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Patient experiences and perspectives on hypertension at a major referral hospital in rural southwestern Uganda: a qualitative analysis

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ABSTRACT

Objectives Novel care models are needed to address the large burden of hypertension globally. We aimed to explore how patients in rural Uganda experience and perceive hypertension in order to understand factors that may inform development of a patient-centred care model for hypertension management in this setting.

Design We conducted one-time, in-depth qualitative interviews focusing on participants' experiences and perceptions of the meaning and management of hypertension.

Setting Outpatient clinic at Mbarara Regional Referral Hospital in Uganda.

Participants We enrolled patients who had hypertension and had used antihypertensive medication for at least 1 month. We used purposive sampling to recruit 30 participants with similar representation by gender and by absence or presence of comorbid conditions.

Results Participants had been diagnosed and initiated care at various clinical stages of hypertension, which impacted their understanding of hypertension. Several participants saw hypertension as a chronic disease that can lead to complications if not controlled, while others attributed symptoms typically associated with other diseases to hypertension. Participants described inconsistent access to antihypertensive medications and difficulty with transport to the clinic (time needed and expense) as the major barriers to access to care. Initiation and maintenance of care were facilitated by family support and ready access to health facilities. Many participants identified an understanding of the important lifestyle and dietary changes required to control hypertension.

Conclusions Patients with hypertension in rural Uganda demonstrated a varied understanding and experience with hypertension. Interventions leveraging family support may help with patient education and clinical management. Integration of patient perspectives into the care model, patient-centred care, may serve as a successful model for hypertension and potentially delivery of care for other non-communicable diseases in Uganda and other similar resource-limited settings.

Strengths and limitations of this study

- A major strength of this study is the fact that participants reflect a range of comorbidities and experiences with their hypertension. They were also interviewed at the same clinic and could comment on the same care delivery model for hypertension.
- The rigour of our approach is supported by the achievement of thematic saturation and detailed coding process.
- The study was limited in not including the perspective of family members or healthcare workers. Additionally, the focus on one clinic at a referral hospital means that our findings may not apply to other clinics involving different types of patients or other care delivery models.
- We also did not assess the participants' education level and the role it could have played in their understanding of disease or their medical care.

INTRODUCTION

In 2016, 71% of global deaths were attributed to non-communicable diseases (NCDs), with the largest portion of those attributed to cardiovascular disease.[1] Hypertension is the leading risk factor for cardiovascular disease, with estimates that it directly leads to as high as 13% of deaths worldwide.[2] In Uganda, an estimated one in every four adults has hypertension, and only 10% are aware of their disease or access care.[3] Moreover, a prior study of a validated medication adherence tool found that only 15% of patients met the tool's level of moderate or high adherence to antihypertensive medications.[4] Given such a high burden and treatment challenges, improved methods of delivering hypertension care are clearly needed.[5]

Patients' experiences and perspectives on hypertension can help shape their treatment. Patient-centred care is a form of health delivery in which multilayered issues, including access to care, disease factors and patient characteristics, are addressed with specific decisions and plans to respond to individual patient's needs and desired outcomes.[6] This model has been

shown to be effective at increasing access and adherence to treatment and at improving clinical outcomes.[7] The WHO considers patient-centred care essential for sustainable NCD management.[8] Despite the benefits of patient-centred care, few studies have explored how to provide patient-centred hypertension care in low/middle-income countries (LMICs) like Uganda. Of the studies available, most have focused on non-adherence or disease management,[9–11] and none has used qualitative methods to assess patient-level factors in NCD care in Uganda. However, Siddharthan *et al* did evaluate a patient-centred tool with educational booklets in the management of heart failure in Kampala, Uganda and noted improved patient engagement with physicians and comfort with self-management of disease.[12]

To inform the development of a patient-centred care model for hypertension management in LMIC settings, we conducted qualitative interviews of patients at a regional referral hospital in rural southwestern Uganda. We specifically sought to understand how patients experience their diagnosis of hypertension, understand the disease and its treatment, access care and manage their hypertension.

METHODS

Study setting and population

Care for hypertension in Uganda can be sought at a variety of health centres from Health Centre IV to tertiary care facilities. Specifically, complex cases, often with complications of hypertension, are referred to general, regional or national referral hospitals, which offer increasing degrees of expertise and specialised care, although direct care is available at all facilities. The national level has three levels of hospital: general, regional referral and national referral. Hypertension is typically treated by general practitioners or physicians with training in internal medicine.[13]

Participants for this study were identified from the outpatient hypertension clinic at the Mbarara Regional Referral Hospital, which is located approximately 260 km southwest of the capital, Kampala. This clinic provides NCD care to over 3000 patients, with an average of 75–120 patients with hypertension seen each week.[4] Patients are seen on different days of the week based on disease: nephrology and neurology on Monday, hypertension on Tuesday, gastrointestinal on Wednesday, diabetes on Thursday and urology on Friday. Healthcare providers treat patients on a first come, first serve basis. Although medication is provided free of charge, it is often not available due to stock-outs, and patients must buy medications from private pharmacies. When available, primarily calcium channel blockers and thiazide diuretics are used, followed by ACE inhibitors and angiotensin II receptor blockers for those with uncontrolled hypertension.

Patient and public involvement

Patients and the public were not involved in the design of the study in this report.

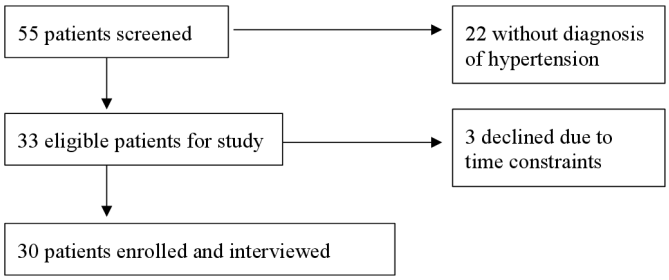

Figure 1 Recruitment and screening of participants.

Sampling and recruitment

We purposively recruited participants in conjunction with the clinic staff, who used clinic registries and/or personal knowledge to identify potential candidates with a similar ratio of men and women and known comorbid conditions. We aimed for a balanced distribution among participants with hypertension only and hypertension with comorbid diabetes and/or HIV. Potential candidates were approached for written informed consent (online supplemental appendix 1). Recruitment continued until thematic saturation was reached on analysis (figure 1).

In this study, all participants had to have an established diagnosis of hypertension, be 18 years or older, and be able to speak either English or one of the local languages (Runyankole or Rukiga). Pregnant patients were excluded from the study, as pregnancy-related hypertension was considered beyond the scope of the project goals. Patients unable to provide informed consent, including impairment from intoxication or psychosis, were excluded from the study.

