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RESEARCH REPORT

BURDEN OF TREATMENT AND BLOOD PRESSURE CONTROL OF PATIENTS WITH HYPERTENSION AT A PRIMARY CARE FACILITY, SEDIBENG DISTRICT, GAUTENG PROVINCE

Submitted in partial fulfilment of the requirements for the award of the MMED (Family Medicine) Degree at the University of Witwatersrand, Johannesburg, South Africa

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Johannesburg,7TH November 2018

Declaration

I, Dr. Kevin Pender, declare that this Research Report is my own, unaided work. It is being submitted for the degree of MMED Family Medicine at the University of Witwatersrand, Johannesburg. It has not been submitted previously for any degree or examination at any other university.

…….

(Signature of candidate)

at Johannesburg…….

……7th……. day of…November……..2018…….

Dedication

In memory of my Father and Mother

Presley Dafinone Pender (1944-2017)

Rose Nkechinyere Pender (1946-2018)

ABSTRACT

Background

Burden of treatment (BOT) refers to the tasks patients, must perform in order to achieve optimal outcomes in their disease management. Hypertension is the commonest chronic disease of lifestyle, and previous studies have shown its control is suboptimal in most settings. Although studies conducted elsewhere have associated poor blood pressure (BP) control with high BOT, it is not known whether this holds true in South Africa, yet this information is important for a comprehensive management approach to hypertension. Previous studies in Sedibeng district have illustrated prevalent poor blood pressure control, however local studies providing understanding of how this relates to BOT are lacking.

Objectives

1. To assess BOT among patients with hypertension at Johan Heyns Community Health Centre (CHC).
2. To determine the proportion of participants with BP controlled to target.
3. To explore the relationship between BOT and BP control.

Methods

This was a cross sectional study involving patients at Johan Heyns CHC with hypertension who have been on treatment for a minimum of three months. A treatment burden questionnaire (chronbach alpha 0.89) was administered to participants to collect information on burden of treatment relating to:

- Medication regimen.
- Navigating the healthcare system.
- Life style changes, social and financial impacts.

In addition, information on participants' socio-demography and BP readings in the last three months were extracted from medical records. Data was entered into Epi info statistical software, and analysis included descriptive and association tests. Main outcome measures included: Proportion of

participants with BP controlled to target, mean total BOT and the association between BOT and blood pressure control.

Results

Of 239 participants, most were white (54.2%), female (60.1%), had completed matric or further education (71.9%), married (56.3%), older than 55 years (52.9%) and did not have clinical co-morbidities (56.7%).

The mean duration of treatment was 113.8 months, with white people and female participants significantly more likely to have longer duration of treatment (p=0.03 and p=0.04 respectively).

Most participants had uncontrolled BP (60.1%), with a mean BP of 143.7/87.2mmHg. Being divorced or african was associated with higher mean systolic BP (p=0.00 and p= 0.012 respectively); being single or male was associated with higher mean diastolic BP (p=0.00 and p=0.03 respectively).

The mean total BOT score was 19.7(out of possible 140). Most participants (75%; n=177) reported a low mean BOT score (<47). In the three sub-aggregates of burdens (medication regimen, navigating the health system and lifestyle/social and financial), only 28.4% (n=67) and 15.7% (n=37) reported moderate to high BOT in the components of lifestyle modification/social support and navigating the health system respectively. Among those with clinical comorbidity (n=103), most (66.3%) did not consider hypertension to be more burdensome than the other co-morbid illnesses. Single participants were significantly more likely to have a higher mean BOT score (p= 0.00). Although total BOT was not significantly associated with BP control (p=0.53), participants with a higher BOT related to medication regimen were significantly more likely to have an uncontrolled BP (p= 0.04).

Conclusion

This study found that patients with hypertension reported low BOT despite most having poorly controlled BP. Considering only a minority reported moderate to high score in the three components of BOT, other elements in the process of care, such as poor healthcare providers' adherence to guidelines and inertia in

intensifying treatment, as well as poor patient compliance to treatment may be responsible for the prevalent poor BP control in the research setting.

TABLE OF CONTENTS

CONTENTS **PAGE**

Declaration…… ii

Dedication …….. iii

Abstract…….....iv-vi

Table of content…… vii-ix

List of figures……..... x

List of tables…… xi

CHAPTER ONE-INTRODUCTION

1.1 Background…….…… 1

1.2 The problem statement and rationale for this study……..... 2

1.3 Aim of study and objectives……2

CHAPTER TWO- LITERATURE REVIEW

2.1 The outlay for literature review…….. 3

2.2 The concept of BOT…… 3

2.2.1 Theoretical framework underpinning BOT……3

2.2.2 Evolution and development of definition of BOT…….. 4

2.2.2.1Definition……4

2.2.3 Components of BOT……6

2.2.3.1 Challenges associated with daily medication regimen……6

2.2.3.2 Relationship with healthcare workers…… 7

2.2.3.3 Relationship with family members…….. 7

2.2.3.4 Patient's Self Perception…….. 8

2.2.3.5 Lifestyle changes, adaptation and self-care…… 8

2.2.3.6 BOT and Sociodemographics…….. 8

2.3 Measuring BOT…… 9-11

2.4 Blood pressure control …….. 11-12
2.4.1 Blood pressure control and the social context……..12-13
2.4.2 Blood pressure control and socio-demographic context…… 13-14
2.5 Summary……...14-15

