Cardiovascular disease prevention in a health insurance program in rural Nigeria
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Chapter 10

Summary and general discussion
The research described in this thesis aimed to evaluate the feasibility and effects of providing CVD prevention care within a community-based health insurance program (CBHI) in sub-Saharan Africa (SSA). In this chapter, the main results are summarized and discussed. First, the burden of CVD risk factors in several SSA populations is described. Second, the feasibility of CVD prevention guideline implementation, and associated quality of CVD prevention care within the Hygeia Community Health Care (HCHC) insurance program, from a healthcare provider perspective, are discussed. The third part focuses on the effect of the HCHC program on CVD risk reduction and the financial challenges of providing chronic disease care within voluntary CBHI programs from an insurer’s perspective. Next, scale-up of CVD prevention services in SSA is discussed including different models of healthcare financing and service delivery. Finally, recommendations for future research are given.

BURDEN OF CVD RISK FACTORS

We found a high age-standardized prevalence of hypertension in four different populations in urban and rural SSA, ranging from 19.3% in rural Nigeria to 38.0% in urban Namibia (chapter two). Awareness of hypertension among respondents with hypertension was low, ranging from 8% in rural Nigeria to 38% in urban Namibia. The proportion of respondents with hypertension reporting anti-hypertensive treatment ranged from 7% in those with grade 1 hypertension to 17.5% in those with grade 3 hypertension. Blood pressure control (i.e. blood pressure on target) in patients with hypertension was poor with control rates ranging from 2.6% in Kenya to 17.8% in Namibia. The prevalence of hypertension was higher in the urban populations compared to the rural populations. This is not unexpected as in rural areas people lead more “traditional” lifestyles compared to urban areas. However, the observed prevalence of hypertension in rural Nigeria was much higher compared to earlier studies from rural populations in SSA, including populations from rural Nigeria.\textsuperscript{1-4} Whereas mean systolic blood pressure is decreasing since 1980 in high income countries, trends in blood pressure show an increase in mean systolic blood pressure in many SSA regions and mean systolic blood pressures in SSA are amongst the highest in the world\textsuperscript{5} (chapter two). The combination of changing lifestyles, a genetic predisposition for hypertension in people from African descent and an aging population is likely to lead to a further increase in the overall and age-adjusted prevalence of hypertension in SSA in the coming years, in both rural and urban areas.\textsuperscript{5}\* Hypertension can cause (sub-) clinical target organ damage if not appropriately treated. This was demonstrated among adults with hypertension in a population-based survey in rural Nigeria, in whom a high target organ damage prevalence of 32% was found (chapter three). These findings confirm the need for CVD prevention programs in SSA, as is advocated by multilateral organizations such as the World Health Organization (WHO) and endorsed by a United Nations General Assembly Meeting.\textsuperscript{9,10} However, how such programs should be implemented remains to be determined. The remaining chapters of this thesis aim to make a contribution to this.
FEASIBILITY OF CVD PREVENTION GUIDELINES WITHIN A CBHI PROGRAM

Quality of care
The QUICK-I study demonstrated that implementation of WHO and other international CVD prevention guidelines in one of the HCHC clinics resulted in high quality CVD prevention care. Scores on quality indicators were high, comparable to scores reported from primary care settings in high income countries (chapter five). Patient retention in care was over 90% and very high in comparison with patient retention in other CVD prevention program in SSA countries (chapter five). The results of the QUICK-I study are encouraging as they demonstrate that high quality care can be delivered in SSA under certain conditions. The context of the insurance program has most likely contributed to the success of the program. First, insured hypertension patients mentioned that the HCHC program facilitated medication adherence because they did not incur out-of-pocket expenditures for drugs (chapter eight). Costs of care is frequently reported as a reason to drop-out of care by patients in other studies. Second, the insurance program provided resources for quality improvement such as upgrading of facilities and training of staff. Other elements that have likely contributed to the high quality of care include implementation of treatment algorithm-based international guidelines, combined with training and feedback sessions. Standardization of patient files and laboratory forms supported registration of treatment follow-up (chapter five). Finally, research participation effects (also called the Hawthorne effect), in which study participants are aware of being studied, may also contribute to better outcomes, although the size of these effects and the conditions under which they occur are unknown.