Data collection

We conducted one in-depth, in-person qualitative interview with each participant. The goals of the interviews were to explore the participants' experiences with their diagnosis of hypertension, their understanding of the disease and its treatment, factors involved in access to care and how they approach managing hypertension. Interviews were conducted in an office away from the clinic to ensure privacy and confidentiality. A trained research assistant (GN) fluent in English and Runyankole/Rukiga conducted all interviews following a prespecified interview guide (online supplemental appendix 2). The interview guide was developed by reviewing previous qualitative hypertension studies and discussing key aspects of disease that could be influenced by care delivery models. We used a grounded approach to avoid biasing participant responses. The initial interview guide was tested among members of the team and with two informal interviews of people with hypertension with improvements made in phrasing to increase clarity. The Runyankole/Rukiga version of the interview guide was back translated to confirm consistency with the English version. Interviews were audio-recorded, translated and transcribed at the same time in English, and reviewed for quality. Data collection lasted approximately 3 months.

Data analysis

We analysed qualitative transcripts according to conventional content analysis.[14] Author AGH reviewed the first five transcripts, analysed content to develop labels, and then created operational definitions and developed a codebook with selected illustrative quotes with significant input from author JH. For quality control, approximately 10% of interviews were double-coded (authors AGH and PO) and any discrepancies were discussed until consensus was obtained. The codebook was then refined using an iterative process as further interviews were coded. Following completion of the codebook, the remaining transcripts were coded using Dedoose software (V.8.3.11, Los Angeles, California, USA). These codes were used to create a descriptive analysis based on the themes generated from the data and the goals of the study. Quotes were selected to reflect each category and illustrate themes. We used the Standards for Reporting Qualitative Research and Consolidated Criteria for Reporting Qualitative Research checklists when writing our report (online supplemental appendices 3 and 4).[15]

RESULTS

Participant characteristics

We screened 55 patients for the study. Of those, 22 were ineligible, primarily because they did not have a documented diagnosis of hypertension. Three additional eligible patients declined participation due to personal time constraints. We thus enrolled and interviewed 30 participants, of whom 20 (67%) were women; the average age was 60 years (SD 14.5 years). Ten (33%) participants had hypertension only, 10 (33%) had hypertension and diabetes, 1 (3%) had hypertension and HIV, and 9 (30%) had hypertension, diabetes and HIV. Interviews averaged 49 min (SD 12 min) in length.

Overview of qualitative interview results

We identified four themes representing the experience of participants receiving a hypertension diagnosis and related care over time, starting with (1) participants' initial connection to care, which impacted to how they (2) understood hypertension as a disease. Through the course of their treatment, participants also identified factors that affect (3) access to care and (4) management of hypertension.

Connection to care

Participants initiated care for hypertension at various stages of disease. Those not yet connected for any general care typically presented when symptomatic; however, some noted that they were asymptomatically diagnosed after screening during an outpatient appointment for another disease or at a local health fair.[16]

Many participants noted that they received a diagnosis of hypertension after a presentation to the hospital with symptoms from another disease, typically either diabetes or a common complication of hypertension, such as myocardial infarction or stroke.

> How I came to know that I have hypertension, the same time I was diagnosed with diabetes, I also used to urinate so much. When I narrated the story to someone, how my situation was because I was not having comfortable sleep, he just told me that I am suffering from diabetes, and indeed it was confirmed that I have diabetes and hypertension when I went for treatment. (Male, 86)

> I used to be a very sickly person at school in secondary level. I would even collapse, my heart would at times pump so fast…They then brought me to this hospital and diagnosed me with hypertension. They treated me from the outpatients' department, and from there they directed me to the section of the hypertension clinic. They continuously kept checking my hypertension levels…The levels were continuously high. (Female, 28)

We also noted trends among participant characteristics and how they received their diagnosis. For instance, participants with HIV tended to receive their diagnosis of hypertension during a routine clinic visit for HIV care.

> I was attending to my usual routine of HIV treatment, and then they took some tests of hypertension and diabetes, and they found out that I had both diseases. My hypertension was very high at 190. From there, I started taking hypertension medication. (Female, 50)

Hypertension as a disease

When asked what hypertension meant to them as a disease, participants expressed a range of understanding. Most participants were focused on the long-term preventive aspects and cardioprotective nature of hypertension treatment, though how they described their symptomatology depended on the setting of their hypertension diagnosis. Participants who were diagnosed with hypertension either in the outpatient setting during a routine appointment or after symptomatic presentation from hypertension complications tended to prioritise hypertension's long-term risk of stroke and heart disease.

> Whenever I come here at the hypertension clinic, I get a chance of meeting people…who were hit by stroke and got paralyzed because of poor management of hypertension. I have to make sure that I always have enough medication of hypertension in order to avoid being hit by stroke and getting paralyzed, too. (Female, 50)

Those diagnosed during a hospitalisation for diabetes or an unrelated illness were more likely to associate hypertension with an array of symptoms. In particular, patients with dual diagnoses of diabetes and hypertension often attributed symptoms of diabetes to hypertension or were unable to differentiate the symptoms of the two diseases.

P: Hypertension and diabetes are very hard to describe. I actually understand diabetes more than hypertension. The body generally loses all its abilities to do anything. You totally feel so weak. You just feel death is grabbing your entire life. At times you get so dizzy, feel confused in the head, the eyes completely become squinted and start looking at everything in doubles.

I: Is this hypertension or diabetes?

P: I cannot tell the difference of which is which. I take them as one disease. (Female, 71)

Other participants simply stated that they were unsure how to describe hypertension, whereas several participants described hypertension as a 'catch-all' for any unexplained symptoms they may be experiencing.

I don't know, because hypertension is so difficult to explain. Sometime I feel a lot of heat that covers me abruptly, and I start sweating seriously all over my body. But I cannot tell you exactly what hypertension is or how it pains. Not at all. (Female, 72)

Participants generally understood hypertension as a chronic disease. Even with this idea of a chronic disease, they demonstrated resilience and acceptance toward the disease.

It is a very important thing to know your hypertension status because you start treating yourself seriously, maybe you can live longer and do wonderful things in life that you have always wished to do. (Male, 45)

In some, faith played a role in the acceptance.

I just thought about it deeply, and my mind told me, God has a purpose for everything. If this is what he has decided for me, then I will accept it as well. (Female, 71)

Access to care

Participants noted structural and clinic-based factors that contributed to how and when they accessed care and how it ultimately impacted their approach to management.

Barriers to care

The cost of hiring transport, both local motorcycles and longer distance taxis, was a significant barrier to care and increased the cost for participants to attend the clinic and make scheduled follow-up appointments.

The medicine I take is very expensive. I also have to come here with a boda boda [motorcycle], which I must pay, and I have to feed as well. (Male, 45)

Participants repeatedly noted financial strain as a major barrier. Decreased available funds, combined with a shortage of the free hypertensive medications supplied by the government at the clinic, led to difficulties purchasing medications with out-of-pocket funds and a decrease in self-reported medication adherence.

