Cardiovascular disease prevention in a health insurance program in rural Nigeria
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Chapter 1
General introduction
Chapter 1

CARDIOVASCULAR DISEASE IN SUB-SAHARAN AFRICA

Cardiovascular diseases (CVD) are the leading cause of death and disability worldwide.\textsuperscript{1,2} Globally, 15.6 million people died from CVD in 2010, a 31% increase compared to 1990 when 11.9 million people died from CVD.\textsuperscript{1} Over 80% of CVD-related mortality occurs in low- and middle-income countries (LMICs).\textsuperscript{3} While CVD mortality in high income countries is decreasing due to improved prevention and treatment of CVD and CVD risk factors, mortality due to CVD in LMICs is increasing.\textsuperscript{1,4-6} The INTERHEART and INTERSTROKE studies demonstrated that, similar to high income countries, CVD risk factors such as hypertension, diabetes, obesity and dyslipidemia account for the majority of the risk of CVD in LMICs.\textsuperscript{7,8} The prevalence of CVD risk factors in LMICs is increasing due to aging of populations and a change from traditional lifestyles to a western lifestyle with changing diets, more sedentary lifestyles and increasing tobacco and alcohol intake.\textsuperscript{1,9-15} Sub-Saharan Africa (SSA) faces a double burden of disease with a rising prevalence of CVD and other non-communicable diseases (NCDs), while at the same time the burden of communicable diseases is still very high.\textsuperscript{1} This double burden puts an enormous constraint on already overburdened health systems in SSA.

CVD prevention, including population-based interventions to promote healthy lifestyles and individual interventions such as drug treatment for CVD risk factors (e.g. drug treatment for hypertension, diabetes and high cholesterol), greatly reduces CVD morbidity and mortality.\textsuperscript{9-18} For example, treatment of hypertension can reduce the risk of stroke by 40%.\textsuperscript{19} However, awareness of CVD risk factors and treatment coverage for CVD risk factors for primary prevention of CVD in SSA is very low. A recent systematic review evaluated awareness of hypertension (proportion of people with hypertension who are aware of their condition), anti-hypertensive treatment coverage and blood pressure control (proportion of people with hypertension with a blood pressure on target) in SSA.\textsuperscript{20} Awareness of hypertension was below 30% and anti-hypertensive drug coverage amongst patients aware of their condition below 20% in most studies. Less than 1% to 38% of the patients who were using anti-hypertensive drugs had a blood pressure on target.\textsuperscript{20} In contrast, awareness of hypertension was nearly 83% in the United States in 2011-2012 while nearly 76% of adults with hypertension were taking anti-hypertensive drugs and nearly 52% of all hypertension patients had a controlled blood pressure.\textsuperscript{21} A study that evaluated drug use for secondary prevention of CVD in patients who had a cardiovascular event in several high- and low-income countries, including countries in SSA, found that less than 20% of patients were receiving at least one drug for secondary CVD prevention in low income countries compared to 89% in high income countries.\textsuperscript{22} This discrepancy between CVD burden and CVD preventive treatment coverage can be explained by dysfunctional health systems with poor infrastructure and a lack of qualified staff, essential equipment and supplies.\textsuperscript{23} In settings where CVD preventive care is available, it is not accessible for many patients because of high costs.\textsuperscript{24,25} Total healthcare expenditures per capita was USD 158 per year (purchasing power parity adjusted, (PPP)) in SSA in 2012 compared to USD 4512 (PPP) in high income countries, and around one third of the healthcare expenditures in SSA are paid out-of-pocket by patients.\textsuperscript{26} These figures would even be worse when "outlier" South Africa
would be excluded that spent USD 982 (PPP) per capita on health in 2012 of which only 7% was paid out-of-pocket. In addition, the focus of health programs in SSA has traditionally been on communicable diseases such as malaria, tuberculosis and HIV. Governments, international health organizations and global health funders have only recently recognized the need for NCD prevention in LMICs. A high-level meeting of the United Nations in September 2011 resulted in a political declaration to prevent and combat NCD in LMICs, including CVD.

