Examining the prevention and management of cardiovascular disease risk in Kenyan primary care settings



Tonny Brian Mungai Muthee

Green Templeton College

University of Oxford

A thesis submitted for the degree of

Doctor of Philosophy

Hilary 2022



A level 2 primary healthcare facility in Kilifi County, Kenya (fieldwork)

Acknowledgements

Professor Carl Heneghan, Dr David Nunan, Dr Veronika Williams and Dr Anthony Etyang provided academic supervision of this thesis. Their professional expertise in evidence-based medicine, cardiovascular epidemiology and mixed-methodology research, and their familiarity with context, has contributed immensely to my professional development as a researcher and scientist. I am particularly inspired by their patience, kindness, mentorship, and commitment to excellence throughout this academic process. I will strive to emulate these values moving forward.

It is through the generosity of the Rhodes Scholarships that this work was made possible. Further to the financial support provided by the Rhodes Trust, the trust has provided me with a community of colleagues, friends and family who went above and beyond to support me and my dreams. I am forever grateful.

To my father and sister, John Muthee and Cynthia Claire Muthee, I cannot thank you enough for always allowing, supporting and giving space to my dreams. Your encouragement has been the bedrock of my successes.

I am grateful to my friends, colleagues and mentors for their support: Mary Jiyani, Dr Nelisa Tebeka, Dr Fredah Temwani, Krishna Parshotam, Steve Molikande, Dr Nhlakanipho Mkhize, Dr Georgia Richards, Dr Derick Kimathi, Dr Kome Gbinigie, and Kamau Wairuri. And to my partner, Deshon Jahrel Muthee, I extend immeasurable gratitude for keeping me grounded and sane these past few months. I cannot imagine a better person to weather a pandemic and a new strange world with – thank you for the laughter, food, joy and graceful reminders that it gets better and brighter. Special shout out to my therapist, Juliet Bulman, who for the past two years has been my cheerleader towards mental wellbeing and healing. Thank you all.

This thesis is dedicated to my late and beloved mother, Jane Wangari Muthee, for being the first and most phenomenal teacher in my life, encouraging my curiosity and championing my difference.

Abstract

Background: Cardiovascular diseases (CVD) such as ischaemic heart disease and cerebrovascular incidents cause up to 12% of the total deaths in all ages for both males and females, and one in four of all hospital admissions in Kenya. Further, risk factors for these diseases have increased by a third in the last ten years (2005-2016). The use of simple and efficient interventions such as CVD risk assessment and scoring tools is largely suboptimal in primary care settings. Current practice in the prevention and management of CVD risk in Kenyan primary care settings remain poorly characterised for clinicians, patients and policy makers. Therefore, the aim of this thesis was to examine the prevention and management of CVD risk in Kenyan primary care settings by proactively identifying and characterising important elements relevant to optimising practice in these settings.

Objectives: 1) Assess the potential burden of CVD in the Kenyan population by modelling CVD risk and factors underpinning this burden; 2) Systematically synthesise evidence on the implementation of CVD risk assessment in primary care and how factors that influence implementation relate to and impact on Kenyan primary care settings; 3) Understand current practice by characterising the experiences of key stakeholders in the prevention and management of CVD risk in Kenyan primary care; and identifying factors influencing the adoption of recommended practices; 4) Explore the inaccessibility of essential CVD medicines in Kenyan primary care as a significant challenge in the assessment and management of CVD risk in these settings.

Methodology: This thesis consists of an epidemiological study providing the most up-to-date information on the potential burden of CVD in the Kenyan population, illustrating the importance of the growing burden and highlighting potential drivers of this burden (Chapter 3). It also includes a mixed-methods systematic review (Chapter 4) that synthesises the evidence on the implementation of CVD risk assessment in primary care (as a means to address the burden identified in Chapter 3) and how factors that influence implementation relate to and impact on Kenyan or similar primary care settings. A qualitative study (Chapter 5) identifies key stakeholder practice experiences in CVD risk prevention and management in Kenyan primary care and the factors influencing the adoption of recommended practices. Lastly, a cross-sectional observational study of retrospective data, i.e. latest national essential medicine lists to compare the recommended levels of use of essential medicines to treat the leading causes of mortality in Eastern sub-Saharan Africa (CVD, TB and HIV/AIDs) (Chapter 6).

Results:

Study 1: Using data from 1627 participants from the Kenya STEPwise survey carried out between April and June 2015 as part of the international WHO approach to surveillance of chronic disease risk factors, this study provided the most up-to-date information on the potential burden of CVD in the Kenyan population by modelling

CVD risk and factors underpinning this burden. This risk modelling was based on the updated CVD risk prediction model for Eastern sub-Saharan Africa which was developed by the WHO with the International Society of Hypertension (ISH). The median CVD risk score in the study sample was 3.0% (IQR 0.3, 46.2), and the majority (69.1% [95% CI 66.8-71.3]) of the subjects were grouped in the lowest CVD risk category (< 5% CVD risk). According to the national guidelines on CVD prevention and management, up to 11.9% of the study population (moderate, high and highest-risk categories) are eligible for both pharmacological and lifestyle interventions. Women recorded a higher mean CVD risk score than men: 5.0% (SD 5.5) vs. 4.6% (SD 4.7). This is in addition to more women (14%) than men (9%) in the study population having a CVD risk score of more than 10%. The mean CVD risk scores differed significantly across socio-demographic and behavioural groups. The data for the subjects showed that their educational levels, marital statuses, ethnicities, their frequency of consumption of processed food that was high in sugar, the number of days on which they ate vegetables in a typical week, whether they had received lifestyle advice on reduction of their salt intake in the previous three years and the number of days in a typical week on which they undertook vigorous-intensity activities as part of their work were significantly associated with their CVD risk scores. Factors such as ethnicity, level of education, marital status, dietary practices and physical activity could be used to refine further the entry points for targeted CVD risk screening, prevention and management in Kenyan primary care settings. This study suggests that public primary care facilities are a critical entry point for targeted screening and the delivery of interventions aimed to prevent and manage CVD risk. This work will be submitted for peer review shortly.

Study 2*:* A mixed methods systematic review was conducted in accordance with PRISMA guidelines to synthesise evidence on the implementation of CVD risk assessment in primary care and how factors influencing implementation relate and impact on Kenyan or similar primary care settings. An extensive search was conducted through seven electronic databases, hand-searching references, and in grey literature. The quality of studies was assessed through the MMAT tool, the critical appraisal checklist by NICE and the Axis tool, depending on the study design of the studies included; mixed-methods, qualitative and cross-sectional studies, respectively. Of the 3010 studies screened, only 25 studies were included in the review. This review broadly conceptualises factors influencing implementation of CVD risk assessment as those relating to CVD risk scoring tools, users, clinical settings and the healthcare system. This review explains that the implementation of CVD risk assessment interventions is complex and is often affected by the interaction of the interventions with the real world: the users and the environment in which they are being used. Notably, this study illuminates a critical gap in CVD related implementation research from LMICs. This work is published in *BMC Implementation Science.*

Study 3*:* This study qualitatively 1) examined current practice by understanding how prevention and management of CVD risk was experienced by clinicians, patients, and

policymakers in everyday clinical practice; and 2) identified contextual factors that influenced the adoption of recommended practice in Kenyan primary-care facilities. This involved conducting 560 hours of observations, 15 interviews with clinicians and policymakers, 30 exit interviews with patients and a documents analysis across seven healthcare facilities in Kilifi County, Kenya. The use of both thematic and framework analysis helped to 1) sufficiently identify a critical gap in knowledge and practice partly due to a lack of familiarity with clinical guidelines related to CVD risk and to better understand the use of clinical judgement in CVD risk assessment by clinicians in these facilities; 2) categorise factors that influence the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care into three levels: micro (clinician and patient), meso (clinical setting and local government), and macro (global and national influences); and 3) explore the intricate relationships across these three levels. As such, findings from this study can be used to develop and support meaningful and pragmatic change in CVD prevention and management in these settings. This work will be submitted for peer review shortly.

Study 4*:* This study is follows on from one of the main findings of the qualitative study: inaccessibility of essential CVD medicines, which poses a significant challenge in the assessment and management of CVD risk in Kenyan primary care settings. By comparing the recommended level of use of 42 essential medicines extracted from nine National Essential Medicines Lists (NEMLs): CVD (*n*=29), HIV (*n*=8) and TB (*n*=5), this cross-sectional observational study of retrospective data confirmed the hypothesis that there is a disproportionate percentage difference in the recommended levels of use of essential medicines used in communicable diseases compared with those for NCDs in NEMLs. The findings from this study show that at level 1 (proxy for primary care), more essential medicines were recommended for HIV and TB treatment than for CVD risk prevention and management. A majority of the countries recommended the use of essential CVD medicines at level 2 (proxy for secondary care). Notably, Acetylsalicylic acid was commonly recommended in NEMLs for use at level 1, and Kenya was the only country in this study that did not recommend any essential CVD medicines for prescription at level 1. Instead, Kenya recommended use of essential CVD medicines at level 3 (proxy for tertiary care). This study contributes to a new dimension in the policy discourse on the availability and affordability of essential NCD medicines. Specifically, the study suggests a need to expand WHO's access to drugs and medicine framework by highlighting the importance of harmonising across NEMLs the recommended levels of use for essential medicines. This work will be submitted for peer review shortly.

Conclusions: This thesis provides new and urgently required evidence on the landscape of prevention and management of CVD risk in Kenyan primary care settings. It also adds up to date information on the potential burden of CVD in the Kenyan population, illustrating the importance of the growing burden and highlighting potential drivers of this burden. Specifically, it provides novel input to key questions of interest to policy

makers, the crucial ones being: (1) what percentage of the Kenyan population might be eligible for consideration of pharmacotherapy and lifestyle interventions to mitigate the risk of CVD; (2) what nuances inform current practice in the prevention and management of CVD risk in Kenyan primary-care settings; and (3) what might it take to scale up the recommended practice. It has also provided some insight into the future of research in this field by highlighting a need for high-quality implementation research on this topic within LMICs. Policymakers and practitioners may also use this thesis's methodology to plan future studies, and use its findings and recommendations judiciously to plan evidence-based strategies to improve practice.

Statement of Contributions

I certify that the work in this thesis is my own. I have used initials to indicate where others contributed to the work. This is summarised below as follows:

- **Derick Kimathi** (DK) conducted duplicate screening of articles for inclusion and duplicate data extraction, as described in Chapter 4.
- **Georgia Richards** (GR) conducted duplicate screening of articles for inclusion and duplicate data extraction, as described in Chapter 4. Georgia also conducted duplicate assessment of the quality of the studies included in Chapter 4.
- **Nia Roberts** (NR) reviewed the search strategy as described in Chapter 4.

Contents

Acknowledgements 3
Abstract 4
Statement of Contributions 8
Contents 9
List of Abbreviations 15
Chapter 1. Overview and Structure of Thesis 18
1.1 Overview and aim the thesis 18
1.2 Objectives 18
1.3 Structure of thesis 18
1.4 Key accomplishments 24
1.4.1 Research collaborations 24
1.4.2 Funding 25
1.4.3 Fieldwork 25
1.4.4 Knowledge dissemination and translation 26
1.4.5 Training and skills development 27
1.4.6 Awards 27
Chapter 2. Background 28
2.1 Introduction 28
2.2 Overview of the Kenyan healthcare system and context 28
2.3 Epidemiology of cardiovascular disease 30
2.3.1 Global burden 30
2.3.2 Burden in Kenya 31
2.3.3 Risk factors 33
2.4 Global and national policy response 35
2.4.1 Global response 35
2.4.2 Kenya's policy response 37
2.5 Cardiovascular disease risk prevention and management strategies 39
2.5.1 Population approach 39
2.5.2 Individual approach 40
2.6 Implementation of CVD risk-assessment interventions 42

2.7 Conclusions 44
2.8 Chapter summary 45
Chapter 3. The distribution of cardiovascular risk scores in the Kenyan population and factors associated with risk score variation 46
3.1 Publication statement 46
3.2 Introduction 46
3.3 Aim and objectives 48
3.3.1 Aim 48
3.3.2 Objectives 48
3.4 Methods 48
3.4.1 Study design 48
3.4.2 Study subjects and data sources 48
3.4.3 Data extraction 49
3.4.4 Data management 50
3.4.5 Statistical analysis 50
3.4.6 Methodology reporting 52
3.4.7 Ethics and Data protection 52
3.5 Results 52
3.5.1 Study subjects 52
3.5.2 Characteristics of the study subjects 53
3.6 Discussion 63
3.6.1 Summary of findings 63
3.6.2 Interpretation of findings 66
3.6.3 Findings in the context of existing research 67
3.6.4 Strengths and limitations 70
3.6.5 Implications for practice and research 71
3.7 Conclusions 72
3.8 Chapter summary 72
Chapter 4. Factors that influence the implementation of cardiovascular risk scoring in primary care: a mixed-method systematic review 74
4.1 Publication statement 74
4.2 Introduction 74

4.3 Aim and objectives 75
4.3.1 Aim 75
4.3.2 Objectives 75
4.4 Methods 76
4.4.1 Search strategy 76
4.4.2 Selection criteria 76
4.4.3 Assessing the quality of the studies 77
4.4.4 Assessing for bias in the review 78
4.4.5 Data extraction strategy 78
4.4.6 Data synthesis and presentation 79
4.4.7 Additional analyses 82
4.5 Results 83
4.5.1 Study selection and characteristics 83
4.5.2 Quality assessment of included studies 84
4.5.3 Factors that influenced the implementation of cardiovascular risk scoring in primary care 86
4.5.4 A summary of additional analysis 97
4.6 Discussion 98
4.6.1 Summary and interpretation of findings 98
4.6.2 Findings in context 99
4.6.3 Strengths and limitations 102
4.6.4 Implications for research and practice 103
4.7 Conclusion 103
4.8 Chapter summary 104
Chapter 5. Understanding current practice and the factors that influence the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care 105
5.1 Introduction 105
5.2 Aim and objectives 106
5.2.1 Aim 106
5.2.2 Objectives 106
5.3 Methods 107
5.3.1 Setting 107

5.3.2 Study design 107
5.3.3 Participants and recruitment 108
5.3.4 Data collection and management 110
5.3.5 Data analysis 113
5.3.6 Ethical approval 119
5.3.7 Reporting 120
5.4 Results 120
5.4.1 Participants 120
5.4.2 Data 121
5.4.3 Examination of current practice by understanding how prevention and management of CVD risk is experienced by policymakers, clinicians and patients in everyday clinical practice 122
5.4.4 Factors that influence the adoption of recommended practice in the assessment and management of risk of CVD 145
5.5 Discussion 157
5.5.1 Summary of findings 157
5.5.2 Findings in the context of existing research 158
5.5.3 Strengths and limitations 161
5.5.4 Implications for research and practice 162
5.6 Conclusion 164
5.7 Chapter summary 165
Chapter 6. The recommended level of use for essential medicines: a comparison between medicines for cardiovascular disease and the leading communicable diseases in Eastern sub-Saharan Africa 166
6.1 Publication statement 166
6.2 Introduction 166
6.3 Aim and Objectives 169
6.3.1 Aim 169
6.3.2 Objective 169
6.4 Methods 169
6.4.1 Study design 169
6.4.2 Data sources 169
6.4.3 Data extraction 169

6.4.4 Data management....170
6.4.5 Data analysis....171
6.4.6 Methodology reporting....171
6.4.7 Ethics and data protection....171
6.5 Results....171
6.5.1 Extraction of leading causes of mortality and NEMLs....171
6.5.2 Salient characteristics of NEMLs....172
6.5.3 Comparison of the recommended level of use for essential medicines in CVD, HIV and TB....176
6.6 Discussion....178
6.6.1 Summary of findings....178
6.6.2 Interpretation of findings....179
6.6.3 Findings in the context of existing research and policy....180
6.6.4 Strengths and limitations of this study....181
6.6.5 Implications for policy and research....183
6.7 Conclusions....183
6.8 Chapter summary....184
Chapter 7. Discussion and conclusion....185
7.1 Introduction....185
7.2 Summary of findings....186
7.3 Implications for policy, practice and patients....191
7.3.1 Policy and practice....191
7.3.2 Service delivery....197
7.3.3 Patients....198
7.4 Future research....199
7.5 Lessons learnt: implementation of recommended practice in CVD risk prevention and management in Kenyan primary-care settings....201
7.6 Overall strengths and limitations....202
7.7 Conclusions....204
Bibliography....206
Appendices....237
Appendix 1. Visiting PhD student fellowship offer letter....237

Appendix 2. Derivation of the basic risk equation (BRSe) and calculation of the risk probabilities for coronary heart disease, stroke and CVD (Steps 1-7) 239

Appendix 3. Table 1.6 in Supplement Appendix 1 of the revised models for WHO CVD Risk Charts 244

Appendix 4. Defining the independent variables.....245

Appendix 5. Methods supplement - Checking for the multivariate regression model assumptions.....247

Appendix 6. Results supplement.....254

Appendix 7. Search strategy 269

Appendix 8. Characteristics of excluded studies and reasons for exclusion 278

Appendix 9. Characteristics of included studies.....280

Appendix 10. Appraisal of quality for the included studies 285

Appendix 11. Summary of facilitators and barriers as coded using the Consolidated Framework of Implementation Research.....290

Appendix 12. Summary of the qualitative findings with their CERQual evidence profile and confidence assessments 299

Appendix 13. Table summary of the Consolidated Framework for Implementation Research (CFIR) 307

Appendix 14. Interviewers guide – healthcare professionals 310

Appendix 15. Interview guide – policymakers.....312

Appendix 16. Observer's guide (Consultation between the healthcare professional and patient).....315

Appendix 17. Final coding framework and code frequencies for describing current practice in the assessment and management of CVD 319

Appendix 18. Ethics review approval letters 320

Appendix 19. Recruitment process for a fieldworker.....324

Appendix 20. Initiative to Develop African Research Leaders (IDeAL) program visiting PhD Fellowship.....326

Appendix 21. Participant information sheets.....328

Appendix 22. List of Anatomical Therapeutic Classification (ATC) chemical substance codes for the Essential Medicines (HIV, TB and CVD) 343

List of Abbreviations

AIC	Akaike information criterion
BeHEMoTh	Behaviour of interest, health context, exclusions, and models and theories
BRSe	Basic risk score equation
CENTRAL	Cochrane central register of controlled trials
CERQual	Confidence in the evidence from reviews of qualitative research
CFIR	Consolidated framework for implementation research
CHD	Coronary heart disease
CI	Confidence interval
CINAHL	Cumulative index to nursing and allied health literature
COM-B	Capacity, opportunity, motivation and behaviour framework
CVD	Cardiovascular disease
DALYs	Disability-adjusted life years
EMBASE	Excerpta Medica database
ENTREQ	Enhancing transparency in reporting the synthesis of qualitative research
FHS	Framingham heart study
GNI	Gross national income
HICs	High-income countries

HIV/AIDS	Human immunodeficiency virus/acquired immune deficiency syndrome
IHME	Institute for Health Metrics and Evaluation
IQR	Interquartile range
ISH	International Society of Hypertension
KEMRI	Kenya Medical Research Institute
KeNADA	Kenya National Bureau of Statistics national data archive
KEPH	Kenya essential package on health
KWTRP	KEMRI-Wellcome Trust research programme
LMICs	Low- to medium-income countries
MEDLINE	Medical literature analysis and retrieval system online
MI	Myocardial infarction
MMAT	Mixed methods appraisal tool
NCD	Non-communicable disease
NEMLs	National essential medicines lists
NICE	National Institute for Health and Care Excellence
PEN	WHO package of essential non-communicable diseases
PRISMA-P	Preferred reporting items for systematic review and meta-analysis protocol
PROCAM	Prospective cardiovascular Munster study

PsycINFO	Database of abstracts of literature in the field of psychology
QRISK	Prediction algorithm for cardiovascular disease using risk factors
SCORE	European systematic coronary risk evaluation
SBP	Systolic blood pressure
SD	Standard deviation
STROBE	Strengthening the reporting of observational studies in epidemiology
TB	Tuberculosis
UN	United Nations
WHO	World Health Organisation

Chapter 1. **Overview and Structure of Thesis**

1.1 Overview and aim the thesis

I aimed to examine the prevention and management of cardiovascular disease (CVD) risk in Kenyan primary care settings.

1.2 Objectives

The objectives of this thesis were:

1. To describe the distribution of CVD risk in the Kenyan adult population and identify factors associated with the variation of CVD risk scores;
2. To synthesise evidence on factors that influence the implementation of CVD risk assessment in primary care settings;
3. To understand current practice in the prevention and management of CVD risk in Kenyan primary care by characterising the experiences of key stakeholders, and to identify contextual factors that influence the adoption of the recommended practice; and
4. To determine current Essential Medicine Lists (EMLs) priorities in the region by comparing the recommended level of use for essential medicines that treat the leading causes of mortality in Eastern sub-Saharan Africa (CVD, tuberculosis (TB) and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) in the latest national essential medicines lists (NEMLs).

1.3 Structure of thesis

Figure 1 below shows an overview and the flow of the thesis. It includes an explanation of how knowledge gaps that are described in the background chapter (a review of existing literature) and findings that are discussed in other chapters (data-driven knowledge gaps) informed the four objectives of this thesis. These objectives, in turn, informed the empirical chapters of this thesis.

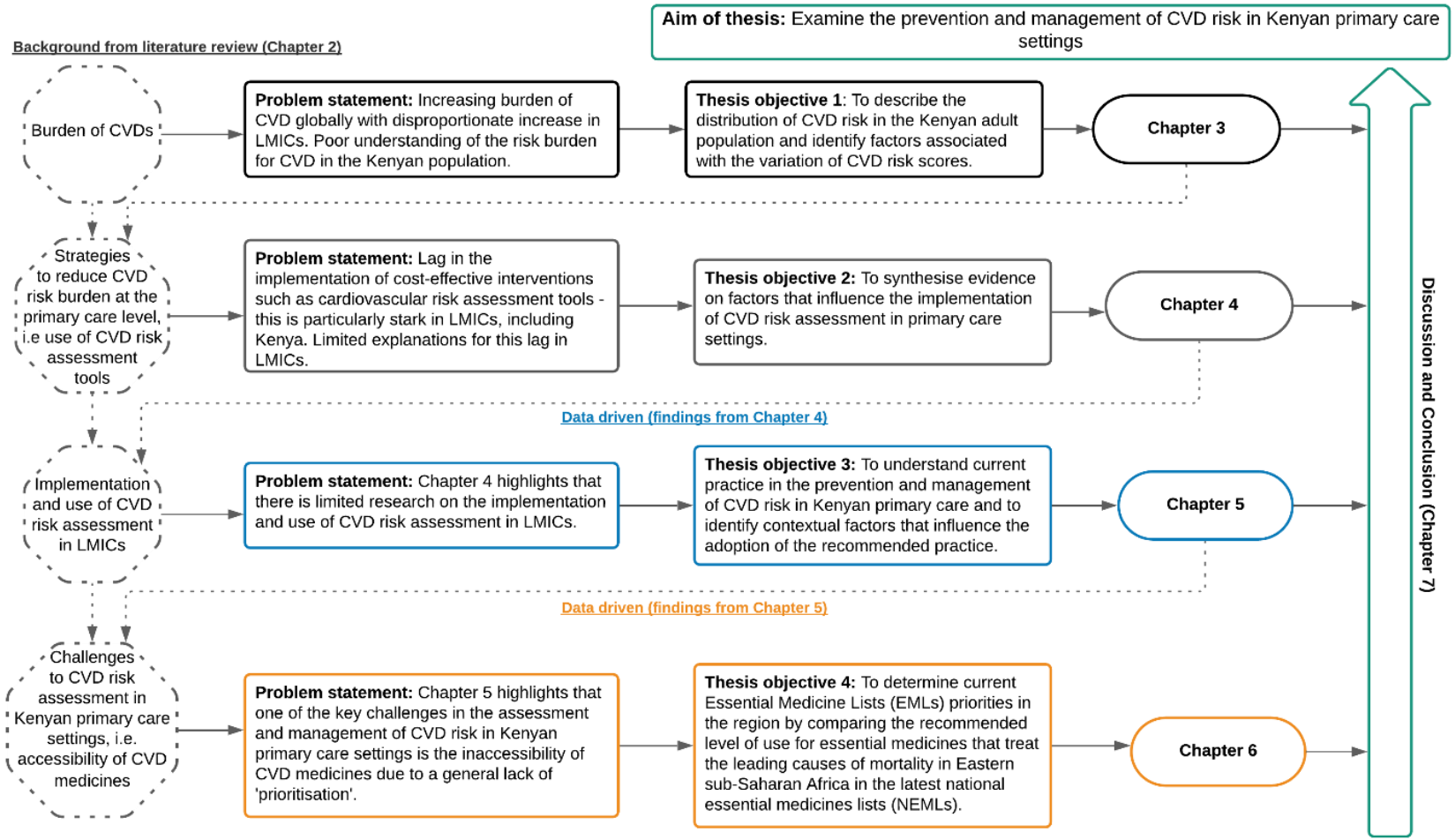


Figure 1. Overview and flow of the thesis

Chapter 2: Background

Chapter 2 forms the foundation of this thesis as I broadly examine, discuss and summarise the existing literature on the burden of CVD, its risk factors, strategies for the prevention and management of CVD risk and their implementation. This chapter highlights the epidemiology of CVD both globally and at the Kenyan national level. It also looks at the global and national policy responses to the CVD burden. It explores the use of evidence-based interventions, particularly CVD-risk scoring, to prevent and manage CVD risk in primary care settings. Notably, this chapter highlights that despite the commitment at a high political level to improve CVD outcomes globally by 2025, countries such as Kenya and many other low- to medium-income countries (LMICs) are off course to meet global action plan targets that have been set by the World Health Organisation (WHO). The chapter concludes with a rationale for the need to i) better understand the risk burden for CVD in the Kenyan population, and ii) synthesise evidence on the factors that influence the implementation of CVD risk assessment in primary care.

Chapter 3: The distribution of CVD risk in the Kenyan population and factors associated with CVD risk score variation

This chapter describes the distribution of CVD risk in the Kenyan adult population and identifies factors that are associated with the variation of CVD risk scores in this population. The updated risk prediction model for Eastern sub-Saharan Africa, which was developed by the WHO with the International Society of Hypertension (ISH), was used to calculate the population's CVD risk scores (1). However, to enable this calculation, the basic risk score equation (BRSe) that was used in the WHO/ISH risk prediction model was first derived to calculate the risk probability for CVD. The

median CVD risk score in the study sample was 3.0% (IQR 0.3, 46.2), and the majority (69.1% [95% CI 66.8-71.3]) of the subjects were grouped in the lowest CVD risk category (< 5% CVD risk). According to the national guidelines on CVD prevention and management, up to 11.9% of the study population (moderate, high and highest-risk categories) are eligible for both pharmacological and lifestyle interventions. Women recorded a higher mean CVD risk score than men: 5.0% (SD 5.5) vs. 4.6% (SD 4.7). This is in addition to more women (14%) than men (9%) in the study population having a CVD risk score of more than 10%. The mean CVD risk scores differed significantly across socio-demographic and behavioural groups. The data for the subjects showed that their educational levels, marital statuses, ethnicities, their frequency of consumption of processed food that was high in sugar, the number of days on which they ate vegetables in a typical week, whether they had received lifestyle advice on reduction of their salt intake in the previous three years and the number of days in a typical week on which they undertook vigorous-intensity activities as part of their work were significantly associated with their CVD risk scores. Factors such as ethnicity, level of education, marital status, dietary practices and physical activity could be used to refine further the entry points for targeted CVD risk screening, prevention and management in Kenyan primary care settings. This study suggests that public primary care facilities are a critical entry point for targeted screening and the delivery of interventions aimed to prevent and manage CVD risk.

Chapter 4: Factors that influence the implementation of cardiovascular risk scoring in primary care: a mixed-method systematic review

This review synthesises the current evidence on factors that influence the implementation of cardiovascular risk scoring as a CVD prevention strategy in primary care settings. The synthesis broadly conceptualises these factors as those that relate to

CVD risk tools, users, clinical settings and the healthcare system. This review explains that the implementation of CVD risk assessment interventions is complex and often affected by the interaction of those clinical interventions with the real world: the users and the environment in which they are being used. Notably, this chapter illuminates the lack of research on the implementation of CVD risk assessment from LMICs.

Chapter 5: Understanding current practice and the factors that influence the adoption of recommended practices in CVD risk prevention and management in Kenyan primary care

Chapter 5 qualitatively explores how patients at risk of CVD are identified, stratified and managed in Kenyan primary care facilities. The work that is described in this chapter involved six months of fieldwork in seven primary care facilities in Kilifi County, Kenya. Data was collected through observation of participants (n=81, 560 observation hours), performance of semi-structured interviews (n=15), and a review of CVD risk prevention and management policy documents both at the study sites and in literature. This chapter examines current practice through a description of how prevention and management of CVD risk are experienced by policy makers, clinicians and patients in everyday clinical practice. In addition, this chapter uses the same framework of implementation research that is used in Chapter 3 in order to explore contextual factors that influence the adoption of recommended practices in the assessment and management of risk of CVD in Kenyan primary care settings.

Recommended practice infrequently guides current practice due to the unavailability of guidelines and knowledge either at the first level (clinicians and patients) or at the second level (clinical settings and local government). Clinicians rely on clinical judgement to provide CVD risk prevention and management services where needed. Notably, clinicians possess many positive and enabling intrinsic qualities that facilitate

innovation, knowledge-seeking, and the overcoming of some challenging physical conditions in their practice. Factors that influence performance of recommended practice in CVD risk prevention and management in Kenyan primary care appear to cluster around the third level (global and national influences) and second level (clinical settings and local government). Some of these factors result from the residual challenges of devolution, a need for service delivery redesign, challenges in scaling up implementation, and weak priority setting mechanisms that are non-partisan to external funding.

Chapter 6: The recommended levels of use of essential medicines: a comparison between medicines for cardiovascular disease and those for the leading communicable diseases in Eastern sub-Saharan Africa

Chapter 6 follows on from the main findings of Chapter 5: inaccessibility of essential CVD medicines due to a general lack of 'prioritisation', which poses a significant challenge in the assessment and management of CVD risk in Kenyan primary care settings. This chapter arises iteratively from the preceding chapters, in particular Chapter 5, and determines current priorities of Essential Medicine Lists (EMLs) in the region.

By comparing the recommended level of use of 42 essential medicines that treat the leading causes of mortality in Eastern sub-Saharan Africa; CVD (*n*=29), HIV (*n*=8) and TB (*n*=5), this cross-sectional observational study of retrospective data confirmed the hypothesis that there is a disproportionate percentage difference in the recommended levels of use of essential medicines used in communicable diseases compared with those for NCDs in NEMLs. The findings from this study show that at level 1 (proxy for primary care), more essential medicines were recommended for HIV and TB treatment than for CVD risk prevention and management. A majority of the countries

recommended the use of essential CVD medicines at level 2 (proxy for secondary care). Notably, Acetylsalicylic acid was commonly recommended in NEMLs for use at level 1, and Kenya was the only country in this study that did not recommend any essential CVD medicines for prescription at level 1. Instead, Kenya recommended use of essential CVD medicines at level 3 (proxy for tertiary care). This study contributes to a new dimension in the policy discourse on the availability and affordability of essential NCD medicines. Specifically, the study suggests a need to expand WHO's access to drugs and medicine frameworks by highlighting the importance of harmonising across NEMLs, informed by epidemiological trends, the recommended levels of use for essential medicines.

Chapter 7: Discussion and conclusions

Chapter 7 summarises the main findings of the empirical chapters (3 to 6) and discusses their implications for policy, practice and the Kenyan population. This chapter also explores the strengths and limitations of the work that has been described in the thesis, and infers the direction for future research, policy and practice.

1.4 Key accomplishments

1.4.1 Research collaborations

This thesis would not have been written without several research collaborations. First, I developed a tripartite research collaboration between the Department of Primary Care Health Sciences at the University of Oxford, the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme (KWTRP) and the County Government of Kilifi, Kenya. This collaboration was formalised through the award of a visiting PhD student fellowship (Chapter 5) – see Appendix 1. This process involved formal in-person meetings with senior researchers from KWTRP and senior

government officials from Kilifi County to gain written approvals to be hosted, and after that, to conduct my research in Kilifi County. The second was a collaboration with Dr Nav Persaud and his group at the Centre for Urban Health Solutions at the University of Toronto in Canada. This collaboration was formalised as an invitation to a two-day scientific meeting, which was held in November 2019 in Toronto, to discuss how we could use comparisons of NEMLs to promote health globally (Chapter 6).

1.4.2 Funding

As I was a Rhodes Scholar, I did not have any dedicated funding for fieldwork. However, through a successful grant application to the Global Challenges Research Fund, I was able to secure £12,577 to cover all my research expenses (airfare, accommodation, transport and hiring a fieldworker) for the six months of fieldwork in Kenya. I was further successful in obtaining the Murray Speight Award, the Wardens Discretionary Fund Award (Rhodes Trust) and the Green Templeton College Fund Award, which supplemented the above grant and enabled me to undertake a scoping mission in preparation for my fieldwork.

1.4.3 Fieldwork

Fieldwork is unpredictable. It calls for practicality, pragmatism, patience and sometimes the acknowledgement that one is not an expert in the fieldwork environment. This experience propelled me onto a steep learning curve and towards becoming a better scientist. To accomplish objective 3 of this thesis, I spent six months in Kilifi County (January 2019 to July 2019). I visited first in August 2018 for a scoping mission. This trip was instrumental in laying the foundations for collaboration and fieldwork. Over the six-month field trip, I visited seven health facilities across the county, where I engaged with the local government and community leaders. I also spent weeks camped

in the facilities to complete the equally important task of conducting structured observations of consultations and semi-structured interviews with front-line health workers and policymakers.

1.4.4 Knowledge dissemination and translation

In addition to putting together this thesis to fulfil the partial requirement to receive a Doctor of Philosophy degree in primary health care at the University of Oxford, I have equally invested my time in contributing to the dissemination of knowledge and teaching. During my tenure as a doctoral student, I have taught the course entitled 'Global and public health: a focus on Africa' as part of the Stanford University in Oxford programme. I have provided teaching support to courses that are organised by the Health Experiences Research Group at the University of Oxford. These courses were in NVivo, observation and ethnography, and an introduction to analysing qualitative interviews.

In line with knowledge translation, I have also collaborated on various projects with other students and colleagues as a co-author (2,3). I have shared my research protocols, study findings and various experiences through open science platforms, publications and blogs (4–6). I have presented my research at various conferences and scientific meetings; Oxford Global Health Systems/Crossing Boundaries 2018 (Oxford, December 2018); the 30th Epidemiology and Demography Quarterly scientific meeting (Kenya, May 2019); the 37th Kenya Cardiac Society annual scientific conference (Kenya, August 2019); and the Global Essential Medicines scientific meeting (Canada, November 2019).

I have also been invited to present and act as a panel discussion member on implementation science by the Kenya Cardiac Society for the CVD guideline dissemination workshop.

1.4.5 Training and skills development

Guided by the training needs analysis form and as instructed by my supervisors, I have completed an array of courses through the university's information technology services, the Medical Sciences Graduate School and the Nuffield Department of Primary Care Health Sciences. These courses can be broadly categorised into: research skills, communication skills, ethical and legal understanding of the research process, teaching skills and career development.

1.4.6 Awards

I have received a few awards that were related to my work and passion for contributing to the strengthening of primary healthcare systems on the African continent. During the 37th Kenya Cardiac Society annual scientific conference, I was awarded first place for the best oral presentation of research and an abstract. In September 2020, I joined the 2020 cohort of the World Bank's young professionals programme as a global health and health systems specialist in Washington DC, USA.

Chapter 2. **Background**

2.1 Introduction

In this chapter, I have synthesised and summarised the following five topics:

1. An overview of the Kenyan healthcare system
2. The epidemiology of cardiovascular disease globally and in Kenya
3. The policy landscape for CVD risk prevention and management
4. Strategies for CVD risk prevention and management
5. Implementation of CVD risk assessment interventions.

This synthesis has been conducted through a review of literature from relevant text books, scientific databases, policy documents, legislation materials, expert bulletins and official reports from high-level meetings, i.e., WHO and United Nations (UN) agencies. Besides providing a foundation on which to position the thesis, this synthesis highlights gaps in knowledge that exist across these topics, and consequently, has contributed to the design of the empirical work that is described in the later chapters of this thesis.

2.2 Overview of the Kenyan healthcare system and context

According to the 2019 results of the population and housing census, Kenya has an estimated population of 47.6 million people, a population growth rate of 2.3% and a median population age of 19.7 years (7). The country's gross national income (GNI) per capita for 2019 is estimated at US$1750. While Kenya's economy is the largest in eastern and central Africa, 36.1% of the population lives below the poverty line (US$1.90 per day). Three quarters of the population has received some formal education and 23.7% of the population has wage employment. The main source of employment is agriculture at 32.0%. Currently, only 27.3% of the population is urban (8).

The country has made significant progress in tackling various health challenges, a majority of which are linked to communicable diseases. In the past decade (2010-2019), there has been a steady decline in the prevalence of and mortality caused by diarrhoea (-30.1%), vaccine preventable diseases and lower respiratory infections (-4.9%) (8). This is alongside decreasing maternal mortality (which fell from 423 per 100,000 live births in 2010 to 342 per 100,000 live births in 2019) and under-five mortality (which fell over the same period from 57.9 to 43.2 per 1000 live births) (9). Conversely, in the past decade (2009 – 2019) there has been a steady rise in prevalence of non-communicable diseases (NCDs) in adults, which is estimated at 3.8% (10).

Kenya's government has stated its commitment to health as a strategic sector in short, medium- and long-term national development policy through its Kenya Vision 2030 development blueprint (11). In this blueprint, the government commits to strategic investments in quality healthcare and service provision to all of its population. These commitments are echoed and expounded in the Kenya Health Policy 2014-2030, the aim of which is to achieve universal health coverage through the prioritisation and scaling up of the provision of health services to those in need (12). Of particular interest to the topic of this thesis is policy objective two of the Kenya Health Policy 2014-2030: to halt and reverse the increase in the incidence of NCDs. The priority policy strategies that have been drawn up to meet this objective include, inter alia, ensuring that services related to NCDs are of high-quality standard and are accessible to and used to maximum effect by the population. Another milestone in the operation of the Kenyan healthcare system was the promulgation of a new constitution in 2010. This led to the decentralisation of governance to 47 county governments, which shifted the organisation of primary health-care systems to county governments while tasking the national government with the provision of policy direction and management of national

referral hospitals. Over the last decade, this adjustment has resulted in a lot of teething problems and has inadvertently become a significant barrier to the functioning of primary health systems (13).

Currently, the Kenyan healthcare model follows a six-tier system. The most local level is community health services (level 1), followed by primary healthcare facilities (levels 2 and 3), county hospitals (level 4), regional hospitals (level 5) and national referral hospitals (level 6) (14). The primary health-care facilities (levels 2 and 3) form the first level of care of the health system. Level 2 facilities provide health-promotion activities and preventive and curative care to 10,000 people on average, while level 3 facilities offer the same services to approximately 30,000 people on average. In addition to providing outpatient services, level 3 facilities allow for at least four births per day. Level 4 facilities take referrals from levels 2 and 3, which enables a comprehensive essential package to be offered close to the communities. Levels 5 and 6 offer secondary and tertiary care services in the form of secondary referral services, highly specialised care, training of specialists, biomedical research, internship and apprenticeship centres.

2.3 Epidemiology of cardiovascular disease

2.3.1 Global burden

CVDs such as ischaemic heart disease and cerebrovascular disease were in 2020 the leading causes globally of death (240 [95% confidence interval (CI); 221-255] deaths per 100,000) and disability (5081 [95% CI; 4753-5393] cases per 100,000), and the figures are growing, particularly in LMICs (15,16). Over the last three decades (1990-2019), the prevalence of CVD has almost doubled from 271 million (95% CI; 227 million to 285 million) in 1990 to 523 million in 2019 (95% CI; 497 million to 550 million) according to the recent 2020 Global Burden of Disease (GBD) study from 201

countries and territories. The number of CVD-related deaths has also increased from an estimated 12.1 million (95% CI; 11.4 million to 12.6 million) in 1990 to 18.6 million (95% CI; 17.1 million to 19.7 million) in 2019; disability-adjusted life years (DALYs) and years of life lost (YLLs) have almost doubled over this period (17).

A majority (85%) of CVD-related deaths were due to ischaemic heart disease and cerebrovascular disease, and over 75% of all global CVD-related deaths occurred in LMICs. This disproportionate burden has led to an increasing burden of premature mortality (at < 70 years old) in LMIC populations due to NCDs. For example, in sub-Saharan Africa, more than 50% of CVD-related mortality occurs in those aged between 30 and 69 years (18,19). This range is at least ten to 20 years earlier than in HICs. Economically, the CVD burden in LMICs translates to an estimated annual loss of $3.7 trillion (2010) which is more than 50% of the total NCD burden and up to 2% of the gross domestic product of LMICs (20).

This global burden is expected to increase in the future and LMICs will continue to incur an increasing share of this burden. The increase is due to shifts in socio-demographic indices which, in turn, influence the age structure and the adaptability of health systems (21). Also, the ongoing COVID-19 pandemic has exposed the clinical vulnerability of those with CVDs or elevated risk factors to poor health outcomes (22). This intensifies the call to act to reduce the global burden of CVD. If left unmitigated, the health and economic impacts of CVDs in LMICs will jeopardise ongoing global efforts to reduce poverty and boost more equitable levels of prosperity in all economies.

2.3.2 Burden in Kenya

In Kenya, CVDs cause 12% of total deaths, which translates as 81 deaths (95% CI; 68-94) per 100,000 per year in all ages for both males and females, 5% of the total DALYs

and 25% of all hospital admissions (10,23,24). Data from the Institute of Health Metrics and Evaluation (IHME) show that the numbers of deaths caused specifically by ischaemic heart disease increased by 37% while those attributed to cerebrovascular disease increased by 21% between 2005 and 2016 (10,15). These figures place ischaemic heart and cerebrovascular diseases as the fourth and fifth leading causes of

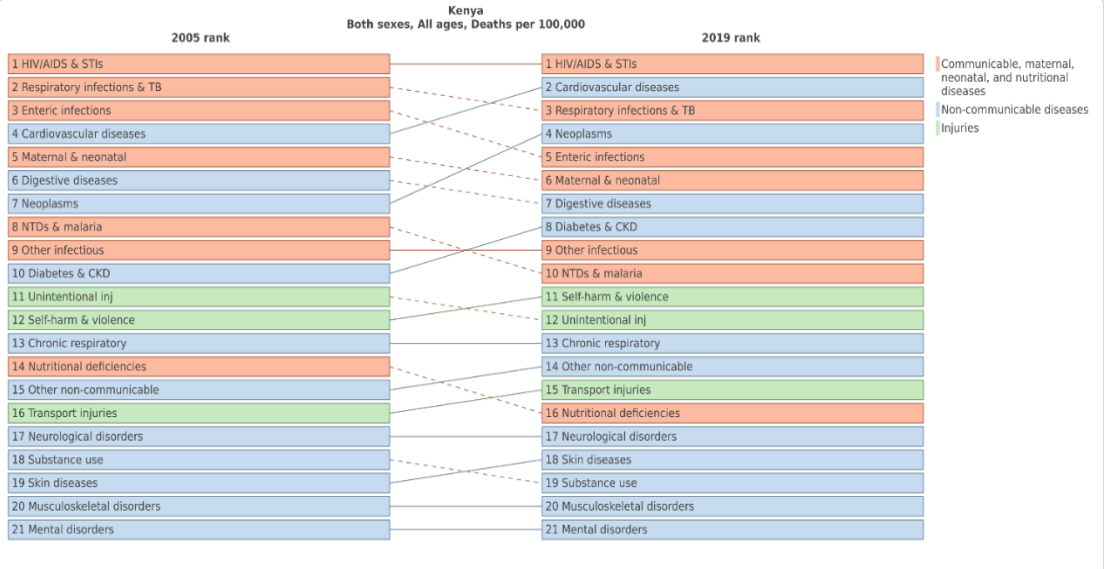


Figure 2. Age- and sex-standardised all-cause mortality, ranking of deaths per 100,000, in Kenya. Adapted from IHME, 2020 [STIs- Sexually Transmitted Infections, NTDs – Neglected Tropical Diseases, CKD – Chronic Kidney Disease, Inj – Injuries**]**

morbidity and mortality in the country (Figure 2).

CVDs are costly to diagnose and manage in the Kenyan healthcare system. They have been a pivotal contributor to poverty due to the economic burden that is caused by costs of CVD care and the loss of contribution to the economy due to death and disability of working-age Kenyans (15,25). There is no clear picture of the CVD risk burden in the Kenyan population due to the suboptimal CVD and risk surveillance systems that operate in these settings. This lack of clarity might be attributable to an inadequate capacity to document, implement, monitor and evaluate NCD-related interventions in the health system. For example, the latest Kenya service availability and readiness

assessment mapping study shows that only 5% of the facilities in Kenya offer all NCD services that are defined in the Kenya essential package of health (KEPH) (26,27).

2.3.3 Risk factors

Until about 1948, knowledge of the causes of CVD and its management was static and rife with many fallacies. In that year, the revolutionary Framingham heart study 'Framingham' was set up in the USA. This was the first attempt to determine systematically the factors or characteristics that contributed to CVD (28). Since then, a lot of research has been conducted with much of the focus on ischaemic heart disease and cerebrovascular disease. As a result of the FHS and other similar studies, there has been significant insight into the epidemiology of CVD and its risk factors (29).

The risk factors for CVD are many and interrelated. However, they can be broadly classified into two categories – modifiable and non-modifiable risk factors (30). Modifiable risk factors are those that can be controlled, such as hypertension, hypercholesterolaemia, smoking, diabetes, obesity, physical inactivity, harmful use of alcohol, unhealthy diet and psychosocial factors such as stress. On the other hand, non-modifiable risk factors cannot be controlled. These constitute: age, sex, race, genetics and family history. It is estimated that modifiable risk factors contribute up to 90% of the attributable risk of development of ischaemic heart disease and stroke in the global population (31). This offers a strong chance of successful prevention and management of CVD risk (32).

To better understand CVD risk factors and the pathophysiology of CVD, one has to situate them in the context of the causal relationship between modifiable risk factors and cardiometabolic outcomes (Figure 3). Socio-cultural-economic factors, also referred to as socio determinants of health, such as income, education, occupation and

belief systems, shape an individual's lifestyle behaviours. These behaviours, if unhealthy, may result in a cluster of cardiometabolic conditions such as hypertension, hypercholesterolaemia, diabetes and obesity. An individual's genetic predisposition can also cause cardiometabolic conditions. Unhealthy lifestyle behaviours impacting

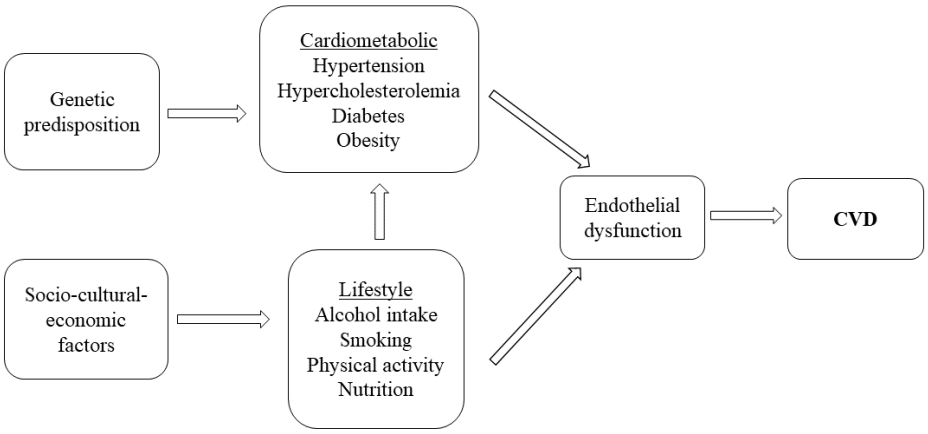


Figure 3. Causation pathway for CVD. Adapted from Stoner et al. 2012 (40)

cardiometabolic parameters individually or synergistically compromise the function of the endothelial system, causing a sequela of CVDs (32–36).

A trend analysis that was conducted by the IHME from the 2017 GBD study showed a more than 30% increase in the prevalence of CVD risk factors (high blood pressure, dietary risks and high levels of fasting plasma glucose) between 2005 and 2015 in Kenya (10). As of 2019, trend analysis reports show that Kenya is not making progress towards attainment of sustainable development goal 3.4 by 2030 (reduce by one third premature mortality from NCDs), and instead, is retreating from it (37). The increase in the prevalence of CVD risk factors in the past decade can be attributed to secular epidemiological and demographical transitions that are currently pervasive in LMICs, especially in those in sub-Saharan Africa (38,39). These trends include improvements in healthcare systems that prolong survival (approximately 7 years in the last decade)

and alterations in the age strata, global mobility and cultural exchanges that modify people's lifestyle behaviours. These trends, however, are taking place against the backdrop of existing social inequalities regarding access to healthcare and in a health system that is skewed towards the prevention and management of infectious diseases.

2.4 Global and national policy response

2.4.1 Global response

In response to the growing threat of NCDs, which include CVD, to human and economic development, the WHO led a prioritised research agenda for the prevention and control of NCDs in 2011 (40). Later that year, in September, a UN high-level meeting was convened to rally support for the prevention and management of NCDs across the globe. At this meeting, participants deliberated cost-effective interventions for NCD prevention and management and discussed opportunities for global action. Two years later, at the 66th World Health Assembly, a global action plan for the prevention and control of NCDs 2013-2020 was endorsed (41). This action plan called upon all partners, international and national, to commit to coordinated action with the aim to attain nine voluntary global NCD targets by 2025. These targets tackle risk factors for NCDs and offer goals for treatment (Table 1).

Most of these targets require population-wide interventions such as regulatory policies and concerted national support to reduce risk factor exposure. However, goals 1, 8 and 9 of the plan centre on interventions that affect individuals, such as cardiovascular risk scoring at the clinical level in primary care. Cardiovascular risk scoring (also referred to as absolute risk assessment, total risk assessment or global CVD risk assessment) is considered a high-impact essential NCD intervention. It enables the timely identification of those at risk of CVD and can be used to signpost towards lifestyle

interventions and preventive drug therapy (42). It is estimated that if all nine targets are met, at least two million premature deaths may be averted each year, with more significant benefit in LMICs than in HICs (41).

Table 1. Global voluntary targets of the WHO's global action plan for the prevention and control of NCDs, 2013-2020

Target	Goal
Premature mortality	A 25% relative reduction in risk of premature mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases.
Harmful use of alcohol	At least 10% relative reduction in the harmful use of alcohol, as appropriate, within the national context.
Physical inactivity	A 10% relative reduction in the prevalence of insufficient physical activity.
Salt intake	A 30% relative reduction in mean population intake of salt/sodium
Tobacco use	A 30% relative reduction in the prevalence of tobacco use in persons aged 15+ years.
Blood pressure	A 25% relative reduction in the prevalence of raised blood pressure or a target to contain the prevalence of raised blood pressure, according to national circumstances.
Diabetes and obesity	Halt the rise in incidence of diabetes and obesity.
Preventive pharmacotherapy	At least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes.
Essential NCD medicines and technologies	An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities.

Given that countries with the highest burden of CVD have limited resources, the WHO, in 2010, drafted a set of cost-effective interventions that could be delivered in resource-poor settings to an acceptable quality of care (42). The result was the first version of the WHO package of essential non-communicable (PEN) disease interventions for primary healthcare in 2010. The WHO PEN acknowledges that most LMICs do not have strong enough primary healthcare systems to identify and manage people with NCDs. This package thus seeks to provide technical guidance for the integration of NCD into primary healthcare by providing tools and protocols to strengthen national capacity and scale up NCD care. These tools are simple and affordable. They include clinical measurements, simple laboratory tests, CVD risk assessment charts and blood pressure measurement devices. They support a targeted screening approach in primary

healthcare. Notably, one of the protocols (protocol one - for the prevention of heart attacks, strokes and kidney disease through integrated management of diabetes and hypertension) uses total CVD risk scoring to initiate preventive treatment.

There have been many iterations of the WHO PEN to date. The latest is the HEARTS technical package 2020, which provides a set of effective, evidence-based, practical interventions that are aimed at strengthening the management of risk factors for CVDs in primary healthcare (43). The HEARTS technical package comprises three elements targeting the reduction of intake of tobacco and salt, and primary healthcare-based CVD management. The key components of HEARTS are:

- Healthy lifestyle;
- Evidence-based treatment protocols;
- Access to essential medicine and technology;
- Risk-based management;
- Team-based care and task-sharing; and
- Systems for monitoring.

2.4.2 Kenya's policy response

Despite a thriving global response to the NCD burden, many LMICs, particularly those in sub-Saharan Africa, struggle to re-orientate their services towards the management of two types of disease (infectious diseases and NCDs) that are prevalent in their populations. Kenya is one of these countries. Its policy regarding the prevention and management of CVDs in primary healthcare is not in tandem with the global response and the growing burden of CVDs in the country (24).

However, some progress has been made in the last few years. Specifically, in 2018 the government formulated the Kenyan national guidelines for CVD management, which advocate targeted risk assessment and therapeutic management that are based on an

absolute CVD risk score premise (25). These guidelines are the country's latest attempt at prioritising CVD prevention and management in the health sector. The attempts run parallel to other strategies such as the national strategy for prevention and control of NCDs 2015-2020, and regulatory policies on smoking (the Tobacco Control Act, 2007), alcohol consumption (Alcoholic Drinks Control (Licensing) Regulations 2010 and the Alcoholics Drinks Control Amendment Act 2015) and nutrition (the national nutrition action plan, 2012-2017) (44). Currently, there is no standalone policy regarding physical activity.

Much of the debate now centres on the integration of NCD prevention and management into the existing primary healthcare system to minimise duplication of already scarce resources and to promote efficiency. However, these strategies and policies lack essential information, for example, the true burden of CVD risk and existing practice in the adoption of CVD risk assessment. Data on both of these are needed to support the implementation of evidence-based interventions that are tailored for context – the population and the health-care system. Findings from the Kenyan STEPwise survey for NCDs (2015) show that there is limited access to care, especially screening, and suboptimal management of the risk factors that are associated with CVD (45). Specifically, these findings match those from across sub-Saharan Africa, where less than <40% of those with hypertension have had their condition diagnosed, <35% receive treatment and 10–20% have their condition under control (46). More than 40% of patients with diabetes are not aware of their condition (18). The potential adoption of simple and efficient interventions such as cardiovascular risk assessment and scoring tools within the Kenyan primary care system is not well known or understood (47,48).

2.5 Cardiovascular disease risk prevention and management strategies

CVD prevention and management strategies are best explored through two mainstream approaches that are used in preventive medicine: population and individual-level approaches. Both are based on what is arguably a highly influential public health article - *Sick Individuals and Sick Populations*, written in 1985 by Geoffrey Rose, then an epidemiologist at the London School of Hygiene and Tropical Medicine (49). What mix of these approaches offers the best result, and when and how they should be used, have been the subjects of much debate over the past two decades (50).

2.5.1 Population approach

This approach entails interventions that influence population-wide changes in exposure to CVD risk factors. A population approach is rooted in the fundamental understanding that social and environmental factors shape health behaviours and the ability of the public to access health services. Often, it involves multiple fiscal and education policies that are required to target CVD reduction at a national level. These policies include: increased taxes on and prices of tobacco products; provision of safe and accessible spaces for physical activities; increased excise tax on alcoholic beverages and reduced marketing particularly to children of foods and drinks that are high in salt, fats and sugars, among many others (51). A population strategy is understood to work through reduction of CVD risk factors by relatively small amounts throughout the population, which lead to large reductions in the incidence of CVD. This concept was first described by Rose and is now statistically explained and explored through regression dilution and attenuation analyses (49,50,52).

2.5.2 Individual approach

An individual approach, which is also commonly referred to as the high-risk strategy, seeks to identify those at high risk of CVD and offer them a form of protection through lifestyle adjustment and preventive drug therapy (53). Approximately 50% of CVD events happen in those who are clinically asymptomatic. This necessitates a need for tools that can identify and manage this category of people (54). Evidence shows that individual risk factors in and of themselves are poor predictors of CVD events (30,53,55,56). This is because individual risk factors act synergistically to elevate an individual's absolute risk of development of CVD. A solution to this problem, the continued use of individual risk factors in isolation to estimate CVD risk in clinical practice, has been the use of cardiovascular risk scoring. This tool shifts treatment from individual risk-factor management to one that assesses an individual's overall risk. Combining risk factors has better predictive value and is preferred.

2.5.2.1 Cardiovascular risk scoring as a clinical intervention

Clinical interventions that are aimed at reducing CVD risk can be grouped into primary and secondary prevention tools. Primary prevention is considered for asymptomatic individuals, while secondary prevention is for those with existing CVD. Cardiovascular risk scoring is used for primary prevention. Those with existing CVD are regarded as high risk for CVD events, and therefore, do not need to be scored for CVD (43).

Cardiovascular risk scoring enables healthcare professionals to make better clinical decisions by use of risk-scoring tools that quantitatively predict the absolute risk of occurrence of a cardiovascular event during a defined period. These tools, which comprise over 363 different models, are widely accepted as the mainstay in CVD prevention guidelines (54,57–59). Examples of these tools include the European

systematic coronary risk evaluation (SCORE) algorithm, the German prospective cardiovascular Munster (PROCAM) model, the equations that form the United Kingdom prediction algorithm for CVD using risk factors (QRISK), the WHO CVD risk chart, the American College of Cardiology / American Heart Association 2013 pooled cohort risk equations, and the globorisk cardiovascular risk equation (1,60–63). CVD risk-scoring tools follow on from the findings of the FHS, which showed that CVD risk factors tended to cluster together to act synergistically in individuals. Often, the variables that are included in the CVD risk models are similar for various populations. These variables include: age, gender, smoking status, diabetes mellitus status, cholesterol levels (total, low-density or high-density lipoprotein), systolic blood pressure, family history of CVD, and ethnicity (64,65).

Provision of cardiovascular risk scores has been shown to increase the number of prescriptions of lipid-lowering and blood-pressure-lowering medication in higher-risk patients and have a small effect in reducing cardiovascular risk factor levels in low-risk patients (60,66,67). The reduction of risk factors (values) in an individual, albeit to a small degree, is beneficial. Rose's prevention theory explains that a small effect on the reduction of risk contributes to a leftward shift of the risk distribution bell curve and therefore reduces the risk at a population level (63). Use of these tools has been shown to escalate prevention efforts as these efforts are matched to a person's absolute risk of developing a cardiovascular event (68). This, therefore, helps to direct patients who are at high risk of developing CVD into treatment, from which they would benefit more than those at low risk, for whom the harms of medication might outweigh the benefits (57,58,63,69). Epidemiological evidence shows that the absolute benefits of cholesterol-lowering and blood pressure-lowering treatments are associated with baseline CVD risk (70–73). The subsequent use of these tools leads to an overall

reduction of a patient's absolute cardiovascular risk by reducing the magnitude of their pre-treatment risk (31).

There is not yet any high-quality evidence as to whether the use of these tools influences cardiovascular outcomes of mortality. However, their usefulness in the reduction of cardiovascular risk factors is well-reported and hard to ignore (64).

2.6 Implementation of CVD risk-assessment interventions

Despite the recommendation in most clinical guidelines around the world that CVD risk tools should be the mainstay of CVD prevention, a global survey conducted by the WHO in 2019 reported a lag in implementation of these tools in most LMIC countries (74). For example, while nearly 50% of the countries reported that CVD risk stratification was available in more than 50% of health-care facilities, about 29% reported that there was availability in less than 25% of facilities. A further 9% of the countries were not aware of the extent to which CVD-risk stratification was offered. Notably, most countries with availability in over 50% of facilities were in HICs or UMICs, and a majority of these were in Europe. Almost 50% of the countries in Africa reported that risk stratification was not available in any health-care facilities. There is negligible implementation research that has explained the lag in implementation of these tools globally and has contextualised the stark disparities in adoption in most LMICs (75). The limited research in this area highlights a need to assess evidence systematically on factors influencing the implementation of CVD risk-assessment interventions and how they relate to Kenyan primary care settings.

Theoretical approaches underpinned by implementation science provide an opportunity to improve understanding of how and why the implementation of clinical interventions succeeds or fails (76–79). These theoretical approaches seek to achieve three

overarching aims. These are: to describe the process of translating evidence into practice (process models); to understand what influences implementation outcomes (determinant frameworks, classic theories, and implementation theories); and to evaluate implementation (evaluation frameworks). The choice of the approach is often based on underlying assumptions, aims, and other characteristics, which have implications for their use (80). It is also important to note that, due to the general multifariousness and complexity of intervention implementation in health-care settings, it is unlikely that a single theory will explain all eventualities. Therefore, combining the merits of multiple theoretical approaches offers a more complete understanding and explanation of any given implementation process, outcome or evaluation (81,82).

To explain the challenges in implementation of CVD risk-assessment tools (both globally and in LMICs) and to contextualise the stark disparities in their adoption in LMICs, I have employed determinant frameworks and implementation theories that I have deemed to be the most suitable approaches. The suitability of determinant frameworks is based on the need to understand the broad influences of implementation outcomes to inform an appropriate design and execution of strategies to implement CVD risk assessment. Determinant frameworks in implementation science are wide-ranging (83). Many of them are drawn from synthesis of empirical studies of facilitators and barriers to implementation success, for example, the Promoting Action on Research Implementation in Health Services (PARIHS) theory (84–86). A sub-set of these determinant frameworks have been developed from existing frameworks and theories drawn from disciplines such as psychology, sociology, and organisational theory, e.g., the Consolidated Framework for Implementation Research (CFIR) theory (87–92).

Broadly, determinant frameworks constitute five elements that are evaluated based on their characteristics: implementation objects, adopters, end-users, context, and strategies for facilitating implementation. While most determinant frameworks encompass these five elements, the choice of which framework to use is often based on the focus of the implementation challenge and the operationalisation of these elements to understand the relationships within and across levels and different types of determinants.

The reason for the employment of implementation theories in this thesis, such as the Capability, Opportunity, Motivation and Behaviour (COM-B) theory, is to achieve an enhanced understanding and explanation of specific aspects of implementation and their interaction, such as capacity and readiness, especially at the individual level. This is critical when further strategies are refined to support the implementation of CVD risk assessment, a course of action which improves the relevance and appropriateness of strategies to the circumstances at hand (76,80,93).

2.7 Conclusions

Despite the high-level political commitment to improve CVD outcomes by 2025, countries such as Kenya and many other LMICs are off course to meet the global action plan targets. Their departure from these targets is against a backdrop of the increasing availability of cost-effective, evidence-based and practical interventions such as cardiovascular risk-assessment tools. Evidence shows that these tools, while cost-effective and evidence-based, are least adopted in LMICs. There are limited explanations for why this lag in implementation is stark in these countries Further, the use of CVD risk-assessment strategies in Kenyan primary care is largely unknown or undocumented.

One possible explanation is a poor understanding of the risk burden for CVD in the Kenyan population due to suboptimal use of CVD- and risk-surveillance systems in these settings. Improved knowledge of salient features such as the distribution of CVD risk in the population can help to identify the overall risk burden and better target implementation strategies. This information is also vital in the interrogation, advocating and championing of CVD prevention and management priorities in Kenyan primary care settings. Better knowledge of CVD epidemiology and burden can guide the application of evidence-based practices in risk prevention and management, in particular in CVD risk assessment.

2.8 Chapter summary

- CVDs such as ischaemic heart disease and cerebrovascular disease are the leading causes of death and disability globally. The burden is growing and this disproportionally impacts LMICs;
- CVDs cause 12% of total deaths in all ages among both males and females, 5% of total DALYs and 25% of all hospital admissions in Kenya;
- despite the high-level political commitment to the improvement of CVD outcomes by 2025, countries such as Kenya and many other LMICs are currently unlikely to meet the global action plan targets;
- the global and national (Kenyan) preventive policy response to the health burden of CVD has been commendable and provides a set of effective, evidence-based, and practical interventions to strengthen the management of risk factors for CVDs in primary health care;
- however, implementation of some of these interventions such as CVD risk assessment continue to lag, particularly in LMICs such as Kenya;
- an improved understanding of the Kenyan CVD risk burden and current risk-assessment knowledge and practice within Kenyan primary care settings may help to guide targeted CVD risk assessment and other preventive and management strategies.

Chapter 3. **The distribution of cardiovascular risk scores in the Kenyan population and factors associated with risk score variation**

3.1 Publication statement

The protocol for this chapter was published on the open science framework [https://osf.io/] of the non-profit Center for Open Science based in Virginia in the USA (4).

3.2 Introduction

Chapter 2 highlights a lack of clarity in knowledge regarding CVD risk and burden in the Kenyan population due to suboptimal CVD risk-surveillance in these settings. Broadly, improved knowledge of the burden of CVD risk and factors that are associated with this risk in Kenya will help to fill the many knowledge gaps that exist in global health cardiology (38). Specifically, in Kenya, it will help to identify salient features of the distribution of CVD risk in the country. This information can be used to interrogate further, advocate and champion priorities for CVD prevention and management.

Findings from the work that is described in Chapter 4 reinforce the importance of system-level prioritisation, as in many cases this directly influences and informs resource allocation in health-care systems. Greater knowledge of the burden of CVD risk in Kenya, as part of the broader morbidity profile of the Kenyan population, may provide the evidence that policymakers need to shift the focus towards addressing CVD prevention and management in Kenya. Chapter 4 also explores how individual attributes of key stakeholders such as patients, clinicians and policymakers may influence implementation. Notably, some of these individual characteristics that inform behaviour or actions are modelled upon having correct and up-to-date knowledge.

Thus, better knowledge of CVD epidemiology in Kenya will guide application of evidence-based public health practices in risk prevention and management at a population level and clinical management strategies at various levels of care. Due to this paucity of contextual data, application of the recommended guidelines could lead to the imposition of generalised Western-centric strategies and policies on CVD risk prevention and management without a good understanding of the contextual nuances. This imposition might delay or hinder uptake and implementation of lauded interventions.

Previous research on CVD risk has adequately documented the prevalence of individual risk factors in the Kenyan population (43). However, the understanding that cardiovascular risk factors are additive and synergistically associated with development of CVD strongly suggests that the use of combined cardiovascular risk-factor scores should be favoured over the use of values for individual factors in the assessment of the risk of CVD (42,94,95). Based on this, I, therefore, aimed to describe the distribution of CVD risk scores in the Kenyan adult population and to identify factors that were associated with the variation of these scores in this population through use of a nationally representative study sample (Kenya STEPwise survey 2015).

Given that Kenya has an undeveloped surveillance system for NCDs and, in particular, for CVD risk, this study sample was deemed the best available dataset through which to explore this analysis. The household survey was the first of its kind to be conducted in Kenya as part of the international WHO approach to surveillance of chronic disease risk factors, and offered the most recent data. It remains the main surveillance system that is used to track NCD risk factors at national and local levels.

3.3 Aim and objectives

3.3.1 Aim

To describe the distribution of CVD risk scores in the Kenyan adult population and to identify factors associated with the variation of these scores in this population.

3.3.2 Objectives

To achieve this aim, the objectives of the work that is described in this chapter were to:

1. Derive the distribution of CVD risk in the Kenyan adult population based on data from the Kenya STEPS survey, which was a survey of NCD risk factors that was carried out under the auspices of the WHO in 2015.
2. Identify the association between socioeconomic factors and health behaviours that were measured in the survey and CVD risk scores.

I hypothesised that there were several factors, including location (rural vs. urban), county of residence, ethnicity, level of education, marital status, socio-economic status/wealth, alcohol consumption, fruit and vegetable intakes, sugar and salt intakes, physical activity and prior lifestyle advice, which would be associated with the variation in cardiovascular risk scores in this population.

3.4 Methods

3.4.1 Study design

A cross-sectional study of survey data.

3.4.2 Study subjects and data sources

The Kenya STEPwise survey was carried out between April and June 2015 as part of the international WHO approach to surveillance of chronic disease risk factors (96). The details of the design of the survey have been published previously (45).

Briefly, Kenya STEPwise was a nationwide household survey that targeted adults above the age of 18 years. Participants were selected in three stages from the master frame of the fifth national sample surveys and evaluation programme, which was generated from a 2009 census. Stage one involved the selection of primary sampling units, which were urban and rural clusters, using the probability-proportional-to-size method. The second stage involved the random selection of households, and finally, in the last stage, one adult was randomly selected using the Kish sampling method from the selected households (97). A total of 6000 eligible individuals were identified and were approached to participate, of which 4500 (75%) were successfully interviewed in the survey.

Data were collected via the modified eSTEPS tool (questionnaire). This tool collected data on four components: the demographic details of the participants, their behavioural risk factors, physical measurements, and biochemical risk factors for NCDs. Data collection was standardised and validated, and risk factor measurement was defined as per the *WHO STEPS Surveillance Manual* (96). This dataset is publicly accessible via the Kenya National Bureau of Statistics national data archive (KeNADA) under the reference ID: KEN-KNBS-STEPS-2015-V0.1.

3.4.3 Data extraction

I downloaded the dataset from KeNADA's online portal in November 2019, and extracted variables onto Stata 16 and MS Excel. The variables of interest from the dataset are listed in Table 2 below as per the work objectives.

Table 2. Variables extracted for the study

Objectives	**↓Variables extracted**
Calculation of CVD risk scores	Age, sex, *smoking history, history of diabetes mellitus (types 1 and 2), ↑systolic blood pressure (SBP) readings, and total cholesterol levels

Factors associated with variation in CVD risk-score distribution	Location (rural or urban), ethnicity, level of education, marital status, socio-economic status/wealth, alcohol consumption, sugar and salt intakes, fruit and vegetable intakes, physical activity and history of lifestyle advice

ˬThe definitions of these variables are as per the WHO STEPwise questionnaire (Appendix 4). *For the history of smoking, current smokers were combined with those who had quit smoking only in the last 12 months (193). ˆThe average for each participant of the three SBP readings that were collected in the survey was used.

3.4.4 Data management

Stata 16 and MS Excel was used to clean the data. Data cleaning involved: removal of variables that were not of interest to the study, labelling variables, replacing missing values with baseline values, creating new variables (i.e. average SBP) and recoding most of the variables of interest. Stata 16 was used to analyse and generate figures from the data (98).

The Stata code for this cleaning and analysis process has been published on the open science framework (4).

3.4.5 Statistical analysis

3.4.5.1 Calculation and distribution of CVD absolute risk scores

The Kenya national guidelines for CVD management were used to identify participants in the original survey who were eligible for risk assessment in this study (25). The inclusion criteria to calculate CVD risk scores were based on the availability of the information that is shown in Table 3.

Table 3. Inclusion and exclusion criteria for the calculation and distribution of CVD risk scores

History	**Age (40 years and above)** **Gender (male or female)** **Smoking status (smoker or non-smoker)**
Past medical history	Diabetes (with or without) No history of CVD (myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft, angina, ischaemic stroke,

	transient ischaemic attack, peripheral vascular disease)
Measurement	SBP reading Total cholesterol level

The absolute ten-year CVD risk was then estimated for each eligible participant through use of the updated WHO/ISH risk calibrations for Eastern sub-Saharan Africa (1). This prediction model includes gender, age, SBP, total blood cholesterol, smoking status and the presence or absence of diabetes mellitus (Table 3).

To utilise this model for this dataset, I derived the basic risk score equation (BRSe) that was used in the risk prediction model (steps 1-4) and then calculated the risk probabilities for coronary heart disease or myocardial infarction (CHD/MI), stroke and CVD (steps 5-7) – see Appendix 2.

The following summary measures of CVD risk-score categories were obtained: <5%, 5% to 10%, 10% to <20%, 20% to <30% and ≥30%. The distribution of these categories, according to socio-demographic and behavioural groups (independent variables), was determined. These independent variables included: location (rural or urban), ethnicity, level of education, marital status, socio-economic status/wealth, alcohol consumption, sugar and salt intakes, fruit and vegetable intakes, physical activity and history of lifestyle advice.

Descriptive statistics were used to calculate, produce graphs of and visualise data, including measures of central tendency and variation. Chi-square and T-tests were used to assess for differences in baseline socio-demographic characteristics between groups. A Kruskal-Wallis H-test was conducted to determine whether the mean ranks for CVD risk scores were different for various socio-demographic and behavioural groups. The mean rank was used because the distribution of scores for the indicators was not identical, i.e. they had different shapes and variabilities.

3.4.5.2 Identification of factors associated with the variation of CVD risk score

Multivariable regression was performed to identify factors that were associated with the variation of the CVD risk score in the study cases. Variable selection was based on automated criterion-based procedures – the best subset selection (99). The regression model was assessed for how good the fit was, multicollinearity, influential outliers, heteroscedasticity and functional form problems [Appendix 5]. Statistical significance was defined as a two-tailed p-value of less than 0.05.

The regression model with the best fit was selected based on the adjusted R-squared value and the Akaike information criterion (AIC). Missing data were excluded from the analysis.

3.4.6 Methodology reporting

The methods for this chapter were reported according to the strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies (100).

3.4.7 Ethics and Data protection

The data that were used for this study are publicly available, and ethics committee approval was not required.

3.5 Results

3.5.1 Study subjects

Data from 1627 (36.2%) of 4500 (75%) participants in the original STEPS survey were included in the final analysis. Data from 2752 (61.2%) participants in the original survey who were under the age of 40 years and 121 (2.7%) participants who reported histories of CVD or who were taking aspirin regularly to prevent or treat heart disease were excluded.

Data on personal history that could be used to evaluate CVD 'risk equivalents', such as the occurrence of gestational diabetes, polycystic ovarian syndrome, known impaired glucose tolerance, genetic lipid disorders or diabetes with nephropathy, was not available. There was no documentation of transient ischaemic attack, atrial fibrillation, peripheral vascular disease or previous coronary artery surgery. These omissions were unlikely to impact significantly on the number of eligible subjects for this study.

3.5.2 Characteristics of the study subjects

3.5.2.1 Socio-demographic and behavioural characteristics

These characteristics of the study population are shown in Table 25 [Appendix 6]. Of the 1627 cases, 58.0% were female, and slightly more than a quarter of the total cases were aged between 40 and 44 years. A total of 44.7% (95% CI 42.3-47.2) of the subjects had not completed primary school level education. In both sex categories, rural residence was more prevalent than urban residence. Similarly, most of the subjects were married at the time of data collection. About a fifth of the participants were of the Kikuyu ethnicity.

Of those who consumed alcohol, among both men and women, 30.4% (95% CI 25.6-35.5) reported having had at least one standard alcoholic drink on one to two days a week in the previous 12 months. The mean number of servings of fruit consumed was two (standard deviation (SD) 2.3) on each of the two (SD 1.7) days of a typical week that fruit was eaten. Almost half of the study subjects did not add salt or salty sauce to food. Similarly, slightly more than half of the subjects did not consume processed food that was high in salt. More than two-thirds, 64.9% (95% CI 62.5-67.2), of the subjects thought that they consumed 'just the right amount' of salt or salty sauce. Also, the vast majority of the subjects (85.4%) reported that they rarely or never consumed processed

food high in sugar. Generally, the participants consumed one (SD 1.3) 300ml bottle of soda on the one (SD 0.7) day of a typical week in which they drank soda. More than half of the subjects also thought that they consumed 'just the right amount' of sugar. Both men and women spent, on average, five (SD 2.2) hours a day for five (SD 1.7) days of a typical week engaged in activities of vigorous intensity as part of their work.

Less than a quarter of the study subjects in the previous three years had received any lifestyle advice concerning smoking, diet, healthy body weight or physical exercise. The main source of healthcare for most of the subjects was a public primary healthcare facility.

3.5.2.2 CVD risk characteristics

Table 4 shows the CVD risk characteristics of the subjects. The mean age in years of the study cases was 51.7 years (SD 8.6 years), ranging from 40 to 70 years. While 10.6% (95% CI 9.1-12.2) of the subjects reported that they were smokers, 23 times more men smoked than women. The mean SBP for the study subjects was 135.1mmHg (SD 23.9mmHg), and the mean total Cholesterol was 4.0mmol/l (SD 1.1mmol/l). Of the study subjects, 3.5% (95% CI 2.7-4.5) had a history of diabetes mellitus, and 17.0% (95% CI 15.2-19.0) had a history of hypertension. However, only 54.5% (95% CI 52.0-56.9) of the subjects had ever had their blood pressure measured.