Operational feasibility: barriers to care
The QUICK study also demonstrated that it was not feasible to implement specific recommendations of international guidelines, despite the availability of the insurance program.

Target organ damage screening was perceived as too time consuming, too complicated and too expensive by the healthcare provider (chapter five). Another study that evaluated barriers to hypertension care in primary and secondary healthcare clinics in Nigeria also reported that target organ damage screening was not available in the majority of health facilities. WHO and other international guidelines recommend drug treatment initiation in hypertensive individuals with (sub-) clinical target organ damage. For settings where target organ damage screening is not available, WHO recommends to use ten year CVD risk assessment charts based on age, gender, blood pressure, cholesterol, smoking and diabetes status only. However, our study in rural Kwara State demonstrated that 24% of the population with grade 1 hypertension would not be classified as eligible for treatment when using these risk charts, despite the fact that they were at very high risk for CVD based on the presence of target organ damage (chapter three). Therefore, simplified risk-stratification tools are needed for settings with limited laboratory and test facilities. A possible solution would be to treat all patients with hypertension grade 1 and above. Critics may argue that patients with mild hypertension and no other CVD risk factors have a low ten year CVD risk, especially in younger age.
groups, and that this solution would result in over-treatment. However, the current risk charts are based on data from predominately Caucasian cohorts and have not been validated for African populations. If anything, evidence points to higher risk in the latter group, with a higher incidence of cardiovascular events and cardiovascular mortality at a younger age and at lower blood pressure levels.¹⁹-²³

Combination pills and high dose formulas were not available for patients in the HCHC program, leading to a large numbers of pills prescribed per day in case of high dose multidrug regimes (chapter five). Patients perceived this as barrier to treatment adherence (chapter eight). In addition, the lack of combination pills led to high costs of drugs for the healthcare provider (chapter seven). The unaffordability of high dose multidrug regimes may explain why almost none of the patients in the QUICK-I cohort with uncontrolled blood pressure were prescribed the recommended maximum dose drug regime (chapter five). Therefore, cheap, generic fixed-dose combination formulations are an essential component of CVD prevention programs in SSA.

WHO and other international guidelines recommend frequent follow-up visits during the drug titration phase (every two to four weeks) but subsequent reduction of the visit frequency to every two to six months, depending on CVD risk of the patient.¹³,¹⁴,²⁴ Nevertheless, monthly doctor appointments were perceived as necessary for all patients by doctors in the QUICK study clinic. Providing a drug supply for longer periods to patients posed logistical barriers due to the high number of pills per day for multidrug regimes and because doctors feared that large amounts of drugs would get lost. In addition, they emphasized that regular appointments were needed to keep patients in care. Yet, for patients the frequent visits posed a barrier to treatment adherence because of inflexible clinic hours, long waiting times in the clinic, resulting income loss and associated travel costs (chapter five and eight).

Financial feasibility
The costs of CVD prevention care in the QUICK-I study were USD 144 (range 130-158) per patient per year from a healthcare provider perspective (chapter seven). The healthcare provider perspective includes all direct and indirect costs for the hospital, such as costs for drugs, consumables, staff and overheads. Additional costs for patients or for society, such as travel costs or productivity losses due to illness, were excluded. The main cost drivers were drugs (USD 39) and diagnostic tests (USD 36). Costs of care of USD 144 per year are unaffordable for many patients given that annual per capita consumption (expenditures on all food and non-food goods) in two districts neighbouring the study clinic was USD 640 (adapted from chapter two) and CVD prevention care would represent 23% of their yearly expenditures if individuals were to pay for care. These findings illustrate the need for other sources of healthcare financing to ensure access to CVD prevention care for patients, for example through health insurance programs such as the HCHC program or through government funded programs. In the next paragraph we discuss the financial feasibility of CVD prevention programs from a societal perspective, while affordability of care within insurance programs is discussed in the next section.
Affordability of CVD prevention care from a societal perspective