Guidelines for CVD prevention in LMICs
The World Health Organization (WHO) has published several reports emphasizing the need for CVD prevention in LMICs and has published guidelines for CVD prevention that include treatment for hypertension, diabetes and dyslipidemia. WHO recommends initiating CVD preventive drug treatment in all individuals with a high ten year risk of CVD. This includes all individuals who already had a cardiovascular event, individuals with (sub-)clinical target organ damage, individuals with very high levels of individual risk factors (such as grade 2 hypertension), and all individuals who have a high risk based on a combination of different risk factors. For the last category, WHO has published risk charts for different WHO regions that assess ten year CVD risk based on age, gender, smoking status, diabetes, blood pressure- and cholesterol level (see Addendum). The guidelines list preferred CVD preventive drugs. However, it is unclear how feasible it is to implement these guidelines in settings with dysfunctional and overburdened health systems. Operational research that assesses how guidelines can be translated into practice in SSA is highly needed.

Guidelines in practice: CVD prevention programs in SSA
There are several studies that describe CVD prevention programs in SSA or other LMICs. Most programs were set up in local health facilities by (international) research teams and were financed through international (research) funds or donor money from foreign governments. The programs included one or several interventions such as screening for CVD risk factors, health education, drug treatment for CVD risk factors, training of hospital staff in CVD prevention care and implementation of treatment guidelines and protocols. Although most studies report a decrease in CVD risk factors in patients in care after the intervention, patient retention rates are generally low. Long-term treatment of CVD risk factors is essential for prevention of CVD, therefore, retention in care and patient adherence to drugs should be a priority of any CVD prevention program. The lack of symptoms of CVD risk factors and high costs of care for patients are frequently reported reasons for non-compliance with therapy and patient drop-out of care. In addition, poor access to health facilities, and low quality of care contribute to poor risk factor control. To implement and sustain CVD prevention programs in SSA successfully, access to care for patients and quality of care should be guaranteed.

ACCESS TO HIGH QUALITY CARE: HEALTH INSURANCE FOR CVD PREVENTION IN SSA
Insurance programs offer opportunities to improve access to care for patients with CVD risk factors in SSA. Insurance programs rely on the concept of risk pooling: healthcare expenditures
will be high for some enrollees while others rarely utilize care and will therefore have low healthcare expenditures. In other words, healthy people partly pay for the healthcare services for sick people. Because of this risk sharing, patients with chronic conditions such as CVD risk factors will have access to care that would have been unaffordable for these patients if they had to pay out-of-pocket. WHO and other expert organizations have advocated universal health coverage, for example through prepaid health insurance, to reduce financial impoverishment caused by health spending and to increase access to health services, which should ultimately lead to an improvement in population health.

There are several models of health system financing that can be used to achieve universal coverage. Historically, two systems were identified. The first system is exemplified by the United Kingdom’s National Health Service model, or Beveridge model that relies on general taxes, one national risk pool, and publicly provided services available to all. Germany’s social health insurance model, or the Bismarck model, which relies on household premiums and payroll taxes, many risk pools, and services purchased largely from private providers available to those who enrolled, is a typical example of the second system. Many countries use mixed systems to collect revenues for healthcare, to pool funds and to purchase healthcare services. Other models of risk pooling and prepayment for healthcare include private, for-profit insurance schemes and Community-Based Health Insurance (CBHI), also referred to as health insurance for the informal sector or micro-health insurance. Although a clear definition of CBHI is lacking, the term usually refers to not-for-profit, voluntary health insurance with a focus on individuals who work in the informal sector or who are unemployed and community empowerment. This model is often applied in SSA and Asia where functional national systems are lacking, for-profit schemes are inaccessible for the majority of the population and where the majority of the population works in the informal sector (i.e. self-employed, for example street vendors) or is unemployed.