CHAPTER THREE- METHODS

3.1 Study design…… 16
3.2 Site of study…….. 16
3.3 Sample size and sampling methods…… 16
3.4 Measurement tools and data collection…… 16-18
3.4.1 Data organisation…….. 19
3.5 Data analysis…… 19-20
3.6 Ethics……..20-21

CHAPTER 4-RESULTS

4.1 Participant sociodemographic characteristics…… 22-23
4.2 Presence of co-morbidities…… 24
4.3 Blood pressure control…….. 25
4.4 Treatment duration by sociodemographic and BP control groups26-27
4.5.1 Distribution of mean systolic blood pressures by sociodemographic groups…… 28-29

4.5.2 Distribution of mean diastolic blood pressures by sociodemographic groups…… 29-30
4.6 Burden of treatment…… 31
4.7.1 Mean BOT scores and sociodemographic group…… 32-33
4.7.2 Socio-demographics and blood pressure control…… 33
4.7.3 BOT and BP control…… 34
4.7.4 Sociodemographic variables and mean systolic and diastolic blood Pressures…… 35

CHAPTER 5-DISCUSIONS AND LIMITATIONS

5.0 Participant's characteristics…… 36-38
Presence of Co-mobidity…… 38
Blood pressure control…… 38-40
Burden of Treatment…… 40-41
5.1 Limitations and Biases …… 41-42

CHAPTER 6- CONCLUSION AND RECOMMENDATION

6.1 Conclusion…… 43
6.2 Recommendations……43-44
7.0 REFERENCES…… 45-50
8.0 APPENDICES…… 51-64

LIST OF FIGURES **PAGE**

Fig 1. Flow chart for data collection…… 18

LIST OF TABLES **PAGE**

1. Participant sociodemographic characteristics……24-25
2. Presence of co-morbidities…….. 26
3 .Blood pressure control…… 27
4 .Treatment duration by sociodemographic and BP control group…. 28
5.1. Distribution of mean systolic blood pressure by sociodemographic group…….. 29
5.2. Distribution of mean diastolic blood pressure by sociodemographic group…….. 30-31.
6. Burden of treatment…… 32
7. Mean BOT scores and sociodemographic groups……. 33-34
8. Sociodemographics and blood pressure control……..... 34-35
9 .BOT and BP control……. 35
10. Sociodemographic variables and mean systolic and diastolic blood pressures…… 36

CHAPTER 1: INTRODUCTION

1.1 Background

Burden of Treatment refers to the required tasks patients must perform in order to achieve optimal outcomes in their disease management, and the effects these treatments pose on their functionality and wellbeing.[1,2] Increased burden of treatment has potential for adverse outcomes both for the patient and the healthcare system,[1-4] which could culminate in patient non-adherence to treatment, [5,6,7] poor disease control, [2,7,8] increased hospitalisation, [9,10] increased mortality, increased costs of healthcare [3,4] and low quality of life.[11,12]

In recent years the world, inclusive of South Africa, has experienced an epidemiological transition from acute infectious diseases with high mortality to chronic medical conditions with long term survival.[1] This has newer implications of increased treatment burden,[1-4] especially because the prevalence of chronic diseases of lifestyle have increased, reaching epidemic proportions in diseases such as hypertension. According to the last WHO report of 2013,developing countries, especially sub-Saharan Africa, are at the epicentre of the hypertension epidemic, with 46% of adults in sub-Saharan Africa reportedly having the disease.[13] In South Africa, current reports estimate 46% of females and 44% of males above 15 years of age have hypertension.[14]

Despite the availability of pharmacological treatments and access to health facilities, blood pressure (BP) control rates remain low globally, varying between 19.6% and 44% in most reports – Denmark 33.2%, Nepal 35.3%, Malaysia 22.6% to 34%, USA 19.6% to 24.8%, Cameroon 36.8% and South Africa 24.5% to 44%.[15-18, 20-23] Studies on BP control among patients with hypertension in primary care settings in South Africa have also found suboptimal control.[15,16] In one district hospital in Sedibeng district, where the current study was carried out, the proportion of hypertensive patients whose blood pressure was <140/90MMHq was 31.5% at current visits, and this fell to 16.7% if previous visits were included.[15] Another study in Sedibeng district found a maximum of 57% control of blood pressure in a primary care facility used for Family Medicine training.[16] In Sub Saharan Africa, the reasons for poor blood pressure control are poorly

understood,[18] however, it has been noted that multiple and complex factors can interplay in blood pressure control, and these may vary from one region to another.[19]

1.2 The problem statement and rationale for this study.

In Sedibeng Health District, almost one in three patients attending a primary care centre has a chronic disease of lifestyle, and more than 60% have hypertension.[15] At best, BP control is achieved in about half of these patients[16] but no local studies provide an understanding of the issues that drive this poor BP control. While studies outside of South Africa have reported high BOT as one of the major factors associated with poor chronic disease control,[1-4] it is not known whether BOT is related to poor control of hypertension in South Africa and particularly in the primary healthcare setting. Studies investigating the relationship between BOT and poor BP control are clinical and public health imperatives in South Africa. The aim of this study was therefore to determine the burden of treatment and its relationship to BP control amongst patients undergoing treatment for hypertension at Johan Heyns Community Health Centre in Sedibeng District, Gauteng Province. It is hoped the outcomes of this study will provide an entry into understanding the concept of BOT in hypertension in South African PHC, and inform interventions aimed at improving BP control in patients with hypertension in this district and in similar settings.