Table 4. Participants' CVD risk characteristics

Indicator	Female	Male	Total	P-value
Mean age in years (SD)	52.0 (8.6)	51.4 (8.5)	51.7 (8.6)	0.145
Per cent smoking (95% CI)	1.1 (0.9-5.1)	23.8 (20.6-27.2)	10.6 (9.1-12.2)	<0.000*
Mean SBP in mmHg (SD)	135.7 (24.7)	134.2 (22.8)	135.1 (23.9)	0.211
Mean total cholesterol in mmol/l (SD)	4.1 (1.1)	3.8 (1.0)	4.0 (1.1)	<0.000*

Percent with history of diabetes mellitus (95% CI)	4.2 (3.0-5.7)	2.5 (1.5-4.0)	3.5 (2.7-4.5)	0.103

* $p<0.05$

3.5.2.2.1 How are CVD risk scores distributed in the study population?

The median CVD risk score for the study population was 3.0% (interquartile range (IQR) 0.3, 46.2) with a distribution skewed to the right (skewness, 2.65) with kurtosis of 12. Of the subjects, 69.1% (95% CI 66.8-71.3) were in the lowest risk category (<5%), 19.0% (95% CI 17.1-21.0) in low-risk category (5% to <10%), 9.8% (95% CI 8.4-11.3) were in the moderate risk category (10% to <20%), 1.5% (95% CI 0.9-2.2) were in the high-risk category (20% to <30%) and 0.6% (95% CI 0.3-1.1) were in the highest risk category (30% and above). Table 5 shows the distribution of risk according to sex. Figures 4 to 8 show a graphical distribution of the CVD risk categories according to the socio-demographic and behavioural characteristics of the study population.

Table 5. Distribution of CVD risk scores by sex

CVD risk score category	Female (95% CI)	Male (95% CI)
Lowest risk (<5%)	68.5 (65.4-71.5)	69.9 (66.2-73.3)
Low risk (5% to <10%)	17.4 (15.0-20.0)	21.2 (18.2-24.6)
Moderate risk (10% to <20%)	11.5 (9.6-13.8)	7.3 (5.5-9.6)
High risk (20% to <30%)	1.9 (1.1-3.0)	0.9 (0.3-1.9)
Highest risk (30% and above)	0.6 (0.2-1.4)	0.6 (0.1-1.5)

Table 26 [Appendix 6] shows that women had a slightly higher mean CVD risk score than men: 5.0% (SD, 5.5) vs. 4.6% (SD, 4.7). Similarly, compared with men (9%), more women (14%) in the study population had a CVD risk score of more than 10% (Table 5).

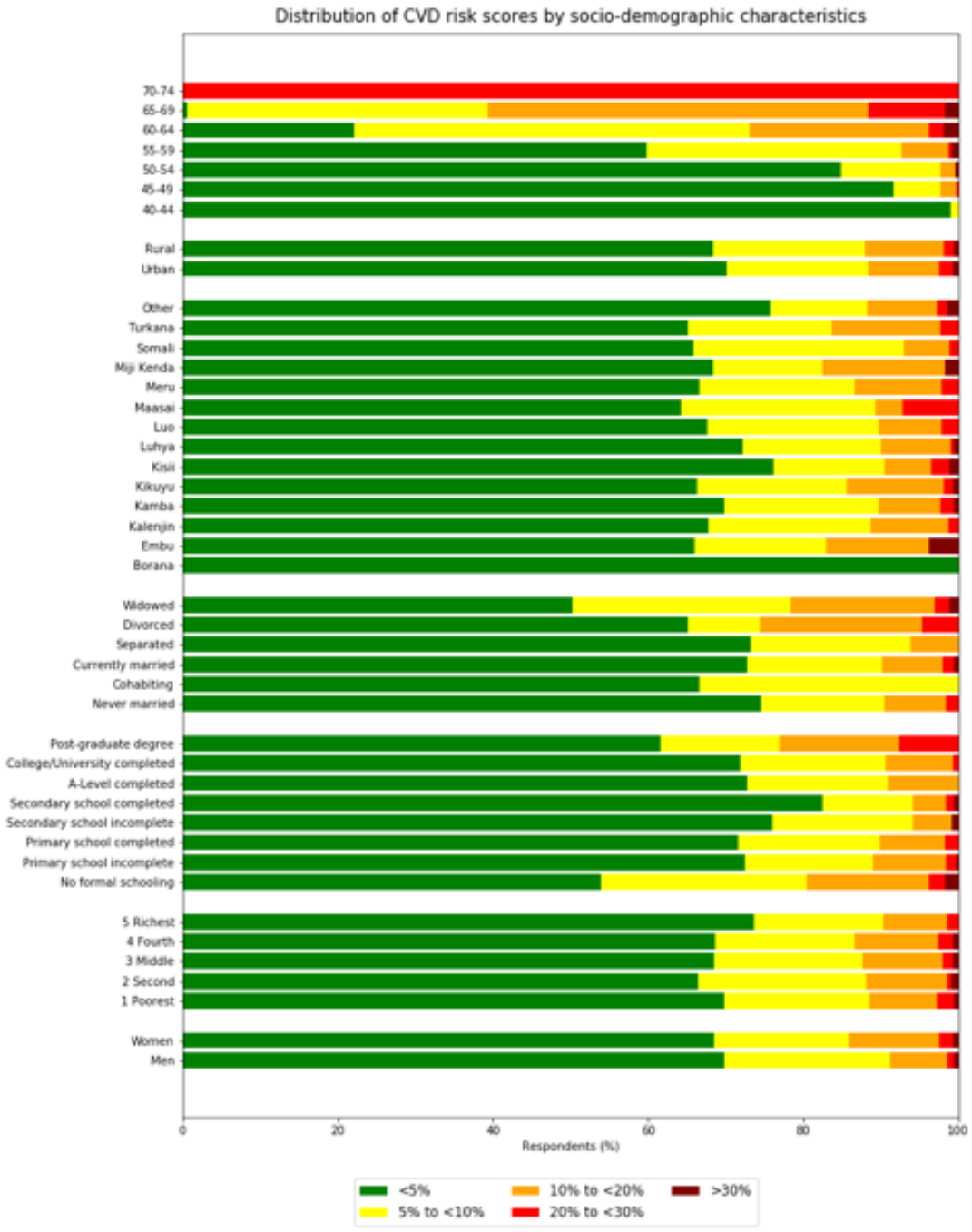


Figure 4. Distribution of CVD risk scores by socio-demographic characteristics

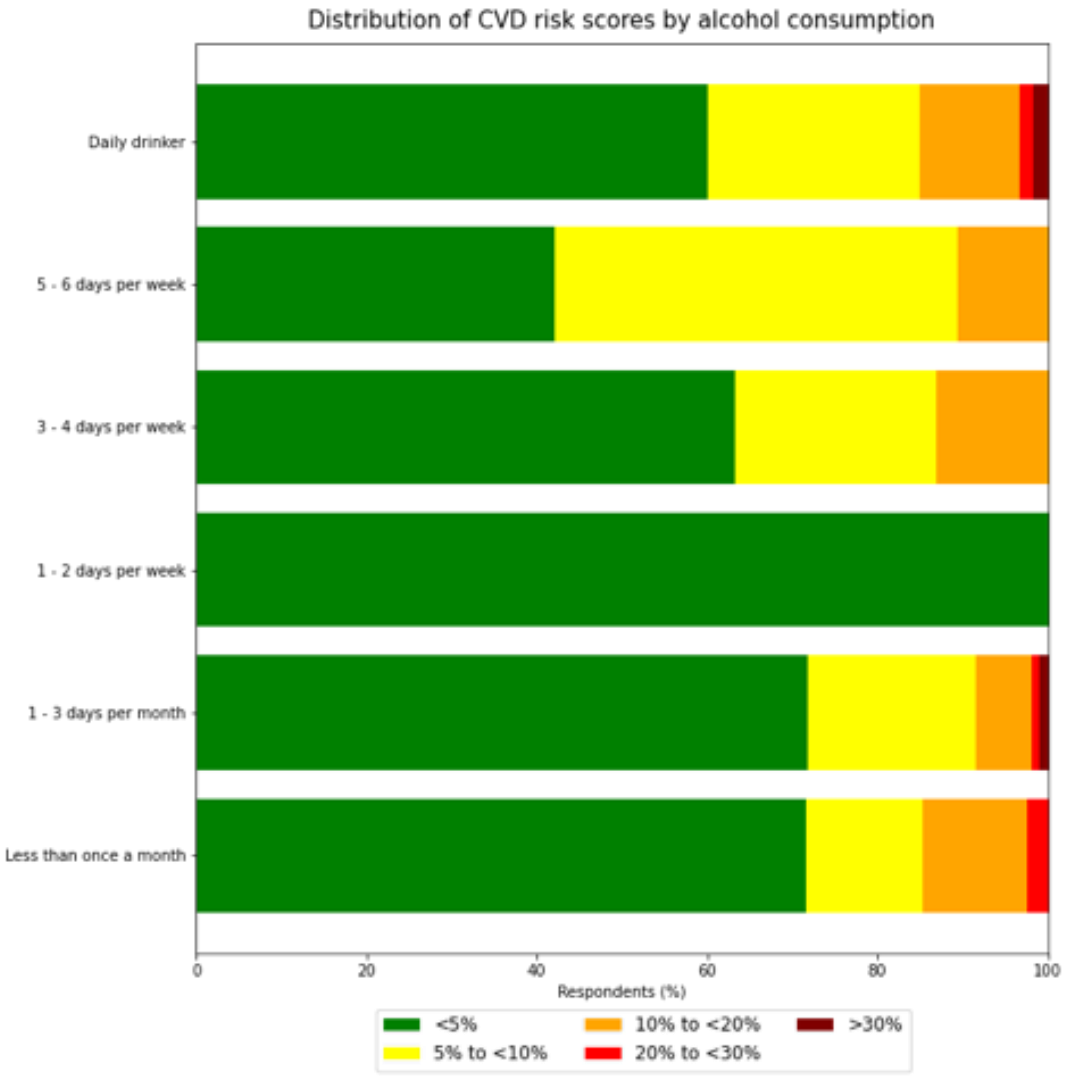


Figure 5. Distribution of CVD risk scores by alcohol consumption

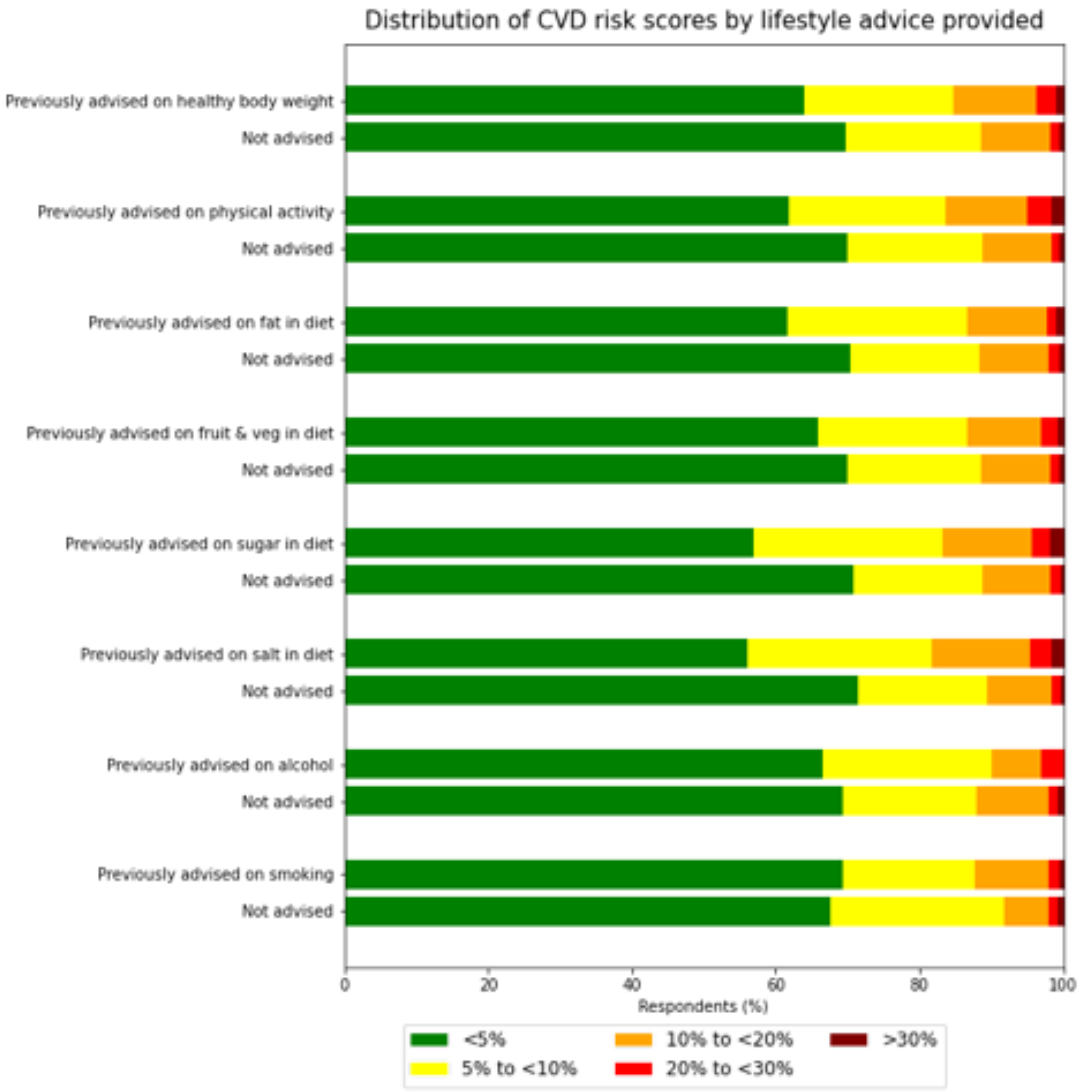


Figure 6. Distribution of CVD risk scores by lifestyle advice provided

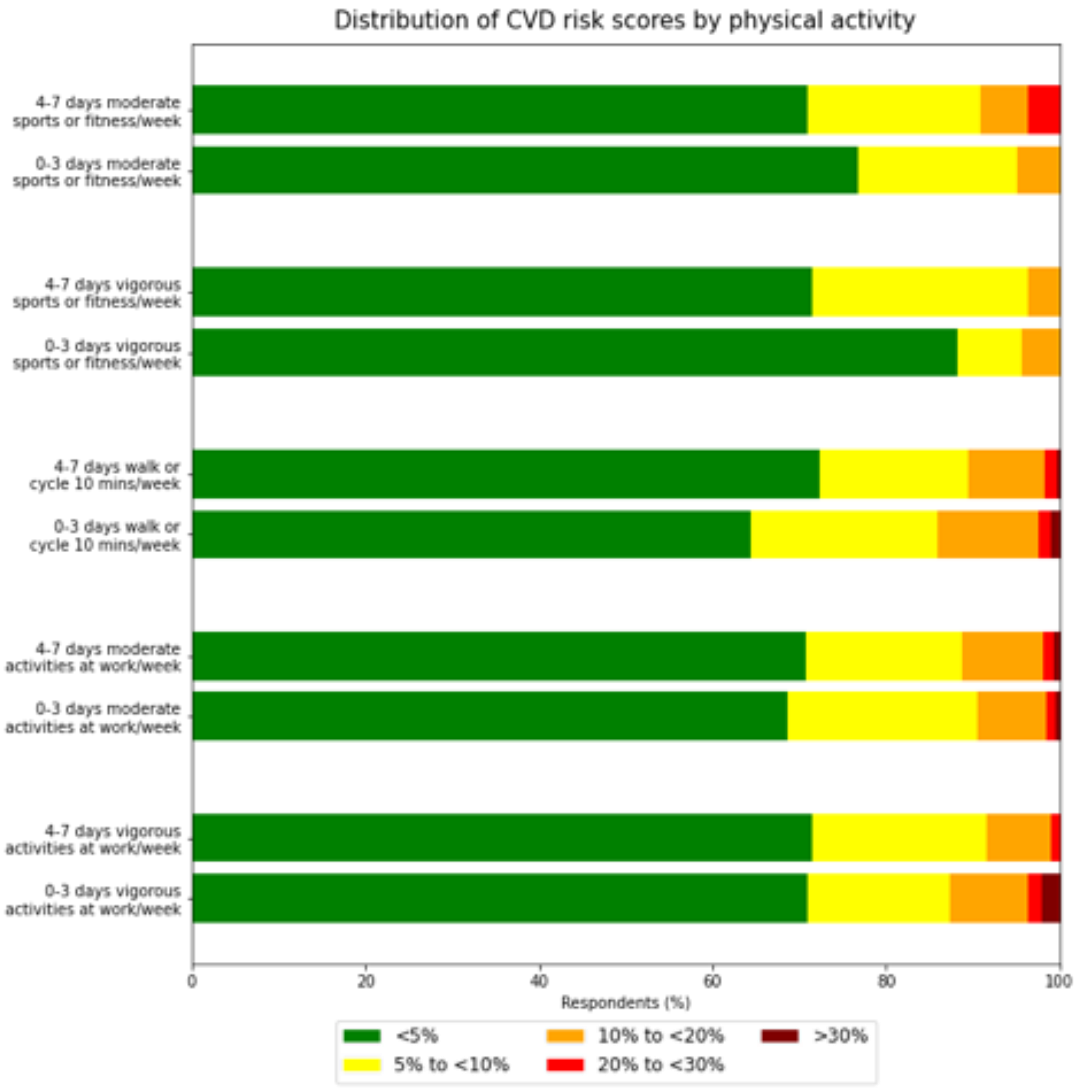


Figure 7. Distribution of CVD risk scores by physical activity

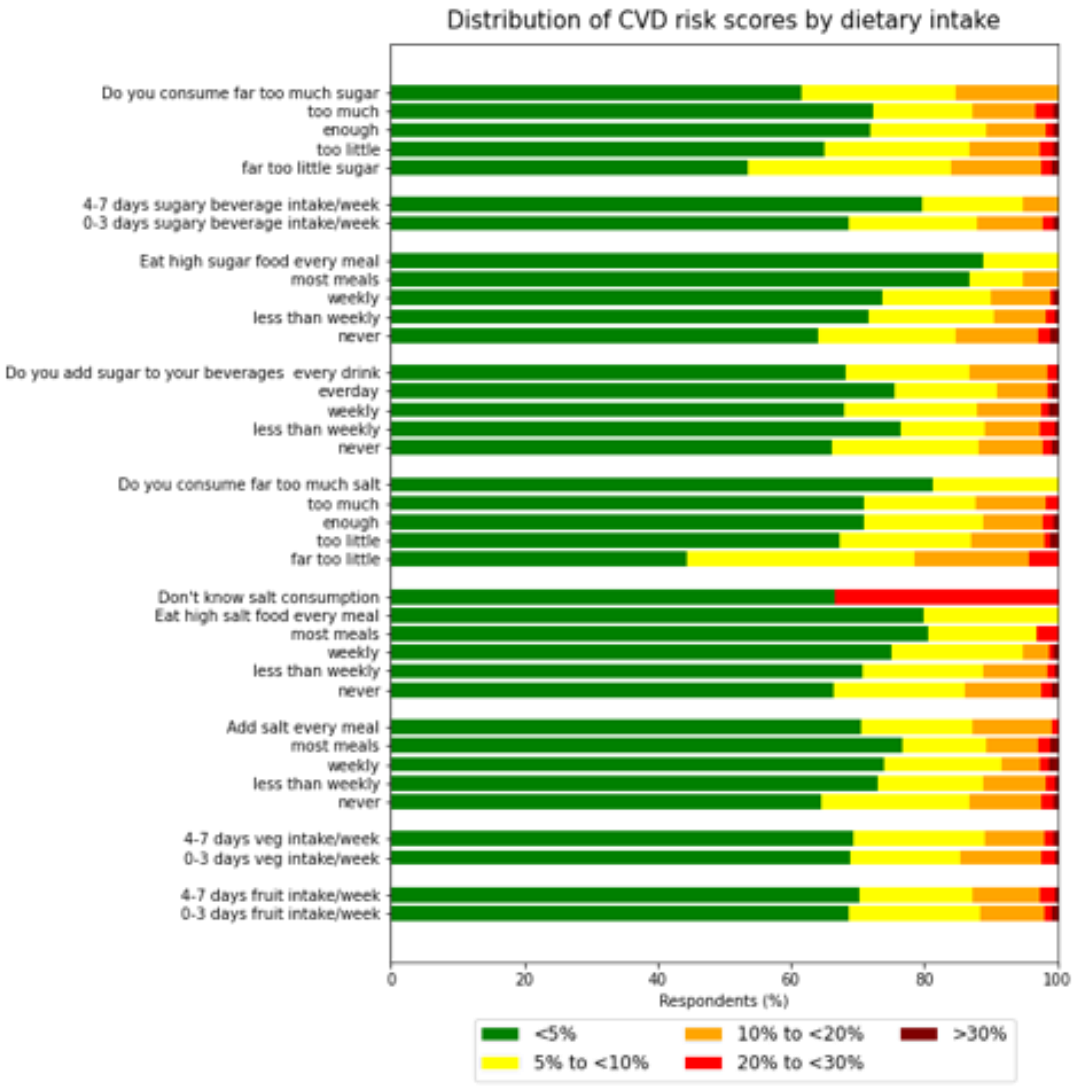


Figure 8. Distribution of CVD risk scores by dietary intake

These bar charts show that CVD risk scores increased with age. Subjects who had no formal education and those with a post-graduate degree had a higher mean CVD risk score compared with other education level groups: 6.6% (SD 6.4) and 6.0% (SD 6.9) respectively. Those who lived in rural areas had a higher mean CVD risk score than those who lived in urban residences. Subjects who were divorced or widowed had a higher mean risk score compared with those of other marital statuses: 6.9% (SD 7.1) and 6.8% (SD 6.0) respectively. Those in the wealthiest category had a lower mean risk score compared with the other wealth quintiles. Subjects who were of Embu and Somali

ethnicities had higher mean risk scores than other ethnicities: 6.2% (SD 6.7) and 6.2% (SD 6.9).

Subjects who reported having at least one standard alcoholic drink on more than five days per week had a higher mean risk score compared with those who drank on fewer than five days per week: 5.6% (SD 5.3). Cases whose work involved fewer than three days of vigorous-intensity activities had a higher mean risk score than those who were involved in vigorous activity over more than three days (Table 26) [Appendix 6]. Those who reported eating fruit on six days of a typical week had a higher mean risk score compared with those who ate fruit on fewer than six days or during all the seven days: 6.0% (SD 7.6). Similarly, those who reported eating vegetables for five days of a typical week had a higher mean risk score compared with those who ate vegetables for fewer or more than five days: 6.3% (SD 5.6). Subjects who reported that they never added salt to food or sugar to beverages had a higher mean risk score than those who did. Equally, those who thought that they consumed 'too little' or 'far too little' salt or sugar had higher mean risk scores (salt: 'too little', 5.1% [SD 5.3] 'far too little', 6.9% [SD 6.0] and sugar: 'too little', 5.3% [SD 5.6] 'far too little', 6.0% [SD 5.5]) compared with those in other categories.

3.5.2.2.2 What is the association between factors measured in the survey and CVD risk scores?

The following variables were included in the regression model: education level, marital status, ethnicity, the number of days on which vegetables were eaten in a typical week, the amount of salt/salty sauce the subjects thought they consumed, how often processed food high in sugar was eaten, the amount of sugar they thought they consumed, the number of days during which vigorous-intensity activities were part of the subjects'

work in a typical week, and whether or not they had received lifestyle advice (in the previous three years) to reduce salt and sugar in the diet (see Table 27, Appendix 6).

All regression model assumptions were met, aside from the presence of functional form problems. This unmet assumption was allayed through the log transformation of the CVD risk score, which resulted in the passing of the Ramsey RESET test.

Table 27 (Appendix 6) shows the results of the analysis of variables that were associated with CVD risk score: $F(52,743) = 2.64$, $p < 0.00$, $R^2 = 0.16$. Education level was negatively associated with CVD risk score; having any level of education reduced the subjects' CVD risk score. Compared with those who had never been married, widowhood and widowerhood were positively associated with cardiovascular risk score: $\beta = 0.50$ (95% CI 0.16-0.84). CVD risk scores were both positively and negatively associated with various ethnicities. The CVD risk score was positively associated with the number of days on which vegetables were eaten in a typical week and negatively associated with the number of days during which vigorous-intensity activities were part of a subject's work in a typical week: $\beta = -0.57$ (95% CI -0.91, -0.24).

When collapsed to group level, several groups were found to add statistically significantly to the risk score. These were: education level: $\beta = -0.04$ (95% CI -0.09, -0.00); marital status: $\beta = 0.11$ (95% CI 0.06, 0.16); how often the subjects ate processed food that was high in sugar: $\beta = 0.12$ (95% CI 0.04, 0.20); and whether they had been given lifestyle advice on salt reduction in the previous three years: $\beta = -0.24$ (95% CI -0.48, -0.01) (Table 6).

Table 6. Multivariable regression showing the association between factors measured in the survey and CVD risk scores (grouped)

Log CVD risk score	Coef.	St.Err.	t-value	p-value	95% Conf.	interval	Sig
Education level	-0.04	0.02	-2.06	0.04	-0.09	-0.00	*
Marital status	0.11	0.03	4.38	0.00	0.06	0.16	*
Ethnicity	-0.01	0.01	-0.79	0.43	-0.03	0.01	
Number of days vegetables were eaten in a typical week	0.00	0.02	0.15	0.88	-0.03	0.03	
The amount of salt/salty sauce subjects thought they consumed	0.04	0.05	0.93	0.36	-0.05	0.14	
How often processed food high in sugar was eaten	0.12	0.04	2.87	0.00	0.04	0.20	*
The amount of sugar subjects thought they consumed	-0.01	0.04	-0.16	0.87	-0.09	0.08	
The number of days that vigorous-intensity activities were part of subjects' work in a typical week	0.02	0.02	1.19	0.23	-0.01	0.06	
Whether subjects had received lifestyle advice (in the previous three years):							
to reduce salt in the diet	-0.24	0.12	-2.04	0.04	-0.479	-0.009	*
to reduce sugar in the diet	0.02	0.13	0.15	0.88	-0.238	0.277	
Constant	0.53	0.37	1.44	0.15	-0.194	1.255	

Mean dependent variation	1.09	SD dependent variation	0.90
R-squared	0.03	Number of observations	796.00
F-test	5.26	Prob > F	0.00
AIC	2051.97	Bayesian criterion	2103.45
* p<0.05			

3.6 Discussion

3.6.1 Summary of findings

3.6.1.1 CVD risk distribution

Through this cross-sectional study of survey data, I aimed to describe the distribution of CVD risk scores in the Kenyan adult population and to identify factors associated with the variation of these scores in this population. The median CVD risk score in the study sample was 3.0% (IQR 0.3, 46.2), and the majority (69.1% [95% CI 66.8-71.3]) of the subjects were grouped in the lowest CVD risk category (< 5% CVD risk). According to the national guidelines on CVD prevention and management, up to 11.9%

of the study population (moderate, high and highest-risk categories) are eligible for both pharmacological and lifestyle interventions. Women recorded a higher mean CVD risk score than men: 5.0% (SD 5.5) vs. 4.6% (SD 4.7). This is in addition to more women (14%) than men (9%) in the study population having a CVD risk score of more than 10%.

The mean CVD risk scores differed significantly across socio-demographic and behavioural groups. The data for the subjects showed that their educational levels, marital statuses, ethnicities, their frequency of consumption of processed food that was high in sugar, the number of days on which they ate vegetables in a typical week, whether they had received lifestyle advice on reduction of their salt intake in the previous three years and the number of days in a typical week on which they undertook vigorous-intensity activities as part of their work were significantly associated with their CVD risk scores.

3.6.1.2 Socio-demographic and behavioural characteristics

Most socio-demographic characteristics of the subjects differed by gender. More men had completed secondary school education than women (17.0% vs. 7.6%). More women were living in rural homes than men (63.6% vs. 54.0%). There were more married men than women (84.9% vs. 61.6%) and more widows than widowers (23.9% vs. 5.0%). Similarly, most of the behavioural characteristics of the subjects varied according to gender. About 23 times as many men smoked as women, and more men consumed alcohol than women.

Regarding diet, the subjects of this study did not fulfil the recommendations set by the WHO on fruit and vegetable intake either in number of servings or in frequency (the WHO recommends five servings of fruit and vegetables per day) (101). However, a

large proportion of the subjects (>40%) did not add sugar or salt to their food and did not eat processed food high in sugar or salt. More than half of the subjects reported that they consumed 'just the right amount' of sugar and salt. These findings regarding salt and sugar consumption may need to be interpreted with caution due to the subjectivity of the survey questions and show cards.

Regarding physical activity, both men and women fell slightly short of the WHO recommendations on the frequency of physical activity (101). The subjects performed an average of five days of moderate-intensity activities in a typical week instead of seven (daily). However, they exceeded the recommended duration (30 minutes per day) by 2.5 hours in moderate physical activities. Less than a fifth of the subjects had received lifestyle advice from a doctor or health worker in the previous three years. Given that a significant proportion (71.9%) of the subjects reported that their primary sources of healthcare were public primary-care facilities, this might suggest that non-pharmacological therapies such as lifestyle interventions were being offered sub-optimally in these facilities.

Notably, CVD risk score was positively associated with the number of days on which subjects ate vegetables in a typical week and negatively associated with the number of days that they undertook vigorous-intensity activities as part of their work in a typical week. These results may be an effect of previous health advice that had been given to at-risk subjects on lifestyle adjustment. This trend was also seen among those who had been advised in the previous three years by a health worker to adjust their lifestyle behaviour; these subjects had a higher mean risk score compared with those who had not been given the advice.

3.6.2 Interpretation of findings

The distribution of CVD risk scores in the study population suggests that approximately 11.9% of the population (those with CVD risk above 10%) would be eligible for consideration for both pharmacotherapy and lifestyle interventions (102). This estimate contributes to the evidence that is needed to prioritise the prevention and management of CVD both at the population level and in Kenyan primary care settings.

Results showing that the mean CVD risk scores varied by socio-demographic and behavioural groupings reiterate the importance of knowing these characteristics if clinicians are to understand further the epidemiology of CVD in this population. For example, a majority of the study subjects who reported that they consumed alcohol drank on fewer than eight days a month on average – twice a week. However, during each of these drinking sessions, the mean number of standard alcoholic drinks that they consumed was nine. This suggests a high prevalence of binge drinking (defined as the imbibing of more than four standard alcoholic drinks during one period) in this group. Further, the observed breakdown of socio-demographic characteristics according to gender may have an impact on behaviour and the lifestyle choices of the subjects, and, in turn, on their CVD risk-factor characteristics.

These findings also reinforce the importance of addressing these socio-demographic and behavioural characteristics for public health impact. The association between factors that were measured in the survey and CVD risk scores suggest that attention should focus on education level, marital status, ethnicity, dietary practices, physical activity and previous lifestyle advice during the performance of targeted screening in this population. Health services, and in particular primary-care systems, should be

reoriented urgently to assess and address proactively these local social determinants of health.

3.6.3 Findings in the context of existing research

Few studies have explored the risk of CVD in populations through descriptions of the distribution of CVD risk scores as an outcome measure of CVD risk. This is the first study to my knowledge to make such an assessment at a national level, which was through use of a nationwide survey in Kenya. Most of the research currently available reports on the prevalence and number of individual CVD risk factors that are present in populations as a quasi-measure of CVD risk.

The proportion of people (88.1%) in this study who showed a CVD risk of <10% generally matched the proportions observed elsewhere. For example, a study by Mendis et al. (2011), which was performed in 'resource-constrained' settings, found similar percentages (79% to 96%) in eight countries that included China; another by Otgontunya et al. (2013) reported figures from Cambodia (98%), Malaysia (94%) and Mongolia (90%); and one by Ndindjock et al. (2011) found a similar figure (89%) in Seychelles (103–105). A similar study that was conducted in Kenya but focused on a slum population in Nairobi reported that a majority of its population (95%) had a total CVD risk score of <10% (106). Conversely, a study in Indonesia reported that a third of its study population had a CVD risk score of >30%, which is thought to represent the varying burden of CVD and prevalence of CVD risk factors (including age) in that country.

In studies that compared the prevalence and number of CVD risk factors in populations such as those in Bangladesh, India, Vietnam, Indonesia and Thailand, the Kenyan population seemed, on average, to match the number of CVD risk factors. For example,

more than 70% of the populations in the majority of the five Asian countries had three or more risk factors compared with the 85.6% in a study of Kenyan adults by Wekesah et al. (2018) (107). A study that was conducted in Uganda – which has a population more comparable with that of Kenya – reported that only 17.3% of the population showed three or more risk factors (108). Many factors could explain these differences; from methodological and study design incomparability to the number and varying definitions of the risk factors that were included in these studies.

Still, the average number of individual CVD risk factors is not the same as the average CVD risk score when it is based on the validated CVD risk-assessment tool. The latter is based on the understanding that cardiovascular risk factors are additive and synergistic, and growing evidence posits that this measure is more accurate to describe a population's CVD risk distribution than single risk factors alone (31). Notwithstanding, this approach of reporting the prevalence of individual CVD risk factors is essential as it gives critical insight into CVD epidemiology. However, it has been criticised for its lack of accurate information on the proportion of the population that is at risk of CVD in ways that are actionable for the delivery of preventive services, primarily in the various levels of the health system (109).

Findings from this study highlight an element according to gender in the distribution of CVD risk scores by various socio-demographic and behavioural characteristics, and cardiovascular risk factors. This gender aspect, perhaps, explains why, in similar studies that calculated CVD risk scores, females scored higher CVD risk scores compared with males (110,111). Higher CVD risk scores in females compared with males contradicts previous evidence that the clustering of CVD risk factors is mainly associated with the male gender (112). Until very recently, CVD and the risk of CVD were extensively

considered to be predominant among men. Emerging findings now show increased mortality and morbidity from CVD in females of comparable age groups (113). Results from this study confirm these findings in the Kenyan population.

Concerning the prevalence of behavioural CVD risk factors, this study confirmed some of the findings that have been reported before with regard to insufficient consumption of fruits and vegetables, and physical inactivity in the Kenyan population (114). However, there were conflicting findings on salt consumption in the population. Results from this study showed that more than 70% of the study population rarely or never added salt to their food, or consumed processed food high in salt. Conversely, the study by Wekesah et al. (2018), which was conducted in Kenya, reported that more than 89% of the study population had high salt intakes (107). This conflict broadly illustrates the challenges of 'measuring' behavioural characteristics due to their subjective nature and the need for better measurement systems in these settings. These measurement tools and systems should also address the recall bias that is inherent in the current designs of data collection methods. Some of the options may include continuous collection of data at primary care level on behavioural CVD risk factors as opposed to one-off national-level surveys. However, for this to be successfully implemented, health information systems would have to be robust, standardised and dynamic for national-level consolidation.

Notably, factors such as ethnicity, level of education, urban or rural living, socio-economic status and marital status are increasingly associated with a population's CVD risk. Similar findings from this study support a call for more targeted preventive approaches based on these factors (115). A systematic review by Allen et al. (2020), which explored what such an approach could look like in primary care, provided a

three-tiered action plan that focused on targeting high-risk individuals, communities and public policies (116). However, all the studies that were included in the review were from high- or middle-income countries.

3.6.4 Strengths and limitations

By application of CVD risk-scoring tools that were updated and appropriate for the region (WHO CVD risk charts, revised models for 2019), this study has provided the most up-to-date and specific CVD risk scores and their distribution in the Kenyan population. This approach has been lauded as an accurate and actionable way to inform health planning and delivery of CVD prevention and management services (43).The study also utilised a standardised chronic disease risk surveillance approach (WHO STEPS) that conferred comparability of this study's findings to other settings. However, the study has some limitations. First, the data on behavioural risk factors was based on self-reporting and thus may suffer from reporting and recall bias. This bias is especially rife regarding socially discouraged practices such as smoking and alcohol consumption. Second, it was not possible to exclude from this study those participants in the original WHO survey who had suffered transient ischaemic attacks, atrial fibrillation, peripheral vascular disease, or had undergone previous coronary artery surgery as this information was not available from the survey. In addition, it was not possible to evaluate thoroughly all risks, such as would be shown through collection of family and current medical histories. Lastly, there is a possibility of a selection bias as the analysis was from a subsample of the original survey. These limitations mean that the findings here might underestimate the population's full CVD risk and its distribution.

3.6.5 Implications for practice and research

As the early onset of CVD is mainly asymptomatic, the capacity of the health system to provide information, prevention and diagnostic services to its population is vital to increase awareness and mitigate cardiovascular risk. The findings of this study advance the importance of population- and individual-level strategies to prevent CVD risk as part of health policies. At the population level, health promotion activities based on the WHO 'best buys' to create awareness of CVD risk in the population are of utmost importance as supplements to targeted approaches (51).

Targeted approaches include targeting high-risk individuals and communities. One way in which this could be done is through application of proactive screening that would use CVD risk-scoring tools to inform prevention and management strategies in primary care. This would mainly be used to plan pharmacological and non-pharmacological interventions in these settings appropriately. Clinicians and policymakers would need to work together, through the formulation of new policies and closure of the policy-practice gap, to address the local socio-political determinants of health that have been explored in this study. Specifically, more attention should be paid to socio-demographic-behavioural factors such as ethnicity, level of education, marital status, dietary practices and physical activity in order to refine the existing entry points to targeted screening in Kenyan primary care settings.

Future research should focus on three concerns: first, understanding current practice in the prevention and management of CVD risk to incorporate CVD risk screening fully in these settings (Chapter 5); second, introduction of better measurement systems and tools that adequately capture the population's behavioural CVD risk characteristics at the national and sub-national levels; and lastly, production of more contextual research

on interventions that address local socio-political determinants of health in Kenyan primary care settings.

3.7 Conclusions

The distribution of CVD risk scores in the Kenyan population suggests that approximately 11.9% of the population (who showed a CVD risk of more than 10%) would be eligible for consideration for both pharmacotherapy and lifestyle interventions. However, more than 75% of the population report having never received any lifestyle advice concerning CVD risk factors. Public primary-care facilities, which serve more than 70% of the Kenyan population, are critical points of entry through which to institute targeted interventions for the prevention and management of CVD risk. Consideration of factors such as ethnicity, level of education, marital status, dietary practices and physical activities may refine the existing entry points for CVD risk screening, prevention and management in Kenyan primary-care settings.

3.8 Chapter summary

- It was found that 11.9% of the Kenyan population (who show a risk of CVD > 10%) could be eligible for consideration for pharmacotherapy and lifestyle interventions to mitigate their risk of CVD;
- the distribution of CVD risk scores by socio-demographic and behavioural characteristics shows a gender bias, and cardiovascular risk factors place women at higher risk of CVD in this population;
- factors such as ethnicity, level of education, marital status, dietary practices and physical activity could be used to refine the existing entry points for targeted CVD risk screening, prevention and management in Kenyan primary care settings;
- public primary-care facilities are a critical entry point for targeted screening and the delivery of interventions for CVD risk prevention and management;

- future research should focus on three issues: understanding current practice in the prevention and management of CVD risk to incorporate CVD risk screening fully in these settings; introduction of better measurement systems and tools that adequately capture the population's behavioural CVD risk characteristics; and the conduct of more contextual research on interventions that address local socio-political determinants of health in Kenyan primary-care settings.

Chapter 4. Factors that influence the implementation of cardiovascular risk scoring in primary care: a mixed-method systematic review

4.1 Publication statement

Features of this chapter have been published in the BMC journal *Implementation Science* (86). The protocol for this chapter was also accepted for publication in the *British Medical Journal Open*; however, I was unable to raise the article processing charges that were required for publication.

4.2 Introduction

The findings of the work described in Chapter 3 showed a high CVD risk burden in the Kenyan population; up to 11.9% of the population (who showed a CVD risk of more than 10%) may be eligible for consideration for both pharmacotherapy and lifestyle interventions. A key strategy to reduce the CVD risk burden in Kenya was the formulation of national guidelines for CVD prevention and management in 2018. These guidelines advocated targeted CVD risk assessment and therapeutic management based on an absolute CVD risk-score premise. This is in line with the WHO's recommendations for the use of CVD risk-assessment tools in primary care as a key preventative strategy. However, there is evidence of poor uptake and use, especially in LMICs.

A global survey conducted by the WHO in 2019 reported a lag in implementation of these tools in most LMIC countries (117). For example, while nearly 50% of the countries reported that CVD risk-stratification tools were available in more than 50% of health-care facilities, about 29% reported availability in less than 25% of facilities. In a further 9% of the countries, the health authorities were not aware of the extent to which CVD risk stratification was offered. Notably, most countries with availability in more than 50% of facilities were HICs or UMICs, and most of these were in Europe.

Almost 50% of African countries reported that risk stratification was not available in any health-care facilities. Evidence that has explored the factors that underpin the implementation of CVD risk-assessment tools has not been robustly reviewed (75). Such a review may reveal factors that have particular relevance to LMICs.

Therefore, I hypothesised that there would be a multitude of evidence to explain the lag in the adoption of CVD risk-scoring tools in primary care, and perhaps also to explain the global disparities in their use. This understanding could guide implementation policy and practice, and provide insight into how cardiovascular risk assessment tools could be best utilised in various settings that included those in Kenya.

4.3 Aim and objectives

4.3.1 Aim

The aim of the work that is described in this chapter was to systematically synthesise existing evidence of factors that influence the implementation of cardiovascular risk scoring in primary care settings.

4.3.2 Objectives

Primary objective

To explore the facilitators and barriers to the implementation of cardiovascular risk scoring in primary care.

Secondary objective

To examine these factors within different contexts, such as a country's GNI classification, and among the users of the intervention.

4.4 Methods

I prospectively registered the protocol on the PROSPERO database of prospectively registered systematic reviews in health and social care (registration ID: CRD42018092679). Any deviation from the protocol that was made during conduct of the review was documented with reasons.

4.4.1 Search strategy

With the aid of an information specialist (Nia Roberts, University of Oxford), I conducted a systematic search to identify all the relevant studies that had reported on facilitators and barriers to cardiovascular risk scoring in primary care. Terms that related to facilitators, barriers, implementation, total cardiovascular risk assessment scores and primary care were populated on: the biomedical databases Excerpta Medica database (EMBASE) and the medical literature analysis and retrieval system online (MEDLINE); the Cochrane central register of controlled trials (CENTRAL); the cumulative index to nursing and allied health literature (CINAHL); the database of abstracts of psychology literature (PsycINFO); Global Health; Web of Science; and in grey literature. The full search strategy is shown in Appendix 7. This search was not limited by date or language. In addition, and for pragmatic reasons, I searched the references of all the included studies alongside forward and backward citation of key articles that were already known to me.

4.4.2 Selection criteria

For inclusion, studies had to report on factors that were related to increased, decreased or no use of total cardiovascular risk assessment tools. This included aspects that influenced the usability and uptake of these tools, opportunity costs and resources that were associated with their use or/and uptake. Only primary studies, i.e. qualitative,

quantitative and mixed-method reports, were included. Studies of mixed populations in primary and secondary care were only included when there was access to data that came exclusively from primary care populations. Where this was not clear, I sought clarification from the authors. Only studies that assessed the systematic provision of an absolute cardiovascular risk assessment, by the integration of three or more risk factors to a patient by a physician or a non-physician as a strategy for primary prevention of cardiovascular disease, were included.

Studies were excluded if they involved participants who were under 18 years old and who had pre-existing CVD. Studies that assessed cardiovascular risk by use of two or fewer risk factors were excluded. Those that assessed self-administration of total cardiovascular risk assessment scores via online calculators or charts were also excluded.

At first instance, I screened all the retrieved studies for title and abstract screening while DK and GR independently screened half of these studies each. The full-text screening was done by two reviewers (GR and TBM), and disagreements were settled by consensus or by consulting the third reviewer (DK). A record of the studies that were excluded after full-text screening and the reasons for exclusion is available in Appendix 8. The decision process that led to the choice of included studies was documented on a preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow chart (Figure 4 in the results section). This selection process was managed using Covidence (118).

4.4.3 Assessing the quality of the studies

The methodological quality of mixed-method studies was assessed by use of the mixed methods appraisal tool (MMAT), and, for qualitative studies, through use of the critical

appraisal checklist that was developed for the purpose by the National Institute for Health and Care Excellence (NICE) (119,120). For the quantitative studies, all of which were cross-sectional studies, the appraisal tool for cross-sectional studies, known as AXIS, was used (121). Two reviewers (GCR and TBM) appraised all the studies independently and disagreements were resolved by consensus.

4.4.4 Assessing for bias in the review

This review has been reported in accordance with the PRISMA guidelines for 2015 and the enhancing transparency in reporting the synthesis of qualitative research (ENTREQ) statement (122,123). This promoted the explicit and comprehensive reporting of review processes and outcomes.

4.4.5 Data extraction strategy

The characteristics of the included studies, i.e. the country's classification according to its GNI, study design, demographics of the participants, type of cardiovascular assessment tools that were used and the study outcomes were extracted independently and in duplicate by GR and I using Microsoft Excel 2016. Discrepancies were resolved by consensus.

4.4.6 Data synthesis and presentation

Synthesis took a ‘best fit’ framework approach and utilised an integrated mixed-methods methodology (124,125) [Figure 9 and Table 6].

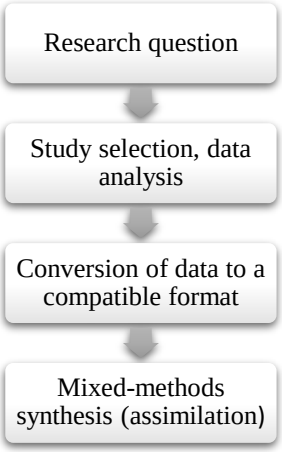


Figure 9. An integrated methodology for mixed-methods reviews

The ‘best fit’ framework synthesis, which is an approach based on the framework analysis technique, was then used to identify the facilitators and barriers. This approach was employed because it pragmatically reduces the time taken to generate theory de novo and enriches the process of theory generation by engaging with existing theory, i.e. it provided a pragmatic means to situate my findings within existing theories of implementation science. More importantly, this approach allows for the systematic presentation of actionable outcomes, which is apt for the identification of key strategies that will support implementation (126). The approach has been used before to synthesise employees’ views of workplace smoking cessation interventions and to explore the views of adults regarding the taking of potential chemo-preventive agents within the context of the primary prevention of colorectal cancer (127,128). Additionally, the seven steps of the approach allowed for an inductive and deductive approach to data synthesis (Table). An integrated mixed-methods methodology involved ‘combining’ qualitative and quantitative data by having the quantitative data contribute to the thematic typology.

Table 6. Steps to use of a 'best-fit' framework synthesis

What are the factors that influence the implementation of cardiovascular risk scoring in primary care?	
Systematically identified relevant ('best fit') publications of frameworks, conceptual models or theories using the BeHEMoTh approach	Systematically identified relevant primary research studies (n=25)
Identified an existing framework from literature – Consolidated Framework for Implementation Research (CFIR)	Extracted data on study characteristics from included studies and appraised the quality of the studies
Coded data from the included studies against the CFIR framework	
Generated new themes by performing thematic analysis on any data that could not be coded against the framework	
Produced new framework composed of a priori and new themes that were supported by the evidence	
Revisited evidence to explore relationships between themes and concepts Tested synthesis by exploring issues of dissonance and the impact of variables such as quality	

After the relevant primary studies for the review had been identified, an a priori ('best-fit') framework was similarly identified from existing frameworks in the literature through use of the behaviour of interest, health context, exclusions, and models or theories (BeHEMoTh) strategy. This strategy was focused on implementation of science theories and frameworks. Consequently, the consolidated framework for implementation research (CFIR) was identified as the 'best fit' framework (Table 7).

There are two main reasons why the CFIR was identified as the best framework to use: it is a multilevel, determinant type of implementation framework (see Chapter 2, section 2.6); and it provides a 'meta-view' of all the factors that influence an implementation process in a well-organised and operationalised manner (129). The CFIR is also preferred to other frameworks because it draws on psychological and organisational theories that are important during exploration of human behaviour and how behaviour is reinforced or hindered by settings (91). The CFIR has been used widely across many topic areas with regard to health-related interventions (130). However, it has been applied mostly in HICs and has had limited use in LMICs. For example, a 2020 systematic review identified 26 meaningful applications of the CFIR, of which only two took place in LMICs (131). While the framework has been praised for its

comprehensiveness, flexibility, and meta-theoretical approach, implementation determinants in LMICs might manifest differently due to variations in resource availability, health-system structures, morbidity profiles, and socio-cultural-political norms. Thus, a potential limitation of this framework is the possible need to adapt or contextualise it to fit the requirements of practitioners in these settings.

The CFIR framework subsumes its multiple constructs into five domains, namely: intervention characteristics, outer setting, inner setting, characteristics of individuals and process. Data that were extracted from the included studies were sorted and indexed onto this framework.

Table 7. An outline of the consolidated framework of implementation research (CFIR)

	CFIR domains	CFIR constructs
IMPLEMENTATION	Intervention characteristics	Intervention source, evidence strength & quality, relative advantage, adaptability, trialability, complexity, design quality & packaging and cost
	Outer setting	Patients' needs & resources, cosmopolitanism, peer pressure and external policy & incentives
	Inner setting	Structural characteristics, networks and communications, culture, implementation climate and readiness for implementation
	Characteristics of individuals	Knowledge & belief about the intervention, self-efficacy, individual stage of change, individual identification with the organisation and other personal attributes
	Process	Planning, engaging, executing, reflecting & evaluating

For quantitative and mixed-methods studies, data on the facilitators and barriers were extracted and collated on an Excel spreadsheet. These data were then thematically coded under the CFIR constructs outlined above. This conversion process is adapted from the Joanna Briggs Institute methodology for aggregative mixed-method synthesis. It is a method that is aimed at producing a single overarching synthesis by combining the results of separate syntheses (124). In this conversion, quantitative data lends itself to the derivation of defined themes that can then be codified. The facilitators and barriers in qualitative studies were presented textually as participants' quotations. This

data, both the converted and those from qualitative studies, were then coded by use of NVivo 12 onto the 39 constructs of the CFIR.

4.4.7 Additional analyses

The variations between the facilitators and barriers across countries' GNI indices and the users of cardiovascular risk tools were identified, categorised and explored.

In addition, the confidence/certainty of the review findings was assessed to strengthen the rigour of our review. Each review finding was assessed using the confidence in the evidence from reviews of qualitative research (CERQual) approach (132). CERQual is an innovative approach that provides a systematic and transparent framework for the assessment of confidence in individual qualitative review findings. This assessment is based on four components: methodological limitations, coherence, adequacy of data, and relevance. In this review, the 'confidence' of a finding was the assessment of its ability to represent reasonably the phenomenon of interest, such that this finding did not differ substantially from the phenomenon of interest. These four components were assessed as having minor, moderate, or serious concerns. An overall assessment on the confidence in the evidence for each finding, based on these four components, was assessed as high, moderate or low.

Notably, this assessment was only carried out for individual findings from qualitative studies. This is because the CERQual approach is designed to assess the confidence of the individual conclusions in a qualitative review synthesis as opposed to a mixed-method review synthesis. However, there is an acknowledgement of concern in that, in assessing the qualitative elements of this mixed-methods review separately, there was a risk that the contribution of the review findings that were based on integrated data

would be undervalued. To alleviate this, the results of this assessment are given as an adjunct to the main conclusions of the review.

4.5 Results

4.5.1 Study selection and characteristics

After removing duplicate studies, the titles and abstracts of 3010 studies were screened and the full text of 52 studies. Twenty-five studies were included in this review (Figure 10). A summary of the study characteristics is available in Appendix 9. Most (*n*=20) of the included studies were conducted in HICs and the other five were conducted in middle-income countries. There were no studies from low-income countries. All the studies reported on healthcare professionals' perspectives of cardiovascular risk scoring but only five reported on patients' perspectives. Most of the studies (*n*=23) involved physicians with only four of the studies involving non-physicians, i.e. practice nurses, health promoters, pharmacists, practice managers, administrators and policymakers.

Eleven cardiovascular risk-scoring tools were used in the studies that were included (Table 8). Five studies did not mention the specific cardiovascular risk scoring tool that was used in their evaluation, but reported using an absolute cardiovascular risk assessment strategy in their methods.

Table 8. Cardiovascular risk-scoring tools reported in the review

Tool Acronym and definition		Countries in which these tools were used
ESC SCORE risk charts	The European Society of Cardiology systematic coronary risk evaluation	Switzerland, Brazil, United States of America, Greece, Chile, Venezuela, Portugal, The Netherlands, Central America (Costa Rica, Panama, El Salvador and Guatemala), Austria, Belgium, France, Germany, Ireland, Norway, Russia, Spain, Sweden, Switzerland, Turkey and United Kingdom

Framingham risk score		Switzerland, Germany, Turkey, Brazil, United States of America, Greece, Chile, Venezuela, Portugal, The Netherlands, Central America (Costa Rica, Panama, El Salvador and Guatemala), Austria, Belgium, Egypt, France, Norway, Russia, Spain, Sweden and United Kingdom
Modified Framingham risk score		Turkey, Austria, Belgium, France, Germany, Greece, Norway, Russia, Spain, Sweden, Switzerland and United Kingdom
PRECARD	A program for the Copenhagen risk score	Denmark
Cardiovascular risk PROCAM score	Cardiovascular risk (prospective cardiovascular Munster) score	Switzerland, Brazil, United States of America, Greece, Chile, Venezuela, Portugal, The Netherlands, Central America (Costa Rica, Panama, El Salvador and Guatemala)
AGLA risk score (ARS)	A PROCAM-derived Swiss risk score	Switzerland
New Zealand risk score		Australia, Switzerland and New Zealand
Framingham - REGICOR	Registre Gironi del cor – a Spanish adaptation of the Framingham study	Spain
JBS risk calculator	Joint British societies for the prevention of cardiovascular disease risk calculator	Australia, United Kingdom, Brazil, United States of America, Greece, Chile, Venezuela, Portugal, Germany, The Netherlands, Central America (Costa Rica, Panama, El Salvador and Guatemala) and Egypt
WHO/ISH cardiovascular risk prediction charts	The World Health Organisation and the International Society of Hypertension	Argentina, Egypt and Jordan
QRisk		United Kingdom and Egypt

4.5.2 Quality assessment of included studies

The response rates of all but one of the quantitative studies, a study by Tawfik et al. (2015), were inadequate – only two studies had a response rate above 50% (133). No information about non-responders was described in any of the studies. Of the 12 studies, only six reported how ethical approval or consent of the participants was attained.

Of the nine qualitative studies, eight had an overall rating of good (++) according to the NICE qualitative appraisal tool. This rating meant that most of the checklist criteria had

been fulfilled and where they had not been fulfilled the conclusions were very unlikely to be altered.

Two out of the four mixed-methods studies scored 100% (****) on the MMAT appraisal tool. The other two scored 75% (***): studies by Kirby et al. (2009) and Oriol-Zerbe et al. (2007) did not consider how the findings related to the researcher's influence in the interactions with the participants. A summary of the quality appraisal of all the included studies is available in Appendix 10.

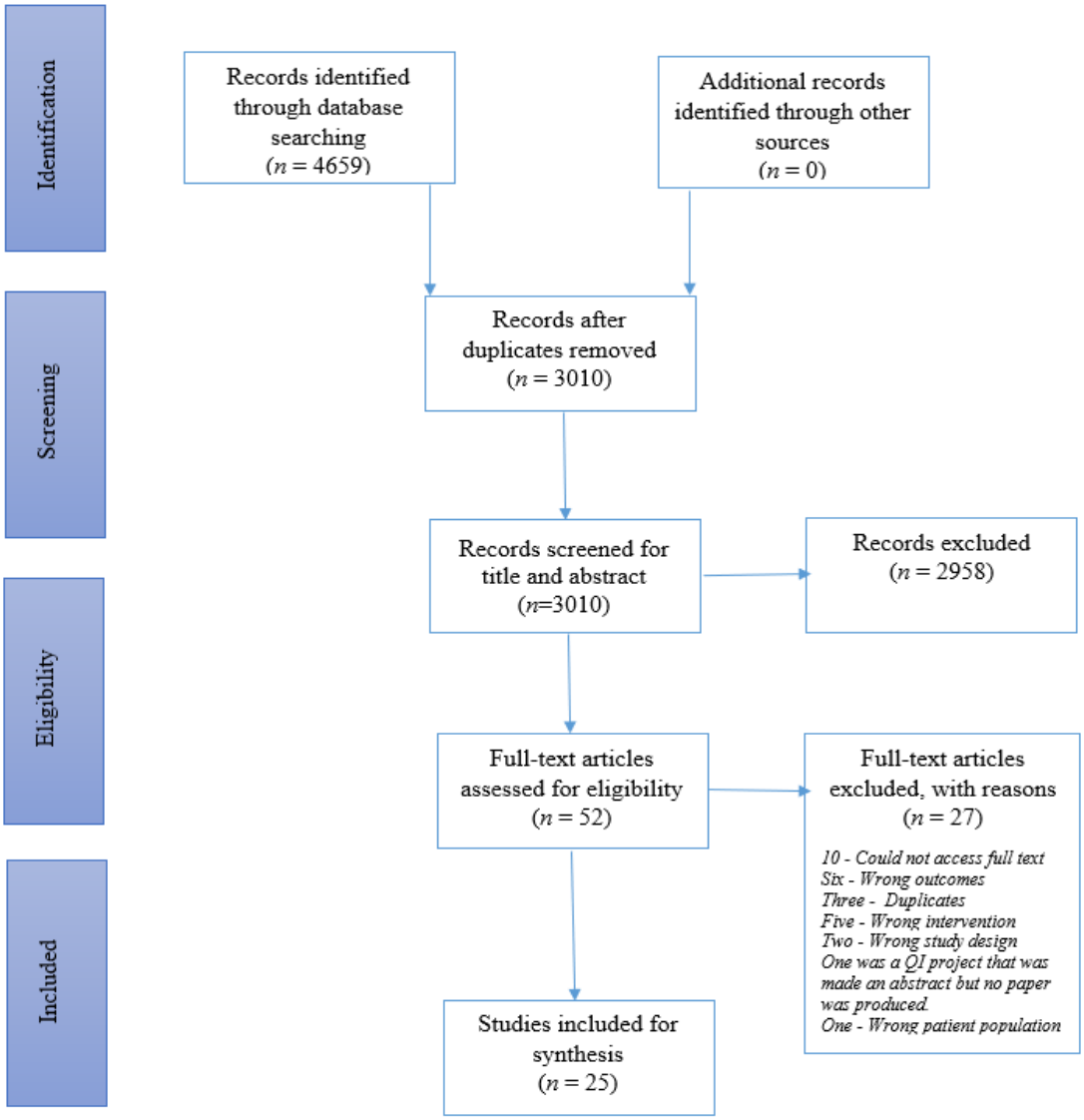


Figure 10. PRISMA flow diagram for the systematic review

4.5.3 Factors that influenced the implementation of cardiovascular risk scoring in primary care

Four overarching constructs - the healthcare system and clinical setting, the users of cardiovascular risk scoring tools and the tools themselves - were identified (see Figure 11). The presentation of these results in this format should not suggest that each construct and underlying factor exists in isolation. These constructs and underlying factors interact in rich and multifarious ways to influence implementation effectiveness. This review suggests that these factors have porous boundaries. The knowledge and

understanding of cardiovascular risk, CVD and its management was a primary influence across these three overarching concepts.

We have presented these factors against the backdrop of the five domains of the CFIR. A summary of the CFIR coding framework and the contribution of the included studies to key concepts and synthesis are presented in Appendix 11.

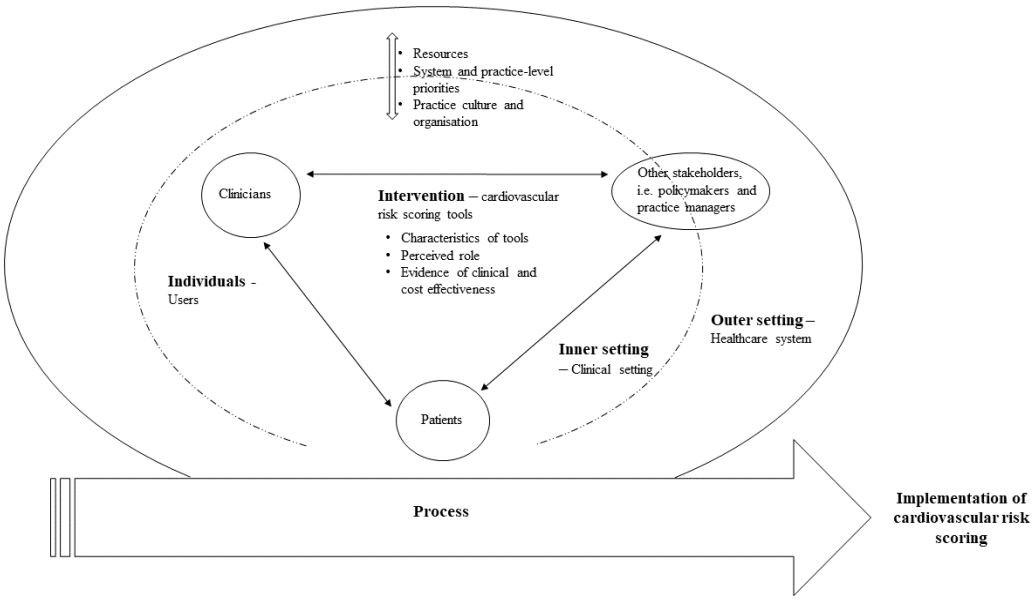


Figure 11. Factors that influence cardiovascular risk scoring in primary care settings

4.5.3.1 The healthcare system and clinical setting

The factors that emerged within this construct included resources, system and practice-level priorities, the practice culture of the clinical setting, and how the practice was organised.

4.5.3.1.1 Resources

Physical and human resources acted as facilitators or barriers to cardiovascular risk scoring in primary care settings. An adequately resourced health system with a dedicated budget for the prevention of CVD was viewed as a facilitator (134). However,

most studies, regardless of setting, reported that there was a lack of adequate resources to support cardiovascular risk assessment (135–137). There was a lack of health information systems, lack of equipment to measure all the risk factors, and a scarcity of human resources due to staff shortages and high workload. The lack of health information systems and equipment was only reported in middle-income countries at the lower end of the scale (138).

4.5.3.1.2 System and practice-level priorities

In healthcare systems in which prevention of CVD was not prioritised, cardiovascular risk scoring was implemented sub-optimally (135,136,139). This was both in high and middle-income countries. However, for middle-income countries, one reason that was given for not prioritising prevention was that the healthcare system was satisfying a higher demand for 'more urgent' social and health problems (135,136). This shifted the priority away from primary prevention and chronic condition management. Furthermore, in some settings in which prevention of cardiovascular disease was a priority, conflict was endemic in deciding to whom this mandate belonged, i.e. clinicians or local authorities (140).

4.5.3.1.3 Practice culture and organisation

Practice culture and organisation encompassed a set of routine activities that were characteristic of a healthcare system or clinical setting. The shifting and reallocation of tasks, and sharing in GP practices, helped to focus tasks into either risk assessment or risk management, which necessitated the use of cardiovascular risk-scoring tools by clinicians (134). GP practices that had existing cardiovascular prevention care programmes and pathways took up cardiovascular risk scoring (134). To ensure efficient conduct of these prevention activities, adequate organisation of them was

important, i.e. appropriate staff were required to run them and they had to be held close to the clinical settings, for the ease of the clinician and the patients (134,139).

The practice of defensive medicine, which is a practice by which clinicians recommend tests or treatments that are not necessarily the best option for the patient but act as protection of the clinician against liability, was a barrier to the use of cardiovascular risk scoring (140). Another barrier was the presence of disruptive professional hierarchies (140). Specialists or clinicians who ranked high in the practice were held in high regard even when they did not adhere to guidelines such as those that mandated cardiovascular risk scoring. This set a precedent for practice in the clinical setting, which junior clinicians did not feel empowered to question or disrupt. Also, lack of collaboration between healthcare workers and administrative staff, either due to increased workloads or a lack of communication, threw up obstacles to the use of cardiovascular risk scoring (138). This practice of defensive medicine and the presence of disruptive professional hierarchies were only reported in the studies of HICs. On the other hand, lack of collaboration between healthcare workers and administrative staff was reported only in the studies of countries in the low strata of middle-income countries.

4.5.3.2 The users

The attributes of the users of the risk-scoring methods (direct and indirect) and the interactions between those involved in the use of the risk scoring were given in the studies.

4.5.3.2.1 Attributes of the users

The review explored the characteristics of clinicians, patients and other stakeholders that influenced the use of cardiovascular risk scoring. These characteristics acted as

either facilitators or barriers in various settings. For both patients and clinicians, the perception and understanding of cardiovascular risk, CVD and the management of both were significant drivers of the practice of cardiovascular risk scoring (133,135,136,139,141–144). In most studies and among both clinicians and patients, there was an indication that cardiovascular risk, its assessment and management was marred by negative perceptions that were unsupported by evidence. For example, both clinicians and patients reported an understanding of cardiovascular risk that was focused only on individual risk factors.

Personal circumstances and experiences of patients also influenced the uptake of cardiovascular risk scoring (134). These circumstances and experiences included the environment in which the patients lived, their socioeconomic standing, their fears, motivations and expectations of cardiovascular risk assessment, and the support available (134,135,139,143,145). Patients who lived in surroundings that were not conducive to making lifestyle behavioural adjustments were not keen on being assessed for cardiovascular risk. Those who had shared experiences of loss of a family member or loved one through a cardiovascular fatality reported being open to routine risk assessment. In lower-middle income countries, patients reported that they were unable to afford risk-assessment procedures and consequent management in terms of both pharmacological and lifestyle adjustment (135). The patients' priorities, which were set either by the patients or the clinicians, leaned towards what was considered 'urgent for the patient'.

In many cases, cardiovascular risk scoring was not viewed as urgent enough in this hierarchy (136,139,146). However, some patients demanded that they be assessed for cardiovascular risk and this facilitated cardiovascular risk scoring (141,143,145).

Conversely, there were instances in which patients demanded treatment regardless of their cardiovascular risk. This was a barrier to cardiovascular risk scoring (135,143).

The lack of knowledge regarding how to use cardiovascular risk tools was unique to clinicians (135,137,147). This was complicated by factors such as the lack of sufficient knowledge of cardiovascular risk and disease, and the role that cardiovascular risk scoring could play in informing the management of the condition. Other complicating factors included the need to treat patients of advanced age (137,147,148). Clinicians also expressed their difficulties in communicating cardiovascular risk scores to their patients after the risk assessment. This was coupled with challenges in offering prevention and self-management aids to patients (134). There was also a general lack of motivation to use cardiovascular risk scoring tools (138). However, knowledge about the tools and their benefits in clinical practice, such as improvement of care and of therapeutic decision making by clinicians, facilitated the use of these tools (133,135,136,141,144,147–150).

Stakeholders, i.e. decision-makers, who included policymakers and practice managers, were also reported to lack interest or have conflicting views regarding the prevention and management of cardiovascular risk (139,150,151). These conflicts revolved around whether prevention and management of cardiovascular risk was a priority, and whose priority it was in the clinical setting. They lacked consensus on the use of risk-scoring tools and the processes they used in the clinic were not suitable for continual review of risk-scoring tools that would be used in practice (139). In lower-middle income countries, stakeholders were reported to have a disruptive influence on the prevention and management of cardiovascular risk. In some cases, clinicians perceived that

stakeholders in health authorities intended to ‘misuse’ the tools that were used for cardiovascular risk scoring (152).

4.5.3.2.2 Interactions between the users

The existence of a supportive and longstanding relationship between the clinician and patient facilitated the use of cardiovascular risk scoring (153). Clinicians felt that ‘floating’ patients already had regular doctors who should take responsibility for CVD prevention; the clinicians were only interested in dealing with the patient’s immediate complaint. Interaction between clinicians and other stakeholders was at a policy level only. There was no consensus on the use of these tools, which was partly explained by the lack of communication and clinician involvement in decision making (139).

4.5.3.3 Cardiovascular risk-scoring tools

These tools varied in complexity, design and packaging. For example, some of the tools were presented as risk tables, calculators or charts; some involved the coding of risk levels by colour or percentage and others were designed for specific countries or regions. It is important to note that close to half (*n*=5) of these tools, though designed for specific geographical regions and populations, were often used outside these jurisdictions (Table 8).

The factors that influenced the performance of cardiovascular risk scoring were linked to the characteristics of the tools, the perceived role of the tools in clinical practice and the evidence of their efficiency and effectiveness.

4.5.3.3.1 Characteristics of the tools

The use of charts, calculators and colour codes was reported to facilitate cardiovascular risk scoring due to the perceived ease of use. The incorporation of these tools into existing clinical systems as software or web-based applications was also facilitative

(134,135,138,152). However, some participants in the studies reported that these tools were complex to use and to explain to patients and that there were technical problems associated with them (139,141,148,154). For example, some of the tools did not communicate with other clinical programs. Many of the studies, irrespective of the type of tool used, reported that the participants found these tools time-consuming, which led to prolonged and low-quality consultations (135,137,140,152). Other studies pointed out that the tools became outdated rapidly and consequently did not include all the important risk factors that were required for assessment of cardiovascular risk (136,143,147).

4.5.3.3.2 The perceived role of the tools

Similarly, the perceptions of the roles of these tools in clinical practice acted as both facilitators and barriers. For example, clinicians who used the tools saw them as helpful for them to understand the patients' level of risk, to motivate patients, to improve follow up, to educate patients, and as a checklist for risk assessment (135,137,145,146,153,155–157). However, other clinicians did not use the tools because they viewed cardiovascular risk scoring as an intervention that over or/and underestimated risk, and therefore use of the tools would lead to therapeutic inaccuracies. These tools were also perceived to interfere with the clinician's decision-making process (148). This, perhaps, related to clinicians considering these tools to be inferior to their clinical judgement (158–160).

4.5.3.3.3 Evidence of clinical and cost-effectiveness

Unclear prediction rules formed a barrier to the use of cardiovascular risk-scoring tools, as this was associated with prediction inaccuracies (135,137,144–146,153,156,161). However, clinicians were more likely to use them if they were provided with evidence

that these tools were accurate in the prediction of risk, that they included the main risk factors for CVD and that their use led to improved therapeutic decisions (135,137,144,150,153,156,161). Lastly, in some studies, there was uncertainty regarding the role of cardiovascular risk scoring in reducing health costs in healthcare systems. This, too, influenced use and implementation both at a policy and practice level.

A summary of these factors that influenced use of cardiovascular risk scoring in primary care, categorised as facilitators or barriers, is presented in Table 9.

Table 9. Facilitators and barriers to use of cardiovascular risk scoring in primary care

CFIR domains involved	Factors that influence use of cardiovascular risk scoring in primary care		Facilitators	Barriers
Outer setting **Inner setting** **Process**	Healthcare system and clinical setting	Resources	Adequately resourced healthcare systems with dedicated funding for the prevention of CVD	Staffing shortages that result in high workload, inadequate or no budget for preventive services, lack of health information systems, lack of equipment to measure all the risk factors essential for risk scoring
		System and practice-level priorities	None reported	Prevention not prioritised for practice in health systems
		Practice culture and organisation	Supportive prevention care programmes and pathways, task shifting, reallocation and sharing, having the appropriate individuals involved in prevention activities	Lack of interest and motivation to engage in preventive services, the practice of defensive medicine, a lack of collaboration between health workers and other staff, presence of disruptive professional hierarchies
Individuals **Process**	Users	Attributes of the users	Patients: knowledge and understanding of cardiovascular risk, disease and management, reinforcing personal circumstances and experiences, support from family, patients' demands and knowledge of their rights	Patients: complex patients (comorbidities and advanced age), patients who do not want to know their cardiovascular risk, negative perception of risk assessment, lack of knowledge of cardiovascular risk, disease and its management, patients' health priorities, undermining personal circumstances, experiences and demands, surrounding environment, socioeconomic factors, fears and expectations of risk assessment Clinicians: negative perception of risk assessment, inadequate knowledge of cardiovascular risk, disease and its management, lack of knowledge on how to use cardiovascular risk-scoring tools, lack of motivation to use these tools, difficulty in communicating cardiovascular risk to patients, challenges in communicating prevention and self-management aids to patients

			Clinicians: knowledge and understanding of cardiovascular risk, disease and management, knowledge of the benefits of cardiovascular risk scoring regarding patient care and therapeutic decision making	Other stakeholders: perceived interference and misuse of cardiovascular risk scoring as an intervention, lack of consensus on the use of risk-scoring tools, general lack of interest, conflicting interests and poor tool-reviewing processes
		Interaction between the users	A supportive and longstanding relationship between the clinician and patient	Lack of communication and involvement in decision making between clinicians and other stakeholders
Intervention Process	Cardiovascular risk scoring tools	Characteristics of the tools	Easy to use, use of charts or calculators, presentation of risk scores as colour codes instead of percentages, incorporation of risk tools into clinical systems as programmes or software	Outdate rapidly, time-consuming leading to prolonged consultations, reduce the quality of the consultation, do not include all the principal risk factors, the risk period calculated is too long, complex to use and explain to patients, have technical problems and do not communicate with other programs
		The perceived role of the tools	Supportive role to clinical practice, i.e. to help understand risk, motivate patients, improve follow up, educate patients and serve as a checklist for risk assessment	Over and underestimate risk leading to over or under treatment, they interfere with the clinicians' decision-making process, they are inferior to clinical judgement
		Evidence of clinical and cost-effectiveness	Provision of evidence that these tools are accurate in predicting risk, that they include the main risk factors for CVD and that they lead to better therapeutic decisions	Their use does not contribute to reductions in healthcare costs. Unclear prediction rules associated with prediction inaccuracies

4.5.4 A summary of additional analysis

4.5.4.1 Variations across GNI classifications

Many of the factors that were found to influence use of cardiovascular risk scoring were similar across GNI groups. Nevertheless, two salient barriers were reported only in lower-middle-income countries; the disruptive influence of stakeholders and the inability of patients to afford some of the investigations that were essential to risk scoring.

4.5.4.2 Variations between patients and clinicians

For both clinicians and patients, knowledge and understanding of cardiovascular risk, CVD and their management acted as both facilitators and barriers to use of cardiovascular risk scoring. However, some factors were specific to either patients or clinicians. The factors that were attributed to patients were more diverse in that they were not confined to the clinical setting as they were in the clinicians' case. Among patients, these factors included their circumstances and experiences, familial relations, awareness of their rights to health, their priorities, socioeconomic factors, emotions and their relationships with the clinicians. As for clinicians, the factors included the clinicians' perceptions of the role of the risk-scoring tools in the context of their practices and their abilities in the delivery of care.

4.5.4.3 Variations across physicians, non-physicians and other stakeholders

For clinicians, i.e. physicians and nurses, the facilitators and barriers to use of cardiovascular risk scoring were similar and spanned the overarching concepts of cardiovascular risk-scoring tools, users, the clinical setting, and the healthcare system. For non-clinicians, two salient barriers were reported; the lack of collaboration between

clinicians and non-clinicians, and the non-prioritising of prevention and management of cardiovascular risk in the clinical setting and health-care system.

4.5.4.4 The appropriateness of the CFIR to the review

In addition to the a priori themes that were set out in the CFIR, one new theme emerged from the synthesis; *knowledge and beliefs about disease and risk.* This was classified under the domain entitled characteristics of individuals in the CFIR. This, perhaps, highlights the vital difference between individuals who have sufficient knowledge about an intervention and those who have adequate knowledge of the disease, its aetiology and risk factors.

4.5.4.5 Confidence/certainty of the review findings – qualitative synthesis

Appendix 12 presents a summary of the qualitative findings with their CERQual evidence profile and confidence assessments. All the findings in this synthesis were assessed as being of moderate or high confidence. The attributes of the users of the cardiovascular risk-scoring tools and their characteristics were assessed as high in confidence.

4.6 Discussion

4.6.1 Summary and interpretation of findings

This synthesis aimed to gather current knowledge on the factors that influence the implementation of cardiovascular risk scoring as a CVD prevention strategy in primary care settings. The synthesis broadly conceptualised these factors into those that related to cardiovascular risk tools, users, clinical settings and healthcare systems.

This review adds to the understanding that the implementation of an intervention is affected by its interaction with the real world in terms of the users and the environment in which it is used (162). The review shows adequately that the factors influencing use

of cardiovascular risk scoring are intricately related and that no single factor is identifiable as a more influential facilitator or barrier. For example, not prioritising prevention in a healthcare system may inform the allocation of resources in these settings. At the user level, the users' attributes, i.e. their perceptions about cardiovascular risk scoring, may inform their interaction with the tools and in turn, influence uptake. These perceptions may be informed by the users' knowledge, skill levels, personal circumstances, experiences, socioeconomic statuses, fears and expectations. An important note was the elucidation that the users of an intervention comprised various people who could be classified as having either a direct or indirect interaction with the tool – i.e. clinicians, patients and other stakeholders. These users were equally important in understanding with whom to engage when an intervention was implemented.

