ORIGINAL RESEARCH

Nurse Management of Hypertension in Rural Western Kenya: Implementation Research to Optimize Delivery

Rajesh Vedanthan, Jemima H. Kamano, Carol R. Horowitz, Deborah Ascheim, Eric J. Velazquez, Sylwester Kimaiyo, and Valentin Fuster

ABSTRACT

Background: Hypertension is the leading global risk factor for mortality. Hypertension treatment and control rates are low worldwide, and insufficient human resource capacity is among the contributing factors. Thus, a critical component of hypertension management is to develop novel and effective solutions to the human resources challenge. One potential solution is task redistribution and nurse management of hypertension in these settings.

Objectives: The aim of this study is to investigate whether nurses can effectively reduce blood pressure in hypertensive patients in rural western Kenya and, by extension, throughout sub-Saharan Africa.

Methods: An initial phase of qualitative inquiry will assess facilitators and barriers of nurse management of hypertension. In addition, we will perform usability and feasibility testing of a novel, electronic tablet-based integrated decision-support and record-keeping tool for the nurses. An impact evaluation of a pilot program for nurse-based management of hypertension will be performed. Finally, a needs-based workforce estimation model will be used to estimate the nurse workforce requirements for stable, long-term treatment of hypertension throughout western Kenya.

Findings: The primary outcome measure of the impact evaluation will be the change in systolic blood pressure of hypertensive individuals assigned to nurse-based management after 1 year of follow-up. The workforce estimation modeling output will be the full-time equivalents of nurses.

Conclusions: This study will provide evidence regarding the effectiveness of strategies to optimize task redistribution and nurse-based management of hypertension that can be applicable to noncommunicable disease management in low- and middle-income countries.

Key Words: facilitators and barriers, hypertension, impact evaluation, implementation research, low- and middle-income countries, nurse management, usability and feasibility testing, workforce estimation

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INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of mortality in the world, with 80% of CVD deaths occurring in low- and middle-income countries (LMICs).[1] Hypertension, a major risk factor for ischemic heart disease, heart failure, and stroke,[2] is the leading global risk for mortality.[3] The global cost of suboptimal blood pressure (BP) is estimated to reach nearly $1 trillion over the next decade.[4] Unless adequately controlled, hypertension will continue to be responsible for significant morbidity and mortality worldwide.[5] In sub-Saharan Africa (SSA), CVD is the leading cause of death among individuals over the age of 30.[6] Several studies in SSA have confirmed a significant prevalence of hypertension that is increasing over time.[7-18]

Hypertension awareness, treatment, and control rates are low in every region of the world.[19] Poor treatment and control of hypertension in LMICs is due to lack of a widespread chronic disease management platform,[20] inadequate access to essential cardiovascular medicines,[21] and insufficient human resources.[22,23] In

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Kenya, only physicians are currently authorized to manage hypertension,[24] and this situation is similar in other LMICs. However, SSA has an insufficient physician workforce to contend with the dual burden of infectious and noncommunicable, chronic diseases.[22,25-28] Therefore, task redistribution is an essential strategy to meet the human resource challenge of management of chronic diseases such as hypertension and CVD.

Task redistribution, in which specific tasks are redistributed among health workers of different levels of training, allows for more efficient use of available human resources for health.[28,29] Nonphysicians have been effective in child health and HIV care in LMICs, as well as in hypertension, heart failure, and diabetes management in high-income countries.[29-41] However, there have been no rigorous studies examining the feasibility and effectiveness of task redistribution of hypertension care from physicians to nurses in rural LMIC settings. Given the growing global need for cost-effective and population-wide chronic disease management, rigorous evaluation of task redistribution strategies is urgently required. Therefore, we plan to use a multidisciplinary implementation research approach[42] to evaluate the feasibility and effect of nurse management of hypertension in SSA.