1.3 Aim of study and objectives

Aim

To determine the burden of treatment and its relationship to blood pressure control in patients with hypertension attending Johan Heyns CHC, Vanderbijlpark, Gauteng Province.

Objectives

1. To assess BOT among patients with hypertension at Johan Heyns Community Health Centre.
2. To determine the proportion of participants with BP controlled to target.
3. To explore the relationship between BOT and BP control.

CHAPTER 2: LITERATURE REVIEW

2.1 The outlay for literature review

The purpose of this chapter is to position this study within the body of knowledge on BOT. The researcher used the PubMed central search engine, with search words “treatment burden,” “chronic medical conditions” and “blood pressure control.” The literature search yielded little in terms of BOT, underpinning the assertion that much research is needed in this area, particularly in the developing countries such as South Africa. Articles were limited to those in English and published within the last 5 years and were selected and stored on Mendeley. The study designs of articles included qualitative, quantitative and systematic reviews.

The literature review will be laid out as follows: the concept of burden of treatment, definitions and theoretical framework, workload and patient functionality, measuring BOT, factors associated with BOT and blood pressure control.

2.2 The concept of BOT

2.2.1 Theoretical framework underpinning BOT

In developing the concept burden of treatment, earlier researchers used the Normalization Process Theory (NPT) as a theoretical framework[2,5 8] to explain BOT. The Normalization Process Theory is made up of four components:

- Coherence: This deals with the sense a given task makes to a patient. Patients may be unable to proceed with tasks that are perceived as not of value to them or tasks that are not clear.[5]
- Cognitive participation: Even when such tasks are meaningful, or of importance, patients must consider if it is worthwhile and of good to them before proceeding with the tasks.[5]
- Collective participation: Tasks considered worthwhile must be incorporated into the normal routine of patients and internalised. Difficulties in incorporating these tasks into normal routine of the patient may reflect such task as burdensome.[5]

- Reflexive monitoring: At the end of the process, patients reflect if a given task they have incorporated has been advantageous or disadvantageous. Tasks that are seen as not beneficial only worsen the burden if patients must continue with them. [5]

This theory deals with the understanding that over time tasks or practices are first organised, then incorporated into daily activities of living through embedment, and these practices are then sustained by integrating them into one's social context. [2, 5,8] This theory when applied to the burden of treatment may imply that if after integration patients consider these health tasks as advantageous, the burden may essentially fade away; however, if not considered beneficial, imposing them on patients will generate some burden. The healthcare tasks and practices that patients must perform in terms of BOT are best understood if the Normalization Process Theory is applied.

2.2.2 Evolution and development of definition of BOT

2.2.2.1 Definition

In developing the concept of BOT, Eton, May and Demain 2014 came up with parameters for its definition.[1-4] The key parameters that were proposed included: workload of healthcare, patient's functionality, patient well-being and impact.[1-4] Based on these parameters, these authors proposed that BOT be defined as "the workload of healthcare and its impact on patients functionality and well-being".[1-4] Other authors produced additional parameters, such as self-care practices, own management strategies, response, demand of healthcare providers, and demand of service systems.[8] This alternative definition states that BOT as self-care "practices that patients must perform to enact their own management strategies and respond to the demand of healthcare providers and service systems."[8] Of the two definitions, the most widely used is "the workload of healthcare and its impact on patients functionality and well-being," because it takes into account the impact of both on patients.

Chronic diseases of life style, hypertension inclusive, have been reported to exact a heavy toll on patients[1] particularly when these exist as chronic comorbidities.[2-4] In explaining BOT, it is reported that patients with multiple

chronic conditions must often surmount a range of activities that are considered necessary for their wellbeing.[2] Some of the activities that patients must surmount are related to issues around their medications, navigating healthcare facilities and all its multi-disciplinary and interdisciplinary management, and adopting life style modifications that cut across diet, social habits and exercise regimes.[2-4] Enmeshed within these activities are often complex routines that patients must follow , including self-care, self-monitoring for disease control, periodic invasive and non-invasive investigations, drastic life style changes.[2] These complex routines are such that patients must gather support from people in their social contexts.[2]

These cumulative activities, complex routines and requirements, including support, which patients require, summate to the burden of treatment.[1-4]

To be able to surmount BOT, earlier authors have pointed out two important key variables - functional performance and social skills.[2]

Functional performance" is described as being composed of two elements: possession of relevant knowledge by patients regarding their diagnosis and treatment requirements[1] and the resources that enable patients to cope with the demands of their health problems;[1,5] these resources may be financial or the social support available from relatives.[1-5] However, possessing the functional performance may not be sufficient to surmount the subjective feeling of treatment load, which creates the weight of the burden of treatment.[1,2] Each patient's ability to utilise the above resources will depend on their ability to muster cooperation of close relatives, friends or support groups;[1,2] to be able to do this, patients must possess social skills.[1]

The difficulties patients may experience with their treatment burden can have dire consequences for adherence and disease control.[2] A high burden of treatment has been implicated by certain authors as responsible for treatment default.[5] If the subjective treatment load and the summative treatment burden are high, patients may provide valid reasons why they cannot continue with the treatment – this phenomenon is referred to as rationalised non-adherence.[2]

It is widely reported in literature that disease outcomes of patients who engage in treatment non-adherence are poor, and that disease complications are rife within these groups.[2,5 8]

2.2.3 Components of BOT

In order to develop a working framework for this new concept- burden of treatment, researchers have engaged in qualitative studies and systematic reviews of qualitative studies with the overall aim of determining its thematic components.[2-9]