The review also places the importance of tool design and quality at the centre of the implementation process. The tool's assembly and presentation must be appropriate for its users. Notably, there was a lack of research from low and middle-income countries. This may be because these tools are sub optimally used in these settings, as reported in a global surveys conducted by the WHO in 2015 and 2019 (74). Further, the findings of this review support the use of the CFIR as an a priori framework for implementation-driven research.

4.6.2 Findings in context

The findings of this review support the understanding that there are numerous obstacles to the implementation of targeted risk-reduction interventions such as CVD risk scoring. Other studies have broadly highlighted these obstacles to include patients, clinicians, healthcare organisations, socioeconomic barriers and policies (163). These

barriers to implementation may partly explain the commonly observed suboptimal control of cardiovascular risk factors, especially in high-risk patients (155,164).

Various forms of resources, i.e. fiscal and human, are vital in the implementation process (165). Scarcity in either leads to the disruptive practice of prioritising curative care over prevention (166). Consequently, essential tasks such as educating patients on risk and self-management have taken a back seat. Efforts to counter this inadequacy have been successful through use of innovative practices such as sharing and shifting of tasks (155,167). Some countries have recognised community health workers as principal and resourceful caregivers and have placed them at the forefront of prevention efforts in communities (157,163,168). However, this should not detract from the central fact that healthcare systems should focus on the building of structural and human infrastructure in support of preventive medicine in primary-care settings. The presence of supportive software programs and pathways such as health-information systems in clinical practice has been shown to support the use of risk scoring in the prevention of CVD (169,170). Conversely, in acknowledging the complexity that healthcare systems posit, some findings have also shown that adequately resourced systems do not necessarily lead to positive implementation outcomes. This aptly brings out the complex nature of implementation processes (171).

Users' attributes, i.e. their knowledge, skills and perceptions, were seen in this review to play a vital role in realising the use of cardiovascular risk scoring. This is not surprising, as many other studies have reported that primary care health workers often report that they lack the skills to manage cardiovascular risk (165,166). Patients' understanding of cardiovascular risk has been associated with their socioeconomic status and level of education (172,173). There is a positive association between the level

of knowledge of CVD and its risks with the use of cardiovascular risk scores (174). However, it is generally reported that clinicians find it challenging to communicate risk to their patients (171,175–178), and communication of cardiovascular risk is no different (134). This is notwithstanding that risk-scoring tools have been credited with assisting clinicians in better relaying risk messages (179–181). Communication of risk to patients has been lauded in improving cardiovascular risk outcomes in asymptomatic patients (182).

The role of risk scoring in clinical practice is the subject of ongoing debate. Many studies in this review reported that the use of risk scores was time-consuming and led to prolonged and consequently reduced-quality consultations. However, numerous studies have shown that the general use of personalised risk estimates adds value by improving patients' satisfaction levels and strengthening the intention to change behaviour (174,183,184). It is unclear what role clinical judgement takes in the use of risk-scoring tools, as many clinicians regard these tools as inferior to their clinical judgement. However, evidence from various studies has shown that there is a significant mismatch between the cardiovascular risk to a patient that is estimated by a clinician and that assessed through use of risk-scoring tools, especially in high-risk patients (160,166). This, necessitates the need for the existing assessment system and management algorithms for CVD (185,186). Equally, although these guidelines are known to clinicians, studies have shown that they are consistently not implemented in practice (187); perhaps because the clinician may understand probabilistic risk information, but that does not necessarily influence the clinician's decision making or practice (188).

The efficacy of cardiovascular risk-scoring tools that has been shown in systematic reviews indicates that provision of cardiovascular scores is beneficial in a reduction of levels of cardiovascular risk factors (57,62). However, there is still no evidence that the use of these tools influences mortality outcomes. This lack of evidence has been a significant barrier to influencing the uptake of these tools by clinicians. Some of the challenges of showing association between the use of these tools and terminal outcomes such as mortality may be tied to the challenges of implementation (189). Issues regarding the technical complexity of the risk-scoring tools have been addressed through changes in design and packaging - the use of charts and tables in settings that do not have computer connectivity and the use of embedded software programs in settings with existing, electronic health information systems (148,190). However, there is a need to train system users and retrain frequently to keep up with the dynamism of these tools (191).

While acknowledging that healthcare systems vary greatly, one commonality of these systems is their effort to deliver affordable, cost-effective and good-quality care. Patients have emphasised their inability to afford some of the laboratory-based investigations that are used in cardiovascular risk scoring in resource-limited healthcare systems (152). However, organisations such as the WHO have provided affordable solutions through the simplification of risk assessment and management in these settings through the provision of tailor-made packages (1,43,190).

4.6.3 Strengths and limitations

This review was strengthened by its methodology, which was of a design that adequately addressed the burgeoning gap between research and practice by providing actionable outcomes of direct relevance to policy and practice (192). An exhaustive

search was undertaken; however, it is possible that some primary studies were missed for various reasons, such as lack of publication. This may introduce publication bias.

Most of the studies (80%) that were included in this review were from HICs. Very few studies were from LMICs. Therefore, caution should be taken when attempting to apply these findings to these settings. Lastly, mixed-methods systematic reviews of this kind are an emerging methodology and consequently, have limited methodological literature (124).

4.6.4 Implications for research and practice

Whilst this review found a small but good-quality evidence based on current knowledge of the factors that influence the implementation of cardiovascular risk-scoring in primary care settings, these were limited to HICs and targeted research is needed in LMICs. Across settings, there remains the need for high-quality evidence for the prospective use of cardiovascular risk-scoring tools on health outcomes. This could take the form of hybrid effectiveness-implementation designs that combine the elements of clinical effectiveness and implementation research to enhance public health impact.

4.7 Conclusion

This review reinforces the understanding that implementation processes are complex. In order to achieve favourable implementation outcomes, acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, coverage and sustainability, policymakers and implementation practitioners must be willing to engage with the various rudiments that have been put forward in this review. These rudiments involve the gathering of enough understanding of the intervention, the environment, the users and their various interactions with all of the above. While these findings bolster the understanding of implementation complexity, there exists limited research in the

context of LMICs. Notwithstanding the need to direct resources in bridging this gap, it is also crucial that these efforts are in concert with the provision of high-quality evidence on the clinical effectiveness of the use of cardiovascular risk scoring to improve CVD mortality and morbidity outcomes.

4.8 Chapter summary

- Factors that influence the implementation of cardiovascular risk scoring in primary care settings reinforce the general understanding that implementation processes are complex, intricately related and dependent on context;
- this synthesis conceptualises four factors that influence the implementation of cardiovascular risk scoring in primary care settings; those relating to cardiovascular risk tools, users, the clinical setting and the healthcare system;
- research on the use of cardiovascular risk-prediction tools is needed in LMICs in the form of hybrid effectiveness-implementation designs that combine the elements of clinical effectiveness and implementation research to enhance public health impact; and
- a mixed-methods approach enabled the placement of the findings in existing theories of implementation science while adequately accommodating an inductive interpretation of data.

Chapter 5. **Understanding current practice and the factors that influence the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care**

5.1 Introduction

The work that is described in this chapter addressed some of the gaps that were raised in Chapters 2 and 4. Chapter 2 highlights the progress that has been made regarding CVD risk prevention and management globally, i.e. availability of evidence-based and cost-effective interventions for use both at a population level and in primary healthcare. The majority of the research on these interventions, such as CVD risk scoring, has been conducted in the global north (HICs). There is limited knowledge regarding how patients at risk of CVD are identified, stratified and managed in resource-limited settings. The factors that might influence the adoption of the recommended practices and the utility of these interventions is also unknown. For example, the work described in Chapter 4, which explored the use of CVD risk scoring in primary care, added to the understanding that the implementation of targeted risk interventions such as CVD risk scoring is complex and is often affected by its interaction with the users and the environment in which it is being used. Notably, this chapter also illuminated the lack of implementation research from LMICs.

The work that is described in Chapter 3 suggested that 11.9% of the Kenyan population (those with a CVD risk above 10%) could be eligible for pharmacotherapy and lifestyle interventions to mitigate CVD risk. Public primary-care facilities are a critical entry point for targeted screening and the delivery of interventions for CVD risk prevention and management. Chapter 3 concludes by recommending that future research should focus on three concerns: understanding current practice in the prevention and management of CVD risk to incorporate CVD risk screening fully in these settings;

designing improved measurement systems and tools that adequately capture the population's behavioural CVD risk characteristics; and a need for more contextual research on interventions that address local socio-political determinants of health in Kenyan primary-care settings.

In January 2019, I travelled to Kilifi County, Kenya, to collect qualitative data that would provide insight into the current practice in the prevention and management of CVD risk in Kenyan primary-care facilities and identify the factors that influenced adoption of the recommended practices.

5.2 Aim and objectives

5.2.1 Aim

Through this study, I aimed to:

1. examine current practice by understanding how prevention and management of CVD risk was experienced by policymakers, clinicians and patients in everyday clinical practice; and
2. identify contextual factors that influenced the adoption of recommended practice for CVD risk assessment in Kenyan primary-care facilities.

5.2.2 Objectives

The objectives of this study were to:

1. Observe, record and describe current practice based on key clinical practice behaviours in CVD risk prevention and management;
2. use the capacity, opportunity, motivation and behaviour (COM-B) framework to explore how prevention and management of CVD risk is experienced by policymakers, clinicians and patients in everyday clinical practice; and
3. identify contextual factors that influence the adoption of the recommended practice in the assessment and management of CVD risk in these settings.

5.3 Methods

5.3.1 Setting

The study was conducted in Kilifi County, Kenya. Kilifi County covers a geographical area of 12,610km^2, with an estimated population of 1,453,787 (7). A significant proportion (48%) of the population is below 15 years of age, and the youth population (15-24 years) makes up 19% of the population. Those aged between 25 and 59 years make up 28% of the population, and those of 60 years and above comprise 5% of the population.

The county is divided into seven sub-county units. It has 132 primary-care facilities, which are run by the Ministry of Health. These comprise dispensaries, health centres and primary-care referral facilities (193).

5.3.2 Study design

A qualitative study design that utilised a single case with embedded units' approach was used. The overarching case was the primary-care arm of the health services. The embedded units were the various levels (2 to 4) of primary care: dispensaries, health centres and primary referral facilities (Figure 12). This approach guided data collection and analysis by informing exploration within and across units.

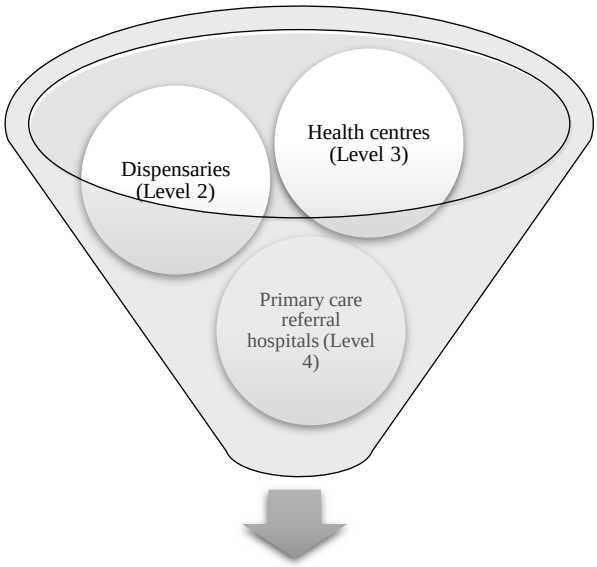


Figure 12. Illustration of the single case with embedded units' approach

5.3.3 Participants and recruitment

Seven facilities were selected using a stratified purposeful sampling approach (Figure 13). The selection was based on the facility's administrative unit, care level, and operational status. This information was available through the Kenya Master Health Facilities List (194). The participants included patients who sought care at a primary-care facility, clinicians (e.g. nurses, clinical officers and doctors) in primary-care facilities and policymakers (e.g. those involved in the organisation and administration of health services) at county and national level. An eligibility assessment for these participants was carried out before recruitment (Table 10).

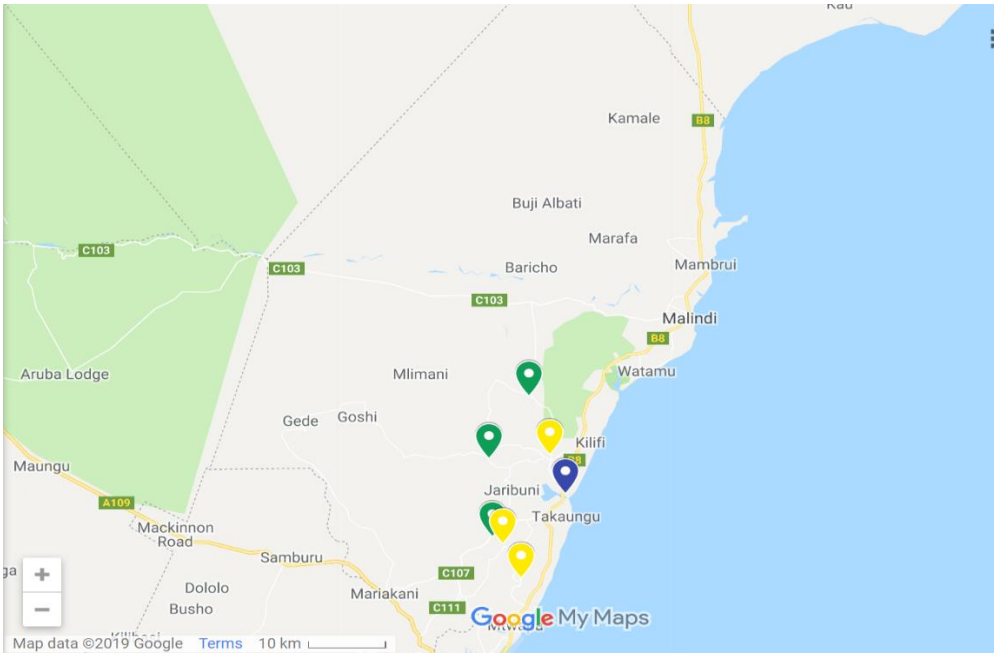


Figure 13. Map of the study sites

Participant information sheets were then given to the clinicians in the selected facilities, which enabled recruitment. Subsequently, patients who attended the selected facilities were informed about the study by the facility manager during routine morning health talks. These health talks take the form of 20- to 30-minute conversations that are held before morning consultations start, in order to promote health and to create awareness of various health conditions. After these health talks, the fieldworker and I provided verbal explanations to the patients in the waiting bay about the research, its importance and my desire to recruit participants. If needed, a verbal explanation was also provided individually. Those who were interested and eligible were recruited and their written, informed consent was sought.

Policymakers were selected using purposeful and snowball sampling approaches. They were recruited at the county and national levels via email and follow-up telephone calls; the email included a participant information sheet with the researcher's contacts. Those

who were interested were informed about the study in detail and their written consent was sought.

Table 10. Inclusion and exclusion criteria for the field study in Kilifi County

Participants	Inclusion	Exclusion
Policymakers	Aged 18 years and above Responsible for or involved in formulating healthcare-related policies at county or national level Willing and able to give informed consent	Those without a clinical background, i.e. not registered as healthcare professionals with the appropriate professional regulating body
Healthcare professionals and line managers	Aged 18 years and above Registered to practice as clinical officers, nurses or medical officers by the respective professional regulating body Currently working in a primary-care facility Willing and able to give informed consent	Those not registered with the appropriate professional regulating body
Patients	Aged 30 years and above Attending a primary-care facility Requiring consultation with a healthcare professional Willing and able to consent	Those with a known CVD (this does not include the presence of a risk factor, i.e. hypertension) Those on medication to manage CVD

5.3.4 Data collection and management

Data collection started at the lowest level of care (dispensaries) and ended at the highest level of care (primary referral hospital). Data collection methods included participant observations, interviews and a review of policy documents regarding CVD prevention and management both at the study sites and in literature, i.e. the Kenya National Guidelines for Cardiovascular Disease Management (2018). The data collection process started through the conduct of observations and reviews of relevant documents at the study sites. Data that were collected through these two methods were used iteratively to refine the content of the semi-structured interviews. The use of these three methods enabled triangulation to seek convergence and corroboration (195).

5.3.4.1 Participant observations

The observation of participants during consultations enabled the recording of the space, people, language, interactions and activities that were related to the prevention and

management of cardiovascular risk. In particular, this involved my presence in the consultation room to observe the consultation between the clinician and patient. If my presence made the patient feel uncomfortable, this was imparted either by the patient verbalising discomfort or if the clinician sensed discomfort in the patient and let me know. In either case, I left the room. I also left the room if there was a need for a physical examination by the healthcare professional. The patient's comfort as the top priority during the consultation was reiterated and reinforced before the consultation. At the end of the consultation and in a separate room, patients were asked about their experience of the consultation regarding cardiovascular risk assessment and management, and their response was recorded as field notes. Patient exit interviews were important in understanding and situating observational data.

In an attempt to mitigate observer effects, which would have been exhibited as a change of behaviour that resulted from the knowledge of being observed, rapport was built by performance of repeat and progressively longer observations per facility instead of one-off sessions (196,197). Besides, building rapport and lengthening observations in each facility enhanced the understanding and interpretation of participants' performances, whether staged or influenced by me as the observer. Observations were recorded as unstructured field notes and then summarised on a summary template form. This was based on the literature on writing field notes (198). This template form contained semi-structured sections that captured the time and place of the observation, a short description of the situational context (space, people, language, interactions and activities) and a guided notes/comments section, the design of which was based on the Kenyan guidelines for CVD management (25) [Appendix 16].

As a result, in addition to qualitative data, these observations and patient exit interviews led to the generation of descriptive data that were related to the observed practice in CVD risk assessment, classification of blood pressure measurements, availability of human resources for CVD care, availability of diagnostic equipment and medications that were offered for CVD care.

5.3.4.2 Semi-structured interviews

Interviews involved clinicians who worked in the selected facilities, and key informants such as line managers and policymakers at the county and national levels. The individual, semi-structured interviews were conducted in the workplace but in locations that ensured confidentiality (e.g. office). These interviews were conducted after obtaining written informed consent and lasted for 30 to 45 minutes. There were no prior relationships with the interview participants. Interviews were recorded using an audio recorder, transcribed verbatim by a professional transcribing service and stored in encryption-enabled, password-protected computer and storage devices.

All data were anonymised and de-identified by giving each a generic label based on the participant's role, the KEPH level of care or jurisdiction (e.g. nurse 1/level 3, policymaker 2/county level). If a category had only one participant, an aggregated generic category was created to protect the participant’s identity.

Through these semi-structured interviews, the researcher sought to understand current practice in preventing and managing cardiovascular risk in these settings. The interviewer's guide can be found in Appendix14.

5.3.4.3 Document review

Policy and legislation documents, health promotion materials and clinical practice guides that were related to cardiovascular risk prevention and management at the study

sites and the national level were collected. These data were collected in tandem with the performance of participant observations before the start of the interviewing process.

Access to the collected data was granted to authorised representatives from the University of Oxford, and the KEMRI-Wellcome Trust research programme as described in the protocol, which was approved by review boards of the Oxford Tropical Research Ethics Committee and the KEMRI Scientific and Ethics Review Unit (Appendix 18).

5.3.5 Data analysis

Data that were collected were analysed, separately, in line with the two objectives of the study. The analytical approach is described in the next sections.

5.3.5.1 Objective 1: to describe and understand current practice in the assessment and management of risk of CVD

Thematic analysis was used because of its potential to provide a rich and detailed, yet complex, account of data. This was made possible due to the approach's theoretical freedom, rigour and flexibility (199–201). The aim was to identify, analyse and report patterns within the data that were collected, based on the explicit meanings of data. The analysis was inductive and recursive; themes that were identified were data-driven and strongly linked to the data themselves.

This analytical approach followed these six steps (202).

i. *Familiarisation with the data* – data were read and re-read by me and a second analyst. This step was used to familiarise me with the various data forms that were collected, check the accuracy of the transcriptions, and note down initial ideas for analysis.
ii. *Organisation of the data* – this step was based on the overarching research question and the interesting features that were found across the data (203).

This organisation of data was divided into four domains that were based on the recommended practice in CVD risk prevention and management: identification, stratification and management, while a miscellaneous domain was added to capture vital information that was not incorporated into the outline. Each of these domains had four categories: provider's context, patient's context, policymaker's context and document review context. The description of these categories is provided in Table 11. This outline was piloted by application to three observations, three interviews and documents that were reviewed from one site, independently and in duplicate, using NVivo 12.

Table 11. Outline for data organisation

Domain	Category	Description
Identification	Provider's context	The circumstances of the provider that inform how they identify patients at risk of CVD
	Patient's context	The circumstances of the patient that inform how they are identified as being at risk of CVD
	Policymaker's context	The circumstances of the policymaker that inform how patients at risk of CVD are identified
	Document review	The direction given in the documents on how patients at risk of CVD are to be identified
Stratification	Provider's context	The circumstances of the provider that inform how they stratify patients at risk of CVD
	Patient's context	The circumstances of the patient that inform how they are stratified as being at risk of CVD
	Policymaker's context	The circumstances of the policymaker that inform how patients at risk of CVD are stratified
	Document review	The direction given in the documents on how patients at risk of CVD are to be stratified
Management	Provider's context	The circumstances of the provider that inform how they manage patients at risk of CVD
	Patient's context	The circumstances of the patient that inform how they are managed when at risk of CVD
	Policymaker's context	The circumstances of the policymaker that inform how patients at risk of CVD are managed
	Document review	The direction given in the documents on how patients at risk of CVD are to be managed
Miscellaneous	Provider's context	Any noteworthy text that did not appear to fit into one of the above codes
	Patient's context	
	Policymaker's context	
	Document review	

iii. *Coding* – the outline in Table 11 was used to code the remaining observations, interviews and document reviews. Coding was done independently and in duplicate with discrepancies resolved through consensus. During the entire coding process, memos were used to clarify codes and to keep track of ideas and impressions.

iv. *Generation of potential themes* – the codes were then collated into potential themes. Themes were checked through a thorough interpretation and relation to the coded data, i.e. the coded extracts and the entire data set.

v. *Review and refinement of themes* – this was done through naming and defining the themes. This process was recursive and involved iterative refinement of each theme's specifics and the overall story told by the analysis.

vi. *Writing the report* – here, key themes that were based on the research question were selected, interrogated and compared back to the coded data to produce a scholarly report of the analysis. Further, to guide the interpretation of the data and better understand current practice, the COM-B model was used; see Chapter 2, section 2.6. The COM-B model has been widely used as an implementation science theory to understand and change practice (clinical and otherwise) in various areas of applied sciences (204). This model forms the core of the behaviour change wheel, which is a systematic synthesis of 19 frameworks of behaviour change. The behaviour change wheel uses the COM-B model to identify behaviour sources as an initial step in the design of targets for interventions. Conceptually, the COM-B model is a simple framework for understanding practice as it provides three essential conditions for behaviour (Figure 14). First, capability (physical and psychological) represents an individual's capacity to engage in an activity and involves strength, skills, stamina, knowledge and memory. Second, opportunity (physical and social) represents factors that are external to the individual and that make a behaviour possible, such as time, interpersonal influences, social cues and cultural norms. Third, motivation (automatic and reflective) is defined as the psychological processes that direct and amplify behaviour. Motivation is influenced by opportunity and capability, and it encompasses wants, habits, needs, impulses, beliefs, choices and intentions.

The final analytical frameworks, codes and frequencies of use are tallied in Table (Appendix 17). This data should not be used to infer meaning or priority to the codes but as a tool to understand how the coding was done.

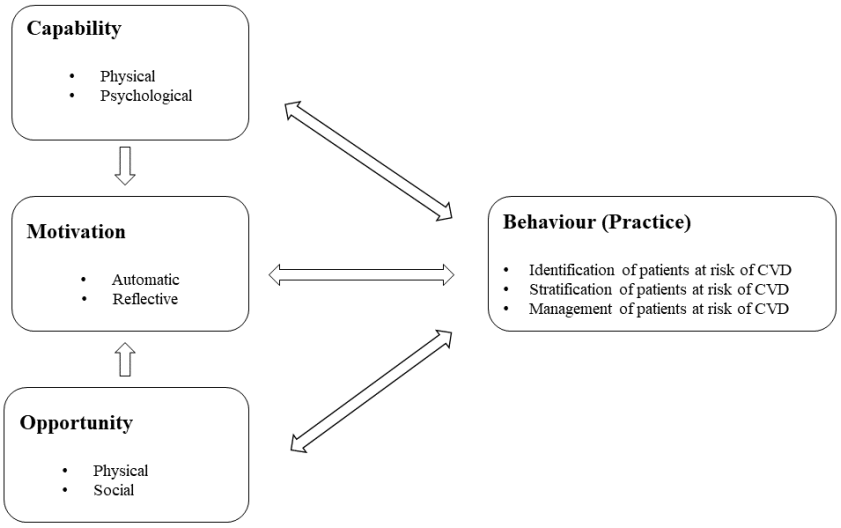


Figure 14. The COM-B framework for understanding behaviour [practice] (227)

5.3.5.2 Objective 2: Identification of the factors that influence the adoption of recommended practice in the assessment and management of CVD risk

Framework analysis was used for this section because it has characteristic tenets that make it aptly suited to meet this research objective (205). These tenets include, inter alia, the ways in which framework analysis can be adapted to answer research questions based on a priori issues in a limited time frame (206). Framework analysis was an appropriate data analysis method for use in this study since this objective was building on findings from Chapter 4. This analysis aimed to describe and interpret the data that were collected, based on its explicit meanings, through sifting, charting and sorting it by key themes identified a priori. The analysis was both deductive and inductive: deductive because themes were strongly linked to an a priori framework (the consolidated framework for implementation research (CFIR) that was used in the work described in Chapter 4); and inductive, since any noteworthy text that did not fit into the prescribed themes was noted in a miscellaneous domain.

The analytical approach followed five steps.

i. *Familiarisation with the data* – Again, data was read and re-read by me and by a second analyst. This step was used to familiarise the researcher with the data that had been collected, check the accuracy of transcription, and note down initial ideas for analysis.

ii. *Identification of a thematic framework* – A priori themes were adapted from the CFIR (Table 12). This framework is referred to as a determinant framework in implementation science. It helps to explain the influences on implementation outcomes such as acceptability, adoption, feasibility, fidelity, implementation cost, coverage and sustainability (83). The CFIR is a widely used framework, the emphasis of which is that the determinants of implementation may be active primarily, but not exclusively, at a collective level. The CFIR comprises 39 constructs that are incorporated into five domains. These constructs are defined in Appendix 13, Table 28. The framework is used to attempt to bring in a multi-level, meta-view to the determinants of implementation (91).

Table 12. A priori themes and their constructs adapted from the CFIR conceptual framework

Domains/themes	Constructs/categories
Intervention characteristics	Intervention source, evidence strength & quality, relative advantage, adaptability, trialability, complexity, design quality & packaging and cost
Outer setting	Patients' needs & resources, cosmopolitanism, peer pressure and external policy & incentives
Inner setting	Structural characteristics, networks and communications, culture, climate of implementation and readiness for implementation
Characteristics of individuals	Knowledge & belief about the intervention, self-efficacy, individual stage of change, individual identification with the organisation, other personal attributes
Process	Plan, engage, execute, reflect & evaluate
Miscellaneous - any noteworthy text that did not appear to fit into one of the above themes	

iii. *Indexing* – Portions and sections of data that corresponded to the framework's themes were indexed using NVivo 12. This was first piloted on the data collected from three interviews, independently and in duplicate, so that the process and the meanings that had been ascribed to the themes could be compared. Discrepancies were addressed through consensus. This pilot led to production of a refined thematic framework. After this, indexing was carried out on all transcripts.

iv. *Charting* – In a bid to manage and summarise data, a spreadsheet (generated through NVivo 12) was used to create a matrix on which data was charted. The result of this step was a matrix output in which data were condensed by category from each transcript. The aim of this step was to strike a balance between reducing the amount of data and retaining the interviewees' original meanings by including references to illustrative quotations from the transcripts.

v. *Mapping and interpretation* – Throughout the analysis process, I kept a separate notebook where I noted impressions, ideas, and initial data interpretations. Characteristics, similarities and differences between data were interrogated to generate typologies and to examine further the a priori concepts from the conceptual framework. Connections were mapped to explore and describe relationships and sometimes to offer explanations. Specifically, based on the data mapping and interpretation, I explored these connections according to three overarching levels. The first level was related to individuals at the lowest levels of care (clinicians and patients). The second level was the immediate environment with which these individuals interacted, i.e., the clinical setting and the local government. The third level represented the national and global influences within which the first two levels operated.

5.3.5.3 Reflexivity

Reflexivity in qualitative research is a way in which the researcher acknowledges the relationship between them self and the research process (207). I approached reflexivity by acknowledging my position regarding: access to the field, the relationship between the researched and me, and my prior knowledge. This acknowledgement informed the potential effect that my positionality could have on the research process i.e. data collection and analysis.

I conducted all the participant observations, interviews and document reviews. I was assisted in patient recruitment and logistical planning by a field worker who was

recruited independently through the KEMRI-Wellcome Trust research programme staff recruitment process at the beginning of the study (see the advertisement for the position in Appendix 19). I am a clinician (registered nurse and midwife, public health practitioner) with a keen interest in the implementation of evidence-based healthcare interventions. I was familiar with the setting as I am Kenyan and have worked in similar primary-care settings before I started my doctoral research. However, I do not speak the ethnic languages, Mijikenda dialects, fluently. I was hosted by the KEMRI-Wellcome Trust research programme as an affiliate of the Initiative to Develop African Research Leaders (IDEAL) through a six-month visiting PhD fellowship (Appendix 1).

Throughout the research process, I remained aware, cognizant and reflective of my positionality, which included my values, beliefs, knowledge, and biases. This consciousness was especially deliberate in the data collection process. To facilitate this reflective process, I kept two reflective journals, one which was written during data collection and the other during analysis. In addition, during data analysis, the presence of an independent and more senior analyst further promoted this skill of self-reflection and appraisal, particularly regarding how data was coded and interpreted. That said, I may still have influenced the research process through my identity as a Kenyan nurse and midwife, since, as a colleague who had worked in similar settings, I may have had similar sentiments to those of the participants.

5.3.6 Ethical approval

This study was reviewed and approved by the Oxford Tropical Research Ethics Committee (OxTREC Reference 544-18), the KEMRI Scientific and Ethics Review Unit (KEMRI/SERU/CGMR-C/148/3807) and by the County Research Regulatory

Office, Kilifi (Appendix 18). The participant information sheets and participant consent forms that were used in this study are shown in Appendix 21.

5.3.7 Reporting

This study was reported according to the standards for reporting qualitative research (208).

5.4 Results

5.4.1 Participants

Table 13 highlights the characteristics of the participants. The mean age of the patients who were observed was 53 years. Of the 81 patients who were observed, just 14 were male. Five of the ten clinicians who were interviewed were male, and three of the five policymakers interviewed were female. All the interviewed clinicians had a basic level of training for their profession, i.e. a college diploma for clinical officers and nurses, and a medical degree for the medical officers. The work experience in the primary health facilities for the clinicians ranged from less than one year to 15 years.

Table 13. Characteristics of participants

Patients	
Age, years (mean)	53
Sex (*n*)	
Female	67
Male	14
Level of education (*n*)	
No formal education	15
Primary level completed	41
Secondary level completed	25
Tertiary level completed	0
Healthcare professionals	
Sex (*n*)	
Female	5
Male	5
Profession (*n*)	
Nurse	4
Clinical Officer	5
Medical Officer	1
Period since qualification, years (*n*)	
0-9	7
10-19	3

20-29	0
Policymakers	
Sex (*n*)	
Female	3
Male	2

5.4.2 Data

A total of 81 observations of consultations between clinicians and patients were conducted in seven facilities (Table 14). The total duration of observations in the seven facilities was 560 hours. As well, 15 interviews were conducted across all levels of care (levels 2 to 4) with clinicians and policymakers. Data were collected between February 2019 and July 2019. Table 15 shows the distribution of these interviews by role and level of care.

Table 14. Distribution of observations by the level of care

Level of care	Observations (n)
Level 2 (3 facilities)	34
Level 3 (3 facilities)	27
Level 4 (1 facility)	20

Table 15. Distribution of interviewees by the level of care

Level of care	Clinicians	Line managers	Policymakers
Level 2 (3 facilities)	Nurses (n=2)	Health facility in-charge (n=1)	County level (n=3) Members of the sub-county and county health management teams National level (n=2) Division of Non-Communicable Diseases at the Ministry of Health and professional societies
Level 3 (3 facilities)	Nurses (n=1), clinical officers (n=1)	Health facility in-charge (n=3)	
Level 4 (1 facility)	Medical officers (n=1), clinical officers (n=1)		

The mean interview period with clinicians and policymakers was 30 minutes. Thirty exit interviews, 10 per level of care, were also conducted with patients. These exit interviews were conducted immediately after the observations. However, unlike the interviews with clinicians and policymakers, these were not tape-recorded and instead served as informal conversations to add context to the observational and interview data. Therefore, only field notes were recorded (209).

For the document review, only the Kenyan national guidelines for CVD management were available for analysis at the national level (25). There were no policy or health promotion materials at the study sites that related to CVD risk prevention and management during the conduct of this study.

5.4.3 Examination of current practice by understanding how prevention and management of CVD risk is experienced by policymakers, clinicians and patients in everyday clinical practice

To fully appreciate context and nuance, findings are presented in two parts. In the first part, I descriptively map out and record current practice based on key clinical practice behaviours in CVD risk prevention and management. For the second part, I am more interpretative as I seek to understand how current practice is implemented and negotiated using the COM-B framework.

5.4.3.1 Describing and recording current practice based on key clinical practice behaviours

Clinicians did not seem to be aware of any national guidelines or tools that could be used for CVD risk prevention and management in their settings. These guidelines were also not available in any of the seven recruitment sites. Current practice, as identified through data collection, was categorised into three domains based on the recommended practice in CVD risk prevention and management, that is, patients at risk of CVD were identified, stratified and managed. Each domain consisted of themes that helped in describing current practice (Figure 15).

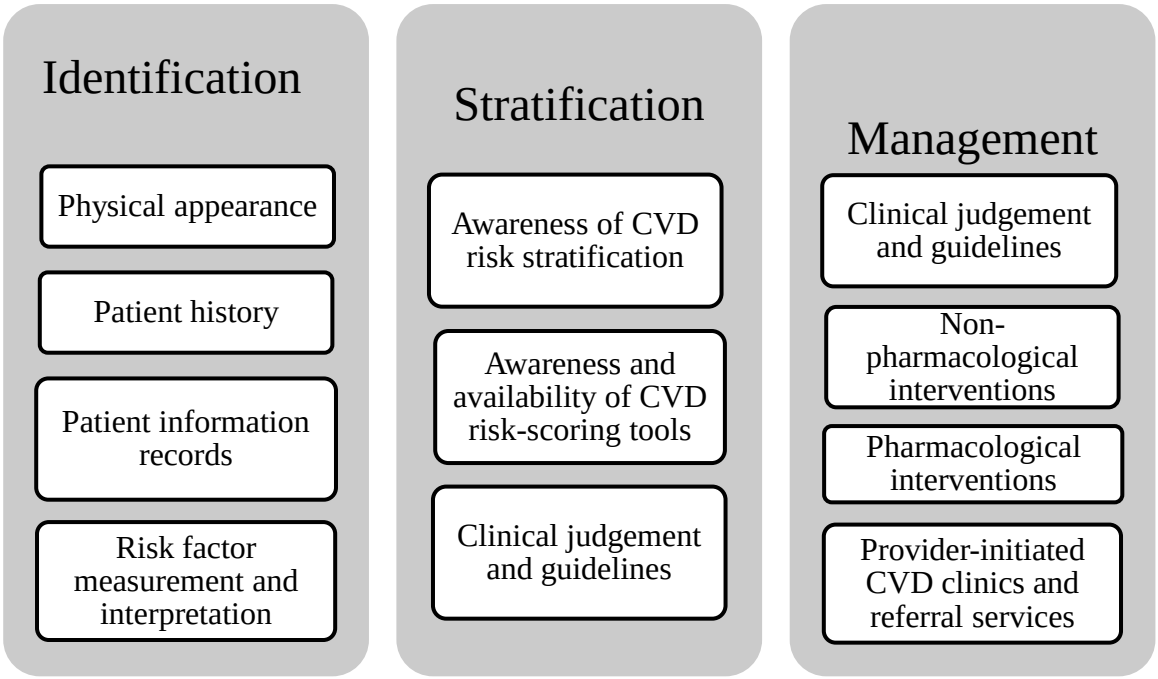


Figure 15. Domains and themes that describe current practice in the assessment and management of CVD

5.4.3.1.1 Identification

Patients at risk of CVD were identified through conduct of a cardiovascular risk assessment that involved a combination of observation of the physical appearance of the patient, recording their history, reviewing their health records, and measuring and interpreting CVD risk factors.

a) The physical appearance of a patient

Clinicians across all levels said that a patient's physical appearance was one of the initial signs they observed as they decided on the need for CVD risk assessment. Mainly, physical appearance was related to a patient's weight. The appearance was generally interpreted as a patient being obese or at risk of being obese and hence at risk of CVD.

Level 3 clinical officer 2: "So as patients walk in…you can tell whether somebody is obese. So that is when you will take a history of pre-existing heart conditions,

hypertension or diabetes in the family. After this, you will then go ahead and screen for hypertension or diabetes."

b) Recording patient history

History-taking is a vital but complex process that involved the type of history that was taken, the clinicians who would be involved, and the platform for recording or noting this information. There was no standard or structure regarding the way in which this information should be collected across any of the levels of care. However, clinicians were guided by their clinical judgement and prior training to gather information. This information then informed the plan of care for the patient. Often, history taking did not prompt the CVD risk prevention and management practices that were subsequently recommended by the clinicians. When it did, a comprehensive and systematic assessment was still lacking as clinicians frequently perceived blood pressure measurement to be synonymous with CVD risk assessment. The subsections below delve into various elements of history taking that were observed and which were described by the clinicians.

i. The chief complaint

By definition, this was the patient's reason for attending the facility. This was articulated and observed to be a significant determinant of whether the clinician conducted a CVD risk assessment. Recurrent headaches, palpitations, and blurred vision were the chief complaints that triggered an attempt at CVD risk assessment, which often translated only to the taking of a blood pressure reading.

> **Level 2 nurse 1**: "When they walk in, first of all, I ask them questions on their present complaints. If the clinical presentations involve recurrent headaches and blurred vision, and they are having palpitations…I take their blood pressure."

> **Level 3 clinical officer 3**: "Yeah, generally, I am interested in clinical presentation. Particularly patients with recurrent headaches and joint pains, I assess by having their blood pressure taken…"

ii. Health behaviour

Health behaviour was defined as a set of habits that put a patient at risk of a disease or illness. In this case, smoking was of particular interest to the clinicians. During the interviews that were held with me, clinicians expressed the need to have this documented as it helped to inform the level of CVD risk.

> **Level 3 clinical officer 1:** "When taking history and doing a full examination, it is important to point out the behaviour of that patient, to be aware of whether the patient is a chain smoker and such like things; yeah, this can help you identify whether the patient is at high risk or low risk."

However, during the 81 observations that were conducted during this study, only one patient was asked about their smoking history. In this case, the patient had a blood pressure reading above the normal range. On probing the clinician about this case, the clinician explained that they had only enquired about the patient's smoking history as a possible explanation of the patient's blood-pressure reading.

> **Level 4 medical officer 1:** "Yeah, we usually do it [taking behavioural history], especially when I see that the patient's blood pressure is high, or the patient has been on antihypertensive treatment and is not improving or being controlled, so most of the time, even as I think that maybe the medication is not enough, perhaps it is the case of a low dose, I usually ask them the other things, like 'Do you smoke?'"

iii. Past medical history

This was an enquiry on a patient's past health and wellbeing. Clinicians thought this examination was vital to understand the patient's current state of health and to inform their plan of care.

> **Level 3 clinical officer 1:** "Okay basically, the past medical history will first tell you whether the current complaint is related to that…it will also tell you the type of medication the patient is on. Particularly it is important for certain types of illness such as hypertension and diabetes."

However, clinicians said that they found it a challenge to obtain this information adequately. Medical histories that were related to CVD risk and disease posed a unique challenge because they were not easily understood by the patients. The problem was exacerbated because the patient was the custodian of their health histories. As explained in section v, patients at levels 2 and 3 of care were given their medical records after completion by the clinician and tasked with keeping their medical records safe at home, but often these were not brought to any subsequent consultation. As a result, clinicians found that their patients were not aware of their past or current diagnoses and the clinicians could not check past records. This may explain why only 34 out of the 81 patients observed were asked for or had recorded any form of medical history during the consultation.

> **Level 4 medical officer 1:** "For us, some of these risk factors, I don't know what to do with them, like asking for histories of hypercholesterolaemia or lipid disorders in the family or a patient. Who knows that? And how do I even ask my patient that question? None of my patients knows that."

iv. Family history

This was a record made by a clinician about a patient's family's past and present health and wellbeing. As with the patient's medical history, this was rarely asked or recorded. Clinicians stated that due to a blend of existing family and societal dynamics, including the lack of knowledge or awareness about assigned diagnoses, it was often challenging to get this information. Consequently, family history, especially relating to CVD risk and disease, was not used to inform a patient's current diagnosis or plan of care.

> **Level 4 medical officer 1:** "Here we are not a society that follows to know familial histories of disease. How will you expect my patient to

> tell me that their second-born died of coronary artery disease? This patient doesn't know that their family member died of a heart attack. They know that he collapsed one day and died. Getting CVD-related history can be so challenging."

v. Patient information records

Only patients who attended care facilities at level 4 benefitted from a formal information records system instituted at the facility. At levels 2 and 3 of care, the patient's health record was a notebook in which the clinician wrote down their notes and which was then handed back to the patient. It was expected that the patient would keep the book safely and remember to carry it with them to the health facility when they next sought medical care.

Often, when the patient sought medical care, this notebook was unavailable due to misplacement or damage at home. Both clinicians and patients articulated concern over this system, which led clinicians frequently to be unable to get a complete picture of the patient's medical history. Often the patients were not aware of their diagnosis or management. This was also the case for CVD risk and disease. Further, patients complained that they always had to pay to acquire another notebook when theirs was lost. Those in charge of the health facilities said that taking responsibility for a patients' health information system would impose an additional administration layer for which they did not have resources.

c) Risk factor measurement and interpretation

According to the national guidelines, clinicians show a good understanding of what CVD risk factors comprise. However, this did not translate into what was documented or measured during the consultations. For example, the clinicians rarely asked the patient's age or recorded it on the patient's medical records. In place of the exact age, the patient was registered as an adult. The age was noted for only 33 of the 81 patients

who were observed across all levels of care, although it should be noted that the exact age was recorded for all the patients who were observed at level 4.

Blood pressure measurements were taken for 75 of the 81 patients. Measurement of other risk factors was suboptimal. A quarter of the patients were weighed – a majority of these were attending one facility that followed a weight measurement policy for all its patients. Waist circumference and non-fasting lipid profile were not measured for any of the observed patients, while the fasting blood glucose was measured for only one patient. Body mass index was calculated for only two patients. The recording of age and measurement of weight and height were often dependent on the availability of a casual worker in a facility. A casual worker was an untrained assistant to the health worker whose tasks included cleaning the facility, and recording the arrival of and organising patients as they waited to see the clinician. The measurement of blood pressure was a clinician's task.

> **Level 2 nurse 1:** "They assist us…the only thing after they have taken the weight and written the age for me is to take the blood pressure. It is the clinician who takes the blood pressure."

While the clinicians' understanding of CVD risk factors seemed adequate, the interpretation of these risk factors regarding how they potentiated CVD risk was not. Clinicians equated a patient's blood pressure reading to their level of CVD risk. They did not express adequate understanding of the synergistic relationship of CVD risk factors in contributing to a patient's absolute CVD risk.

> **Level 4 clinical officer 2:** "We have triaging and assessment whereby blood pressure is taken, and then the history of the patient. And from that, the clinician is able to gauge the client's CVD risk status."

5.4.3.1.2 Stratification

Clinicians across all levels of care did not appear to be aware of CVD risk stratification. Accordingly, none of the patients who were observed was stratified according to their

level of CVD risk. Clinicians and county-level policymakers were also not aware of any guidelines or policy to facilitate this practice.

> **Level 3 clinical officer 2:** "What I know is that there's no way that you can calculate the [CVD] risk, but you just know that such a patient is directly at risk of developing cardiovascular disease, for example, the ones that have already pre-existing hypertension, and diabetes, yeah…"
>
> **Sub-county level policymaker 2:** "Yeah, I tend to think it is actually very late, because of course without a guideline, then I may be doing something different in my facility with no evidence or that is outdated...so having a standardised guideline will help us in trying to tackle the rising burden of cardiovascular disease in our sub-county and county as a whole, so I tend to think the guidelines are very important to have but their appropriate implementation is even more important."

Most clinicians also seemed to be unaware of any of the tools that can be used in CVD risk stratification, such as CVD risk-scoring tools. Those who were aware of these tools had heard of them during their professional school training but had never used them in clinical practice. CVD risk-scoring tools were not available for use in any of the facilities.

> **Level 4 medical officer 1:** "I know of cardiovascular risk factors, the risk scoring itself. I have just seen it right now as I was looking at this guideline online."
>
> **Level 3 clinical officer 1:** "I have heard of them [CVD risk-scoring tools], but I have never seen them or used them. I heard about them in school, but when it comes to teaching or in clinical practice, I have never seen them ever since I stepped out of school."

In place of CVD risk-scoring tools, clinicians used their clinical judgement to estimate a patient's risk level. They also relied on their clinical judgement to be aware of when they should refer a patient to the next level of care for further management. Often, clinicians stated that they felt guilty and unable to cater adequately to their patients' needs regarding CVD risk prevention and management.

> **Level 2 nurse 1:** "They [patients] need the services, but then I cannot fully satisfy their needs [in CVD risk prevention and management]. So, yeah, there is a lot of guilt in me, it is my power to do this, but I cannot

> help this patient because I am not equipped, you know. It is demoralising."

However, national-level policymakers were aware of the CVD risk prevention and management guidelines, which had been launched and disseminated over a year before this study was conducted (May 2018). Notably, national-level policymakers were also aware that patients were not being stratified at the primary healthcare level.

> **National level policymaker 2:** "So, to my knowledge on the ground, for the most part, especially in primary healthcare levels, there isn't any CVD risk scoring that is taking place. Well, the bulk of the practice there is detection and diagnosis of CVD conditions and a non-standardised way of managing these conditions. The introduction of CVD stratification and scoring is novel in this setting, and it definitely requires a lot of advocacy and education around it and guidance on how we go about implementation for it."

5.4.3.1.3 Management

This domain covered the measures that were taken by stakeholders to prevent and manage CVD risk. These measures were categorised as involving non-pharmacological and pharmacological interventions, and the establishment of provider-initiated CVD clinics and referral pathways.

5.4.3.1.3.1 Non-pharmacological interventions

Broadly, these included lifestyle-adjustment interventions, CVD risk communication and health-promotion activities. All the stakeholders - clinicians, patients and policymakers - deemed these interventions to be important in the prevention and management of CVD risk. However, clinicians and policymakers expressed their views that, at present, these interventions posed an implementation challenge in primary healthcare. Clinicians stated that they felt overwhelmed by their existing workloads. They also said that they felt unsupported to carry out these interventions. As a result, they preferred to use pharmacological interventions such as the prescription of medicines rather than non-pharmacological interventions.

> **Level 3 clinical officer 3:** "Sometimes, these lifestyle management things are challenging because we are doing a lot of unsupported multi-tasking. So sometimes we are just so overwhelmed to help with adapting lifestyles for our patients. Many times, we just give medications without lifestyle advice. Honestly, we do not have enough time, but we sometimes try if the facility is not busy with patients, we take even like five minutes and try to highlight the main areas to change lifestyle."

Some clinicians stated that health promotion and lifestyle adjustment advice were roles best delegated to other professionals such as nutritionists. Clinicians and policymakers also expressed the opinion that more work would be needed to provide support for patients to implement the advice given to them.

In tune with these findings, some patients reported that they had not received any communication about their blood pressure measurement or risk of CVD. Further, patients who were aware of their CVD risk and had received information about changing their lifestyle were sceptical of the practicality and affordability of these adjustments.

> **Patient exit interview notes:** "I would have preferred to be told what food to eat so that I can see whether I can afford it. If I change my diet, will I still get the same nutrients they have told us? The doctors should have answered these questions first.".

Policymakers also felt that more work was required to enhance patient compliance with lifestyle advice.

> **National level policymaker 1:** "Patients have different priorities and especially when they are not in pain or feeling sick. How do you convince them to take part in risk management when they are not feeling sick? So yes, compliance will definitely be a big issue."

Health-promotion activities that were related to CVD risk prevention and management were lacking at all levels of care. For example, there were no posters on CVD in the patients' waiting bays. In comparison, there were many posters, care information in the form of algorithms and outreach programmes for infectious diseases, immunisation and family planning, at all levels of care. This was also reflected in the service delivery

charters that were espoused by the facilities. The accords were centred on provision of services for the prevention and management of infectious diseases. It was only at level 4 that the service delivery charter contained a mention of CVD prevention and management-related activities. The charter services that came under this category were blood-pressure measurements, blood-glucose measurements, weight measurements, group health talks, and individualised counselling.

5.4.3.1.3.2 Pharmacological interventions

These included pharma-interventions or medicines that were prescribed by clinicians for CVD prevention and management. Two key aspects were pertinent in describing pharma-practice; the availability and cost of medicines, and prescription practice. Often, the recommended CVD medicines were not available in the facilities. However, clinicians noted that there had been an improvement in the availability of medicines over the years. The issue, however, was related to inconsistent supply, which led to recurrent stockouts.

> **Level 2 nurse 1:** "Medicines have been a challenge, but now we have a few drugs, but the consistency of how these drugs come is, you know, very uncertain."
>
> **National level policymaker 1:** "We need to look at the availability of commodities. This is a big challenge. This includes access to medication, a big component in risk scoring because once you are scored, this should guide management which also includes pharmacological. Do we have these basic medicines at these primary care levels? Not consistently."

The stockouts in the facilities perpetuated the medicines' inaccessibility and made them unaffordable, because patients who were determined to obtain them had to purchase them in private pharmacies. Both clinicians and patients said that drugs were more expensive in private pharmacies than in public facilities. The knock-on effect was that

patients often were unable to take their required dose of medication and thus were unable to meet their clinical outcomes, such as controlled blood-pressure levels.

> **Level 3 clinical officer 3:** "Also, economically, in terms of buying medications, that has been one of the biggest challenges, because in our setup many times we run short of medicines, like for one, two, three months, and many of the patients are not in a position to purchase those medicines elsewhere, so when you are doing the clinics' follow-ups, you see most of these patients' blood pressure is not controlled. When you probe further on what could be the problem, many will tell you that they have not taken their medication for almost two weeks, the reason is that they did not have money to buy medication and even coming to the facility was a problem, they had to walk as they did not have money for transport."

Another issue was the type of CVD medicines that were available in these facilities. While most first-line medicines, such as thiazide diuretics and calcium-channel blockers, were usually out of stock only for a short period, other first-line medications were unavailable for long periods for prescription at all care levels. These unavailable medications were angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers and statins, which are treatments for high blood pressure and heart failure. The lower care levels (2 and 3) were comparatively less stocked with essential CVD medicines than level 4. Some medications such as furosemide and aspirin, which are not commonly recommended for CVD prevention and management, are available at levels 2, 3 and 4. Nifedipine and hydrochlorothiazide were widely prescribed medications at all levels of care. Methyldopa and aspirin were also commonly prescribed at levels 2 and 3.

Generally, at all levels, I observed no standard prescribing practice. This was related to the lack of guidelines at the practice level. Also, staff were unclear regarding their ability to prescribe certain drugs, particularly at level 2. Nurses were sometimes unsure of the limits of their scope of practice regarding CVD prevention and management. Due to this lack of clarity, these clinicians often took the cautious choice by referring

patients whom they had assessed as in need of pharmacological interventions to level 4.

> **Level 2 nurse 1**: "Yeah, we sometimes have them [CVD medicines], but I cannot prescribe most of them, I think I have to wait for a clinical officer who does not operate at this level of care. And because the clinical officer is not around to prescribe the treatment for the patient, I am forced to just refer them to level 4. Though currently, we have nifedipine and hydrochlorothiazide in the pharmacy."

5.4.3.1.3.3 Provider-initiated CVD clinics and referral services

There were no standard CVD prevention and management strategies at levels 2 and 3. This lack of planning facilitated innovation at the facility level; clinicians and facility managers organised provider-initiated CVD clinics. Broadly, these were planned based on the needs of the patients and the availability of clinicians. Most clinics were viewed as separate from routine services and were assigned a specific time of the week and a clinician to attend to those diagnosed with hypertension and diabetes.

> **Level 3 clinical officer 1**: "For those who are at high risk, we try to put them in a clinic where we do a regular check up on a monthly basis."

In addition to these provider-initiated clinics, at level 3, there was a cluster of externally organised and managed clinics, which were run by foreign (visiting) clinicians in two facilities. These visiting clinicians took the responsibility of managing hypertension and diabetes while the resident clinicians ran routine services in the facilities. The visiting clinicians brought their own equipment and medications while the facilities provided space for them to set up.

> **County level policymaker 1:** "We also have visiting doctors who come to the clinics for missions, and they are quick to challenge us on remaining behind. They often ask – why are you still doing this? This is not enough. And so, that way, we are aware of the new things coming up and the fact that we are not doing enough. This gives us a push to do better."

At level 4, specialist services were provided to at-risk CVD patients through the medical outpatient department. These services included diabetic care through the diabetes clinic, and hypertension and heart-failure care through the medical clinic.

Patients were referred for care across, up and down the levels of care. At level 4, many patients were referred down to levels 3 or 2 for routine follow-up and monitoring. However, in levels 2 and 3, patients were referred up and across. Referral across occurred if the clinician had prior knowledge of a neighbouring facility that ran a CVD clinic; referral depended on the clinician's perception of the complexity of the patient's condition. Sometimes, clinicians at levels 2 and 3 did not refer patients up to level 4 due to the patients' socio-economic challenges. For example, many patients could not afford the transport costs to visit the level 4 site. Further, clinicians did not feel valued or supported in the referral process as they felt that their clinical work was not built upon on referral, but rather was discarded.

> **Level 2 nurse 3:** "There is no support because once you send your patient there, instead of taking it from where you left them, the patient has to start again afresh. You have already assessed this patient and found that the patient's blood pressure is high, and you gave the medication here to start a dose. Then you refer the patient to the referral hospital there. When they go there, the clinicians there do not recognise your work. They start afresh, and even sometimes the patient goes without being seen by the doctors there. There is no proper continuity of care."
>
> **Level 2 nurse 1:** "Most of my patients will not go to the referral facility because of the additional costs such as transport."

5.4.3.2 Exploration of how policymakers, clinicians and patients experience prevention and management of CVD risk in everyday clinical practice through use of the COM-B framework

The description and recording of CVD prevention and management practice provided context for the study. In this part of the project, I explored themes in the data through application of the COM-B framework to improve understanding of the current practice.

As in part one, I categorised themes across three practice domains that were based on key clinical behaviours in CVD prevention and management: identification, stratification and management of patients at risk of CVD (Table 16).

Table 16. Using the COM-B framework to understand current practice in CVD risk prevention and management

COM-B model		**Practice domains and themes from the data**	
		Identification and management	Stratification
Capability	Physical	Ongoing shifting and sharing of tasks Energy to do more, but no time Complex patients; comorbidities and socio-economic status Organisation of care; utilisation of referral services	
	Psychological	Lack of sufficient knowledge on the interaction of CVD risk factors to cause CVD Use of clinical judgement Role conflict	Lack of knowledge on CVD risk and stratification Use of clinical judgement
Opportunity	Physical	CVD risk prevention and management guidelines not available No training available for NCDs Insufficient infrastructural support; space, equipment, information systems, medicines and personnel Reliance on donor funding/support Use of internet services Lack of communication and feedback	CVD risk-scoring tools not available CVD risk prevention and management guidelines not available No training available for NCDs
	Social	Cross-cultural practice exchange through visiting clinicians Demand for services from the community Socio-cultural/economic dimensions of CVD risk and disease Collaboration and teamwork among colleagues	

		Patients' socio-economic status	
Motivation	Reflective	Personal initiative and curiosity Perceived health priorities of patients, health system and policymakers Perceptions of CVD risk prevention and management in primary healthcare Commitment to the profession and guilt	
	Automatic	Desire to do more for patients Client satisfaction efforts	Desire for CVD risk-stratification tools Credibility of CVD risk-scoring tools

Findings from part one set a scene of minimal resources (infrastructure and personnel) and showed that current practice in these settings was rarely informed by guidelines or understood notions of the recommended practice in CVD risk prevention and management. As such, the focus of this part of the work was on the salient concepts that involved psychological capability, social opportunity and motivation. This is because these concepts could elucidate how clinicians made sense of their practice in the milieu of their realities, i.e. limited resources, lack of awareness and unavailability of clinical guidelines.

The remaining themes, which involved physical capability and opportunity, are explored during the explanation of how the project met objective two – the discovery of contextual factors that influenced the adoption of the recommended practice in the assessment and management of the risk of development of CVD. This is also to avoid unnecessary repetition in this chapter. These salient concepts are the use of clinical judgement, lack of knowledge, demand for services, professional commitment and feelings of guilt, teamwork and collaboration, personal will and desire to do more for patients, socio-cultural/-economic dimensions of risk and disease, and role conflict (Figure 16).

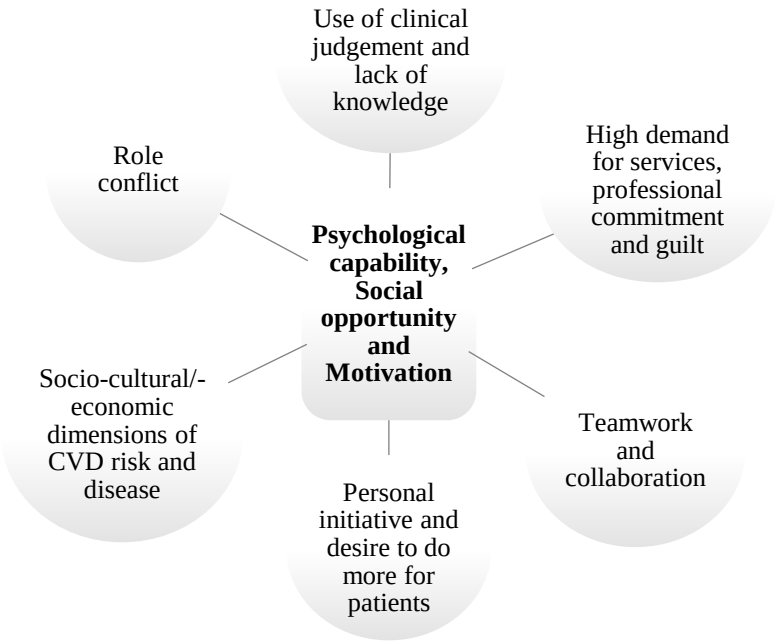


Figure 16. Salient concepts in the practice of CVD prevention and management in Kenyan primary-care settings

a) Clinical judgement and lack of knowledge

Although clinicians lacked adequate knowledge due to poor awareness and unavailability of clinical guidelines, they regarded clinical judgement as central in guiding their CVD prevention and management practices. However, their clinical judgement, in compensation for their limited knowledge, seemed to rely heavily on experience, practicality and continuous critical analysis. Consequently, clinicians also seemed to innovate by generating and adjusting their practical knowledge based on their everyday experiences and availability of resources. This may have been due to an over-reliance on experience and past practice. As a result, clinicians across all levels formed pockets of non-standardised 'communities of practice' that were not rooted in evidence-based practice.

> **Level 3 clinical officer 3:** "To be sincere, what we normally do in our practice is use a lot of our clinical judgement. So, when you use the clinical judgement to assess the patient, you decide that the patient could be at risk. After that, you advise the patient about their chances of

> developing cardiovascular disease. But we are not in a position of classifying risk in categories or classes."
>
> **Level 4 medical officer 1:** "As for calculating risk, we do not know – we do not do that. Basically, most of the time I just use observation, and it often depends on the patient I get…"

Unsurprisingly, these pockets of non-standard practice brought professional challenges that were detrimental to the recommended practice. For example, clinicians highly prioritised the assessment of specific CVD risk factors, particularly blood pressure measurement, over other risk factors. This, then, invited the standard interpretation that a patient's blood-pressure reading was synonymous with their level of CVD risk. As a result, this was the leading risk factor that guided practice in these settings.

> **Level 2 nurse 3:** "Most of the time I identify these patients [patients at CVD risk] by taking their blood pressure…"

Notably, both clinicians and policymakers stated that, although clinical guidelines were essential to guide practice, they often preferred to use their clinical judgement. This preference was rationalised on the grounds that, regularly, guidelines did not consider various complexities of the presenting patient. The complexities that were highlighted by the clinicians and policymakers included social and economic situations and existing comorbidities.

> **County level policymaker 1:** "The other thing is that because of the various types of patients that we have in the facilities, clinicians tend to trust their clinical judgement more than these guidelines because these recommended interventions do not take into account social issues or the entire condition of the patient in front of you."

b) High demand for services, professional commitment and guilt

Clinicians reported that, increasingly, patients came to the facilities because they needed CVD risk prevention and management services. Clinicians believed that, although they did not have adequate information on the burden of CVD in the community, there was a steady increase in the numbers of patients who came to the

facilities with hypertension and who required and often demanded care and interventions to address their conditions.

> **Level 2 nurse 1:** "Most of the patients coming here are in need of these services [CVD]…they want these services."

This increasing need coincided with the clinicians' strong commitment to their professions and the oaths they had taken to save lives and to uphold the wellbeing of the communities they served. The result was that clinicians made efforts to try to do something about the situation. However, they often found themselves unable and unempowered to fulfil their professional mandates. The consequences of this inability were expressed by clinicians in terms of feelings of neglect by policymakers and health systems, guilt, lack of morale and a general sense of self inadequacy in fully addressing the patients' needs.

> **Level 2 nurse 1**: "As a health worker, I am always committed to my profession…I am ready to accommodate anything that comes around."
>
> **Level 2 Nurse 1**: "And then you cannot fully satisfy their needs [CVD], so, yeah, there a lot of guilt, you know. It is in my power to do something about it but then I cannot help this patient because of all the things [limited resources]…it demoralises and lowers your ego."

c) Teamwork and collaboration

Generally, clinicians reported that there was a good level of teamwork and collaboration among senior staff and colleagues in the facilities. This teamwork facilitated sharing and shifting of tasks with other co-workers to address gaps in service provision. Specifically, casual workers in the facilities were informally given the role of helping clinicians with various risk-assessment tasks. For example, it was observed that casual workers were often involved in taking demographic histories such as a patient's name and age, weighing the patient and even performing an initial triage to alert the clinician of those patients who needed urgent attention.

This spirit of collaboration was also seen in clinicians' expressions of gratitude to visiting clinicians on foreign missions. Space and access to patients were readily offered to these visiting clinicians as this openness facilitated more service provision, often in regard to CVD prevention and management.

> **Level 2 nurse 1**: "Thankfully, we have a programme around run by [visiting] doctors….and in two other facilities."
>
> **Level 3 clinical officer 1**: "We are lucky to have our clinic jointly run by us and the [visiting] doctors in our facility."

However, clinicians also alluded to tension between themselves, policymakers and referral services. Regarding policymakers, clinicians said they often felt neglected and uninvolved in general setting of priorities. They often opined that they received no feedback to their frequent, urgent calls for more support that they made to policymakers at sub-county and county levels. As for referral services, specifically to level 4 of care, clinicians voiced a level of mistrust. They stated that they often preferred to refer across (to the same level) rather than to higher levels of care because all the background clinical work they had done would often be disregarded by clinicians at level 4. This concern was exacerbated by the economic barrier to care that they considered they might be placing in their patients' way.

> **Level 2 nurse 3:** "There is no support because once you send your patient there [level 4] sometimes, instead of taking it from where you have started, the patients start again afresh…Even sometimes the patient goes without being seen by the doctors there…There is no proper continuity from there."

d) Personal initiative and desire to do more for patients

Similarly, because the clinicians considered the burden of CVD to be increasing in their communities, many of these clinicians launched a plethora of personal initiatives in their facilities. These initiatives were aimed at doing more, albeit temporarily, to address gaps in service provision. They ranged from the introduction of a compulsory

weight measurement for all patients who visited one facility to the setting up of provider-initiated CVD follow-up clinics. This was in addition to taking up CVD-related courses on the internet, leveraging social media to share new information with colleagues and advocating for more rights to prescribe for nurses at the lowest level of care.

> **County level policymaker 1:** "Some clinicians in public facilities institute their own personal initiatives. At primary-care level, clinicians want to do a lot, they really want to, I know but sometimes the current setup fails them…"
>
> **Level 2 nurse 1:** "It is your initiative to search [the internet], your initiative to see what is the best that you can do when there are no guidelines..."
>
> **Level 3 nurse 2:** "Individually, I have subscribed to journals and international associations. Thankfully, some associations usually offer short courses on CVD management so I get updates from them. But this is very expensive for me to do."

While these initiatives were lauded by clinicians and policymakers alike, most of them served as temporary fixes, and some of them had unintended consequences. For example, some clinicians stated that they often prescribed medications unnecessarily to cover a patient when lifestyle adjustment was not possible for various reasons. Another example was the incurring of expensive costs that were attached to taking online courses to gain adequate knowledge to serve the community.

> **Level 3 clinical officer 3:** "Sometimes, these lifestyle management things are challenging. We are just so overwhelmed to help with adapting lifestyles for our patients. So, sometimes we just prescribe medications without lifestyle advice to cover our patients…but we sometimes try."

e) Socio-cultural/-economic dimensions of CVD risk and disease

First, this category was related to the recording of medical history as a practice for the assessment of CVD risk in a patient. Clinicians stated that, in particular, collection of patients' medical and family histories posed a substantial challenge for them.

Consequently, this information was often not recorded or available to guide practice. Further, clinicians stated that many patients did not provide medical and family histories, mainly because they did not have an adequate understanding of diagnoses. This is notable because, as reported in part one, patients were expected to be the custodians of their medical records at this level of care.

Exit interviews with patients inferred that adequate information about diagnoses was often not provided. Beneath this tension and information gap lay a cultural dimension, which was expressed by some clinicians and patients. This was that a patient's disease and illness were culturally sensitive topics, mainly regarding how they were communicated in the socio-cultural context. For example, while members of a patient's family were well aware that one of their members was unwell, discussion of the disease specifics was frowned upon. This was also the case regarding death in a family; many members of the family would not discuss disease specifics, the reason for death or previous diagnoses of family members, especially across age groups.

> **Level 4 medical officer 1:** "Here we are not a society that follows familial histories of disease. How will you expect my patient to tell me that their second-born died of coronary artery disease? This patient doesn't know that their family member died of a heart attack. They know that he collapsed one day and died. Getting CVD-related history can be so challenging."

Similarly, there was a cultural dimension to taking a behavioural history, particularly for women, which may have been the reason why most people were not asked for this information. It was viewed as insensitive and disrespectful to ask a woman whether she smoked. This was important as it was confounded by the finding that women disproportionately sought healthcare services rather than men in this study. Inexorably, these socio-cultural dimensions of risk and disease awareness played a crucial role in the resulting challenge of communicating medical and familial histories to clinicians

and vice-versa – clinicians also did not adequately communicate risk or provide clarity in their diagnoses to patients.

Second, decisions in clinical practice were often influenced by the high poverty levels and healthcare costs in the community. Specifically, the cost of medicines in private pharmacies was prohibitive, yet essential medicines were often unavailable in public facilities, so patients had great difficulty obtaining prescribed medication.

> **Level 2 nurse 3**: "So, whenever I prescribe for a patient here, the patient has to move out, maybe to the next facility or sometimes go to a private pharmacy, and many of my patients don't have money to purchase those drugs…"
>
> **Level 3 clinical officer 3**: "When doing follow up, you will see some of the patients' blood pressure is not controlled, when you try to probe further on what could be the problem, many will tell you that they have not taken their medications for two weeks. The reason, they did not have money to buy medication – coming to the facility was also a problem as they did not have money for transport."

Cost was also an issue in regard to lifestyle adjustment advice. Patients were sceptical of the affordability of adjustments that would improve their diet.

> **Patient exit interview notes:** "I would have preferred to be told what food to eat so that I can see whether I can afford it. If I change my diet, will I still get the same nutrients they have told us? The doctors should have answered these questions first."**-.**

f) Role conflict

Clinicians seemed to value cardiovascular risk assessment and to understand the various risk factors for CVD. However, observational data indicate that this knowledge did not translate into practice. Often, risk factors were only assessed when staff explained to patients why they were unwell, i.e., when their blood pressure was high. Risk assessment succeeded diagnosis rather than vice versa; assessment was used to facilitate management and not prevention. For example, smoking history was only

sought when a clinician wanted to explain to a patient why their blood pressure was high.

It often seemed that clinicians avoided performance of risk assessment and more generally avoided mention of prevention measures. This was evident in the way that clinicians steered away from risk assessment and communication. This observation led to an informal discourse between the observer and clinicians about role definition and scope; it transpired that many clinicians saw themselves first as prescribers and only when necessary as patient educators. Often, clinicians deferred health promotion to other colleagues. For example, clinical officers deferred the role to nurses and nutritionists. In contrast, nurses often chose to refer these patients to higher levels of care, where they assumed the patient would receive more health promotion support. The result of this was the evolution of an uncoordinated referral system, which left patients' basic needs in disease prevention unresolved.

> **Level 4 clinical officer:** "My view on it [lifestyle adjustment] is that people should get advice and counselling, but we should have a specific person to do that. Here, we do not have that person. Currently, I am not able to do it and manage all of my patients. This is mainly due to the workload. If you look outside at the waiting bay, I still have that very long queue to clear. In terms of lifestyle advice, I only touch on the little bits that I can, and this is not all the time."

Key factors in this conflict in roles were: a shortage of staff, high workloads for primary healthcare workers and a lack of support to carry out non-pharmacological interventions.

5.4.4 Factors that influence the adoption of recommended practice in the assessment and management of risk of CVD

In the previous section, I described and provided an understanding of current practice by exploring how clinicians implemented and negotiated their practice. In doing so, I began to provide some insight into some of the contextual factors that influenced the

adoption in Kenyan primary care settings of the recommended practices in CVD risk prevention and management. In this section, I will address the remaining factors.

To better show the relationship between these factors, findings were categorised according to three overarching levels that could be mapped from the data (Figure 17). As stated earlier, the first level represented factors that were related to individuals; in this case, the clinician and patient. The second level comprised factors that were associated with the clinical setting and local government. Lastly, the third level represented global and national influences on the adoption of the recommended practice.

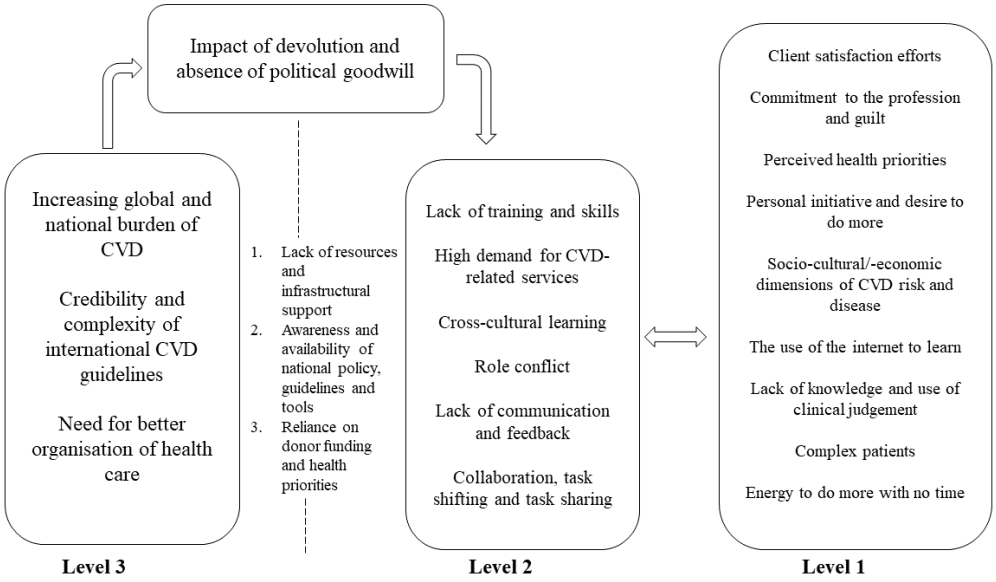


Figure 17. Factors influencing the adoption of recommended practice in CVD prevention and management in Kenyan primary-care settings

As depicted in Figure 17, various types of relationships and boundaries emanated from the data. For example, factors such as availability of resources, policy, guidelines, health priorities and donor funding were indirectly shared between the macro and meso levels but they were directly influenced by the devolution process and political

goodwill. The relationship between the meso and micro levels was porous and bidirectional.

Themes and relationships that emerge from the data are explored further below, except those that were addressed in the previous section. By now, it was clear that the recommended practice was infrequently followed in these clinical settings. Additionally, clinicians mainly relied on their clinical judgement and other intrinsic factors to practice. Lastly, guidelines and policies were in place to guide CVD prevention and management practice in Kenyan primary-care settings, though these were only available at the national level. As such, findings are presented from the macro to the micro level.

5.4.4.1 Devolution and political commitment

Health service delivery was devolved to local (county) governments in 2013 according to the system set out in the new Constitution of Kenya (2010). The national government retained policy and regulatory functions. While this political milestone gave explicit mandates to the two government levels, weak coordination mechanisms between these two functions influenced the adoption of a recommended practice in CVD risk prevention and management in primary-care settings.

> **National level policymaker 1:** "We have the Ministry of Health, both at national and county levels. So at least at national level they are determined to make sure these guidelines are cascaded down. At county level I think awareness is a problem; we know that many counties are probably not even aware there's a guideline."

Specifically, policymakers stated that the political commitment and goodwill to address competing priorities was of value. However, both national and county level policymakers reported a lack of such commitment from politicians in CVD prevention

and management. This, they said, had influenced the way in which resources were allocated at both levels of government.

> **National level policymaker 1:** "At national level they have supported guideline development, but at the moment, given the devolution of health, they may not support us with resources, which is what we need now…the national level cannot really influence the counties as such in terms of implementation, the counties have to drive the agenda."

Further, although health service functions seemed to be explicitly stated in the devolution strategy for health services, some policymakers at the county level expressed their frustration that they felt uninvolved in broader policy formulation. While some policymakers seemed to understand their stipulated mandate and facilitated the implementation of policies at county level, policymakers voiced a need for clear pathways that would enable local input to inform policy formulation.

> **County level policymaker 1**: "Sometimes I am confused...on paper, yes, we should be making and informing policy. But at the moment we are just trying to implement old and new policies. Policy making especially with regard to clinical practice is still very much a national-level activity. But we are the people who know what is possible and what is not…"

One of the policymakers noted that the result of a devolved government with weak coordination mechanisms was variability and uncoordinated progress in adoption of the recommended practice. This progress was often dependent on political commitment and goodwill.

> **National level policymaker 2:** "So, it's difficult to give a blanket statement because with devolution there's a lot of variability among counties; some counties have really strengthened their primary healthcare systems, some are lagging behind. So, for the counties that have strengthened primary healthcare it would have more success because in these counties their primary health facilities have favourable levels of staffing, lab services, commodities, and things like that. So, it is variable – there will be hits and misses, in some counties the existing health systems will support CVD risk scoring and some counties will not."

5.4.4.2 Capacity strengthening

A key requirement for adoption of the guidelines was strengthened capacity. The need for, and gaps in, capacity to perform CVD risk prevention and management tasks lend themselves to three distinct areas: competence and knowledge management, the healthcare workforce, and infrastructural support.

a) Competence and knowledge management

There was a general acknowledgement among both policymakers and clinicians that current practice in preventing and managing CVD risk was rife with incompetence and a lack of sufficient knowledge. They concurred that current practice in primary care that was related to CVD risk prevention and management was unfit for purpose, and potentially posed some risk to patients due to non-standard CVD management practices. Specifically, this risk was observed in the prescription practices (type and dose) of CVD medicines. Additionally, there was an implicit disregard of lifestyle adjustment interventions, which are a mainstay of CVD risk prevention and management. This disregard could lead to an over-reliance on scarce pharmacological interventions (see Part 1, section 3b).