Several studies have evaluated the effect of health insurance schemes in LMICs, including SSA. Most studies report a positive effect of insurance on access to care (increased healthcare utilization) and financial protection (reduced out-of-pocket payments). Studies from LMICs assessing the effect of insurance on population health status are scarce and results are conflicting. Some studies found health improvements in formerly uninsured groups, while others did not show improvements in health status. A wide range of health indicators was used in these studies including birth weight, newborn Apgar scores, (child-)mortality, complications after delivery, child growth indicators, (child-) anemia, body mass index, life expectancy, incidence of infectious diseases, presence of acute infection, reported health status, physical functioning, number of sick days, chronic illness, EQ-5D (a standardized index measuring general health) and sickness or injury in the past month. A study that evaluated the effect of the Seguro Popular insurance program in Mexico found that being insured was associated with greater use of anti-hypertensive treatment and better blood pressure control in hypertensive patients and better glucose control in diabetics. Health insurance was associated with a reduction in blood pressure among male adults in lower income groups in Indonesia but not in other subgroups. Methodological limitations may explain the conflicting results in these studies. Most studies were retrospective or used cross-sectional data. In addition, health
outcome measures were often not suitable to capture the changes in health status that may result as a consequence of improved access to care provided by health insurance.\textsuperscript{50,54} Another explanation for the lack of effect in many studies is inadequate quality of care. Therefore, insurance programs should not only address the demand side (access to care for enrollees) but also the supply side (high quality of care in the health facilities) of the health system. Output-based contracts between healthcare providers and insurers offer opportunities to improve and monitor the quality of care provided by the healthcare providers.\textsuperscript{52}

**Health insurance in Nigeria: the Health Insurance Fund**

The research described in this thesis was done in the context of a CBHI program in rural Nigeria. The insurance program provided a unique opportunity to evaluate the effect of health insurance on reduction of CVD risk factors, and to evaluate the feasibility of implementation of international CVD prevention guidelines in the health facilities participating in the program. The insurance program was funded by the Health Insurance Fund (HIF). The HIF is a program which originated from the international development organization PharmAccess. The PharmAccess Group is committed to providing access to quality healthcare for low- and middle-income groups in several African countries through innovative financing mechanisms and improvement of the quality of healthcare.\textsuperscript{59-63} The HIF is developing and supporting the implementation of CBHI programs, which focus on the informal sector. The aim of the HIF program is twofold: improving the demand for and access to healthcare, by introducing CBHI for individuals with low and middle incomes as well as improving the quality of care provided in these communities. The key elements on the demand side of the HIF program are the focus on organized groups in the informal sector and their dependents, for example communities of farmers; the provision of subsidized insurance premiums; co-payment of the premium by enrollees to encourage the groups to demand quality care; and voluntary enrolment. On the supply side, the key elements include capacity building, quality assurance, involvement of the private and public sector, focus on performance-based financing, and management (Figure 1).

The HIF program uses a public-private partnership model and is implemented by PharmAccess and private African Health Maintenance Organizations (HMOs) or health insurance companies. The HMOs are responsible for execution of the program and for contracting a network of healthcare providers to provide the care for the enrollees. Donor money - from both international and local sources - is used to develop and set up the insurance program and to upgrade the medical and administrative capacity of the HMOs and healthcare providers contracted under the program. The payment of healthcare providers is related to their performance. The program started in Lagos and Kwara State in Nigeria in 2007 in collaboration with the HMO Hygeia Limited under the name of Hygeia Community Health Care (HCHC).

**Quality assurance within the HCHC program**

Quality and efficiency of care in health facilities participating in the HCHC program are monitored through independent audits of an international quality improvement and assessment body called SafeCare\textsuperscript{61}, a partnership of PharmAccess, the American Joint Commission International and the South-African Council for Health Services Accreditation of Southern
When a healthcare provider is contracted by the HMO, a baseline assessment in the health facility is conducted by SafeCare and a quality improvement plan is formulated. The improvement plans are implemented by the healthcare providers with technical and financial support from the HMO while SafeCare monitors the progress on quality improvement through annual follow-up assessments with the SafeCare Quality Standards. Examples of quality improvement interventions include implementation of treatment guidelines (for example for hypertension), training of staff in guideline-based care, upgrading of laboratory equipment and training of laboratory staff to enable basic laboratory testing, assurance of continuous essential drug supplies, adequate medical file keeping, waste management protocols and hospital infection control protocols.