Key themes identified were:

2.2.3.1 Challenges associated with daily medication regimen

Qualitative studies on BOT identified that daily medication regimens were an important theme across patients. Some patients needed clarity on issues of dosing and side effects, others had problems in remembering to take their medication, while others experienced difficulties in taking the medication.[2-6] One of the studies, a systematic review, termed this as the biological theme.[2] Chronic conditions, when they occur as co-morbidities, are associated with an increasing complexity of regimens, and their additive side effects may be too overwhelming for patients to comply with appropriate and correct dosing.[1] Rationalised non-adherence,[2] as previously explained, may have dire consequences. Researchers on treatment burden agree that patients who engage in treatment non-adherence have negative outcomes, which include poor disease control, prolonged hospitalisation if admitted and overall increased mortality.[2,7-10] It means the biological component of a patient's treatment burden are likely to be greater if there is chronic disease co-morbidity. It is evident from literature that physicians may be unaware of the treatment burden imposed on their patients, and measures that could be undertaken to ameliorate this.[7] It is known that only about 50% of patients globally with chronic diseases conditions adhere to their treatments, and that increasing treatment burdens induces non-adherence.[5] Despite this, physicians often respond to poor disease control by escalating

treatment regimens, without exploring non-adherence as being responsible, thereby worsening BOT in patients with already high subjective treatment loads.[4]

2.2.3.2 Patient's relationship with healthcare workers

The relationship with healthcare workers is another important issue that emerged from studies on BOT.[3] Patients reported experiencing difficulties in their relationship with their physicians,[3] difficulties which may be due to insufficient information provided by healthcare workers, physicians not taking into account patients contextual situations, or patients self-explanatory model for their disease condition which is not explored by the physician.[9]

Patients are unlikely to adhere to treatment regimens if they perceive the benefits as minimal, particularly if this is associated with treatment adverse effects and feelings of frustration,[2] and this may be compounded if such regimen decisions were non-collaborative.[3-6] Patients prefer a patient–centred approach, where they are actively involved in their care and management.[7]

Excessive treatment load resulting from poor physician/patient relationship could culminate in treatment struggles and non-adherence.[3] Feelings of frustration can provide patients with "valid" self-reasons to disrupt treatment, which was earlier described as rationalised non- adherence.[2] It is important therefore to create time during consultations to explain the diagnosis, treatment requirements and consequences of noncompliance to patients and ensuring safe netting. If this is done during consultations, it may help reduce the treatment burden patients may experience. [4]

2.2.3.3 Relationship with family members

Relationship with family members is another important theme emerging from qualitative studies and systematic reviews on BOT.[2,3,5] This theme deals with all the family dynamics that interplay in health and disease.[2,3,5]. In other words, patients may refuse a treatment if the financial burden is high and impinges on other family requirements, an act aimed at allowing family leisure.[2] A systematic review has described this family dynamic and BOT as Relational [2]

2.2.3.4 Patients self-perception

This incorporates the patients' perception of the magnitude of the problem their condition imposes on others. It includes expressing feelings of guilt, worthlessness, being burdensome on others, or perceptions that family members may view them as burdensome.[2] A systematic review on BOT has classified these perceptions as Biographical.[2] It is in the biographical theme that emotional tensions within the family contribute to treatment burden aggravation.

2.2.3.5 Life style changes, adaptation and self-care

Lifestyle changes, adaptation and self-care is another theme emerging from studies on BOT.[5,6,8] Disease conditions can impose limitations in activities and cause financial burden on patients.[3] Chronic diseases require self-monitoring and this might increase BOT.[5] Modification of behaviour and lifestyle changes are important issues for patients and often a source for increased BOT.[5,6,8] Patients have reported experiencing difficulties in adapting to new lifestyles and behavioural changes as well as planning care and integrating into society post discharge.[8] These experienced difficulties can aggravate BOT.[8]

2.2.3.6 BOT and Sociodemographics

Literature ascribes the importance of patients' sociodemographic characteristics with the BOT they may experience, and in separate studies unrelated to BOT highlights the important effects on blood pressure control.[9,13,34-35] Reports of other disease models suggest that patients with similar illnesses and treatment regimens may have different BOT and that these variations are influenced by the sociodemographic factors mentioned above.[29] History has shown that not taking patients' contextual and psychosocial situations into consideration can create a difficult patient/physician relationship,[9] and this can worsen the BOT patients may experience.[9]

Literature has reported that educational levels and literacy improve a patients capacity to manage the BOT associated with their illnesses,[28] whereas low literacy levels increase the subjective loads of treatment.[29] This may have particular implications for communities with low literacy levels in terms of high BOT.

BOT itself is influenced by race.[29] Literature reports allude to the fact that subjective treatment load varies with patients in a racial pattern.[29] The subjective treatment load is the patients perception of their BOT. [29] Language barriers may make explanations on diagnosis, treatment and prognosis harder. Poor clarity has also been reported as an important factor affecting medication adherence within the concept of BOT.[3, 4, 5, 6]

Age has been reported as an important determinant of BOT by influencing subjective treatment loads.[29] In a very recent systematic review, younger patients with chronic diseases were reported to experience significantly greater magnitudes of BOT compared to older populations, and experienced poorer disease control. [36]

There are also gender variations in subjective treatment loads, which in turn influence the magnitude of BOT.[29] In a recent study on BOT, unrelated to hypertension, female gender was associated with higher BOT due to greater anxiety and depression accompanying their ailments when compared to their male counterparts.[34]

2.3 MEASURING BOT

The studies cited above,[1-9] have developed a framework for the burden of treatment by identifying key themes through qualitative studies and systematic reviews of qualitative studies. If this subjective treatment load and its summative BOT is to be quantified, it warrants a means of measurement using quantitative measures.