OBJECTIVES

The central hypothesis of this study is that nurses can effectively reduce BP in hypertensive patients in rural western Kenya and, by extension, throughout SSA. Thus, the aims of this study are:

1. Assess facilitators and barriers to nurse-based management of hypertensive patients in rural western Kenya, using qualitative and participatory research methods.[43-51]
2. Evaluate the usability and feasibility of an innovative tablet-based **DE**cision **S**upport and **I**ntegrated **RE**cord-keeping (DESIRE) tool, using a participatory, iterative, human-centered design process.[52-54]
3. Conduct an impact evaluation of a pilot program for nurse-based management of hypertension to be implemented in rural western Kenya, in the context of human, financial, and logistical constraints of real-world conditions.[55,56]
4. Estimate the nurse workforce requirements for stable, long-term treatment of hypertension throughout western Kenya, using a needs-based workforce estimation model.[57-60]

METHODS

Setting

The US Agency for International Development-Academic Model Providing Access to Healthcare Partnership (AMPATH) was initiated in Kenya in 2001 and has established an HIV care system in western Kenya that serves more than 100,000 patients.[61] Based on that foundation and in partnership with the government of Kenya, AMPATH is expanding its clinical scope of work to address comprehensive primary care, including hypertension.[62] This study will be conducted within the AMPATH infrastructure in western Kenya, in Kosirai and Turbo divisions (Fig. 1). Each division has one rural health center staffed primarily by nonphysician clinical officers trained to deliver a range of clinical health services,[33] and decentralized rural dispensaries staffed by nurses.

Facilitators and Barriers to Nurse Management of Hypertension

In this study, we are using a variety of qualitative methods to assess the facilitators and barriers to implementation of nurse management of hypertension in rural western Kenya. We thus far have conducted 6 key informant interviews and 7 focus group discussions, using purposive sampling to include nurses, clinical officers, physicians, dispensary staff, patients, and community leaders. For all qualitative sessions, we developed structured interview and moderator guides, which have been used by trained moderators fluent in the local languages. Participatory techniques were used to elicit emotional elements and promote group interactions.[63] All sessions were audio recorded, transcribed, and translated into English. Content analysis of the transcripts is being performed using both deductive (a priori) and inductive (emerging) codes.[64] We randomly selected 10% of the transcribed pages to be coded and grouped by 2 different individuals, and κ-statistic calculation has demonstrated good interrater reliability. The coded items will be grouped together into themes, and relationships among these themes will be formulated.

Evaluate a DESIRE Tool

We will develop a tablet-based DESIRE tool for hypertension management to be used by nurses in rural western Kenya. We will modify the existing AMPATH decision support tools and electronic data-capture systems to create the DESIRE tool.[65-70] The clinical algorithms and decision rules are derived from the World Health Organization[71] and Joint National Commission 7[72] guidelines for hypertension management using drugs contained in the Kenyan national formulary.[24]

Inherent in the life cycle of the design and development process is testing the DESIRE tool for usability and feasibility, in line with rapid assessment for clinical informatics interventions.[73] The planned participatory, iterative, human-centered design process consists of a design and evaluation cycle in which prototypes are: 1) designed, 2) evaluated by the users (nurses) to obtain feedback, 3) modified based on the feedback, and then 4) evaluated again by the users, repeating the iterative