The HCHC program in Kwara
Since 2007, the HCHC program has been rolled out in three regions in Kwara State, Nigeria: Kwara North (Shonga, Bacita, Lafiagi, Tsaragi), Kwara Central (Afon, Owode, Onire) and Kwara South (Oyun, Odo-Ogun, Oke-Ogun, Ifelodon) (Figure 2). Over 64,000 people were enrolled in the HCHC program in April 2014 in all three regions. The details and advantages of the health insurance program were communicated to the public by the HMO through several channels. Activities included face-to-face information sharing (e.g. through house visits by enrolment officers, health education and advocacy visits to community opinion leaders) and large scale communication and marketing activities in the target communities (through billboards, comics, brochures, flyers and announcements on the radio). All households living in the districts in which the program is operational are eligible for enrolment. Individuals can register in the communities during community outreach activities of the insurer or in the health facilities participating in the program. There is no pre-enrolment screening for chronic diseases. After enrolment, new members can access care from the first day of the next month. Beneficiaries are enrolled individually (as opposed to household enrolment) on an annual basis and pay a share of the premium, the so called co-premium. The co-premium ranges from 0.15% of the average annual per capita consumption (a socioeconomic measure of wealth based on household expenditures on food and non-food items) for the lowest wealth quintile to 0.04% for the highest wealth quintile (consumption data 2009, corrected for inflation). The total cost of the yearly insurance premium was 28 USD in May 2014. The Kwara State Government pays 60% of the premium, the participants 12% and the HIF 28%. The Kwara State Government started contributing to the premium subsidies in 2009. Its contribution has increased from 20% to 60% and it plans to eventually take over all costs of the premium subsidy. Prior to 2009, the HIF paid the greater part of the premium subsidy through a grant from the Dutch Ministry of Foreign Affairs. The transfer of premium payment from the HIF to the Kwara State Government is evidence of local political commitment and ownership which is needed to ensure the financial sustainability of the program.

The HMO has contracted 18 public and private health facilities to provide the care for their enrollees. Most health facilities are primary and secondary care clinics that provide outpatient services and have admission capacity. Referral to two tertiary health facilities in Ilorin, the Kwara State capital, is possible if needed. The program uses a mixed reimbursement system of capitation fees and fee for service. Capitation fee refers to a fixed payment remitted at regular intervals...
intervals for each enrolled patient. In the HCHC program, all enrollees are registered in one of the health facilities contracted by the insurer. The healthcare provider receives a yearly fee for each enrollee registered in their facility, irrespective of use of services. In addition, the providers receive a fee for service for specific services, such as surgery or specific tests. At the time of the studies presented in this thesis, reimbursement of CVD prevention care was an exception to this system. In addition to the capitation fee, healthcare providers received a fixed monthly fee for each hypertension and diabetes patient if the patient visited the clinic that month, but irrespective of tests or drugs provided. For patients who were referred from another HCHC health facility for a specific service, the provider received a fee for service.

The insurance package provides coverage for consultations, diagnostic tests and drugs for all disease categories, including hypertension and diabetes, that can be managed at a primary care level and limited coverage of secondary care services. Secondary care services provided include radiological and more complex laboratory diagnostic tests, hospital admissions for different disease categories, minor and intermediate surgeries, antenatal care and delivery care, neonatal care, immunizations, annual check-ups and HIV/AIDS treatment. Excluded from the program are high-tech investigations (CT, MRI), major surgeries and complex eye surgeries, family planning commodities, treatment for substance abuse/addiction, cancer care requiring chemotherapy and radiation therapy, provision of spectacles, contact lenses and hearing aids, dental care, intensive care treatment and dialyses. Management of acute cardiovascular events such as thrombolysis for stroke or for myocardial infarction is excluded. In case of an acute cardiovascular event, admission to a hospital for supportive care is covered including for example treatment with intravenous fluids, and antibiotics for infectious complications. There is no limit to the number of visits to the health facilities for patients, but as a large share of the payment from the insurer to the healthcare provider is paid through capitation fees, healthcare providers are encouraged to prevent overutilization of services.