Initially there was no instrument for the global assessment of BOT in chronic diseases.[11] Various illnesses in which disease burden were studied included only a question related to treatment regimen as the BOT.[11] The first effort to develop a measuring tool for BOT started in France, where a weak effect of physician/patient agreement on the BOT was noted.[11] Although family physicians responsible for coordinating patient healthcare fared much higher than other specialists, the task of evaluating this BOT was daunting to them.[11] This necessitated the development of a reliable instrument that could quantify the treatment burden .[11]

The leading study in developing a measuring instrument in France involved 502 patients, of which 237 were in-hospital patients.[11] The disease spectrum included diabetes, mental health conditions and cancers .[11] It was noted that sections of the questionnaire being developed had a large floor effect because a greater proportion of participants answered not applicable.[11] The final questionnaire consisted of seven items, two of which had four sub items giving a total of 15 questions. A Cronbach alpha of 0.89 was determined for this measuring instrument, indicating a high level of internal consistency.[11] The weakness of this questionnaire was because it was developed on patients with diabetes, mental health conditions and cancers, other chronic diseases were not used. Furthermore, since BOT is a patient's subjective measurement, some of the domains that were eliminated due to the large floor effect may be important domains to patients with other disease conditions and those in other contexts. [11]

Using back to back translation, the 15 questions of the French instrument were translated into an English Treatment Burden Questionnaire.[12] Using an online survey, 3000 patients were invited to complete the questionnaire and 610 responded. Multiple invites were sent to participants in different countries, but the majority of respondents were from the UK, USA, Canada, New Zealand and Australia.[12] Of those who responded, the completion rate was high, with minimal floor effect on the 15 items of the questionnaire.[12] Construct validity was used to validate the English format by comparing it to standard questionnaires, such as Morisky Medication Adherence scale (MMAS-8) and Quality of life (QOL).[12] A low MMAS-8 score was associated with a high TBQ total score ($p<0.0001$) which was overwhelmingly statistically significant.[12] Reliability was assessed on 286 patients using a test-retest method.

The TBQ was composed of three main sections: burden related to medication regimen comprised four questions; burden related to navigating the healthcare system comprised five questions; burden related to support and life style changes comprised six questions.[12] Each question has a numerical rating scale ranging from 0 (no burden) to 10 (high burden).[12]

The disadvantage of the English validation lay in the fact it was computer based, which may have eliminated several participants who were not computer literate. This may have accounted for the fact that despite sending invites to many countries, most respondents were from few countries, all of which were developed. Such a methodology might eliminate patients with potentially higher burdens and those unable to assess the internet or use a computer, particularly in low income and developing countries. Both questionnaire development and re-validation were cited in the developed world, silent on racial composition of its study participants, and based on multiple chronic disease models. However, it may be that the treatment burden questionnaire remains the only reported validated measuring tool for the quantification of treatment burden. This underscores the need for new studies (both qualitative and longitudinal) in developing countries to validate or modify this tool for appropriateness to African settings, however, for the purpose of this study, this questionnaire was utilised. Studies on BOT, using the TBQ, dealt with global BOT scores, but there are important implications to this, in that it does not portray the relationship of a patients' BOT score to the individual domains of BOT (medication regimen, navigating the healthcare system and lifestyle modifications and support). Patients having the same BOT scores may differ in their respective burdens regarding the component domains. Further studies are therefore required to explore the component domains of BOT in relation to global BOT scores. This study attempts to explore this within the context of Sedibeng district.

2.4 BLOOD PRESSURE CONTROL

There are reports that patients experiencing a lower treatment burden may have better disease control.[1, 2] This formed the basis of this research in trying to discover if the burden of treatment for hypertension may be responsible for poor control levels reported in South Africa and particularly the district where this study was conducted. It is important to state that during the literature search no direct studies linking BOT and blood pressure control were retrieved, therefore there is a big research gap which future studies should explore, although this study will try to explore this relationship within the context of Sedibeng district;

bigger studies will have to be done to obtain national data. Similar sociodemographic factors, which have been implicated earlier, with regard to BOT, will be explored in relationship to blood pressure control.

As illustrated earlier, blood pressure control of patients with hypertension is poor (19.6-44%).[16-18,20-23] A study in a primary care setting in South Africa has found suboptimal control,[15, 16] creating an urgent need to explore factors that could be responsible for this and mitigate the untoward effects. In a district hospital in Sedibeng district, the proportion of patients with hypertension, whose blood pressure was <140/90MMHq, was 31.5% at current visits and this fell to 16.7% if previous visits were included.[15] Another study in a primary care comprehensive clinic, a training place for family physicians,[16] in the Sedibeng district area showed a maximum of 57% control of blood pressure. The reasons for this higher control in same district were not explored.

Reports outside South Africa, as stated earlier, indicate that blood pressure control is low, despite numerous physician visits and treatment availability.[17,18, 20-23] The Danish report is particularly important in two aspects, its blood pressure control rate (33%) fell within the nationally reported rate for South Africa, and its healthcare system shares similar aspects to that of South Africa: most patients with hypertension are seen in primary care and treatment is free in public facilities or insured by the government.[20]

What could therefore be the problem with blood pressure control in patients with hypertension in the South African setting?