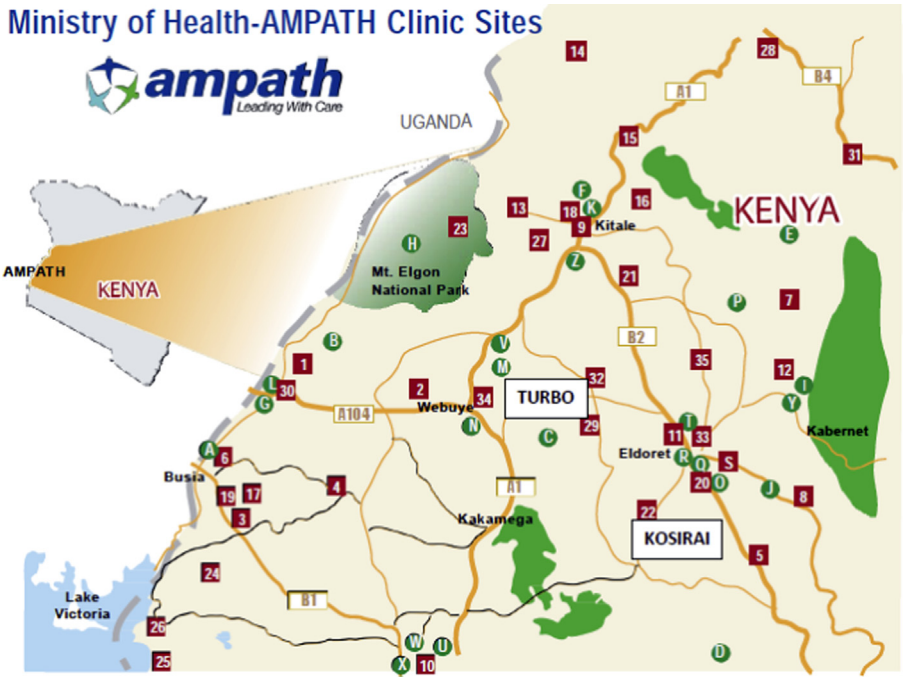

Figure 1. AMPATH centers in Kenya numbered 1-35 and lettered A-Z; Kosirai and Turbo divisions highlighted.

process until the final version has been created (Fig. 2). The purpose of following this approach is to learn from the users and incorporate their feedback and suggestions into the ultimate design of the DESIRE tool.[74]

Domains of usability include 1) effectiveness (task completion), 2) efficiency (time requirements for task completion), and 3) user satisfaction (ease of use, ease of learning, error minimization, and recall capacity).[75-77] Feasibility is comprised of both acceptability and infrastructure testing. Components of acceptability include 1) confidence using the DESIRE tool on a day-to-day basis in the work setting, 2) likelihood of recommending the DESIRE tool to one's peers, 3) value added by the tool to the workflow, 4) effect on the practitioner-patient relationship, and 5) empowerment of the end users.[43]

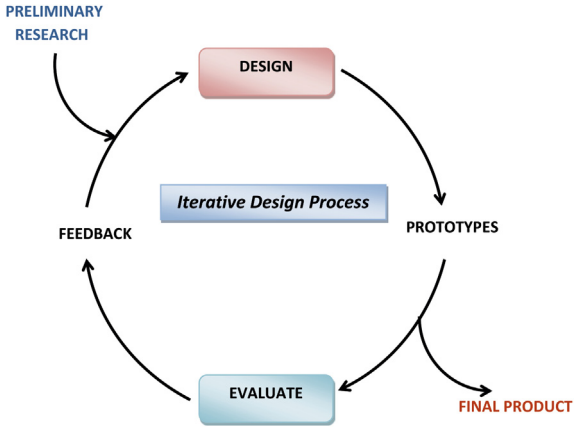

Figure 2. Schematic depicting the participatory, iterative human-centered design process.

Infrastructure testing involves identifying technical, logistical, human, and cultural barriers to the deployment of the DESIRE tool (Fig. 3).

The methods used to conduct usability testing include the "think-aloud" technique, mock nurse-patient encounters, semistructured interviews, and focus group discussions.[77] The think-aloud technique is a method for evaluating usability of a product in which the users are asked to say out loud what they are seeing, thinking, doing, and feeling as they use the product.[78] In mock nurse-patient encounters, a member of the research team acts as a mock patient to enact selected case scenarios, and the nurse is required to examine, diagnose, and treat the mock patient using the DESIRE tool. To date, we have conducted 5 think-aloud exercises and 5 mock nurse-patient encounters, because it has been proven that using 5 subjects can detect more than 80% of usability problems.[79] The content analysis of these sessions will include assessment of "critical incidents," which had a significant effect (negative or positive) on usability.[80] We also will be conducting focus group discussions with the nurses in order to understand their perceptions of the tool, and to obtain recommendations for improvement.