P: They always tell me to go and buy, but I do not have the money.

I: How long have you spent without swallowing your hypertension drugs?

P: I have spent about four month, but I am not very sure. I think I last swallowed in March. Whenever they tell me to go and get hypertension from the hospital pharmacy, I do not get anything…They always prescribe the medicine, but the money to buy it is the challenge. (Female, 72)

In addition to accessibility of the clinic impacting care seeking, many participants noted characteristics of the clinic structure that were frustrating and impacted their attitude toward care. Many noted having to arrive at the clinic over 2 hours before the clinic started.

I finished my treatment early today because I woke up so early at around 5:30am. It rained on me, but I wanted to be among the first patient to be treated. In fact, I was the second patient to arrive, and I had to wait…I do not know whether it is because of the many patients or few doctors. Sometimes you wake up early but still you finish your treatment late at around 4:00pm or 5:00pm, when you are very exhausted and tired. (Male, 45)

Several participants compared the ease of accessing treatment and management of HIV to the difficulties of accessing care for hypertension, with some considering it worse than HIV in certain regards.

This disease is more of a risk than HIV. Its rating should be classified as a very dangerous disease. If it is in order, we should be given much more attention than the patients of HIV. These patients of HIV are given counseling, medicine, outreach programs. Really, we should also receive this kind of attention; hypertension is a major risk in families. (Female, 35)

Participants noted a contrast between the availability of care services between different diseases, with more accessible programmes in place for HIV services.

Facilitators to care

Participants often asked for clinics more easily accessible from their home, either by walking or inexpensive, short-distance transportation.

How I wish the services were extended nearer to the people in the communities. If they are able to test our hypertension levels in the community, it would be one way of easing treatment for us. (Male, 74)

Additionally, the relationship with health workers was generally positive and encouraged participants to go to the clinic regularly for care.

What I like most is the good relationship we have with these health workers at this hospital. We talk together nicely about health issues. Sometimes, you even

forget about the challenges you go through. If they were using bad language, people would not be coming to this health facility. (Male, 86)

Participants also expressed the importance of social support, balanced with independence and motivation to manage their own disease. Participants placed particular importance on family and community support, including caregiving, transportation and financial support.

My children are now very helpful. Their father is the one who used to take care of me when he was still alive, but when he passed away, they each gave themselves months when they would buy for me medicine…They usually buy for me the food that I cannot afford, for example fish. They show me so much care and love that keeps me at peace. (Female, 65)

These variable experiences in accessing care shaped the participants' abilities to manage disease and their motivation to seek extensive treatment.

Management of hypertension

Pharmacological therapies

Most participants noted that when they had access to medications at home, they always remembered to take their medications and recognised the importance of medication adherence.

No, I have never missed [taking medication]. It is not easy for me to forget. Wherever I go, I have to make sure that I carry my medicine. If I am to spend a night there, I have to make sure that I carry some. It has really never happened. (Male, 72)

Oftentimes, however, participants were unable to pick up medications at the hospital pharmacy, where it is free, due to stock-outs. They were advised to purchase the medication at a private pharmacy. With this added out-of-pocket expense, several participants noted that they would return home without any medications, as they could not afford the costs at private pharmacies.

Money is the most challenging thing while seeking hypertension treatment, especially in buying medicine. For example, the medicine they have prescribed me today is not available here in the hospital, and I have to go and buy it from the drug shops, and I do not have money to buy it. So that becomes a big challenge. (Female, 53)

Alternative therapies

Participants reported mixed opinions regarding alternative therapies. Many reported not using these therapies because healthcare providers counselled them that the dosing and utility of these therapies were unknown, although some used these therapies in place of medication that they could not afford.

Most of those herbs are so expensive, and I have seen people who stopped swallowing their hypertension or diabetes drugs, and they die so abruptly and painfully. So, I do not trust such medicines. (Female, 53)

I use herbal medicine these days for hypertension because the drugs are very expensive. (Female, 56)

Non-pharmacological therapies

Participants with hypertension and HIV contrasted the significant non-pharmaceutical management required with NCDs with the primarily pharmaceutical management for HIV care.

HIV is very manageable. I used to do my activities as usual, eat all the foods I want, but with hypertension and diabetes, it's very different. They weaken the body and prevent me from doing all my other activities. You become a real patient and very delicate because you become very selective with the foods… These make life very difficult. (Female, 56)

Many participants noted an understanding of the necessary dietary and physical activity changes that they should make to improve their health and help manage their disease. They noted receiving some form of counselling during the course of their hypertension and diabetes care, listing dietary changes and the importance of exercise.

I was tested and was told I had hypertension. The health workers told me what I should and shouldn't do. In case I was drinking alcohol or smoking I should stop, time reached when I was told to stop eating salt. (Female, 65)

I think it is important because they educate us with how to control it. They say that even if you do not have medicine you can be able to do your exercises very well, do your work very well, your condition may improve somehow. (Male, 64)

Participants endorsed a significant understanding of lifestyle modifications necessary for NCD management, though noted difficulties in maintaining those lifestyle changes. Participants also highlighted finances as a barrier to adherence and alternative therapies as options when they were unable to access their hypertension medications.

DISCUSSION

In our qualitative study of patients with hypertension in a regional referral hospital in rural Uganda, we found that patients were likely to be connected to care earlier when they had access to health screenings or regular outpatient appointments, presented for another disease, or had easy access to a clinic and family support to encourage care. Participant understanding of hypertension was variable, but closely tied to their symptoms at presentation and/or presence of comorbidities. Financial strain and

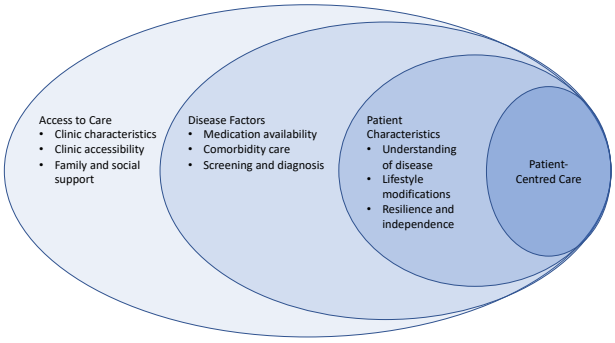

Figure 2 Patient-centred care: factors impacting the patient receipt of care with increasing individualisation of experience.

difficulty travelling to the clinic were among the primary barriers to care, whereas family support and accessible clinics promoted access to care. Additionally, a diagnosis of hypertension was understood to be a chronic, lifelong disease, and participants were generally resilient and eager to continue with disease management through good medication adherence (when possible) and lifestyle changes. All of these components can be used to incorporate patient perspectives into a system that includes generalised patient support, disease integration and patient-level factors as major factors to this patient-centred care model (figure 2).

