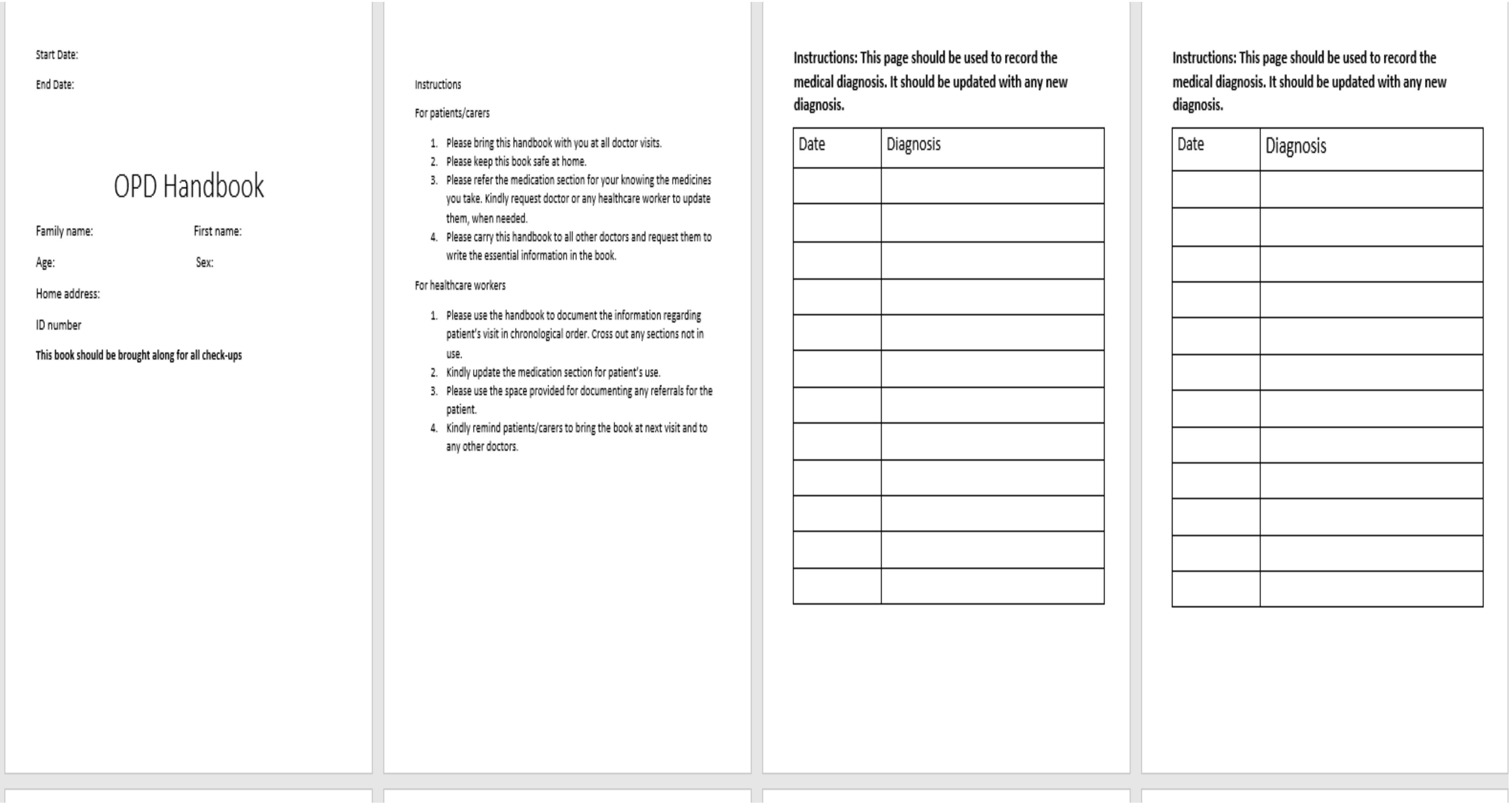
		After a referral to GH (general hospital), three things can happen. Mostly people will return to us with the OP ticket or sheet; others come and verbally report what happened at the consultation at GH. The last category never will come back. HCP 10
	Potential advantage of electronic health record	It is easy to get patients history especially patient's medical history. We get to know what medications they have taken. Usually, we write in the OP tickets and most of the patients may not bring it. But in the E-system, if we enter all details at first, doctors can view the same during the subsequent visits. By looking at records it easy for us to understand the patients. We write bio data and diagnosis clearly which helps everyone to understand and do tally easily. HCP 10
		Now that eHealth is implemented, there is a lot less paperwork. Because once we give the token to the patient at the registration, the same details (demographic) will be available until pharmacy. HCP 8
		Since eHealth is not fully implemented and functional in the health system. It will be difficult to say whether there is any need for paper-based records. If everything works according to plan, of course it is a good thing for us. HCP 6
	Workplace issues (lack of supervision, hierarchical issues)	Then these issues as some doctors who work hard will continue their work but some people are there do not work at all. Therefore, like some sort of hierarchy, which makes some work more, and they may have difficulty to give more care to patients. HCP 12
Emotion	Treating patients who do not bring records is frustrating	People who do not bring papers and then say they take medicines for sugar or pressure then that becomes more difficult. If it was a new patient, I would have started them on something but now they have already been on medicines but we don't know what it is, that's really disappointing. HCP 4
Social influence	Encouraged to record in PHRs by senior colleagues	I used to ask doctors who joined at my PHC to record well. Although there is no stipulated checks for documentation, I used to guide them if they had any issues. We are more focused on maintaining our registers at PHC, which will be audited. HCP 16
Behavioural regulation	Formats can help with recording	Currently, there is no such option in the E system. Templates of each patient show different combinations of drugs. Patients come every two week for medicines. If the system shows all repeated medicines or displays 'continuously taking' for the patients who come for frequent check-ups, which would be very useful. HCP 10
	Lack of supervision	Then, there is no method anywhere, to improve the staffs those who work less. Even if they do not document well, there is no checks or penalty. HCP 12