> **County level policymaker 1:** "We know what is happening in primary healthcare is very different from what is recommended. The services there are below basic, I know that we are missing so many people. I see it all the time in referral facilities where you wonder how was this case even missed at levels 2 and 3. So yes, the difference between what is recommended and what is in practice differs by a big magnitude."
>
> **Level 2 nurse 1**: "To be honest, there is insufficient knowledge on NCDs. We depend on the little knowledge from our training in schools. That was a long time ago. Probably going on 20 years now."

This finding highlighted an urgent need for training to build knowledge and skills for clinical practice. This need was widely acknowledged by both clinicians and policymakers in both levels of government. Clinicians continued to make great effort

to equip themselves with some knowledge to guide their practice by leveraging ease of internet access. However, this was unsustainable due to the costs that they incurred in taking expensive online courses. Additionally, these knowledge sources were often non-standardised and erratic.

> **County level policymaker:** "Yeah, there is need to give capacity through knowledge support and training."
>
> **Level 3 clinical officer 3:** "For cardiovascular diseases, I've never attended any training. Most of the training on this is just my initiative of looking through Google. Most of the training available in our facilities is on infectious diseases like diarrhoea, pneumonia, malaria and TB. I have not heard of any training for non-communicable diseases and especially on cardiovascular disease."

b) Healthcare workforce

Clinicians and policymakers alike reported an acute shortage of health workers across all levels of care. This shortage meant that the high workload in facilities always overstretched clinicians. As a result, clinicians lacked time to engage in essential activities such as evaluation and critical analysis of their practice outcomes.

> **County level policymaker 1:** "At primary care level, clinicians want to do a lot, they really want to, but sometimes, the current setup of how you're working fails them. These clinicians are seeing like over 100 people per clinician per day. Given how overly stretched they are, it is hard to expect so much from them because we know that they are doing their best."
>
> **Level 2 nurse 1:** "We do not have enough human resources, in fact, we do not have any. There is an acute shortage. An example right now is, my colleague is on mandatory leave and as you can see in this facility, I am all alone. I have been alone for one month now and I have a few weeks to go."

However, it was notable that most of the clinicians and policymakers voiced many positive and enabling intrinsic qualities. One of these was the high levels of collaboration and teamwork that they observed in facilities. By leveraging these qualities, clinical staff were observed to share and shift tasks easily and informally among themselves and casual workers in the facilities.

On the flip side, this shortage of staff also had other consequences such as role conflict. Clinicians seem occasionally to oscillate from role expansion in line with their desire to do more to role contraction when they were overwhelmed with the high workload (see Part 2, section f). For example, clinicians often opted to prescribe medicines as a key role in their practice while making the case that lifestyle adjustment was a nutritionist's role. Yet only one nutritionist was employed in the seven facilities where this study was conducted.

> **Level 4 clinical officer 2**: "My view is that, yes, people should get advice and counselling, but we should have a specific person to do that, perhaps a nutritionist or nurse. In the outpatient department, where I work, we don't have that person. Currently I am not able to do it and then still manage all my patients…"

c) Infrastructural support

There was a general acknowledgement that infrastructural support had improved in the previous few years, but only in relation to better prevention and management of infectious diseases, and availability of reproductive, maternal and child health services.

> **Level 3 clinical officer 3:** "I don't know how to explain this because in our current health system there are conditions or diseases that are taken into high consideration, like malaria, diarrhoeal diseases, and pneumonia. We have guidelines, medication and special reporting documents for them even at a facility level. So we are focusing on that mostly."

Infrastructural support remained insufficient, and occasionally was absent, for NCD prevention and management. This was apparent in terms of a lack of diagnostic equipment, essential medication and appropriate health information systems. For example, across all facilities, there were no CVD risk-assessment tools or lipid assays available. At levels 2 and 3, patient health records were unfit for chronic care models of management (see Part 1 section 1b).

> **Level 4 clinical officer 2:** "We do not have vital equipment such as blood pressure machines, currently we only have one – you have seen

> me walk in and out to try and borrow one if possible, meaning that one BP machine can be shared across the entire department…We have frequent drug shortages…and our other biggest challenge is laboratories…most of the tests are on and off, sometimes you will send the patient for a lipid profile which is never available here, forcing the patient to go outside [private laboratory], which is more expensive compared to public facilities. Most of these patients do not even come back when you give them tests so I tend to make a diagnosis without confirmatory tests and give them medications."

First-line CVD risk-prevention medicines such as statins, calcium-channel blockers, thiazide diuretics, angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers were often unavailable in facilities, especially at levels 2 and 3 of care. This often led to non-standard and unsuitable pharmacological practice in these facilities (see Part 1 section 3b).

5.4.4.3 Organisation of healthcare services

Policymakers said that, due to decades of investment into health programmes, although focused on infectious disease prevention and management, primary healthcare systems could offer the required CVD services. However, the key issue was figuring out how to better organise and incorporate NCD service delivery by leveraging existing primary healthcare infrastructure and systems.

> **National level policymaker 1:** "In terms of space and equipment etc, that I think is already there and set up due to years of investment in infectious disease management. We also have diabetic clinics, hypertension clinics, so I think it's just about how best we organise how we do the work."

Policymakers also claimed that this need to redesign service delivery in the primary healthcare system was related to the consequences of the previous positioning of CVD care in the system. For decades, CVD risk prevention and management had been implicitly considered as a service to be offered at secondary-care level.

> **County level policymaker 1:** "Well you know, initially, a lot of cardiovascular related interventions were basically seen as interventions to be done at level 4 or level 5 [secondary]. So, initially at levels 1, 2 and 3, if someone was suspected to be at risk of CVD, it would mean direct referral to levels 4 and 5. So, yeah, initially and for a long time, it used to be not really a primary-care package."

Consequently, this has led to reduced demand for these services in primary care and, instead, has generated an unsustainable demand for these services in secondary care. This increase in demand for CVD-related services, mainly curative, has led to a shift of focus to prevention and health promotion, which is best done in primary care. The secondary level of care is characterised by long wait times and sub-standard quality of care.

> **National level policymaker 2:** "Detection of cardiovascular risks and disease at the primary-care level will greatly increase the utilisation of health services by unclogging the secondary level of care, where the current situation is characterised by long waiting times, sub-standard quality of care, commodity stock-outs, and things like that."

5.4.4.4 Policy, guidelines and clinical-practice gap

Policies and clinical guidelines for CVD risk prevention and management in primary-care settings at the national level have been drawn up or updated to be evidence-based. Clinicians and policymakers viewed these policies and guidelines as credible, since they were modelled on international guidelines and best practice from the WHO. There was some concern regarding the practicality and validity of some of the recommended tools such as CVD risk-scoring tools; however, there was a consensus that the existence of these guidelines and tools was better than nothing to guide practice.

> **National level policymaker 1:** "Yes, we have guidelines in line with the overall Kenya health policy strategy. So, our national guideline, which was launched in 2018, now has included and centred the prevention of CVDs and also introduced the use of the CVD risk scores. These try to identify and manage high-risk patients and the patients who are at risk."

> **National level policymaker 2:** "There was a lot of discussion and actual debate on it [CVD risk scores], principally because the tools available for cardiovascular risk scoring have their limitations and none of them really have been tested in our healthcare setting. So, a number of stakeholders felt that they were not sensitive enough to be applied, but, after discussions and consultations, it was agreed that it is better to have a tool in place rather than there being none, and improve on the tool as we go along, and generate evidence on the same."

However, knowledge of these guidelines and tools seemed to be restricted to national-level policymakers. A few county level policymakers were aware of them, but most were not. Yet, all but one of the clinicians who were interviewed in this study were aware of such guidelines and tools (see Part 1 section 2). These findings demonstrate a discordance between policy and practice. This was often created by weak coordination and communication systems between these three key stakeholders: clinicians, and local and national governments.

> **Level 2 nurse 1:** "I have not heard of anything like that [guidelines for CVD clinical practice] here in this facility or ever. No, we do not have any."

National-level policymakers who were questioned about this gap between policy and practice said that they had done their job, which was to formulate and package evidence-based policies and clinical guidelines to ensure that they were ready for adoption, but that they did not have any mandate to influence uptake of these guidelines. Adoption of the guidelines was left to the county governments. National-level policymakers stood ready to offer technical assistance but only at the invitation of local governments.

> **National level policymaker 2:** "From where I sit at the national level, it is really a little beyond my mandate principally because health service delivery is now within the purview of county health departments. So, I have no explicit role in engaging health workers and requiring of them to make commitment to any of the guidelines we develop. Our main work is to develop policies and disseminate them to the health department. We have tried to do that. The county health departments

> should now cascade it to the practice level through their implementation strategies."

This demarcation presented a barrier to the cascade of these guidelines to where they were needed most – in facilities. The next section will explore some of the reasons why this dissemination and implementation process seemed to have stalled.

5.4.4.5 Scaling up implementation

Generally, dissemination and implementation strategies of the CVD prevention and management guidelines were suboptimal, which led their dissemination and use to be haphazard and uncoordinated. Often, implementation was left to chance, stakeholders' interest and political goodwill. Interviews with policymakers at both levels of government showed that implementation challenges often centred around two key issues: a lack of clarity on implementation leadership and a lack of resources. While the county government was formally mandated to lead in the implementation of guidelines formulated by the national government, county-level policymakers expected the national government also to provide good dissemination strategies. Often, these strategies were not provided and therefore guidelines did not reach facilities.

> **County level policymaker 1: "**From the national government, we need good strategies for dissemination of guidelines. We need them to be timely when they're making these policies, we need them to invest in technology and new advancement. But also we need to create a conducive environment for uptake, mainly in a way that is realistic – most of the policies that are rolled out feel like they're asking us to go to the moon without a space programme, they are drastic and dramatic. Where is the framework or structure to take up these policies? Most of these policies make some of us feel like 'okay, how do we use that and where do we even go from here?'"

In terms of resources, policymakers said that there was a lack of adequate resources to support implementation at the national and county levels. This frequently delayed the implementation of many guidelines that were disseminated to counties. Specifically, county-level policymakers said that, when guidelines were disseminated to them for

implementation, there was a lack of capacity to support new practice, especially for NCDs. This need for capacity strengthening has been explored in the previous section (see section 4.2c).

> **National level policymaker 2**: "So, we are currently doing the dissemination of the guideline as a whole. This began in May 2018. It has been fragmented because of the lack of resources, so some counties have been disseminated the whole document and some counties have been disseminated part of the document…"

5.4.4.6 Donor support and health priorities

Historically, the burden of disease for the Kenyan population has been characterised by increasing incidence of infectious diseases such as HIV/AIDS, TB, malaria, and upper respiratory infections such as pneumonia. Therefore, the government and multilateral institutions have focused support on the scale-up of prevention and management of these communicable diseases and on provision of essential health services related to reproductive, maternal and child health.

> **National level policymaker 1**: "NCDs' focus is still fresh for us, so we are sort of still buried in communicable diseases strategies, so it is now we're getting into the NCD space, and cardiovascular space…"

However, in the last decade, the epidemiology of the population has shifted towards a triple burden of disease: a backlog of common infections, malnourishment and maternal mortality, and the emerging challenges of NCDs such as CVD. Unfortunately, these findings suggest that the health priorities for practice have barely shifted.

> **Level 3 clinical officer 3:** "I don't know how to explain this because in our current health system there are conditions or diseases that are taken into high consideration, like malaria, diarrhoeal diseases, and pneumonia. We have guidelines, medication and special reporting documents for them even at a facility level. So we are focusing on that mostly."

Notably, priorities at the policy level, which are heavily influenced by global discourse and the national burden of disease, have changed. A testament to this change is in the

clear articulation of these priorities in the updated Health Policy for Kenya and the formulation of the national clinical guidelines for CVD risk prevention and management. Interviews with policymakers and clinicians highlighted that, in settings in which resources were limited, setting priorities on paper was not enough. Often, the 'real' priorities were set according to the resources that were available. While policymakers criticised the government for not matching NCD policy commitment with funding, they also indicated that external donors often set priorities through programme funding. At present, there is a scarcity of such financing for NCDs in general, and therefore, minimal funding is available to support the scaling up of CVD risk prevention and management at a time of most need.

> **County level policymaker 1:** "Initially we paid a lot of attention to the programme issues, like HIV, maternal and infant mortalities and malaria – mainly influenced by mortalities yes, but also the availability of funding mainly from the central government through donors. But now we are realising that CVD and NCD issues are creeping up on us and we are not ready. We have not been paying attention to these conditions as we should have…"
>
> **National level policymaker 1:** "Let me talk particularly about health prevention; I would say a very minimal amount has been done by our government. One of the main reasons is funding because if you look at funding, first NCD funding, including government allocation, is very little, and then prevention funding is even more scarce… the reality is that even most of these infectious disease priorities are donor driven and thus there is a lot of donor resourcing. And in turn prioritisation."

5.5 Discussion

5.5.1 Summary of findings

This chapter reported qualitatively on current practice in CVD risk prevention and management in Kenyan primary-care settings, and on contextual factors that influenced the adoption of the recommended practice of the same. These factors were shown through the use of Kilifi County, Kenya, as a case study.

It was found that recommended practice infrequently guided current practice due to a lack of guidelines and knowledge at the micro (clinicians and patients) and meso levels (clinical settings and local government). Clinicians relied on their clinical judgement to provide CVD risk prevention and management services where needed. Although the clinicians lacked sufficient knowledge, their judgement was heavily informed by experience, practicality and continuous critical analysis. Notably, clinicians possessed many positive and enabling intrinsic qualities that facilitated innovation, knowledge-seeking, and measures they took to overcome some challenging physical conditions in their practices.

Factors that influenced the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care appeared to cluster around the macro (global and national influences) and meso (clinical settings and local government) levels. Some of these factors resulted from the residual challenges of a recent political process, i.e. weak coordination mechanisms in the devolution of health service functions. Other factors stemmed from a need for service delivery redesign, challenges in scaling up implementation, and a need for better mechanisms to set priorities that are not heavily influenced by external funding.

Findings from this study also highlighted the existence of a gap between policy and practice. On the one hand, policies and guidelines were evidence-based and modelled on international best practice, yet on the other hand, current practice members were unaware of such policies and guidelines.

5.5.2 Findings in the context of existing research

The work that is described in this chapter addressed an existing gap in literature, which was raised in Chapters 2 and 4, by providing insight into CVD prevention and

management practices in Kenyan primary-care settings. Doing so adds to the limited knowledge of how clinicians in LMICs negotiate and make sense of their practice in the absence of clinical guidelines in facilities. To my knowledge, this is the first study to describe and understand CVD risk prevention and management in this manner, through use of the COM-B model of understanding behaviour, in Kenya or the region.

This study also adds to various discourses. The challenges that befall the implementation of clinical guidelines are age-old, but they continually evolve and require contextualisation. Cabana et al. (1999) and Florian et al. (2016) outlined many of the barriers that inhibit the application of clinical guidelines (210,211). These include: the physician's knowledge (awareness and familiarity), physician's attitudes (agreement and motivation), and external factors (organisational constraints, resources, heavy workload etc.) (212,213). Many of these factors were observed to be barriers to the adoption of the recommended practice in CVD risk prevention and management in Kenya, and they are known to exist in many other LMICs, such as Botswana, Ghana, Uganda, Benin and Togo (165). Top of the list, and perhaps age-old, is the lack of capacity in health systems to adopt and implement these guidelines due to limited domestic resource allocation for health services, the influence of siloed donor funding and an unprepared healthcare workforce.

Funding for NCD related activities is a global priority but it remains scarce. For example, according to surveys that were conducted in 2017 and 2019 regarding global capacity for NCD prevention and control, less than 2% of programme-specific investments across all disease areas were allocated to NCDs (74,214). Additionally, many LMICs, including Kenya, have allocated limited domestic funding to NCD prevention and management. External funders continue to fund programmes that are of

interest to them, in isolation, instead of focusing on system-level support, i.e. the primary healthcare system. This programmatic type of funding, which is often related to infectious diseases, has been widely reported to upset implementation priorities, especially in limited-resource settings (215–219).

In this study, it was found that the clinicians' attitudes and other intrinsic factors that have been raised by Cabana et al. (1999) and Florian et al. (2016) were possible facilitators for adoption of new practices. These factors combined with smart policies regarding human resources for health, such as strengthening retention, training, education and appropriate remuneration, have the potential to propel implementation and adoption of recommended practice (175). An excellent example of a place where success has been realised along these lines is Botswana, a country which four years ago had similar challenges. Through investment in human resource strengthening, Botswana now has fully integrated NCD services that include CVD risk prevention and management in primary healthcare (220).

The effects of devolution of healthcare management formed a glue between many of the factors that influenced the adoption of recommended practice at the local level and in clinical settings. Devolution of health service functions has been lauded as the catalyst for significant improvement in development of the local-level health structure in Kenya (221). However, the rapidity with which the process was done, with limited technical expertise, has led to partisan decision making and prioritisation processes that currently serve political and power interests (13). This study adds to this discourse.

Lastly, findings from this study also contribute to a better understanding of how clinical judgement is used by clinicians, especially in the absence of sufficient knowledge support. This study's synthesis supports the notion that clinical judgement is a central

tenet of clinical practice despite a lack of adequate knowledge (222–224). Yet, sufficient and evidence-based knowledge is a critical component of the appropriate use of clinical judgement in practice (225).

5.5.3 Strengths and limitations

Methodological rigour strengthens this study. Strategies to ensure rigour included use of purposive sampling and selection of cases to enable comparison between and inclusion of a wide range of perspectives. Use of three data-collection methods - structured observations, semi-structured interviews and document analysis - further improved the triangulation of findings which helped further explore various dimensions providing a richer understanding. The fact that I alone conducted the observations and follow-up interviews with patients, clinicians and policymakers enabled me to gain depth in the collection and analysis of the qualitative data. The help of a second and more senior qualitative analyst (VW) ensured consistency in coding. The use of deductive (framework analysis) and inductive (thematic analysis) approaches to address the study's aims reduced the chance of excluding important but unanticipated information. Further, the use of theoretical frameworks in behaviour change and implementation science (the COM-B and CFIR, respectively) allowed for thorough interpretation of the study's findings.

This study had some limitations. First, it covered an extensive topic; perhaps the development of more specific and sequential aims would have improved the coverage of the many issues that this study raises. However, this study was deemed necessary due to the paucity of published work in this area and setting. As such, this work sits best as exploratory research.

In terms of reflexivity, my position as a nurse and midwife affected my access to the field. During the interviews, it seemed beneficial that I was a clinician because I could ask about technical concepts in CVD risk prevention and management. My affiliation with the KEMRI-Wellcome Trust and the University of Oxford may have affected the responses of interviewees. However, when I conducted interviews with participants, I made it clear that I did not work for the KEMRI-Wellcome Trust and was a doctoral student at the University of Oxford. It is reasonable to assume that these complexities in my identity in the field may have made participants less comfortable and perhaps more hesitant to be critical of themselves or their workplace.

Additionally, the majority of the patient participants in the observed consultations were female. It is likely that men's experiences, framed by an additional lens of care-seeking behaviours, would offer different findings. However, it is well documented that persuading men to seek healthcare services in these settings is a challenge.

A further limitation was a lack of participant validation of the analysis. The gaining of such validation was planned; however, the consequences of a global pandemic, which included travel and social gathering restrictions, made it difficult for me to reach out to the participants.

Lastly, the study involves one case study, Kilifi County, to report on the topic. While the county has many similarities (demographics and disease epidemiology) with most other counties in the country, care should be taken not to generalise these findings, but rather to transfer and build on them as appropriate for various contexts.

5.5.4 Implications for research and practice

First, the findings are consistent with others in showing that there is a gap between policy and practice in CVD risk prevention and management. This study also supports

previous findings that the challenges of implementation of recommended practice in settings such as Kenya are longstanding. However, these challenges continually evolve and require contextualisation. Given the lack of familiarity among healthcare providers with guidelines on CVD risk prevention and management, support for training of clinicians should be offered urgently. Such training should include detailed practical exercises on the measurement of risk factors and the calculation of risk scores in line with the recently updated WHO CVD risk charts for Eastern sub-Saharan Africa (1). Since this study found that the internet, particularly social media, was an important vector for information, this platform should be considered to ramp up training and other innovations.

Second, capacity strengthening in NCD prevention and management is essential for the successful implementation of recommended practice. This will include making available resources that are specific to CVD risk prevention and management, as required; these include staffing, equipment and essential CVD medicines in primary healthcare. This should happen in tandem with training support of healthcare workers. Second, the already strong communicable disease prevention and management models of care should be leveraged, and this process should include a service redesign that focuses on chronic care management and the mitigation of the population's risk to CVD.

Third, patient engagement is needed to create awareness of CVD risk factors, and to increase demand for CVD risk prevention and management services at the primary-care level. Further research such as of facilitated participatory learning and action is required to improve contextualisation of many of the issues that were raised in this study, such

as the identification and correction of myths, and the incorporation of cultural awareness and support in lifestyle adjustment advice.

Particular attention should be paid to communication and feedback mechanisms between the national and county levels of government. While devolution of health service functions is aimed at promoting health equality for all Kenyans, it may be doing the exact opposite by creating uncoordinated silos of information that are critical to the improvement of practice. Explicit strategies to increase the local government's involvement in policy formulation, dissemination and implementation are urgently needed.

Future research should also focus on implementation support strategies for CVD risk prevention and management. Findings presented in this study are a great place to start. They provide a good understanding of behaviour as the first of a three-step process in the design of implementation interventions as per the behaviour change wheel framework (204).

5.6 Conclusion

Considerable challenges lie ahead in the full adoption of recommended practice in CVD risk prevention and management in Kenyan primary-care settings. This study uses complex theoretical frameworks to provide an understanding of current practice and the contextual factors that influence the implementation of recommended practice. As such, findings from this study can be used to develop and support meaningful and pragmatic change in CVD prevention and management in these settings.

5.7 Chapter summary

- I conducted 560 hours of observations, 15 interviews with clinicians and policymakers, 30 exit interviews with patients and a documents analysis across seven healthcare facilities in Kilifi County;
- through use of thematic analysis, current CVD risk prevention and management practices in these settings were described and explored. This process helped to identify a lack of familiarity with clinical guidelines related to CVD risk in clinical settings and to better understand the use of clinical judgement by clinicians in these facilities;
- by application of framework analysis, factors that influenced the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care were analysed and categorised into three levels: micro (clinician and patient), meso (clinical setting and local government), and macro (global and national influences). The intricate relationships across these levels were also explored;
- the findings of this chapter helped to identify opportunities to improve the implementation of recommended practice. These included the need for:
    - detailed training, which would involve practical exercises and the leveraging of use of the internet, on the measurement of risk factors and the calculation of risk scores with the recently updated WHO CVD risk charts for Eastern sub-Saharan Africa;
    - urgent capacity strengthening in NCD prevention and management. This would include making available resources specific to CVD risk prevention and management, such as adequate staffing, equipment and essential CVD medicines in primary healthcare;
    - greater engagement with patients to create awareness of CVD risk factors and to increase demand for CVD risk prevention and management services at the primary-care level;
    - improved communication and feedback mechanisms between the national and county levels of government; and
    - future research on strategies to support contextual implementation of CVD risk prevention and management methods.

Chapter 6. **The recommended level of use for essential medicines: a comparison between medicines for cardiovascular disease and the leading communicable diseases in Eastern sub-Saharan Africa**

6.1 Publication statement

The protocol for this chapter was published on the open science framework (OSF) (226).

6.2 Introduction

The work that is described in Chapter 5 highlighted an urgent need for capacity strengthening in CVD prevention and management, specifically by ensuring that essential CVD medicines are available in Kenyan primary care. During the period of this study, essential CVD medicines were often not available due to inconsistent supply, which led to recurrent stockouts. Clinicians emphasised that the difficulty in obtaining regular supply of these medicines was a significant challenge to CVD risk assessment in Kenyan primary care settings.

Notably, in addition to limited capacity, i.e., infrastructure and human resources, a general lack of prioritisation of CVD prevention and management in primary care was a key theme of the findings. Historically, the burden of disease among Kenyans has been high and increasing levels of infectious diseases such as HIV/AIDS, TB, malaria, and upper respiratory infections such as pneumonia. Therefore, the government and multilateral institutions have focused on the scale-up of prevention and management of these communicable diseases and the provision of essential health services related to reproductive, maternal, and child health. This approach has led to perhaps an unintended lack of focus on CVD risk prevention and management compared with other leading causes of morbidity and mortality in the country.

Essential medicines are defined as those medicines that should be available within normally functioning health systems at all times in adequate amounts, in the appropriate dosage forms, at assured quality, and at a price that the individual and the community can afford (227). These medicines are usually shown in national essential medicines lists (NEML). These lists are intended to improve health equity and inform the appropriate (efficient and effective) use of health resources (227–229). Importantly, essential medicines should satisfy the population's priority healthcare needs as informed by their public health relevance.

The global WHO target that essential medicines should be available at a rate of 80% in private and public facilities by 2020 is far from being attained (41,74). Currently, these medicines are available at consistently lower rates than this in LMICs (230). Some of the reasons for this pattern include inadequate funding, lack of incentives to maintain stocks, inability to forecast accurately and inefficient purchasing and distribution systems. However, these medicines' disproportionate unavailability for NCDs remains unaddressed in private and public sectors (231–234). According to studies conducted between 2007 and 2012 using WHO/Health Action International (WHO/HAI) survey methods, there was a comparative mean difference of 11.5% (private facilities) and 17.5% (public facilities) in the availability of medicines that were required for acute or chronic conditions in 40 LMICs (235,236).

Pharmacological treatment plays a vital role in the prevention and management of diseases. For example, in prevention and management of CVD risk, treatment with first-line antihypertensive medicines can reduce the combined mortality and morbidity caused by CVD by about a third, regardless of the pre-treatment absolute risk (237). Similarly, statin treatment produces a coronary heart disease mortality benefit of 30%

through a reduction in a patient's cholesterol level of 1mmol/l (275). Many CVD risk prevention and management guidelines focus on initiation of treatment at the primary-care level for those at high-risk. One suggestion that has been made to aid in the attainment of the 80% availability target for essential medicines is that these medicines must be rationally selected and used at all levels of care (41). It is paramount that essential medicines are made available at the primary healthcare level, as this affords patients easy access to these medicines.

However, in many countries in sub-Saharan Africa where the healthcare systems face a dual burden of communicable and non-communicable diseases, this practice is lacking (238–240). Prevention and management of infectious, communicable diseases takes precedence in primary healthcare settings, despite surging rates of NCD-related morbidity and mortality (241,242). This prioritisation is also inferred in policies and guidelines that inform clinical practice and resource allocation at various levels of care – including in NEMLs.

Therefore, I aimed to describe and compare the recommended level of use of essential medicines for the leading causes of mortality in Eastern sub-Saharan Africa (CVD, TB and HIV/AIDs) in the latest NEMLs to explore whether this was the case. To enable this comparison, the recommended levels of use were used as proxy measures of accessibility. The recommended level is defined as the lowest level of the health-care system at which a medicine is expected to be appropriately used, i.e. following a correct diagnosis and current best practice. This analysis was deemed to be a crucial starting point to advocate for the revision of NEMLs to reflect the population need and, in turn, to support the implementation of CVD risk assessment in Kenyan primary care settings.

6.3 Aim and Objectives

6.3.1 Aim

For the work that is described in this chapter, I aimed to describe and compare the recommended levels of use of essential medicines for the leading causes of mortality in Eastern sub-Saharan Africa (CVD, TB and HIV/AIDs) in the latest NEMLs.

6.3.2 Objective

To describe the recommended levels of use of essential medicines in CVD risk prevention and management and to compare them to the recommendations for use of essential medicines for TB and HIV/AIDs.

I hypothesised that there would be a disproportionate percentage difference in the recommended levels of use of each of these groups of essential medicines.

6.4 Methods

6.4.1 Study design

A cross-sectional observational study of retrospective data was performed.

6.4.2 Data sources

The following datasets were used:

1. the global burden of disease (GBD) study (2019) to identify the leading causes of mortality in Eastern sub-Saharan Africa (243), and
2. the WHO's repository for NEMLs (244).

6.4.3 Data extraction

First, the data regarding the top two leading causes (communicable) of mortality in Eastern sub-Saharan Africa according to the GBD 2019 study were extracted. The study was accessed through the Institute for Health Metrics and Evaluation (IHME) data

visualisation hub; this is a public domain used to explore findings from the GBD 2019 study (10). Table 17 shows the web input used to extract the top five leading causes of mortality in Eastern sub-Saharan Africa from the IHME data visualisation hub.

Table 17. IHME data visualisation hub web input for leading causes of mortality in Eastern sub-Saharan Africa

Setting	Input
Display	Cause
Rank	Cause
Category	All causes, level 2
Measure	Deaths
Location	Eastern sub-Saharan Africa
Year	2019
Age	All
Sex	Both
Units	Rate

Second, based on the output above, a list of essential medicines and their anatomical therapeutic classification (ATC) chemical substance codes were extracted from the latest (21st) WHO essential medicines list (EML) (245). For CVD, only medicines used in the prevention and management of CVD risk were included, i.e. antihypertensives, antiplatelet therapies and lipid-reducing therapies. Medicines used to manage angina, arrhythmias and heart failure were excluded unless their intended use, as listed in the NEMLs, was as an antihypertensive, antiplatelet therapy or lipid-lowering therapy. Third, the latest NEMLs for Eastern sub-Saharan Africa were extracted from the WHO's repository. Only NEMLs that included the recommended levels of use for the essential medicines were used. Lastly, essential medicines from the included NEMLs were extracted onto an Excel spreadsheet.

6.4.4 Data management

All data were extracted onto an Excel spreadsheet before analysis. Stata version 16 and Excel were used to analyse the data, and Datawrapper was used to generate figures (98,246).

6.4.5 Data analysis

The recommended levels of use were categorised as levels one, two and three, which mirrored primary, secondary and tertiary care, respectively. Table 18 provides details and definitions based on the NEMLs that were extracted.

Descriptive statistics, which included measures of central tendency (mode and average) and variation (range), were used for analysis. Data were then displayed graphically for visual interpretation. Missing data were not excluded from the analysis.

6.4.6 Methodology reporting

The methods that were used in the work described in this chapter were reported according to the STROBE guidelines for the reporting of observational studies (100).

6.4.7 Ethics and data protection

The data that were used for this study are publicly available, and therefore ethics committee approval was not required.

6.5 Results

6.5.1 Extraction of leading causes of mortality and NEMLs

The leading causes of mortality (2019) were respiratory infections and TB (93.88 deaths per 100,000), CVDs (87.11 deaths per 100,000), maternal and neonatal diseases (73.58 deaths per 100,000), and HIV/AIDs (66.26 deaths per 100,000). HIV and TB were the communicable diseases that were selected for analysis due to the ease with which data on essential medicines that were used to treat these conditions could be extracted from the NEMLs. The maternal and neonatal diseases group was excluded due to the complexity of disease classification, i.e. it was difficult to delineate their aetiology as communicable, congenital or nutritional.

Appendix 22 lists the essential medicines data that were extracted from the NEMLs and the WHO list for HIV, TB and CVD. Table 19 lists the NEMLs that were included in the analysis. NEMLs in French and Portuguese, such as those from Burundi, Mozambique, Madagascar and Rwanda, were translated into English by use of Google Translate.

Table 19. List of NEMLs that were included in the analysis

Source country for NEML	Year published
Burundi	2012
Eritrea	2010
Kenya	2016
Madagascar	2008
Mozambique	2017
Rwanda	2010
Somalia	2006
Uganda	2012
Zambia	2013

6.5.2 Salient characteristics of NEMLs

Regarding essential HIV treatments, dolutegravir, which is widely used in Western countries to treat HIV, was missing from the nine NEMLs that were used for this analysis (Figure 18). Five out of the nine countries recommended the use of essential HIV medicines at level 1, while three recommended use at level 2. Somalia did not list any essential HIV medicines on its NEML.

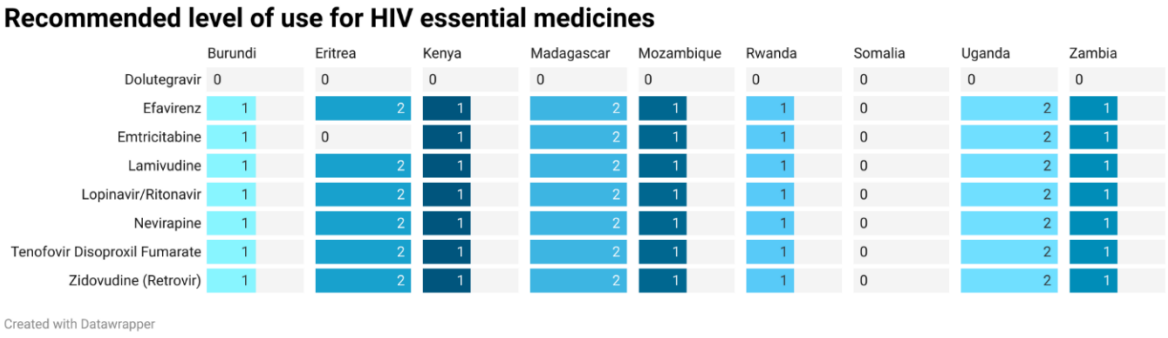


Figure 18. Recommended level of use for HIV essential medicines as shown in NEMLs of nine countries included in the analysis

Table 18. Categorisation of the recommended levels of use of essential medicines based on the included NEMLs

	Burundi	Eritrea	Kenya	Madagascar	Mozambique	Rwanda	Somalia	Uganda	Zambia
Level 1	Health centres	Use in health centres and high health-care levels	Dispensaries/clinics, health centres	Health posts, health centres	Medicines that may be prescribed by medical agents, nurses and staff in higher categories	Health centres	Health centres close to and a distance from referral	Health centres level 2 (enrolled comprehensive nurse), health centres level 3 (clinical officer)	Health posts, Health Centres
Level 2	1st and 2nd referral hospitals	For use in all hospitals	Primary hospitals, secondary hospitals	District hospitals, regional referral hospitals	Medicines that may be prescribed by technicians (of general medicine, surgery), general doctors and staff in higher categories	District hospitals	Hospitals	Health centres level 4 (medical officer), hospitals, regional referral hospitals	District hospital, provincial/ general hospitals
Level 3	National referral hospitals	Speciality medicines (to be used in special cases and kept only in the highest referral hospital)	Tertiary hospitals	University teaching hospitals	Medicines prescribed by expert doctors	Referral hospitals		National referral hospitals	Central/ specialist hospital

Except for Somalia, all the countries that were included in this study had the requisite essential TB medicines listed in their NEMLs. These medicines were all recommended for level 1 use in NEMLs (Figure 19). Unlike the other countries, Somalia did not include isoniazid on its essential TB medicines list and recommended use of essential TB medicines at level 3.

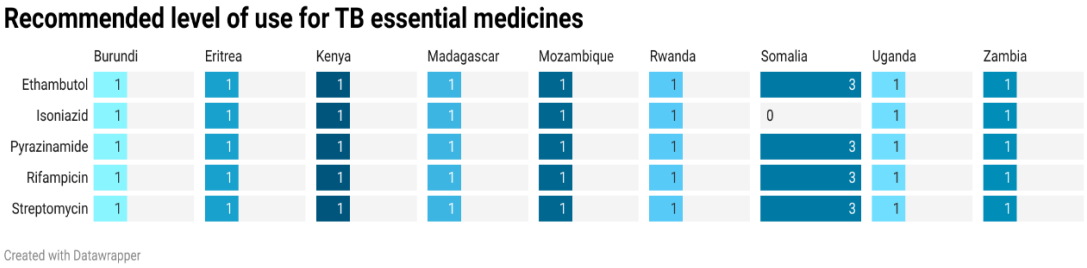


Figure 19. Recommended level of use of essential TB medicines in the nine countries that were analysed

A total of 29 medicines were included as essential CVD medicines; 18 were extracted from the WHO EML and 11 more from NEMLs. On average, 54.32% of countries' essential CVD medicines were included in the WHO EML. Zambia had the greatest number of WHO-listed essential CVD medicines (77.78%), while Madagascar had the smallest number (33.33%) (Figure 20). About half of the essential CVD medicines (48.28%) that were extracted were listed by four or fewer countries. Telmisartan, which is used to treat high blood pressure and heart failure in Western countries, was not listed in any of the NEMLs.

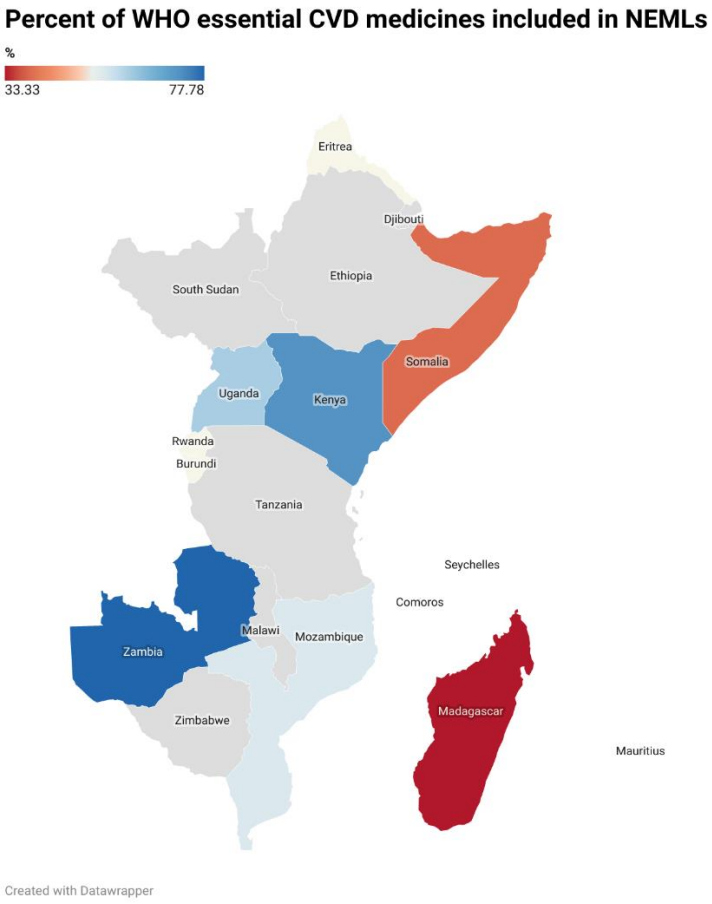
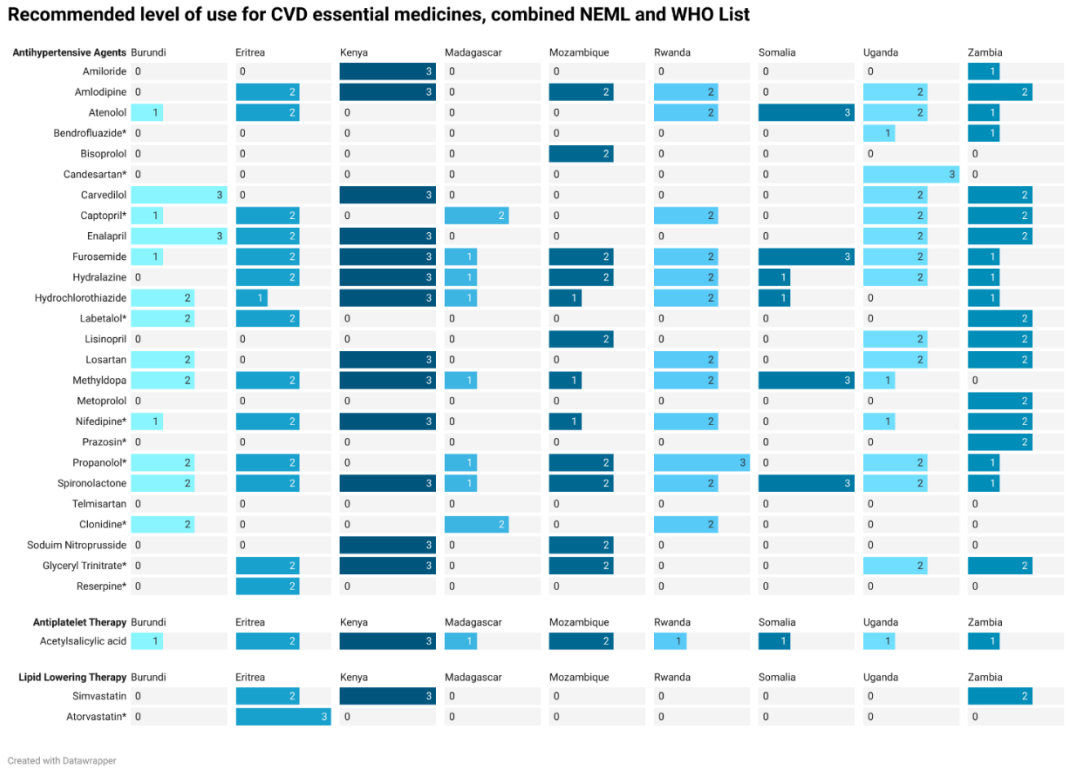


Figure 20. Map shows percentage of essential CVD medicines that are listed by the WHO and included in NEMLs

The recommended level at which CVD essential medicines could be used varied (Figure 21). Six of the nine countries recommended the use of acetylsalicylic acid at level 1. Kenya recommended use of all its essential CVD medicines at level 3. Statins were listed in only three countries and were for use at levels 2 and 3. The most commonly listed antihypertensive agents, which were listed by all countries, were diuretics: furosemide and spironolactone.



***** Essential medicines not classified as essential CVD medicines, i.e. antihypertensives, antiplatelet therapies or lipid-reducing therapies in the WHO EML

Figure 21. Recommended levels of use for essential CVD medicines, combined NEML and WHO list

6.5.3 Comparison of the recommended level of use for essential medicines in CVD, HIV and TB

6.5.3.1 Level 1

More essential medicines for HIV and TB were recommended for use at level 1: 48.61% and 88.89%, respectively; than for CVD: 12.64%. Somalia did not recommend any essential HIV and TB medicines for level 1 (Figure 22). Similarly, Uganda, Madagascar and Eritrea did not recommend any essential HIV medicines at this level. Kenya was the only country that did not recommend any essential CVD medicines at level 1.

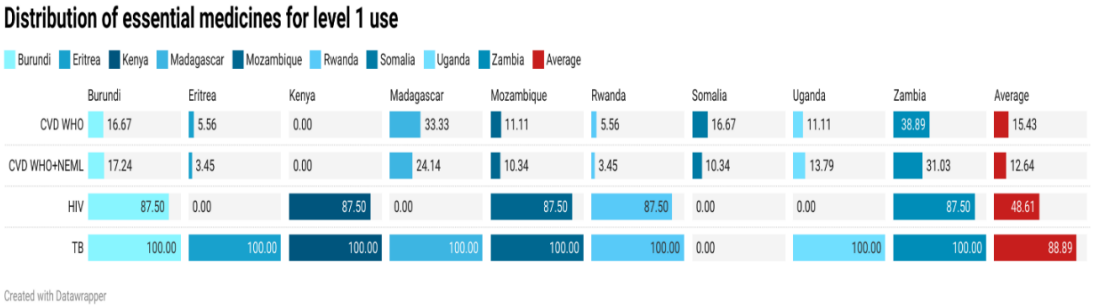


Figure 22. Essential medicine distribution for level 1 use according to country

6.5.3.2 Level 2

An almost equal proportion of essential medicines for HIV and CVD were recommended for use at level 2, 27.78% and 26.44%, respectively. No essential TB medicines were recommended for use at level 2. Countries that did not recommend prescription of essential HIV medicines at level 1 recommended their use at level 2; these countries were Uganda, Madagascar and Eritrea. Figure 23 shows that a majority of the countries, six out of nine, recommended use of essential CVD medicines at level 2. Kenya and Somalia did not recommend the use of essential CVD medicines at this level.

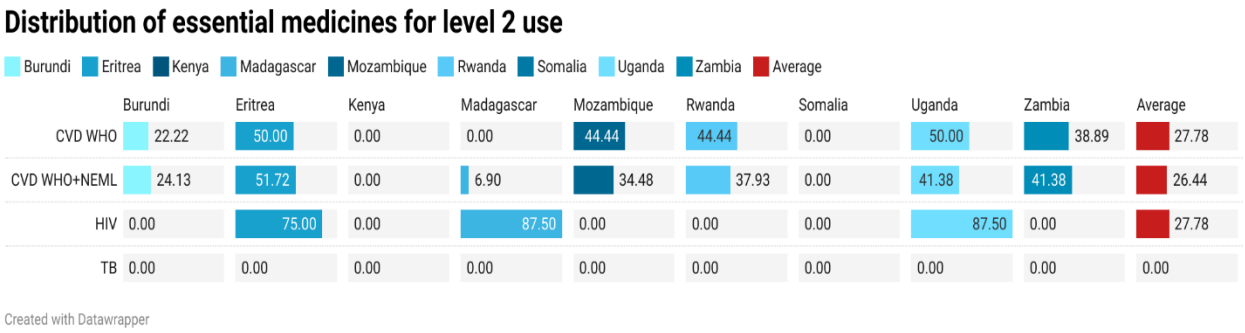


Figure 23. Essential medicine distribution for prescription at level 2 according to country

6.5.3.3 Level 3

No essential HIV medicines were recommended for use at level 3. Essential TB medicines were recommended for use at this level only in Somalia. A total of 11.73% of essential CVD medicines were recommended for use at level 3. Notably, all essential CVD medicines listed in Kenya were recommended for use at level 3 (Figure 24).

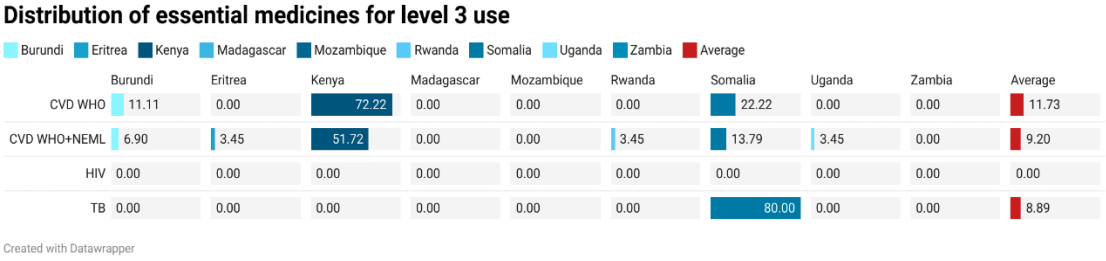


Figure 24. Distribution of essential medicines for prescription at level 3 according to country

6.6 Discussion

6.6.1 Summary of findings

A total of 42 essential medicines were extracted from nine NEMLs: CVD (*n*=29), HIV (*n*=8) and TB (*n*=5). On average, slightly more than half of the countries' essential CVD medicines were included in the WHO EML. Dolutegravir, an essential HIV medicine, was missing from all nine NEMLs. Somalia did not list any essential HIV medicines on its NEML. Except for Somalia, which did not include isoniazid, all the countries that were considered in this study included all the requisite essential TB medicines in their NEMLs.

At level 1, more essential medicines were recommended for HIV and TB treatment than for CVD. The majority of the countries recommended the use of essential CVD medicines at level 2. Acetylsalicylic acid was commonly recommended in NEMLs for use at level 1. Kenya was the only country in this study that did not recommend any

essential CVD medicines for prescription at level 1. Instead, Kenya recommended use of essential CVD medicines at level 3.

6.6.2 Interpretation of findings

These findings confirm the hypothesis set out in this study, which was that there is a disproportionate percentage difference in the recommended levels of use of the essential medicines that are used in communicable diseases compared with those for NCDs in NEMLs. The difference was most noticeable at the lowest level of care: level 1.

The purpose of EMLs is to improve health equity by informing the appropriate use of essential medicines, i.e. medicines that are 'intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price that the individual and the community can afford' (227). This disproportionate difference in the recommended level of use of essential medicines that are used to treat HIV and TB compared with CVD in NEMLs questions the utility of EMLs in enabling access and prioritising the healthcare needs of the population as informed by their public health relevance. In this case, the relevance is the epidemiological landscape of the Eastern sub-Saharan African population.

However, most NEMLs, although stated to be the 'most recent', were out of date, which could explain their inconsistencies with recent research, development and updated clinical guidelines. Examples of these inconsistencies include: the omission of drugs such as dolutegravir for HIV; use of reserpine as an antihypertensive; the widespread recommendation of acetylsalicylic acid for use at level 1 (i.e. primary prevention of CVD risk); and the poor adherence to WHO-recommended essential CVD medicines

in NEMLs. Somalia showed the most inconsistencies in listings and recommended levels of use of the medication across the three diseases. Unlike the other eight countries that were investigated in this study, Somalia is listed by the World Bank as a state in fragile and conflicted-situations due to ongoing intensive conflict (247).

6.6.3 Findings in the context of existing research and policy

Since their inception in 1977, NEMLs have been widely lauded as cost-effective means of providing safe, effective treatment for most high-burden diseases (248). NEMLs are vital to the WHO's sustainable development goal 3.8, which states the aim that people should have "access to safe, effective, quality and affordable essential medicines and vaccines for all". In practice, NEMLs are used nationally to guide procurement and supply practices for medicines that are prescribed in the public sector, to train health workers, to inform local medicine production and national schemes that reimburse medicine costs, and to focus national efforts on universal health coverage (249).

Past discourse on the use of NEMLs has been centred on their vital role to influence the availability and affordability of medicines globally (228,229,232,250,251). Studies have shown that, although the disease burden from NCDs in regions such as Eastern sub-Saharan Africa is growing, disproportionate gaps exist in the availability of medicines to treat NCDs. Studies have shown that, generally, NCD-related medication is often less available and affordable than that for communicable diseases (231,235,236,252–254). This is also confirmed in this study's findings, which showed that, on average, only about half of the WHO-classified essential CVD medicines were listed in NEMLs compared with almost all those that were classified as such for HIV and TB. Poor availability and affordability of essential CVD medicines have been associated with a higher risk of major adverse cardiovascular events and mortality,

which highlights the importance of access to these medicines as a key strategy to reduce the global incidence of CVD (255,256).

However, this study's findings posit that the availability and affordability of essential medicines is just one factor in ensuring that people have access to these medicines. The contents of these lists constitute important determinants of health. To my knowledge, this is the first study to highlight the need to harmonise the recommended levels at which essential medicines are prescribed, particularly in the case of NCDs. This emphasis on adjustment of the recommended levels at which essential medicines are used is implicitly supported by the actions outlined to meet the ninth global voluntary target of the WHO's global action plan to prevent NCDs (2013-2020). Specifically, it recommends the rational selection and use of medicines at all levels of care, including primary healthcare (41).

Such harmonisation is a challenge due to the variation in dynamic and complex health systems at national and sub-national levels. However, findings from the study that is described in this chapter and those explained in Chapters 4 and 5 show that a lack of prioritisation of NCD medicines may create policy- and supply-related barriers to access, which may impact other processes in the health system. This may have a detrimental effect on patients' ability to adhere to treatment regimes. Due to limited resources, it is reasonable that some treatments may be initiated at higher levels of care; however, patients need easy access to these medicines at the lowest levels of care if they are to adhere to long-term treatment regimens.

6.6.4 Strengths and limitations of this study

This study contributes to a new dimension in the policy discourse on the availability and affordability of essential NCD medicines, since it highlights the disproportionate

percentage difference in the recommended levels at which essential medicines used to treat HIV and TB are made available compared with those that are used to treat CVD. As such, it illustrates a need to expand WHO access to drugs and medicine frameworks by highlighting explicitly the importance of harmonisation across NEMLs of recommended levels of use of essential medicines.

The limitations of this study are many and findings should be interpreted against this backdrop. For example, the recommended level at which drugs are made available is used as a proxy measure of accessibility. As such, it does not infer accurately the availability of these medicines at various levels of care. This is confirmed by the findings that are discussed in Chapter 5, which show that in Kenya, for example, antihypertensive agents such as methyldopa and nifedipine are commonly prescribed at the lowest level of care – this is not reflected in Kenya's NEML and, consequently, in this chapter's findings. Caution is warranted when the availability and accessibility of essential medicines are interpreted in terms of the recommended level of use in the countries that have been studied.

Similarly, most NEMLs that were included in this study, although considered to be the 'most recent', were out of date. Progress may have been made since publication of these NEMLs in the rational selection and use of essential medicines in these countries. Lastly, to analyse these NEMLs, there was a need to recategorise and harmonise levels of care to mirror three categories of care: primary, secondary and tertiary. This categorisation requires the assumption that levels of care across nine healthcare systems can fit neatly into these three levels. It is possible that there was a misclassification due to the complexity and dynamism of these healthcare systems. However, this was

addressed through the provision of definitions in the methods section, which guided the analysis.

6.6.5 Implications for policy and research

This study's findings could aid in the expansion of the WHO's recommendations regarding drugs and medicine frameworks (257). Currently, these frameworks, which include NEMLs, do not explicitly mention recommendations on the use of medicines at the 'correct' levels of care, which may affect accessibility to and availability of the medication. These frameworks focus on rational selection, regulatory systems, sustainable procurement and pricing systems, and multi-stakeholder action. Future research in this area should focus on understanding how, in practice, the NEML recommended level at which medicines should be used influences the availability and affordability of essential medicines at the lowest levels of care in various healthcare systems.

6.7 Conclusions

There may be a disproportionate percentage difference in the recommended levels of use for essential medicines that are used in communicable diseases compared with those for NCDs, particularly in the lowest levels of care, in NEMLs of Eastern sub-Saharan African countries. This study highlights the need to reorient and strengthen health systems to enable a more effective and equitable response to NCDs as recommended in the WHO action plan for the global prevention and control of NCDs. Precisely, this study advocates the rational selection and use of essential medicines at all healthcare levels, including primary healthcare.

6.8 Chapter summary

- A total of 42 essential medicines were extracted from nine NEMLs: those that are used to treat CVD (*n*=29), HIV (*n*=8) and TB (*n*=5). Dolutegravir, an essential HIV medicine, was omitted from all nine NEMLs. On average, only slightly more than half of the essential CVD medicines that are listed by the WHO were included in the countries' NEMLs.
- More essential medicines for treatment of HIV and TB were recommended for use in level 1 than were listed for treatment of CVD. The majority of the countries recommended the use of essential CVD medicines at level 2.
- Kenya was the only country in this study that did not recommend use of any essential CVD medicines at level 1. Instead, essential CVD medicines in Kenya were recommended for use only at level 3.
- These findings confirm the hypothesis set out in this study that NEMLs show a disproportionate percentage difference in the recommended level of use of the essential medicines that are used in communicable diseases compared with those that are used to treat NCDs. The problem is most apparent at the lowest level of care: level 1.

Chapter 7. **Discussion and conclusion**

7.1 Introduction

CVD has occupied the position as the leading cause of death globally for the past two decades, and mortality remains on a steady rise (258). This CVD burden is disproportionately higher in LMICs, causing premature mortality and loss of human capital. In Kenya, CVDs cause 12% of total deaths at all ages among both males and females, 5% of total DALYs and 25% of all hospital admissions (10). The UN and the WHO have prioritised CVD prevention through support of the development of effective, evidence-based, practical interventions that strengthen the management of risk factors for CVDs in primary healthcare. CVD risk stratification in primary healthcare has been a central strategy of the WHO's policy response (43).

The second (2020) WHO global assessment of national capacities for the prevention and management of NCDs shows large implementation gaps in LMICs. For example, while nearly 50% of the countries reported that tools to stratify CVD risk were available in more than 50% of health-care facilities, about 29% reported that these tools were available in less than 25% of facilities. A further 9% of the health authorities of countries were not aware of the extent to which CVD risk stratification was offered. Notably, most countries with availability in more than 50% of facilities were HICs or UMICs – a majority of which were in Europe. Almost 50% of the countries in Africa reported that risk stratification was not available in any health-care facilities (74).

Further, coronavirus disease 2019 (COVID-19), which was caused by a strain of coronavirus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and which was identified in December 2019, has become a global pandemic (259). This pandemic has affected billions of lives as it has killed over 5.5 million people in

the past year (2020/2021) and has upended livelihoods. Clinical studies have reported an association between COVID-19 infection and CVD. Worse outcomes and increased risk of death among COVID-19 infected patients have been linked to the pre-existence of CVD and its risk factors (260).

LMICs have increased their attention and commitment to strengthened prevention and management of CVD risk in primary healthcare over the last two years (261). This attention has been reinforced by: the raging pandemic, which predisposes people with CVD to increased risk of mortality; the magnitude of the CVD burden; large implementation gaps; and the WHO's endorsed strategy for the use of CVD risk assessment in primary healthcare.

It is within this context that the findings of my work are situated today. At the outset, I aimed to examine the prevention and management of CVD risk in Kenyan primary-care settings.

7.2 Summary of findings

Chapter 1 presented the structure and overview of this thesis and highlighted vital accomplishments by the author. Chapter 2 provided background information that set the foundation of this thesis. This chapter broadly examined, discussed and summarised the existing literature on the burden of CVD, its risk factors, strategies for preventing and managing CVD risk, the implementation and use of these strategies, and an overall rationale for the studies that would be described in the rest of the thesis. Importantly, this chapter also set out critical gaps in the comprehension of ways to prevent and manage CVD risk in Kenyan primary-care settings and how these gaps might have been related to each other to create an overall impact on the adoption of recommended practice. First, it was found that there was a poor understanding of the risk burden for

CVD in the Kenyan population, possibly due to suboptimal population risk-surveillance systems. Second, there was a disproportionate lag in implementation of cost-effective interventions such as CVD risk assessment in LMICs, and limited explanations for this lag. Lastly, there was a lack of research on the implementation and use of CVD risk-assessment tools in LMICs, which include Kenya. The work that was described in the chapters that follow Chapter 2 aimed to address these gaps.

Consequently, the first aim of the work presented in Chapter 3 was to describe the distribution of CVD risk scores in the Kenyan adult population and identify factors that were associated with the variation of these scores in this population. A cross-sectional study of the Kenya STEPwise survey data was performed. Data from 1627 (36.2%) of 4500 (75%) participants in the original survey were included in the final analysis. To calculate CVD risk scores from these data, I derived the basic risk score equation (BRSe) that was used in the updated WHO/ISH risk calibrations to produce an Eastern sub-Saharan African prediction model and then calculated the risk probabilities for CHD/MI, stroke and CVD. The results of the work described in this chapter show that 11.9% of the Kenyan population (who had a CVD risk above 10%) could be eligible to be considered for pharmacotherapy and lifestyle interventions that could mitigate the risk of CVD. The results also suggested that there was a gendered element in the distribution of CVD risk scores by socio-demographic, behavioural and cardiovascular risk factors, which may put women at higher risk of CVD in this population. Another key result was that factors such as ethnicity, level of education, marital status, dietary practices and physical activity could be used to refine the existing entry points for targeted CVD risk screening, prevention and management in Kenyan primary-care settings.

This chapter also provided insights into recommended future research on this topic, which should focus on two areas: understanding current practice in the prevention and management of CVD risk to incorporate CVD risk screening fully in these settings; and the development of better measurement systems and tools that could adequately and routinely capture the population's behavioural CVD risk characteristics.

The aim of the work described in Chapter 4 was to synthesise the current knowledge on factors that influence the implementation of cardiovascular risk scoring as a CVD prevention strategy in primary-care settings. A mixed-methods systematic review was performed, in which 25 studies were investigated. Most (*n*=20) of the included studies were conducted in HICs; only five were conducted in middle-income countries; and there were no studies from low-income countries. All the studies reported health-care professionals' perspectives on cardiovascular risk scoring but only five reported patients' perspectives. This synthesis conceptualised four factors that influenced the decision to use or not to use cardiovascular risk scoring in primary-care settings: the cardiovascular risk tools available, the users, the clinical setting, and the healthcare system.

The review reinforced the general understanding that implementation processes are complex, intricately related and significantly dependent on context. Using a mixed-methods approach enabled the placement of the findings in theories of implementation science while adequately accommodating an inductive interpretation of data. Notably, there was a lack of implementation research from LMICs and consequently, limited information on context in such settings. However, these findings from HICs were relevant to inform the knowledge gaps and the direction of future research in LMIC settings.

This chapter's main conclusion was that further research on the use of cardiovascular risk prediction tools was needed in LMICs and that such research should take the form of effectiveness-implementation hybrid designs that combined elements of clinical effectiveness and implementation research to enhance its public health impact.

The work presented in Chapter 5 had two aims: (1) to examine current practice by understanding how policymakers, clinicians and patients experience prevention and management of CVD risk in everyday clinical practice; and (2) to identify contextual factors that influence the adoption of recommended practice in Kenyan primary-care facilities. A qualitative study was designed to utilise a single case with embedded units' approach. The study setting was Kilifi County, Kenya. The study encompassed 560 hours of observations, 15 interviews with clinicians and policymakers, 30 exit interviews with patients, and a documents analysis, all of which were conducted across seven Kilifi County facilities. I used thematic analysis to describe and explore current CVD risk prevention and management practices in these settings. This helped me to identify a lack of familiarity with clinical guidelines related to CVD risk in clinical settings and to better understand clinicians' use of their clinical judgement in these facilities. I used framework analysis that built on the findings from Chapter 3 to identify contextual factors that influenced the adoption of recommended practice in CVD risk prevention and management in Kenyan primary care. These factors were categorised into three levels: first (clinician and patient), second (clinical setting and local government), and third (global and national influences). I also explored the intricate relationships across these levels. The main conclusion of the work that was discussed in this chapter was that considerable challenges lie ahead in the full adoption of recommended practice in CVD risk prevention and management in Kenyan primary-care settings. Some of these challenges stem from recent political changes; for example,

the devolution of health-service functions has led to the creation of weak coordination mechanisms between functions. Other challenges arise from the limits on resources that are available to scale up implementation; and a need for service delivery redesign, and for better mechanisms to set priorities that are not heavily influenced by the availability of external funding. The study's findings could be used to develop and support meaningful and pragmatic change in CVD risk prevention and management in these settings.

The aim of the work discussed in Chapter 6 was to determine the priorities that were considered in order to draw up current NEMLs in the region by describing and comparing the recommended care level at which essential medicines were made available to treat the leading causes of mortality in Eastern sub-Saharan Africa (CVD, TB and HIV/AIDS). This work arose iteratively from that explained in the preceding chapters. In particular, the findings from the work described in Chapter 5 regarding the inaccessibility of essential CVD medicines posed a significant challenge in the assessment and management of CVD risk in Kenyan primary-care settings.

A cross-sectional observational study of retrospective data was undertaken. A total of 42 essential medicines were extracted from the NEMLs of nine countries: those used for CVD (n=29), HIV (n=8) and TB (n=5). On average, it was found that the nine countries included slightly more than half of the essential CVD medicines as categorised by the WHO in their NEMLs. At the lowest level of care, level 1, the countries recommended the use of a larger number of essential medicines for treatment of HIV and TB than for treatment of CVD. Notably, Kenya was the only country to be included in this study that did not recommend that any essential CVD medicines be made available at level 1. Instead, essential CVD medicines in Kenya were

recommended for prescription in level 3. The majority of the countries recommended that essential CVD medicines be prescribed at level 2.

The main conclusion of the work described in this chapter was that there might be a disproportionate difference in NEMLs in the recommended level at which essential medicines were made available to treat communicable diseases compared with NCDs. This was most noticeable at the lowest level of care: level 1. This could be a contributing factor to the inaccessibility of essential CVD medicines in Kenyan primary care settings. Future research in this area should focus on understanding how, in practice, the recommended level according to the NEML at which essential medicines are prescribed influences the availability and affordability of these medicines at the lowest levels of care in various healthcare systems.

7.3 Implications for policy, practice and patients

7.3.1 Policy and practice

Given the commendable progress that Kenya has made in the production of national policies for the control of CVD, my recommendations for policymakers and practitioners focus on scaling up implementation based on the generation and judicious use of local evidence. I use the framework of the primary health care performance initiative (PHCPI) as a guide to expand on these recommendations (262), which are categorised into three areas: the system, inputs and service delivery. Table 20 provides a summary.

Table 20. Policy and practice recommendations for improving CVD risk prevention and management in Kenyan primary-care settings

System	Inputs	Service delivery
Governance and leadership • Improve communication and feedback mechanisms between national and county governments with regard to CVD risk prevention and control • Tighten collaboration between county health system managers, political leaders and national level bureaucrats in development of CVD-related strategic plans	**Essential CVD medicines** • Revise the latest NEML to incorporate the full list of essential CVD medicines as recommended by WHO and at the correct level of use: primary healthcare • Ensure that all primary healthcare facilities have the right drugs and supplies at the right time and that patients have access to them	**Service redesign** • Leverage the existing community-based platform for HIV and TB treatment to deliver integrated and comprehensive NCD prevention and management service in primary healthcare
Health financing • Build feasible and sustainable health-financing models in primary healthcare to ensure that adequate resources are raised, pooled and appropriately allocated to provide equal access to good-quality CVD health services without financial hardship	**Facility infrastructure and information systems** • Invest urgently in CVD-related infrastructure, technologies, information systems and equipment guided by the WHO package of essential non-communicable disease interventions for primary-care, resource-limited settings	
Adjustment to population health needs • Assess regularly the needs of local populations to adapt priorities and modalities of service delivery to epidemiological changes or service demands • Design better measurement systems and tools or adapt existing tools to capture the local	**Workforce** • Introduce measures to sustain a primary healthcare workforce that is available and accessible to the population and that has the requisite competencies and motivation to deliver CVD risk prevention and care • Leverage the internet to provide training on CVD risk communication and practical exercises on the measurement of risk factors and the calculation of risk scores with use of the recently updated WHO CVD risk charts for Eastern sub-Saharan Africa	

	population's behavioural CVD risk characteristics adequately	• Provide on-the-job supportive supervision to improve knowledge and performance

7.3.1.1 System

7.3.1.1.1 Governance and leadership

Findings from the work described in Chapters 4 and 5 emphasise the importance of getting buy-in from various stakeholders to improve CVD risk prevention and management in Kenyan primary care. Specifically, key people in the county governments must be brought on board as an essential first step to ensure rapid and sustainable adoption of the interventions that are outlined in national policies. It is clear that these policies, especially the national guidelines for the prevention and management of CVD risk, must be adapted to local contexts and county capabilities especially with regard to the tools and technologies needed to assess CVD risk. This level of tailoring will mean that county health system managers will have to work in close collaboration with political leaders and national level bureaucrats to develop strategic plans towards local adaptation and capacity building. Specifically, and perhaps more urgently, improved communication and feedback mechanisms must be formed between national and county governments regarding CVD risk prevention and control. The findings of the work performed for Chapter 5 highlight a crucial breakdown in communication between the national and county governments with regard to CVD prevention and management policies. Improved communication will ensure that strategic policy frameworks are combined with effective oversight, partnership, regulation, attention to system needs, and accountability.

7.3.1.1.2 Health financing

This subject is beyond the scope of this thesis; however, findings explained in Chapter 5 point to a serious need to protect the Kenyan population from financial risk due to out-of-pocket payments for CVD medicines in primary health care. More feasible and sustainable health financing models in primary healthcare than are currently in place

are needed to ensure that adequate monetary resources are raised, pooled and appropriately allocated to provide the people with equal access to good-quality CVD health services so that they do not sustain financial hardship. For example, in 2016, Makueni County implemented MakueniCare, a health coverage scheme for its constituents, which pools funding from the national and county governments along with donor funding and household contributions for public, primary healthcare facilities. Policymakers should review this programme for scalability.

7.3.1.1.3 Adjustment to population health needs

Chapter 3 provides evidence of the burden of CVD risk in the Kenyan population. While these findings are crucial for clinicians to advocate for a general shift of focus towards addressing CVD prevention and management in Kenya, primary healthcare systems at the county level should also regularly assess their populations' needs to adapt their priorities and modalities of service delivery to these changes. Consequently, CVD risk prevention and management will involve designing improved measurement systems and tools that adequately capture the local population's behavioural CVD risk characteristics. This might involve local adaptation of the STEPs survey to fit local practices. After this, routine data collection at the facility level will be required in order to perform appropriate analysis. This information should be used to set and implement priorities and continual learning at the county level.

7.3.1.2 Inputs

7.3.1.2.1 Essential CVD medicines

It is imperative that all primary healthcare facilities have the right drugs and supplies at the right time and that patients have access to them (263). The findings of Chapter 5 suggest that this has not been the case in Kenyan primary health-care facilities, where

there is often inconsistent supply that leads to recurrent stockouts. While supply-chain management for health services is outside the scope of this thesis, it is vital to improve the uptake of recommended CVD risk prevention and management practices (264). Specifically, the appropriate selection of medicines relates to NEMLs and procurement, warehousing and distribution. Policymakers should consider revising the latest NEML to incorporate the full list of essential CVD medicines that are recommended by the WHO and at the right level of use, which is primary healthcare. This may ensure equitable access to quality, safe and efficacious, essential CVD medicines.

7.3.1.2.2 Facility infrastructure and information systems

Findings from Chapter 5 infer that there is a significant need to invest in CVD-related infrastructure, technologies, information systems and equipment. Such investment should include provision of appropriate patient information records systems. Such an investment may be guided by the WHO package of essential NCD interventions (the WHO PEN) for primary-care, resource-limited settings (190). This package entails the acquisition of a set of innovative, practical and action-oriented technologies and tools, such as: blood pressure machines, weighing machines, glucometers, WHO CVD risk-prediction charts, flow charts with referral criteria, patient clinical record samples, medical information registers and audit tools. These tools must be adapted, piloted and optimised for various local contexts.

7.3.1.2.3 Workforce

Policymakers must sustain a primary healthcare workforce that is available and accessible to the population, and that has the requisite competencies and motivation to deliver CVD care. There is currently a shortage of such a workforce, though the findings of Chapter 5 posit that the existing healthcare workforce possesses many positive and enabling intrinsic qualities that may facilitate innovation and knowledge-

seeking, particularly in CVD risk prevention and management. Healthcare workers who participated in this study seemed to lack sufficient knowledge of CVD prevention and management. This presents an opportunity to improve through provision of detailed training on CVD risk communication and practical exercises to measure risk factors and the calculation of risk scores with use of the recently updated WHO CVD risk charts for Eastern sub-Saharan Africa. Such training should leverage the internet to widen its reach; this approach seems already to be popular among health workers in primary care settings (section 6.1.4). On-the-job supportive supervision can also improve the workers' knowledge and performance (175). Some of these measures should include decentralised in-facility training and coaching, assisted by mobile devices. WHO's HEARTS technical package provides six technical modules that can support Ministries of Health in providing such training (43). While most of these modules are ready for use, there may be a need to adapt them to various local contexts.

7.3.2 Service delivery

7.3.2.1.1 Service redesign

Findings described in Chapter 5 suggest that the current organisation of health-care services concerning CVD risk prevention and management is not fit for purpose. This may be a consequence of the previous positioning of CVD care, i.e., as a service to be offered at the secondary-care level. However, Kenya can learn from its success with primary-care programmes designed to control chronic infectious diseases such as HIV, TB and malaria. The maturation and viability of these systems in primary healthcare provide a unique opportunity to integrate CVD care within service delivery. Extensive evidence suggests that the workable and community-based platforms for HIV and TB can be used to deliver integrated and comprehensive NCD prevention and management services in primary healthcare (265). Health system officers must also reach out

proactively to communities to establish practices in CVD risk prevention and management, particularly those communities that are underserved or marginalised, and link those in need to the primary healthcare system. This will augment the demand side of CVD services.

Similarly, these outreach activities can be incorporated into or modelled from successful delivery of reproductive, maternal, new born and child health services, which include: risk-stratified care with a referral; mobile health units; proactive follow-up regarding adherence to medication or lifestyle changes; and transport support. This integration will ensure the provision of high-quality CVD care that is characterised by first-contact accessibility, continuity, comprehensiveness, coordination and person-centred care. These are the central tenets of a high-quality primary healthcare system (262). However, this integration will bring its implementation challenges regarding resources and apt coordination, and thus, adequate preparation should precede such efforts.

7.3.3 Patients

The development of recommendations for patients was beyond this thesis's scope. However, they are the beneficiaries of an effective CVD risk prevention and management programme. From the work discussed in Chapter 5, important patient-centred themes emerged that affected CVD risk assessment, management and communication. Many of these themes related to socio-economic circumstances and affordability of medicines and lifestyle interventions. These concerns can be adequately addressed through feasible and sustainable health-financing models in primary healthcare, as discussed previously in this chapter. However, increased engagement with patients is crucial to create awareness of CVD risk factors and to increase demand

for CVD risk prevention and management services at the primary care level. Interventions to help raise such awareness could include: provision of locally adapted educational pamphlets for adults; and educational interventions to teach primary school children about CVD risk (266–268). Self-care to mitigate CVD, though an emerging field in LMICs, is also essential. Preliminary studies in LMICs report that self-management may be effective as a means of improving health outcomes (269).

7.4 Future research

This thesis illustrates four main areas in which future research should focus: sub-national mapping of the burden of CVD and its risk factors; development of better measurement tools for this purpose; contextual implementation and effectiveness studies for CVD risk assessment and management; and improved understanding of the role of NEMLs in influencing the availability and affordability of essential medicines at the lowest levels of care.

With regard to the sub-national mapping of the burden of CVD and its risk factors through the development of better measurement tools, the focus should be on addressing the recall bias that is inherent in the current designs of data collection methods, i.e. the STEPs survey tool that is used in Kenya for NCD population risk surveillance. Some preferred options may include the continuous collection of data at the facility level on behavioural CVD risk factors instead of through one-off, national-level surveys. However, for this to be implemented successfully, health information systems must be robust, standardised and dynamic for sub-national and national-level consolidation. This remains a challenge in the Kenyan context.

Chapter 2 highlights that there is not yet any high-quality evidence as to whether the use of CVD risk-scoring tools influences cardiovascular outcomes of mortality.

Findings from Chapter 4 highlight this lack of evidence as a significant factor that influenced the implementation of cardiovascular risk-scoring in primary-care settings. However, these findings were limited to HICs due to a paucity of studies in LMICs. Across settings, including Kenya, there remains a need for high-quality evidence regarding the effect of widened use of cardiovascular risk-scoring tools on health outcomes. This evidence could be gathered through performance of hybrid effectiveness-implementation studies that combine evaluation of the clinical effectiveness of CVD risk assessment in primary care and of strategies to implement such risk assessments to enhance public health impact (270). Importantly, findings explained in Chapter 5 provide a good understanding of behaviour concerning CVD risk assessment. The capture of such understanding is the first in a three-step process to design implementation interventions according to the behaviour change wheel framework. Blended design components of clinical effectiveness and implementation research are particularly apt in the Kenyan context. Such blended study designs provide rapid translational gains, effective implementation strategies for scale up, and information that has direct utility for policymakers.

Chapter 6 outlines the limitations of using NEMLs to explore the availability and accessibility of essential CVD medicines in Kenyan primary care. Thus, future research in this area should focus on: i) the accurate reporting of the availability of essential CVD medicines in primary care settings; and ii), understanding how, in practice, the NEML recommended level at which medicines should be used influences the availability and affordability of essential medicines. Routine facility-level assessment, such as the use of the updated service provision assessment surveys, may help to fill this gap and to provide a more accurate picture (271).

7.5 Lessons learnt: implementation of recommended practice in CVD risk prevention and management in Kenyan primary-care settings

The findings of this thesis clarify that there are considerable challenges to the implementation of recommended CVD risk-prevention and management practices in Kenyan primary-care settings. It is vital that these challenges are overcome because the population impact of evidence-based technologies and interventions such as CVD risk assessment can only be maximised when systems can optimally identify and reach target populations. Additionally, health systems must support the adoption of these interventions and sustain their effective use.

The use of implementation theories early in the work that was performed for this thesis facilitated the refinement of the research questions and data collection efforts in Chapters 4 and 5. This refinement strengthened the applicability of the thesis's findings to the Kenyan context. Moreover, this enabled the improvement of understanding of the gaps that exist between policy and practice in CVD risk prevention and management. Determinant theories such as the CFIR provided a framework to interrogate systematically the appropriateness and adequacy of the central tenets known to facilitate positive implementation outcomes. Use of the COM-B theory enhanced the understanding and explanation of specific aspects of implementation and their interaction, such as capacity and readiness, especially at the individual level. This knowledge is critical during refinement of strategies to support the implementation of CVD risk assessment and thus to improve the relevance and appropriateness of strategies to the circumstances at hand.