2.4.1 Blood pressure control and the social context:

Numerous psychosocial measures associated with hypertension have been reported in literature and which point to the importance of social support as a determinant of hypertension.[17,24] Social support has been reported to operate through two theories: the main theory which had a direct impact on influencing healthy lifestyle modifications such as exercise, dietary changes,[24] and the buffer theory, which prevented the harmful effects of stressors on blood pressure control. [24]

The link between the burden of treatment and hypertension may lie in contextual and psychosocial parameters. It has been reported in literature, particularly in older populations, that having a live-in spouse was associated with lesser odds for uncontrolled blood pressure, as this was associated with better adherence to treatment recommendations.[17] It's also possible the reasons for poor blood pressure control may lie in the psycho-social context of these patients, outside the parameters of health facilities.[17,24]

2.4.2 Blood pressure control and sociodemographic characteristics: Blood pressure control, and response to medications, may be influenced by sociodemographic factors such as socioeconomic status, living conditions, literacy, race/culture, age, gender. [13,24-35] Although there were no direct studies linking BOT, Blood pressure control and sociodemographic factors, it is hoped that this knowledge gap may be bridged with further research. Patients' socioeconomic situations could therefore be important in making treatment recommendations if control is to be achieved.

Literacy levels may influence blood pressure levels.[27] In a report by the American Heart Association education was the recurring index of social determinant of cardiovascular outcome [25] and possibly poorer blood pressure control.

Racial variations in BP control have been reported, with blacks exhibiting an exaggerated physiological response of their blood pressure to stressors.[24] There is evidence in literature indicating that race influences blood pressure control.[30] Caucasians have shown to achieve a better control compared to blacks.[30] In an urban district hospital in KwaZulu Natal, blacks accounted for 55.6% of all races with uncontrolled pressure.[30] When this was adjusted to demographic numbers of different races, it was still significant.[30] Language barrier and cultural differences may affect the standard of care a patient receives resulting in poor hypertension control.[26]

Reports have indicated that chronological age influences blood pressure control and BOT.[26,29,33-36] Variation in age responses to anti-hypertensive treatment have been reported,[26] particularly in response to ACE-I medications because of

varying levels of plasma renin activity within the different age groups.[26] The literature reports on age and blood pressure control are conflicting, with some authors purporting better or poorer control of blood pressure in elderly patients respectively.[33,35] Reports have conflicted, one indicating that patients older than 65 years were twice as likely to adhere to their medications and achieve a better blood pressure control,[33] whereas another stated younger patients achieved better control.[35] Older populations were reported to accept their disease conditions and adapt to treatment better and achieve better control. [36] Authors reporting lesser control of blood pressure in older populations above 80 years, state that this might be due to less aggressive treatment in these older age groups.[35] This is why South Africa did not adopt the JNC-8 recommendation to keep the target blood pressure for those above 60 years to<150/90,[37] the opinion being this would reverse the level of control attained and increase the mortality and morbidity from CVAs in this age group.[37]

There are gender variations influencing BOT and blood pressure control from separate reports.[15,29,31-35] Although it has been reported in South Africa that females seek help and utilise health facilities earlier than males[15] and that males exhibit lower awareness of their hypertension compared to females,[31] studies have shown that women have poorer cardiovascular outcomes. [32] Females have been shown to have a 60% less chance of adhering to medications and achieving blood pressure control compared to their male counterparts.[33] While one report indicated better blood pressure control for females,[33] another indicated better blood pressure control in males.[35]

2.5 SUMMARY

The new concept of BOT has multiple associated factors influencing patients' self-reported perceptions of treatment burdens.[28,29,36] Increased treatment loads, and hence higher BOT, is reported in literature to be associated with poorer disease outcomes.[2,7] Globally and regionally, reported blood pressure controls are gloomy,[15-35] and these low levels of control have implications for complications that worsen morbidity and mortality from hypertension.[15]

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In summary, there are multiple factors responsible for poor blood pressure control locally and internationally.[15-27,30-35] The blood pressure control rate for the Sedibeng district is low and it is not known whether BOT plays a role in this among patients with hypertension. This study aimed to use the only available tool (the Treatment Burden Questionnaire) to quantify BOT, and explored the relationship between BOT and blood pressure control in patients with hypertension in a primary care centre in this district.

CHAPTER 3: METHODS

A cross sectional design was used to answer the research question. This design describes the situation at a point in time and is deemed appropriate because it allows for quantification and exploration of associations at a given time.[38]

3.2 Site of study

This study was conducted at the outpatient department of Johan Heyns Community Health Centre (CHC), Vanderbijlpark, Gauteng Province. This site was chosen because it has a large volume of patients, cutting across all racial and educational profiles. It is the primary healthcare (PHC) facility for the southwest, southeast, central west and central east areas of Vanderbijlpark. In addition, it receives feeders from the following farm areas; Saspark, Nordene, Stokkiesdraai, Rosshashar, Kruispad, Zurfontein. The total population it serves is 74,075, and provides curative and preventative care, family planning, antenatal services, immunisation, HAST clinic, chronic care clinic, rehabilitative care and basic radiological services.

3.3 Sample size and sampling methods

The samples were selected from the patients attending for hypertension over the four-month period, November 2016 to March 2017. Considering a target population of 627 (obtained from the chronic care register), a confidence interval of 95%, an expected frequency of 50% and confidence limits of 5%, sample size, calculated using Epi info 7^{TM,} was determined to be 239.