Appendix 8: Sample PHR template for co-design events



Start Date:

End Date:

OPD Handbook

Family name: First name:

Age: Sex:

Home address:

ID number

This book should be brought along for all check-ups

Instructions

For patients/carers

1. Please bring this handbook with you at all doctor visits.
2. Please keep this book safe at home.
3. Please refer the medication section for your knowing the medicines you take. Kindly request doctor or any healthcare worker to update them, when needed.
4. Please carry this handbook to all other doctors and request them to write the essential information in the book.

For healthcare workers

1. Please use the handbook to document the information regarding patient's visit in chronological order. Cross out any sections not in use.
2. Kindly update the medication section for patient's use.
3. Please use the space provided for documenting any referrals for the patient.
4. Kindly remind patients/carers to bring the book at next visit and to any other doctors.

Instructions: This page should be used to record the medical diagnosis. It should be updated with any new diagnosis.

Date	Diagnosis

Instructions: This page should be used to record the medical diagnosis. It should be updated with any new diagnosis.

Date	Diagnosis

Instructions: These pages allow for recording of medications to be taken by patient. (This should be filled by health care provider). Any discontinued medication should be crossed out and enter the date for discontinuation.

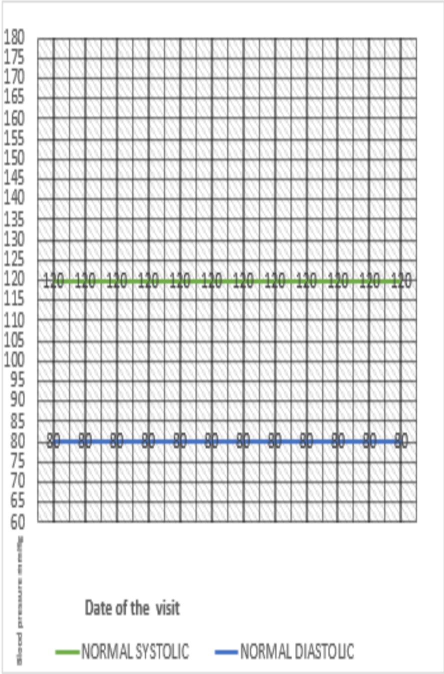
Date of entry	Name of medicine	Dose	Route	Frequency	Medication start date	Medication end date

Instructions: These pages allow for recording of medications to be taken by patient. (This should be filled by health care provider). Any discontinued medication should be crossed out and enter the date for discontinuation.