In chapter seven, a rough estimate of the costs of scale-up of CVD prevention care in rural Kwara was given. Based on the CVD risk factor burden in the population observed in chapter two and three, costs of CVD prevention were estimated at USD 8 (7-9) per head of the population in rural Kwara. Because CVD risk burden in urban areas is higher than in rural areas, costs per capita for the whole country are likely to be higher. Total healthcare expenditure per capita in Nigeria was USD 94 in 2012 of which only USD 29 (31%) was funded by public means. Within this healthcare budget, CVD prevention care is most likely not affordable. However, healthcare budgets in most countries in SSA are disproportionately low compared to the Gross Domestic Product (GDP). In April 2001, heads of state of African Union countries set a target of allocating at least 15% of their annual GDP for healthcare. Ten years later only Rwanda and South Africa had achieved this, the other 44 countries did not meet the target. Total healthcare expenditure in Nigeria was only 6.1% of GDP in 2012 and 66% of total healthcare expenditures came from out-of-pocket payments by patients. In addition, economies in SSA countries are growing fast with an average increase in GDP of 6% in 2013 (excluding South Africa) and an expected yearly economic growth of 6% in the coming two years. The average growth rate of GDP in Nigeria was 7% over the past decade, and a recent revision of the GDP showed that Nigeria has taken over South Africa’s position of the biggest economy in Africa. If the increase in GDP is accompanied by the promised “15% for healthcare”, resources for health will greatly increase. Finally, treatment of CVD risk factors will prevent CVD in the long term. This reduces direct healthcare costs of CVD and reduces indirect economic costs to society such as loss of human capital and productively losses due to CVD. Modelling studies estimated that CVD prevention care will be a cost-effective intervention in SSA. These studies only included healthcare-related costs of CVD and did not include societal costs or the impact on households if the main breadwinner suffers from CVD, thereby even underestimating the potential impact of CVD prevention.

The HIV epidemic demonstrated that it is feasible to provide care for chronic conditions in SSA. For example, annual costs of antiretroviral treatment in Nigeria range from USD 238 to 306 per patient per year. The need for HIV treatment is widely accepted and subsidized by donor and government funds in many countries in SSA, including Nigeria. With hypertension being the leading risk factor for death in SSA, CVD prevention in SSA should be a top priority for local and global policymakers. In addition, global funding for health should shift from a focus on infectious diseases alone to a broader agenda that also covers non-communicable diseases. If there is a political will to allocate sufficient resource to CVD prevention and healthcare in general, it should be possible to implement large scale CVD prevention programs in SSA.

HEALTH INSURANCE TO PREVENT CVD

Effect of CBHI on blood pressure in patients with hypertension

The QUICK study demonstrated that the HCHC program facilitated the delivery of high quality
CVD prevention care in a HCHC health facility, as described above. We hypothesized that increased access to improved quality health care could lead to blood pressure reduction in hypertension patients. Indeed, the HCHC program was associated with a significant decrease in blood pressure in the hypertensive population (chapter nine). More specifically, hypertensive respondents living in the area where the HCHC program was operational had a twofold greater reduction in blood pressure compared to subjects living in a control area. Systolic blood pressure decreased by 10.41 (95%CI, 13.28 to 7.54) mmHg in the program area, constituting a 5.24 (9.46 to 1.02) mmHg greater reduction compared with the control area, where systolic blood pressure decreased by 5.17 (8.29 to 2.05) mmHg. Diastolic blood pressure decreased by 4.27 (95%CI, 5.74 to 2.80) mmHg in the program area, a 2.16 (4.27 to 0.05) mmHg greater reduction compared with the control area, where diastolic blood pressure decreased by 2.11 (3.80 to 0.42) mmHg. This is an important reduction as each 10 mmHg reduction in systolic blood pressure at the population level is associated with a 38% reduction in the risk of stroke and a 26% reduction in the risk of ischemic heart disease.

These results highlight the potential of health insurance programs for long-term disease management in SSA and other LMICs. Coverage of CVD prevention care within an insurance program is a first step to reduce CVD-related morbidity and mortality. However, care for acute cardiovascular events, other than admission for basic supportive care, and chronic supportive care for patients disabled after CVD, such as physiotherapy or wheelchairs for stroke patients, was not covered in the HCHC program. More comprehensive insurance packages that include care for CVD will not only benefit the enrollees affected by CVD but may also provide a financial incentive for insurers to deliver high quality CVD prevention care, as this reduces long term costs of cardiovascular events. However, provision of chronic care within CBHI programs also faces several challenges as discussed below.