**OPERATIONAL RESEARCH OF CVD PREVENTION PROGRAMS**

Operational research in healthcare can be defined as the search for knowledge about interventions, strategies, or tools that can enhance the quality, effectiveness, or coverage of programs in which the research is being done. Operational research is needed to improve program outcomes, to assess the feasibility of new strategies or interventions in specific settings or populations, and to advocate for policy change. While randomised controlled trials determine the efficacy of an intervention in a strictly controlled environment with inclusion and exclusion criteria, operational research assesses effectiveness within routine settings, thereby contributing to the translation of effective interventions into routine practice. Operational research in LMICs is increasingly recognised as an essential part of program evaluation, but the focus of operational research projects in LMICs has so far been on infectious disease control programs. Operational research on CVD prevention programs in SSA is urgently needed to evaluate operational and financial feasibility of (the scale-up of) programs, to assess determinants of successful implementation and to evaluate different models for delivery of care.
Operational research of CVD prevention within the HCHC program

CVD prevention was chosen as a focus area for operational research within the HCHC program for several reasons. First, analysis of healthcare utilization data from the insurer demonstrated that hypertension and diabetes were among the most frequently reported reasons for enrollees to visit the HCHC clinics in the first year of the program. Hypertension was the second most frequently reported reason to visit a HCHC clinic in the Lagos program, diabetes ranked eighth. In the Kwara program hypertension was the fifth most frequent reason for a clinic visit, diabetes ranked sixteenth. Second, a pilot household survey amongst a random selection of households representative of the target groups of the HCHC programs in Lagos and Kwara North in 2008, showed that hypertension was one of the most prevalent chronic afflictions. Finally, the HMO and several healthcare providers of the HCHC program perceived CVD prevention as an important topic for operational research. They emphasized the need for high quality CVD prevention care, especially because it was not feasible to provide specialist care for acute cardiovascular events in the setting of the program. They expressed the need for capacity building for treatment of CVD risk factors in the HCHC clinics, as most doctors were mainly trained in the management of communicable diseases and clinics were not organized to provide care for chronic illnesses.

Blood pressure in patients with hypertension was chosen as one of the primary outcomes of the impact evaluation of the HCHC program that measured the effect of the program on health status of the target population. Besides the high prevalence of hypertension observed in the target populations and the observed healthcare utilization for hypertension in the program clinics, blood pressure was also chosen because of predefined hypotheses about which components of health status could be influenced by an insurance program in the short term (two years). We hypothesized that an insurance program could particularly benefit people with hypertension by providing uninterrupted access to quality care.

The studies in this thesis have all been conducted within the HCHC program in Kwara. As described above, CVD prevention was also an important health issue in the Lagos program. However, the Lagos program was re-designed at the time of the start of the operational research projects with (partly) new target groups and new healthcare providers. Therefore, it was not feasible to conduct prospective studies in Lagos.

AIM OF THE THESIS

CVD prevention programs in SSA should address different levels of the health system in order to be successful. Awareness of CVD risk factors should be promoted at a community level. Continuous access to high quality primary care is needed for patients at high risk of CVD with referral to secondary care for complicated cases. Consistent healthcare financing is essential to set up and sustain CVD prevention programs. The studies presented in this thesis cover these different aspects.

The aim of this thesis was to evaluate the feasibility and effects of providing CVD prevention care within a CBHI program in Kwara State, Nigeria. The HCHC program is a community-based
intervention that provides access to primary and secondary care health facilities (Figure 1). It was hypothesized that the insurance program would facilitate the provision of high quality CVD prevention care through improved access to care for patients at risk of CVD, as well as through quality improvements in the health facilities participating in the program. On the demand side of the healthcare system, prevalence and awareness of CVD risk factors in the communities eligible for the HCHC program (and other CBHI programs) were studied. In addition, access to care for hypertension patients, as well as factors that inhibit and facilitate adherence to anti-hypertensive treatment were evaluated. Finally, the effect of the insurance program on blood pressure in the hypertensive population was measured. On the supply side, the operational and financial feasibility of implementation of international CVD prevention guidelines from a healthcare provider perspective were studied.

**Figure 1** Demand and supply side interventions of the Hygeia Community Health Care Program

Interventions targeted at the general population such as tobacco control, reduction of harmful alcohol use, and promotion of healthy lifestyles are also extremely important to reduce the population CVD burden. However, the HCHC insurance program provides access to care in health facilities. Therefore, this thesis focuses on interventions targeted at individuals at risk of CVD.