In recruiting samples, health promoters addressed patients each morning in the waiting hall about the study and informed them that patients who chose to participate in the study would be placed back in the order of their initial position in the queue to see a doctor. Patients who agreed to participate received an information sheet in the vital signs room, and if they met the inclusion criteria, they proceeded to a private room to meet the researchers. To be eligible, a patient had to be an adult above 18 years of age, consent to participate in the study, have attended the clinic for at least three months, and be on anti-hypertensive medication.[11] Patients were considered not eligible if they were only on lifestyle modifications and unable to comprehend the treatment burden

questionnaire despite adequate explanation. In the private room, the researchers repeated the summary of the study purposes to each participant and elicited their understanding. Participants were also informed that full details were on the information sheet they received, and that there were numbers to call or emails to write to, if any questions arose. Finally, consenting participants were aided to fill the consent form. The above routine was followed throughout the period of recruiting participants, by consecutive sampling until desired sample size was attained. Participants were recruited Monday to Friday between 08H00 - 16H00. Two medical doctors who provided usual care in the outpatient department recruited participants and administered the measurement tools.

3.4 Measurement tools and data collection

Three tools were used to collect data:

a. Participant Characteristic Form
b. Treatment Burden Questionnaire
c. Hypertension control form

The Participant Characteristic Form was adapted from the participant tools used in two previous studies in the same district.[15,16] This tool was used to collect patients' information regarding age, sex, race, marital status, educational level, from diagnosis of hypertension to present date, if any other co-morbidity and if hypertension was more problematic to the index study participant.

The TBQ was used to obtain information from participants in three major areas: burden related to medication; burden related to navigating the health care system; burden related to life style changes, social and financial impacts.[12]

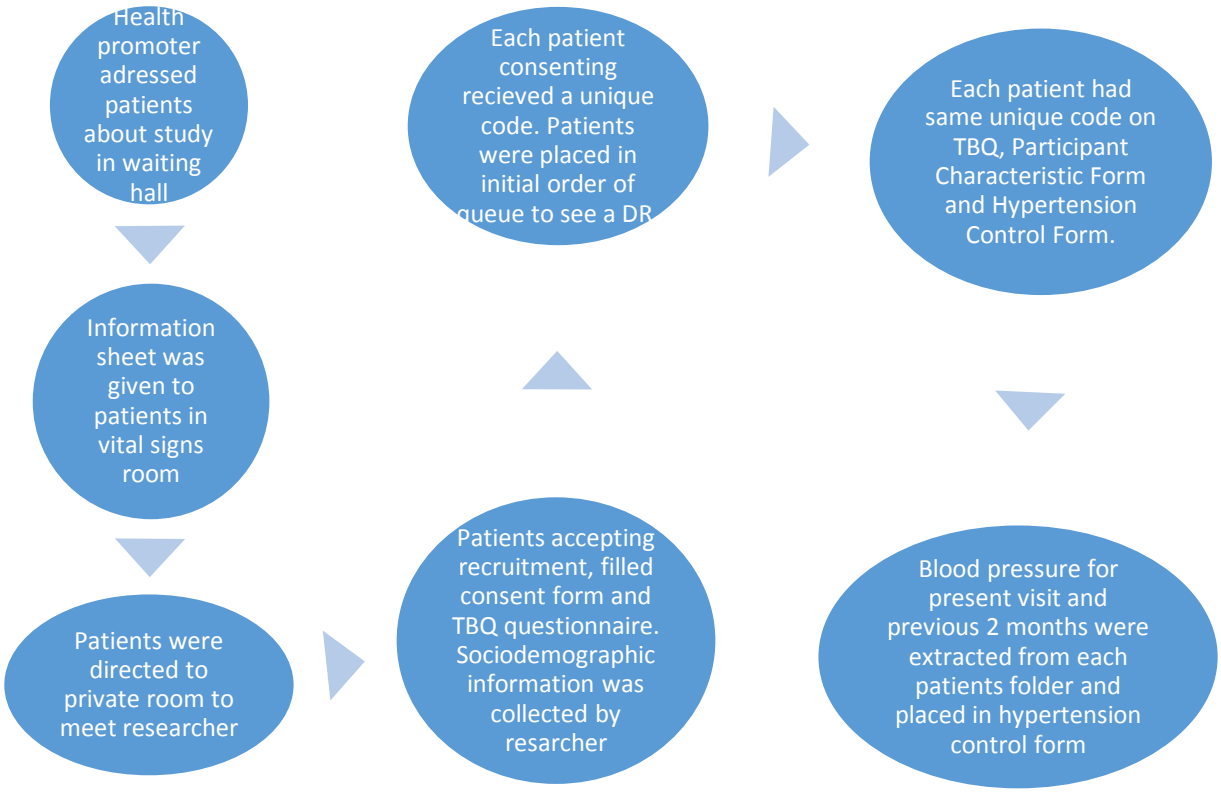
The hypertension control form was developed by the researcher and assisted by the supervisor in alignment with Objective 3 of the research. It was used to record the blood pressure readings of the current and two previous consecutive visits of index participants.

The blood pressure measurements were performed by the clinics' trained nursing sisters using the oscillometric method of fully automated and calibrated electronic blood pressure instruments. These instruments, CONTEC^{TM} PATIENT

MONITOR, are routinely re-calibrated every quarter by the Department of Health. As of 2016, this instrument was re-calibrated in October just prior to commencement of data collection and again in January. The South African Hypertension Society guidelines were followed for measuring the blood pressures.[37]

Figure 1 is a graphic illustration/flow diagram of the recruitment and data collection process.