**Affordability of CVD prevention care from an insurers perspective**

Provision of chronic disease care within voluntary CBHI program in LMICs may be perceived as unaffordable by insurance providers. The management of the HCHC program mentioned the high costs of care for hypertension and diabetes patients as a threat to the sustainability of the program (Odusola et al, unpublished data). Insurance programs rely on the concept of risk pooling. Where healthcare utilization and related healthcare expenditures will be high for some enrollees, others rarely use care. The premium from healthy enrollees is used to co-finance care for sick enrollees. The insurance provider of the HCHC program actively promoted awareness of CVD risk factors in the program area. Community outreach activities included health screenings with blood pressure measurements and people with hypertension were encouraged to enrol. In addition, healthcare providers screened for CVD risk factors in patients attending their clinics for other reasons. These efforts are desirable from a health perspective but enrolment of too many patients with a chronic condition will lead to higher costs for the insurer. This problem can be solved if enrolment of high numbers of sick individuals is accompanied by enrolment of sufficient numbers of healthy individuals, to increase the insurer's budgets, for example through obligatory enrolment of large populations.
Another mechanism that may increase insurer’s costs for chronic conditions is adverse selection caused by asymmetric information about predictable healthcare expenditures between individuals eligible for health insurance and the insurer. For example, individuals who know they have a chronic illness may be more likely to enrol compared to healthy individuals. Within the HCHC program in Kwara, individuals with hypertension were more often insured compared to non-hypertensives living in the same household. This suggests adverse selection, although the previously mentioned health screenings may also explain this finding. Obligatory enrolment of large populations (state or nationwide) solves the problem of adverse selection. However, the recent roll out of the Affordable Care Act in the United States demonstrated that this is very difficult to achieve even in some high income countries, let alone in countries with weak governments. Possible other solutions to avoid adverse selection include higher co-payments for patients with pre-existing chronic diseases, introduction of deductibles, supplementary insurance packages for chronic diseases, or obligatory group enrolment.

**Sustainability of subsidized CBHI insurance**

Besides affordability of CVD prevention care within insurance programs, critics may also argue that the CBHI program in itself is not sustainable due to the fact that the premium is subsidized. 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. However, almost all countries with universal health coverage use subsidies for low income populations. For example, subsidy of health insurance premiums is approximately 80% for the lowest income groups in 2014 in the Netherlands. In addition, initial high subsidies can be used to promote large scale enrolment and to build trust in settings where people are not familiar with health insurance. When enrollees have benefitted from the program, their willingness to pay for health insurance may be higher and subsidies can be decreased. The initial subsidy of the premium in HCHC program was 93% and further lowering of the subsidy is planned. Finally, demand side subsiding of healthcare, such as subsidy of insurance premiums, can be targeted at low income groups which is much more efficient compared to subsiding healthcare for all. Studies from LMICs showed that so-called blanket subsidies, in which governments subsidize healthcare for everyone (mostly through supply side subsidies to hospitals), are of most benefit for the higher income groups. The feasibility of income-based subsidies within the HCHC program is an interesting topic for future studies.

**RECOMMENDATIONS FOR SCALE-UP OF CVD PREVENTION CARE IN SSA**

If CBHI programs in SSA would be implemented on a large scale in SSA, it should theoretically be possible to deliver similar high quality CVD prevention care as was delivered in Kwara,
in other settings. However, the QUICK study also demonstrated that CVD prevention care was resource intense and time consuming for healthcare providers that already face a high workload. In addition, it was not feasible to implement several aspects of the guidelines, such as target organ damage screening and high dose multidrug regimes. The context of the QUICK study solved some of these barriers, for example by provision of consumables for target organ damage screening. However, outside the study context this would not be possible. In addition, CVD prevention care within CBHI programs may be constrained by limited budgets of insurers. The rapid economic growth in many SSA countries offers opportunities to increase healthcare budgets. However, in the short term, current guidelines for CVD prevention care are most likely too demanding for rapid scale-up in SSA, even in settings where health insurance is available.