This approach, which involves utilisation of implementation theories, paves the way for future CVD risk prevention and management implementation efforts. Given that

this thesis's findings suggest that currently, implementation of the recommended practice in CVD risk prevention and management requires improvement, these two theories can be used prospectively to investigate implementation issues during scale-up and maintenance of the provision. This provides an opportunity for the critical redesign of existing implementation programmes, increasing the likelihood of successful dissemination and implementation of recommended practices.

7.6 Overall strengths and limitations

The work that was performed for this thesis had limitations. The methodological limitations of each study design are described in Chapters 3 to 6. Broadly, there were three key limitations to my thesis. First, the aim of the thesis was too broad and extensive for a time-bound doctoral programme. Perhaps the development of a more specific aim would have improved the coverage of the many issues that this thesis raised. However, I deemed this work necessary due to the paucity of published work in this area and setting. As such, this work sits best as exploratory research and should be built upon to develop more specific research aims in CVD risk prevention and management in Kenya.

In addition, due to the paucity of primary studies in these settings, i.e. CVD prevention and management in Kenyan primary care, publication bias may have occurred, specifically in terms of duplicate (or multiple) publication bias. This may have led to overestimation of effects and overamplification of findings. More research in this field is needed to address this bias.

Second, I could use only one case study, Kilifi County, to report on the current practice in CVD risk prevention and management in Kenyan primary-care settings. The use of one case study limits the external validity and generalisability of these findings.

However, the county has many similarities, i.e. demography and disease epidemiology, with most other counties in the country. It was not feasible to study another setting due to the time required to negotiate international research agreements with various stakeholders and limited financial resources. Study of additional counties in Kenya would probably provide more context and opportunities for this examination. This thesis provides a template for such future studies.

Lastly, patients are vital stakeholders in any examination of the prevention and management of CVD risk in any primary care setting. Research on awareness and attitudes among patients towards CVD risk factors may shed additional light on ways to optimise CVD risk prevention and management services at the primary-care level.

The strengths of each study are described in their respective chapters. Generally, this thesis was strengthened by its diverse methodological approaches through fieldwork and by its contributions of fresh knowledge to this field. Through these diverse methodological approaches, and in particular, through fieldwork, I was able to explore and synthesis evidence from multiple perspectives. Spending seven months doing fieldwork in Kilifi was a considerable achievement that underpinned my programme of research. It required an arduous process of application for successful grant funding and then development of tripartite research collaboration between the Department of Primary Care Health Sciences at the University of Oxford, the Kenya Medical Research Institute-Wellcome Trust Research Programme (KWTRP) and the County Government of Kilifi, Kenya. This collaboration resulted in an award to me of a PhD student fellowship by KWTRP. I continue to be invited to present and advise on national

strategies for CVD guidelines dissemination by the Kenya Cardiac Society[1]. Similarly, as part of my thesis output, I will prepare a policy brief for the Government of Kenya on ways to improve CVD risk prevention and management in Kenyan primary-care settings.

7.7 Conclusions

The global and national policy responses that aim to control CVD are commendable as they provide a set of effective, evidence-based, practical interventions for strengthening the management of CVD risk in primary healthcare. However, despite the high-level, global-political commitment to improvement of CVD outcomes by 2025, countries such as Kenya and many other LMICs are off course on their path to meet the WHO's global action plan targets. This thesis has shown that, while such commitment is needed to move countries in the right direction, i.e. drafting and endorsing relevant policies; there is a significant policy-practice gap in countries such as Kenya. The focus should be shifted towards bridging this gap through support of high-quality implementation science research and alignment of the system's needs, inputs and service delivery with the integration of CVD care in primary healthcare systems.

Throughout the period of production of this thesis, given the need for primary studies in LMICs on this topic (Chapters 2 and 4), I have made the effort to publish my thesis outputs in open-source journals (4,86,266). I hope that researchers in resource-limited settings can build on this knowledge and advance the field further. This is in addition

[1] The Kenya Cardiac Society represents those working in the fields of cardiovascular care and research in Kenya and its environs. It aims to represent and support both the professionals who work in cardiology and patients to encourage the best possible treatment. The society is committed to enhancing and maintaining the highest standards in training, education and research and to set standards of clinical excellence for the benefit of patients.

to teaching and presenting at international conferences. I am currently collaborating with researchers from Botswana in a Medical Research Council (MRC) grant application in applied global health research to scale up cardiovascular risk management in primary healthcare in Botswana and Kenya.

In conclusion, this thesis has produced knowledge that adds to what is already known and has provided novel input to key questions, the crucial ones being: (1) what percentage of the Kenyan population might be eligible for consideration of pharmacotherapy and lifestyle interventions to mitigate the risk of CVD; (2) what nuances inform current practice in the prevention and management of CVD risk in Kenyan primary-care settings; and (3) what might it take to scale up the recommended practice? It has also provided some insight into the future of research in this field by highlighting a need for high-quality research on the topic within LMICs. Policymakers and practitioners may use this thesis's methodology to plan future studies, and use its findings and recommendations judiciously to plan evidence-based strategies to improve practice.

Bibliography

1. WHO CVD Risk Chart Working Group S, Pennells L, Bacquer D De, Cooney MT, Kavousi M, Stevens G, et al. World Health Organization cardiovascular disease risk charts: revised models to estimate risk in 21 global regions. Lancet Glob Heal [Internet]. 2019 Aug 30 [cited 2019 Sep 11];0(0). Available from: http://www.ncbi.nlm.nih.gov/pubmed/31488387

2. Richards GC, Mahtani KR, Muthee TB, Devito NJ, Koshiaris C, Aronson JK, et al. Factors associated with the prescribing of high-dose opioids in primary care: A systematic review and meta-Analysis. Vol. 18, BMC Medicine. BioMed Central Ltd.; 2020.

3. Ban J-W, Chan MS, Muthee TB, Paez A, Stevens R, Perera R. Design, methods, and reporting of impact studies of cardiovascular clinical prediction rules are suboptimal: A systematic review. J Clin Epidemiol [Internet]. 2021 Jan 27 [cited 2021 Feb 1]; Available from: https://linkinghub.elsevier.com/retrieve/pii/S0895435621000275

4. Muthee TB, Etyang A, Williams V, Milburn-Curtis C, Heneghan C, Nunan D. The distribution of cardiovascular risk scores in the Kenyan population and factors associated with risk score variation [Internet]. OSF. 2020 [cited 2020 Apr 12]. Available from: https://osf.io/qxurc/#show_login

5. Muthee TB. Fieldwork in Kilifi County, Kenya – Reflections — Nuffield Department of Primary Care Health Sciences [Internet]. NDPCHS Research and Teaching Blog. 2020 [cited 2021 Jan 8]. Available from: https://www.phc.ox.ac.uk/news/blog/fieldwork-in-kilifi-county-kenya-2013-reflections

6. Muthee TB, Kimathi D, Richards GC, Etyang A, Nunan D, Williams V, et al. Factors influencing the implementation of cardiovascular risk scoring in primary care: a mixed-method systematic review. Implement Sci [Internet]. 2020 Dec 20 [cited 2020 Jul 24];15(1):57. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-01022-x

7. Kenya National Bureau of Statistics. 2019 Kenya Population and Housing Census Volume I: Population by County and Sub-County - Kenya National Bureau of Statistics [Internet]. 2019 [cited 2020 Jun 5]. Available from: https://www.knbs.or.ke/?wpdmpro=2019-kenya-population-and-housing-census-volume-i-population-by-county-and-sub-county

8. World Bank. Kenya Data [Internet]. The Data Catalog. 2015 [cited 2021 Feb 19]. p. 3. Available from: http://who.int/gho/mortality_burden_disease/en/%5Cnhttp://data.worldbank.org/indicator/IP.PAT.RESD/countries/KE?display=graph

9. Achoki T, Miller-Petrie MK, Glenn SD, Kalra N, Lesego A, Gathecha GK, et al. Health disparities across the counties of Kenya and implications for policy makers, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Glob Heal [Internet]. 2019 Jan 1 [cited 2021 Feb 19];7(1):e81–95. Available from: www.thelancet.com/lancetgh

10. IHME. Institute for Health Metrics and Evaluation [Internet]. University of Washington. 2015 [cited 2017 Oct 25]. Available from: http://www.healthdata.org/gbd/data-visualizations

11. The Ministry of Planning and Devolution. The Kenya Vision 2030. The Popular Version. Gov Repub Kenya, [Internet]. 2007;32. Available from: http://www.vision2030.go.ke/cms/vds/Popular_Version.pdf

12. MOH. Kenya Health Policy. 2014;XXXIII(2):81–7. Available from: http://www.americanbanker.com/issues/179_124/which-city-is-the-next-big-fintech-hub-new-york-stakes-its-claim-1068345-1.html%5Cnhttp://www.ncbi.nlm.nih.gov/pubmed/15003161%5Cnhttp://cid.oxfordjournals.org/lookup/doi/10.1093/cid/cir991%5Cnhttp://www.scielo

13. Mccollum R, Theobald S, Otiso L, Martineau T, Karuga R, Barasa E, et al. Priority setting for health in the context of devolution in Kenya: implications for health equity and community-based primary care. Health Policy Plan [Internet]. 2018 Jul 1 [cited 2020 Jul 20];33(6):729–42. Available from: http://www.worldbank.org/en/country/kenya/overview.

14. Ministry of Health. TRANSFORMING HEALTH : Accelerating Attainment of Universal Health Coverage: KENYA HEALTH SECTOR STRATEGIC AND INVESTMENT PLAN (KHSSP) 2014-2018. 2014;(July).

15. WHO. WHO Fact Sheet: Cardiovascular Diseases (CVDs) [Internet]. WHO. World Health Organization; 2016 [cited 2016 Nov 20]. Available from: http://www.who.int/mediacentre/factsheets/fs317/en/

16. WHO. World Health Statistics 2020 [Internet]. 2020 [cited 2020 Nov 15]. Available from: https://www.who.int/gho/publications/world_health_statistics/2020/EN_WHS_2020_TOC.pdf?ua=1

17. Roth GA, Mensah GA, Johnson CO, Addolorato G, Ammirati E, Baddour LM, et al. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. J Am Coll Cardiol [Internet]. 2020 Dec 22 [cited 2021 Nov 15];76(25):2982–3021. Available from: https://pubmed.ncbi.nlm.nih.gov/33309175/

18. Baingana FK, Bos ER. Changing Patterns of Disease and Mortality in Sub-Saharan Africa: An Overview [Internet]. Disease and Mortality in Sub-Saharan Africa. The International Bank for Reconstruction and Development / The World Bank; 2006 [cited 2020 Nov 15]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21290642

19. Yuyun MF, Sliwa K, Kengne AP, Mocumbi AO, Bukhman G. Cardiovascular Diseases in Sub-Saharan Africa Compared to High-Income Countries: An Epidemiological Perspective. Glob Heart [Internet]. 2020 Feb 12 [cited 2020 Nov 23];15(1):15. Available from: /pmc/articles/PMC7218780/?report=abstract

20. WHO. From Burden to " Best Buys ": Reducing the Economic Impact of Non-Communicable Diseases in Low- and Middle-Income Countries. World Econ Forum [Internet]. 2011 [cited 2017 Oct 26];1–12. Available from:

http://www.weforum.org/EconomicsOfNCD

21. University of Washington. Socio-demographic Index (SDI) | Institute for Health Metrics and Evaluation [Internet]. Institute for health Metrics and Evaluation. 2019 [cited 2020 Nov 15]. Available from: http://www.healthdata.org/taxonomy/glossary/socio-demographic-index-sdi

22. Fulchand S. Covid-19 and cardiovascular disease Shivali Fulchand editorial registrar. BMJ [Internet]. 2020 May 20 [cited 2020 May 29];369. Available from: http://www.bmj.com/permissionsSubscribe:http://www.bmj.com/subscribeBMJ2020;369:m1997http://www.bmj.com/

23. World Health Organisation (WHO). GLOBAL STATUS REPORT on noncommunicable diseases 201 4 " Attaining the nine global noncommunicable diseases targets; a shared responsibility ". 2014.

24. Asiki G, Shao S, Wainana C, Khayeka-Wandabwa C, Haregu TN, Juma PA, et al. Policy environment for prevention, control and management of cardiovascular diseases in primary health care in Kenya. BMC Health Serv Res [Internet]. 2018 Dec 9 [cited 2018 Nov 9];18(1):344. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-3152-4

25. Ministry of Health. Kenya National Guidelines for Cardiovascular Diseases Management. 2018 [cited 2018 Jul 6]; Available from: www.health.go.ke

26. Gheorghe A, Griffiths U, Murphy A, Legido-Quigley H, Lamptey P, Perel P. The economic burden of cardiovascular disease and hypertension in low- and middle-income countries: A systematic review [Internet]. Vol. 18, BMC Public Health. BioMed Central Ltd.; 2018 [cited 2020 Nov 23]. p. 975. Available from: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-5806-x

27. Health KM of. Kenya Service Availability and Readiness Assessment Mapping. 2013;

28. Hajar R. Risk factors for coronary artery disease: Historical perspectives. Hear Views [Internet]. 2017 [cited 2020 Nov 15];18(3):109. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5686931/

29. Mahmood SS, Levy D, Vasan RS, Wang TJ. The Framingham Heart Study and the epidemiology of cardiovascular disease: A historical perspective [Internet]. Vol. 383, The Lancet. Lancet Publishing Group; 2014 [cited 2020 Nov 15]. p. 999–1008. Available from: /pmc/articles/PMC4159698/?report=abstract

30. Kumar A. Recent Trends in Cardiovascular Risks. Recent Trends in Cardiovascular Risks. InTech; 2017.

31. Karmali KN, Persell SD, Perel P, Lloyd-Jones DM, Berendsen MA, Huffman MD. Risk scoring for the primary prevention of cardiovascular disease. Cochrane Database Syst Rev. 2017;(3).

32. Steyn K, Sliwa K, Hawken S, Commerford P, Onen C, Damascene A, et al. Risk factors associated with myocardial infarction in Africa: The

INTERHEART Africa Study. Circulation. 2005;112(23):3554–61.

33. Stoner L, Stoner KR, Young JM, Fryer S. Preventing a Cardiovascular Disease Epidemic among Indigenous Populations through Lifestyle Changes. Int J Prev Med [Internet]. 2012 Apr [cited 2020 May 25];3(4):230–40. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22624079

34. D.C. F, C.G.C. S, F.M. B, A.D. B, D.G. B. Endothelial damage and angiogenesis in hypertensive patients: Relationship to cardiovascular risk factors and risk factor management. Am J Hypertens [Internet]. 2003;16(1):11–20. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed9&NEWS=N&AN=36078585

35. Marinou K, Tousoulis D, Antonopoulos AS, Stefanadi E, Stefanadis C. Obesity and cardiovascular disease: From pathophysiology to risk stratification. Int J Cardiol. 2010;138(1):3–8.

36. Tekola-Ayele F, Adeyemo A a, Rotimi CN. Genetic epidemiology of type 2 diabetes and cardiovascular diseases in Africa. Prog Cardiovasc Dis [Internet]. 2014;56(3):251–60. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3840391&tool=pmcentrez&rendertype=abstract

37. Bennett JE, Stevens GA, Mathers CD, Bonita R, Rehm J, Kruk ME, et al. NCD Countdown 2030: worldwide trends in non-communicable disease mortality and progress towards Sustainable Development Goal target 3.4. Lancet [Internet]. 2018 Sep 22 [cited 2018 Sep 21];392(10152):1072–88. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673618319925

38. Mendoza W, Miranda JJ. Global Shifts in Cardiovascular Disease, the Epidemiologic Transition, and Other Contributing Factors: Toward a New Practice of Global Health Cardiology [Internet]. Vol. 35, Cardiology Clinics. W.B. Saunders; 2017 [cited 2020 Jul 27]. p. 1–12. Available from: /pmc/articles/PMC5134924/?report=abstract

39. Mensah GA. Descriptive epidemiology of cardiovascular risk factors and diabetes in sub-saharan Africa. Prog Cardiovasc Dis [Internet]. 2013 Nov 1 [cited 2017 Oct 18];56(3):240–50. Available from: http://www.sciencedirect.com.oxfordbrookes.idm.oclc.org/science/article/pii/S0033062013001874

40. WHO. A prioritized research agenda for prevention and control of NCDs: CVD, cancer, chronic respiratory disease, diabetes. WHO Website [Internet]. 2011 [cited 2018 Jan 10];58. Available from: http://www.who.int/cardiovascular_diseases/publications/ncd_agenda2011/en/

41. World Health Organization. Global action plan for the prevention and control of noncommunicable diseases 2013-2020. World Heal Organ [Internet]. 2013 [cited 2017 Jun 16];102. Available from: http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf

42. World Health Organization. Package of Essential Noncommunicable (PEN) disease interventions for primary health care in low-resource settings. 2010

[cited 2018 Jan 16];1–65. Available from: http://www.who.int/cardiovascular_diseases/publications/pen2010/en/

43. World Health Organization. Hearts: Technical package for cardiovascular disease management in primary health care. 2016 [cited 2017 Nov 12];76. Available from: http://www.who.int/cardiovascular_diseases/hearts/Hearts_package.pdf

44. Ministry of Health. Kenya National Strategy for the Prevention and Control of Non-Communicable Diseases. 2015 [cited 2016 Dec 19];80. Available from: https://extranet.who.int/nutrition/gina/sites/default/files/KEN-2015-NCDs.pdf

45. MoH-Kenya. Kenya STEPwise Survey for Non Communicable Diseases Risk Factors 2015 Report. 2015 [cited 2017 Nov 8];8–210. Available from: http://aphrc.org/wp-content/uploads/2016/04/Steps-Report-NCD-2015.pdf

46. Geldsetzer P, Ortblad K, Bärnighausen T. The efficiency of chronic disease care in sub-Saharan Africa. BMC Med [Internet]. 2016;14(1):8–11. Available from: http://dx.doi.org/10.1186/s12916-016-0675-6

47. World Health Organization. Assessing national capacity for the prevention and control of noncommunicable diseases: report of the 2019 global survey [Internet]. 2020 [cited 2021 Nov 15]. Available from: https://www.who.int/publications/i/item/ncd-ccs-2019

48. World Health Organization. Assessing national capacity for the prevention and control of noncommunicable diseases: report of the 2015 global survey. 2015 [cited 2018 Jan 22];130. Available from: http://apps.who.int/iris/bitstream/10665/246223/1/9789241565363-eng.pdf?ua=1

49. Rose G. Sick individuals and sick populations. Int J Epidemiol [Internet]. 1985 Mar 1 [cited 2020 Nov 17];14(1):32–8. Available from: https://academic.oup.com/ije/article/14/1/32/694724

50. Feigin VL, Brainin M, Norrving B, Gorelick PB, Dichgans M, Wang W, et al. What Is the Best Mix of Population-Wide and High-Risk Targeted Strategies of Primary Stroke and Cardiovascular Disease Prevention? [Internet]. Vol. 9, Journal of the American Heart Association. American Heart Association Inc.; 2020 [cited 2020 Nov 17]. Available from: https://www.ahajournals.org/doi/10.1161/JAHA.119.014494

51. WHO. “Best buys” and other recommended interventions for the prevention and control of noncommunicable diseases [Internet]. Vol. 17, World Health Organisation. World Health Organization; 2017. Available from: http://apps.who.int/iris/bitstream/10665/259232/1/WHO-NMH-NVI-17.9-eng.pdf?ua=1

52. McLaren L, McIntyre L, Kirkpatrick S. Rose’s population strategy of prevention need not increase social inequalities in health. Int J Epidemiol [Internet]. 2010 Apr 1 [cited 2017 Feb 24];39(2):372–7. Available from: https://academic.oup.com/ije/article-lookup/doi/10.1093/ije/dyp315

53. Frolkis JP. Screening for cardiovascular disease. Concepts, conflicts, and

consensus. Med Clin North Am [Internet]. 1999;83(6):1339–73. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=10584598 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:10584598&id=doi:&issn=0025-7125&isbn=&volume=83&issue=6&spage=1339&pages=1339-73&date=1999&titl

54. Kerr AJ, Broad J, Wells S, Riddell T, Jackson R. Should the first priority in cardiovascular risk management be those with prior cardiovascular disease? Heart [Internet]. 2009 Jan [cited 2020 Nov 18];95(2):125–9. Available from: https://pubmed.ncbi.nlm.nih.gov/18381374/

55. Knuiman MW, Divitini ML, Buzas JS, Fitzgerald PEB. Adjustment for regression dilution in epidemiological regression analyses. Ann Epidemiol [Internet]. 1998 Jan [cited 2020 Nov 17];8(1):56–63. Available from: https://pubmed.ncbi.nlm.nih.gov/9465995/

56. Emberson J. Evaluating the impact of population and high-risk strategies for the primary prevention of cardiovascular disease. Eur Heart J [Internet]. 2004 Mar 1 [cited 2020 Nov 17];25(6):484–91. Available from: https://academic.oup.com/eurheartj/article-lookup/doi/10.1016/j.ehj.2003.11.012

57. Kumar A. Introductory Chapter: Recent Trends in Cardiovascular Risk Factors. In: Recent Trends in Cardiovascular Risks. InTech; 2017.

58. Yotov Y, Festchieva N. Assessment of global cardiovascular risk. Gen Med [Internet]. 2001;3(3):15–21. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed8&AN=34023847 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:&issn=1311-1817&isbn=&volume=3&issue=3&spage=15&pages=15-21&date=2001&title=General+Med

59. J.S. B, C.O. J, D. L-J. Screening for Cardiovascular Risk in Asymptomatic Patients. J Am Coll Cardiol [Internet]. 2010;55(12):1169–77. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed12&NEWS=N&AN=358431316

60. Palmieri L, Rielli R, Brignoli O, Cuffari A, Ciccarelli P, Giampaoli S. Cardiovascular risk assessment: An important measure for cardiovascular diseases prevention in primary care. Eur J Cardiovasc Prev Rehabil [Internet]. 2010;2):S1. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed12&AN=70349682 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:&issn=1741-8267&isbn=&volume=17&issue=SUPPL.+2&spage=S1&pages=S1&date=2010&title=Europ

61. Routledge J, Vilca-Melendez H, Bowles M, Littlejohn WA, Heaton N. Cardiovascular risk scoring using PROCAM in patients following liver transplantation attending a nurse-led health promotion clinic. Hepatology [Internet]. 2009;4):802A-803A. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed12&AN=70074476 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:10.1002%2Fhep.23304&issn=0270-9139&isbn=&volume=50&issue=SUPPL.+4&spage=802A&pages=802

62. Hippisley-Cox J, Coupland C, Brindle P. Development and validation of QRISK3 risk prediction algorithms to estimate future risk of cardiovascular disease: prospective cohort study. BMJ [Internet]. 2017;357:j2099. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=28536104 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:28536104&id=doi:10.1136%2Fbmj.j2099&issn=0959-535X&isbn=&volume=357&issue=&spage=j2099&pages=j2

63. Hajifathalian K, Ueda P, Lu Y, Woodward M, Ahmadvand A, Aguilar-Salinas CA, et al. Articles A novel risk score to predict cardiovascular disease risk in national populations (Globorisk): a pooled analysis of prospective cohorts and health examination surveys. LANCET Diabetes Endocrinol [Internet]. 2015 [cited 2017 Nov 16]; Available from: www.thelancet.com/diabetes-endocrinology

64. Studziński K, Tomasik T, Krzysztoń J, Jóźwiak J, Windak A. Effect of using cardiovascular risk scoring in routine risk assessment in primary prevention of cardiovascular disease: An overview of systematic reviews. BMC Cardiovasc Disord [Internet]. 2019 Jan 9 [cited 2020 Apr 29];19(1):11. Available from: https://bmccardiovascdisord.biomedcentral.com/articles/10.1186/s12872-018-0990-2

65. Ahmed SM, Hadi A, Razzaque A, Ashraf A, Juvekar S, Ng N, et al. Clustering of chronic non-communicable disease risk factors among selected Asian populations: levels and determinants. Glob Health Action [Internet]. 2009;2(1):1986. Available from: https://www.tandfonline.com/doi/full/10.3402/gha.v2i0.1986

66. D'Agostino RB, Vasan RS, Pencina MJ, Wolf PA, Cobain M, Massaro JM, et al. General Cardiovascular Risk Profile for Use in Primary Care: The Framingham Heart Study. Circulation [Internet]. 2008 Feb 12 [cited 2018 Jan 23];117(6):743–53. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18212285

67. Ishikawa S, Matsumoto M, Kayaba K, Gotoh T, Nago N, Tsutsumi A, et al. Risk Charts Illustrating the 10-year Risk of Stroke among Residents of Japanese Rural Communities: The JMS Cohort Study. J Epidemiol [Internet]. 2009 [cited 2018 Jan 23];19(2):101–6. Available from: http://joi.jlc.jst.go.jp/JST.JSTAGE/jea/JE20080092?from=CrossRef

68. Collins DRJ, Tompson AC, Onakpoya IJ, Roberts N, Ward AM, Heneghan CJ. Global cardiovascular risk assessment in the primary prevention of cardiovascular disease in adults: systematic review of systematic reviews. BMJ Open [Internet]. 2017 Mar 24 [cited 2017 Dec 10];7(3):e013650. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28341688

69. Mendis S, Lindholm LH, Mancia G, Whitworth J, Alderman M, Lim S, et al. World Health Organization (WHO) and International Society of Hypertension (ISH) risk prediction charts: assessment of cardiovascular risk for prevention and control of cardiovascular disease in low and middle-income countries. J Hypertens [Internet]. 2007 Aug [cited 2018 Mar 8];25(8):1578–82. Available from: https://insights.ovid.com/crossref?an=00004872-200708000-00009

70. T. R, A. O. Review on Cardiovascular Risk Prediction. Cardiovasc Ther [Internet]. 2015;33(2):62–70. Available from: http://www.blackwell-synergy.com/loi/CDR

71. Mendis S, Lindholm LH, Anderson SG, Alwan A, Koju R, Onwubere BJC, et al. Total cardiovascular risk approach to improve efficiency of cardiovascular prevention in resource constrain settings. J Clin Epidemiol [Internet]. 2011 [cited 2017 Nov 6];64:1451–62. Available from: https://ac.els-cdn.com/S0895435611000503/1-s2.0-S0895435611000503-main.pdf?_tid=edf9e590-c2f0-11e7-b86f-00000aacb35f&acdnat=1509972750_e1cdeb612e060d3f9366eed16ee02f1d

72. Sohn C, Kim J, Bae W. The framingham risk score, diet, and inflammatory markers in Korean men with metabolic syndrome. Nutr Res Pract. 2012;6(3):246–53.

73. Ker J a, Oosthuizen H, Rheeder P. Decision-making using absolute cardiovascular risk reduction and incremental cost-effectiveness ratios: a case study. Cardiovasc J Afr. 2008;19(2):97–101.

74. WHO WHO. Assesing National Capacity For The Prevention and Control of Noncommunicable Diseases : Report of the 2019 Global Survey [Internet]. 2019 [cited 2021 Jan 7]. Available from: https://www.who.int/publications/i/item/ncd-ccs-2019

75. Ezzati M, Pearson-Stuttard J, Bennett JE, Mathers CD. Acting on non-communicable diseases in low- and middle-income tropical countries. Nat 2018 5597715 [Internet]. 2018 Jul 25 [cited 2021 Nov 15];559(7715):507–16. Available from: https://www.nature.com/articles/s41586-018-0306-9

76. Nilsen P, Ståhl C, Roback K, Cairney P. Never the twain shall meet? - a comparison of implementation science and policy implementation research. Implement Sci. 2013 Jun 10;8(1).

77. Kitson AL, Rycroft-Malone J, Harvey G, McCormack B, Seers K, Titchen A. Evaluating the successful implementation of evidence into practice using the PARiHS framework: Theoretical and practical challenges. Implement Sci. 2008;3(1).

78. Sales A, Smith J, Curran G, Kochevar L. Models, strategies, and tools. Theory in implementing evidence-based findings into health care practice. J Gen Intern

Med [Internet]. 2006 Feb [cited 2021 Nov 16];21 Suppl 2(Suppl 2). Available from: https://pubmed.ncbi.nlm.nih.gov/16637960/

79. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. Implement Sci. 2010 Feb 9;5(1).

80. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci [Internet]. 2015 [cited 2019 Jan 25];10(1). Available from: https://implementationscience.biomedcentral.com/track/pdf/10.1186/s13012-015-0242-0?site=implementationscience.biomedcentral.com

81. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. Implement Sci [Internet]. 2017 Dec 5 [cited 2018 Jun 28];12(1):2. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0534-z

82. Plsek PE, Greenhalgh T. Complexity science: The challenge of complexity in health care. BMJ Br Med J [Internet]. 2001 Sep 15 [cited 2021 Nov 17];323(7313):625. Available from: /pmc/articles/PMC1121189/

83. Fixsen DL, Blase KA, Naoom SF, Wallace F. Core Implementation Components. 2009 [cited 2018 Apr 3]; Available from: http://rsw.sagepub.com/

84. Rycroft-Malone J, Kitson A, Harvey G, McCormack B, Seers K, Titchen A, et al. Ingredients for change: revisiting a conceptual framework. Qual Saf Health Care [Internet]. 2002 [cited 2021 Nov 17];11(2):174–80. Available from: https://pubmed.ncbi.nlm.nih.gov/12448812/

85. Ullrich PM, Sahay A, Stetler CB. Use of Implementation Theory: A Focus on PARIHS. Worldviews Evidence-Based Nurs [Internet]. 2014 Feb 1 [cited 2021 Nov 17];11(1):26–34. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/wvn.12016

86. Stetler CB, Damschroder LJ, Helfrich CD, Hagedorn HJ. A Guide for applying a revised version of the PARIHS framework for implementation. Implement Sci. 2011 Aug 30;6(1).

87. Gurses AP, Marsteller JA, Ozok AA, Xiao Y, Owens S, Pronovost PJ. Using an interdisciplinary approach to identify factors that affect clinicians' compliance with evidence-based guidelines. Crit Care Med [Internet]. 2010 [cited 2021 Nov 16];38(8 Suppl). Available from: https://pubmed.ncbi.nlm.nih.gov/20647785/

88. Hammond KR. Principles of Organization in Intuitive and Analytical Cognition. [Internet]. 1981 [cited 2021 Nov 16]. Available from: https://apps.dtic.mil/sti/citations/ADA096570

89. Mascia D, Cicchetti A. Physician social capital and the reported adoption of

evidence-based medicine: exploring the role of structural holes. Soc Sci Med [Internet]. 2011 Mar [cited 2021 Nov 16];72(5):798–805. Available from: https://pubmed.ncbi.nlm.nih.gov/21306807/

90. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. Qual Saf Health Care [Internet]. 2005 Feb [cited 2021 Nov 16];14(1):26–33. Available from: https://pubmed.ncbi.nlm.nih.gov/15692000/

91. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci [Internet]. 2009 Dec 7 [cited 2018 Mar 13];4(1):50. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-4-50

92. Wensing M, Wollersheim H, Grol R. Organizational interventions to implement improvements in patient care: a structured review of reviews. Implement Sci [Internet]. 2006 [cited 2021 Nov 16];1(1). Available from: https://pubmed.ncbi.nlm.nih.gov/16722567/

93. Michie S, van Stralen MM, West R, Grimshaw J, Shirran L, Thomas R, et al. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci [Internet]. 2011 Apr 23 [cited 2017 Apr 15];6(1):42. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-42

94. Gryglewska B, Sulicka J, Fornal M, Wizner B, Wilkins A, Grodzicki T. Cardiovascular risk in patients with uncontrolled hypertension and its estimation in outpatient setting in Poland. Results of nationwide RAPORT NT programme. [Polish] TT - Ryzyko sercowo-naczyniowe chorych z niekontrolowanym nadcisnieniem tetniczym i jeg. Nadcisnienie Tetnicze [Internet]. 2007;11(3):187–94. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed11&AN=47441553 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:&issn=1428-5851&isbn=&volume=11&issue=3&spage=187&pages=187-194&date=2007&title=Nadcis

95. Murray Matangi M, Armstrong D, Niznick J, Del Grande R, Hollett P, De Young P. Knowledge and implementation of cardiovascular risk scores by family physicians in southeastern Ontario, Canada. Eur J Prev Cardiol [Internet]. 2013;1):S21. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed15&AN=71705766 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:10.1177%2F2047487314530052&issn=2047-4873&isbn=&volume=20&issue=1+SUPPL.+1&spage=S21&p

96. World Health Organization (WHO). World Health Organization: WHO STEPS surveillance Manual: The WHO stepWISE approach to chronic disease risk factor surveillance. [Internet]. WHO Website. 2005 [cited 2019 Oct 28]. p. 490. Available from: https://scholar.google.com/scholar_lookup?title=WHO STEPS Surveillance Manual%3A The WHO STEPwise Approach to Chronic Disease Risk Factor Surveillance&publication_year=2008

97. Kish L. A Procedure for Objective Respondent Selection within the Household. J Am Stat Assoc [Internet]. 1949 Sep [cited 2020 Jul 30];44(247):380. Available from: https://www.jstor.org/stable/2280236

98. StataCorp LLC. StataCorp. 2019. Stata Statistical Software: Release 16 [Internet]. College Station, TX. 2019 [cited 2019 Oct 28]. Available from: http://www.stata.com/support/faqs/resources/citing-software-documentation-faqs/

99. Heinze G, Wallisch C, Dunkler D. Variable selection – A review and recommendations for the practicing statistician [Internet]. Vol. 60, Biometrical Journal. Wiley-VCH Verlag; 2018 [cited 2020 Jul 31]. p. 431–49. Available from: /pmc/articles/PMC5969114/?report=abstract

100. Vandenbroucke JP. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. Ann Intern Med [Internet]. 2007 Oct 16 [cited 2019 Oct 8];147(8):W. Available from: http://annals.org/article.aspx?doi=10.7326/0003-4819-147-8-200710160-00010-w1

101. WHO. Diet, nutrition and the prevention of chronic diseases. World Health Organ Tech Rep Ser [Internet]. 2003;916:i-viii-1-149-backcover. Available from: http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=12768890&retmode=ref&cmd=prlinks%5Cnpapers3://publication/uuid/734F6B31-260B-4545-A8E4-57F7D35DDEB8

102. World Health Organization. Package of essential noncommunicable disease interventions for primary health care in low-resource settings. Geneva Wold Heal Organ. 2010;66.

103. Mendis S, Lindholm LH, Anderson SG, Alwan A, Koju R, Onwubere BJC, et al. Total cardiovascular risk approach to improve efficiency of cardiovascular prevention in resource constrain settings. J Clin Epidemiol. 2011 Dec 1;64(12):1451–62.

104. Otgontuya D, Oum S, Buckley BS, Bonita R. Assessment of total cardiovascular risk using WHO/ISH risk prediction charts in three low and middle income countries in Asia. BMC Public Health [Internet]. 2013 Dec 5 [cited 2019 Apr 1];13(1):539. Available from: http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-13-539

105. Ndindjock R, Gedeon J, Mendis S, Paccaud F, Bovet P. Impact potentiel de la prise en charge du risque principal par rapport à la prise en charge du risque total dans la prévention des événements cardiovasculaires aux Seychelles. Bull World Health Organ. 2011 Apr;89(4):286–95.

106. Vusirikala A, Wekesah F, Kyobutungi C, Oyebode O. Assessment of cardiovascular risk in a slum population in Kenya: Use of World Health Organisation/International Society of Hypertension (WHO/ISH) risk prediction charts-secondary analyses of a household survey. BMJ Open. 2019;9(9).

107. Wekesah FM, Nyanjau L, Kibachio J, Mutua MK, Mohamed SF, Grobbee DE, et al. Individual and household level factors associated with presence of multiple non-communicable disease risk factors in Kenyan adults. BMC Public Health [Internet]. 2018 Nov 7 [cited 2019 Apr 5];18(S3):1220. Available from: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-6055-8

108. Wesonga R, Guwatudde D, Bahendeka SK, Mutungi G, Nabugoomu F, Muwonge J. Burden of cumulative risk factors associated with non-communicable diseases among adults in Uganda: evidence from a national baseline survey. Int J Equity Health. 2016 Dec 1;15(1):1–10.

109. Mendis S. Cardiovascular risk assessment and management in developing countries. Vasc Heal Risk Manag [Internet]. 2005;1(1):15–8. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=17319094 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:17319094&id=doi:&issn=1176-6344&isbn=&volume=1&issue=1&spage=15&pages=15-8&date=2005&title=Vasc

110. Ahmed H, Naik G, Willoughby H, Edwards AGK. Communicating risk. BMJ [Internet]. 2012 Jun 18 [cited 2019 Mar 29];344:e3996. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22709962

111. Brindle P, Beswick A, Fahey T, Ebrahim S. Accuracy and impact of risk assessment in the primary prevention of cardiovascular disease: A systematic review. Heart [Internet]. 2006 Dec 1 [cited 2018 Aug 20];92(12):1752–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16621883

112. Zaman MM, Bhuiyan MR, Karim MN, MoniruzZaman, Rahman MM, Akanda AW, et al. Clustering of non-communicable diseases risk factors in Bangladeshi adults: An analysis of STEPS survey 2013. BMC Public Health [Internet]. 2015 Jul 14 [cited 2020 May 3];15(1):659. Available from: http://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-015-1938-4

113. Galiuto L, Locorotondo G. Gender differences in cardiovascular disease. Short Commun J Integr Cardiol J Integr Cardiol. 2015;1(1):20–2.

114. Bloomfield GS, Mwangi A, Chege P, Simiyu CJ, Aswa DF, Odhiambo D, et al. Multiple cardiovascular risk factors in Kenya: evidence from a health and demographic surveillance system using the WHO STEPwise approach to chronic disease risk factor surveillance. Heart [Internet]. 2013 Sep 15 [cited 2018 Aug 30];99(18):1323–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23872588

115. Marmot M, Bell R. Social determinants and non-communicable diseases: Time for integrated action. BMJ. 2019 Jan 28;364.

116. Allen LN, Smith RW, Simmons-Jones F, Roberts N, Honney R, Currie J. Addressing social determinants of noncommunicable diseases in primary care: A systematic review [Internet]. Vol. 98, Bulletin of the World Health Organization. World Health Organization; 2020 [cited 2020 Nov 11]. p. 754-765B. Available from: http://www.who.int/bulletin/volumes/98/11/19-248278/en/

117. WHO WHO. Assesing National Capacity For The Prevention and Control of Noncommunicable Diseases : Report of the 2019 Global Survey [Internet]. 2019 [cited 2020 Dec 10]. p. 116. Available from: https://www.who.int/publications/i/item/ncd-ccs-2019

118. Mavergames C. Covidence (Systematic Review Software) [Internet]. Melbourne, Australia; 2013 [cited 2018 May 23]. Available from: https://www.covidence.org/

119. Pluye P, Robert E, Cargo M, Bartlett G, O'Cathain A, Griffiths F, et al. Mixed Methods Appraisal Tool (MMAT) – Version 2011 For dissemination, application, and feedback: Please contact pierre. 2011 [cited 2018 Mar 13];(Part I):1–8. Available from: http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/84371689/MMAT 2011 criteria and tutorial 2011-06-29updated2014.08.21.pdf

120. NICE. Methods for the development of NICE public health guidance (third edition) | Guidance and guidelines | NICE. 2012 [cited 2018 May 21]; Available from: https://www.nice.org.uk/process/pmg4/chapter/appendix-i-quality-appraisal-checklist-economic-evaluations%0Ahttps://www.nice.org.uk/process/pmg4/chapter/appendix-h-quality-appraisal-checklist-qualitative-studies#ftn.footnote_17

121. Downes MJ, Brennan ML, Williams HC, Dean RS. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). BMJ Open [Internet]. 2016 Dec 8 [cited 2018 Nov 25];6(12):e011458. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27932337

122. Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist : recommended items to address in a systematic review protocol *. Bmj. 2015;349(jan02 1):g7647–g7647.

123. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. BMC Med Res Methodol [Internet]. 2012 Dec 27 [cited 2018 May 21];12(1):181. Available from: http://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-12-181

124. The Joanna Briggs Institute. Methodology for JBI Mixed Methods Systematic Reviews [Internet]. The Joanna Briggs Institute Reviewers' Manual 2014. 2014 [cited 2018 Mar 6]. Available from: http://joannabriggs.org/assets/docs/sumari/ReviewersManual_Mixed-Methods-Review-Methods-2014-ch1.pdf%0Awww.joannabriggs.org

125. Booth A, Carroll C. How to build up the actionable knowledge base: the role of

"best fit" framework synthesis for studies of improvement in healthcare. BMJ Qual Saf [Internet]. 2015 Nov 25 [cited 2018 Nov 2];24(11):700–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26306609

126. Carroll C, Booth A, Cooper K. A worked example of "best fit" framework synthesis: A systematic review of views concerning the taking of some potential chemopreventive agents [Internet]. 2011 [cited 2018 Nov 19]. Available from: http://www.biomedcentral.com/1471-2288/11/29

127. Fishwick D, McGregor M, Drury M, Webster J, Rick J, Carroll C. BOHRF smoking cessation review [Internet]. Vol. 44. 2012 [cited 2019 Jan 29]. Available from: http://www.bohrf.org.uk/downloads/BOHRF_Smoking_Cessation_Review-April 2012.pdf

128. Cooper K, Squires H, Carroll C, Papaioannou D, Booth A, Logan R, et al. Chemoprevention of colorectal cancer: Systematic review and economic evaluation. Health Technol Assess (Rockv) [Internet]. 2010 Jun 21 [cited 2019 Jan 29];14(32):1–205. Available from: https://www.journalslibrary.nihr.ac.uk/hta/hta14320/

129. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. Implement Sci [Internet]. 2017 Dec 5 [cited 2018 May 14];12(1):2. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0534-z

130. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implement Sci [Internet]. 2016 May 17 [cited 2022 Jan 5];11(1):1–13. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0437-z

131. Means AR, Kemp CG, Gwayi-Chore MC, Gimbel S, Soi C, Sherr K, et al. Evaluating and optimizing the consolidated framework for implementation research (CFIR) for use in low- And middle-income countries: A systematic review. Implement Sci [Internet]. 2020 Mar 12 [cited 2022 Jan 5];15(1):1–19. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-0977-0

132. Lewin S, Booth A, Glenton C, Munthe-Kaas H, Rashidian A, Wainwright M, et al. Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series. Implement Sci [Internet]. 2018 Jan 25 [cited 2018 Apr 4];13(S1):2. Available from: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0688-3

133. Dallongeville J, Banegas JR, Tubach F, Guallar E, Borghi C, De Backer G, et al. Survey of physicians' practices in the control of cardiovascular risk factors:

the EURIKA study. Eur J Prev Cardiol [Internet]. 2011 [cited 2018 Mar 21];19(3):541–50. Available from: http://journals.sagepub.com/doi/pdf/10.1177/1741826711407705

134. Doolan-Noble F, Mann S, Tracey J. An exploratory study of the barriers and facilitators to the optimal management of high CVD risk within primary health care. Hear Lung Circ [Internet]. 2010;1):S9. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed12&AN=70160241 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:10.1016%2Fj.hlc.2010.04.017&issn=1443-9506&isbn=&volume=19&issue=SUPPL.+1&spage=S9&pag

135. Liew SM, Blacklock C, Hislop J, Glasziou P, Mant D. Cardiovascular risk scores: qualitative study of how primary care practitioners understand and use them. Br J Gen Pract [Internet]. 2013;63(611):e401-7. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=23735411 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:23735411&id=doi:10.3399%2Fbjgp13X668195&issn=0960-1643&isbn=&volume=63&issue=611&spage=e401&pag

136. Oriol-Zerbe C, Abholz HH. Primary prevention of cardiovascular diseases by lipid-lowering treatment in German general practice: results from GPs ignoring guidelines and risk calculators. Eur J Gen Pract [Internet]. 2007;13(1):27–34. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=17366291 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:17366291&id=doi:&issn=1381-4788&isbn=&volume=13&issue=1&spage=27&pages=27-34&date=2007&title=Eu

137. Bonnevie L, Thomsen T, Jorgensen T. The use of computerized decision support systems in preventive cardiology--principal results from the national PRECARD survey in Denmark. Eur J Cardiovasc Prev Rehabil [Internet]. 2005;12(1):52–5. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=15703506 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:15703506&id=doi:&issn=1741-8267&isbn=&volume=12&issue=1&spage=52&pages=52-5&date=2005&title=Eur

138. Ferrante D, Konfino J, Linetzky B, Tambussi A, Laspiur S. Barriers to prevention of cardiovascular disease in primary care settings in Argentina. Rev Panam Salud Publica/Pan Am J Public Heal [Internet]. 2013 Apr [cited 2018 Mar 13];33(4):259–66. Available from: http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S1020-49892013000400004&lng=en&nrm=iso&tlng=en

139. Elisaf M, Tzouvelekis E, Nikas N, Greek EI. Primary prevention of

cardiovascular disease in Greece: Greek results of the EURIKA study. Hjc Hell J Cardiol [Internet]. 2014;55(3):217–26. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=24862614 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:24862614&id=doi:&issn=1109-9666&isbn=&volume=55&issue=3&spage=217&pages=217-26&date=2014&title=

140. Van Steenkiste B, Van Der Weijden T, Timmermans D, Vaes J, Stoffers J, Grol R. Patients' ideas, fears and expectations of their coronary risk: barriers for primary prevention. Patient Educ Couns [Internet]. 2004 [cited 2018 Mar 18];55:301–7. Available from: https://ac.els-cdn.com/S0738399103003227/1-s2.0-S0738399103003227-main.pdf?_tid=4adacc2e-1324-4149-8641-12b0205a8894&acdnat=1521653093_282241e82ea91b83ae500d871546a4aa

141. Schmieder RE, Goebel M, Bramlage P. Barriers to cardiovascular risk prevention and management in Germany – an analysis of the EURIKA study. Vasc Health Risk Manag [Internet]. 2012 [cited 2018 Mar 18];8:177–86. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3333468/pdf/vhrm-8-177.pdf

142. Sposito AC, Ramires JAF, Jukema JW, Molina JC, Silva PM da, Ghadanfar MM, et al. Physicians' attitudes and adherence to use of risk scores for primary prevention of cardiovascular disease: cross-sectional survey in three world regions. Curr Med Res Opin [Internet]. 2009 May 26 [cited 2018 Mar 21];25(5):1171–8. Available from: http://www.tandfonline.com/doi/full/10.1185/03007990902846423

143. A. I, S. Q. General practitioners' use of cardiovascular risk calculators. Aust Fam Physician [Internet]. 2010;39(1):57–60. Available from: http://www.racgp.org.au/afp/201001/201001imms.pdf

144. Torley D, Zwar NN, Comino EJ, Harris M. Gps' views of absolute cardiovascular risk and its role in primary prevention. Aust Fam Physician [Internet]. 2005 Jun [cited 2018 Mar 21];34(6):503–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15931411

145. Wan Q, Harris MF, Zwar N, Vagholkar S. Sharing risk management: an implementation model for cardiovascular absolute risk assessment and management in Australian general practice. Int J Clin Pract [Internet]. 2008;62(6):905–11. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med6&AN=18479283 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:18479283&id=doi:10.1111%2Fj.1742-1241.2008.01769.x&issn=1368-5031&isbn=&volume=62&issue=6&spage

146. Wan Q, Harris MF, Zwar N, Vagholkar S, Campbell T. Prerequisites for implementing cardiovascular absolute risk assessment in general practice: a qualitative study of Australian general practitioners' and patients' views. J Eval Clin Pract [Internet]. 2010;16(3):580–4. Available from:

http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med6&AN=20438609
http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:20438609&id=doi:10.1111%2Fj.1365-2753.2009.01170.x&issn=1356-1294&isbn=&volume=16&issue=3&spage

147. Byrne D, O'Connor L, Jennings S, Bennett K, Murphy AW. A survey of GPs awareness and use of risk assessment tools and cardiovascular disease prevention guidelines. Ir Med J [Internet]. 2015 [cited 2018 Mar 17];108(7). Available from: https://core.ac.uk/download/pdf/43414956.pdf

148. Eichler K, Zoller M, Tschudi P, Steurer J. Barriers to apply cardiovascular prediction rules in primary care: A postal survey. BMC Fam Pract [Internet]. 2007 [cited 2018 Mar 17];8. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1766351/pdf/1471-2296-8-1.pdf

149. Tawfik MY, Mohamed RA. The impact of communicating cardiovascular risk in type 2 diabetics on patient risk perception, diabetes self-care, glycosylated hemoglobin, and cardiovascular risk. J Public Heal [Internet]. 2016;24(2):153–64. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed18&AN=609035612
http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:10.1007%2Fs10389-016-0710-2&issn=0943-1853&isbn=&volume=24&issue=2&spage=153&pages=15

150. Kirby M, Machen I. Impact on clinical practice of the Joint British Societies' cardiovascular risk assessment tools. Int J Clin Pract [Internet]. 2009 Dec 1 [cited 2018 Mar 21];63(12):1683–92. Available from: http://doi.wiley.com/10.1111/j.1742-1241.2009.02201.x

151. Collins DRJ, Jobanputra K, Frost T, Muhammed S, Ward A, Shafei AA, et al. Cardiovascular disease risk and prevention amongst Syrian refugees: mixed methods study of Medecins Sans Frontieres programme in Jordan. Confl Health [Internet]. 2017;11(14). Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=cagh&AN=20183115096
http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:caghdb&id=pmid:&id=doi:10.1186%2Fs13031-017-0115-z&issn=1752-1505&isbn=&volume=11&issue=14&spage=&pages=%281

152. Tawfik MY, Fahim AE, Ismail MA, Moussa SA. Barriers to the utilization of cardiovascular risk prediction tools as perceived by primary health care and family physicians. Egypt J Community Med [Internet]. 2015 [cited 2018 Mar 17];33(1):15–32. Available from: https://www.researchgate.net/profile/Ayman_Fahim/publication/278848629_Barriers_to_The_Utilization_of_Cardiovascular_Risk_Prediction_Tools_as_Perceived_by_Primary_Health_Care_and_Family_Physicians/links/5586fa9f08aeb0cdade0abd2/Barriers-to-The-Utilization

153. Wan Q, Zwar N, Vagholkar S, Campbell T, Harris M. Cardiovascular absolute

risk assessment and management - engagement and outcomes in general practice patients. Aust Fam Physician [Internet]. 2010;39(12):954–8. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med6&AN=21301679 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:21301679&id=doi:&issn=0300-8495&isbn=&volume=39&issue=12&spage=954&pages=954-8&date=2010&title=

154. Dallongeville J, Banegas JR, Guallar E, Borghi C, De Backer G, Halcox JP, et al. A survey of physicians' attitudes toward the control of cardiovascular risk factors. The eurika study. Value Heal [Internet]. 2010;13 (7):A363–4. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed12&AN=70514715 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:embase&id=pmid:&id=doi:&issn=1098-3015&isbn=&volume=13&issue=7&spage=A363&pages=A363-A364&date=2010&title=Val

155. Torley D, Zwar N, Comino EJ, Harris M. Gps' views of absolute cardiovascular risk and its role in primary prevention. Aust Fam Physician [Internet]. 2005 Jun [cited 2018 Mar 21];34(6):503–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15931411

156. Vaidya R, Pandya K V, Denney-Wilson E, Harris M. Sustaining cardiovascular absolute risk management in Australian general practice. Aust J Prim Health [Internet]. 2012;18(4):304–7. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=22950805 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:22950805&id=doi:&issn=1448-7527&isbn=&volume=18&issue=4&spage=304&pages=304-7&date=2012&title=A

157. Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. General practitioners' use of different cardiovascular risk assessment strategies: a qualitative study. Med J Aust [Internet]. 2013;199(7):485–9. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=24099210 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:24099210&id=doi:&issn=0025-729X&isbn=&volume=199&issue=7&spage=485&pages=485-9&date=2013&title=

158. Byrne D, O'Connor L, Jennings S, Bennett K, Murphy AW. A Survey of GPs Awareness and Use of Risk Assessment Tools and Cardiovascular Disease Prevention Guidelines. Ir Med J [Internet]. 2015;108(7):204–7. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=26349349 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmi

d:26349349&id=doi:&issn=0332-3102&isbn=&volume=108&issue=7&spage=204&pages=204-7&date=2015&title=

159. Dallongeville J, Banegas JR, Halcox J, Guallar E, Borghi C, De Backer G, et al. Physicians' attitudes towards cardiovascular guidelines and risk assessment tools: relation with the management of risk factors in the primary prevention setting. Eur Heart J. 2011 Aug;32(1):973.

160. van Steenkiste B, van der Weijden T, Stoffers H, Grol R. Barriers to implementing cardiovascular risk tables in routine general practice. Scand J Prim Health Care. 2004 Mar;22(1):32–7.

161. Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. General practitioners' use of different cardiovascular risk assessment strategies: a qualitative study. Med J Aust [Internet]. 2013 Oct 8 [cited 2018 Mar 18];199(7):485–9. Available from: https://www.mja.com.au/journal/2013/199/7/general-practitioners-use-different-cardiovascular-risk-assessment-strategies

162. Greenhalgh T, Papoutsi C. Studying complexity in health services research: Desperately seeking an overdue paradigm shift. Vol. 16, BMC Medicine. BioMed Central Ltd.; 2018.

163. Scardi S, Mazzone C. [Barriers to cardiovascular prevention]. Ital Hear J Suppl [Internet]. 2001;2(10):1068–73. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=11723608 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:11723608&id=doi:&issn=1129-4728&isbn=&volume=2&issue=10&spage=1068&pages=1068-73&date=2001&titl

164. Shillinglaw B, Viera AJ, Edwards T, Simpson R, Sheridan SL. Use of global coronary heart disease risk assessment in practice: A cross-sectional survey of a sample of U.S. physicians. BMC Health Serv Res [Internet]. 2012 Dec 24 [cited 2018 Mar 21];12(1):20. Available from: http://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-12-20

165. Mendis et al S. Gaps in Capacity in Primary Care in Low-Resource Settings for Implementation of Essential Noncommunicable Disease Interventions. Int J Hypertens [Internet]. 2012 [cited 2018 Jan 16];584041. Available from: http://www.who.int/ncds/management/Gaps_in_capacity_Int_Journal_of_Hypertension2012.pdf?ua=1

166. Subramanian S, Kibachio J, Hoover S, Edwards P, Amukoye E, Amuyunzu–Nyamongo M, et al. Research for Actionable Policies: implementation science priorities to scale up non–communicable disease interventions in Kenya. J Glob Health [Internet]. 2017 Jun [cited 2017 Oct 25];7(1). Available from: http://jogh.org/documents/issue201701/jogh-07-010204.pdf

167. Imms A, Quinn S, Nelson M. General practitioners' use of cardiovascular risk calculators. Repr from Aust Fam PhysiciAn [Internet]. 2010 [cited 2018 Mar

21];39(12). Available from: https://www.racgp.org.au/download/documents/AFP/2010/Jan-Feb/201001imms.pdf

168. WHO. WHO Guideline on Health Policy and System Support to Optimize Community Health Worker Programmes [Internet]. 2018 [cited 2019 Mar 27]. Available from: https://apps.who.int/iris/bitstream/handle/10665/275474/9789241550369-eng.pdf?ua=1

169. Webster RJ, Heeley EL, Peiris DP, Bayram C, Cass A, Patel AA. Gaps in cardiovascular disease risk management in Australian general practice. Med J Aust [Internet]. 2009;191(6):324–9. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med6&AN=19769555 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:19769555&id=doi:&issn=0025-729X&isbn=&volume=191&issue=6&spage=324&pages=324-9&date=2009&title=

170. Hermans MP, De Bacquer D, De Block C, Truyers C, Vankeirsbilck A, De Backer G. Cardiovascular risk factors: Belgian target achievement. Acta Cardiol [Internet]. 2014;69(5):473–81. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=25638834 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:25638834&id=doi:&issn=0001-5385&isbn=&volume=69&issue=5&spage=473&pages=473-81&date=2014&title=

171. Keller H, Hirsch O, Kaufmann-Kolle P, Krones T, Becker A, Sonnichsen AC, et al. Evaluating an implementation strategy in cardiovascular prevention to improve prescribing of statins in Germany: an intention to treat analysis. BMC Public Health [Internet]. 2013;13:623. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=23819600 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:23819600&id=doi:10.1186%2F1471-2458-13-623&issn=1471-2458&isbn=&volume=13&issue=1&spage=623&pag

172. Tsolekile LP, Abrahams-Gessel S, Puoane T. Healthcare Professional Shortage and Task-Shifting to Prevent Cardiovascular Disease: Implications for Low- and Middle-Income Countries. Curr Cardiol Rep [Internet]. 2015 Dec 19 [cited 2017 Feb 14];17(12):115. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26482758

173. Ogedegbe G, Gyamfi J, Plange-Rhule J, Surkis A, Rosenthal DM, Airhihenbuwa C, et al. Task shifting interventions for cardiovascular risk reduction in low-income and middle-income countries: a systematic review of randomised controlled trials. BMJ Open [Internet]. 2014 Oct 16 [cited 2016 Nov 20];4(10):e005983. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25324324

174. Sheridan SL, Crespo E. Does the routine use of global coronary heart disease risk scores translate into clinical benefits or harms? A systematic review of the literature. BMC Health Serv Res [Internet]. 2008;8:60. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med6&AN=18366711 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:18366711&id=doi:10.1186%2F1472-6963-8-60&issn=1472-6963&isbn=&volume=8&issue=1&spage=60&pages=6

175. World Health Organization. Global strategy on human resources for health: Workforce 2030 [Internet]. Who. 2016 [cited 2019 Mar 27]. Available from: http://apps.who.int/iris/bitstream/10665/250368/1/9789241511131-eng.pdf?ua=1%5Cnhttp://www.who.int/hrh/resources/pub_globstrathrh-2030/en/

176. S A-G, Denman CA, Ta G, Ns L, T P. Challenges Facing Successful Scaling Up of Effective Screening for Cardiovascular Disease by Community Health Workers in Mexico and South Africa: Policy Implications. Heal Syst policy Res [Internet]. 2016 [cited 2017 Mar 6];3(1):1–10. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27158629

177. Sheerin I, Hamilton G, Humphrey A, Scragg A. Issues in the assessment of cardiovascular risk in selected general practices in Canterbury, New Zealand. N Z Med J [Internet]. 2007;120(1261):U2714. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med5&AN=17853935 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:17853935&id=doi:&issn=0028-8446&isbn=&volume=120&issue=1261&spage=U2714&pages=U2714&date=2007&t

178. Marrugat J, Elosua R, Icaza G, Morales-Salinas A, Degano IR. [Practicality of cardiovascular risk functions]. Medwave [Internet]. 2016;16(Suppl4):e6792. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=28055992 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:28055992&id=doi:10.5867%2Fmedwave.2016.6792&issn=0717-6384&isbn=&volume=16&issue=4&spage=e6792&

179. Aekplakorn W, Suriyawongpaisal P, Sirirassamee B. Assessment of capacity for cardiovascular disease control and prevention in Thailand: a qualitative study. Southeast Asian J Trop Med Public Health [Internet]. 2005;36(3):741–7. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=cagh3&AN=20053165251 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:caghdb&id=pmid:&id=doi:&issn=0125-1562&isbn=&volume=36&issue=3&spage=741&pages=741-747&date=2005&title=Sout

180. Wang WZ, Tang JL, Hu YH, An JG, Wang YL, Ren ZH, et al. Gap between

evidence and physicians' knowledge and practice regarding hypertension and its drug treatment: a survey in a Chinese city. Chin Med J (Engl) [Internet]. 2011;124(8):1235–41. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=21543003 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:21543003&id=doi:&issn=0366-6999&isbn=&volume=124&issue=8&spage=1235&pages=1235-41&date=2011&tit

181. Alwan H, William J, Viswanathan B, Paccaud F, Bovet P. Perception of cardiovascular risk and comparison with actual cardiovascular risk. Eur J Cardiovasc Prev Rehabil. 2009;16(5):556–61.

182. Bove AA, Santamore WP, Homko C, Kashem A, Cross R, McConnell TR, et al. Reducing cardiovascular disease risk in medically underserved urban and rural communities. Am Heart J [Internet]. 2011;161(2):351–9. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=21315219 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:21315219&id=doi:10.1016%2Fj.ahj.2010.11.008&issn=0002-8703&isbn=&volume=161&issue=2&spage=351&p

183. Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. Communicating cardiovascular disease risk: an interview study of General Practitioners' use of absolute risk within tailored communication strategies. BMC Fam Pract [Internet]. 2014;15:106. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=24885409 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:24885409&id=doi:10.1186%2F1471-2296-15-106&issn=1471-2296&isbn=&volume=15&issue=1&spage=106&pag

184. Lipkus IM, Peters E. Understanding the Role of Numeracy in Health: Proposed Theoretical Framework and Practical Insights. Heal Educ Behav [Internet]. 2009 Dec 15 [cited 2019 Mar 29];36(6):1065–81. Available from: http://journals.sagepub.com/doi/10.1177/1090198109341533

185. Welschen LMC, Bot SDM, Kostense PJ, Dekker JM, Timmermans DRM, van der Weijden T, et al. Effects of Cardiovascular Disease Risk Communication for Patients With Type 2 Diabetes on Risk Perception in a Randomized Controlled Trial The @RISK Study. Diabetes Care. 2012;35(12):2485–92.

186. Naik G, Ahmed H, Edwards AG. Communicating risk to patients and the public. Br J Gen Pr [Internet]. 2012 Apr 1 [cited 2019 Mar 29];62(597):213–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22520906

187. Erhardt LR. Barriers to effective implementation of guideline recommendations. Am J Med [Internet]. 2005 Dec 1 [cited 2018 Mar 21];118(12):36–41. Available from: https://www.sciencedirect.com/science/article/pii/S0002934305007989?via%3Dihub

188. Polak L, Green J. Using quantitative risk information in decisions about statins: a qualitative study in a community setting. Br J Gen Pract [Internet]. 2015;65(633):e264-9. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=25824187 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:25824187&id=doi:10.3399%2Fbjgp15X684433&issn=0960-1643&isbn=&volume=65&issue=633&spage=e264&pag

189. Karmali KN, Persell SD, Perel P, Lloyd-Jones DM, Berendsen MA, Huffman MD. Risk scoring for the primary prevention of cardiovascular disease [Internet]. Vol. 2017, Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd; 2017 [cited 2018 Feb 25]. Available from: http://doi.wiley.com/10.1002/14651858.CD006887.pub4

190. WHO, World Health Organization, WHO, World Health Organization, WHO, World Health Organization. Package of essential noncommunicable disease interventions for primary health care in low-resource settings. Geneva Wold Heal Organ [Internet]. 2010 [cited 2016 Dec 19];66. Available from: http://www.who.int/cardiovascular_diseases/publications/pen2010/en/

191. Adang EM, Gerritsma A, Nouwens E, van Lieshout J, Wensing M. Efficiency of the implementation of cardiovascular risk management in primary care practices: an observational study. Implement Sci [Internet]. 2016;11:67. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med8&AN=27177588 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:27177588&id=doi:10.1186%2Fs13012-016-0434-2&issn=1748-5908&isbn=&volume=11&issue=&spage=67&page

192. Pearson A, White H, Bath-Hextall F, Salmond S, Apostolo J, Kirkpatrick P. A mixed-methods approach to systematic reviews. Int J Evid Based Healthc [Internet]. 2015 Sep [cited 2019 Jan 6];13(3):121–31. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=01787381-201509000-00003

193. Kilifi D of H. Kilifi County Government County Department of Health Kilifi County Health Sector Strategic and. 2018;(June).

194. Ministry of Health K. Kenya Master Health Facility List: Find all the health facilities in Kenya [Internet]. 2019 [cited 2019 Apr 12]. Available from: http://kmhfl.health.go.ke/#/facility_filter/results?search=training

195. Bowen GA. Document Analysis as a Qualitative Research Method. Qual Res J [Internet]. 2009 [cited 2018 Jul 3];9(2):27–40. Available from: https://www.academia.edu/8434566/Document_Analysis_as_a_Qualitative_Research_Method?ends_sutd_reg_path=true

196. Hart J, Kinzie M, Lassiter LE, Barzun J, Lipson C, Becker HS, et al. In the Field: Participating, Observing, and Jotting Notes Ethnographers. In: Writing Ethnographic Field Notes. Chicago and London: University of Chicago Press; 2011. p. 21–43.

197. Frey BB. Observer Effect. In: The SAGE Encyclopedia of Educational Research, Measurement, and Evaluation. SAGE Publications, Inc.; 2018.

198. Emerson RM, Fretz RI, Shaw LL. Writing Ethnographic Fieldnotes [Internet]. Writing Ethnographic Fieldnotes. 2013 [cited 2020 Jun 18]. p. 320. Available from: http://www.press.uchicago.edu/ucp/books/book/chicago/W/bo12182616.html

199. Braun V, Clarke V. Qualitative Research in Psychology Using thematic analysis in psychology Using thematic analysis in psychology. Qual Res Psychol [Internet]. 2006 [cited 2018 May 14];3(2):77–101. Available from: http://www.tandfonline.com/action/journalInformation?journalCode=uqrp20

200. Creswell J. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches [Internet]. 2nd ed. SAGE Publications; 2002 [cited 2018 Jul 2]. 203–227 p. Available from: https://ucalgary.ca/paed/files/paed/2003_creswell_a-framework-for-design.pdf

201. Creswell JW. Qualitative Inquiry and Research Design: Choosing Among Five Approaches. Book [Internet]. 2007 [cited 2018 Apr 30];2nd ed:424. Available from: https://charlesbickenheuserdotcom.files.wordpress.com/2015/03/creswell_2007_qualitative_inquiry_and_research_design__choosing_among_five_approaches__2nd_edition.pdf

202. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol [Internet]. 2006 Jan [cited 2019 Jan 27];3(2):77–101. Available from: http://www.tandfonline.com/doi/abs/10.1191/1478088706qp063oa

203. Saldana J. The Coding Manual for Qualitative Researchers lfJ ZAPADOCESKA UNIVERZITA v PLZNI Univerzitnl knihovna 55 City Road Librury of Congress Control Number: 2008931307 British Librnry Cataloguing in Publication datll [Internet]. 2009 [cited 2019 Apr 12]. Available from: http://stevescollection.weebly.com/uploads/1/3/8/6/13866629/saldana_2009_the-coding-manual-for-qualitative-researchers.pdf

204. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci [Internet]. 2011 Apr 23 [cited 2021 Jan 3];6(1):42. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-42

205. Srivastava A, Thomson SB. Framework Analysis: A Qualitative Methodology for [Internet]. Vol. 4, Applied Policy Research. JOAAG. 2009 [cited 2019 Apr 16]. Available from: http://research.apc.org/images/a/ad/Framework_analysis.pdf

206. English M. Designing a theory-informed, contextually appropriate intervention strategy to improve delivery of paediatric services in Kenyan hospitals. Implement Sci [Internet]. 2013 Mar 28 [cited 2021 Jan 3];8(1):39. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-39

207. Berger R. Now I see it, now I don't: researcher's position and reflexivity in

qualitative research. Qual Res [Internet]. 2015 [cited 2019 Apr 12];15(2):219–34. Available from: https://ezproxy-prd.bodleian.ox.ac.uk:7218/doi/pdf/10.1177/1468794112468475

208. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: A synthesis of recommendations. Acad Med [Internet]. 2014 [cited 2020 Jun 24];89(9):1245–51. Available from: https://pubmed.ncbi.nlm.nih.gov/24979285/

209. Swain J, Spire Z. The Role of Informal Conversations in Generating Data, and the Ethical and Methodological Issues. Forum Qual Sozialforsch / Forum Qual Soc Res. 2020;21(1).

210. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PAC, et al. Why don't physicians follow clinical practice guidelines?: A framework for improvement [Internet]. Vol. 282, Journal of the American Medical Association. American Medical Association; 1999 [cited 2021 Jan 7]. p. 1458–65. Available from: https://jamanetwork.com/journals/jama/fullarticle/192017

211. Fischer F, Lange K, Klose K, Greiner W, Kraemer A. Barriers and Strategies in Guideline Implementation—A Scoping Review. Healthcare [Internet]. 2016 Jun 29 [cited 2021 Jan 7];4(3):36. Available from: /pmc/articles/PMC5041037/?report=abstract

212. Kredo T, Cooper S, Abrams A, Muller J, Volmink J, Atkins S. Using the behavior change wheel to identify barriers to and potential solutions for primary care clinical guideline use in four provinces in South Africa. BMC Health Serv Res [Internet]. 2018 Dec 14 [cited 2021 Jan 3];18(1):965. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-3778-2

213. Essack SY, Sartorius B. Global antibiotic resistance: of contagion, confounders, and the COM-B model [Internet]. Vol. 2, The Lancet Planetary Health. Elsevier B.V.; 2018 [cited 2021 Jan 3]. p. e376–7. Available from: www.thelancet.com/planetary-health

214. WHO. Assessing National Capacity for the Prevention and Control of Noncommunicable Diseases Report of the 2017 Global Survey [Internet]. 2017 [cited 2020 Feb 20]. Available from: https://apps.who.int/iris/bitstream/handle/10665/276609/9789241514781-eng.pdf

215. Kutzin J, Sparkes S, Soucat A, Barroy H. From silos to sustainability: transition through a UHC lens [Internet]. Vol. 392, The Lancet. Lancet Publishing Group; 2018 [cited 2021 Jan 7]. p. 1513–4. Available from: http://ees.elsevier.com/thelancet/www.thelancet.com

216. Gotsadze G, Chikovani I, Sulaberidze L, Gotsadze T, Goguadze K, Tavanxhi N. The challenges of transition from donor-funded programs: Results from a theory-driven multi-country comparative case study of programs in Eastern Europe and central Asia supported by the Global Fund. Glob Heal Sci Pract [Internet]. 2019 [cited 2021 Jan 7];7(2):258–72. Available from:

/pmc/articles/PMC6641812/?report=abstract

217. Bank W. Navigating the health financing transition in LMICs toward UHC. World Bank, Washington, DC; 2017.

218. Rowe AK, Rowe SY, Peters DH, Holloway KA, Chalker J, Ross-Degnan D. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. Lancet Glob Heal [Internet]. 2018 Nov 1 [cited 2021 Jan 7];6(11):e1163–75. Available from: /pmc/articles/PMC6185992/?report=abstract

219. Kruk ME, Gage AD, Arsenault C, Jordan K, Leslie HH, Roder-DeWan S, et al. High-quality health systems in the Sustainable Development Goals era: time for a revolution [Internet]. Vol. 6, The Lancet Global Health. Elsevier Ltd; 2018 [cited 2020 Nov 25]. p. e1196–252. Available from: www.thelancet.com/lancetgh

220. Tapela NM, Tshisimogo G, Shatera BP, Letsatsi V, Gaborone M, Madidimalo T, et al. Integrating noncommunicable disease services into primary health care, Botswana. Bull World Health Organ [Internet]. 2019 Feb 1 [cited 2021 Jan 7];97(2):142–53. Available from: /pmc/articles/PMC6357568/?report=abstract

221. Masaba BB, Moturi JK, Taiswa J, Mmusi-Phetoe RM. Devolution of healthcare system in Kenya: progress and challenges. Vol. 189, Public Health. Elsevier B.V.; 2020. p. 135–40.

222. Kienle GS, Kiene H. Clinical judgement and the medical profession. J Eval Clin Pract [Internet]. 2011 Aug [cited 2021 Jan 7];17(4):621–7. Available from: /pmc/articles/PMC3170707/?report=abstract

223. Ofri D. The practice of medicine: neither science nor art. Lancet [Internet]. 2006 Mar 11 [cited 2021 Jan 7];367(9513):807–8. Available from: www.mlythgoe.com/

224. Montgomery K. How Doctors Think: Clinical Judgment and the Practice of Medicine. Oxford University Press; 2005.

225. Weed LL, Weed L. Opening the black box of clinical judgment-an-overview. BMJ [Internet]. 1999 Nov 13 [cited 2021 Jan 7];319(7220):1279. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1129058/

226. Muthee TB, Etyang A, Williams V, Nunan D, heneghan C, Persaud N. The recommended level of use for essential medicines: a comparison between cardiovascular disease and the leading communicable diseases in Eastern sub-Saharan Africa. 2021 Mar 6 [cited 2021 Mar 7]; Available from: https://osf.io/z92r3

227. WHO. The selection and use of essential medicines. Report of the WHO Expert Committee, 2009 (including the 16th WHO model list of essential medicines and [Internet]. Vol. 2009, Who. 2009 [cited 2019 Oct 29]. Available from: http://www.who.int/bookorders%0Ahttp://www.who.int/bookorders%0Ahttp://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:THE+SELECTION+AND+USE+OF+ESSENTIAL+MEDICINES+Report+of+the+WHO+Expe

rt+Committee+,+2009+(+including+the+16th+WHO+Model+List+of+Ess

228. Bazargani YT, Ewen M, De Boer A, Leufkens HGM, Mantel-Teeuwisse AK. Essential medicines are more available than other medicines around the globe. PLoS One [Internet]. 2014 [cited 2019 Nov 5];9(2). Available from: www.plosone.org

229. Pai M, Walia K, Boehme CC. Essential medicines and essential diagnostics: a package deal. Lancet Public Heal. 2019 Aug;

230. Masters SH, Burstein R, DeCenso B, Moore K, Haakenstad A, Ikilezi G, et al. Pharmaceutical Availability across Levels of Care: Evidence from Facility Surveys in Ghana, Kenya, and Uganda. Launois P, editor. PLoS One [Internet]. 2014 Dec 11 [cited 2018 Nov 24];9(12):e114762. Available from: https://dx.plos.org/10.1371/journal.pone.0114762

231. Cameron A, Roubos I, Ewen M, Mantel-Teeuwisse AK, Leufkens HGM, Laing RO. Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. Bull World Health Organ. 2011;89(6):412–21.

232. Chow CK, Ramasundarahettige C, Hu W, AlHabib KF, Avezum A, Cheng X, et al. Availability and affordability of essential medicines for diabetes across high-income, middle-income, and low-income countries: a prospective epidemiological study. Lancet Diabetes Endocrinol [Internet]. 2018 Oct [cited 2018 Nov 24];6(10):798–808. Available from: http://www.ncbi.nlm.nih.gov/pubmed/30170949

233. Robertson J, Macé C, Forte G, de Joncheere K, Beran D. Medicines availability for non-communicable diseases: the case for standardized monitoring. Global Health [Internet]. 2015 Dec 7 [cited 2018 Nov 24];11(1):18. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25947094

234. Kibirige D, Atuhe D, Kampiire L, Kiggundu DS, Donggo P, Nabbaale J, et al. Access to medicines and diagnostic tests integral in the management of diabetes mellitus and cardiovascular diseases in Uganda: insights from the ACCODAD study. Int J Equity Health [Internet]. 2017 Dec 24 [cited 2018 Nov 24];16(1):154. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28836972

235. Ewen M, Zweekhorst M, Regeer B, Laing R. Baseline assessment of WHO's target for both availability and affordability of essential medicines to treat non-communicable diseases. Podobnik B, editor. PLoS One [Internet]. 2017 Feb 7 [cited 2021 Jan 13];12(2):e0171284. Available from: https://dx.plos.org/10.1371/journal.pone.0171284

236. Husain MJ, Datta BK, Kostova D, Joseph KT, Asma S, Richter P, et al. Access to Cardiovascular Disease and Hypertension Medicines in Developing Countries: An Analysis of Essential Medicine Lists, Price, Availability, and Affordability. J Am Heart Assoc [Internet]. 2020 May 5 [cited 2021 Jan 12];9(9):e015302. Available from: https://www.ahajournals.org/doi/10.1161/JAHA.119.015302

237. WHO. Prevention of cardiovascular disease : guidelines for assessment and

management of total cardiovascular risk. WHO Press [Internet]. 2007; Available from: http://www.who.int/cardiovascular_diseases/guidelines/Full text.pdf

238. Lim SS, Gaziano TA, Gakidou E, Reddy KS, Farzadfar F, Lozano R, et al. Prevention of cardiovascular disease in high-risk individuals in low-income and middle-income countries: health effects and costs. Lancet. 2007;370(9604):2054–62.

239. Valluri S, Gaziano TA. Progress in national and regional guidelines development and deployment for the clinical prevention and control of CVD and diabetes in Africa. Prog Cardiovasc Dis [Internet]. 2013;56(3):336–43. Available from: http://dx.doi.org/10.1016/j.pcad.2013.09.014

240. Mendis S, Abegunde D, Oladapo O, Celletti F, Nordet P. Barriers to management of cardiovascular risk in a low- resource setting using hypertension as an entry point. J Hypertens J Hypertens [Internet]. 2004 [cited 2018 Feb 21];22(22):59–6459. Available from: https://insights.ovid.com/pubmed?pmid=15106795

241. Dalal S, Beunza JJ, Volmink J, Adebamowo C, Bajunirwe F, Njelekela M, et al. Non-communicable diseases in sub-Saharan Africa: What we know now. Int J Epidemiol. 2011;40(4):885–901.