Feasibility testing occurred during the time when each nurse used the DESIRE tool to manage the first real patients. To evaluate acceptability, we will use semi-structured interviews and focus group discussions with the dispensary nurses. Infrastructure testing will be conducted using participant and nonparticipant observation of actual nurse–patient encounters. The assessment will focus on whether any technical, logistical, human, and cultural constraints are impeding the use of the DESIRE tool in the dispensary setting.

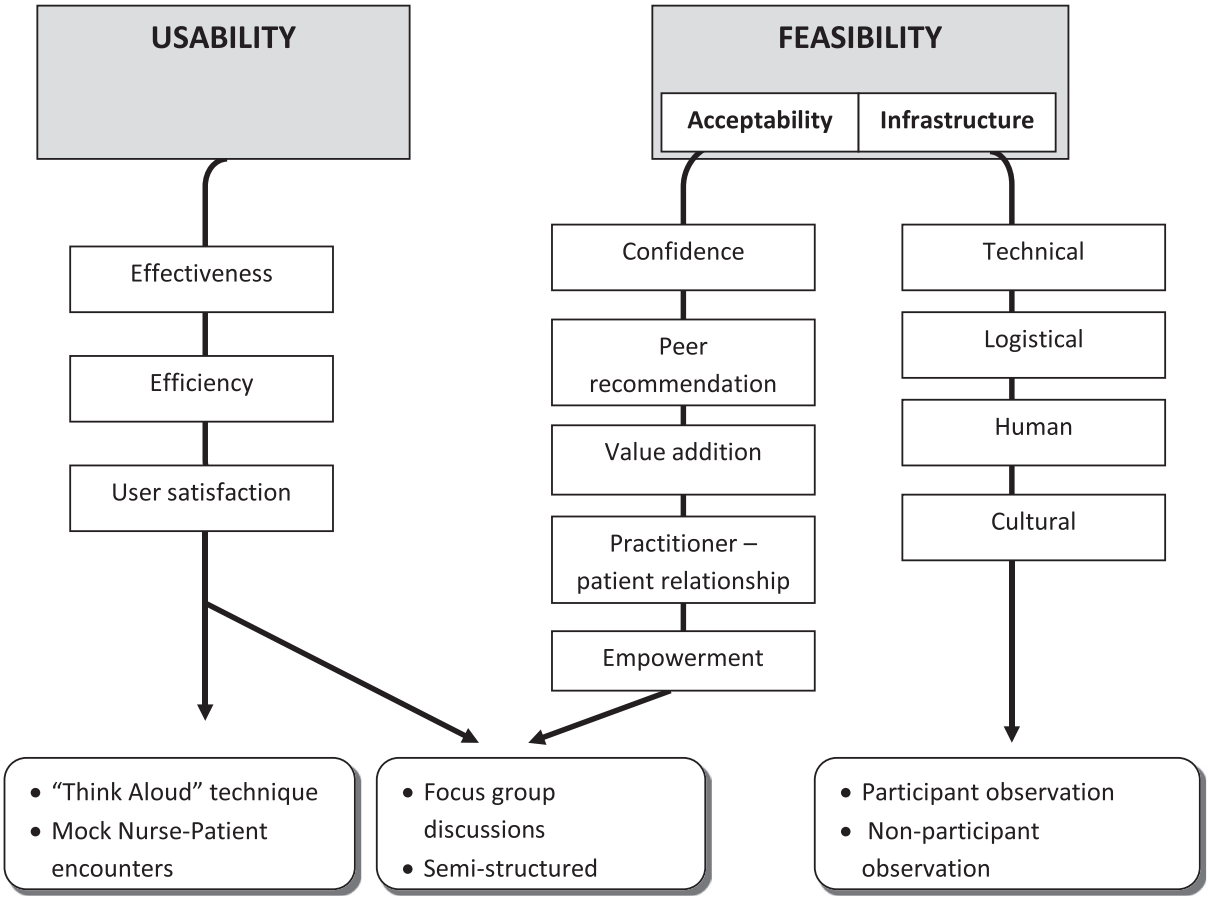

Figure 3. Components of usability and feasibility testing of the DESIRE tool.