Date of entry	Name of medicine	Dose	Route	Frequency	Medication start date	Medication end date

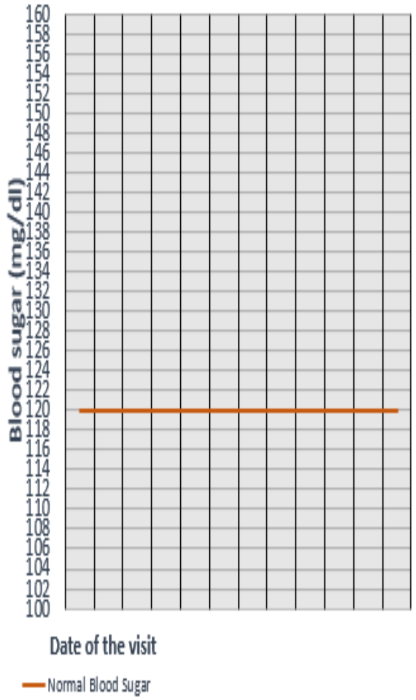
Instruction to HCP: Use this section to record the date of visit and the blood pressure values.

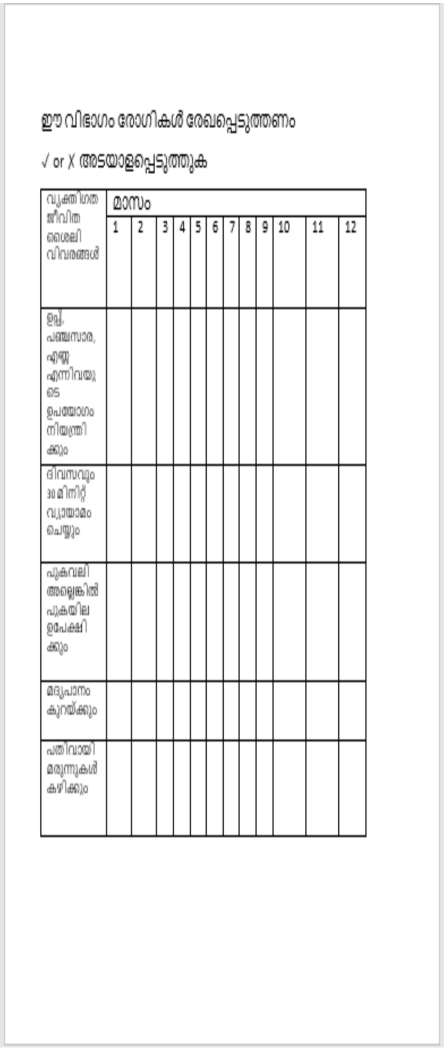
Note: Any higher or lower value can be written on the graph.



Instruction to HCP: Use this section to record the date of visit and the blood sugar values

Note: Any higher or lower value can be written on the graph.





ഈ വിഭാഗം രോഗികൾ രേഖപ്പെടുത്തണം

√ or X അടയാളപ്പെടുത്തുക

വ്യക്തിഗത ജീവിത ശൈലി വിവരങ്ങൾ	മാസം											
	1	2	3	4	5	6	7	8	9	10	11	12
ഉപ്പ്, പഞ്ചസാര, എണ്ണ എന്നിവയുടെ ഉപയോഗം നിയന്ത്രിക്കും												
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പതിവായി മരുന്നുകൾ കഴിക്കും												

Date:

HTN+DM2 v4.2 ○M ○F <40○ >55○ >65○

○ 1st visit/Follow-up month: ○1 ○3 ○6 ○≥12 Seroreaction +○ -○ ?○

○ Missed last appt. by >7d

Diagnoses ○HTN ○DM2 ○CRD ○Chr. heart disease

Cardiovasc. risk factors

↑ *Lipids* Y○ N○ ?○

Family h/o CVD (in 1° relatives <50y) Y○ N○

h/o CVD Stroke/MI Y○ N○

Smoking Y○ N○

Alcohol Y○ N○

BMI <25○ 25-30○ ≥30○

Time since diagnosis (DM2)