242. Horton R. Non-communicable diseases: 2015 to 2025. Lancet. 2013;381(9866):509–10.

243. Abbafati C, Machado DB, Cislaghi B, Salman OM, Karanikolos M, McKee M, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet [Internet]. 2020 Oct 17 [cited 2021 Jan 11];396(10258):1204–22. Available from: http://ghdx.healthdata.org/gbd-

244. Persuad N. EMLs Around The World [Internet]. WHO Bulletin. 2019 [cited 2021 Jan 31]. Available from: https://global.essentialmeds.org/dashboard/medicines/215

245. WHO. WHO Model List of Essential Medicines [Internet]. World Health Organization. 2019 [cited 2021 Jan 31]. p. 1–43. Available from: http://www.who.int/medicines/organization/par/edl/expcom13/eml13_en.pdf

246. Datawrapper. Datawrapper [Internet]. 2021 [cited 2021 Mar 4]. Available from: https://app.datawrapper.de/

247. World Bank. Classification of Fragile and Conflict-Affected Situations [Internet]. 2020 [cited 2021 Mar 5]. Available from: http://pubdocs.worldbank.org/en/179011582771134576/FCS-FY20.pdf

248. Laing R, Waning B, Gray A, Ford N, 'T Hoen E. 25 Years of the WHO essential medicines lists: Progress and challenges [Internet]. Vol. 361, Lancet. Elsevier Limited; 2003 [cited 2021 Jan 13]. p. 1723–9. Available from: http://www.thelancet.com/article/S0140673603133752/fulltext

249. Organization WH. Equitable access to essential medicines: a framework for collective action. 2004 [cited 2021 Jan 13]; Available from:

https://apps.who.int/iris/bitstream/handle/10665/68571/WHO_EDM_2004.4_rus.pdf

250. Wirtz VJ, Kaplan WA, Kwan GF, Laing RO. Access to medications for cardiovascular diseases in low- and middle-income countries. Circulation [Internet]. 2016 May 24 [cited 2021 Jan 13];133(21):2076–85. Available from: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.115.008722

251. Jingi AM, Noubiap JJN, Onana AE, Nansseu JRN, Wang B, Kingue S, et al. Access to diagnostic tests and essential medicines for cardiovascular diseases and diabetes care: Cost, availability and affordability in the west region of Cameroon. PLoS One. 2014;9(11).

252. Nyarko KM, Ameme DK, Ocansey D, Commeh E, Markwei MT, Ohene S-AA. Capacity assessment of selected health care facilities for the pilot implementation of Package for Essential Non-communicable Diseases (PEN) intervention in Ghana. Pan Afr Med J [Internet]. 2016 [cited 2018 Jan 21];25(1):16. Available from: http://www.panafrican-med-journal.com/content/series/25/1/16/full

253. Hogerzeil H V., Liberman J, Wirtz VJ, Kishore SP, Selvaraj S, Kiddell-Monroe R, et al. Promotion of access to essential medicines for non-communicable diseases: Practical implications of the un political declaration [Internet]. Vol. 381, The Lancet. Lancet Publishing Group; 2013 [cited 2021 Jan 13]. p. 680–9. Available from: http://www.thelancet.com/article/S014067361262128X/fulltext

254. Twagirumukiza M, Annemans L, Kips JG, Bienvenu E, Van Bortel LM. Prices of antihypertensive medicines in sub-Saharan Africa and alignment to WHO's model list of essential medicines. Trop Med Int Heal [Internet]. 2010 Mar 1 [cited 2021 Jan 13];15(3):350–61. Available from: http://doi.wiley.com/10.1111/j.1365-3156.2009.02453.x

255. Chow CK, Nguyen TN, Marschner S, Diaz R, Rahman O, Avezum A, et al. Availability and affordability of medicines and cardiovascular outcomes in 21 high-income, middle-income and low-income countries. BMJ Glob Heal [Internet]. 2020 Nov 3 [cited 2021 Jan 11];5(11):2640. Available from: http://dx.doi.org/10.1136/bmjgh-2020-002640

256. Persaud N, Bedard M, Boozary AS, Glazier RH, Gomes T, Hwang SW, et al. Effect on Treatment Adherence of Distributing Essential Medicines at No Charge: The CLEAN Meds Randomized Clinical Trial. JAMA Intern Med. 2020 Jan 1;180(1):27–34.

257. Organization WH. WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy [Internet]. 2000 [cited 2021 Jan 13]. Available from: https://apps.who.int/iris/bitstream/handle/10665/66503/WHO_EDM_2000.1.pdf

258. Gebreyohannis T, Shibeshi W, Asres K, International Diabetes Federation (IDF), Litwak L, Goh S-Y, et al. Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of

Non-communicable Diseases The. UN New York [Internet]. 2013;5(1):37–44. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20431354%5Cnhttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3046748&tool=pmcentrez&rendertype=abstract%5Cnhttp://jama.jamanetwork.com/article.aspx?articleid=2088852%5Cnhttp://dmsjournal.biomedcentral.com/articl

259. WHO. Coronavirus: Events as they happen [Internet]. World Health Organisation. 2020 [cited 2021 Mar 7]. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen

260. Nishiga M, Wang DW, Han Y, Lewis DB, Wu JC. COVID-19 and cardiovascular disease: from basic mechanisms to clinical perspectives [Internet]. Vol. 17, Nature Reviews Cardiology. Nature Research; 2020 [cited 2021 Mar 7]. p. 543–58. Available from: www.nature.com/nrcardio

261. World Health Organization (WHO). WHO reveals leading causes of death and disability worldwide: 2000-2019 [Internet]. World Health Organization (WHO). 2020 [cited 2021 Mar 7]. p. https://www.who.int/news/item/09-12-2020-who-revea. Available from: https://www.who.int/news/item/09-12-2020-who-reveals-leading-causes-of-death-and-disability-worldwide-2000-2019

262. Primary Health Care Performance Initiative. The PHCPI Conceptual Framework [Internet]. 2018 [cited 2020 Nov 28]. Available from: https://improvingphc.org/phcpi-conceptual-framework

263. International Union for Health Promotion and Education. Beating NCDs equitably – ten system requirements for health promotion and the primary prevention of NCDs [Internet]. 2018 [cited 2020 Apr 29]. Available from: https://www.iuhpe.org/images/IUHPE/Advocacy/IUHPE_NCDs_positionstatement.pdf

264. John Snow I. The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities [Internet]. 2017 [cited 2021 Mar 7]. Available from: www.jsi.com

265. Abimbola S, Thomas E, Jan S, McPake B, Wickramasinghe K, Oldenburg B. Prevention and control of noncommunicable diseases: Lessons from the HIV experience [Internet]. Vol. 97, Bulletin of the World Health Organization. World Health Organization; 2019 [cited 2021 Mar 7]. p. 239–41. Available from: https://pubmed.ncbi.nlm.nih.gov/30992637/

266. Harmsen CG, Jarbol DE, Nexoe J, Stovring H, Gyrd-Hansen D, Nielsen JB, et al. Impact of effectiveness information format on patient choice of therapy and satisfaction with decisions about chronic disease medication: the "Influence of intervention Methodologies on Patient Choice of Therapy (IMPACT)" cluster-randomised trial in gener. BMC Health Serv Res [Internet]. 2013;13:76. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med7&AN=23442351 http://oxfordsfx.hosted.exlibrisgroup.com/oxford?sid=OVID:medline&id=pmid:23442351&id=doi:10.1186%2F1472-6963-13-76&issn=1472-

6963&isbn=&volume=13&issue=1&spage=76&pages

267. Nsangi A, Semakula D, Oxman AD, Austvoll-Dahlgren A, Oxman M, Rosenbaum S, et al. Effects of the Informed Health Choices primary school intervention on the ability of children in Uganda to assess the reliability of claims about treatment effects, 1-year follow-up: A cluster-randomised trial. Trials [Internet]. 2020 Jan 6 [cited 2021 Mar 7];21(1):27. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3960-9

268. Woloshin S, Schwartz LM, Welch HG. The effectiveness of a primer to help people understand risk: Two randomized trials in distinct populations. Ann Intern Med [Internet]. 2007 Feb 20 [cited 2021 Mar 7];146(4):256–65. Available from: https://pubmed.ncbi.nlm.nih.gov/17310049/

269. Hearn J, Ssinabulya I, Schwartz JI, Akiteng AR, Ross HJ, Cafazzo JA. Self-management of non-communicable diseases in low- and middle-income countries: A scoping review. Joshi R, editor. PLoS One [Internet]. 2019 Jul 3 [cited 2021 Mar 7];14(7):e0219141. Available from: https://dx.plos.org/10.1371/journal.pone.0219141

270. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact. Med Care [Internet]. 2012 Mar [cited 2019 Jun 11];50(3):217. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22310560

271. USAID. The DHS Program - Service Provision Assessments (SPA) [Internet]. Demographic Health Surveys. 2019 [cited 2022 Jan 9]. p. 1–2. Available from: https://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm

Appendices

Appendix 1. Visiting PhD student fellowship offer letter

Initiative to Develop African Research Leaders

TONNY MUTHEE
University of Oxford

Dear **Tonny,**

RE: VISITING STUDENT ATTACHMENT

We are pleased to offer you a **6 Months** attachment at the KEMRI-Wellcome Trust Research Programme (KWTRP) as a visiting PhD student. The aim of the attachment is to enable you conduct interviews with health workers on their cardiovascular risk assessment behaviour. This attachment is offered under the following terms and conditions.

1. The attachment will be for a period of **6 Months** from **21 Jan 2019** to **31 July 2019**.

2. The attachment will not be considered a contract of employment with KEMRI - Wellcome Trust Research Programme (KWTRP) and hence will not attract any salary or benefits normally offered to KWTRP employees.

3. Supervision and management:
   a. Your supervisor within the Programme will be **Dr. Anthony Etyang**, assisted by **Prof. Carl Heneghan** (your primary supervisor).
   b. Your line manager with regard to general visiting PhD student matters will be **Dr. Dorcas Mbuvi**.
   c. Your administrator with regards to general student matters will be **Ms. Elizabeth Murabu**.

4. Student attachment/research cost:
   a. You and/or your supervisors will cover your attachment and research costs.

5. Health insurance:
   a. You will be expected to hold a valid health insurance certificate during the duration of this attachment.
   b. You will **not** be covered by the Programme's group personal accident policy and life assurance scheme.
   c. It is a requirement of the Programme that you make yourself familiar with our Health and Safety Policy.

6. Services and facility support:
   a. You will be allowed access to KWTRP laboratories and other research infrastructure.
   b. You will have access to the KWTRP students' administrative support.
   c. You will be allowed access to KWTRP ICT and internet system.
   d. Please note that all software is licensed for the sole use of the KWTRP and authorized users while on attachment by the Programme, and working within the Programme. Any private or commercial use of such software will be contravening the copyright and licensing laws and could lead to your prosecution.

7. Roles and responsibility
   a. You will be considered a member of KWRTP student body and will be expected to participate in scientific meetings such as journal clubs, seminars, protocol development and review meetings.

Hosted By:
KEMRI | Wellcome Trust
230 - 80108, Kilifi | +254 709 983 676/7 | ideal_info@kemri-wellcome.org | www.kemri-wellcome.org | Twitter: @IDeAL_KEMRI_WT

b. You will be expected to keep the Training Department updated on your progress through a brief monthly report. If your university requires monthly reports, a copy of same may be submitted to avoid duplication.
c. All your research work must adhere to KWTRP standard operating procedures for the development of research protocols and their subsequent scientific and ethical review. In addition, during the execution of the research you must adhere to KWTRP and all other international standards for the ethical practice of research.
d. You will be expected to adhere to KWTRP policy and code of conduct with regards to your interactions with fellow staff and in the use of the KWTRP facilities such as ICT.
e. You will appreciate that in the performance of your duties with the KWTRP you will from time to time have access to confidential information. It is a condition of your attachment that such information is treated in a confidential way at all times, and that you will only use or disclose it as authorized by the KWTRP. The copyright of any work/material which you do for the KWTRP will belong to the Programme.
f. You will be expected to adhere to KWTRP Health and Safety policy.

8. Withdrawal of attachment

This appointment may be withdrawn under the following circumstance.
a. If you are found to act contrary to the KWTRP policies and code of conduct outlined in clauses 7b to 7f.

NOTE: All visiting students should report to the Training Department on reporting to the Programme before starting any activities in the Programme premises.

Yours Sincerely,



Dr. Sam Kinyanjui
Head of Training, KWTRP

Acceptance of Attachment Offer

I _____Tonny Muthee_____ accept the attachment indicated above under the terms and conditions outline thereafter.

Signed _____ _____ Date ____17/01/19_____

CC: Hillary Ondatto (*Head of HR*); Dr. Francis Ndungu (*RDC*); Prof Philip Bejon (*Director, KWTRP*); David Adede (*Head of Security*); Racheal Ogalo (*Head of IT*)

Appendix 2. Derivation of the basic risk equation (BRSe) and calculation of the risk probabilities for coronary heart disease, stroke and CVD (Steps 1-7)

1) Identify variables for baseline values for each participant; age (centred at 60 years as the midpoint of the defined 40-80 years' prediction range); means for total cholesterol levels and SBP by gender, region and age group (Table 20 and 21) (1). These baseline values were used for subjects whose data values were missing from the dataset.

Table 20. Total baseline cholesterol values (mmol/l) for Eastern sub-Saharan region

Age in years	Male	Female
Up to 40	4.40	4.30
41 - 45	4.35	4.40
46 - 50	4.30	4.50
51 - 55	4.25	4.51
56 - 60	4.20	4.52
61 - 65	4.15	4.60
66 - 70	4.10	4.60
71 - 75	4.10	4.60

Table 21. SBP baseline values (mmHg) for Eastern sub-Saharan region

Age in years	Male	Female
Up to 40	129	128
41 - 45	131	131
46 - 50	134	135
51 - 55	138	140
56 - 60	140	143
61 - 65	142	148
66 - 70	144	150
71 - 75	145	151

2) The value for each risk factor in the model was calculated by multiplying the log hazard ratios for the laboratory-based model (death following fatal or non-fatal MI/CHD and stroke) by the difference between the recorded value of the risk factor and the baseline values that are given in Tables 20 and 21. The resultant data are shown in Table 22. The log hazard ratios are provided in Supplement Appendix 1 (Table 1.6) of the revised models for the WHO CVD risk charts paper (1) [Appendix 9].

Table 22. Risk factor value in the laboratory-based prediction model: death after fatal or non-fatal MI/CHD and stroke

CVD risk factor	MI/CHD death		Stroke	
	Male	Female	Male	Female

Age	0.0719227 x (age - 60)	0.1020713 x (age - 60)	0.0986578 x (age - 60)	0.1056632 x (age - 60)
Total cholesterol	0.2284944 x (cholesterol value - baseline cholesterol)	0.2050377 x (cholesterol value - baseline cholesterol)	0.029526 x (cholesterol value - baseline cholesterol)	0.0257782 x (cholesterol value - baseline cholesterol)
SBP reading	0.0132183 x (SBP value - baseline SBP)	0.015823 x (SBP value - baseline SBP)	0.0222629 x (SBP value - baseline SBP)	0.0206278 x (SBP value - baseline SBP)
History of diabetes	0.6410114 x diabetes score	1.070358 x diabetes score	0.6268712 x diabetes score	0.8581998 x diabetes score
Current smoking	0.5638109 x smoking score	1.053223 x smoking score	0.49812217 x smoking score	0.7443627 x smoking score

3) The interaction of each risk factor with baseline age over time was calculated. The difference between baseline age and the age of the participant was multiplied by the difference between the recorded value of the interacting risk factor and its baseline (see Table 23). This was then multiplied by the log hazard ratios for the laboratory-based model as before and which are shown in Supplement Appendix 1 (Table 1.6).

Table 23. Interaction between risk factors and age in the laboratory-based prediction model: death after fatal or non-fatal MI/CHD or stroke

Interaction of CVD risk factors with age*	**MI/CHD death**		**Stroke**	
	Male	Female	Male	Female
Total cholesterol	-0.0045806 x (age - 60) x (cholesterol value - baseline cholesterol)	-0.0051932 x (age - 60) x (cholesterol value - baseline cholesterol)	0.00142 x (age - 60) x (cholesterol value - baseline cholesterol)	-0.0021387 x (age - 60) x (cholesterol value - baseline cholesterol)
SBP reading	-0.0001576 x (age - 60) x (SBP value - baseline SBP)	-0.0001378 x (age - 60) x (SBP value - baseline SBP)	-0.0004147 x (age - 60) x (SBP value - baseline SBP)	-0.0004897 x (age - 60) x (SBP value - baseline SBP)
History of diabetes	-0.0124966 x (age - 60) x (diabetes score)	-0.0234174 x (age - 60) x (diabetes score)	-0.026302 x (age - 60) x (diabetes score)	-0.0209826 x (age - 60) x (diabetes score)
Current smoking	-0.0182545 x (age - 60) x (smoking score)	-0.0332666 x (age - 60) x (smoking score)	-0.0150561 x (age - 60) x (smoking score)	-0.0200822 x (age - 60) x (smoking score)

*Age implies age at baseline. Baseline age was centred at 51 for males and 52 for females. Baseline total cholesterol and SBP as indicated in Tables 20 and 21.

4) The values for each risk factor (step 2) were added to their interaction with age over time (step 3) to form the BRSe[MI/CHD] and BRSe[stroke] for males and females (see Equations 1 and 2 below).

Equation 1: BRSe [MI/CHD] and BRSe [stroke] for males

For males:

BRSe [MI/CHD] = (0.0719227 x (age - 60)) + (0.2284944 x (cholesterol value - baseline cholesterol)) + (0.0132183 x (SBP value - baseline SBP)) + (0.6410114 x (diabetes score)) + (0.5638109 x (smoking score)) + (-0.0045806 x (age - 60) x (cholesterol value - baseline cholesterol)) + (-0.0001576 x (age - 60) x (SBP value - baseline SBP)) + (-0.0124966 x (age - 60) x (diabetes score)) + (-0.0182545 x (age - 60) x (smoking score))

BRSe [stroke] = (0.0986578 x (age - 60)) + (0.029526 x (cholesterol value - baseline cholesterol)) + (0.0222629 x (SBP value - baseline SBP)) + (0.6268712 x (diabetes score)) + (0.49812217 x (smoking score)) + (0.00142 x (age - 60) x (cholesterol value - baseline cholesterol)) + (-0.0004147 x (age - 60) x (SBP value - baseline SBP)) + (-0.026302 x (age - 60) x (diabetes score)) + (-0.0150561 x (age - 60) x (smoking score))

Equation 2: BRSe[MI/CHD] and BRSe[stroke] for females

For females:

BRSe [MI/CHD] = (0.1020713 x (age - 60)) + (0.2050377 x (cholesterol value - baseline cholesterol)) + (0.015823 x (SBP value - baseline SBP)) + (1.070358 x (diabetes score)) + (1.053223 x (smoking score)) + (-0.0051932 x (age - 60) x (cholesterol value - baseline cholesterol)) + (-0.0001378 x (age - 60) x (SBP value - baseline SBP)) + (-0.0234174 x (age - 60) x (diabetes score)) + (-0.0332666 x (age - 60) x (smoking score)).

BRSe [stroke] = (0.1056632 x (age - 60)) + (0.0257782 x (cholesterol value - baseline cholesterol)) + (0.0206278 x (SBP value - baseline SBP)) + (0.8581998 x (diabetes score)) + (0.7443627 x (smoking score)) + (-0.0021387 x (age - 60) x (cholesterol value - baseline cholesterol)) + (-0.0004897 x (age - 60) x (SBP value - baseline SBP)) + (-0.0209826 x (age - 60) x (diabetes score)) + (-0.0200822 x (age - 60) x (smoking score))

5) The risk probability for MI/CHD and stroke was calculated using the equations below:

Equation 3: Risk probability for MI/CHD

$$pMI = 1 - (0.9540^{BRSe[MI]})$$

Equation 4: Risk probability for stroke

$$pStroke = 1 - (0.9849^{BRSe[Stroke]})$$

where 0.9540 and 0.9849 are the baseline survival estimates as given in the WHO risk model.

6) The risk probability for CVD was calculated using the equation below:

Equation 5: Risk probability for CVD

$$p[CVD] = 1 - (1 - p[MI]) \times (1 - p[Stroke])$$

7) Lastly, p [CVD] was then multiplied by 100 to obtain the 10-year CVD risk score as a percentage. Table 24 shows an example of how the predicted 10-year risk of CVD for any given case/participant was calculated.

Table 24. Example calculation of predicted 10-year risk of CVD

Case:	**Calculation of predicted risk using laboratory-based models**			
Age = 62 years **Sex = Female**	Step 1 – Calculation of the risk probability of MI/CHD using logHRs from ERFC model (*pMI*)	Step 2 – Calculation of the risk probability of stroke using logHRs from ERFC model (*pStroke*)	Step 3 – Calculation of the risk probability of CVD (*pCVD*)	Step 4 – Calculation of the 10-year CVD risk score in percentage
SBP (average) = 164 mmHg **Total cholesterol = 4.37 mmol/l** **Diabetes score = 0.3** **Smoking score = 0.1**	= (0.1020713 x (62 - 60)) + (0.2050377 x (4.37 – 4.55)) + (0.015823 x (164 - 148)) + (1.070358 x 0.3) + (1.053223 x 0.1) + (-0.0051932 x (62 - 60) x (4.37 – 4.55)) + (-0.0001378 x (62 - 60) x (164 - 148)) + (-0.0234174 x (62 - 60) x 0.3) + (-0.0332666 x (62 - 60) x 0.1)	= (0.1056632 x (62 - 60)) + (0.0257782 x (4.37 – 4.55)) + (0.0206278 x (164 - 148)) + (0.8581998 x 0.3) + (0.7443627 x 0.1) + (-0.0021387 x (62 - 60) x (4.37 – 4.55)) + (-0.0004897 x (62 - 60) x (164 - 148) + (-0.0209826 x (62 - 60) x 0.3)	= 1 - ((1 - 0.1013) X (1 - 0.0343)) = 0.1321	= 0.1321 x 100 = 13.21%

		+ (-0.0200822 x (62 - 60) x 0.1)
= 0.8184		
= 1 – 0.9540^EXP(0.8184)		= 0.8306 = 1- 0.9849^EXP(0.8306)
pMI = 0.1013		pStroke = 0.0343

Appendix 3. Table 1.6 in Supplement Appendix 1 of the revised models for WHO CVD Risk Charts

Table 1.6: Log hazard ratios, standard errors and heterogeneity statistics for the laboratory and non-laboratory based WHO risk models

	Men					Women				
	log HR	se logHR	I^2	P-value for heterogeneity by: region*	P-value for heterogeneity by: calendar year§	Log HR	se logHR	I^2	P-value for heterogeneity by: region*	P-value for heterogeneity by: calendar year§
Laboratory-based model: Fatal/non-fatal MI or CHD death										
Age at baseline per year	0.0719227	0.0023323	3% (0%, 28%)	0.013	0.247	0.1020713	0.0039237	24% (0%, 44%)	0.015	0.851
Total cholesterol per 1 mmol/L	0.2284944	0.0087117	13% (0%, 41%)	0.214	0.723	0.2050377	0.0132977	12% (0%, 35%)	0.955	0.876
Systolic blood pressure per 1 mmHg	0.0132183	0.0005011	4% (0%, 30%)	0.010	0.583	0.015823	0.0008139	22% (0%, 42%)	0.437	0.627
History of diabetes	0.6410114	0.0377504	0% (0%, 35%)	0.511	0.709	1.070358	0.0592361	0% (0%, 28%)	0.965	0.135
Current smoking	0.5638109	0.0239946	35% (6%, 55%)	0.277	0.041	1.053223	0.0414629	28% (2%, 46%)	0.366	0.622
T. cholesterol interaction with age‡	-0.0045806	0.0008194	35% (6%, 56%)	0.467	0.205	-0.0051932	0.0012386	0% (0%, 28%)	0.908	0.687
SBP interaction with age‡	-0.0001576	0.000051	0% (0%, 35%)	0.409	0.547	-0.0001378	0.0000805	0% (0%, 28%)	0.888	0.571
Diabetes interaction with age‡	-0.0124966	0.0037293	0% (0%, 35%)	0.520	0.168	-0.0234174	0.0058091	0% (0%, 28%)	0.932	0.088
Smoking interaction with age‡	-0.0182545	0.0024031	26% (0%, 49%)	0.789	0.505	-0.0332666	0.0042843	16% (0%, 38%)	0.150	0.532
Laboratory-based model: Fatal/non-fatal stroke										
Age at baseline per year	0.0986578	0.0035568	3% (0%, 28%)	0.478	0.540	0.1056632	0.0038126	0% (0%, 31%)	0.868	0.510
Total cholesterol per 1 mmol/L	0.029526	0.0160403	13% (0%, 41%)	0.749	0.587	0.0257782	0.0183081	16% (0%, 40%)	0.357	0.914
Systolic blood pressure per 1 mmHg	0.0222629	0.0007668	4% (0%, 30%)	0.277	0.348	0.0206278	0.0008984	26% (0%, 47%)	0.122	0.406
History of diabetes	0.6268712	0.0580946	0% (0%, 35%)	0.016	0.429	0.8581998	0.0689703	25% (0%, 46%)	0.263	0.188
Current smoking	0.4981217	0.0373988	35% (6%, 55%)	0.066	0.103	0.7443627	0.0468753	16% (0%, 40%)	0.846	0.628
T. cholesterol interaction with age‡	0.00142	0.0015228	35% (6%, 56%)	0.295	0.870	-0.0021387	0.0017473	0% (0%, 31%)	0.652	0.769
SBP interaction with age‡	-0.0004147	0.0000745	0% (0%, 35%)	0.015	0.780	-0.0004897	0.0000862	25% (0%, 46%)	0.769	0.160
Diabetes interaction with age‡	-0.026302	0.0056366	0% (0%, 35%)	0.502	0.835	-0.0209826	0.0067253	7% (0%, 33%)	0.743	0.153
Smoking interaction with age‡	-0.0150561	0.0036925	26% (0%, 49%)	0.562	0.446	-0.0200822	0.0047554	10% (0%, 35%)	0.325	0.867
Non-laboratory-based model: Fatal/non-fatal MI or CHD death										
Age at baseline per year	0.073593	0.002364	0% (0%, 35%)	0.003	0.164	0.1049418	0.0038628	8% (0%, 32%)	0.019	0.548
BMI per 1 kg/m^2	0.0337219	0.0029849	0% (0%, 35%)	0.234	0.360	0.0257616	0.0037581	0% (0%, 28%)	0.466	0.088
Systolic blood pressure per 1 mmHg	0.0133937	0.0005155	3% (0%, 29%)	0.060	0.494	0.016726	0.0008287	16% (0%, 38%)	0.099	0.465
Current smoking	0.5954767	0.0245956	36% (7%, 56%)	0.164	0.088	1.093132	0.0419601	38% (18%, 54%)	0.571	0.360
BMI interaction with age‡	-0.0010432	0.0002944	27% (0%, 50%)	0.864	0.176	-0.0006537	0.0003743	4% (0%, 28%)	0.398	0.578
SBP interaction with age‡	-0.0001837	0.000052	0% (0%, 35%)	0.106	0.279	-0.0001966	0.0000798	0% (0%, 28%)	0.856	0.653
Smoking interaction with age‡	-0.0200831	0.0024515	24% (0%, 48%)	0.958	0.635	-0.0343739	0.00426	13% (0%, 36%)	0.220	0.499
Non-laboratory-based model: Fatal/non-fatal stroke										
Age at baseline per year	0.097674	0.0035366	32% (1%, 53%)	0.869	0.563	0.1046105	0.0037452	9% (0%, 34%)	0.945	0.306
BMI per 1 kg/m^2	0.0159518	0.0047759	14% (0%, 41%)	0.019	0.528	0.0036406	0.0043984	8% (0%, 33%)	0.335	0.162
Systolic blood pressure per 1 mmHg	0.0227294	0.0007844	9% (0%, 36%)	0.263	0.246	0.0216741	0.0009094	29% (2%, 49%)	0.117	0.808
Current smoking	0.4999862	0.0381793	47% (26%, 63%)	0.057	0.086	0.7399405	0.0474139	14% (0%, 39%)	0.944	0.817
BMI interaction with age‡	-0.0003516	0.000456	23% (0%, 47%)	0.672	0.471	-0.0000129	0.0004273	0% (0%, 31%)	0.217	0.195
SBP interaction with age‡	-0.0004374	0.0000752	0% (0%, 34%)	0.067	0.839	-0.0005311	0.0000857	25% (0%, 46%)	0.901	0.236
Smoking interaction with age‡	-0.0153895	0.0037523	22% (0%, 47%)	0.662	0.347	-0.0203997	0.0047773	6% (0%, 32%)	0.328	0.614

* By region implies ERFC studies from America/Canada vs Western Europe vs other. § By calendar year implies before and after 1990.
‡ age implies age at baseline. Age was centred at 60 years, SBP at 120mmHg, total cholesterol at 6mmol/l and BMI at 25kg/m^2
WHO: World Health Organisation

Appendix 4. Defining the independent variables

Independent variable	Definition
Location	Rural or urban
County of residence	County name
Ethnicity	Ethnic background
Level of education	No formal schooling, Primary school incomplete, Primary school completed, Secondary school incomplete, Secondary school completed, A-level completed, College/University completed Postgraduate degree
Marital status	Never married, Currently married, Separated, Divorced, Widowed, Cohabitating
Wealth quantile*	1 – Poorest, 2 – Second, 3 – Middle, 4 – Fourth, 5 – Richest *proxy index for wealth generated using principal component analysis (PCA)
Alcohol consumption	a) Frequency as having at least one standard alcoholic drink in the last 12 months; Daily, 5-6 days per week, 3-4 days per week, 1-2 days per week, 1-3 days per month, less than once a month b) Amount as the average number of standard alcoholic drinks during one drinking occasion in the last 30 days;
Fruit intake	a) Frequency as the number of days fruit is eaten in a typical week b) Amount as the number of servings of fruit eaten on one of those days in a typical week
Vegetable intake	a) Frequency as the number of days vegetables are eaten in a typical week b) Amount as the number of servings of vegetables eaten on one of those days in a typical week
Salt intake	Frequency as; a) How often salt/salty sauce/salty seasoning is added to food Always (every meal), Often (most meals), Sometimes (every week), Rarely (not every week), Never, Don't know b) How often processed food high in salt is eaten Always (every meal), Often (most meals), Sometimes (every week), Rarely (not every week), Never, Don't know Amount as; a) Amount as how much salt/salty sauce one thinks they consume Far too much, Too much, Just the right amount, Too little, Far too little, Don't know
Sugar intake	Frequency as; a) How often sugar is added to beverage Always (every drink), Often (every day but not every drink), Sometimes (every week), Rarely (not every week), Never, Don't know b) How often processed food high in sugar is eaten Always (every meal), Often (every day), Sometimes (every week), Rarely (not every week), Never, Don't know c) How many days in a week one takes soda (carbonated drinks) or other sugary drinks

	Amount as; a) How many 300ml bottles of soda taken in one of the days in typical week b) How much sugar one thinks they consume Far too much, Too much, Just the right amount, Too little, Far too little, Don't know
Physical activity	Frequency as; a) How many days is vigorous-intensity activities part of one's work in a typical week b) How many days is moderate-intensity activities part of one's work in a typical week c) How many days does one walk or bicycle for at least 10 minutes continuously to get to and from places in a typical week d) How many days does one engage in vigorous-intensity sports, fitness or recreational (leisure) activities in a typical week e) How many days does one engage in moderate-intensity sports, fitness or recreational (leisure) activities in a typical week Amount as; a) How much time (hrs.) does one spend doing vigorous- intensity activities at work on a typical day? b) How much time (hrs.) does one spend doing moderate- intensity activities at work on a typical day? c) How much time (hrs.) does one spend walking or bicycling for travel on a typical day? d) How much time (hrs.) does one spend doing vigorous- intensity sports, fitness or recreational activities on a typical day? e) How much time (hrs.) does one spend doing moderate- intensity sports, fitness or recreational activities on a typical day? f) How much time (hrs.) does one usually spend sitting or reclining on a typical day?
Lifestyle advice	In the past three years, has a doctor or other health worker advised you to; a) Quit using tobacco or don't start b) Reduce the use of alcohol or don't start c) Reduce salt in the diet d) Reduce use of refined sugar in your diet e) Eat at least five servings of fruit and/or vegetables each day f) Reduce fat in your diet g) Start or do more physical activity h) Maintain a healthy body weight or lose weight

Appendix 5. Methods supplement - Checking for the multivariate regression model assumptions

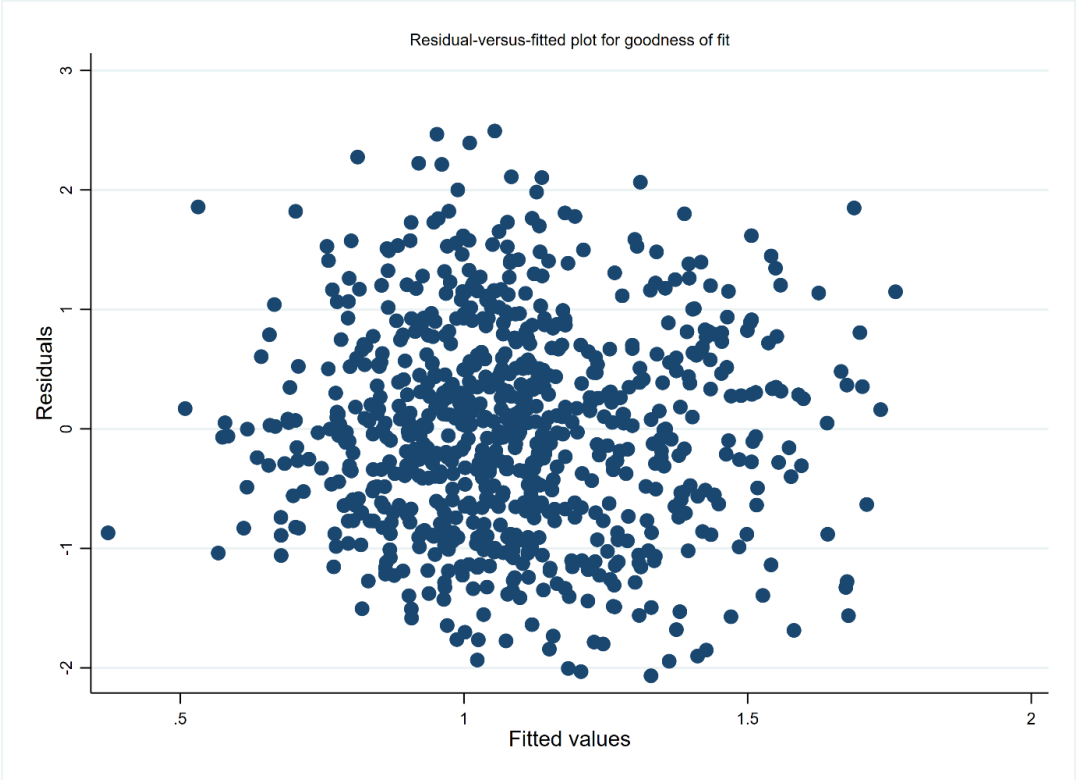


Figure 25. Residual-versus-fitted plot for goodness of fit

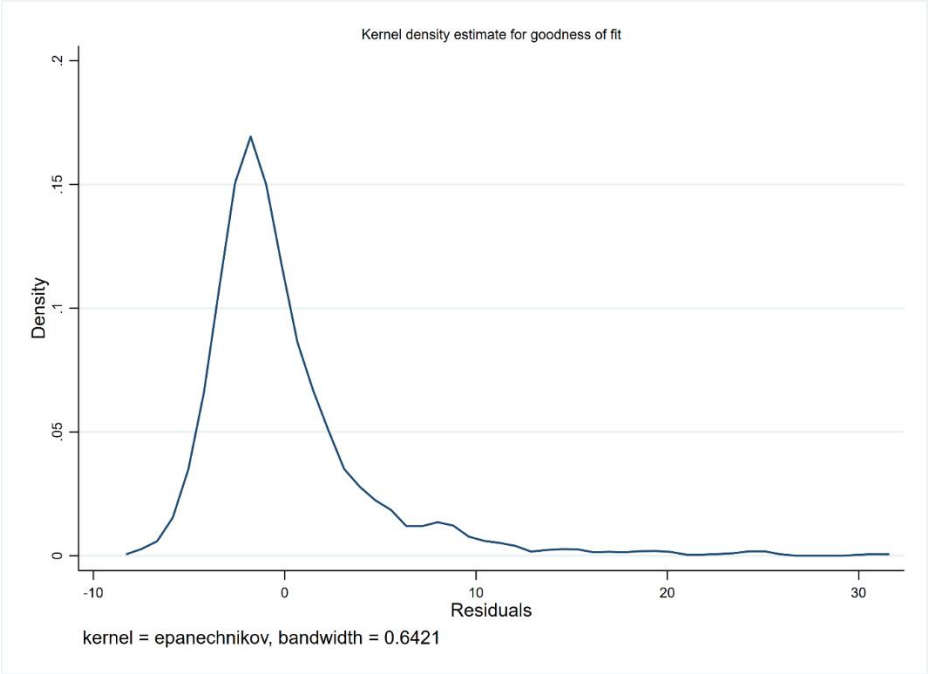


Figure 26. Kernel density estimate for goodness of fit

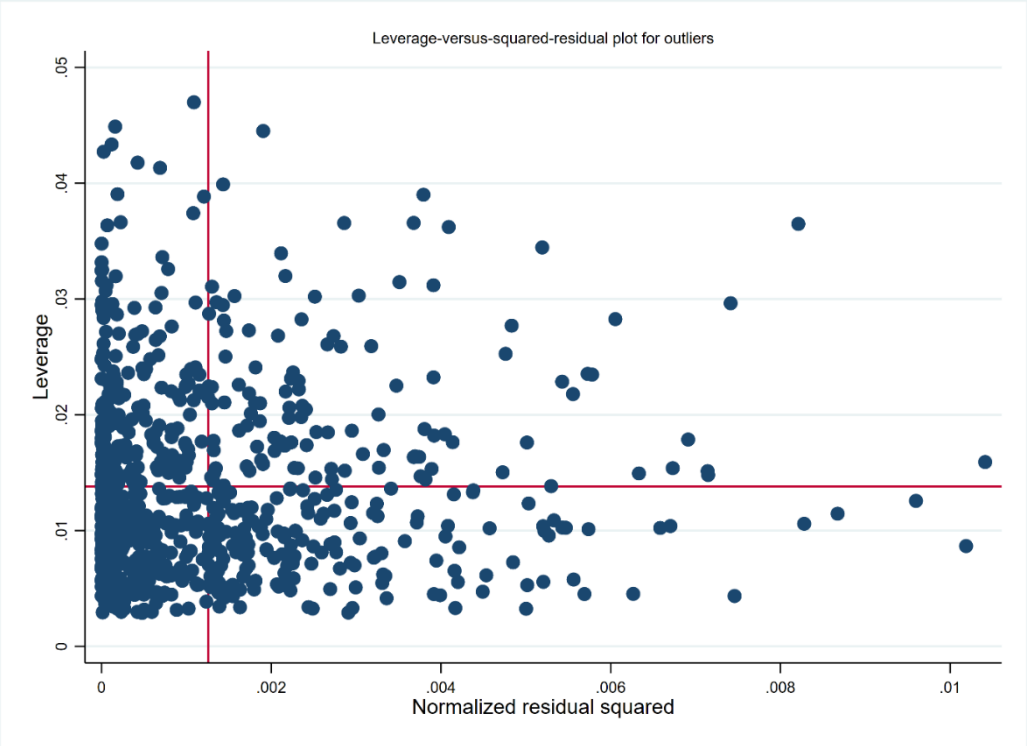


Figure 27. Leverage-versus-squared-residual plot for outliers

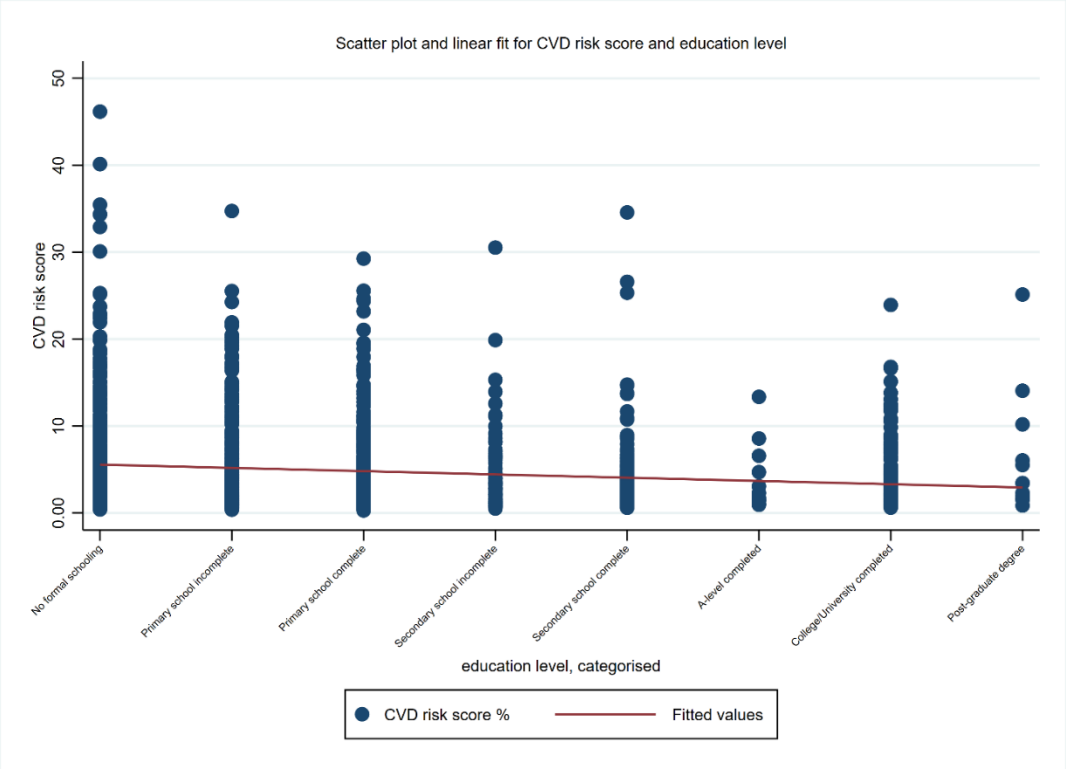


Figure 28. Scatter plot and linear fit for CVD risk score and education level

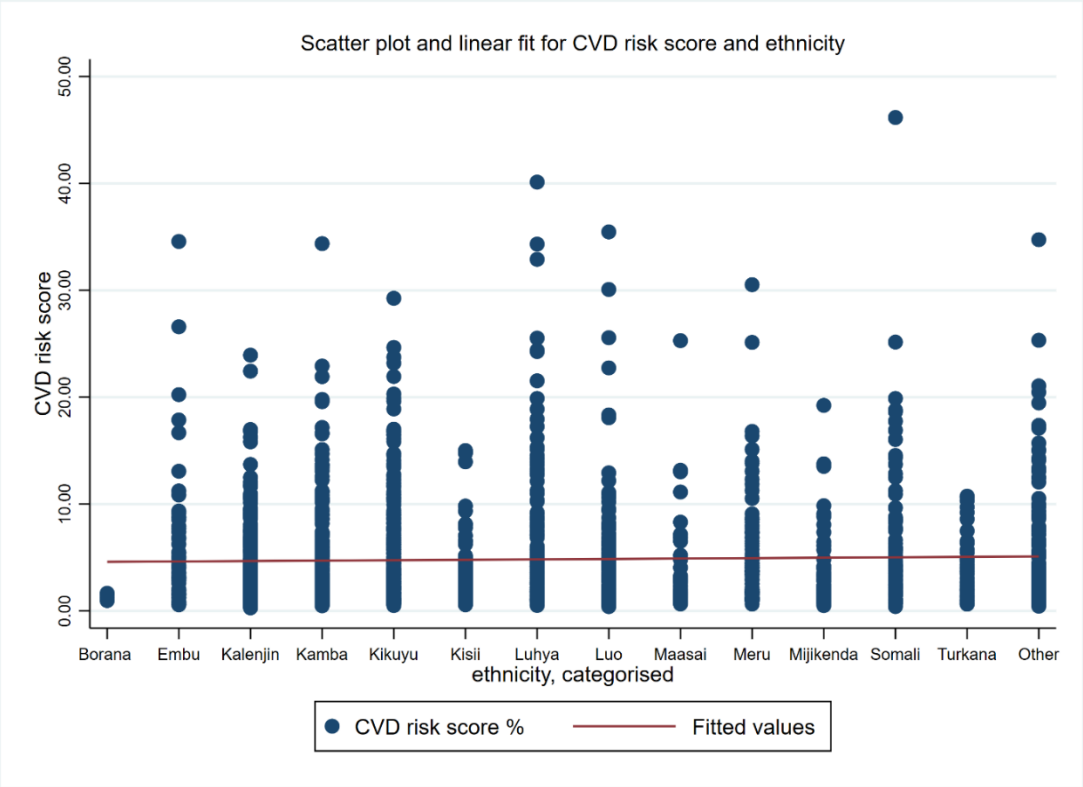


Figure 29. Scatter plot and linear fit for CVD risk score and ethnicity

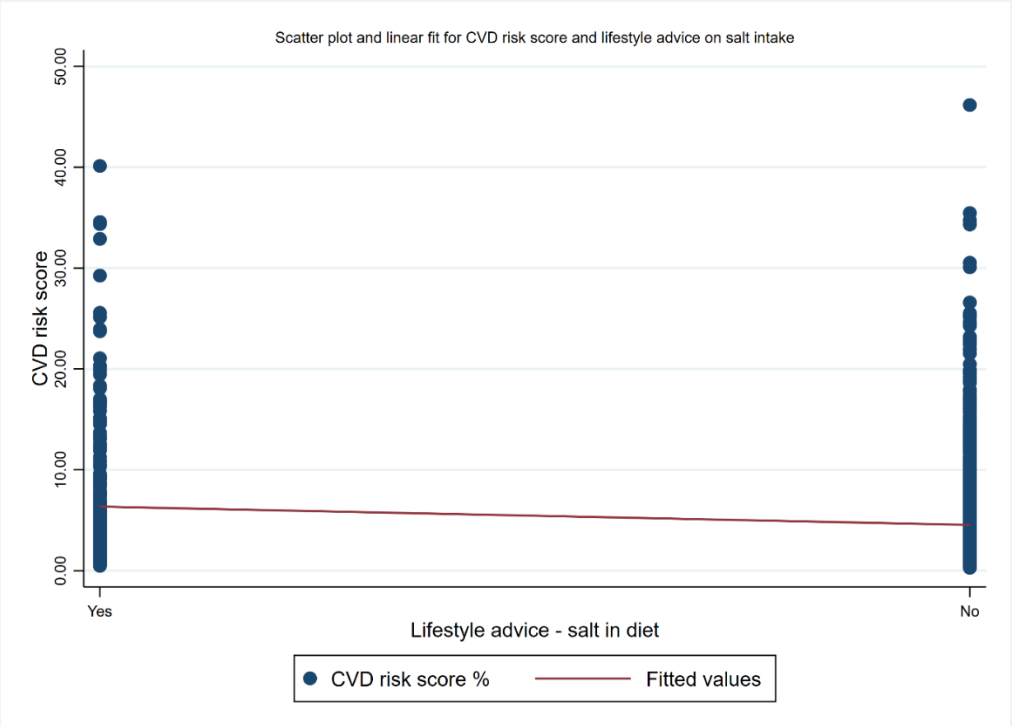


Figure 30. Scatter plot and linear fit for CVD risk score and lifestyle advice on salt intake

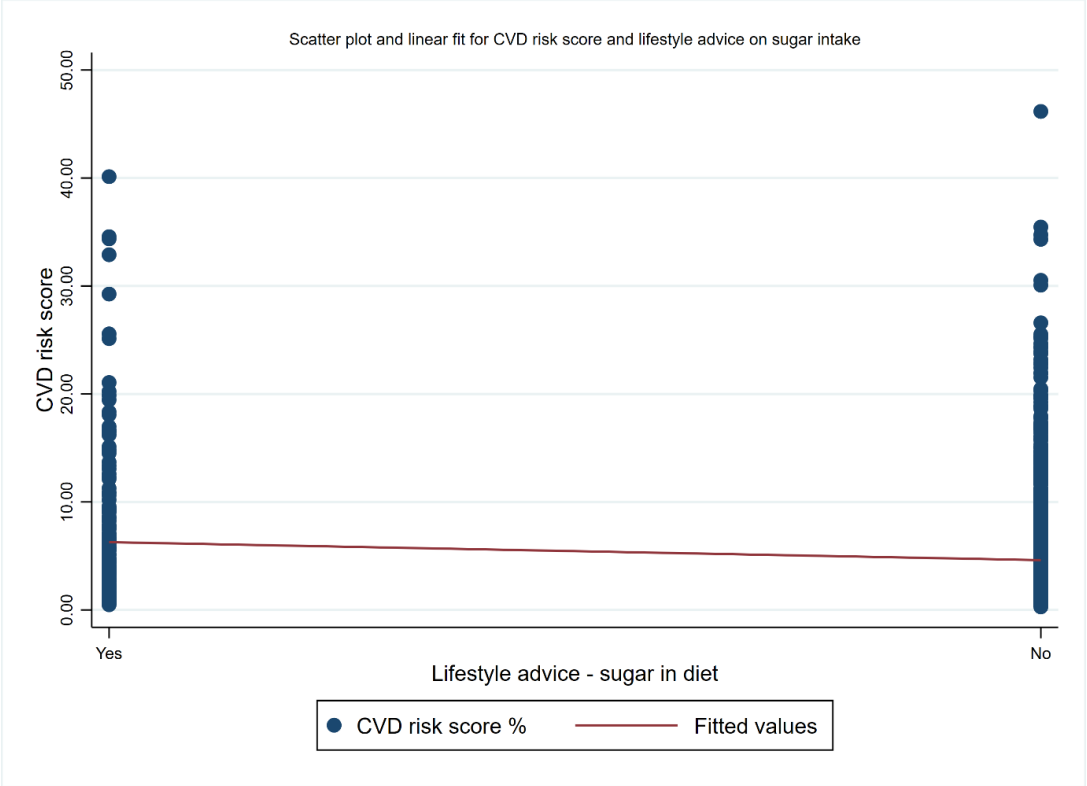


Figure 31. Scatter plot and linear fit for CVD risk score and lifestyle advice on sugar intake

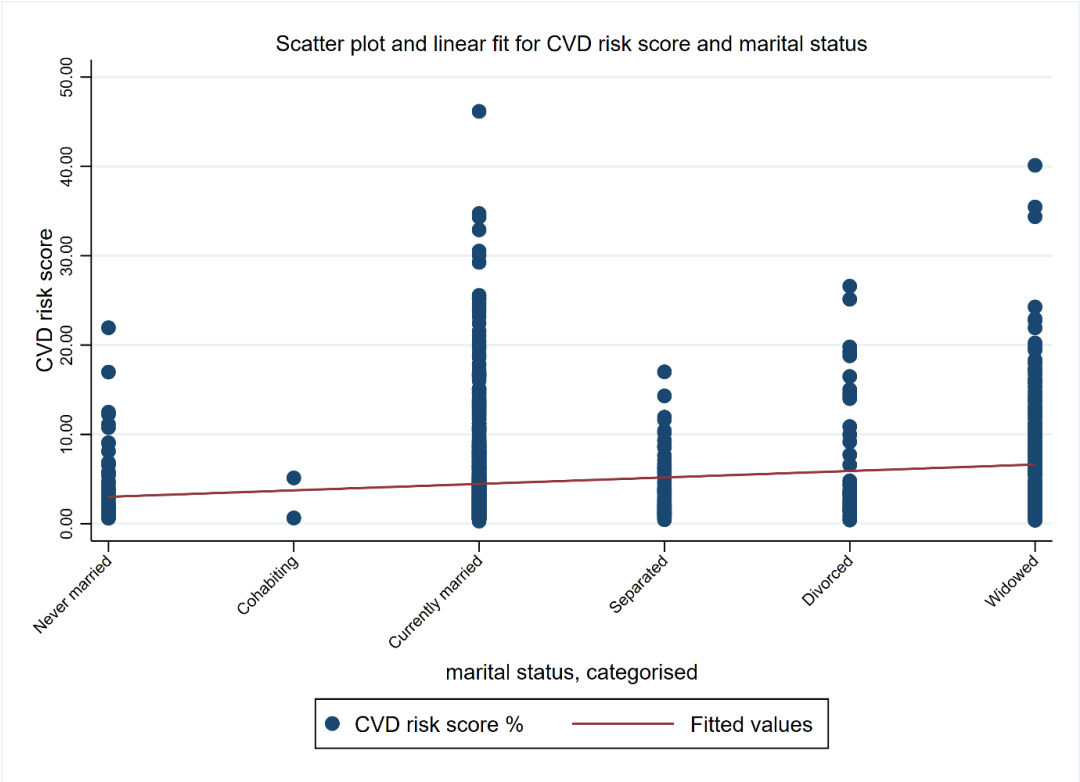


Figure 32. Scatter plot and linear fit for CVD risk score and marital status

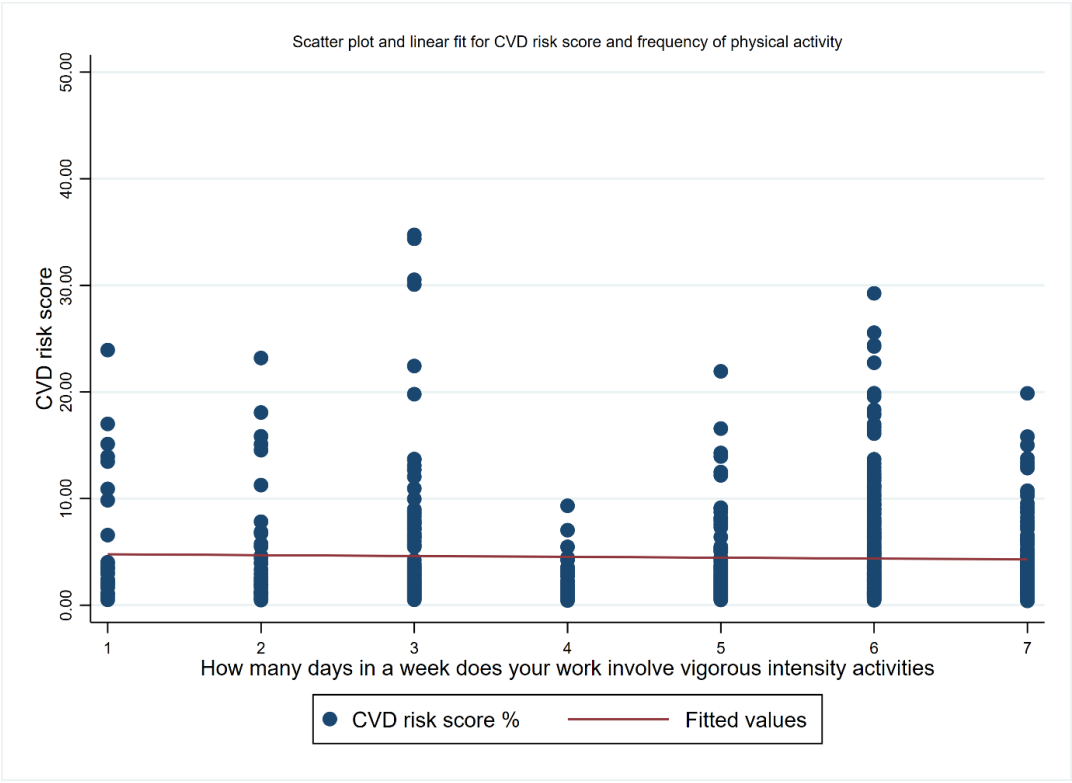


Figure 33. Scatter plot and linear fit for CVD risk score and frequency of physical activity

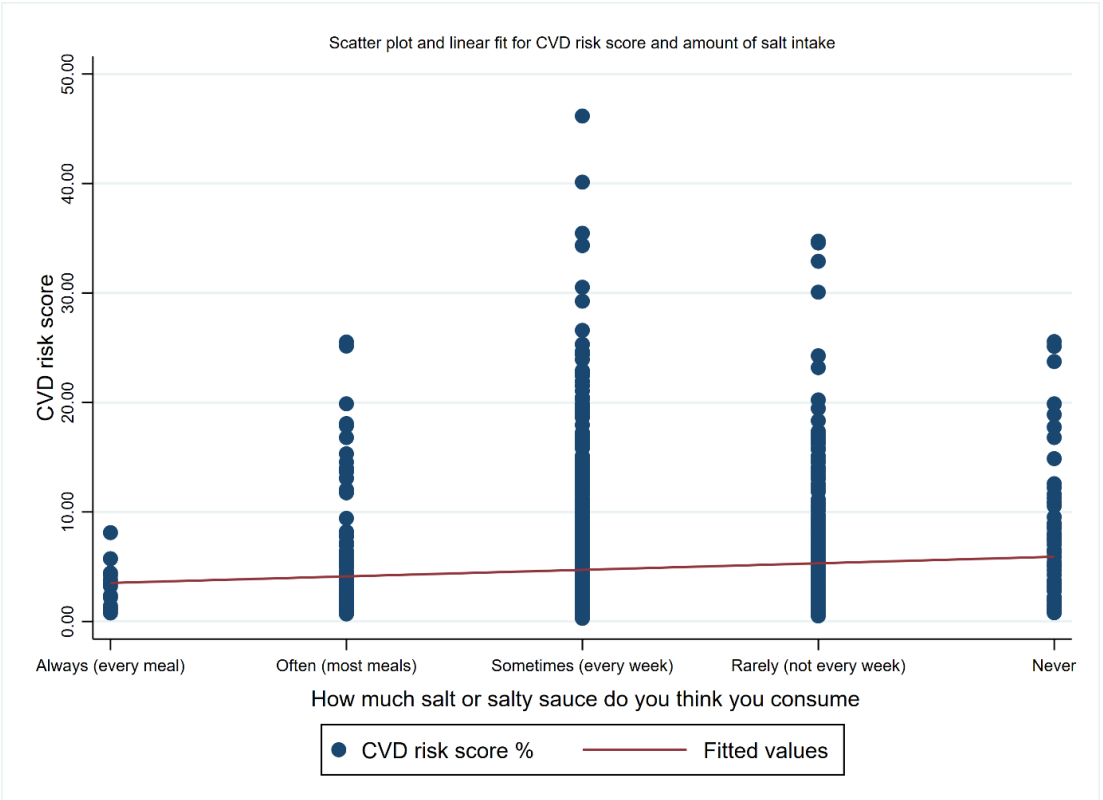


Figure 34. Scatter plot and linear fit for CVD risk score and amount of salt intake

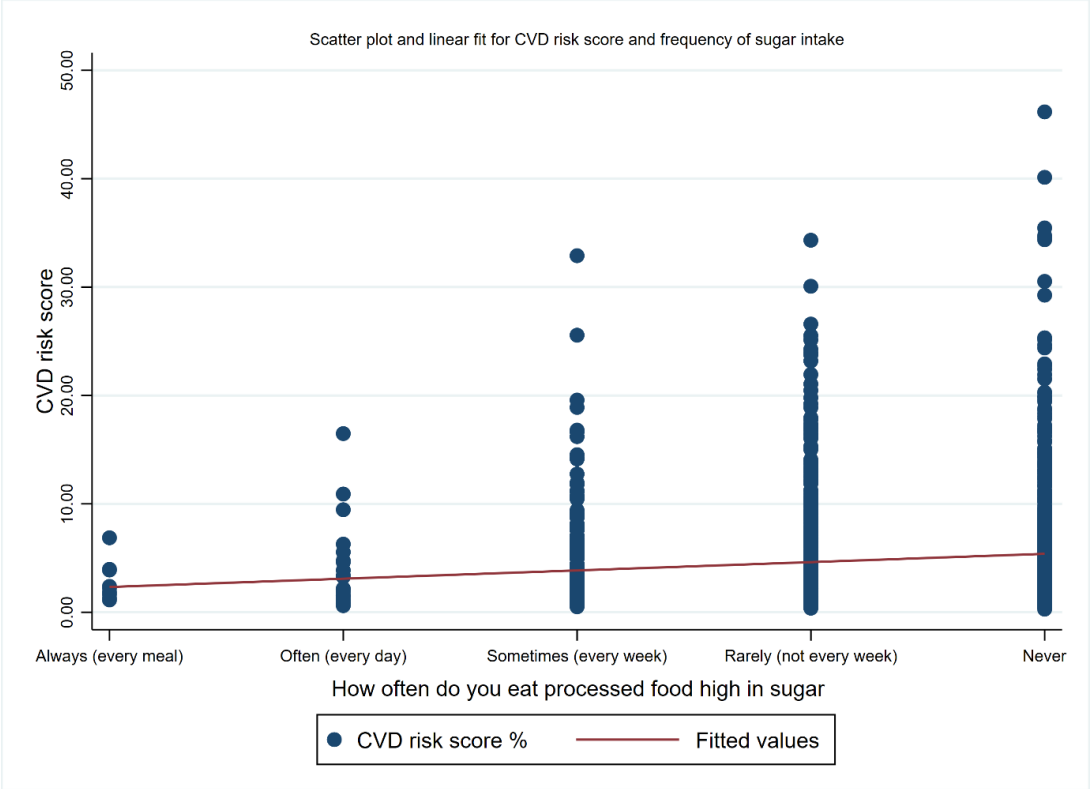


Figure 35. Scatter plot and linear fit for CVD risk score and frequency of sugar intake

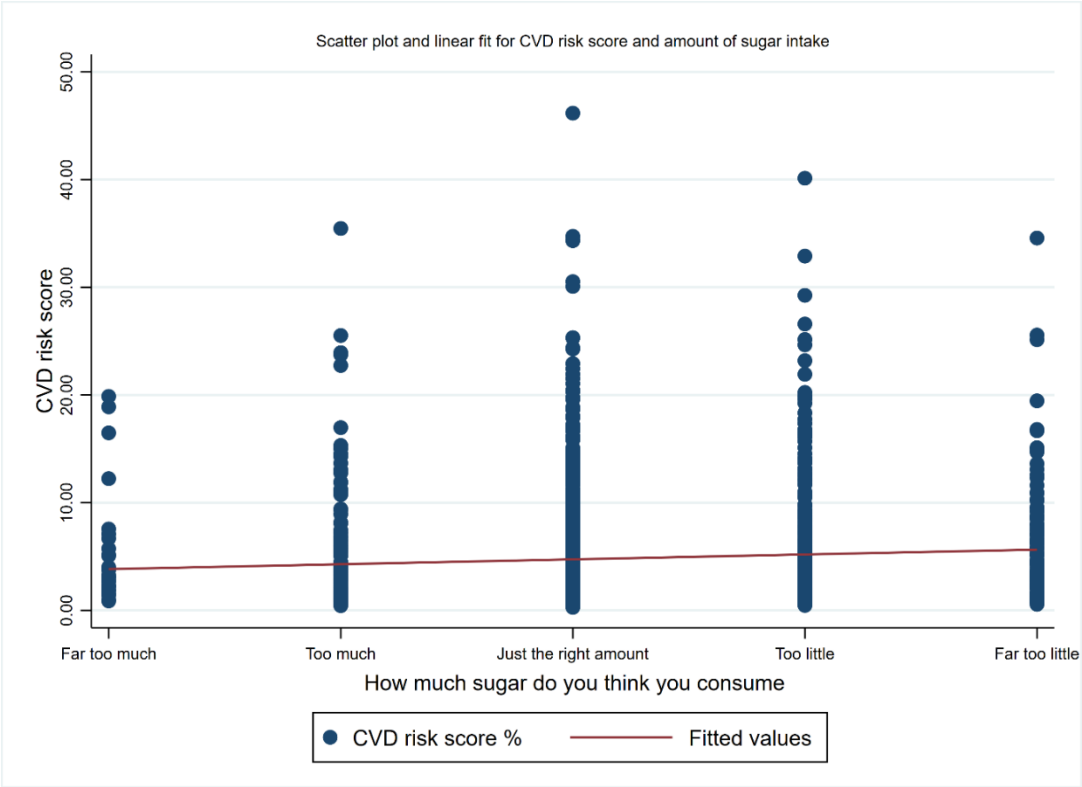


Figure 36. Scatter plot and linear fit for CVD risk score and amount of sugar intake

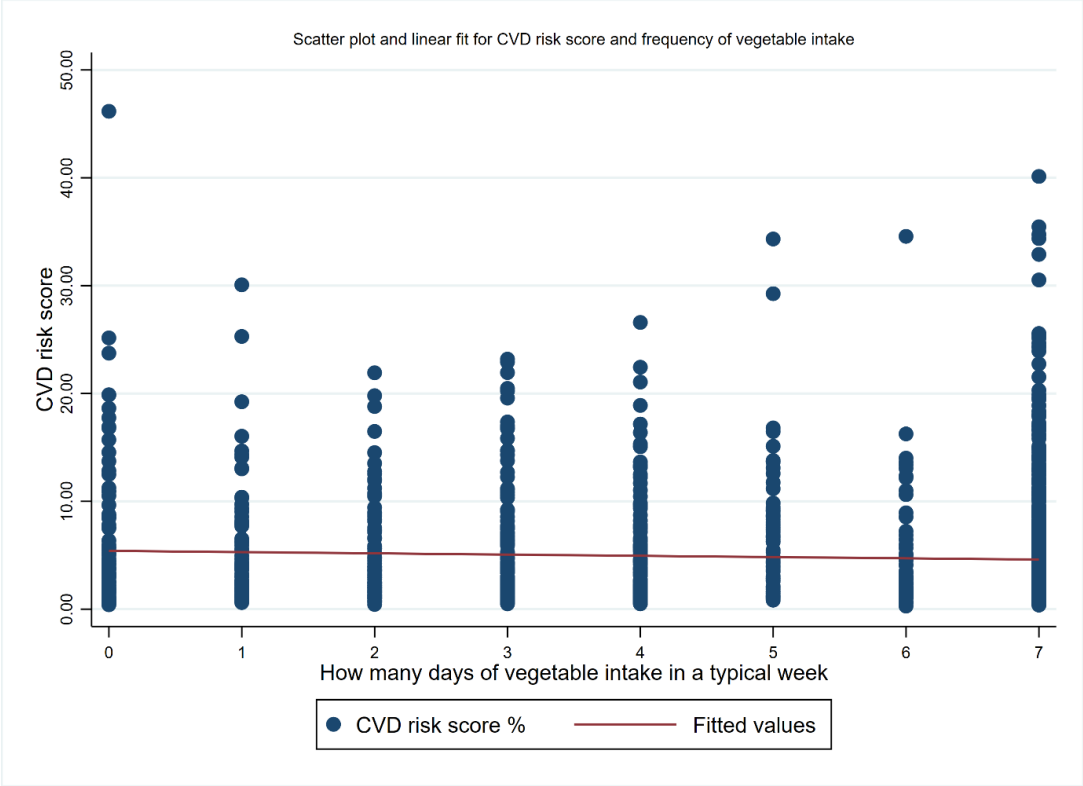


Figure 37. Scatter plot and linear fit for CVD risk score and frequency of vegetable intake

Appendix 6. Results supplement

Table 25 Socio-demographic and behavioural characteristics of the study participants

Indicator	Female (%) *n*=945	Male (%) *n*=682	Total (%) *n*=1626	P-value
Age groups (95% CI)				0.583
40-44	25.2 (22.2, 28.0)	28.3 (25.0, 31.9)	26.5 (24.4, 28.7)	
45-49	19.2 (16.7, 21.8)	19.1 (16.2, 22.2)	19.1 (17.2, 21.1)	
50-54	16.2 (13.9, 18.7)	16.2 (13.5, 19.1)	16.2 (14.4, 18.1)	
55-59	14.7 (12.5, 17.1)	14.0 (11.4, 16.8)	14.4 (12.7, 16.2)	
60-64	12.9 (10.8, 15.2)	13.2 (10.8, 16.0)	13.0 (11.4, 14.8)	
65-69	11.8 (9.8, 14.0)	9.3 (7.2, 11.7)	10.7 (9.2, 12.3)	
70-74	0.1 (0.0, 0.6)	0.1 (0.0, 0.5)	0.1 (0.0, 0.3)	
Education level (95% CI)				<0.000*
No formal schooling	32.1 (29.1, 35.1)	13.2 (10.8, 16.0)	24.2 (22.1, 26.3)	
Primary school incomplete	28.3 (25.4, 31.2)	23.5 (20.4, 26.9)	26.3 (24.1, 28.5)	
Primary school complete	19.5 (17.0, 22.1)	22.0 (19.0, 25.3)	20.5 (18.6, 22.6)	
Secondary school incomplete	6.5 (5.0, 8.2)	8.8 (6.8, 11.2)	7.4 (6.2, 8.8)	
Secondary school complete	7.6 (6.0, 9.5)	17.0 (14.3, 20.1)	11.6 (10.0, 13.2)	
A-level completed	0.3 (0.0, 0.9)	1.2 (0.5, 2.3)	0.7 (0.3, 1.2)	
College/University completed	5.2 (3.9, 6.8)	13.2 (10.8, 16.0)	8.6 (7.2, 10.0)	
Post-graduate degree	0.6 (0.2, 1.4)	1.0 (0.4, 2.1)	0.8 (0.4, 1.4)	
Residence (95% CI)				<0.000*
Rural	63.6 (60.4, 66.7)	54.0 (50.2, 57.8)	59.6 (57.2, 62.0)	
Urban	36.4 (33.3, 39.6)	46.0 (42.2, 49.8)	40.4 (38.0, 42.8)	
Marital status (95% CI)				<0.000*

Never married	4.6 (3.3, 6.1)	2.9 (1.8, 4.5)	3.9 (3.0, 4.9)	
Cohabiting	0.3 (0.1, 0.9)	0.0 (0.0, 0.0)	0.2 (0.0, 0.5)	
Currently married	61.6 (58.4, 64.7)	84.9 (82.0, 87.5)	71.3 (69.1, 73.5)	
Separated	6.0 (4.6, 7.7)	5.9 (4.2, 7.9)	6.0 (4.9, 7.2)	
Divorced	3.6 (2.5, 5.0)	1.3 (0.6, 2.5)	2.6 (1.9, 3.5)	
Widowed	23.9 (21.2, 26.8)	5.0 (3.5, 0.7)	16.0 (14.2, 17.9)	
Wealth status (95% CI)				0.003*
Poorest	23.8 (21.1, 26.7)	19.5 (16.6, 22.7)	22.0 (20.0, 24.1)	
Second	22.4 (19.8, 25.2)	20.7 (17.7, 23.9)	21.7 (19.7, 23.8)	
Middle	25.2 (22.4, 28.1)	22.5 (19.4, 25.8)	24.0 (22.0, 26.2)	
Fourth	17.6 (15.2, 20.1)	20.7 (17.7, 23.9)	18.6 (16.8, 20.6)	
Richest	11.0 (9.1, 13.2)	16.6 (13.9, 19.6)	13.4 (11.7, 15.1)	
Ethnicity (95% CI)				0.024*
Borana	0.1 (0.0, 0.6)	0.4 (0.1, 1.3)	0.3 (0.1, 0.6)	
Embu	3.2 (2.2, 4.5)	3.4 (2.2, 5.0)	3.3 (2.5, 4.2)	
Kalenjin	12.9 (10.8, 15.2)	14.4 (11.8, 17.3)	13.5 (11.9, 15.3)	
Kamba	12.3 (10.3, 14.5)	8.8 (6.8, 11.2)	10.8 (9.4, 12.4)	
Kikuyu	20.4 (17.9, 23.1)	17.8 (15.0, 20.9)	19.3 (17.4, 21.3)	
Kisii	4.8 (3.5, 6.3)	5.7 (4.1, 7.7)	5.2 (4.1, 6.4)	
Luhya	10.2 (8.3, 12.3)	14.0 (11.4, 16.8)	11.8 (10.2, 13.4)	
Luo	9.0 (7.2, 11.0)	7.5 (5.6, 9.7)	8.4 (7.1, 9.8)	
Maasai	1.9 (1.1, 3.0)	1.6 (0.8, 2.9)	1.8 (1.2, 2.6)	
Meru	5.0 (3.7, 6.6)	6.3 (4.6, 8.4)	5.5 (4.5, 6.8)	
Miji Kenda	2.8 (1.8, 4.0)	4.6 (3.1, 6.4)	3.5 (2.7, 4.5)	

Somali	6.0 (4.6, 7.7)	4.1 (2.7, 5.9)	5.2 (4.2, 6.4)	
Turkana	2.2 (1.4, 3.4)	3.2 (2.0, 4.9)	2.6 (1.9, 3.5)	
Other	9.3 (7.5, 11.3)	8.2 (6.3, 10.5)	8.9 (7.5, 10.3)	
Alcohol consumption				
Percentage having at least one standard alcoholic drink in the last 12 months (95% CI)				0.003*
Daily	13.7 (6.8, 23.8)	18.1 (13.8, 23.2)	17.2 (13.4, 21.6)	
5-6 days per week	2.7 (0.3, 9.5)	6.2 (3.6, 9.7)	5.4 (3.3, 8.4)	
3-4 days per week	5.5 (1.5, 13.4)	12.3 (8.7, 16.8)	10.9 (7.8, 14.6)	
1-2 days per week	26.0 (16.5, 37.6)	31.5 (26.1, 37.4)	30.4 (25.6, 35.5)	
1-3 days per month	11.0 (4.9, 20.5)	13.4 (9.6, 18.0)	12.9 (9.6, 16.9)	
Less than once a month	38.4 (27.2, 50.5)	18.1 (13.8, 23.2)	22.4 (18.1, 27.1)	
Don't know	2.7 (0.3, 9.5)	0.4 (0.0, 2.0)	0.9 (0.2, 2.5)	
Mean number of standard alcoholic drinks during one drinking occasion in the last 30 days (SD)	8.0 (10.6)	9.0 (8.8)	9.0 (9.1)	0.493
Diet				
Fruit intake				
Mean number of days fruit is eaten in a typical week (SD)	2.0 (2.4)	2.0 (2.3)	2.0 (2.3)	0.762
Mean number of servings of fruit eaten on one of those days in a typical week (SD)	2.0 (1.4)	2.0 (2.0)	2.0 (1.7)	0.021*
Vegetable intake				
Mean number of days vegetables are eaten in a typical week (SD)	5.0 (2.4)	5.0 (2.4)	5.0 (2.4)	0.373
Mean number of servings of vegetables eaten on one of those days in a typical week (SD)	2.0 (1.2)	2.0 (1.0)	2.0 (1.1)	0.251
Salt intake				
Frequency (percentage); How often salt/salty sauce/salty seasoning is added to food (95% CI)				<0.000*
Always (every meal)	12.6 (10.6, 14.9)	16.9 (14.2, 20.0)	14.4 (12.7, 16.2)	
Often (most meals)	5.5 (4.1, 7.2)	7.5 (5.6, 9.8)	6.4 (5.2, 7.6)	
Sometimes (every week)	12.5 (10.5, 14.8)	16.1 (13.4, 19.0)	14.0 (12.3, 15.8)	
Rarely (not every week)	17.8 (15.4, 20.4)	20.0 (17.1, 23.2)	18.7 (16.9, 20.7)	
Never	51.6 (48.3, 54.8)	39.5 (35.8, 43.3)	46.5 (44.1, 19.0)	