Impact Evaluation of Nurse-Based Management of Hypertension in Rural Western Kenya

AMPATH has implemented a pilot program of hypertension management in western Kenya to be based at the rural dispensaries staffed by nurses. We will conduct an impact evaluation of this pilot program to determine how effectively nurses can reduce BP among hypertensive individuals, by performing secondary analysis of routine clinical data collected by AMPATH.

Participants. Community-wide home-based testing of BP, using automatic BP machines, has been initiated by AMPATH in Turbo and Kosirai divisions, with a plan to cover one-third of the population every year (J.J. Mamlin and S. Kimaiyo, personal communication, January 2014).[82] Individuals with elevated BP (systolic BP [SBP] $\geq$140 mm Hg or diastolic BP [DBP] $\geq$90 mm Hg) will be referred to the local dispensary for further evaluation. At the dispensary, each individual will have a repeat BP measured in order to minimize regression to the mean, and those with repeat elevated BP will be entered into the hypertension management program. Exclusion criteria include individuals with symptoms (dyspnea with exertion; lower extremity edema) or high-risk features (pregnant; age <35 years; history of myocardial infarction, stroke, heart failure, or renal failure). High-risk individuals will receive their care at the health center instead of the dispensary. Management of hypertension will be standardized according to AMPATH protocols, and includes lifestyle counseling, nurse prescribing of initial medication (hydrochlorothiazide), and clear algorithmic criteria for escalation of pharmacotherapy and referral to higher level of care.

Data sources. All clinical patient-level data will be entered into the AMPATH Medical Record System, per routine AMPATH protocol, and we will extract clinical data such as demographics, diet history, physical activity, smoking history, personal history of CVD or diabetes, family history of CVD or diabetes, CVD symptoms, BP, height, weight, prescribed medications, medication adherence, medication dosage adjustments, suspected adverse medication reactions, development of complication from hypertension, and death.

Outcomes and statistical analysis. We estimate that the annual number of patients enrolled in the pilot program will be ~1300 based on the following assumptions:

1) The total population of Kosirai and Turbo divisions is ~120,000.
2) Almost half (45.3%) of the population is over the age of 20 years.[81]
3) One-third of the population will be screened each year.
4) Estimated hypertension prevalence is 15% among adults throughout the division.
5) Estimated 60% participation rate was expected.
6) An estimated 20% of hypertensive individuals will be excluded due to high-risk status.

As a conservative estimate, we will have 80% power to detect a mean change in SBP of 2 mm Hg using a paired *t* test with a 0.050 two-sided significance level,[83] assuming SD of SBP of 18.8 mm Hg.[11] Other studies of nurse-based management of hypertension have reported change in SBP in the range from 4.0 to 8.9 mm Hg.[30,84] Figure 4 illustrates the power we will use to detect different mean changes in SBP as a function of sample size. Except for the scenario of mean change in SBP of 2 mm Hg, 90% power will be achieved at sample sizes that are well below our anticipated sample size.

The primary outcome measure will be the change in SBP of hypertensive individuals assigned to nurse-based management after 1 year of follow-up, using paired *t* test of mean change in SBP. Those lost to follow-up will be assigned their last known result at the end of follow-up. Results will be determined overall, and further analyses will involve stratification by sex, age group, location, dispensary, and whether or not the patient was referred to the health center for more intensive management. Multivariate linear regression will also be performed, using change in SBP as the outcome measure, and the factors mentioned previously as covariates.

Secondary outcomes include percentage of hypertensive individuals with controlled BP (<140/90 mm Hg) at the final clinic visit, medication adherence, and behavioral changes. We will perform sensitivity analyses to evaluate the effect of loss to follow-up.

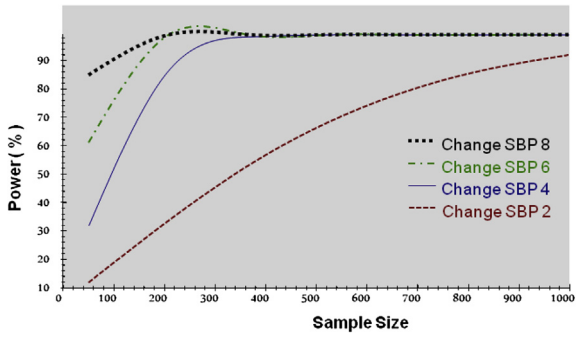

Figure 4. Power as a function of sample size for different mean changes in systolic blood pressure (SBP).