A major strength of this study is the fact that participants reflect a range of comorbidities and experiences with their hypertension. All participants were seen at the same clinic and could comment on the same care delivery model for hypertension. Furthermore, enrolment continued until thematic saturation was reached. This study is also the first of its kind in trying to understand patient-centred characteristics of hypertension care in Uganda. The study was limited in not including the perspective of family members or healthcare workers. Future studies may benefit from interviewing both caregivers of patients and healthcare providers in order to facilitate a care delivery model that is feasible for both the recipients and deliverers of care. Additionally, the assessment of a single clinic which operates as a referral centre for the region may not be generalisable to other clinics. Also, we did not assess the participants' education level and the role it could have played in their understanding of disease or their medical care.

Considering patient-level factors in healthcare delivery can help ensure adequate management of hypertension and other NCDs by aligning the clinic structure and resources with patient values and beliefs.[17] Perera *et al* conducted a similar study to ours in Sri Lanka and also stressed the importance of public education and improved communication between healthcare providers and patients to facilitate care.[10] Furthermore, Wekesah *et al* reported similar findings regarding health promotion and awareness in a qualitative study of cardiovascular disease in Nairobi.[9] Coordinated NCD specialty clinics are currently rare in LMICs; instead, care is divided among specific specialties. Kruk *et al* suggest redesigning care models in LMICs with a focus on patient and community outreach; this could include integrating care team services and using community healthcare workers to increase access to affordable care.[18] In the Ugandan setting, this model could be used to overcome structural barriers to care or to model the clinic in a way that allows patients to receive care for multiple diseases on 1 day. Routine hypertension care could also be extended into the community, for example, by using health centre II clinics that rely on community health workers. When possible, connecting patients with ways to receive transport or medications at an affordable rate may improve access to care and management of disease. More stable patients may benefit from extended time between follow-up visits to combat expenses for hiring transport to the clinic.

Our study highlights the many ways that patient-centred care can help in improving the delivery of hypertension care in Uganda. As noted, most NCD care in Uganda is provided in specialty clinics, predominantly located at referral centres. Prior groups have integrated NCD care so that patients can receive all their care for chronic diseases at once, thus saving significant time and expense in obtaining care.[17 19 20] For example, Peck *et al* and Wroe *et al* found integrating NCD care with a patient-centred approach helps to reach patients beyond certain barriers to care and prepare clinics for managing these diseases.[19 20] By integrating NCD care, patients will have decreased travel burden as they receive all their disease care at once. Further, when managing patients' multiple diseases, time can be allotted to customise treatment approaches that fit particular patient preferences and disease burden. Our findings are also supported by studies such as the HOPE-4 programme, which used similar qualitative research in Malaysia and Colombia to incorporate the findings into care models with physicians, non-physician health workers and family members, ultimately determining through a cluster-randomised controlled trial that these interventions can significantly reduce blood pressure and cardiovascular disease.[21] Similar adaptation of healthcare delivery models should be considered in Uganda.

Patients in general understood the chronicity of the disease and steps required to prevent long-term outcomes, although it may be difficult to follow these steps without support from caregivers and family. Counselling family members alongside patients, including topics related to long-term outcomes of hypertension and what to expect from treatment, may help bridge this gap. By including family and community support in care, patients can better access care and manage their NCDs with appropriate lifestyle management options.[22] While lifestyle changes may be physically difficult to enact, they can also have significant financial burden, especially for dietary changes. Traditional dietary modification recommendations may be difficult to enact for patients without clear examples of healthy foods that are both affordable and locally available. Increasing community engagement or integrating

care may facilitate these other changes, and further study toward this is necessary. Participants repeatedly noted that strong social support improved their motivation to manage their disease, suggesting that including family in care would be a welcome approach to combating NCDs. Engagement of family could be particularly important in both the initiation and persistence of lifestyle changes.[23]

Interestingly, participants did not report challenges with medication adherence, although this problem has been widely cited in the literature, including in this setting.[4 24] They did note financial constraints to medication adherence, which may be addressed at least in part by more patient-centric care delivery model as described above. Of note, the study did not formally measure adherence and it may have been a larger concern than reported in the interviews due to social desirability or recall bias.[25]

CONCLUSION

In our study of patients with hypertension in southwestern Uganda, experience varied considerably regarding receiving a diagnosis and comorbid conditions. Structural barriers, including clinic accessibility and availability of medications, play major limitations in disease care. Patient-centred care in this setting should seek to reduce these barriers through integrating NCD care in the community and building up family support in disease education and management. By including the patient perspectives in models of care, patient-centred care may be able to improve healthcare delivery and outcomes.

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Competing interests JH reports grants from NIH, during the conduct of the study; personal fees from Merck, outside the submitted work.

Patient consent for publication Not required.

Ethics approval The study was approved by the Mbarara University of Science and Technology Faculty of Medicine Research Ethics Committee; the Partners Health Care Human Research Committee; and the Harvard Medical School and Harvard School of Dental Medicine Institutional Review Board, via Reliance. We additionally received approval from the Uganda National Council on Science and Technology. All participants provided written informed consent or thumbprint in the case of illiteracy (see online supplemental appendix 5 for full protocol).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Participant data that underlie the results reported in this paper are available following the paper's publication and under appropriate data sharing agreements. We will also provide the study protocol, analysis plan and language of the consent forms. Data are available for researchers who provide a methodologically sound proposal, which should be directed to Austin_Herbst@alumni.harvard.edu.