The specific objectives of this thesis are:

To describe the prevalence of CVD risk factors in four rural and urban populations in SSA, who were (partly) eligible for a CBHI program.

To describe the prevalence of target organ damage in the hypertensive population and the contribution of target organ damage screening to eligibility for anti-hypertensive treatment in Kwara State, Nigeria.
To evaluate the effect of a CBHI program on blood pressure in a hypertensive population in Kwara State, Nigeria.

To assess the operational and financial feasibility of providing high quality guideline-based CVD prevention care within the context of a CBHI program in Kwara State, Nigeria.

To explore patient perspectives on hypertension treatment within a CBHI program in Kwara State, Nigeria.

**RESEARCH SETTING AND STUDY POPULATION**

**Nigeria and Kwara State**

Nigeria is Africa’s most populous country with an estimated population size of 169 million in 2006. Nigeria is ranked as one of the fastest growing economies in the world and is now the largest economy on the African continent. Nigeria’s Gross Domestic Product (GDP) per capita is around USD 2,700 according to the latest GDP revision. Yet, inequity in Nigeria is high, as nearly two-thirds of Nigerians live below the poverty line. Nigeria has a weak health system with inadequate government funding for health, weak governance and legislation, inadequate healthcare infrastructure and poor service quality. Nigeria is one of the countries with the highest out-of-pocket spending for healthcare and poorest health indicators in the world. Nigeria has a federally funded National Health Insurance Scheme (NHIS). The majority of the enrollees, however, are individuals working in the formal sector, mainly civil servants. NHIS started a CBHI program in 2010 that should also be accessible to individuals who are not formally employed, but access to the scheme is limited. A survey carried out in Kwara Central in 2009 before the HCHC program was rolled out showed that less than 1% of the general population was enrolled in a health insurance scheme.

Kwara State in Nigeria is one of the two initial locations of the HIF program. Kwara State is located in western Nigeria (Figure 2) and is the fourth poorest state of the country. The majority of the population lives in rural areas. The dominant ethnic groups in Kwara State are Yoruba, Nupe and Baruba. The main religions are Islam and Christianity. A survey conducted in one of the target communities of the HIF program in Kwara State and a control population that was not eligible for the insurance program but comparable in terms of geographic location and socio-economic status, demonstrated that over 20% of the population lived below the poverty line of 2 USD (PPP adjusted) per day in 2009. In both the program and control area, there were few functional health-care facilities before the start of the program. Most health facilities were primary care clinics; some provided limited secondary care (such as surgery, inpatient care). Facilities were poorly maintained, essential equipment was lacking, and patient numbers were low.
OUTLINE OF THE THESIS

Chapter two describes the prevalence of hypertension and other CVD risk factors and the determinants of hypertension in four populations in Nigeria, Tanzania, Kenya and Namibia. The first three groups were (partly) eligible for the HIF program; the population in Namibia was eligible for a similar CBHI program.

Chapter three focuses on the severity of hypertension in Kwara State by describing the prevalence of target organ damage in the hypertensive population. In addition, this chapter addresses the challenge of adequate CVD risk stratification to decide who is eligible for drug treatment, in settings with limited resources.

Chapter four is a summary of the study protocol of the operational research program “Quality Improvement program Cardiovascular care Kwara-I (QUICK-I)”. The QUICK-I study aimed to assess the operational and financial feasibility of providing guideline-based CVD prevention care in primary care health facilities within the HCHC program.

Chapter five presents the results of the QUICK-I study with a focus on quality of care and health system barriers to care.

Chapter six describes a step-by-step guideline to conduct costing studies in LMICs that was developed for the QUICK-I study to assess the financial feasibility of providing CVD prevention care.

Chapter seven evaluates the financial feasibility of providing CVD prevention care by presenting the costs of providing CVD prevention care from a healthcare provider perspective.
Chapter 1

Chapter eight presents the results from a qualitative interview study to assess patient’s perceptions of hypertension drug treatment and adherence.

Chapter nine describes the results of an impact evaluation of the HCHC program on health status of the target population. More specifically, it addresses the question whether the HCHC program has decreased blood pressure in adults with hypertension.
REFERENCES