How often processed food high in salt is eaten (95% CI)				<0.000*
Always (every meal)	0.3 (0.1, 0.9)	1.0 (0.4, 2.1)	0.6 (0.3, 1.1)	
Often (most meals)	1.0 (0.4, 1.8)	3.2 (2.0, 4.9)	1.9 (1.3, 2.7)	
Sometimes (every week)	8.0 (6.4, 10.0)	11.8 (9.4, 14.4)	9.6 (8.2, 11.1)	
Rarely (not every week)	32.7 (29.7, 35.8)	37.2 (33.6, 41.0)	34.6 (32.3, 37.0)	
Never	57.7 (54.4, 60.8)	46.8 (43.0, 50.6)	53.1 (50.6, 55.6)	
Don't know	0.3 (0.1, 0.9)	0.0 (0, 0.5)	0.2 (0.0, 0.5)	
Amount (percentage); How much salt/salty sauce one thinks they consume (95% CI)				<0.001*
Far too much	0.4 (0.1, 1.1)	1.8 (0.9, 3.1)	1.0 (0.6, 1.6)	
Too much	6.1 (4.6, 7.8)	9.7 (7.6, 12.2)	7.6 (6.3, 9.0)	
Just the right amount	64.6 (61.4, 67.7)	65.3 (61.5, 68.9)	64.9 (62.5, 67.2)	
Too little	24.5 (21.7, 27.4)	18.9 (16.0, 22.1)	22.1 (20.1, 24.3)	
Far too little	4.4 (3.2, 6.0)	4.3 (2.9, 6.1)	4.4 (3.4, 5.5)	
Sugar intake				
Frequency (percentage); How often sugar is added to a beverage (95% CI)				0.152
Always (every drink)	26.1 (23.4, 29.1)	28.7 (25.3, 32.2)	27.2 (25.0, 29.4)	
Often (every day but not every drink)	6.9 (5.3, 8.7)	9.7 (7.6, 12.2)	8.1 (6.8, 9.5)	
Sometimes (every week)	10.7 (8.8, 12.8)	9.7 (7.6, 12.2)	10.3 (8.8, 11.9)	
Rarely (not every week)	13.9 (11.7, 16.2)	13.2 (10.8, 16.0)	13.6 (12.0, 15.4)	
Never	42.4 (39.3, 45.7)	38.7 (35.0, 42.5)	40.9 (38.5, 43.3)	
How often processed food high in sugar is eaten (95% CI)				0.038*
Always (every meal)	0.1 (0.0, 0.5)	1.2 (0.5, 2.3)	0.6 (0.3, 1.1)	
Often (every day)	2.3 (1.5, 3.5)	2.4 (1.4, 3.8)	2.3 (1.7, 3.2)	
Sometimes (every week)	12.3 (10.3, 14.6)	10.9 (8.7, 13.5)	11.7 (10.2, 13.4)	

Rarely (not every week)	42.2 (39.0, 45.4)	39.6 (35.9, 43.4)	41.1 (38.7, 43.5)	
Never	43.1 (39.9, 46.3)	45.9 (42.2, 49.8)	44.3 (41.9, 46.8)	
How many days (mean) in a week one takes soda or other sugary drinks (SD)	1.0 (1.0)	1.0 (1.5)	1.0 (1.3)	<0.000*
Amount; How many 300ml bottles of soda taken in one of the days in a typical week (SD)	1.0 (0.5)	1.0 (0.9)	1.0 (0.7)	0.019*
How much sugar one thinks they consume (percentage) (95% CI)				0.028*
Far too much	1.2 (0.6, 2.1)	2.2 (1.3, 3.6)	1.6 (1.1, 2.4)	
Too much	8.4 (6.7, 10.3)	10.4 (8.2, 12.9)	9.2 (7.8, 10.7)	
Just the right amount	58.8 (55.6, 62.0)	61.3 (57.5, 65.0)	59.8 (57.4, 62.2)	
Too little	22.5 (19.9, 25.4)	20.2 (17.2, 23.4)	21.5 (19.6, 23.6)	
Far too little	9.1 (7.3, 11.2)	5.9 (4.3, 8.0)	7.7 (6.5, 9.2)	
Physical activity				
Frequency (mean) (SD); How many days is vigorous-intensity activities part of one's work in a typical week	5.0 (1.7)	5.0 (1.7)	5.0 (1.7)	0.206
How many days is moderate-intensity activities part of one's work in a typical week	6.0 (1.9)	5.0 (1.9)	5.0 (1.9)	0.001*
How many days does one walk or bicycle for at least 10 minutes continuously to get to and from places in a typical week	5.0 (2.0)	5.0 (2.0)	5.0 (2.0)	<0.000*
How many days does one engage in vigorous-intensity sports, fitness or recreational (leisure) activities in a typical week	2.0 (1.8)	3.0 (2.1)	3.0 (2.0)	0.017*
How many days does one engage in moderate-intensity sports, fitness or recreational (leisure) activities in a typical week	3.0 (1.9)	4.0 (2.2)	3.0 (2.1)	0.004*
Duration (mean) (SD); Time (hrs.) spent doing vigorous-intensity activities at work on a typical day?	4.0 (2.1)	5.0 (2.3)	5.0 (2.2)	<0.000*
How much time (hrs.) does one spend doing moderate-intensity activities at work on a typical day?	3.0 (2.5)	4.0 (2.9)	4.0 (2.7)	<0.000*
How much time (hrs.) does one spend walking or bicycling for travel on a typical day?	1.0 (1.4)	2.0 (2.2)	2.0 (1.8)	<0.000*
How much time (hrs.) does one spend doing vigorous-intensity sports, fitness or recreational activities on a typical day?	1.0 (0.5)	2.0 (2.2)	1.0 (1.8)	0.029
How much time (hrs.) does one spend doing moderate-intensity sports, fitness or recreational activities on a typical day?	1.0 (1.9)	1.0 (1.4)	1.0 (1.7)	0.876
How much time (hrs.) does one usually spend sitting or reclining on a typical day?	3.0 (2.1)	3.0 (2.1)	3.0 (2.1)	0.762
Lifestyle advice				

In the past three years, the percentage of those that a doctor or other health worker has advised to (95% CI);-				
Quit using tobacco or don't start	6.2 (4.8, 8.0)	12.8 (10.4, 15.5)	9.0 (7.6, 10.5)	<0.000*
Reduce the use of alcohol or don't start	7.5 (5.9, 9.4)	13.4 (10.9, 16.2)	10.0 (8.6, 11.5)	<0.000*
Reduce salt in the diet	18.8 (16.4, 21.5)	11.8 (9.4, 14.4)	15.9 (14.1, 17.7)	<0.000*
Reduce the use of refined sugar in your diet	14.1 (11.9, 16.5)	11.0 (8.8, 13.6)	12.8 (11.2, 14.5)	0.070
Eat at least five servings of fruit and/or vegetables each day	25.4 (22.6, 28.3)	15.1 (12.5, 18.1)	21.1 (19.1, 23.2)	<0.000*
Reduce fat in your diet	16.5 (14.2, 19.0)	10.1 (8.0, 12.7)	13.9 (12.2, 15.6)	<0.000*
Start or do more physical activity	11.4 (9.4, 13.6)	10.1 (8.0, 12.7)	10.9 (9.4, 12.5)	0.413
Maintain a healthy body weight or lose weight	12.8 (10.7, 15.1)	9.3 (7.2, 11.7)	11.3 (9.8, 13.0)	0.026*
The primary source of health care				0.132
Self-medication	6.1 (4.7, 7.9)	8.9 (6.8, 11.3)	7.3 (6.1, 8.7)	
Herbal/alternative therapy	0.4 (0.1, 1.1)	0.7 (0.2, 1.7)	0.6 (0.3, 1.1)	
Dispensaries	36.3 (33.3, 39.5)	30.5 (27.0, 34.1)	33.9 (31.6, 36.3)	
Community Health Worker	0.1 (0.0, 0.5)	0.6 (0.2, 1.5)	0.3 (0.1, 0.7)	
Health Centre	16.6 (14.3, 19.2)	16.0 (13.3, 19.0)	16.4 (14.6, 18.3)	
Sub-County/District Hospitals	21.2 (18.6, 23.9)	21.5 (18.4, 24.7)	21.3 (19.3, 23.4)	
County Referral/Provincial Hospitals	6.6 (5.1, 8.3)	6.8 (5.0, 9.0)	6.7 (5.5, 8.0)	
National Referral Hospitals	0.1 (0.0, 0.6)	0.3 (0.0, 1.1)	0.2 (0.0, 0.5)	
Private Clinic	6.4 (4.9, 8.1)	7.4 (5.5, 9.6)	6.8 (5.6, 8.1)	
Private Hospital	5.5 (4.1, 7.2)	6.2 (4.5, 8.3)	5.8 (4.7, 7.1)	
OTC/Pharmacy	0.6 (0.2, 1.4)	1.2 (0.5, 2.3)	0.9 (0.5, 1.4)	

* $p<0.05$

Table 26. Comparing the mean CVD risk scores by socio-demographic and behavioural groups

Indicator	Observations (n)	Mean (SD)	X^2(df)	P-value
Sex			3.2 (1)	0.073
Female	944	5.0 (5.5)		
Male	681	4.6 (4.7)		
Age groups			1154.4 (6)	<0.000*
40-44	431	1.4 (0.9)		
45-49	311	2.6 (2.5)		
50-54	263	3.7 (2.9)		
55-59	234	5.5 (3.9)		
60-64	212	8.7 (5.6)		
65-69	173	13.2 (6.0)		
70-74	1	21.1		
Education level			66.8 (7)	<0.000*
No formal schooling	393	6.6 (6.4)		
Primary school incomplete	426	4.5 (4.8)		
Primary school complete	334	4.5 (4.7)		
Secondary school incomplete	121	3.9 (4.1)		
Secondary school complete	188	3.7 (4.2)		
A-level completed	11	4.1 (3.9)		
College/University completed	139	4.2 (4.0)		
Post-graduate degree	13	6.0 (6.9)		
Residence			0.9 (1)	0.353
Rural	968	4.9 (5.1)		
Urban	657	4.7 (5.2)		
Marital status			74.9 (5)	<0.000*
Never married	63	3.9 (4.2)		

Cohabiting	3	2.1 (2.6)		
Currently married	1160	4.4 (4.9)		
Separated	97	3.7 (3.2)		
Divorced	43	6.9 (7.1)		
Widowed	259	6.8 (6.0)		
Wealth status			4.8 (4)	0.312
Poorest	358	4.8 (5.5)		
Second	352	4.9 (5.0)		
Middle	391	5.0 (5.1)		
Fourth	307	5.0 (5.3)		
Richest	217	4.2 (4.3)		
Ethnicity			34.0 (13)	0.001*
Borana	4	1.3 (0.3)		
Embu	53	6.2 (6.7)		
Kalenjin	219	4.0 (3.9)		
Kamba	176	5.0 (5.0)		
Kikuyu	314	4.9 (4.9)		
Kisii	84	3.5 (3.2)		
Luhya	191	5.7 (6.3)		
Luo	136	4.5 (5.4)		
Maasai	29	4.8 (5.3)		
Meru	90	5.3 (5.2)		
Miji Kenda	57	3.7 (3.6)		
Somali	85	6.2 (6.9)		
Turkana	43	3.8 (3.0)		
Other	144	4.9 (5.5)		
Alcohol consumption				
Frequency as the percentage of having at least one standard alcoholic drink in the last 12 months			10.7 (7)	0.100

Daily	60	5.6 (5.3)		
5-6 days per week	19	5.6 (3.2)		
3-4 days per week	38	5.1 (4.1)		
1-2 days per week	106	4.5 (4.7)		
1-3 days per month	45	4.9 (5.4)		
Less than once a month	78	4.9 (4.9)		
Diet				
Fruit intake				
Frequency as the number of days fruit is eaten in a typical week			3.82 (7)	0.799
0	411	5.2 (5.7)		
1	345	4.8 (5.1)		
2	273	4.2 (4.6)		
3	220	5.0 (5.0)		
4	62	4.5 (4.7)		
5	51	4.7 (4.6)		
6	23	6.0 (7.6)		
7	227	4.8 (5.1)		
Vegetable intake				
Frequency as the number of days vegetables are eaten in a typical week			16.8 (7)	0.019*
0	104	5.8 (6.8)		
1	83	5.2 (5.4)		
2	114	4.6 (4.4)		
3	155	4.8 (5.2)		
4	117	5.0 (5.3)		
5	90	6.3 (5.6)		
6	78	4.4 (5.2)		
7	880	4.5 (4.9)		
Salt intake				
Frequency; How often salt/salty sauce/salty seasoning is added to food			7.5 (4)	0.110

Always (every meal)	234	4.7 (4.5)		
Often (most meals)	103	4.6 (5.5)		
Sometimes (every week)	227	4.6 (5.4)		
Rarely (not every week)	304	4.5 (5.1)		
Never	754	5.1 (5.3)		
How often processed food high in salt is eaten			14.1 (5)	0.015*
Always (every meal)	10	4.0 (2.1)		
Often (most meals)	31	3.7 (4.7)		
Sometimes (every week)	156	4.0 (4.0)		
Rarely (not every week)	562	4.5 (4.6)		
Never	862	5.2 (5.6)		
Amount; How much salt/salty sauce one thinks they consume			17.3 (4)	0.002*
Far too much	16	3.3 (2.1)		
Too much	121	4.6 (5.0)		
Just the right amount	1034	4.7 (5.1)		
Too little	353	5.1 (5.3)		
Far too little	70	6.9 (6.0)		
Sugar intake				
Frequency (percentage); How often sugar is added to beverage			9.1 (4)	0.060
Always (every drink)	442	4.9 (5.1)		
Often (every day but not every drink)	131	4.4 (5.0)		
Sometimes (every week)	166	4.8 (5.7)		
Rarely (not every week)	221	4.5 (5.3)		
Never	664	5.0 (5.1)		
How often processed food high in sugar is eaten			29.7 (4)	<0.000*
Always (every meal)	9	2.8 (1.8)		
Often (every day)	38	2.8 (3.2)		
Sometimes (every week)	190	4.2 (4.6)		
Rarely (not every week)	667	4.4 (4.6)		

Never	718	5.5 (5.8)		
How many days in a week one takes soda or other sugary drinks			11.7 (7)	0.110
0	1092	5.1 (5.4)		
1	392	4.2 (4.2)		
2	99	4.6 (5.1)		
3	40	5.5 (7.1)		
4	13	4.1 (4.4)		
5	13	2.9 (2.1)		
6	6	4.1 (2.7)		
7	27	3.2 (3.4)		
How much sugar one thinks they consume			20.6 (4)	<0.000*
Far too much	26	5.5 (5.4)		
Too much	148	4.7 (5.5)		
Just the right amount	960	4.5 (4.9)		
Too little	346	5.3 (5.6)		
Far too little	125	6.0 (5.5)		
Physical activity				
How many days is vigorous-intensity activities part of one's work in a typical week			18.8 (6)	0.005
1	32	5.2 (5.7)		
2	51	4.2 (5.0)		
3	106	5.1 (6.8)		
4	34	2.3 (2.0)		
5	80	4.1 (4.0)		
6	357	4.7 (4.5)		
7	154	3.9 (3.3)		
How many days is moderate-intensity activities part of one's work in a typical week			9.1 (6)	0.169
1	47	3.7 (2.8)		
2	106	4.9 (5.7)		
3	99	4.6 (3.8)		

4	58	4.6 (6.5)		
5	113	4.1 (4.9)		
6	254	5.0 (5.3)		
7	462	4.6 (4.7)		
How many days does one walk or bicycle for at least 10 minutes continuously to get to and from places in a typical week			6.7 (6)	0.351
1	102	5.2 (5.1)		
2	150	4.9 (4.5)		
3	153	5.6 (6.3)		
4	65	5.2 (5.9)		
5	107	4.2 (5.5)		
6	247	4.8 (5.0)		
7	537	4.3 (4.4)		
How many days does one engage in vigorous-intensity sports, fitness or recreational (leisure) activities in a typical week			10.5 (6)	0.104
1	29	3.6 (4.2)		
2	20	1.6 (1.1)		
3	19	2.8 (2.5)		
4	7	3.4 (2.5)		
5	4	4.8 (3.9)		
6	5	4.9 (5.5)		
7	12	3.0 (2.7)		
How many days does one engage in moderate-intensity sports, fitness or recreational (leisure) activities in a typical week			1.3 (6)	0.974
1	44	3.7 (3.3)		
2	37	3.9 (3.9)		
3	22	3.0 (1.9)		
4	10	4.5 (5.0)		
5	15	5.1 (5.6)		

6	7	3.6 (2.8)		
7	23	4.6 (5.2)		
In the past three years, the percentage of those that a doctor or other health worker has advised to; - Quit using tobacco or don't start			0.5 (1)	0.461
Yes	145	4.8 (4.9)		
No	1479	4.8 (5.2)		
Reduce the use of alcohol or don't start			0.6 (1)	0.441
Yes	161	5.0 (5.0)		
No	1463	4.8 (5.2)		
Reduce salt in the diet			17.4 (1)	<0.000*
Yes	257	6.4 (6.6)		
No	1367	4.5 (4.8)		
Reduce the use of refined sugar in your diet			10.7 (1)	0.001*
Yes	207	6.2 (6.8)		
No	1417	4.6 (4.9)		
Eat at least five servings of fruit and vegetables each day			0.2 (1)	0.629
Yes	342	5.2 (5.7)		
No	1282	4.7 (5.0)		
Reduce fat in your diet			2.3 (1)	0.133
Yes	224	5.4 (5.5)		
No	1400	4.7 (5.1)		
Start or do more physical activity			3.6 (1)	0.058
Yes	176	5.9 (6.5)		
No	1448	4.7 (5.0)		
Maintain a healthy body weight or lose weight			2.3 (1)	0.130
Yes	183	5.5 (5.9)		
No	1441	4.7 (5.1)		

* $p<0.05$

Table 27. Multivariable regression showing the association between factors measured in the survey and CVD risk scores

Log CVD risk score	Coef.	St. Err.	t-value	p-value	[95% Conf	Interval]	Sig
Education level							
No formal schooling	0.00	.	.	.	.	.	
Primary school incomplete	-0.39	0.10	-4.03	0.00	-0.58	-0.20	*
Primary school complete	-0.43	0.10	-4.22	0.00	-0.63	-0.23	*
Secondary school incomplete	-0.34	0.14	-2.47	0.01	-0.60	-0.07	*
Secondary school complete	-0.56	0.13	-4.17	0.00	-0.82	-0.30	*
A-Level completed	-0.09	0.52	-0.17	0.87	-1.10	0.93	
College/University completed	-0.31	0.17	-1.83	0.07	-0.65	0.02	
Post-graduate degree	-0.11	0.52	-0.21	0.83	-1.12	0.90	
Marital status							
Never married	0.00	.	.	.	.	.	
Cohabiting	-0.56	0.53	-1.06	0.29	-1.60	0.48	
Currently married	0.20	0.16	1.28	0.20	-0.11	0.51	
Separated	0.04	0.19	0.21	0.83	-0.34	0.42	
Divorced	0.46	0.27	1.69	0.09	-0.07	0.98	
Widowed	0.50	0.17	2.92	0.00	0.16	0.84	*
Ethnicity							
Borana	-0.94	0.62	-1.52	0.13	-2.15	0.28	
Embu	0.16	0.18	0.92	0.36	-0.19	0.52	
Kalenjin	-0.23	0.11	-2.02	0.04	-0.46	-0.01	*
Kamba	-0.02	0.12	-0.20	0.84	-0.25	0.20	
Kikuyu	0.00	.	.	.	.	.	
Kisii	-0.12	0.14	-0.83	0.41	-0.40	0.16	
Luhya	0.18	0.12	1.50	0.13	-0.06	0.42	
Luo	-0.09	0.12	-0.76	0.45	-0.33	0.15	
Maasai	-0.02	0.62	-0.03	0.98	-1.23	1.19	
Meru	0.14	0.15	0.94	0.35	-0.15	0.43	
Miji Kenda	-0.46	0.19	-2.45	0.02	-0.84	-0.09	*
Somali	-0.36	0.35	-1.03	0.30	-1.04	0.32	
Turkana	0.01	0.31	0.03	0.98	-0.60	0.61	
Others	-0.24	0.13	-1.85	0.07	-0.49	0.02	
Number of days vegetables are eaten in a typical week							
0	0.00	.	.	.	.	.	
1	-0.04	0.24	-0.16	0.88	-0.51	0.43	
2	0.11	0.22	0.47	0.64	-0.33	0.54	
3	0.13	0.21	0.64	0.52	-0.28	0.55	
4	0.23	0.22	1.01	0.31	-0.21	0.66	
5	0.47	0.23	2.08	0.04	0.03	0.92	*
6	0.15	0.23	0.64	0.52	-0.31	0.61	
7	0.11	0.20	0.56	0.58	-0.28	0.49	
The amount of salt/salty sauce one thought they consume							
Far too much	0.00	.	.	.	.	.	

Too much	0.14	0.29	0.49	0.63	-0.43	0.71	
Just the right amount	0.14	0.27	0.52	0.61	-0.39	0.67	
Too little	0.13	0.27	0.47	0.64	-0.41	0.67	
Far too little	0.38	0.31	1.22	0.22	-0.23	0.98	
How often processed food high in sugar is eaten							
Always (every meal)	0.00	.	.	.	.	.	
Often (every day)	-0.33	0.55	-0.60	0.55	-1.42	0.75	
Sometimes (every week)	0.20	0.52	0.39	0.70	-0.82	1.22	
Rarely	0.27	0.52	0.52	0.61	-0.75	1.28	
Never	0.33	0.52	0.65	0.51	-0.68	1.35	
The amount of sugar one thought they consume							
Far too much	0.00	.	.	.	.	.	
Too much	-0.21	0.27	-0.75	0.45	-0.74	0.33	
Just the right amount	-0.26	0.26	-1.02	0.31	-0.77	0.24	
Too little	-0.32	0.26	-1.23	0.22	-0.83	0.19	
Far too little	-0.22	0.28	-0.79	0.43	-0.77	0.33	
The number of days vigorous-intensity activities was part of one's work in a typical week							
0	0.00	.	.	.	.	.	
1	0.09	0.17	0.51	0.61	-0.25	0.43	
2	-0.24	0.15	-1.59	0.11	-0.54	0.06	
3	-0.10	0.11	-0.89	0.37	-0.33	0.12	
4	-0.57	0.17	-3.37	0.00	-0.91	-0.24	*
5	-0.03	0.13	-0.26	0.79	-0.28	0.21	
6	-0.01	0.09	-0.07	0.94	-0.19	0.17	
7	0.00	.	.	.	.	.	
Whether one had received lifestyle advice (in the past three years)							
To reduce salt in the diet							
Yes	0.00	.	.	.	.	.	
No	-0.17	0.12	-1.43	0.15	-0.41	0.06	
To reduce sugar in the diet							
Yes	0.00	.	.	.	.	.	
No	0.02	0.13	0.13	0.90	-0.24	0.28	
Constant	1.47	0.22	6.71	0.00	1.04	1.90	*

Mean dependent var	1.09	SD dependent var	0.90
R-squared	0.16	Number of obs	796.00
F-test	2.64	Prob > F	0.00
Akaike crit. (AIC)	2052.64	Bayesian crit. (BIC)	2300.66

* p<0.05,

Appendix 7. Search strategy

# ▲	Searches - Medline	Results
1	*cardiovascular diseases/ or *heart diseases/ or *vascular diseases/	161316
2	cardiovascular diseases/pc or heart diseases/pc or vascular diseases/pc	34802
3	(((cardiovascular or cardio-vascular or heart or vascular) adj (risk? or disease* or health)) or cvd).ti.	70553
4	1 or 2 or 3	226915
5	Risk Management/mt, st, ut [Methods, Standards, Utilization]	4314
6	Risk Assessment/mt, st, ut	27460
7	*Risk Assessment/	24591
8	Primary Prevention/ and (Risk Management/ or Risk Assessment/ or Risk Factors/)	6231
9	(risk? adj3 (scor* or algorithm? or table? or model* or strateg* or engine? or tool? or index or indices or chart?)).ti,ab.	64688
10	(risk? adj3 (assess* or estimat* or calculat* or reduc* or stratif*)).ti,ab.	279112
11	5 or 6 or 7 or 8 or 9 or 10	348261
12	Ambulatory Care/	40068
13	exp Ambulatory Care Facilities/	51355
14	general practice/ or family practice/	71757
15	general practitioners/ or physicians, family/ or physicians, primary care/ or physicians/	104504
16	Primary Health Care/	67426
17	Office Visits/	6400
18	(ambulatory adj3 (care or setting? or facilit* or ward? or department? or service?)).ti,ab.	15593
19	(((general or family) adj2 (practi* or doctor?)) or physician?).ti,ab.	426348
20	(primary care or primary health care or primary healthcare).ti,ab.	114394
21	(after hour? or afterhour? or "out of hour?" or ooh).ti,ab.	4134
22	(clinic? or visit?).ti,ab.	424796
23	((health* or medical) adj2 (center? or centre?)).ti,ab.	107616
24	Community Health Services/	29742
25	Community Health Workers/	4395
26	(community adj3 (service? or worker? or volunteer? or aide? or assistant?)).ti,ab.	20250
27	(health adj2 (worker? or volunteer? or aide? or assistant?)).ti,ab.	31496
28	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27	1139877
29	Practice Patterns, Physicians'/	51924
30	Health Knowledge, Attitudes, Practice/ or Attitude of Health Personnel/	193726
31	Guideline Adherence/	27996
32	(barrier? or obstacle? or challeng*).ti,ab.	899044
33	(facilitat* or enabl* or opportunit* or influence* or motivat*).ti,ab.	2187847
34	(implement* or uptake or util?e? or utili?ation or adopt*).ti,ab.	1033524
35	(attitud* or perception* or perspective* or view* or opinion* or expectation? or fear?).ti,ab.	1107127
36	(knowledge or understand* or comprehen* or aware* or communicat*).ti,ab.	1976260
37	29 or 30 or 31 or 32 or 33 or 34 or 35 or 36	5794691
38	4 and 11 and 28 and 37	1411

#	Searches - Embase	Results
1	*cardiovascular diseases/ or *heart diseases/ or *vascular diseases/	43877
2	cardiovascular diseases/pc or heart diseases/pc or vascular diseases/pc	7677
3	exp *cardiovascular risk/	34587
4	(((cardiovavascular or cardio-vascular or heart or vascular) adj (risk? or disease* or health)) or cvd).ti.	84974
5	1 or 2 or 3 or 4	159442
6	*Risk Management/	15511
7	*Risk Assessment/	40299
8	Primary Prevention/ and (Risk Management/ or Risk Assessment/ or Risk Factors/)	8817
9	(risk? adj3 (scor* or algorithm? or table? or model* or strateg* or engine? or tool? or index or indices or chart?)).ti,ab.	105059
10	(risk? adj3 (assess* or estimat* or calculat* or reduc* or stratif*)).ti,ab.	398005
11	6 or 7 or 8 or 9 or 10	498352
12	Ambulatory Care/	35223
13	general practice/	77978
14	general practitioner/ or physician/	330789
15	Primary Health Care/ or primary medical care/	145000
16	(ambulatory adj3 (care or setting? or facilit* or ward? or department? or service?)).ti,ab.	20749
17	(((general or family) adj2 (practi* or doctor?)) or physician?).ti,ab.	576576
18	(primary care or primary health care or primary healthcare).ti,ab.	148440
19	(after hour? or afterhour? or "out of hour?" or ooh).ti,ab.	5879
20	(clinic? or visit?).ti,ab.	655465
21	((health* or medical) adj2 (center? or centre?)).ti,ab.	152214
22	health center/	29481
23	health auxiliary/	5330
24	(community adj3 (service? or worker? or volunteer? or aide? or assistant?)).ti,ab.	25328
25	(health adj2 (worker? or volunteer? or aide? or assistant?)).ti,ab.	36670
26	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25	1597532
27	health personnel attitude/ or physician attitude/ or protocol compliance/	131055

28	(barrier? or obstacle? or challeng*).ti,ab.	1111742
29	(facilitat* or enabl* or opportunit* or influence* or motivat*).ti,ab.	2658739
30	(implement* or uptake or util?e? or utili?ation or adopt*).ti,ab.	1301508
31	(attitud* or perception* or perspective* or view* or opinion* or expectation? or fear?).ti,ab.	1371243
32	(knowledge or understand* or comprehen* or aware* or communicat*).ti,ab.	2463078
33	27 or 28 or 29 or 30 or 31 or 32	7067677
34	5 and 11 and 26 and 33	1293

# ▲	**Searches - PsycINFO**	**Results**
1	Cardiovascular disorders/	8914
2	(((cardiovavascular or cardio-vascular or heart or vascular) adj (risk? or disease* or health)) or cvd).ti.	3033
3	1 or 2	11378
4	Risk Management/	4723
5	Risk Assessment/	12447
6	Prevention/ and (Risk Management/ or Risk Assessment/ or Risk Factors/)	2470
7	(risk? adj3 (scor* or algorithm? or table? or model* or strateg* or engine? or tool? or index or indices or chart?)).ti,ab.	12025
8	(risk? adj3 (assess* or estimat* or calculat* or reduc* or stratif*)).ti,ab.	39965
9	4 or 5 or 6 or 7 or 8	57504
10	physicians/ or family physicians/ or general practitioners/	26405
11	Primary Health Care/	16583
12	(ambulatory adj3 (care or setting? or facilit* or ward? or department? or service?)).ti,ab.	1954
13	(((general or family) adj2 (practi* or doctor?)) or physician?).ti,ab.	70964
14	(primary care or primary health care or primary healthcare).ti,ab.	29812
15	(after hour? or afterhour? or "out of hour?" or ooh).ti,ab.	408
16	(clinic? or visit?).ti,ab.	84611
17	((health* or medical) adj2 (center? or centre?)).ti,ab.	18681
18	(community adj3 (service? or worker? or volunteer? or aide? or assistant?)).ti,ab.	13638
19	(health adj2 (worker? or volunteer? or aide? or assistant?)).ti,ab.	7859

20	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19	199427
21	health personnel attitudes/	17762
22	(barrier? or obstacle? or challeng*).ti,ab.	270221
23	(facilitat* or enabl* or opportunit* or influence* or motivat*).ti,ab.	775991
24	(implement* or uptake or util?e? or utili?ation or adopt*).ti,ab.	259587
25	(attitud* or perception* or perspective* or view* or opinion* or expectation? or fear?).ti,ab.	908229
26	(knowledge or understand* or comprehen* or aware* or communicat*).ti,ab.	926641
27	21 or 22 or 23 or 24 or 25 or 26	2121600
28	3 and 9 and 20 and 27	163

# ▲	**Searches – Global Health**	**Results**
1	exp Cardiovascular Diseases/	100004
2	(((cardiovavascular or cardio-vascular or heart or vascular) adj (risk? or disease* or health)) or cvd).ti.	7986
3	1 or 2	100487
4	Risk Analysis/	2078
5	Risk Assessment/	42333
6	Disease Prevention/ and Risk Factors/	7077
7	(risk? adj3 (scor* or algorithm? or table? or model* or strateg* or engine? or tool? or index or indices or chart?)).ti,ab.	15743
8	(risk? adj3 (assess* or estimat* or calculat* or reduc* or stratif*)).ti,ab.	77698
9	4 or 5 or 6 or 7 or 8	115525
10	physicians/ or general practitioners/	18267
11	Primary Health Care.sh.	10286

12	(ambulatory adj3 (care or setting? or facilit* or ward? or department? or service?)).ti,ab.	1556
13	(((general or family) adj2 (practi* or doctor?)) or physician?).ti,ab.	41875
14	(primary care or primary health care or primary healthcare).ti,ab.	21898
15	(after hour? or afterhour? or "out of hour?" or ooh).ti,ab.	302
16	exp health centres/ or Community Health Services/	11893
17	(clinic? or visit?).ti,ab.	80670
18	((health* or medical) adj2 (center? or centre?)).ti,ab.	25171
19	community health workers/	229
20	(community adj3 (service? or worker? or volunteer? or aide? or assistant?)).ti,ab.	6100
21	(health adj2 (worker? or volunteer? or aide? or assistant?)).ti,ab.	15527
22	10 or 11 or 12 or 13 or 14 or 15 or 17 or 18 or 20 or 21	165959
23	attitudes/	41917
24	(barrier? or obstacle? or challeng*).ti,ab.	130295
25	(facilitat* or enabl* or opportunit* or influence* or motivat*).ti,ab.	284795
26	(implement* or uptake or util?e? or utili?ation or adopt*).ti,ab.	180439
27	(attitud* or perception* or perspective* or view* or opinion* or expectation? or fear?).ti,ab.	149051
28	(knowledge or understand* or comprehen* or aware* or communicat*).ti,ab.	287083
29	23 or 24 or 25 or 26 or 27 or 28	783509
30	3 and 9 and 22 and 29	596

#	**Query** - CINAHL	**Results**
S22	S4 AND S9 AND S16 AND S21	277
S21	S17 OR S18 OR S19 OR S20	889,216
S20	TI ((barrier* or obstacle* or challeng*)) OR AB ((barrier* or obstacle* or challeng*)) OR TI ((facilitat* or enabl* or opportunit* or influence* or motivat*)) OR AB ((facilitat* or enabl* or opportunit* or influence* or motivat*)) OR TI ((implement* or uptake or utilis* or utiliz* or adopt*)) OR AB ((implement* or uptake or utilis* or utiliz* or adopt*)) OR TI ((attitud* or perception* or perspective* or view* or opinion* or expectatio*? or fear*)) OR AB ((attitud* or perception* or perspective* or view* or opinion* or expectatio*? or fear*)) OR TI ((knowledge or understand* or comprehen* or aware* or communicat*)) OR AB ((knowledge or understand* or comprehen* or aware* or communicat*))	854,092
S19	(MH "Program Implementation")	16,210
S18	(MH "Guideline Adherence")	6,099
S17	(MH "Practice Patterns") OR (MH "Attitude of Health Personnel+")	64,507
S16	S10 OR S11 OR S12 OR S13 OR S14 OR S15	335,836
S15	TI (((community N3 (service* or worker* or volunteer* or aide* or assistant*))) OR AB ((community N3 (service* or worker* or volunteer* or aide* or assistant*))) OR TI (((health N3 (service* or worker* or volunteer* or aide* or assistant*))) OR AB (((health N3 (service* or worker* or volunteer* or aide* or assistant*)))	66,822
S14	(MH "Community Health Services") OR (MH "Community Health Workers")	15,016
S13	TI ((ambulatory N3 (care or setting* or facilit* or ward* or department* or service*))) OR AB ((ambulatory N3 (care or setting* or facilit* or ward* or department* or service*))) OR TI ((((general or family) N2 (practi* or doctor*)) or physician*)) OR AB ((((general or family) N2 (practi* or doctor*)) or physician*)) OR TI (("primary care" or "primary health care" or "primary healthcare")) OR AB (("primary care" or "primary health care" or "primary healthcare")) OR TI (("after hour*" or afterhour* or "out of hour*" or ooh)) OR AB (("after hour*" or afterhour* or "out of hour*" or ooh)) OR TI (clinic OR clinics OR visit OR visits) OR AB (clinic OR clinics OR visit OR visits) OR TI (((health* or medical) N2 (center* or centre*))) OR AB (((health* or medical) N2 (center* or centre*)))	223,435
S12	(MH "Primary Health Care") OR (MH "Office Visits")	40,307
S11	(MH "Family Practice") OR (MH "Physicians") OR (MH "Physicians, Family")	59,056
S10	(MH "Ambulatory Care") OR (MH "Ambulatory Care Facilities")	10,921
S9	S5 OR S6 OR S7 OR S8	76,241
S8	TI ((risk* N3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*))) OR TI ((risk* N3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*))(risk* N3 (assess* or estimat* or calculat* or reduc* or stratif*))) OR AB ((risk* N3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*))) OR AB ((risk* N3 (assess* or estimat* or calculat* or reduc* or stratif*)))	62,214
S7	(MH "Risk Management/MT/ST/UT") OR (MH "Risk Assessment/MT/ST/UT")	5,545

S6	(MM "Risk Assessment")	11,597
S5	(MM "Risk Management")	5,657
S4	S1 OR S2 OR S3	37,982
S3	TI (((cardiovavascular or cardio-vascular or heart or vascular) N1 (risk* or disease* or health)) or cvd)	12,823
S2	(MH "Cardiovascular Diseases/PC") OR (MH "Heart Diseases/PC") OR (MH "Vascular Diseases/PC")	10,903
S1	(MM "Cardiovascular Diseases") OR (MM "Heart Diseases") OR (MM "Vascular Diseases")	24,538

Web of Science

# 5	**289**	**#4 AND #3 AND #2 AND #1**
# 4	11,867,108	**TOPIC:** ((barrier* or obstacle* or challeng*)) *OR* **TOPIC:** ((facilitat* or enabl* or opportunit* or influence* or motivat*)) *OR* **TOPIC:** ((implement* or uptake or utilis* or utiliz* or adopt*)) *OR* **TOPIC:** ((attitud* or perception* or perspective* or view* or opinion* or expectatio*? or fear*)) *OR* **TOPIC:** ((knowledge or understand* or comprehen* or aware* or communicat*))
# 3	921,764	**TOPIC:** ((ambulatory NEAR/3 (care or setting* or facilit* or ward* or department* or service*))) *OR* **TOPIC:** ((((general or family) NEAR/2 (practi* or doctor*)) or physician*)) *OR* **TOPIC:** (("primary care" or "primary health care" or "primary healthcare")) *OR* **TOPIC:** (("after hour*" or afterhour* or "out of hour*" or ooh)) *OR* **TOPIC:** (clinic OR clinics OR visit OR visits) *OR* **TOPIC:** (((health* or medical) NEAR/2 (center* or centre*))) *OR* **TOPIC:** ((community NEAR/3 (service* or worker* or volunteer* or aide* or aessistant*))) *OR* **TOPIC:** ((health NEAR/2 (service* or worker* or volunteer* or aide* or assistant*)))
# 2	116,169	**TOPIC:** ((risk* NEAR/3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*))) *OR* **TOPIC:** ((risk* NEAR/3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*)))
# 1	134,774	TS=((((cardiovavascular or cardio-vascular or heart or vascular) N (risk* or disease* or health)) or cvd))

Cochrane

ID	Search -
#1	MeSH descriptor: [Cardiovascular Diseases] this term only
#2	MeSH descriptor: [Heart Diseases] this term only
#3	MeSH descriptor: [Vascular Diseases] this term only
#4	(((cardiovavascular or cardio-vascular or heart or vascular) near/2 (risk* or disease* or health)) or cvd):ti,ab,kw (Word variations have been searched)
#5	#1 or #2 or #3 or #4
#6	MeSH descriptor: [Risk Management] this term only
#7	MeSH descriptor: [Risk Assessment] this term only
#8	MeSH descriptor: [Primary Prevention] this term only
#9	(risk* near/3 (scor* or algorithm* or table* or model* or strateg* or engine* or tool* or index or indices or chart*)):ti,ab,kw or (risk* near/3 (assess* or estimat* or calculat* or reduc* or stratif*)):ti,ab,kw (Word variations have been searched)
#10	#6 or #7 or #8 or #9
#11	MeSH descriptor: [Ambulatory Care] this term only
#12	MeSH descriptor: [Ambulatory Care Facilities] explode all trees
#13	MeSH descriptor: [General Practice] explode all trees
#14	MeSH descriptor: [General Practitioners] explode all trees
#15	MeSH descriptor: [Physicians, Family] explode all trees
#16	MeSH descriptor: [Physicians] this term only
#17	MeSH descriptor: [Physicians, Primary Care] explode all trees
#18	MeSH descriptor: [Office Visits] this term only
#19	(ambulatory near/3 (care or setting* or facilit* or ward* or department* or service*)):ti,ab,kw or (((general or family) near/2 (practi* or doctor*)) or physician*):ti,ab,kw or ("primary care" or "primary health care" or "primary healthcare"):ti,ab,kw or ("after hour*" or afterhour* or "out of hour*" or ooh):ti,ab,kw or clinic or clinics or visit or visits:ti,ab,kw (Word variations have been searched)
#20	MeSH descriptor: [Community Health Services] this term only
#21	MeSH descriptor: [Community Health Workers] explode all trees
#22	((health* or medical) near/2 (center* or centre*)):ti,ab,kw or (community near/3 (service* or worker* or volunteer* or aide* or assistant*)):ti,ab,kw or (health near/2 (service* or worker* or volunteer* or aide* or assistant*)):ti,ab,kw (Word variations have been searched)
#23	#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22
#24	MeSH descriptor: [Practice Patterns, Physicians'] explode all trees

#25	MeSH descriptor: [Health Knowledge, Attitudes, Practice] explode all trees
#26	MeSH descriptor: [Attitude of Health Personnel] explode all trees
#27	MeSH descriptor: [Guideline Adherence] explode all trees
#28	(barrier* or obstacle* or challeng*):ti,ab,kw or (facilitat* or enabl* or opportunit* or influence* or motivat*):ti,ab,kw or (implement* or uptake or utilis* or utiliz* or adopt*):ti,ab,kw or (attitud* or perception* or perspective* or view* or opinion* or expectatio*? or fear*):ti,ab,kw or (knowledge or understand* or comprehen* or aware* or communicat*):ti,ab,kw (Word variations have been searched)
#29	#24 or #25 or #26 or #27 or #28
#30	#5 and #10 and #23 and #29

Appendix 8. Characteristics of excluded studies and reasons for exclusion

Author and year	Country	Title	Reason for exclusion
Adang et al., 2016	Netherlands	Efficiency of the implementation of cardiovascular risk management in primary care practices: an observational study	Wrong intervention
Ahmed et al., 2013	Saudi Arabia	Evaluation of risk factors for cardiovascular diseases among Saudi diabetics' patients attending primary health care service	Wrong outcomes
Al-Mohtaseb et al., 2011	-	What do general practitioners know about total cardiovascular risk assessment tool SCORE European Heart Journal	The full paper was not available
Banegas et al., 2011	Spain	Physicians attitudes and frequency of traditional cardiovascular risk factors in primary prevention in Spain: Spanish results of the EURIKA study	The full paper was not available
Bonner et al., 2014	Australia	I don't believe it, but I'd better do something about it: Patient experiences of online heart age risk calculators	Wrong intervention
Brotons et al., 2013	Spain	Implementation of Spanish adaptation of the European guidelines on cardiovascular disease prevention in primary care	Wrong intervention
Bucki et al., 2014	Australia	Finding enablers and knowing barriers - Facilitating primary health care nurses to implement an absolute CVD risk approach in general practice	The full paper was not available
Byrne et al., 2012	Ireland	Preventing cardiovascular disease (CVD): A survey of Irish general practitioners' awareness of risk assessment tools and cardiovascular disease prevention guidelines	The full paper was not available/Duplicate to Byrne et al. 2015 on reading abstract
Dallongeville et al., 2010	-	A survey of physicians' attitudes toward the control of cardiovascular risk factors. The eurika study	The full paper was not available
Dallongeville et al., 2010	France	Physicians' attitudes and frequency of traditional cardiovascular risk factors in primary prevention in France. The EURIKA study	The full paper was not available
Delpech et al., 2016	France	Primary prevention of cardiovascular disease: More patient gender-based differences in risk evaluation among male general practitioners	Wrong outcomes
Du et al., 2010	-	Identifying barriers toward implementing absolute cardiovascular risk assessment tools in primary care setting	The full paper was not available

George et al., 2016	India	Barriers to cardiovascular disease risk reduction: Does physicians' perspective matter?	Wrong outcomes
Graham et al., 2006	Germany, France, Italy, Spain, the UK and Poland	Factors impeding the implementation of cardiovascular prevention guidelines: findings from a survey conducted by the European Society of Cardiology	Wrong intervention
Gupta et al, 2009	Australia	Cardiovascular risk assessment in Australian general practice	Wrong outcomes
Hobbs et al., 2010	Europe	Barriers to cardiovascular disease risk scoring and primary prevention in Europe	Wrong study design
Khambatta et al., 2010	U.S. A	Recognition of cardiovascular risk factors and implementation of primary prevention interventions with utilization of an on-line form	The full paper was not available
Muylder et al., 2004	Belgium	Obstacles to cardiovascular prevention in general practice	Wrong outcomes
Manfrini et al., 2007	Italy	Barriers to clinical risk scores adoption	Wrong study design
Matangi et al., 2013	Canada	Awareness and use of cardiovascular risk scores by family physicians in south-eastern Ontario	Wrong outcomes
Matangi et al., 2013	Canada	Knowledge and implementation of cardiovascular risk scores by family physicians	The full paper was not available
McKillop et al., 2010	New Zealand	Barriers and Enablers to implementation of a New Zealand-wide guideline for assessment and management of cardiovascular risk in primary health care: A template analysis	Wrong intervention
Mendis et al., 2004	Nigeria	Barriers to management of cardiovascular risk in a low-resource setting using hypertension as an entry point	Wrong outcomes
Miserez et al., 2011	Switzerland	A survey of physician's attitudes towards the control of cardiovascular risk factors. Swiss results of the EURIKA study	The full paper was not available
Mohtaseb et al., 2013	-	Total cardiovascular risk assessment: What do doctors know about?	The full paper was not available
Murray et al., 2013	Canada	Knowledge and implementation of cardiovascular risk scores by family physicians in southeastern Ontario	The full paper was not available

Appendix 9. Characteristics of included studies

Author and year	Country	GNI Classification	Study design	Participant characteristics	Type of cardiovascular assessment tool	Outcomes measured
Quantitative studies						
Abaci et al. 2010	Turkey	Upper Middle Income	Cross-sectional study	Doctors	ESC SCORE, Framingham, Modified Framingham, ESC Hypertension	Characteristics of the patients and distribution of risk factors, distribution of the guidelines used to manage the cardiovascular risk, reasons for not using any guidelines, use of scoring methods for the calculation of cardiovascular risk and reasons for not using scoring methods.
Bonnevie et al. 2005	Denmark	High Income	Survey	General Practitioners	Computerised program (PRECARD) that uses the Copenhagen Risk Score	Characteristics of PRECARD users or non-users, how often the program was used with different kinds of patients, the effect of the program on the patients according to general practitioners, reasons for no longer using the program in non-users.
Byrne et al. 2015	Ireland	High Income	Cross-sectional study	General Practitioners	SCORE system	Demographic characteristics, awareness and use of risk assessment tools and CVD prevention guidelines among Irish GP cohort, barriers to the use of RA tools, barriers to the implementation of CVD prevention guidelines, barriers to optimal management of CVD risk
Eichler et al. 2007	Switzerland	High Income	Survey	General Practitioners	PROCAM-score, EU-SCORE, Framingham score, AGLA score (PROCAM-derived Swiss risk score), New Zealand Guidelines	Frequency of specific obstacles for application of cardiovascular prediction rules among physicians
Dallongeville et al. 2012	Austria, Belgium, France, Germany, Greece, Norway, Russia, Spain,	High Income	Survey	Physicians	SCORE system, risk assessment tables contained in the ESC/ESH Guidelines for the Management of Arterial Hypertension, risk assessment systems based on the Framingham study, locally calibrated Framingham study based equations	Characteristics of participating physicians, reasons for not using clinical guidelines among non-users, proportion of physicians using clinical guidelines for CVD prevention, use of global CVD risk factor assessment tools, proportion of physicians using global CVD risk assessment tools, limitation of risk assessment tools, communication strategies usually used for the management of behavioural risk factors and barriers to CVD prevention

	Sweden, Switzerland, Turkey and the UK					
Elisaf et al. 2014	Greece	High Income	Cross-sectional study	Physicians	ESC SCORE, Framingham, ESC & ESH Hypertension 2007	Characteristics of the physicians, patients and distribution of risk factors, distribution of the guidelines used to manage the cardiovascular risk, reasons for not using any guidelines, use of scoring methods for the calculation of cardiovascular risks, reasons for not using scoring methods, limitations of risk assessment tools, barriers to CVD primary prevention, achievement of goals among patients treated for the main risk factors in Greece, residual cardiovascular risk in patients achieving treatment goals.
Elustondo et al. 2013	Spain	High Income	Descriptive transversal study/cross-sectional study	Doctors	Tables; Framingham, ATP III, REGICOR, SCORE	Demographic data, professional circumstances (number of years working in primary care, postgraduate titles, workload), doctors' opinion on the cardiovascular risk tables, the use of these tables in daily clinical practice and main barriers when using them.
Imms et al. 2010	Australia	High Income	Survey	General Practitioners	New Zealand Absolute Risk Calculator, Absolute Risk, Joint British Coronary Risk Prediction Chart 2	General practitioners' demographics, knowledge, cardiovascular risk calculator use, cardiovascular risk factor importance, instrument validation
Schmieder et al. 2012	Germany	High Income	Comparative cross-sectional study	Physicians	ESC CVD prevention, ESC/ESH hypertension, ATP III, JNC VII, Local - ESC score, ESC/ESH hypertension, Framingham study, Framingham localised*	Physicians' attitudes toward risk factor control, patient characteristics and degree of risk factor control, perspectives to improve care
Shillinglaw et al. 2012	U.S.A	High Income	Cross-sectional web-based survey	Physicians	Paper charts, web-based, non-web-based computer program, program on a personal assistant	Demographics, awareness and use of tools to calculate global CHD risk, physicians who use global CHD risk assessment, reasons for not using global CHD risk assessment.
Sposito et al. 2009	Brazil, U.S.A, Greece, Chile, Venezuela, Portugal, The Netherlands, Central	Upper Middle Income, High, Lower Middle Income	Cross-sectional study	Physicians	FRS, Heart Score, PROCAM, JBS score	Respondent characteristics, physicians' presumption of CVD risk, regular use of CVD risk scores, reasons for non-use of CVD risk scores, indication for lipid-lowering therapy,

	America (Costa Rica, Panama, El Salvador and Guatemala)					
Tawfik et al. 2015	Egypt	Lower Middle Income	Cross-sectional study	Physicians	The WHO CVR score, Framingham, British risk score.	Demographics, awareness and use of the cardiovascular risk scoring tools, type of tools used, barriers to use, cardiovascular risk factors.
Qualitative studies						
Bonner et al 2013	Australia	High Income	Qualitative; semi-structured interviews; framework analysis	General Practitioners	Unclear	Use of different cardiovascular risk assessment strategies
Doolan-Noble et al 2010	New Zealand	High income	Qualitative; focus group discussions; thematic analysis	GPs and Practice Nurses	Predict, EDGE	The patient, primary health care providers, the general practice, the health care system
Liew et al 2013	United Kingdom	High Income	Qualitative; face to face interviews; thematic analysis	General Practitioners	Framingham, QRISK	What do practitioners say the risk scores predict? Do practitioners use risk scores in patients already on treatment? How do practitioners take account of treatment? How do practitioners choose which score to use? Do practitioners think score accuracy matters?
Torley et al. 2005	Australia	High Income	Qualitative; focus group discussions; thematic analysis	General Practitioners	New Zealand risk score, Medical Director, Joint British Coronary Risk Prediction Charts.	Respondent demographics, current methods of cardiovascular risk assessment, current use risk of assessment tools, problems with cardiovascular risk assessment tools, absolute vs relative risk
Vaidya et al. 2004	Australia	High Income	Qualitative, semi-structured interviews; thematic analysis	General Practitioners, patients	Absolute cardiovascular risk assessment - unclear about the exact tools	Risk communication, factors promoting/preventing change over 12 months in patients and physicians, factors influencing the maintenance of use in General Practitioners, impact on management after 12 months
Van Steenkiste et al. 2004	The Netherlands	High Income	Qualitative; semi-structured in-depth interviews; thematic analysis	General Practitioners	Risk tables	Demographics, barriers relating to the guideline-Risk table as an instrument, barriers relating to the guideline/content of the risk table (recommendations), attitude, routines, knowledge, skills, society, medical profession, practice organisation.
Van Steenkiste et al. 2004	The Netherlands	High Income	Qualitative; semi-structured in-depth interviews; thematic analysis	Patients	Risk tables	Demographics, barriers related to patients' ideas about cardiovascular disease and risk factors, barriers related to patients' risk perception (fears), expectations for information and treatment

Wan et al 2008	Australia	High Income	Qualitative; focus group discussions and interviews; thematic analysis	GPs, patients and key informants	New Zealand CVAR electronic and paper-based calculators	Demographic information, conducting a cardiovascular risk assessment in a General Practitioners' consultation, patient self-assessment, shared approach in CVAR assessment and management
Wan et al 2008	Australia	High Income	Qualitative; focus group discussions; thematic analysis	GPs and patients	New Zealand CVAR electronic and paper-based calculators	Demographics, patient age, risk factors and wellbeing, pre-existing GP-patient relationship, patient awareness and motivation, initiation of consultation for CVAR assessment
Mixed methods studies						
Collins et al. 2017	Jordan	Lower Middle Income	Mixed methods; quantitative (descriptive) and qualitative (one on one, face to face, semi-structured interviews; thematic analysis) strands of equal priority, integrated during data collection and interpretation	Doctors, nurses, health promoters, pharmacists, and managers	WHO/ISH CVD risk chart	Quantitative: the WHO/ISH CVD risk distribution of the included population, lipid-lowering treatment prescribing patterns based on calculated CVD risk category, agreement between documented and calculated WHO/ISH CVD risk scores and agreement between documented and calculated WHO/ISH CVD after aggregating by the clinically significant threshold of WHO/ISH risk of 20%, where individuals with a history of CVD are categorised as high risk. Qualitative: summary of qualitative findings with example quotations.
Ferrante et al. 2013	Argentina	Upper Middle Income	Mixed methods; qualitative (in-depth interviews following a grounded theory framework) and a cross-sectional before and after analysis study	Physicians, nurses, social workers, primary health care area coordinators/managers, county secretaries of health	WHO/ISH	Barriers to preventing cardiovascular disease and implementing clinical practice guidelines in primary care, the impact of implementing a tailored enactment of the adapted WHO guidelines to prevent cardiovascular diseases.
Kirby et al. 2009	United Kingdom	High Income	Mixed methods; survey and qualitative study (focus group discussions and semi-structured interviews; thematic analysis)	GPs, practice nurses, nurse practitioners and patients	JBS 2 paper charts and calculator	Use of Joint British Societies 2 paper risk charts and electronic cardiovascular risk assessment calculator, reasons for discontinuing use of the electronic calculator and factors that would have facilitated the use of it, patients' understanding of the use of cardiovascular risk tools.

Oriol-Zerbe et al. 2007	Germany	High Income	Mixed methods; quantitative (descriptive cross-sectional study) and qualitative (semi-structured interviews; thematic analysis)	Physicians	US guideline (NCEP III) – Framingham Risk Score, European guideline for risk scoring	Calculation of coronary risk, Summary of comparison between guidelines/risk, use of risk-calculator charts and guidelines for primary prevention, Barriers for prescribing lipid-lowering therapy in primary prevention, tabulations and prescribing by GPs, In what case was the diagnosis of hyperlipidemia given to the patient? Reasons for prescribing/not prescribing.

Appendix 10. Appraisal of quality for the included studies

i) Quantitative studies

Author	Abaci 2012	Bonnevie 2004	Byrne 2015	Dallongeville 2011	Eichler 2007	Elisaf 2014	Elustondo 2013	Imms 2010	Schmieder 2012	Shillinglaw 2012	Sposito 2009	Tawfik 2015
Were the aims/objectives of the study clear?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Was the study design appropriate for the stated aim?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Was the reference population clearly defined? Is it clear whom the research was about?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Was the sample frame taken from an appropriate population base so that it closely represented the reference population under investigation?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Were measures undertaken to address and categorise non-responders?	no	no	no	no	no	no	no	yes	no	no	no	no
Were the risk factor and outcome variables measured appropriate to the aims of the study?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	no	yes	yes	do not know	yes	yes	yes	yes	do not know	yes	do not know	yes

Is it clear what was used to determine statistical significance and/or precision estimates? (e.g. p-values, confidence intervals)	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Were the methods (including the statistical methods) sufficiently described to enable them to be repeated?	yes	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Were the basic data adequately described?	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Does the response rate raise concerns about non-response bias?**	do not know	yes	yes	yes	yes	yes	yes	yes	yes	yes	do not know	no
If appropriate, was information about non-responders described?	no	no	no	no	no	no	no	no	no	no	no	no
Were the results internally consistent?	yes	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes
Were the limitations of the study discussed?	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?**	no	no	no	yes	no	yes	do not know	no	yes	no	no	do not know
Was ethical approval or consent of participants attained?	yes	do not know	yes	yes	do not know	do not know	do not know	yes	yes	yes	do not know	do not know

ii) Qualitative studies

Author	**Bonner 2013**	**Doolan-Noble 2010**	**Liew 2013**	**Torley 2005**	**Vaidya 2012**	**Van Steenkiste 2004**	**Van Steenkiste 2004**	**Wan 2008**	**Wan 2010**
Is a qualitative approach appropriate?	yes	yes	yes	yes	yes	yes	yes	yes	yes

Is the study clear in what it seeks to do?	yes	yes	yes	yes	yes	yes	yes	yes	yes
How defensible/rigorous is the research design/methodology?	defensible	defensible	defensible	defensible	defensible	defensible	defensible	defensible	defensible
How well was the data collection carried out?	appropriately	appropriately	appropriately	appropriately	appropriately	appropriately	appropriately	appropriately	appropriately
Is the role of the researcher clearly described?	clearly described	clearly described	clearly described	unclear	clearly described	clearly described	clearly described	clearly described	clearly described
Is the context clearly described?	clearly described	clearly described	clearly described	clearly described	clearly described	clearly described	clearly described	clearly described	clearly described
Were the methods reliable?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Is the data analysis sufficiently rigorous?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Is the data 'rich'?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Is the analysis reliable?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Are the findings convincing?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Are the findings relevant to the aims of the study?	yes	yes	yes	yes	yes	yes	yes	yes	yes
Conclusions? Is there adequate discussion of any limitations encountered?	yes	yes	yes	yes	yes	yes	yes	yes	yes
How clear and coherent is the reporting of ethics?	appropriate	appropriate	appropriate	inappropriate	appropriate	appropriate	appropriate	appropriate	appropriate
Is the study relevant?	yes	yes	yes	yes	yes	yes	yes	yes	yes

How well was the study conducted? ++, + or -	++	++	++	+	++	++	++	++	++

iii) Mixed methods studies

Author	**Collins 2017**	**Ferrante 2013**	**Kirby 2009**	**Oriol-Zerbe 2007**
Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)?	yes	yes	yes	yes
Do the collected data address the research question (objective)?	yes	yes	yes	yes
Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?	yes	yes	yes	yes
Is the process for analyzing qualitative data relevant to address the research question (objective)?	yes	yes	yes	yes
Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected?	yes	yes	yes	yes
Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?	yes	yes	no	no
Are participants (organizations) recruited in a way that minimizes selection bias?	yes	yes	no	no

Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?	yes	yes	yes	yes
Is the sample representative of the population understudy?	yes	yes	yes	yes
Are measurements appropriate (clear origin, or validity known, or standard instrument)?	yes	yes	can't tell	can't tell
Is there an acceptable response rate (60% or above)?	n/a	n/a	yes	no
Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?	yes	yes	yes	yes
Is the integration of qualitative and quantitative data (or results) relevant to address the research question(objective)?	yes	yes	yes	yes
Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design?	yes	yes	yes	yes
Overall scoring metrics	**100% (****)**	**100% (****)**	**75%(***)**	**75%(***)**

Appendix 11. Summary of facilitators and barriers as coded using the Consolidated Framework of Implementation Research

CFIR Domains (definition and constructs)	Facilitators	Barriers
Intervention characteristics - **Key attributes of an intervention** **Intervention source, evidence strength & quality, relative advantage, adaptability, trialability, complexity, design quality & packaging and cost**	Based on the latest scientific evidence - (113,115,143) 'I kind of assumed that, maybe naively, that the data is updated ... I wouldn't pretend to understand … I think intuitively it makes sense that the older data is probably going to be more useful but I don't know.' – GP (115) Perceived to predict CVD risk accurately and include the main risk factors for cardiovascular disease – (113) Evidence that the tools better therapeutic decisions - (113,124,126,129,131,138–140) 'It depends on the level of risk. If the risk is rela- tively low you would give advice that's relevant to that aspect of risk, and if the risk is high you then you obviously have to think of what things to put in place immediately, down the track, follow up (GP group 1).'' - (121) Evidence that the tools improve patient care - (313,314) 'I think the strength of the absolute risk concept is that it improves the targeting of certain interventions, so that you have a greater accuracy when you're prescribing things like Statins but also a greater accuracy and confidence when you prescribe just behavioural measures like diet and exercise… (KI 6).'' - (121) Evidence that the tools reduce CVD risk adequately - (123) Perceived as beneficial - (124,313) "I think I'm using it with most of patients because the score gives you a clear idea about the risk and how to react so I depend on it a lot."– Doctor B (124) Helps understand CVD risk - (113,116,117,123,124,128,134,140) "So we are just, I mean showing indication that you are in the green area, [...] so you don't need to take aspirin because you might have side effects more than the benefits from aspirin and actually a lot of them they are convinced [...]. So it is very helpful and it is convincing."– Doctor E (124)	Distrust of their predictive ability - (108,113,114) GP8: 'So you take your population at year zero, you follow them all through but you don't actually know who's been treated. Oh gosh, yes, so that actually brings huge inaccuracy into the risk scores then.' - (134) Perceived interference by other stakeholders - (114) Lack of consensus on the use of the tools - (113,119) "I've seen three changes in long-term condition strategies, at a government level. And there is no consistency going down the line about how we should work within those strategies…" (F2) - (119) Perceived lack of prediction accuracy resulting to overestimation or underestimation- (106,108,110,126,134) GP3: 'It's obvious when you think about it, that there's an issue about how treatment is going to change outcomes. And that'll interfere with prediction.' - (134) Tools do not consider some important risk factors - (106,110,114,126,129) 'The calculator of course doesn't include certain factors . . . if someone does do a lot of exercise I would . . . think their risk is probably lower' (ID16, male, 9 years' experience) - (129) Tools focus too much on risk - (117) Tools do not consider the complexity of the patient - (108,114,116,117) 'We actually know the patient quite well and their background and their habits now so it's easier for us to make an overall assessment. (ID6, female, 19 years' experience)' - (129) Tools lead to over treatment or under treatment - (108,113,114) Tools are rapidly outdated - (116,315,316) "At this health center we don't have enough time to keep us up to date with new evidence of guidelines." [attending family physician] - (316) Tools are perceived to not have any beneficial use - (106,110,126,313,317) Tools are perceived as less superior to clinical judgement - (113,116,142,143)

Helps to motivate patients - (117,128,129,140)
“I actually do use the risk calculator to give them a percentage . . . I use the calculator for, as a bit of grounding for me but also as a way of motivating a patient” (ID16, male, 9 years’ experience) - (129)

Helps improve follow up - (117)

Helps in educating patients - (126,136)
...I’ve got one program where you can show the patient how the risk changes as you run the blood pressure down, or change the cholesterol. It’s quite a powerful tool...’ - (136)

Tools are a checklist to avoid missing something - (116,128,129)
Before, I probably would not have instituted treatment, because their blood pressure wasn’t that high and their lipids weren’t that bad. But now when you see the risk score, it has probably made you think I’d better start treatment. – GP - (128)
Tools increased compliance to advice given to patients in consultations - (123)

The use of the tools was perceived as feasible in daily practice - (113)

The tools are easy to use - (123,128,134)
It is not difficult to use, doesn’t take a long time. They can see it in front of them. They like it even more because it is on the computer. – GPs - (128)

Tools are easily understood by patients - (128)
You know, to me 11, 12 percent. I would assume that anybody with no heart problems would have that sort of risk. If it had gone into the 20s and 30s I would have been worried. – patient - (128)

The use of charts - (126,143,313)
“I think the doctors who don’t use paper-based things, they are quite used to [information technology], they are using [absolute risk], but for us like I am in the middle-aged group, still using paper work so it’s a bit of an effort” (passive disregard) - (143)
Use of colours to classify risk - (124)
“From my experience the colours are best for our
patient from numbers.” – Nurse E - (124)

The use of software - (126)

Using a web based application - (313)

[AR assessment] doesn’t take into account your family history, your weight, if you’re active or not . . . when you’ve been in this game for as many years as I have you like to get a big picture.
(ID22, male, 22 years’ experience) - (143)

Tools are time consuming - (106,108,110,113,114,126,139,313,317,318)

Tools prolonged consultations - (117,124)
‘’So if it’s the first time the patient is coming I need to wait for the labs to calculate what the percentage is.” – Doctor A - (124)
Tools lowered the quality of the consultation - (117)

Tools do not allow the calculation of risk in the elderly - (106,110,126)

The risk duration calculated by the tools are too long - (106,110)

Tools interfere with the GPs decision making process - (117)

Some of the risk factors required for risk prediction are not measured in the practice - (108,125)
“At our primary health care centres, we do not have appropriate resources to follow cardiovascular guidelines, particularly with keeping an information system and performing laboratory tests.” [nurse] - (125)

Explaining the results of the tool to patients is complicated – (135,136,319)
The trouble with such a table is that you cannot discuss it with patients. Patients are generally not familiar with statistics, so for nine out of ten of them reading a graph is not something they
Implementing cardiovascular risk tables in general practice are used to. Let alone interpreting tables with red, yellow and white colours. (GP4) - (135)

The prediction rules are unclear - (108,115)
GP18: ‘If someone’s on blood pressure treatment, do you say that treatment of blood pressure reduces [the assessed risk] by two thirds and therefore you need to modify for the third as not being attenuated? It’s all very, very grey, isn’t it?’ - (115)

The tool has technical problems - (117)

The tool does not communicate with other programs - (117)

	Use of a program on a PDA or smartphone - (136,313) Having a computer prompt - (123) Incorporating the tool into the GPs clinical systems - (123,128) We have our own medical program. To use something else on top of that is quite cumbersome. It's gotta be incorporated otherwise it is very unlikely I will ever use it. – GP - (128)	
Outer setting – ***includes;*** **Patients' needs & resources, cosmopolitanism, peer pressure and external policy & incentives**	Patients' demand for risk assessment - (122,135,136) '…But if I decide not to test them, it just means you spend 10 minutes explaining why it's not necessary. Three months later they turn up at your office and say they want it anyway. That annoys me, especially since I've spent an extra 10 minutes on them. I've given up fighting it. (GP8)' - (133) If I want to know, I feel it's my right to know - (127) Patients' perception of cardiovascular risk assessment as essential - (122) 'A media campaign would make it easier for us, because to start with some of the patients may consider this is just a way of us getting more business out of them, and that would make it not valuable for them, but when they come and ask for it because they've seen it in the media they make a lot of value and they will be more motivated and more committed... (GP FG3) ' -(122) Patients' relationship with the GP - (122) 'If they're just a floating patient coming to see you for a cough or cold or whatever it is, they probably have a regular doctor to go back to and follow through, but if you have some problems with your regular doctor, I'll find some time to go through it with you at least then you can get their confidence and show them a reason...it depends how you approach them. (GP FG1)' - (122) The feeling that the society has the right through approved guidelines and tools - (116)	Patients focus on a single risk factor not the total risk - (140) Patients do not want to know their cardiovascular risk - (108,114,124,320) "We tell them that I like to add statin a new medication that's called statin, it's for cholesterol. And they usually react", "I don't have any cholesterol and no I don't have any problems with my cholesterol," or "something like that."– Doctor A - (124) I think that is wrong; you go there for some other disease and they still challenge you about your smoking. If I'm told to stop smoking they should also provide me with the means to quit. – patient - (320) Patients may not afford some of the investigations required by the tool - (114) Patients' personal circumstances and experiences - (119,124,128) "Some patients gradually decrease their cigarettes, but suddenly when they come""I increased my consumption.""Why?""Because my brother left away in Syria, because my son died, because I need more money."– Nurse B - (124) Patients health priorities as perceived by them or by the clinicians - (119,121,125) "Patients usually prioritize urgent health problems and not prevention actions. We have to respond to this demand." [decision maker] - (125) "So as a doctor my first priority is actually to treat the illness… and when I'm treating illness, my first priority is to treat the most urgent illness first." (F3) - (119) Patients' perceptions and understanding of cardiovascular risk - (121,129,133)

The focus of funding by external organisations – (119)
"…if I am blunt about it, guided by where we get our funding from. Care Plus gives us funding. Diabetic Project gives us funding. Immunisation gives us funding." (F3) - (119)

Available supportive care pathways/programs and their longevity - (119)
"There's a really good pathway that was set up when, before we started this, which was, you know, the free GP visit… the dietician visit, the Green Prescription. And it's really good." (F2) - (119)
"Short-term contracts to run pilots, which just as you are gaining some traction the contract runs out, funding ceases and the programme falls over." (F1) - (119)

Patients' access to information - (122)
'It's a lot easier to look after your health now, because they have all these programs, there is the... Program, walking groups, all these places where you can get education. (Patient FG3) - (122)

'As a result, the general public have unrealistic ideas about the contribution of cholesterol to the absolute cardiovascular risk, and the topic is fraught with anxiety. This whole cholesterol story is based on people's anxiety. If you're anxious, get your cholesterol level tested. It used to be: get your blood pressure tested. It's all to do with anxiety. It is linked to something it shouldn't be linked to. (GP5) - (135)

Patients demand for treatment regardless of cardiovascular risk - (124,315)
'If my blood pressure is too high, I should be given medication, whether I'm in the high-risk group or not.' - (315)

"Yes. Many of our women didn't want to follow diet regimen or DM diet… they want medication to lose weight and they ask about medication." // "I told them that it's not useful…but many of them search about them and bring and use."– Nurse E - (124)

Patients' environment and surroundings - (119,124)
"The environment many of our patients live in is not conducive to making lifestyle behavioural changes… multiple fast food outlets, pavements may not be safe, lack of cycle ways etc." (F1) - (119)

Patients' perceptions and understanding of cardiovascular disease and treatment - (124,131,321)
""If I drink a cup of water plus one tablespoon of vinegar, it's bad on the cholesterol?" This is a common question." // "It's something usually in Facebook."– Person A - (124)

"Sometimes they accept the neighbours' opinion more than us."– Nurse A

The use of these tools may be misused externally by health authorities (114)

There are no adequately structured systems in the clinic to ensure primary prevention in CVD i.e. lack of staff, inadequate budgeting, lack of interest by managers and inadequate encouragement of doctors - (106,119,126)
"Ministry talks a lot about prevention of illness and disease, but they just don't fund it. It's expected to happen." (F2) - (119)

Health system's priorities - (119,124,316)
"We are overwhelmed with urgent social and health problems and we can't prioritize prevention activities." [social worker] - (316)
"Our model of care is based on satisfying the demand of patients, mainly acute problems, without a focus on chronic condition follow up." [decision maker] - (316)

Conflicting priorities between stakeholders - (133)

		‘’If we’d really do primary prevention, you’d have to follow hundreds of people for maybe ten or thirty years to prevent one event. And you don’t know who it’s going to be, which is a big problem because it results in lots of tension and disappointment. Let the local health authorities take care of that, that’s fine with me.’’ (GP10) - (133)
Inner setting - **The inner setting is recognized as an active interacting facet which includes;** **Structural characteristics, networks and communications, culture, implementation climate and readiness for implementation**	A sense of group identification with the risk and disease for patients - (124) ““I think the refugees become more relax when they talk together, see same cases like”, “I’m not the only one. I have cardio or I have DM there’s a lot of person like me.” It’s more unique. I think it’s more effective than the individual session.”– Person A - (124) Organisation the prevention activities to which patients are referred - (119) “…if I sent them to a dietician, or to Pacific Health for Quitline or Smokefree they don’t go, but if it’s here somehow I think it’d be easier.” (F3) - (119) The availability of the tools during consultation - (143) I could just never find them [AR charts] when I needed them so . . . it’s being able to put your finger on it when you need it and if it was available. I don’t even know if it’s available on our computer program. (ID1, female, 16 years’ experience) - (143)	Lack of time to assess for risk associated with high workload - (122,316) “We have a lot of workload in order to allow us to review guidelines for each visit.” [nurse] - (316) I think sometimes they’ve got so many patients that and they’ve got so much to do, and they look at you, and they, you know? They actually don’t test you for some of the things that I think they should... it’s been my initiative for nearly everything that’s wrong...I’ve found that I had to ask for a lot of things. (Patient FG2) - (122) Lack of close collaboration between health care workers - (316) “We usually don’t work in close collaboration with physicians and administrative staff due to communication problems due to our work overload.” [administrative staff] - (316) Lack of health information systems - (316) “We don’t have information systems in order to help us to follow up and manage patients with risk factors.” [attending family physician] - (316) Inadequate resources to support risk assessment - (106,113,124,126,316,322) “At our primary health care centers, we do not have appropriate resources to follow cardiovascular guidelines, particularly with keeping an information system and performing laboratory tests.” [nurse] - (316) The difficulty of communicating preventive care and self-management to patients by clinicians - (119) “The concept of preventive care and ‘self-management’ is often a difficult one to impart.” (F3) - (119) Practice culture and professional hierarchy - (133) Specialists have greater influence, in the sense that changing the treatment initiated by a specialist is very difficult for a GP. There are lots of people who’ve been to see the cardiologist for an a-typical angina, who didn’t actually have angina, but a transiently abnormal lipid spectrum, and who comes back with a statin. You just try and reverse that. It’s impossible. (GP1) - (133) The patients’ socio-economic status -(124)

		"Sometimes our patients are shamed to tell you about that. Just you hear""you must take vegetables, fruit just one time a week.""They are still silent, because sometimes they do not have anything. That is the problem. It is better, I think, in the home visit to give a good picture or clear picture"– Nurse F - (124) Lack of knowledge about the tools - (316) "I am not aware of any guide to manage risk factors." [nurse] - (316)
Characteristics of individuals - **Organisations are made up of individuals. Setting and intervention constructs are rooted, ultimately, in the actions and behaviours of individuals. These include;** **Knowledge & belief about the intervention, knowledge & belief about the disease and risk factors, self-efficacy, individual stage of change, individual identification with organisation and other personal attributes.**	That the intervention was evidence-based - (143) I'm comfortable to be guided by the experts rather than try and invent too much on what might be dodgy assumptions on my part. (ID31, male, 30 years' experience) - (143) Clinician perception and understanding of cardiovascular risk and disease - (124,128,136,142,316,322) 'Instead of going in hard to the 80 year olds... we should be going in for longer for the 40 year olds who would not die younger'. - (136) Before, I probably would not have instituted treatment, because their blood pressure wasn't that high and their lipids weren't that bad. But now when you see the risk score, it has probably made you think I'd better start treatment. – GP - (128) Helps understand CVD risk - (113,116,117,123,124,128,134,140) "So we are just, I mean showing indication that you are in the green area, [...] so you don't need to take aspirin because you might have side effects more than the benefits from aspirin and actually a lot of them they are convinced [...]. So it is very helpful and it is convincing."– Doctor E (124) Helps to motivate patients - (117,128,129,140) "I actually do use the risk calculator to give them a percentage . . . I use the calculator for, as a bit of grounding for me but also as a way of motivating a patient" (ID16, male, 9 years' experience) - (129) Helps improve follow up - (117) Helps in educating patients - (126,136) ...I've got one program where you can show the patient how the risk changes as you run the blood pressure down, or change the cholesterol. It's quite a powerful tool...' - (136)	Not knowing how to use the tool - (106,107,110,116,124,126,317,324) "Yes, they are 90 years old. When I look at them", "Okay, we will not do the risk assessment for this patient". Because I don't know how."– Doctor D - (124) "I am not aware of any guide to manage risk factors." [nurse] - (124) Perception that prevention will not reduce total health care costs by clinicians - (108) Perception that the tools would not reduce health care costs - (114) Defensive medicine - (135) 'If you see a cholesterol level of 8 in a 48-year-old man, your first reaction is a statin. But then, if you check the table, it may turn out he doesn't need one. That is a different approach. But in the back of your mind you still think: what if he gets a heart attack and it then turns out he had a cholesterol level of 8 all the time and nothing was done about it? (GP6) - (135) Suppose he gets a myocardial infarction in the future and then they find a cholesterol level of 8.0. There will always be someone who says: ''You mean to say he never checked your cholesterol?'' (GP15) - (135) The prediction rules are unclear - (108,115) GP18: 'If someone's on blood pressure treatment, do you say that treatment of blood pressure reduces [the assessed risk] by two thirds and therefore you need to modify for the third as not being attenuated? It's all very, very grey, isn't it?' - (115) Clinician perceptive of cardiovascular risk and disease -(128,143) I've not used the cardiovascular risk assessment terribly much lately because we find that really at the end of the day the whole thing is just weight reduction. (ID36, male, 25 years' experience) - (143) If someone's got a known high cholesterol, I will treat that. If someone's got a high blood pressure, I will treat that. I don't need the risk

Knowledge about CVD risk, cardiovascular disease and its management. – (124)
"[if] the cardiovascular risk is 20–30 [%], we can decrease it by normalization of blood pressure that's high and the cholesterol level if it's high, we can give him 3 months to 4 months diet and then recheck it. If it's still high we can start statin to reduce it."– Doctor C - (124)

,
Patients' demand for risk assessment - (122,135,136)
'…But if I decide not to test them, it just means you spend 10 minutes explaining why it's not necessary. Three months later they turn up at your office and say they want it anyway. That annoys me, especially since I've spent an extra 10 minutes on them. I've given up fighting it. (GP8)' - (133)

If I want to know, I feel it's my right to know – patient (127)

In fact, I should believe what the doctor says, but then I start to think maybe it's something else and then I ask for a little check-up – patient (315)