○<1y ○1-5y ○5-10y ○>10y

Signs of organ damage

○ Cardiac decompensation *h/o Lower limb swelling / Diff. breathing*

○ Angina *Typical chest pain / Diff. breathing*

○ Renal impairment *Proteinuria / ↑ Creatinine*

○ Other *Periph. vasc. disease / Retinal dmg. / LVH*

Complications of DM2

○ Neuropathy ○ Ulcers/diabetic foot

○ Hypoglycemia *Sweating / Dizziness / Headache Confusion / Nausea / Shakiness*

Tests

BP

○ High-normal *Sys: 120-139 or Dias: 85-89 mmHg*

○ 1°HTN *Sys: 140-159, Dias: 90-99 mmHg*

○ 2°HTN *Sys: 160-179, Dias: 100-109 mmHg*

○ 3°HTN *Sys: >180, Dias: >110 mmHg*

FBS	*RBS*	*HbA1C*	*Dipstick*	
			Gluc	*Prot*
○ ≤6	○ <4	○ Ordered		
○ 6.1-6.9	○ 4-7.8	○ <6%	○	- ○
○ ≥7	○ 7.8-11	○ 6-6.4%	○	+/tr ○
	○ ≥11.1	○ ≥6.5%	○	≥2+ ○

Adherence ○High ○Med ○Low

% days covered ≥80% 40-80% ≤40%

Past 12m:

	Date		Date
○ RFT	/ /	○ ECG/Echo	/ /
○ Lipids	/ /	○ Lifestyle	/ /

Management

Lifestyle○

No meds○

Meds changed○

Statins○

HTN

Thiazide○

CCB○

ACE-I○

ß-blockers○

Other○

DM2

Metformin○

Glibenclamide○

Other OHA○

Insulin

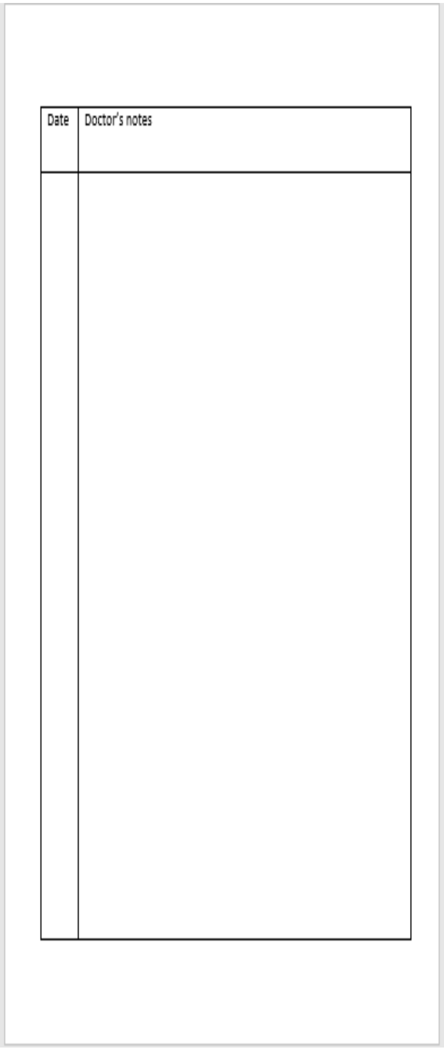
start○

maintain○

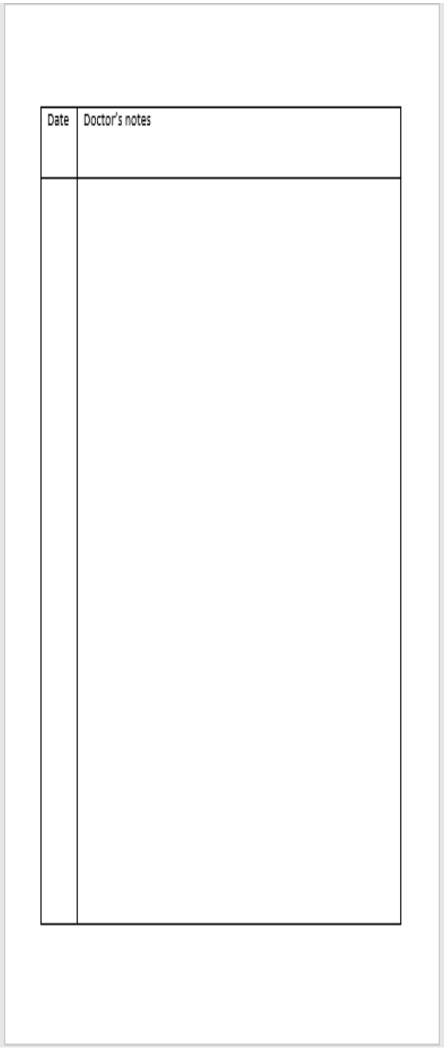
modify○

Follow-up: / /

Referral ○



Date	Doctor's notes



Date	Doctor's notes