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REFERENCES

1 WHO. Global Health Observatory (GHO) data NCD mortality and morbidity. World Health Organization, 2018. Available: http://www.who.int/gho/ncd/mortality_morbidity/en/
2 Arima H, Barzi F, Chalmers J. Mortality patterns in hypertension. *J Hypertens* 2011;29 Suppl 1:S3–7.
3 Guwatudde D, Mutungi G, Wesonga R, *et al*. The epidemiology of hypertension in Uganda: findings from the National non-communicable diseases risk factor survey. *PLoS One* 2015;10:e0138991.
4 Okello S, Nasasira B, Muiru ANW, *et al*. Validity and reliability of a self-reported measure of antihypertensive medication adherence in Uganda. *PLoS One* 2016;11:e0158499.
5 World Health Organization. Uganda non-communicable diseases Factsheet. *World Heal Organ - Noncommunicable Dis Ctry Profiles* 2018;2018.
6 NEJM Catalyst. What Is Patient-Centered Care? *NEJM Catal Innov Care Deliv*, 2017. Available: https://catalyst.nejm.org/what-is-patient-centered-care/
7 De Man J, Mayega RW, Sarkar N. Patient-Centered care and People-Centered health systems in sub-Saharan Africa: why so little of something so badly needed? *Int J Pers Cent Med* 2016;6.
8 Package of Essential Noncommunicable (PEN). Disease interventions for primary health care in low-resource settings
9 Wekesah FM, Kyobutungi C, Grobbee DE, *et al*. Understanding of and perceptions towards cardiovascular diseases and their risk factors: a qualitative study among residents of urban informal settings in Nairobi. *BMJ Open* 2019;9:e026852.
10 Perera M, de Silva CK, Tavajoh S, *et al*. Patient perspectives on hypertension management in health system of Sri Lanka: a qualitative study. *BMJ Open* 2019;9:e031773.
11 Ashoorkhani M, Majdzadeh R, Gholami J, *et al*. Understanding Non-Adherence to treatment in hypertension: a qualitative study. *Int J Community Based Nurs Midwifery* 2018;6:314–23.
12 Siddharthan T, Rabin T, Canavan ME, *et al*. Implementation of patient-centered education for Chronic-Disease management in Uganda: an effectiveness study. *PLoS One* 2016;11:e0166411.
13 Primary health care systems (PRIMASYS): case study from Uganda, abridged version. Geneva, 2017. Available: http://apps.who.int/bookorders
14 Patton MQ, &amp QR;amp, Methods E. *Thousand oaks*. 3rd ed. CA: SAGE Publications, 2002.
15 O'Brien BC, Harris IB, Beckman TJ, *et al*. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89:1245–51.
16 Outcomes H. Progressive entrepreneurship and networks. Available: http://ghcuganda.org/our-work/research-innovation/hopenet/
17 Geldsetzer P, Ortblad K, Bärnighausen T. The efficiency of chronic disease care in sub-Saharan Africa. *BMC Med* 2016;14:127.
18 Kruk ME, Nigenda G, Knaul FM. Redesigning primary care to tackle the global epidemic of noncommunicable disease. *Am J Public Health* 2015;105:431–7.
19 Peck R, Mghamba J, Vanobberghen F, *et al*. Preparedness of Tanzanian health facilities for outpatient primary care of hypertension and diabetes: a cross-sectional survey. *Lancet Glob Health* 2014;2:e285–92.
20 Wroe EB, Kalanga N, Mailosi B, *et al*. Leveraging HIV platforms to work toward comprehensive primary care in rural Malawi: the integrated chronic care clinic. *Healthc* 2015;3:270–6.
21 Schwalm J-D, McCready T, Lopez-Jaramillo P, *et al*. A community-based comprehensive intervention to reduce cardiovascular risk in

hypertension (hope 4): a cluster-randomised controlled trial. *Lancet* 2019;394:1231–42.
22 BeLue R. The role of family in non-communicable disease prevention in sub-Saharan Africa. *Glob Health Promot* 2017;24:71–4.
23 Lawrence M, Kerr S, Watson H, *et al*. An exploration of lifestyle beliefs and lifestyle behaviour following stroke: findings from a focus group study of patients and family members. *BMC Fam Pract* 2010;11:97.
24 Mugwano I, Kaddumukasa M, Mugenyi L, *et al*. Poor drug adherence and lack of awareness of hypertension among hypertensive stroke patients in Kampala, Uganda: a cross sectional study. *BMC Res Notes* 2016;9:3.
25 Choo PW, Rand CS, Inui TS, *et al*. Validation of patient reports, automated pharmacy records, and pill counts with electronic monitoring of adherence to antihypertensive therapy. *Med Care* 1999;37:846–57.

Version Date: February 2019 Screening ID_____

Appendix 1 Informed Consent Form

MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY
INSTITUTIONAL REVIEW COMMITTEE
P.O. Box 1410, Mbarara, Uganda

Tel: 256-4854-33795 Fax: 256 4854 20782
Email: irc@must.ac.ug mustirb@gmail.com
Web site *: www.must.ac.ug*

INFORMED CONSENT DOCUMENT

Study Title: Experiences and Perspectives of Patients with Hypertension in Mbarara, Uganda

Principal Investigators: Dr. Samson Okello, Dr. Jessica Haberer, Dr. Peter Olds, and Austin Herbst

INTRODUCTION

Dr. Samson Okello of Mbarara University of Science and Technology (MUST); Dr. Jessica Haberer, Dr. Peter Olds, and Austin Herbst of the Massachusetts General Hospital/Harvard Medical School in the United States; are conducting this research. Hypertension is another name for high blood pressure. This condition can be managed in multiple ways, including medications, diet, and exercise. Understanding how individuals with high blood pressure perceive it and their experiences living with the condition may provide useful information that may improve care. This study is to understand what it is like for patients to live with high blood pressure and the experience of receiving care at MRRH.

The study will involve interviews with up to 30 individuals with high blood pressure participating in the study. Participants may have other conditions in addition to high blood pressure, such as diabetes or HIV.

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study
- Please read it carefully and take as much time as you need

Leave blank for IRC office only: **MUST-IRC Stamp:**	**IRC OFFICE USE ONLY:** APPROVAL DATE: APPROVED CONSENT IRB VERSION NUMBER: PI NAME: IRB NO:

Version Date: February 2019 Screening ID_____

- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study

Purpose of the research project

The purpose of this research study is to understand what I experience as a person with high blood pressure and the care I receive for high blood pressure.

Why you are being asked to participate

I am being asked to participate in this study because I am an adult with a diagnosis of high blood pressure and/or taking medication for high blood pressure.

Procedures

A research assistant will interview me in a quiet, private room adjacent to the hypertension clinic, MRRH. The interview will last less than one hour, will be digitally recorded, and will be conducted in English or Runyankole depending on my preference. The interview will begin with a few questions about myself (such as my age, residence, and high blood pressure diagnosis).

The research assistant will then ask me about high blood pressure and how it is treated. He or she will ask me about how I treat it, including at the clinic and at home.

Risks / discomforts

Risk: I may feel tired during the interview.
Protection: I will be allowed to take breaks and/or stop the interview at any time.

Risk: I may feel stressed from unpleasant questions.
Protection: I will be allowed to refuse to answer a question or stop the interview at any time.

Risk: I will depart the clinic later than I expected.
Protection: I will be able to stop the interview at any time, and I will be compensated for my participation.

Benefits

While I may receive no direct benefit from participating in this study, my responses will be contributing to the understanding of experiences of people with high blood pressure and the care they receive. This may enable future improvements.

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Version Date: February 2019 Screening ID_____

Cost

There will be no cost to me for participating in this study.

Incentives / rewards for participating

I will be given a medication voucher worth 40,000 UGX for one prescription of my blood pressure medication in appreciation for my time participating in the interview.

Protecting data confidentiality

My research records will be handled as confidentially as possible. The research assistant will help protect my privacy by not discussing my responses with anyone else besides the study investigators. All research records will be coded so that no person outside the study group can identify me. No individual names or other identifying information will be used in any reports or publications that result from this study. No individual names or other identifying information will be included in data shared with other researchers.

Sharing of research records

My research records (without my names) may be shared confidentially among investigators who are working with Dr. Okello, Dr. Haberer, Dr. Olds, and Mr. Herbst. I may decline permission to share your records at any time. Any request that my records not be shared should be made either in writing or verbally to the study staff. Such requests will be honoured for future research.