Task allocation and shifting - (119)
"The doctors are more involved in risk assessment; the practice nurses are more concerned with the lifestyle management." (F1)
Patients' relationship with the GP - (122)
'If they're just a floating patient coming to see you for a cough or cold or whatever it is, they probably have a regular doctor to go back to and follow through, but if you have some problems with your regular doctor, I'll find some time to go through it with you at least then you can get their confidence and show them a reason...it depends how you approach them. (GP FG1)' - (122)

I think it's being able to talk to your doctor, have faith in him and be comfortable with it. (Patient FG3) - (122)

Patients' personal circumstances and experiences - (119)

"I've just felt that I was getting nowhere with, then there's been something else that happened. For one it was another family member had a heart attack, and then it suddenly dawns on them, and all the work that you've done in the past is actually quite helpful." (F2) - (119)

calculator to tell me that I am meant to treat those risk factors. GP - (128)

Patients' perceptions and understanding of cardiovascular risk and disease - (119,121,124,129,133)
I do not think they can conclude from a blood sample whether you'll get cardiovascular disease. I have seen it with my neighbour across the street. He had been in for a check-up and the hospital had said that everything was all right. Well, the day after that he had a heart attack and he was gone – patient (135)

I had 6.3 (mmol/l) serum cholesterol and my GP would not give me those pills. I know, there are all kinds ofother factors involved, but my uncle also had high cholesterol and no risk factors and he still had a heart attack. Give me those tablets anyway. - (315)

"Some of the Maori and Pacific Island… have this perception… that their parents died at such an age so, they're not gonna make it past that age anyway, - (119)

Tools are perceived as less superior to clinical judgement - (113,116,136,142,143)
[AR assessment] doesn't take into account your family history, your weight, if you're active or not . . . when you've been in this game for as many years as I have you like to get a big picture.
(ID22, male, 22 years' experience) - (143)

"I just go by my judgement more than by the risk assessment . . . rather than giving it in percentile I usually go by low risk, high risk" (clinical judgement) -(129)

'...You have to rely on your clinical gut feeling
about that patient. Taking all the information that you have gathered to date, put it all together and compute it in your mind and then decide how hard you are going to chase each of these risk factors...' - (136)

The difficulty of communicating preventive care and self-management to patients by clinicians - (119)
"The concept of preventive care and 'self-management' is often a difficult one to impart." (F3) - (119)

"I personally feel I could spend a lot of time on these patients (those at high risk), but the actual outcome would be possibly minimal." (F3) - (119)

Lack of motivation to use the tools - (316)
"I am not motivated to read a guideline to treat my patients. I prefer to rely on my own knowledge and experience." [attending clinician] - (316)

	Positive relationship with the practice and the presence of supportive programs - (119) "There's a really good pathway that was set up when, before we started this, which was, you know, the free GP visit… the dietician visit, the Green Prescription. And it's really good." (F2) - (119) Patients' motivation/age – (323) The older you get, the less risk you want to run. I never used to think about that before, but now I do. Life's too good to want to die now. Maybe, I should have a cholesterol check-up every 6 months now that I'm almost 60. It does not mean I'm old, but the risk of getting something is increasing. – patient - (320) Presence of a support system (familial) for the patient - (128) It is a big step if you have got your family behind you. They have got to eat what I eat so there is no temptation. – patient (128)	Health system's priorities - (119,124,316) "We are overwhelmed with urgent social and health problems and we can't prioritize prevention activities." [social worker] - (316) "Our model of care is based on satisfying the demand of patients, mainly acute problems, without a focus on chronic condition follow up." [decision maker] - (316) Manifestation of CVD risk - (119) "…because they, don't feel unwell. They don't feel sick, so it's really difficult to get their attention, motivation to get things. Like say they, they come with gout or something, you know they know…" (F3) - (119) Clinicians' feeling of helplessness and unable to control patients behaviour with regard to prevention - (322) Clinicians' ethical values - (322) Patients' fears and expectations of cardiovascular risk assessment - (122,127) I do not need to know; that would only worry me more – patient - (127) Ignorance is bliss, as they say. The more you read about it, the more anxious you get. I know, I'm sticking my head in the sand. – patient - (323) I honestly believe I've been well looked after, but, ah, I don't know, it's hard to say. I hate going to the doctors to get me blood pressure tested. I really do. Just going there it goes up. (Patient FG2) - (122)
Process – ***Includes;*** **Planning, engaging, executing, reflecting & evaluating**	Attracting and involving appropriate individuals - (119,128) It is a big step if you have got your family behind you. They have got to eat what I eat so there is no temptation. – patient - (128)	Health system's priorities - (119,124,316) "We are overwhelmed with urgent social and health problems and we can't prioritize prevention activities." [social worker] - (316) "Our model of care is based on satisfying the demand of patients, mainly acute problems, without a focus on chronic condition follow up." [decision maker] - (316) Physicians' reflections on the use of tools - (119) "I personally feel I could spend a lot of time on these patients (those at high risk), but the actual outcome would be possibly minimal." (F3) - (119) Poor tool reviewing process - (119) "I've seen three changes in long-term condition strategies, at a government level. And there is no consistency going down the line about how we should work within those strategies…" (F2) - (119) The perception that the tool maybe misused - (316,322) Lack of structures such as information systems to execute - (316)

	“We don’t have information systems in order to help us to follow up and manage patients with risk factors.” [attending family physician] - (316) Unsustainable programs and funding to execute - (119) Short-term contracts to run pilots, which just as you are gaining some traction the contract runs out, funding ceases and the programme falls over.” (F1) - (119)

Appendix 12. Summary of the qualitative findings with their CERQual evidence profile and confidence assessments

Summary of the qualitative synthesis findings	Studies contributing to the review finding	Methodological limitations	Coherence	Adequacy	Relevance	CERQual assessment of confidence in the evidence	Explanation of CERQual assessment
<u>Healthcare system and clinical setting</u>: In this review, this refers to the organisation of people, activities, resources, and priorities in primary care settings. The factors that emerged from this construct included resources, system and practice-level priorities, the practice culture of the clinical setting, and how the practice was organised.							
Resources: **This referred to both physical and human resources. An adequately resourced health system with a dedicated budget for the prevention of cardiovascular disease was viewed as a facilitator to the implementation of cardiovascular risk scoring. The absence of cardiovascular risk scoring tools in the consultation room was a barrier to implementation.**	(Bonner et al. 2013, Doolan-Noble et al 2010)	No or very minor concerns about methodological limitations.	No or very minor concerns about coherence.	Serious concerns about adequacy – only two studies contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only two high-income countries (Australia and New Zealand). There was no data from low and middle-income countries.	No or very minor concerns about relevance – in one study, the specific risk scoring tools used was unclear.	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.
System and practice-level priorities: **In healthcare systems where prevention of cardiovascular disease was not seen as a priority for practice, cardiovascular risk scoring was implemented sub-**	(Doolan-Noble et al. 2010, Van Steenkiste, Van Der Weijden, Stoffers, et al 2004)	No or very minor concerns about methodological limitations.	No or very minor concerns about coherence.	Serious concerns about adequacy – only two studies contributed to this and both had relatively thin data. However, this was judged to be a	No or very minor concerns about relevance.	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns

optimally. Further, in some settings where prevention of cardiovascular disease was a priority, there was a conflict in deciding to whom this mandate belonged, i.e. clinicians versus local authorities.				relatively simple and primarily descriptive finding. Data was from only two high-income countries (The Netherlands and New Zealand). There was no data from low and middle-income countries.			about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.
Practice culture and organisation: **This encompasses a set of routine activities that are characteristic of a healthcare system or clinical setting. Task shifting, re-allocation, and sharing in GP practices helped focus tasks into either risk assessment or risk management, necessitating the use of cardiovascular risk scoring tools by clinicians. Uptake of cardiovascular risk scoring was also seen in GP practices that had existing cardiovascular prevention care programs and pathways. However, adequate organisation of these prevention activities was of importance, i.e. staffed by appropriate persons and proximity to the clinical settings, i.e. for the clinician and the patient. Defensive medicine, a practice of recommending tests or**	(Doolan-Noble et al. 2010, Van Steenkiste, Van Der Weijden, Stoffers, et al 2004, Vaidya et al 2012)	No or very minor concerns about methodological limitations.	No or very minor concerns about coherence.	Serious concerns about adequacy – only three studies contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only three high-income countries (The Netherlands, New Zealand and Australia). There was no data from low and middle-income countries.	No or very minor concerns about relevance.	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.

treatment that is not necessarily the best option to the patient but as a function to protect the clinician against liability, was reported to be a barrier to cardiovascular risk scoring. Another barrier was the presence of disruptive professional hierarchies, specialists or clinicians who ranked higher in practice were viewed in high regard even when they did not adhere to guidelines such as cardiovascular risk scoring. This set a precedent for practice in the clinical setting that junior clinicians did not feel empowered to question or disrupt.							
<u>Users</u>: This encompassed factors that related to the direct and indirect users of cardiovascular risk scoring tools, i.e. clinicians, patients, and other stakeholders. These factors included the attributes of these users and the interactions between those involved.							
Attributes of the users: **Both patients and clinicians** **For both patients and clinicians, the perception and understanding of cardiovascular risk, disease and its management was a significant driver for cardiovascular risk scoring. In most studies and for both clinicians and patients, there was a visible indication that cardiovascular risk, its assessment and management was marred with negative perceptions unsupported by evidence. For example, both clinicians and patients**	(Bonner et al 2013, Doolan-Noble et al 2010, Van Steenkiste, Van Der Weijden, Stoffers, et al 2004, Torley et al 2005, Vaidya et al 2012, Wan et al 2008a)	No or very minor concerns about methodological limitations – one the study did not report ethical approval and unclearly described the role of the researcher.	No or very minor concerns about coherence.	Moderate concerns about adequacy - Data was from only three high-income countries (The Netherlands, New Zealand and Australia). There was no data from low and middle-income countries.	No or very minor concerns about relevance - in one study the specific tools used was unclear	High confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were moderate concerns about adequacy, especially relating to the geographical spread of the studies contributing to the finding.

reported an understanding of cardiovascular risk focused on individual risk factors, i.e. relative risk as opposed to absolute or total risk.							
Patients **Personal circumstances and experiences of patients also influenced the uptake of cardiovascular risk scoring. These circumstances and experiences included the environment in which the patients lived, their socioeconomic standing, their fears, motivations and expectations of cardiovascular risk assessment and the support available for them. Patients' priorities, which were set either by the patients themselves or the clinicians, leaned towards what was considered 'urgent for the patient.' In many cases, cardiovascular risk scoring was not viewed as urgent enough in this hierarchy. However, there were patients who demanded to be assessed for cardiovascular risk and this facilitated cardiovascular risk scoring.** **Conversely, there were instances where patients demanded treatment regardless of their cardiovascular risk.**	(Doolan-Noble et al. 2010, Van Steenkiste, Van Der Weijden, Timmermans, et al 2004, Torley et al 2005, Vaidya et al 2012, Wan et al 2010)	No or very minor concerns about methodological limitations – one the study did not report ethical approval and unclearly described the role of the researcher.	Moderate concerns about coherence – the extent of coherence unclear due to limited data.	Moderate concerns about adequacy - Data was from only three high-income countries (The Netherlands, New Zealand and Australia). There was no data from low and middle-income countries.	No or very minor concerns about relevance.	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations and relevance. There were moderate concerns about adequacy and coherence, especially relating to the geographical spread of the studies and the limited data contributing to the finding.
Clinicians **Clinicians expressed difficulty in communicating**	(Doolan-Noble et al. 2010, Torley et	No or very minor concerns about methodological	No or very minor concerns	Serious concerns about adequacy – only three studies	No or very minor concerns	Moderate confidence	The studies contributing to this review finding had no or very minor

cardiovascular risk scores to their patients after risk assessment. This was coupled with challenges in offering prevention and self-management aids to patients. Knowledge about the tools and their benefits in clinical practice, such as improving care and bettering therapeutic decision making by clinicians facilitated the use of cardiovascular risk scoring.	al 2005, Vaidya et al 2012)	limitations – one the study did not report ethical approval and unclearly described the role of the researcher.	about coherence.	contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only two high-income countries (Australia and New Zealand). There was no data from low and middle-income countries.	about relevance		concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.
Stakeholders **Stakeholders, i.e. "decision-makers" who included policymakers and practice managers, were reported to lack interest or have conflicting interests regarding the prevention and management of cardiovascular risk. They lacked consensus on the use of risk scoring tools and had unsatisfactory processes in place to review continually risk-scoring tools used in practice.**	(Doolan-Noble et al. 2010, Van Steenkiste, Van Der Weijden, Stoffers, et al 2004)	No or very minor concerns about methodological limitations.	No or very minor concerns about coherence.	Serious concerns about adequacy – only two studies contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only two high-income countries (The Netherlands and New Zealand). There was no data from low and middle-income countries.	No or very minor concerns about relevance.	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.

Interactions between the users: **This was reported as the relationships between clinicians, patients and other stakeholders. A supportive and longstanding relationship between the clinician and patient facilitated the use of cardiovascular risk scoring. This was because clinicians felt that for 'floating' patients, they already had a regular doctor to whom this responsibility of prevention belonged. Consequently, the clinicians in this case were only interested in dealing with the immediate complaint from the patient. The interactions between the clinicians and the other stakeholders were on a policy level where there was no consensus on the use of these tools. This was partially explained by the lack of communication and involvement in decision making of clinicians and other stakeholders.**	(Doolan-Noble et al. 2010, Wan et al 2010)	No or very minor concerns about methodological limitations	No or very minor concerns about coherence	Serious concerns about adequacy – only two studies contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only two high-income countries (Australia and New Zealand). There was no data from low and middle income countries	No or very minor concerns about relevance	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.
<u>Cardiovascular risk scoring tools</u>: The factors influencing cardiovascular risk scoring were linked to the characteristics of the tools, the perceived role of the tools in clinical practice and the evidence of efficiency and effectiveness.							
Characteristics of these tools: **The use of charts, calculators and colour codes was reported to facilitate cardiovascular risk scoring due to the perceived ease of use. Besides, having these tools incorporated into existing clinical systems as**	(Doolan-Noble et al. 2010, Liew et al. 2013, Van Steenkiste, Van Der Weijden, Stoffers, et al 2004, Vaidya et al 2012)	No or very minor concerns about methodological limitations	No or very minor concerns about coherence	Moderate concerns about adequacy – only four studies contributed to this and all had relatively thin data. However, this was judged to be a relatively simple	No or very minor concerns about relevance	High confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There was moderate concerns about adequacy, especially

software or web-based applications was facilitative. This was while some studies reported that these tools were complex to use, to explain to patients and that they had technical problems. For example, some of the tools did not communicate with other clinical programs. Other studies pointed out that the tools outdated rapidly and consequently did not include all the important risk factors needed to assess for cardiovascular risk.				and primarily descriptive finding. Data was from only four high-income countries (Australia, New Zealand, United Kingdom and The Netherlands). There was no data from low and middle income countries			relating to the number of studies contributing to this finding and the lack of data from low and middle-income countries.
Their perceived role: **The perceived role of these tools in clinical practice was both a facilitator and a barrier to their use. For example, clinicians who used the tools saw it as helpful in understanding risk, motivating patients, improving follow up, educating patients, and as a checklist for risk assessment. Others saw it as an interference to the clinician's decision-making process. This, perhaps, is in relation to clinicians considering these tools to be less superior to their clinical judgement.**	(Bonner et al 2013, Torley et al 2005, Wan et al. 2008a)	No or very minor concerns about methodological limitations – one the study did not report ethical approval and unclearly described the role of the researcher	No or very minor concerns about coherence	Serious concerns about adequacy – only three studies contributed to this and both had relatively thin data. However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only one high-income country (Australia). There was no data from low- and middle-income countries	No or very minor concerns about relevance	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence and relevance. There were serious concerns about adequacy, especially relating to the number of studies contributing to this finding and their geographical spread.
Evidence of efficiency and effectiveness: **Unclear prediction rules were a barrier to using cardiovascular risk scoring tools, as this was associated**	(Bonner et al 2013, Liew et al 2013, Wan et al. 2008b)	No or very minor concerns about methodological limitations	No or very minor concerns about coherence	Serious concerns about adequacy – only three studies contributed to this and they had relatively thin data.	No or very minor concerns about relevance	Moderate confidence	The studies contributing to this review finding had no or very minor concerns about methodological limitations, coherence

with prediction inaccuracies. However, providing evidence that these tools were accurate in predicting risk, that they included the main risk factors for cardiovascular disease and that they led to better therapeutic decisions was facilitative.		However, this was judged to be a relatively simple and primarily descriptive finding. Data was from only two high-income countries (The United Kingdom and Australia). There was no data from low- and middle-income countries	and relevance. There were serious concerns about adequacy especially relating to the number of studies contributing to this finding and their geographical

Appendix 13. Table summary of the Consolidated Framework for Implementation Research (CFIR)

Table 28. Consolidated Framework for Implementation Research (CFIR) constructs with definitions (Damschroder et al., 2009)

Construct		Short Description
I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organisation, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised by the organisation.
B	Cosmopolitanism	The degree to which an organisation is networked with other external organisations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organisations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaborative, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organisation.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organisation.
C	Culture	Norms, values, and basic assumptions of a given organisation.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organisation.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and

		perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organisation.
4	Organisational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
E	Readiness for Implementation	Tangible and immediate indicators of organisational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterisation of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organisation	A broad construct related to how individuals perceive the organisation, and their relationship and degree of commitment with that organisation.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organisation who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
2	Formally Appointed Internal Implementation Leaders	Individuals from within the organisation who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the intervention may provoke in an organisation.

4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Appendix 14. Interviewers guide – healthcare professionals

Title: Exploring the use of Cardiovascular RIsk sCoring in primary care facilities in Kilifi County, Kenya (the CRICK study)

Investigators

Institution	Investigators
KEMRI-Wellcome Trust Research programme	Anthony Etyang
University of Oxford, Nuffield Department of Primary Care Health Sciences	Tonny Muthee, David Nunan, Carl Heneghan,

Ethics Reference No: KEMRI/SERU/CGMR-C/148/3807

Below is a list of questions to be discussed in this study. The study will remain flexible enough to help generate new ideas and accommodate participants' agendas. In addition, as this is a semi-structured interview, we may add new questions as the interviews progress, and data collection continues. However, the objectives of the study will remain key; to understand the current practice in cardiovascular risk scoring and to identify the facilitators and barriers to the use of cardiovascular risk scores in Kenyan primary care settings.

Personal Information - Interviewee

Unique identifier:	**Sex: Male/Female**		**Level of care: 2/3/4**
Name of hospital:			
Speciality/work area:			
Profession (please circle)	Medical Officer Line Manager	Nurse Other	Clinical Officer

Briefing:

1. Thank participant for agreeing to take part.
2. Introduce self
3. This interview is for the CRICK study. The aims were described in the participant information sheet. Cardiovascular risk scoring is an intervention that has been lauded for optimising prevention and management of cardiovascular risk in at-risk patients. There is little or no information on both, the current practice in the assessment of cardiovascular risk factors in resource-limited primary care settings such as Kenya and, the facilitators or barriers that may influence the use of these risk scores. It more about this that we would like to hear and we would value your unique perspective.
4. If at any time during the interview, you do not wish to answer a question, this is okay.
5. I would like to record our conversation digitally. The recording will be typed out, but everything you say will be anonymous. Your name, any names or places you mention will be taken out so that if someone reads your interview they would not know whom you are or where you work.
6. Your interview will remain confidential as discussed and outlined in the consent form.
7. If at any stage you wish to stop the audio recorder, please let me know.
8. Do you have any questions?

Section A: Understanding the current practice

1. What type of patients do you usually see in this practice?
2. Do you come across patients at high risk of cardiovascular disease?
3. How do you identify patients at high risk of cardiovascular disease, i.e. those at high risk of stroke and heart attack?
4. Is there a tool or guideline that you use to calculate or stratify the risk? If YES, which ones?
5. How does stratifying or scoring risk inform or guide patient management?

Section B: Determinants of implementation; cardiovascular risk stratification and scoring in Kenyan primary care settings

1. What kind of information or evidence are you aware of that shows whether or not cardiovascular risk scoring works in your setting?
2. How does this knowledge affect your perception of cardiovascular risk scoring?
3. What do administrative or other leaders think of this intervention?
4. How does the intervention compare to other alternatives that may have been considered or that you know?
5. What kinds of changes or alterations do you think need to be made to the intervention so it can work effectively in your setting?
6. How complicated is the intervention?
7. What supports, such as online resources, marketing materials, or a toolkit, are available to help you implement and use the intervention?
8. How well do you think the intervention will meet the needs of the individuals served by your organisation?
9. What kind of information exchange do you have with others outside your setting, related either to the intervention or more generally about your profession?
10. To what extent are other organisations implementing the intervention?
11. To what extent are other units within your organisation implementing the intervention?
12. Can you describe your working relationship with leaders? Your supervisor? Supervisors of other colleagues?
13. Can you describe your working relationship with influential stakeholders?
14. How do you typically find out about new information, such as new initiatives, guidelines, accomplishments, issues, new staff, and staff departures?
15. To what extent are new ideas embraced and used to make improvements in your organisation?
16. Is there a strong need for this intervention? Why or why not? Do others see a need for the intervention?
17. How well does the intervention fit with existing work processes and practices in your setting?
18. To what extent do you feel like you can try new things to improve your work processes?
19. Do you feel like you have the time and energy to think about ways to improve things?
20. What level of endorsement or support have you seen or heard from leaders?
21. Do you have sufficient resources to implement and administer the intervention?
22. Do you think the intervention is effective in your setting?
23. How confident are you that you will be able to implement the intervention successfully?

Closing question: Is there something else that I have not asked but you would like to tell me?

Thank you for taking the time today to help with our research.

Appendix 15. Interview guide – policymakers

Title: Exploring the use of Cardiovascular RIsk sCoring in primary care facilities in Kilifi County, Kenya (the CRICK study)

Investigators

Institution	Investigators
KEMRI-Wellcome Trust Research programme	Anthony Etyang
University of Oxford, Nuffield Department of Primary Care Health Sciences	Tonny Muthee, David Nunan, Carl Heneghan,

Ethics Reference No: KEMRI/SERU/CGMR-C/148/3807

Below is a list of questions to be discussed in this study. The study will remain flexible enough to help generate new ideas and accommodate participants' agendas. Also, as this is a semi-structured interview, we may add further questions as the interviews progress and, data collection continues. However, the objectives of the study will remain key; to understand the current practice in cardiovascular risk scoring and to identify the facilitators and barriers to the use of cardiovascular risk scores in Kenyan primary care settings.

The interview questions have been adapted from the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF) guides (97,227).

Personal information – interviewee

Unique identifier:	**Sex: Male/Female**		**County/National**
Name of the department:			
Specialty/work area:			
Profession (please circle)	Medical Officer	Nurse	Clinical Officer
	Other		

Briefing:

1. Thank participant for agreeing to take part.
2. Introduce self
3. This interview is for the CRICK study. The aims were described in the participant information sheet. Cardiovascular risk scoring is an intervention that has been lauded for optimising prevention and management of cardiovascular risk in at-risk patients. There is little or no

information on both, the current practice in the assessment of cardiovascular risk factors in resource limited primary care settings such as Kenya and, the facilitators or barriers that may influence the use of these risk scores. It more about this that we would like to hear and we would value your unique perspective.

4. If at any time during the interview, you do not wish to answer a question, this is okay.
5. I would like to record digitally our conversation. The recording will be typed out, but everything you say will be anonymous. Your name, any names or places you mention will be taken out, so that if someone reads your interview they would not know whom you are or where you work.
6. Your interview will remain confidential as discussed and outlined in the consent form.
7. If at any stage you wish to stop the audio recorder, please let me know.
8. Do you have any questions?

Section A: Understanding the current practice from a policymaker's viewpoint

1. Are you involved in any way in the development of clinical practice policies?
2. According to the guidelines and policy, what are the recommendations in identifying patients at high risk of cardiovascular disease, i.e. those at high risk of stroke and heart attack?
3. Is there a tool or guideline that should be used to calculate the risk and after that guide management?

Section B: Determinants of implementation; cardiovascular risk stratification and scoring in Kenyan primary care settings

1. Who developed this intervention?
2. Why is the intervention being implemented in these settings?
3. How was the decision made to implement the intervention?
4. What do influential stakeholders think of the intervention?
5. What kind of supporting evidence or proof is needed about the effectiveness of the intervention to get staff on board? Co-workers? Administrative leaders? Are these people on board?
6. How does the intervention compare to other similar existing programs in your setting?
7. Is there another intervention that people would rather implement?
8. What kinds of changes or alterations do you think will need to be made to the intervention so that it works effectively in your setting?
9. Was the intervention piloted before full-scale implementation?
10. What is your perception of the quality of the supporting materials, packaging, and bundling of the intervention for implementation?
11. What costs were incurred to implement the intervention?
12. To what extent were the needs and preferences of the individuals served by your organisation considered when deciding to implement the intervention?
13. Have you elicited information from participants regarding their experiences with the intervention?

14. Can you tell me what you know about any other organisations that have implemented the intervention or other similar programs?
15. What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention?
16. What kinds of infrastructure changes will be needed to accommodate the intervention? Is the current infrastructure enough to advantage?
17. What is the general level of receptivity in your organisation to implementing the intervention?
18. How do people feel about current programs/practices/process that are available related to the intervention?
19. To what extent do current programs fail to meet existing needs? Will or is the intervention meeting these needs?
20. How will or is the intervention filling current gaps?
21. Is the intervention replacing or complimenting a current program or process? In what ways?
22. What kinds of incentives are there to help ensure that the implementation of the intervention is successful?
23. What is your motivation for wanting to help ensure the implementation is successful?
24. Have you/your unit/your organisation set goals related to the implementation of the intervention? [If yes] What are the goals?
25. How does implementation of the intervention align with other organisational goals?
26. What level of involvement has leadership at your organisation had so far with the intervention? Intentions? Attitudes?
27. What kind of support or actions can you expect from leaders in your organisation to help make implementation successful?
28. What have you done (or what do you plan to do) to get a plan in place to implement the intervention?
29. Who are the key influential individuals to get on board with this implementation?
30. What are influential individuals saying about the intervention?
31. Who will or has led the implementation of the intervention? Why them?
32. Other than the formal implementation leader, are there people in your organisation who are likely to champion (go beyond what might be expected) the intervention?
33. What steps have been taken to encourage individuals to commit to using the intervention? Which individuals will you or have you targeted? How will you or did you approach them? What information will you or did you give them? How frequently and how will you or did you communicate with them?
34. What kind of information do you plan to collect as you implement the intervention or post-implementation?
35. How will you assess progress towards implementation or intervention goals?

Closing question: Is there anything else that I have not asked but you would like to tell me?

Thank you for taking the time today to help with our research.

Appendix 16. Observer's guide (Consultation between the healthcare professional and patient)

Observer's guide – A consultation between a healthcare professional and a patient

Title: Exploring the use of Cardiovascular RIsk sCoring in primary care facilities in Kilifi County, Kenya (the CRICK study)

Investigators

Institution	**Investigators**
KEMRI-Wellcome Trust Research programme	Anthony Etyang
University of Oxford, Nuffield Department of Primary Care Health Sciences	Tonny Muthee, David Nunan, Carl Heneghan,

Ethics Reference No: KEMRI/SERU/CGMR-C/148/3807

Date: ……

Name of the observer/s: …….

Observation start time: …… Observation end time: …….

Healthcare professional Information

Unique identifier (sex, level of care and profession):	**Sex: Male/Female**		**Level of care: 2/3/4**
Name of health facility:			
Speciality/work area:			
Profession (please circle)	Medical Officer	Nurse	Clinical Officer
	Line Manager	Other	

Patient Information

Unique identifier (age, sex, level of care):	**Age:**	**Sex: Male/Female**	**Level of care: 2/3/4**

Other -

- Chief complaint/reason for coming to the facility:

- Observing the assessment of cardiovascular risk (Adapted from the Kenya National Guidelines for Cardiovascular Disease Management, 2018)

How was this assessed (see the checklist below)? What was the interaction between the health professional and the patient?

	Age: **Smoking status:**
Family history:	Premature coronary heart disease or ischaemic stroke in a first-degree relative
	Type 2 diabetes
	Lipid disorder
	Others:

Past medical history:	History of cardiovascular disease (myocardial infarction, angina, ischemic stroke, peripheral vascular disease)
	Lipid disorder
	Renal impairment
	Diabetes
	Atrial fibrillation
	Others:

Measure:	Blood pressure
	Body Mass Index, waist circumference
	Non-fasting lipid profile
	Fasting Blood Glucose
	Others

Other notes on assessment?

- Observing the stratification and scoring of cardiovascular risk.

What are the tools used?

Other notes on stratification and scoring?

- Observing the communication of cardiovascular risk.

5.

How was this done?

Other notes on risk communication?

- Observing the management of cardiovascular risk.

Were these tools used to inform management? Pharmacologic or non-pharmacologic? Lifestyle advice?

Other notes on management of cardiovascular risk?

Appendix 17. Final coding framework and code frequencies for describing current practice in the assessment and management of CVD

Table 31. Final analytic framework and coding frequencies for describing current practice in the assessment and management of CVD

Domain	Codes/themes	Number of *sources	Number of references
Identification	Physical appearance	5	6
	Patient history	14	45
	The chief complaint	6	7
	Behavioural history	7	9
	Past medical history	8	11
	Family history	5	7
	Patient information records	4	4
	Risk factor measurement and interpretation	14	30
Stratification	Awareness of CVD risk stratification	13	15
	Awareness of CVD risk scoring tools	10	14
	Availability of CVD risk scoring tools	7	10
	Clinical judgement and guidelines	3	3
Management	Clinical judgement and guidelines	6	7
	Non-pharmacological interventions	10	28
	Lifestyle adjustment interventions	9	12
	CVD risk communication	3	10
	Health promotion activities	3	6
	Pharmacological interventions	11	27
	Availability of medicines	11	14
	Cost of medicines	3	4
	Prescription practice	6	9
	Provider initiated CVD clinics and Referral services	13	40

*Only includes interviews with clinicians and policymakers

Appendix 18. Ethics review approval letters

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, University Offices
Wellington Square, Oxford OX1 2JD
Tel. +44 (0)1865 (2)82106
E-mail: oxtrec@admin.ox.ac.uk

Tonny Muthee
Nuffield Department of Primary Care Health Sciences
Gibson Building 1st Floor, Radcliffe Observatory Quarter
Woodstock Road
Oxford, OX2 6GG

13 September 2018

Dear Dr. Muthee

Full Title of Study: Optimising cardiovascular risk prevention and management in Kenyan primary care settings; a qualitative study exploring the facilitators and barriers to the use of cardiovascular risk scores

OxTREC Reference: 544-18

Thank you for your email of the 12 September 2018, and for your minimal risk application form.

I am pleased to confirm that approval has now been granted for this study. This is valid for the first five years and is subject to receiving the local ethical approval (if this approval has not yet been received).

The documents approved for this study are as follows:

Documents:	Version:	Date:
Minimal risk application form		
PIS – healthcare professionals	V2.0	10/09/18
PIS – patients	V2.0	10/09/18
PIS – policy makers	V2.0	10/09/18
ICF – healthcare professionals	V2.0	10/09/18
ICF – patients	V2.0	10/09/18
ICF – policy makers	V2.0	10/09/18
Interview guide – healthcare professionals	V1.0	27/07/18
Interview guide – policy makers	V1.0	27/07/18
Observer's guide	V1.0	27/07/18
Poster		

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website: https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrec.

Tel: +44 (0)1865 (2)82106
Email: oxtrec@admin.ox.ac.uk
Web: https://researchsupport.admin.ox.ac.uk/governance/ethics

Finally, please note the following **important information**:

Data safety—all studies
It is the responsibility of the PI to ensure that all data collected during the course of the study is stored and transferred safely and securely. Further guidance and advice is available from the Research Data Team.

Studies that will involve storing human tissue samples in Oxford
As you are planning to import the samples into England, you will need to make arrangements before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages: https://researchsupport.admin.ox.ac.uk/governance/human-tissue.

Yours sincerely

Dr Rebecca Bryant
Research Ethics Manager, OxTREC

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel:(254) (020) 2722541, 2713349, 0722-205901, 0733-400003, Fax: (254) (020) 2720030
E-mail: director@kemri.org, info@kemri.org, Website.www.kemri.org

KEMRI/RES/7/3/1 March 18, 2019

TO: **DR. ANTHONY ETYANG & TONNY MUTHEE**
PRINCIPAL INVESTIGATORS

THROUGH: **THE DIRECTOR, CGMR-C**
KILIFI

Dear Sirs,

RE: **KEMRI/SERU/CGMR-C/148/3807** ***(RESUBMISSION OF INITIAL SUBMISSION)*: OPTIMISING CARDIOVASCULAR RISK PREVENTION AND MANAGEMENT: A QUALITATIVE STUDY EXPLORING THE FACILITATORS AND BARRIERS TO THE USE OF CARDIOVASCULAR RISK SCORES IN KENYAN PRIMARY CARE FACILITIES (CRICK STUDY)**

Reference is made to your letter dated March 6, 2019. The KEMRI Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised study documents on March 8, 2019.

This is to inform you that the Committee noted that the issues raised during the 283rd Committee C meeting of the KEMRI Scientific and Ethics Review Unit (SERU) held on **January 31, 2019** have been adequately addressed.

Consequently, the study is **granted approval** for implementation effective this day, **March 18, 2019** for a period of one year. Please note that authorization to conduct this study will automatically expire on **March 17, 2020**. If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval by **February 03, 2020.**

You are required to submit any proposed changes to this study to the SERU for review and the changes should not be initiated until a written approval from the SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advice the SERU when the study is completed or discontinued. You may embark on the study.

Yours faithfully,

ENOCK KEBENEI
THE ACTING HEAD
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT

KEMRI Centre for Geographic Medicine Research - Coast
RECEIVED
22 MAR 2019
Tel: 0709983676/77
P.O. Box 428, Kilifi

COUNTY GOVERNMENT OF KILIFI

DEPARTMENT OF HEALTH SERVICES

When Replying quote
Email; chmtkilifi@gmail.com
REF: HP/KCHS/VOL.X/217

P. O. Box 9-80108
Kilifi
Date 16th April 2019

OFFICE OF THE COUNTY DIRECTOR

Anthony Etyang,
Principal Investigator
KEMRI-Wellcome Trust Research Programme,
Centre for Geographic Medical Research - Coast (CGMRC),
P.O Box 230, 80108,
Kilifi, Kenya.

RE: DEPARTMENTAL AUTHORIZATION TO CARRY OUT RESEARCH IN KILIFI COUNTY

The Kilifi County Department of Health Services is in receipt of your request to conduct a study titled, **"Exploring the use of Cardiovascular RIsk sCoring in primary care facilities in Kilifi County, Kenya (the CRICK study),"** and that has received approvals from KEMRI/Scientific and Ethics Review Unit ***Ref: KEMRI/SERU/CGMR-C/148/3805).***

The Department is glad to grant you authorization to conduct your study in **Kilifi County Hospital, Chasimba Health Centre, Vitengeni Health Centre, Ganze Health Centre, Ziani Dispensary, Junju Dispensary, and Sokoke Dispensary** in line with the approved study protocol. It is required that you engage the administration within the Sub County and the hospital where participants will be recruited prior to commencing data collection.

Upon completion of the study, you will be required to share your study findings, conclusion and recommendations with the Department of Health Services, Kilifi County.

Sincerely,

COUNTY DIRECTOR OF HEALTH
KILIFI COUNTY
16 APR 2019
P.O. Box 9-80108, KILIFI

Vincent Iduri
Ag. Director of Health
KILIFI COUNTY

Cc:
CEC – Health Services, Kilifi County
Chief Officer of Health, Kilifi County
Chief Officer Public Health, Kilifi County

Appendix 19. Recruitment process for a fieldworker

JOB TITLE: Senior Field Worker for qualitative research (CRICK Study) – 4 months contract

OVERALL JOB PURPOSE:

To assist in the collection of qualitative data for the Cardiovascular Risk sCoring in Kenyan primary care (CRICK) study. The field worker will assist in the recruitment of participants into the study and the planning and preparation for visits to study sites under the supervision of the Principal Investigator.

REPORTS TO: Principal Investigator

DIRECTLY SUPERVISES: None

INDIRECTLY SUPERVISES: None

BUDGET AND RESOURCE RESPONSIBILITY: As approved by PI

JOB DIMENSIONS: Study activity planning, recruitment of participants, responsible for study assets, supplies and equipment

SCOPE OF WORK:

The assignment includes the following tasks:

i) Training and orientation

The field worker will be required to attend a training and orientation session. It is expected at the end of the training they will:

- Be familiar with the research questions, methods to be used and protocols to be implemented
- Have a clear understanding and capacity to recruit participants for the study in an ethical manner per the research protocol
- Have knowledge of the strategies for data protection, and management strategies to ensure participant confidentiality

ii) Participant recruitment and data collection

The field worker will be expected to:

- Work in a sensitive and respectful manner with communities and health facilities to recruit participants into the study
- Organize and assist in observations and interviews
- Ensure protocols to obtain informed consent are adhered to and can be demonstrated
- Ensure field diaries and observation protocols are completed in a timely manner immediately following the observation period
- Ensure equipment such as tape recorders are working, that there is back-up equipment, and that appropriate measures are taken to keep the data safe and back-ups are made

iii) Data Analysis and Results

The field worker will be responsible for:

- Transcribing the data, translating into English, and cleaning the transcript

iv) Communication with participants and Principal Investigator

- Work in a collaborative, respectful, sensitive manner with participants
- Attend meetings and trainings as required
- Undertake any other duties as may be assigned by the Principal Investigator .

QUALIFICATIONS:

1. KCSE C plain
2. Basic computer literacy
3. 20 years of age and above
4. Previous experience in dealing directly with the communities within Kilifi County
5. Must be a resident of Kilifi or its environs
6. MUST speak Giriama dialect fluently
7. Ability to understand and speak Kiswahili and English languages
8. Letter from the chief and village elder

COMPETENCIES:

1. Good communication skills including speaking, active listening and writing
2. Attentive to detail
3. Ability to take and follow instructions
4. Ability to work with minimal supervision
5. Proactive, initiative, flexibility and willingness to help and take on additional roles
6. Team worker, able to work in a multi-cultural environment, punctual and with high integrity
7. Well groomed; neat and clean appearance

PHYSICAL ENVIRONMENT/CONDITIONS: Field and office

Appendix 20. Initiative to Develop African Research Leaders (IDeAL) program visiting PhD Fellowship

Initiative to Develop African Research Leaders

TONNY MUTHEE
University of Oxford

Dear **Tonny,**

RE: VISITING STUDENT ATTACHMENT

We are pleased to offer you a **6 Months** attachment at the KEMRI-Wellcome Trust Research Programme (KWTRP) as a visiting PhD student. The aim of the attachment is to enable you conduct interviews with health workers on their cardiovascular risk assessment behaviour. This attachment is offered under the following terms and conditions.

1. The attachment will be for a period of **6 Months** from **21 Jan 2019** to **31 July 2019**.

2. The attachment will not be considered a contract of employment with KEMRI - Wellcome Trust Research Programme (KWTRP) and hence will not attract any salary or benefits normally offered to KWTRP employees.

3. Supervision and management:
   a. Your supervisor within the Programme will be **Dr. Anthony Etyang**, assisted by **Prof. Carl Heneghan** (your primary supervisor).
   b. Your line manager with regard to general visiting PhD student matters will be **Dr. Dorcas Mbuvi**.
   c. Your administrator with regards to general student matters will be **Ms. Elizabeth Murabu**.

4. Student attachment/research cost:
   a. You and/or your supervisors will cover your attachment and research costs.

5. Health insurance:
   a. You will be expected to hold a valid health insurance certificate during the duration of this attachment.
   b. You will **not** be covered by the Programme's group personal accident policy and life assurance scheme.
   c. It is a requirement of the Programme that you make yourself familiar with our Health and Safety Policy.

6. Services and facility support:
   a. You will be allowed access to KWTRP laboratories and other research infrastructure.
   b. You will have access to the KWTRP students' administrative support.
   c. You will be allowed access to KWTRP ICT and internet system.
   d. Please note that all software is licensed for the sole use of the KWTRP and authorized users while on attachment by the Programme, and working within the Programme. Any private or commercial use of such software will be contravening the copyright and licensing laws and could lead to your prosecution.

7. Roles and responsibility
   a. You will be considered a member of KWRTP student body and will be expected to participate in scientific meetings such as journal clubs, seminars, protocol development and review meetings.

b. You will be expected to keep the Training Department updated on your progress through a brief monthly report. If your university requires monthly reports, a copy of same may be submitted to avoid duplication.
c. All your research work must adhere to KWTRP standard operating procedures for the development of research protocols and their subsequent scientific and ethical review. In addition, during the execution of the research you must adhere to KWTRP and all other international standards for the ethical practice of research.
d. You will be expected to adhere to KWTRP policy and code of conduct with regards to your interactions with fellow staff and in the use of the KWTRP facilities such as ICT.
e. You will appreciate that in the performance of your duties with the KWTRP you will from time to time have access to confidential information. It is a condition of your attachment that such information is treated in a confidential way at all times, and that you will only use or disclose it as authorized by the KWTRP. The copyright of any work/material which you do for the KWTRP will belong to the Programme.
f. You will be expected to adhere to KWTRP Health and Safety policy.

8. Withdrawal of attachment

This appointment may be withdrawn under the following circumstance.

a. If you are found to act contrary to the KWTRP policies and code of conduct outlined in clauses 7b to 7f.

NOTE: All visiting students should report to the Training Department on reporting to the Programme before starting any activities in the Programme premises.

Yours Sincerely,



Dr. Sam Kinyanjui
Head of Training, KWTRP

Acceptance of Attachment Offer

I _____Tonny Muthee_____ accept the attachment indicated above under the terms and conditions outline thereafter.

Signed _____ _____ Date ____17/01/19_____

CC: Hillary Ondatto (*Head of HR*); Dr. Francis Ndungu (*RDC*); Prof Philip Bejon (*Director, KWTRP*); David Adede (*Head of Security*); Racheal Ogalo (*Head of IT*)

Appendix 21. Participant information sheets

KEMRI-Wellcome Trust Research Programme: Patient Information Sheet and Consent Form

Exploring the facilitators and barriers to the use of Cardiovascular RIsk sCores in Kenyan primary care facilities (CRICK study)

Ethics reference number:

Institution	Investigators
KEMRI-Wellcome Trust Research Programme	*Anthony Etyang*
University of Oxford, Nuffield Department of Primary Care Health Sciences	*Tonny Muthee, David Nunan, Carl Heneghan, Veronika Williams*

Heart and blood vessels disease (cardiovascular) is caused by preventable risk factors such as excessive body weight, unhealthy eating, lack of exercise, high blood pressure and smoking. Knowing whether you are at high-risk for cardiovascular disease informs both the health care provider and yourself of the next steps to take to prevent and treat some of the causes (risk factors) associated with the disease. Cardiovascular risk stratification/scoring tools are tools widely recommended by prevention and treatment guidelines to allow healthcare professionals to prevent and manage cardiovascular risk factors better. In this research, we want to learn more about the factors influencing the use of cardiovascular risk scores in Kenyan primary care settings.

Who is carrying out this study and what is this study about?

- The KEMRI-Wellcome Trust Research Programme in collaboration with the University of Oxford, Nuffield Department of Primary Care Health Sciences, is carrying out this study. KEMRI is a government organisation that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.

- In this research, we want to learn more about the factors influencing the use of cardiovascular risk scores in Kenyan primary care settings

Why do you want to talk to me and what does it involve?

- As a client attending this clinic, you will be providing valuable information by allowing the researcher to be part of your consultation process. The information collected by the researcher will relate to the factors influencing the use of these tools.

- During the observation, the researcher will take some notes and will not interrupt your consultation with the health provider. Besides, if you are not comfortable having the researcher in the consultation room at any point during the consultation; you may ask them to leave. After the consultation with the health provider, the researcher will briefly ask you about your experience and notes taken.

- We will also ask you to share information on your cardiovascular risk-related medical history. This history includes features such as; age, smoking status, family history, past medical history, blood pressure, weight, height, blood sugar and fat profiles.

Are there any risks or disadvantages to me of taking part?

- The observations should take approximately the same amount of time as your consultation process (10 to 15 minutes). There are no apparent risks to taking part in this study; however, we are aware that this process might cause you some level of inconvenience and feeling of intrusion. You are free to take a break or breaks in between the observation. If there is a need for a physical examination by the healthcare provider, the researcher will leave the room.

Are there any advantages to me taking part?

- There are no individual benefits to taking part. In taking part, you will contribute to the knowledge of implementation science that may help other people in Kenya and elsewhere in the future, for example by developing new health policies.

Who will have access to the information I give?

- All our documents/ recordings are stored securely in locked cabinets and on password-protected computers. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities.

- In future, information collected or generated during this study may be used to support new research by other researchers in this field. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live and replace this information with number codes. A local or national expert committee, to make sure that the interests of participants and their communities are protected, must first approve any future research using information from this study.

Who has allowed this research to take place and will my information be protected?

- All research at KEMRI has to be approved before it begins by a national (KEMRI Scientific and Ethics Review Unit): and international] committee(s) (Oxford Tropical Research Ethics Committee) who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally recognized research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

- All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree to take part, you can change your mind at any time without any consequences.

What if I have any questions?

- You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Tonny Muthee , KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0724051292 or 0722 203417, 0733 522063, 041 7522063

If you want to ask someone independent anything about this research, please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

KEMRI-Wellcome Trust Research Programme consent form for; a study exploring the facilitators and barriers to the use of Cardiovascular RIsk sCores in Kenyan primary care facilities (CRICK study)

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

□ **Yes** *please tick* **I agree to take part in this research**

□ **Yes** *please tick* **I agree for the researcher to observe and take notes during my consultation with the health professional.**

I understand that I can change my mind at any stage and it will not affect me in any way.

Signature: _____ **Date:** _____

Participant's Name: _____ **Time:** _____

(please print name)

Where participant cannot read, a witness* may observe consent process and sign below if needed:

I attest that the information concerning this research was accurately explained to and apparently understood by the participant and the participant freely gave that informed consent.

Witness' signature: _____ Date _____

Witness' name: **_____ Time _____**

**A witness is a person who is independent from the study or a member of staff who is not involved in gaining the consent.*
Thumbprint of the witness as named above if they cannot write:

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ Date _____

Designee/investigator's name: _____Time _____

(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

……
……

Shirika ra utafiti ra KEMRI Wellcome Trust: Fomu ya habari na idhini ya mukongo

Kuchunguza mambo gawezeshago na garyahu gazuliago mahumizi ga kipimo cha hatari ya kupata ukongo wa moyo kahi za vituo musinji zha huduma zha Kenya

Namba ya maadili:

Shirika	Atafiti
KEMRI-Kilifi	*Anthony Etyang*
University of Oxford, Nuffield Department of Primary Care Health Sciences	*Tonny Muthee, David Nunan, Carl Heneghan, Veronika Williams*

Ukongo wa moyo unasababishwa ni mambo gadimago kukingwa here kukala na uziho wa kuzidi, kurya chakurya kisichofaha, kukosa mazoezi, shinikizo ra damu na kuvuha sigara. Kumanya kala u kahi za hatari bomu ya kupata ukongo wa moyo vinakumanyisa uwe na ahudumu a afya kuhusu hatua za kuhala kukinga na kutibu baadhi ya mambo gasababishago ukongo uu. Vifaa zha kupimira hatari ya kupata ukongo wa moyo ni vipimo ambazho vinapendekezwa kahi za mulongozo wa kukinga na kutibu ili kusaidhia ataalamu a huduma za afya kukinga na kushuhulikira tototo mambo gahatarishago zaidhi. Kahi za utafiti uu, funahenza fudzifundishe zaidi kuhusu mambo gaathirigo mahumizi ga vipimo zha hatari ya kupata ukongo wa moyo kahi za vituo musinji zha huduma haha Kenya.

Ni hani ahendaye utafiti uno na unahusu noni?

- Shirika ra utafiti ra KEMRI Welcome Trust rinahedna utafiti uu rikishirikiana na chuo kikuu cha Oxford, Nuffield Department of Primary Care Health Sciences. KEMRI ni shirika ra kiserikali rihendaro utafiti wa afya kutafuta ngira mbidzo za kukinga na kutibu makongo siku za usoni kwa manufaa ga kila mutu.
- Kahi za utafiti uu, funahenza kudzifundisha zaidi kuhusu mambo gaathirigo mahumizi ga kipimo cha kulola hatari ya kupata ukongo wa moyo kahi za vituo musinji zha huduma haha Kenya.

Kwa noni unamala kunena nami na inahusu noni?

- Here mteja adzekudza kahi za kliniki ii, undalazha habari muhimu kwa kumuruhusu mutafiti kukala sehemu ya utaratibu wa masumuriro ga kwako na dakitari. Habari zindizokusanywa ni mutafiti zindahusiana na mambo gaathirigo mahumizi ga vifaa vivi.
- Kahi za mudha uo, mutafiti andanakili mambo fulani na kandaingirira masumuriro genu na muhudumu wa afya. Kala kuhuru kukala na mutafiti kahi za chumba cha kuhenda masumuriro gago kwa wakati wowosi kwenye masumuriro gago, unadima ukamwambira ambole. Mwisho wa masumuriro gaga, mutafiti andakuza kuhusu go udzigokirira kwa mudha uo.
- Pia fundakuvoya ulazhe habari kuhusu historia ya kwako ya kimatibabu ihusianayo na hatari ya kupata ukongo wa moyo. Historia ii inajumuisha mambo here; umuri, hali ya kuvuha sigara, historia ya famili ya kwako, historia ya kwako ya matibabu, musukumo wa mulatso, uziho, kimo, hali ya kwako ya sukari na mafuha mulatsoni.

Kuna hatari hedu usumbufu wowosi kwangu nikishiriki?

- Kuthuwiriza masumuriro kundahala takriban mudha sawa na uryahu wa masumurirogo na dakitari (dakika 10 – 15). Kakuna hatari fuzimanyazo kwa kushiriki kahi za utafiti uu; hata vizho, funamanya kukala utaratibu uu unadima kusababisha kiwango fulani cha usumbufu na kusikira kukala atu manaingirira mambo ga kwako. Uhuru kuhala mudha wa kuoya kahi kahi ya masumuriro gaga. Kala kundahitajika uchunguzi wa mwiri ni muhudumu wa afya, mutafiti andambola.

Kuna manufaa gogosi kwangu nikishiriki?

- Kakuna manufaa ga kibinafsi kwako kwa kushiriki. Hata vizho kwa kushiriki, undatsangira kahi za ufahamu wa kutekeleza sayansi idimayo kusaidhia atu angine haha Kenya na kungine siku zidzazo, kwa mufano kwa kutengeza sera mbisha za afya.

Ni hani andedima kufikira habari nilazhazo?

- Stakabadhi/rekodi zehu zosi za utafiti zinaikwa salama kahi za makabati gadzigofungwa na komputa zihumirazo namba maalum kuvugulwa. Ufahamu undopatikana kula kwa utafiti uu undasambazwa kwa ufuti bila ya kumanyisa vitambulishi binafsi.
- Siku zidzazo, habari zindizokusanywa au zimbolazo wakati wa utafiti zinadima kuhumika kusaidhia tafiti mbisha za atafiti angine kahi za mambo gaga. Kahi za hali zosi, fundamboza habari kwa atafiti angine kwa ngira ambazo kazinyesa vitambulisho binafsi zha ashiriki. Kwa mufano, fundausa habari ambazo zinadima kuatambulisha atu, here madzina gao na maishiko na zibadilishwe na namba maalumu. Kamati ya haha Kilifi hedu ya kitaifa ni lazima kwanza iidhinishe tafiti zozosi za siku zidzazo zindizohumira habari kula kwa utafiti uu, ili kuhakikisha masilahi ga ashiriki na jamii zao ganarindwa.

Ni hani adzeruhusu utafiti uno uhendeke na je habari zindarindwa?

- Tafiti zosi za KEMRI ni lazima ziidhinishwe kabla zianze ni kamati kadhaa za kitaifa (kitengo cha kukagua sayansi na maadili cha KEMRI): na kamati ya kimataifaa (begins by a national (KEMRI Scientific and Ethics Review Unit): and international] committee(s) (Oxford Tropical Research Ethics Committee) zilolazo kwa makini kazi idziyopangwa. Ni lazima makubali kukala utafiti ni muhimu, unafaha Kenya na unathuwa mulongozo wa utafiti ukubalikao kitaifa na kimataifa. Ii ni hamwenga na kuhakikisha kukala usalama na haki za ashiriki osini zinaheshimika.

Kundakalani nikikahala kushiriki?

- Kushiriki kosi kahi za utafiti ni hiari. Uhuru kuamua kala unahendza kushiriki au kwenzi. Ukikubali kushiriki, unadima kugaluza maazo wakathi wowosi bila ya madhara gogosi.

Nikikala na maswali gogosi?

- U huru kunuza swali rorosi kuhusu utafiti uu. Ukikala na maswali zaidhi kuhusu utafiti uu, u huru kuwasiliana na kundi ra utafiti kwa kuhumira anwani iriyo haho tsini:

Tonny Muthee, KEMRI Wellcome Trust Research Programme, S. L. Posta 230, Kilifi. Simu: 0724051292 hedu 0722 203417, 0733 522063, 041 7522063

Ukimala kumuza mutu huru chochosi kuhusu utafiti uu tafadhali wasiliana na:

Meneja wa kitengo cha uhusiano mudzo na jamii, Shirika ra utafiti ra KEMRI Wellcome Trust, S. L. P 230, Kilifi. Simu: 041 7522 063, Rununu 0723 342 780 hedu 0705 154 386

Na

Kilongozi, Kitengo cha kukagua sayansi na maadili cha KEMRI, S. L. Posta 54840-00200, Nairobi; Namba za simu: 0717 719477; 0776 399979 Barua pepe: seru@kemri.org

Fomu ya idhini ya shirika ra utafiti ra KEMRI Wellcome Trust ya; utafiti wa kuchunguza mambo gawezeshago na garyahu gazuliago mahumizi ga kipimo cha hatari ya kupata ukongo wa moyo kahi za vituo musinji zha huduma zha Kenya

Nidzaelezerwa utafiti uu. Nidzaelewa gosi nidzigoshomerwa/elezerwa na maswali gangu gadzajibiwa kikamilifu.

☐ **Ndio** *tafadhali ika alama ya tiki* **Nakubali kushiriki kahi za utafiti**

☐ **Ndio** *tafadhali ika alama ya tiki* **Nakubali mutafiti akale haho na kunakili wakati wa masumuriro gangu na mutaalamu wa afya**

Naelewa kukala nadima kugaluza maazo gangu wakati wowosi na ii kaindaniathiri kizhozhosi.

Sahihi ya mushiriki: **_____Tarehe _____**

Dzina ra mushiriki: _____ Saa _____
(Tafadhali ndhika dzina kwa herufi bomu)

Ikikala mushiriki kadima kushoma, hakikisha shahidhi* analola utaratibu wa idhini na aike sahihi haho tsini
Ninathibitisha kukala habari kuhusu utafiti uu zaelezwa karakara na ni wazi zaeleweka kwa mushiriki na kwamba idhini yalazhwa ni mushiriki kwa hiari

Sahihi ya shahidhi: _____ Tarehe _____

Dzina ra shahidhi: _____ Saa _____

**Shahidhi ni mutu ariye huru na utafiti au muhenzi wa kazi ambaye kahusikire na kuvoya idhini.*
Alama ya dzalagumbe ra muzhazi here adzizhohadzwa haho dzulu kala kadima kundhika:

Nidzathuwa utaratibu wa kuvoya idhini (SOP) kula kwa mushiriki. Ni wazi adzaelewa hali na lengo ra utafiti na adzalazha idhini ya kushiriki kahi za utafiti. Adzagerwa nafasi ya kuuza maswali ambago gadzajibiwa kikamilifu

Sahihi ya muwakilishi/mutafiti: _____ Tarehe _____

Dzina ra muwakilishi/mutafiti: _____Saa _____
(Tafadhali ndhika dzina kwa herufi bomu)

MUSHIRIKI VIKARA AGERWE NAKALA IDZIYONGIZWA SAHIHI ADZIKIRE

Shirika la utafiti la KEMRI Wellcome Trust: Fomu ya habari na idhini ya mgonjwa

Kuchunguza mambo yanayowezesha na yale yanayozuia matumizi ya kipimo cha hatari ya kupatwa na magonjwa ya moyo katika vituo vya afya vya kimsingi hapa Kenya

Nambari ya maadili

Taasisi	Watafiti
KEMRI Kilifi	*Anthony Etyang*
University of Oxford, Nuffield Department of Primary Care Health Sciences	*Tonny Muthee, David Nunan, Carl Heneghan, Veronika Williams*

Magonjwa ya moyo husababishwa na mambo hatarishi ambayo yanaweza kukingwa kama vile uzito wa mwili, chakula kisichofaa, ukosefu wa mazoezi, shinikizo la damu na kuvuta sigara. Kujua ikiwa uko katika hatari ya kupata ugonjwa wa moyo hukujulisha wewe na mhudumu wa afya kuhusu hatua inayopaswa kuchukuliwa kukinga na kutibu baadhi ya visababishi (mambo hatarishi) yanayohusishwa na ugonjwa huu. Vifaa vya kupima hatari ya kupata ugonjwa wa moyo vinapendekezwa katika muongozo wa kukinga na kutibu ili kuwaruhusu wataalamu wa huduma ya afya kukinga na kushuhulikia mambo hatarishi kwa ugonjwa wa moyo vyema zaidi. Katika utafiti huu, tunataka kujifunza zaidi kuhusu mambo yanayoathiri matumizi ya vipimo vya mambo hatarishi ya ugonjwa wa moyo katika mazingira ya huduma ya msingi ya Kenya.

Ni nani anayefanya utafiti huu na utafiti huu unahusu nini?

- Shirika la utafiti la KEMRI Wellcome Trust linafanya utafiti huu likishirikiana na chuo kikuu cha Oxford, *Nuffield Department of Primary Care Health Sciences. KEMRI ni shirika la kiserikali linalofanya utafiti wa afya kutafuta njia bora za kukinga na kutibu magonjwa kwa manufaa ya watu wote siku zijazo.*
- Katika utafiti huu, tungependa kusoma zaidi kuhusu mambo yanayoathiri matumizi ya kipimo cha hatari ya kupata ugonjwa wa moyo katika mazingira ya kupeana huduma hapa Kenya

Kwa nini unataka kuzungumza na mimi na inahusu nini?

- Kama mteja uliyekuja kwenye kliniki hii, utapeana habari muhimu kwa kumruhusu mtafiti kuwa sehemu ya utaratibu wa maongezi na daktari. Habari zitakazokusanywa ni mtafiti zitahusu mambo yanayoathiri matumizi ya vifaa hivi.
- Wakati huo, mtafiti atanakili habari na hataingilia mazungumzo yako pamoja na muhudumu wa afya. Iwapo huko huru kuwa na mtafiti kwenye chumba mnachofanyia mazungumzo hayo wakati wowote katika mazungumzo hayo; unaweza kumuomba atoke. Mwishoni mwa mazungumzo hayo, mtafiti atakuuliza kuhusu yale ulopitia kwa wakati huo.
- Pia, tutakuomba utupe habari kuhusu historia yako ya kimatibabu inayohusiana na hatari ya kupata ugonjwa wa moyo. Historia hii inajumuisha mambo kama vile; umri, hali ya uvutaji wa sigara, historia ya familia yako, historia ya kimatibabu ya siku zilizopita, shinikizo la damu, uzito, kiwango cha sukari kwenye damu na hali ya mafuta.

Kuna hatari usumbufu wowote kwangu nikishiriki?

- Kufuatilia mazungumzo kutachukua takriban muda sawa na ule wa utaratibu wa mazungumzo yako na daktari (dakika 10 hadi 15). Hakuna hatari zilizo dhahiri kwa kushiriki kwenye utafiti huu; hata hivyo, tunajua kwamba utaratibu huu unaweza kusababisha usumbufu kwa kiwango fulani na kuhisi kwamba faragha yako inaingiliwa. Uko huru kuchukua muda wa mapumziko wakati wa kufuatilia mazungumzo haya. Kukiwa na uhitaji wa muhudumu wa afya kupimwa mwili, mtafiti atatoka nje ya chumba.

Kuna manufaa yoyote kwangu nikishiriki?

- Hakuna manufaa ya kibinafsi kwa kushiriki. Kwa kushiriki, utachangia katika ufahamu wa kutekeleza sayansi ambayo inaweza kusaidia watu wengine hapa Kenya na kwengineko siku zijazo, kwa mfano kwa kubuni sera mpya za afya.

Ni nani atakayeweza kufikia habari ninazopeana?

- Stakabadhi/rekodi zetu zote zinahifadhiwa salama kwenye makabati yaliyofungwa na komputa zinazohitaji neno maalum kufunguliwa. Ufahamu utakaopatikana kutoka kwa utafiti huu utasambazwa kwa ufupi bila ya kufunua vitambulishi binafsi vya washiriki.

- Siku za usoni, habari zitakazokusanywa wakati wa utafiti huu zitatumika kusaidia tafiti mpya zitakazofanywa na watafiti wengine katika suala hili. Katika hali zote, tutasambaza tu habari katika njia ambayo haidhihirishi vitambulishi binafsi vya washiriki. Kwa mfano, tutaondoa habari ambazo zinaweza kutambulisha watu, kama vile majina yao na kule wanakoishi, na tubadilishe na nambari maalum. Ni lazima kamati ya wataalam ya Kilifi na ya kitaifa kitaifa iidhinishe tafiti zozote za siku zijazo zitakazotumia habari kutoka kwa utafiti huu kuhakikisha kwamba maslahi ya washiriki na jamii zao yanalindwa.

Ni nani ameruhusu utafiti huu ufanyike na je habari zangu zitalindwa?

- Tafiti zote za KEMRI ni lazima ziidhinishwe kabla zianze na kamati kadhaa ya kitaifa (Kitengo cha kukagua sayansi na maadili cha KEMRI): na kamati ya kimataifa] (Oxford Tropical Research Ethics Committee) zinazoangalia kwa makini mpango wa kazi. Ni lazima wakubali kwamba utafiti ni muhimu na wafaa Kenya na unafuata taratibu zinazokubalika kitaifa na kimataifa. Hii ni pamoja na kuhakikisha kwamba usalama na haki za washiriki wote zimeheshimika.

Kutafanyika nini nikikataa kushiriki?

- Kushiriki kote katika utafiti ni hiari. Uko huru kuamua ikiwa unataka kushiriki au la. Ukikubali kushiriki, unaweza kubadilisha mawazo wakati wowote bila ya madhara yoyote.

Na iwapo nina maswali yoyote?

- Uko huru kumuuliza mfanyajikazi wetu yeyote swali lolote kuhusu utafiti huu. Ukiwa na maswali mengine zaidi kuhusu utafiti huu, uko huru kuwasiliana na kundi la utafiti kwa kutumia anwani zifuatayo:

Tonny Muthee , KEMRI Wellcome Trust Research Programme, S. L. Posta 230, Kilifi. Simu: 0724051292 au 0722 203417, 0733 522063, 041 7522063

Ukitaka kumuuliza mutu huru chochote kuhusu utafiti huu tafadhali wasiliana na:

Meneja wa kitengo cha uhusiano mwema na jamii, KEMRI Wellcome Trust, S. L. Posta 230, Kilifi. Simu: 041 7522 063, Rununu 0723 342 780 au 0705 154 386

Na

Kiongozi, Kitengo cha kukagua sayansi na maadili cha KEMRI, S. L. Posta 54840-00200, Nairobi; Nambari ya simu: 0717 719477; 0776 399979 Barua pepe: seru@kemri.org

Kuchunguza mambo yanayowezesha na yale yanayozuia matumizi ya kipimo cha hatari ya kupatwa na magonjwa ya moyo katika vituo vya afya vya kimsingi hapa Kenya

Nimeelezewa utafiti huu. Nimeelewa yote yaliyosomwa/elezwa na maswali yangu yamejibiwa kikamilifu.

☐ **Ndio** *Tafadhali weka alama ya tiki* **Nakubali kushiriki/kumruhusu mtoto wangu kushiriki katika utafiti huu wa ufuatilizi**

☐ **Ndio** *Tafadhali weka alama ya tiki* **Nakubali mtafiti awepo wakati wa mazungumzo yangu na muhudumu wa afya na anakili mazungumzo wakati huo**

Ninaelewa kuwa ninaweza badilisha nia wakati wowote na hii haitaniathiri kivyovyote.

Sahihi ya mshiriki_____Tarehe:_____

Jina la mshiriki: _____ Saa:_____

(Tafadhali andika jina kwa herufi kubwa)

Iwapo mshiriki hawezi kusoma, hakikisha shahidi* anafuatilia utaratibu wa kuomba idhini na aweke sahihi hapo chini:

Ninathibitisha kwamba habari kuhusu utafiti huu zimeelezwa kwa usahihi na bila shaka zimeeleweka kwa mshiriki na kwamba mshiriki alipeanwa idhini kwa hiari

Sahihi ya Shahidi_____Tarehe:_____

Jina la Shahidi_____Saa:_____

(Tafadhali andika jina kwa herufu kubwa)

**Shahidi ni mtu ambaye yuko huru kutokana na utafiti au mfanyajikazi ambaye hakuhusika katika kuomba idhini*

Alama ya kidole gumba cha mzazi kama alivyotajwa hapo juu ikiwa hawezi kuandika

---

Nimefuata taratibu zote za kuomba idhini katika utafiti huu kutoka kwa mshiriki. Ameonyesha ya kwamba ameelewa hali na lengo la utafiti, na amepeana idhini ya kushiriki katika utafiti. Mshiriki amepewa nafasi ya kuuliza maswali ambayo yamejibiwa kikamilifu.

Sahihi ya Mtafiti muwakilishi/Mtafiti: _____Tarehe:_____

Jina la Mtafiti muwakilishi/Mtafiti: _____Saa:_____

[Tafadhali andika jina kwa herufi kubwa]

MSHIRIKI SASA APEWE NAKALA ILIYOWEKWA SAHIHI AHIFADHI

KEMRI-Wellcome Trust Research Programme: Participant Information Sheet and Consent Form

Exploring the facilitators and barriers to Cardiovascular RIsk sCoring in Kenyan primary care facilities (CRICK study)

Ethics reference number:

Institution	Investigators
KEMRI-Wellcome Trust Research Programme	*Anthony Etyang*
University of Oxford, Nuffield Department of Primary Care Health Sciences	*Tonny Muthee, David Nunan, Carl Heneghan, Veronika Williams*

This study aims to understand the current practice in the assessment and management of cardiovascular risk in Kenyan primary care facilities and identify the factors influencing the use of cardiovascular risk scoring in these settings. Cardiovascular risk stratification/scoring tools allow health care professionals to make clinical decisions by quantitatively predicting the absolute risk of a cardiovascular event occurring during a defined period. These tools are the mainstay of cardiovascular disease prevention guidelines. However, there is a lag in the implementation of these tools in most countries including Kenya. We want to find out why. This information will have implications for implementation policy, process and practice.

Who is carrying out this study and what is this study about?

- The KEMRI-Wellcome Trust Research Programme in collaboration with the University of Oxford, Nuffield Department of Primary Care Health Sciences, is carrying out this study. KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.
- In this research, we want to learn more about the factors influencing the use of cardiovascular risk scores in Kenyan primary care settings by sitting in in your consultation with the patient and observing the process. This will then be followed by an interview.

Why do you want to talk to me and what does it involve?

- As a primary care practitioner, you are central to the use and implementation process of this intervention. You will be providing valuable information relating to the determinants of implementation that could inform implementation strategies and policies for this intervention in your settings or similar settings.
- First, you will take part in an observation where the researcher will sit in on a consultation with a patient. During the observation, the researcher will take some notes and will not interrupt the consultation process. If at any point you are not comfortable with the researcher being in the consultation room, you can ask them to leave. Should the researcher want to seek any clarifications regarding the consultation, this will be made at the end of the consultation.
- Following this will be a 30 to 45-minute audio-recorded interview with the researcher on the factors influencing the use of cardiovascular risk stratification and scoring tools. If you do not want to answer any of the questions, you may say so and the interviewer will move on to the next question. This recording will assist in fully writing up the information later. No one will be identified by name in the recording. The interview will take place at the facility and no one else, but the interviewer will be present unless you would like someone else there.
- The observations and interviews will be preceded by giving an informed consent to take part in this research.

Are there any risks or disadvantages to me of taking part?

- The observations should take approximately the same amount of time as your consultation process (10 to 15 minutes), and the interviews will take an estimate of 30 to 45 minutes. There are no apparent risks to taking part in this study; however, we are aware that this process might cause you some level of inconvenience and feeling of intrusion. You are

free to take a break or breaks in between the observation and interview if necessary. If there is a need for a physical examination by the healthcare provider, you may ask the researcher to leave the room.

Are there any advantages to me of taking part?

- Taking part in this study will give you as the practitioner time and space to share your thoughts and experiences and to reflect on practice. The findings of this research will provide a better understanding of the factors that influence implementation. This will provide a guide to implementation policy and practice, giving insight as to how cardiovascular risk assessment tools could be best used in various settings.

Who will have access to the information I give?

- All our documents/ recordings are stored securely in locked cabinets and on password-protected computers. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities. The recordings from the interviews will be destroyed at the end of the study.

- In future, information collected or generated during this study may be used to support new research by other researchers in this field. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live and replace this information with number codes. A local or national expert committee to make sure that the interests of participants and their communities are protected must first approve any future research using information from this study.

Who has allowed this research to take place and will my information be protected?

- All research at KEMRI has to be approved before it begins by a national (KEMRI Scientific and Ethics Review Unit): and international] committee(s) (Oxford Tropical Research Ethics Committee) who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally recognized research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

- All participation in research is voluntary. You are free to decide if you want to take part or not. If you agree to take part, you can change your mind at any time without any consequences.

What if I have any questions?

- You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Tonny Muthee , KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 0724051292 or 0722 203417, 0733 522063, 041 7522063

If you want to ask someone independent anything about this research, please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

KEMRI-Wellcome Trust Research Programme consent form for a study exploring the facilitators and barriers to Cardiovascular RIsk sCorimg in Kenyan primary care facilities (CRICK study)

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

□ **Yes** *please tick* **I agree to take part in this research**

□ **Yes** *please tick* **I agree for the researcher to observe and take notes during my consultation with the patient**

□ **Yes** *please tick* **I agree to be interviewed and the interview process audio-recorded**

I understand that I can change my mind at any stage and it will not affect me in any way.

Signature: _____ **Date:** _____

Participant's Name: _____ **Time:** _____

(please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____ **Time** _____

(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

……

KEMRI-Wellcome Trust Research Programme: Participant Information Sheet and Consent Form

Exploring the facilitators and barriers to Cardiovascular RIsk sCoring in Kenyan primary care facilities (CRICK study)

Ethics reference number:

Institution	Investigators
KEMRI-Wellcome Trust Research Programme	*Anthony Etyang*
University of Oxford, Nuffield Department of Primary Care Health Sciences	*Tonny Muthee, David Nunan, Carl Heneghan, Veronika Williams*

This study aims to document the current practice in the assessment and management of cardiovascular risk in Kenyan primary care facilities and identify the factors influencing the use of cardiovascular risk scoring in these settings. Cardiovascular risk stratification/scoring tools allow health care professionals to make clinical decisions by quantitatively predicting the absolute risk of a cardiovascular event occurring during a defined period. These tools are used as part of cardiovascular disease prevention guidelines. However, there is a lag in the implementation of these tools in most countries including Kenya. We want to find out why. This information will have implications for implementation policy, process and practice.

Who is carrying out this study and what is this study about?

- The KEMRI-Wellcome Trust Research Programme in collaboration with the University of Oxford, Nuffield Department of Primary Care Health Sciences, is carrying out this study. KEMRI is a government organisation that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.
- In this research, we want to learn more about the factors influencing the use of cardiovascular risk scores in Kenyan primary care settings by interviewing you and listening to your ideas and opinions about implementation processes and practice.

Why do you want to talk to me and what does it involve?

- As a policymaker, you are central to the use and implementation process of this intervention. You will be providing valuable information relating to the determinants of implementation that could inform implementation strategies and policies for this intervention in your settings or similar settings.
- I would like to ask you several questions in an audio-recorded interview about the factors that influence the use of cardiovascular risk stratification and scoring tools in primary care settings. If you do not want to answer any of the questions, you may say so, and the interviewer will move on to the next question. This recording will assist in fully writing up the information later. No-one will be identified by name in the recording. The interview will take place at a place of your convenience and no-one else, but the interviewer will be present unless you would like someone else there.
- The interview will be preceded by giving informed consent to take part in this research.

Are there any risks or disadvantages to me taking part?

- The interview will take approximately 30 to 45 minutes. There are no obvious risks to taking part in this study; however, we are aware that this process might cause you some level of inconvenience. You are free to take a break or breaks in between the interview if necessary.

Are there any advantages to me taking part?

- Taking part in this study will give you as the practitioner time and space to share your thoughts and experiences and to reflect on practice. The findings of this research will provide a better understanding of the factors that influence

implementation. This will give a guide to implementation policy and practice, providing insight as to how cardiovascular risk assessment tools could be best used in various settings.

Who will have access to the information I give?

- All our documents/ recordings are stored securely in locked cabinets and on password-protected computers. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities. The recordings from the interviews will be destroyed at the end of the study.

- In future, information collected or generated during this study may be used to support new research by other researchers in this field. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live and replace this information with number codes. A local or national expert committee, to make sure that the interests of participants and their communities are protected, must first approve any future research using information from this study.

Who has allowed this research to take place and will my information be protected?

- All research at KEMRI has to be approved before it begins by a national (KEMRI Scientific and Ethics Review Unit): and international] committee(s) (Oxford Tropical Research Ethics Committee) who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally recognized research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

- All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree to take part, you can change your mind at any time without any consequences.

What if I have any questions?

- You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Tonny Muthee, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: [Insert mobile] or 0722 203417, 0733 522063, 041 7522063

If you want to ask someone independent anything about this research, please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

KEMRI-Wellcome Trust Research Programme consent form for a study exploring the facilitators and barriers to Cardiovascular RIsk sCoring in Kenyan primary care facilities (CRICK study)

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

☐ **Yes** *please tick* **I agree to take part in this research**

☐ **Yes** *please tick* **I agree to be interviewed and the interview process audio- recorded**

I understand that I can change my mind at any stage and it will not affect me/my child in any way.

Signature: _____ **Date:** _____

Participant/guardian Name: _____ **Time:** _____

(please print name)

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____ **Time** _____

(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

……

……

Version 3.0_6th November 2018

Appendix 22. List of Anatomical Therapeutic Classification (ATC) chemical substance codes for the Essential Medicines (HIV, TB and CVD)

Drug name	ATC code
HIV/AIDs	
Dolutegravir	J05AX12
Efavirenz	J05AG03
Emtricitabine	J05AF09
Lamivudine	J05AF05
Lopinavir/Ritonavir	J05AR10/ J05AE03
Nevirapine	J05AG01
Tenofovir Disoproxil Fumarate	J05AF07
Zidovudine (Retrovir)	J05AF07
TB	
Ethambutol	J04AK02
Isoniazid	J04AC01
Pyrazinamide	J04AK01
Rifampicin	J04AB02
Streptomycin	A07AA04
CVD	
Amiloride	C03DB01
Amlodipine	C08CA01
Acetylsalicylic acid	B01AC06, N02BA01
Atorvastatin*	C10AA05
Atenolol	C07AB03
Bendrofluazide*	C03AA01
Bisoprolol	C07AB07
Candesartan*	C09CA06
Captopril*	C09AA01
Carvedilol	C07AG02
Clonidine*	C02AC01
Enalapril	C09AA02
Furosemide	C03CA01
Glyceryl Trinitrate*	C01DA02
Hydralazine	C02DB02
Hydrochlorothiazide	C03AA03
Labetalol*	C07AG01
Lisinopril	C09AA03
Losartan	C09CA01
Methyldopa	C02AB
Metoprolol	C07AB02
Nifedipine*	C08CA05
Prazosin*	C02CA01
Propranolol*	C07AA05
Reserpine*	C02AA02
Simvastatin	C10AA01
Sodium Nitroprusside	C02DD01
Spironolactone	C03DA01
Telmisartan	C09CA07

*Essential medicines not classified as CVD essential medicines, i.e. Antihypertensives, Antiplatelet Therapy or Lipid Lowering Therapy in the WHO EML