Estimate the Nurse Workforce Requirements for Hypertension Management in Western Kenya

We will develop a needs-based workforce estimation model for hypertension management in western Kenya, similar to what has been used to estimate HIV workforce requirements in SSA using simple spreadsheet technology,[58] in order to estimate the nurse workforce requirements for stable, long-term hypertension management in western Kenya. The model inputs will be needs and capacity. Data sources will be derived from AMPATH's pilot nurse hypertension management program or published estimates of workforce capacity in SSA.[85] The model output will be full-time equivalents (FTEs). Although the primary focus is to estimate nurse workforce requirements, the model will provide workforce estimates for different types of providers. The duration of the model will be 3 years, although this time period is modifiable.

Need is defined as the total number of clinical encounters per month (v_j) required to care for all patients with hypertension (n_{ij}), for each category of patient (i) and each type of provider (j). Each category of patient would require a different encounter frequency (f_{ij}) with each type of provider. For instance, patients controlled with lifestyle modification can be seen every 3 months with a nurse. On the other hand, high-risk patients require a monthly encounter with a clinical officer. The basic formula for need is given by:

$$v_j = \Sigma_i \left(f_{ij} \times n_{ij} \right)$$

The need domain can be modified to account for loss to follow-up and death. The model also can be adjusted for the rates at which patients may change clinical categories over the duration of the time span of the model.

Capacity is defined as the number of encounters possible per month (E_j) for each type of provider. Capacity is determined by the amount of patient-contact time (t_j) each type of provider can work per month, as well as the average productivity of each type of provider (ie, time per clinical encounter [m_j]), as follows:

$$E_j = t_j / m_j$$

The number of monthly FTEs (F_j) required for each type of provider to meet the total need is given by:

$$F_j = v_j / E_j$$

We will be able to estimate the number of nurse FTEs required at the end of each time period, which will allow for 1) comparison with current nurse staffing levels; and 2) projection of nurse staffing requirements over the 3-year time period. We will also be able to estimate the staffing requirements for other types of providers at each of the 3 time points. Sensitivity analyses will be performed with different needs and capacity inputs.

DISCUSSION

The global burden of hypertension and other noncommunicable diseases is increasing in LMICs. However, insufficient data exist regarding effective health care delivery practices in these settings. Addressing the human resources challenge of controlling noncommunicable diseases can benefit from evidence-based approaches. This study was conceived with these objectives in mind, and offers several unique and innovative elements. First, the study is pursuing a participatory methodology, in which community members and stakeholders are empowered to inform the research, influence the intervention, and affect the research products. Second, we are using a human-centered design approach to develop and evaluate the performance support tools for hypertension management. Although human-centered design has traditionally been used in manufacturing, computer software, and web design, using this approach in the context of hypertension management is novel. Third, we are evaluating the effectiveness of hypertension management by nurses embedded in their own communities in the setting of the human, financial, and logistical constraints of real-world conditions. Fourth, the planned workforce estimation model for hypertension management will be, to our knowledge, among the first of its kind in LMICs, and will serve as a benchmark for future studies. Finally, we aim to demonstrate the ways in which a well-functioning HIV care delivery system can serve as a foundation to expand and include the management of noncommunicable chronic conditions in an integrated fashion.[86] Thus, the results of this project can add to the emerging body of knowledge on scalable and sustainable strategies for effectively managing noncommunicable diseases in LMICs.

CONCLUSION

Given the growing global need for cost-effective and population-wide chronic disease management, rigorous evaluation examining the feasibility and effectiveness of task redistribution strategies is urgently required. This study will provide evidence regarding the effectiveness of strategies to optimize task redistribution and nurse-based management of hypertension that can be applicable to non-communicable disease management in low- and middle-income countries.

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