Therefore, there is an urgent need for simplified guidelines for CVD prevention in SSA. The focus should be on low-cost care with simple treatment protocols and limited diagnostic testing that can be delivered at a community level by non-physician health workers such as nurses, community health workers or even non-professionals such as expert patients. Studies from high income countries demonstrated that nurse-led care for hypertension and diabetes is of comparable quality as care provided by doctors. Successful nurse-led CVD prevention programs have also been described in SSA. Scenario analyses in the QUICK study demonstrated that task-shifting from doctors to nurses, reduction of frequency of clinic appointments for patients, and limited target organ damage screening would result in a direct cost reduction of 42% (chapter seven).

In this light, the so-called “polypill” may be an interesting opportunity for CVD prevention in SSA. The polypill is a fixed-dose combination formula that includes different types of CVD prevention drugs. Different formulas are available; most pills contain two or three anti-hypertensive drugs and a statin for primary CVD prevention, some include aspirin for secondary CVD prevention. The polypill could be an alternative for the current standards of primary and secondary CVD prevention care in patients at risk for CVD. Decisions on treatment eligibility could be based on simple parameters such as age, blood pressure and presence of diabetes, instead of complex risk-stratification tools. Extensive diagnostic testing to decide on drug intensity will not be needed as all patients will receive the same multidrug combination. It has been suggested that the polypill could be prescribed without monitoring of biochemical safety parameters as the low dose of different drug classes will not be associated with significant side effects. This simple risk-stratification and monitoring approach would solve the problem of high screening and monitoring costs observed in the QUICK study. Due to the simplicity of the polypill, treatment could be provided at a community level, without involvement of doctors. Referral to a healthcare centre could be limited to complicated cases. This would reduce transport time and costs for patients as well as the workload of doctors. Studies comparing the use of a polypill with standard care reported an increase in adherence by 33-49% with the polypill strategy. Other advantages are the potential for drug cost savings due to reductions in the costs of packaging and distribution.

There is an ongoing debate if low-intermediate and intermediate CVD risk groups, in addition to high risk groups, should also be eligible for the polypill in order to substantially reduce
population CVD risk. Wald and Law argued that treating all individuals aged 55 and above has the potential to reduce population CVD by 80%. Opponents argue that this approach medicalizes healthy populations. Ongoing trials will provide more data on effectiveness and safety of the polypill for CVD prevention in different risk groups.

Other models of CVD prevention care financing and delivery

Health insurance programs are just one model to finance CVD prevention care. Alternative models for CVD prevention care financing and delivery should be considered. CVD prevention programs could be implemented within workplace programs similar to the Heineken Workplace program that finances and provides HIV and general primary care for all their employees and family members in SSA. CVD prevention could also be integrated into existing vertical (i.e. disease specific) health programs, such as HIV, malaria and tuberculosis programs, thereby benefitting from the infrastructure and tools that are already in place. For example, population screening for hypertension and diabetes has been successfully integrated into HIV screening campaigns. In collaboration with the African Population and Health Research Center (APHRC), the Amsterdam Institute for Global Health and Development (AIGHD) is currently conducting a study in the slums of Nairobi, Kenya, to develop and test a model to scale-up affordable CVD prevention care using community-health workers to screen for CVD risk factors and low-cost drugs for patients at high CVD risk. Mobile phone technology can be used for treatment support to patients, for example by text messages and applications to support a healthy lifestyle and drug treatment adherence. Mobile phone financial services, such as M-PESA in Kenya (a service that allows money transfers between mobile phones), can be used as a tool to facilitate financing of chronic care for patients, for example by offering credits for healthcare expenditures, or vouchers for healthcare on mobile phones that patients use to pay in health facilities.