Right to refuse / withdraw

I may choose to not participate without the risk of affecting your current care at the clinic.

What happens if you leave the study?

I can choose at any time not to take part in the study. I will just inform the research assistant right away if I wish to stop taking part in the study.

Who do I ask/call if I have questions or a problem?

If you have any questions, please discuss them with the research assistant now. If you have questions in the future, you can call the Principal Investigator, **Dr. Samson Okello at 0772325457**. If you have questions for the **Research Ethics Committee at Mbarara University,**

Leave blank for IRC office only: **MUST-IRC Stamp:**	**IRC OFFICE USE ONLY:** APPROVAL DATE: APPROVED CONSENT IRB VERSION NUMBER: PI NAME: IRB NO:

Version Date: February 2019 Screening ID_____

you can call **Dr. Francis Bajunirwe at +256 4854-33795 or write to MUST- Review Ethics Committee, P.O BOX 1410 Mbarara, Uganda**.

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature on this form means

- You have been informed about this study's purpose, procedures, possible benefits and risks
- You have been given the chance to ask questions before you sign
- You have voluntarily agreed to be in this study

_____	_____	_____
Print name of participant	Signature of participant/legally authorized representative	Date
_____	_____	_____
Print name of person obtaining Consent	Thumbprint/Signature	Date
_____	_____	_____
Print name of witness	Thumbprint/Signature of witness	Date

Leave blank for IRC office only: **MUST-IRC Stamp:**	**IRC OFFICE USE ONLY:** APPROVAL DATE: APPROVED CONSENT IRB VERSION NUMBER: PI NAME: IRB NO:

Version Date: February 2019 Screening ID_____

Comprehension Checklist: Please check that the participant has demonstrated full comprehension of the material covered in this consent document.

- ☐ Participant has demonstrated full understanding of the purpose of the study.
- ☐ Participant has demonstrated full understanding of what will be asked of him or her during the course of this study.
- ☐ Participant has demonstrated full understanding of the potential risks of the study.
- ☐ Participant has demonstrated full understanding of the potential benefits of the study.
- ☐ Participant has demonstrated full understanding of what will occur if he or she decides not to participate in the study.
- ☐ Participant has demonstrated full understanding of the study's reimbursable costs.

Copies to: 1) Investigators, 2) Study participant

Leave blank for IRC office only: **MUST-IRC Stamp:**	**IRC OFFICE USE ONLY:** APPROVAL DATE: APPROVED CONSENT IRB VERSION NUMBER: PI NAME: IRB NO:

Appendix 2 Hypertension Patient Interview Guide

Introduction

We are studying what it is like for patients to live with hypertension ("pressure") and receive care at this hospital. We would like to ask you some questions about your experience with "pressure" (high blood pressure) and taking care of it. The interview will take less than an hour, and the interview will be recorded to ensure all of your responses captured without distortion, but the interview will be confidential. You will have the opportunity to stop the interview or skip a question whenever you want.

Key questions for the interview are numbered, and questions in italics are probe questions.

1. Please tell me a little about yourself.
   On a typical day, what do you do from the time you wake up until you go to bed?
2. How did you learn that you have "*pressure*" (high blood pressure)?
   Where did you learn that you have "pressure" (high blood pressure)?
   Who was with you at that time?
   How did you feel when you first learned this?
3. Why is it important to know you have "*pressure*" (high blood pressure)?
   What does it mean to you?
4. Since being diagnosed with "pressure", how do you take care of yourself?
   How often do you visit the health facility?
   Do you seek care for "pressure" from other providers, e.g., traditional healers, herbalists, or spiritualists??
   What's easy?
   What's hard?
5. Other than health care providers, does anyone help you with taking care of your "*pressure*" (high blood pressure)?
   Who helps you?
   How do they help you?
6. I'd like to know how you take your medication for hypertension. Please tell me how you last swallowed your medication.
7. Tell me about your experiences going to the health facility to seek care for pressure.
   How do you get to the health care facility?
   How do you feel about the reception and waiting to see a health care provider (nurse, doctor)?
   What do you expect when you go to the health care facility?
   What do you like about the health care facility?
   Are there times when the experience at the health care facility was different from your expectations?
8. On a typical day, what do you eat?
   Do you eat or not eat certain foods to help your pressure?
9. Tell me what kinds of physical activities you do in a week.
   Is any of it exercise to help your hypertension?
10. Are there any types of support you would like to get for your "*pressure*" (high blood pressure)?

From the health care facility?
From family or friends?

11. Is there anything else you would like to tell me about your "*pressure*" (high blood pressure)?

Thank you for your time.

Appendix 3 Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

		Reporting Item	Page Number
Title			
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract			
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction			
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4
Purpose or research	#4	Purpose of the study and specific objectives or	5

question		questions	
Methods			
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5, 6
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	6
Context	#7	Setting / site and salient contextual factors; rationale	5
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	7
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6

Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6, 21-22
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6-7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	6
Results/findings			
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-8
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	7-14
Discussion			
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	14-17
Limitations	#19	Trustworthiness and limitations of findings	15

Other

Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	18
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	17

Appendix 4 COREQ Checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			GN 1
Personal characteristics			B.A.
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	Male
Occupation	3	What was their occupation at the time of the study?	Research Assistant
Gender	4	Was the researcher male or female?	Course*
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			No 5
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	5-6
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Content 6-7
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	5
Sample size	12	How many participants were in the study?	7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	6
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	6 No
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	6-7
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes 6
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	No
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	Yes 6
Field notes	20	Were field notes made during and/or after the inter view or focus group?	No
Duration	21	What was the duration of the inter views or focus group?	8
Data saturation	22	Was data saturation discussed?	Yes 5
Transcripts returned	23	Were transcripts returned to participants for comment and/or	No

*Qualitative Research Methods - Mbarara University Research Training Initiative (MURTI)

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			3: page 6
Data analysis			
Number of data coders	24	How many data coders coded the data?	6
Description of the coding tree	25	Did authors provide a description of the coding tree?	Data, 6 Dedoose 7
Derivation of themes	26	Were themes identified in advance or derived from the data?	No
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, age/sex Yes
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Yes 8
Clarity of major themes	31	Were major themes clearly presented in the findings?	Yes 8-14
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 5 Study Protocol

SECTION A
STUDY OUTLINE

A.1 TITLE OF PROJECT:

Experiences and Perspectives of Patients with Hypertension in Mbarara, Uganda

A.2 SUMMARY
Explain why this study is being conducted, using lay terminology.
Guidance note:

Please convey what you think is the importance of the research and WHY it is being carried out.

The World Health Organization estimates that 71% of global deaths in 2016 were attributed to non-communicable diseases (NCDs), with cardiovascular disease accounting for the largest portion of those deaths. The burden of these diseases is rising, with disproportionate growth occurring in low- and middle-income countries (LMICs) (1). According to a 2016 estimate, NCDs are responsible for at least a third of all deaths in Uganda, and cardiovascular disease is estimated to cause 10% of all annual deaths (2). Hypertension is a condition of elevated blood pressure, which can put strain on the heart and ultimately contribute to cardiovascular disease. Worldwide, the WHO estimates that hypertension causes 12% of all annual deaths (3).

An important factor in hypertension care is the patient's experience of disease to ensure quality, patient-centered care delivery. Patient-centered care is health delivery in which individual patient needs and desired outcomes are used to tailor decisions and plans (4). Patient understanding, adherence, and feelings toward their diagnosis can help shape treatment. This study seeks to interview patients with diagnosed hypertension to identify key themes in their experience of their disease. By interviewing patients with hypertension alone and with other comorbidities, elements important for health care delivery can be identified and expanded to other NCDs. These interviews will explore how patients become diagnosed with hypertension and initiate treatment, patient understanding of hypertension and its treatment, and their experience with their care.

Sources
1. Global Health Observatory (GHO) data: NCD mortality and morbidity. World Health Organization, 2018. http://www.who.int/gho/ncd/mortality_morbidity/en/.
2. Uganda. World Health Organization - Noncommunicable Diseases (NCD) Country Profiles, 2018. http://www.who.int/nmh/countries/uga_en.pdf.
3. Global Health Observatory (GHO) data: Raised Blood Pressure. World Health Organization, 2018. https://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/.
4. "What is Patient-Centered Care?" NEJM Catalyst, 1 January 2017. https://catalyst.nejm.org/what-is-patient-centered-care/.

A.3 OBJECTIVES
List the major objectives/hypothesis, which have governed your choice of study design

1. To understand the patient experience of living with hypertension, including the process of diagnosis, understanding of disease, medication adherence, and treatment regimens.

A.4 METHODOLOGY

Outline how you intend to achieve the objectives of the study.

Guidance notes:

For each objective/hypothesis:-

- *define the target population*
- *describe how the sample(s) is(are) to be recruited from the target population(s)*

Even if the main thrust of the research is biomedical, the rationale behind your use of social science methods (e.g. patient interviews) should be clear.

We will carry out qualitative, semi-structured interviews with selected patients with hypertension at the Hypertension Clinic at MRRH. We will purposively sample participants with the following categories: duration of hypertension diagnosis, a diagnosis of hypertension alone versus at least 1 other condition (e.g., diabetes mellitus, HIV, hypo/hyperthyroidism); male and female; and patients from both rural and urban communities.

Interviews will be confidential and will be conducted in a private space near MRRH, lasting less than one hour. Interviews will be conducted in the participant's language of choice (Runyankole or English), recorded, and transcribed into English. Qualitative analysis will be applied to transcripts following a content analysis approach.

Interviews will cover the following domains:

-Receiving diagnosis of hypertension

-Patient understanding of hypertension

-Patient management of hypertension

-Patient experience receiving medical care for hypertension

-Lifestyle choices related to hypertension (like exercise and diet)

A.5 PARTICIPANTS

Please provide the following information on the participants with/from whom you expect to be collecting data:

A.5.1 Age / Sex: (please enter the expected number in each of the boxes)

	Neonates (<28 days)	Infants (1-11 months)	Young children (1-9 years)	Adolescents (10-17 years)	Adults (18 yrs & above)
Males	**0**	**0**	**0**	**0**	**15**
Females	**0**	**0**	**0**	**0**	**15**

Guidance notes:-

This age/sex breakdown helps convey how vulnerable the participants will be

If you are unable to give precise figures, state estimates and give an explanatory sentence in the space below

A.5.2 What specific measures are in place to take into account women of childbearing age?

Guidance notes:

Pregnant women may have different responses to disease processes

The developing foetus may be particularly vulnerable in intervention trials

While further research on hypertension care in pregnancy is an important research need, we will exclude pregnant women as that is out of the scope of this project's goals.

A.5.3 Describe how and where the participants are to be recruited?

Guidance notes:

This is distinct from the statistical sampling method described in A.4. You should outline the procedures for recruitment of each group of participants, include details on:

- *the setting (e.g. Country, Town, District, on the ward, out-patient department ,in the home)*
- *inclusion and exclusion criteria for selection, if relevant (e.g. "Women of child-bearing age will be excluded")*

Patients of the MRRH hypertension clinic will be recruited through coordination with the clinic staff. Criteria for inclusion will be: >18 years old, diagnosis of hypertension, and/or taking medication for hypertension, and ability to speak Runyankole or English.

The study research assistant will approach patients to will explain that the team is studying hypertension at the clinic and would like to interview them about their experiences.

A.5.4 Please justify your choice of sample size (as described in A.4)

We will interview participants until we reach thematic saturation. We anticipate a maximum of 30 individuals will be needed for this purpose.

A.6 PROCEDURES

A.6.1 What procedures or methods will be employed in the collection of data (e.g. patient interviews / focus group discussions / blood sampling / biopsies) and by whom (e.g. experienced facilitator / social scientist / teacher/ qualified doctor / nurse, auxiliary, etc.)?

Attach additional sheets if necessary.

Procedure	**To be carried out by:**
Participant interviews	Research assistant (TBD)
Transcription of Interviews	
Translation of Interviews	
Coding	
Analysis	

A.6.2 State the extent to which the procedures to be used are a part of usual clinical management (if appropriate).

N/A

A.6.3 Please indicate that the persons identified in A.6.1 are competent to carry out these procedures. List any training of staff that may be required prior to commencement of the study.

The research assistant will have a background in qualitative research and may undergo additional training in qualitative methods as part of this study. He/she will also be trained in the responsible conduct of research and good clinical practice.

A.7 ANALYSIS

A.7.1 What are the major statistical (or other) methods that you intend to use to analyse the data to fulfill each of the objectives/hypothesis stated in A.3

The qualitative interviews will be analyzed according to conventional content analysis. Specifically, interview transcripts will carefully reviewed, identifying concepts or factors influencing each patient's process of diagnosis, understanding of disease, and medical adherence. Investigators will thematically code the interviews and develop a codebook that can then be iteratively applied to subsequent interviews. These themes will be used to create a descriptive analysis of the patient experience of hypertension in this community. Quotations from the interviews will be chosen to highlight the thoughts and beliefs of the participants that comprise each theme.

A.8 QUALITY ASSURANCE

A.8.1 What procedures are in place to ensure the quality of the data?
Guidance notes:
For qualitative data (for example) what procedures will be used to check translations or compare data obtained from different sources?
For quantitative data (for example) how will transcription errors be minimised?
Give some detail on how methods are going to be piloted, if appropriate

Interview questions will be standardized using an interview guide composed of key questions with probe questions for elaboration. All recorded interviews will be transcribed the interviewer.