Positive effect of CVD prevention care on the general health system

The extraordinary investments in HIV programs in SSA have raised concerns that vertical health programs do not deal with broader health system failures: services for specific diseases are excellent while the overall health system is still weak and service for other patient categories very poor. However, quality improvement of care for chronic conditions such as HIV or CVD risk factors can also result in strengthening the health system, especially when these programs are embedded in more horizontal programs (i.e. programs that address the general health system) such as the HCHC program. The QUICK study showed that implementation of CVD prevention guidelines improved the general clinic management and service administration. For example, in order to better follow patient treatments, single patient files were introduced with standardized forms instead of family folders in which disease courses were difficult to track. In addition, forms were developed for the pharmacy to track drug dispensary and stock outs. Organizational support was provided to reduce the waiting time in the clinic and laboratory staff was trained in standard operational procedures, quality control and administration procedures. Equipment such as laboratory machines for biochemical testing was purchased. These investments will also be of benefit for non-CVD patients and therefore strengthen the local health system.
FUTURE RESEARCH

In addition to (operational) research on new CVD prevention approaches, such as the polypill and different models of service delivery, the findings of this thesis yield several other subjects for future research.

Health economic evaluations
The QUICK-I study evaluated the costs of CVD prevention care. Cost analyses are the first step in health economic analyses. As a next step, cost-effectiveness analyses will provide more insight in the costs of prevention of CVD-related death and disability. Previous modeling studies that evaluated cost-effectiveness of CVD prevention in SSA relied on estimates based on guidelines and international data sources that may not reflect actual costs and effectiveness of care (chapter seven). Cost-effectiveness analyses using empirical data will provide more insight in the cost-effectiveness of CVD prevention in different settings in SSA. In the context of insurance programs, cost-effectiveness analyses can be used to compare "the value for money" of different healthcare interventions. This can be used to decide what services should be included in insurance benefit packages. However, although interventions may be cost-effective, they may still be unaffordable within existing budgets. Budget impact analyses, for example by insurance providers or governments, will provide more insight into the need for additional resources for CVD prevention care. Studies evaluating willingness and ability to pay for different insurance packages from the patient perspective can inform package pricing for insurance providers.

Financial incentives to improve the quality of care
Provision of financial incentives for healthcare providers offers an interesting opportunity to improve the quality of CVD prevention care. There are numerous studies that have evaluated healthcare provider behaviour to different payment methods in primary care. There is some evidence that capitation and salaried payment encourages under-treatment, while fee for service is an incentive for over-treatment. However, most studies fail to correct for physician self-selection (i.e. physicians who choose for a specific payment system have specific characteristics) and the effect of payment methods on patient health outcomes is unclear. More recently, pay for performance systems, in which providers are rewarded for quality of healthcare services, have received particular interest. For example, general practitioners in the United Kingdom are paid depending on their quality score of the Quality and Outcome Framework indicators, a modified version of which was used for the QUICK-I study. However, robust evidence that pay for performance leads to improved quality of care is limited, both from high income countries and from LMICs, and findings are difficult to generalize. Two recent studies from the United States found that pay for performance resulted in better cardiovascular prevention care. A study from Burundi found that performance-based financing was associated with increases in mother and child healthcare utilization and higher scores on quality indicators. Because insurance companies can decide how healthcare providers are reimbursed, health insurance programs provide an opportunity to test the effect of different financial incentives on healthcare utilization, quality of care and patient outcomes in LMICs.
In addition to capitation and fee for service, reimbursements to healthcare providers may be based on Diagnosis Related Groups\textsuperscript{76} or Diagnose Treatment Combinations as used in the Dutch healthcare system.\textsuperscript{77} Different pay for performance systems could be tested, for example by financial incentives to individual doctors or to healthcare clinics.

**CONCLUSIONS**

CBHI programs are a promising opportunity to scale-up CVD prevention care services in SSA. Offering access to care for patients combined with quality improvement of health facilities through a CBHI program was associated with a significant decrease in blood pressure in a hypertensive population in rural Nigeria. In addition, implementation of CVD prevention guidelines with financial and organizational support from the insurance program in one of the program clinics resulted in high quality care. However, CVD prevention care was resource-intensive with relatively high costs. Rapid scale-up of CVD prevention services in SSA does not seem feasible when using current guidelines. Simplified, low-cost treatment protocols with limited risk-stratification, limited monitoring, and task-shifting to non-physician health workers are needed in order to combat the growing CVD burden in SSA.
REFERENCES


Summary and general discussion