A.9 DISSEMINATION OF RESULTS
Please outline what plans you have for dissemination of results.
Guidance notes:
Where possible a mechanism should be in place to inform study participants of the outcomes of the study.
It is important that study findings are made known to local services / policy makers before they are discussed (e.g.) at international scientific meetings

Presentation at the MRRH
Abstract for the annual MUST Dissemination Conference
Publication in a peer reviewed journal
Scholarly Project Report for Harvard Medical School

SECTION B
CONSEQUENCES FOR THE LOCAL COMMUNITY / ENVIRONMENT AND PARTICIPANTS

B.1 Outline the potential adverse effects, discomfort or risks that may result from the study in the following areas:

B.1.1 Participants
Guidance note:
In addition to the physical effects of tissue sampling (for example blood sampling) it should be borne in mind that interviews and focus group discussions may sometimes trigger painful or distressing memories (e.g. questions about sexual practice or the death of a child)

We believe this study poses little risk to participants. The main possibilities are fatigue from the interview and potential concern about expressing any negative comments about the clinic.

B.1.2 Investigators
Guidance notes:
Include here (for example)
- *the biomedical risks to investigators (including local staff) involved in tissue sampling (e.g. Hepatitis B, HIV)*
- *the psychological consequences for social science investigators exposed to narratives of violence or severe grief*
- *the risks from the environment (e.g. in a war zone)*

None expected.

B.1.3 Members of the public

None expected.

B.2 Outline what steps will be taken to minimize the adverse effects, discomfort or risks described above.
B.2.1 For participants
Guidance notes:
In biomedical research, appropriate use of anesthesia prior to procedures (for example) is important.
For social science research it may be necessary to ensure that counseling services are available for those who re-live traumatic experiences through (for example) an in depth interview.

We will protect against fatigue by limiting the interview to a maximum of one hour. Participants will also be given the opportunity to take breaks during the interview as needed. To protect against concern for expressing negative comments, we will keep all data confidential. No identifying information will be included in presentations of study findings.

B.2.2 For investigators
Guidance notes:
Where the research may involve adverse experiences for investigators (see B.3.2), de-briefing / support meetings may be important.

NA

B.2.3 For members of the public

NA

B.3 CONSEQUENCES FOR LOCAL HEALTH SERVICES

B.3.1 What demands will this research place on local health services?
Guidance notes:
For example, how much of a nurse's usual work time will be taken up in acting as an interpreter for an outside investigator?

The project will require coordination with one of the members of the clinic to identify patients who may be candidates for the study.

B.3.2 Detail how the design of the research project takes into account the demands described in 3.1.
Guidance notes:
Disruption to routine services should be kept to a minimum.

A member of the clinic who is already involved in registering patients for the clinic will help identify potential participants present at the clinic for the research team to approach.

B.4 CONFIDENTIALITY AND PRIVACY

B.4.1 What steps will be taken to ensure privacy and confidentiality for participants?

All interviews and patient answers will be completely confidential. No identifying information for patients will be incorporated into the analysis of the interviews.

B.5 INFORMED CONSENT

B.5.1 Information given to participants:

Please indicate what you will tell the participants in simple language. The purpose of the study, type of questions that will be asked, and procedure or treatment which will be applied should be described and reference should be made to possible side effects, discomfort, complications and/or benefits. Please attach consent form typed on MUST-IRC official consent form.

It must be made clear to the participant that he/she is free to decline to participate or to withdraw at any time without suffering any disadvantage or prejudice.

We are studying what it is like for patients to live with hypertension and receive care at this hospital clinic. We would like to ask you some questions about your experience with hypertension and taking care of it. The interview will take less than an hour, and will include a series of questions about hypertension and your feelings toward it. The interview will be recorded to ensure all of your responses are well understood, but the interview will be confidential. You will have the opportunity to stop participating in the interview if you are uncomfortable with any of the questions or no longer wish to participate.

B.5.2 Outline who will deliver the above information and how?

The research assistant will go through the informed consent form prior to the interview.

Obtaining consent from minors requires both consent from the guardian and, where possible, the minor.

Consent will be obtained by a research in the language preferred by the participant (English or Runyankole) in a private, quiet space. The consent form will comprehensively provide the following information: (a) introduction to the consent process, explaining the consent form and compliance with institution policy and country laws; (b) emphasis that participation is voluntary; (c) nature and purpose of the study; (d) explanation of study procedures; (e) potential discomforts and risks, as well as plans to protect participants from these risks; (f) potential benefits; (g) alternatives to participation in the study; (h) confidentiality, including how data will be used and how it will be kept private; (i) refusal/withdrawal, including right to withdraw consent and leave the study at any time; and (j) rights and complaints. After each major section, research staff obtaining consent will pause and check for understanding -- for example, by asking the potential participant to repeat, in their own words, what "the right to refuse" means.

B.5.4 Are any inducements to be offered to either participants or the individuals who will be recruiting them? (e.g. improved patient care / cash) (please tick appropriate box)

Yes	No
X	

B.5.5 If yes, please give details:

Participants will be given a reimbursement of a medication voucher, as well as refreshments during the interview, for their time participating in the study.

B.5.6 Outline any hidden constraints to consent.

Guidance notes:

Examples where hidden constraints may be important include:

- *situations where participants are employees of the investigator*
- *patients who may feel their care could be compromised if they do not consent to research initiated by their carers.*

N/A

SECTION C
RESPONSIBILITY

C.1 Litigation:

In respect of any litigation which may result from this research
a) Who will provide compensation?

(Please provide documentary evidence where appropriate.)

b) What insurance arrangements have been made by the applicant and his/her delegated assistants?

Insurance is not required given the low-risk study consisting of a one-time qualitative interview.

(Please ensure that any professional indemnity insurance is logged with the Director's office)

C.2 **DECLARATION: TO BE SIGNED BY MAIN APPLICANT**

- I confirm that the details of this proposal are a true representation of the research to be undertaken.
- I will ensure that the research does not deviate from the protocol described.
- If significant protocol amendments are required as the research progresses, I will submit these to the Mbarara University Faculty Medicine Research Ethics Committee for approval.
- Where an appropriate mechanism exists, I undertake to seek additional local Ethical Approval in the country(ies) where the research is to be carried out.

I expect the project to commence on (Date): and be completed by (Date):

_____

Signed Date

SECTION D
APPROVALS

D.1 List research team and all collaborators.
(Please include all overseas collaborators and give their affiliations, qualifications and role in the study).

Dr. Samson Okello, MD MSc, Mbarara University of Science and Technology, Principle Investigator
Dr. Jessica Haberer, MD MSc, Massachusetts General Hospital/Harvard Medical School, Principle Investigator
Dr. Peter Olds, MD, Massachusetts General Hospital/Harvard Medical School, Principle Investigator
Austin Herbst, Massachusetts General Hospital/Harvard Medical School, Principle Investigator