FIG1: FLOW CHART FOR DATA COLLECTION



The TBQ was explained to each participant, including the interpretation of its visual analogue scale: participants were asked to score zero if a question posed no issue or problems to them, to score between 1 and 5 if a question was a moderate problem or issue to them, and to score between 6 and 10 if a question posed a big issue or problem to them. As deemed necessary by the researcher, each question was explained or clarified to participants before they were scored.

Questions that were not applicable to patient's circumstances were marked as so. The researchers completed the Participant Characteristic Form for each study participant.

Finally, the blood pressure for the current and two previous consecutive visits were extracted from participant medical records and entered into the Hypertension Control Form.

3.4.1 Data organisation:

Each participant received a unique code, ranging from 001 to 239 depending on the order of recruitment, which was entered into a diary that included patients' names, file numbers and research code. This diary was only accessible to the lead researcher and locked up in a personal drawer. These same codes were placed on the completed TBQ, Participant Characteristic Form and Hypertension Control Form of each participant to link them.

Patients' files were returned to the Queue Marshalls who placed patients in order of initial positions in the queue to see a doctor. At the end of each day, data was extracted from the three research tools into a data entry form. Data was uploaded into Epi info 7^{TM} by the researcher. The completed tools were secured and locked in a private locker, accessible only by the researcher.

3.5 Data analysis:

Data uploaded into Epi Info 7^{TM} was analysed by the researcher. Participant characteristics were analysed with descriptive statistics and reported on frequency tables with 95% confidence intervals. Proportions of participants with BP control at current and all visits over 3-month period were calculated. Proportions of those with co-morbidities, as well as those who considered hypertension more problematic than other comorbidities, were also determined. The mean systolic blood and diastolic blood pressures were determined with their standard deviations. BP control was classified in two ways:

(1) The mean blood pressures over a three month period

(2) The mean blood pressure at the current visit.

The burden of treatment was analysed as follows: The sums of participants' scores for each question in each of the three sections of the TBQ were recorded as BOT 1, BOT 2, and BOT 3 respectively. BOT 1 referred to the burden relating to issues of medication regimen, BOT 2 to the burden relating to navigating the healthcare system/facility and BOT 3 to the burden relating to lifestyle changes and support. The maximum scores in each of the three sections were divided into three equal tertiles and classified as low, moderate and high burden of treatment. The total or composite BOT score was also determined as a sum of the scores in BOT1, BOT2 and BOT3. The maximum composite score was divided into three equal tertiles and classified as low, moderate and high composite burden of treatment, as shown below:

- BOT 1: 1-13(LOW), 14-26(MODERATE), 27-40(HIGH)
- BOT 2: 1-16(LOW), 17-32(MODERATE), 33-50(HIGH)
- BOT 3: 1-16(LOW), 17-32(MODERATE), 33-50(HIGH
- COMPOSITE or TOTAL BOT (TBOT): 1-46(LOW), 47-92(MODERATE), 93-140(HIGH)
- The calculated ranges for BOT 2 &3 are similar because they contain equal number of components

In tests of associations, ANOVA was used to determine if there were significant differences in mean systolic, mean diastolic and BOT among sociodemographic groups. Linear regression analysis was used to test for associations of various explanatory variables with the dependent variables. In each regression analysis, the dependent variables were Mean blood pressures (Systolic and diastolic), BP control, Burden of treatment (BOT1, BOT 2, and BOT 3, TBOT). The explanatory variables were Age groups, Race, Sex, Marital status, Educational levels and Treatment duration. Statistical significance was set at $p < 0.05$.

3.6 Ethics

Patients were informed that they had the right to refuse to participate and this would not affect the quality of care they received in the facility. Individual patients

gave written consent before enrolment in the study. Patients' confidentiality was ensured and no personal identifiers were used, only coded numbers ranging from 001 to 239. Data on completed TBQs, sociodemographic and blood pressure control sheets were accessible only by the researcher and kept locked in a secure drawer. Patients files were returned to the Medical Records clerk the same day.

Written permission to conduct the study in the facility was obtained from the Sedibeng Health District management and ethics clearance was obtained from the Human Research Ethics committee (medical) of the University of the Witwatersrand (Reference number-M160804).

CHAPTER 4: RESULTS

The first part of the chapter presents a description of participants' sociodemographic and comorbidity characteristics and blood pressure treatment and control measures. The latter part of the chapter presents a description of the BOT and results of tests for associations between sociodemographic characteristics, blood pressure control and measures of BOT. Each table will be preceded by a headline and comments on key findings specific to that table, including the statistical significance if any.

4.1. Participants sociodemographic characteristics

Participants' characteristics are shown in Table 1. Most of the participants were White (54.20%), aged 45 to 64 years (54.62%), married/cohabiting (56.30%), female (60.08%) and had matric or further education (71.85%) respectively.

Table 1. Sociodemographic characteristics n=239

Age (years)	**(%)**
25-34	5.04 %(12)
35-44	11.76 %(28)
45-64	54.62%(130)
65-74	22.27 %(53)
75-84	6.30 %(15)
Race	
White	54.20 %(129)
African	42.86 %(102)
Others	2.94 %(7)
Gender	
Male	39.92 %(95)
Female	60.08 %(143)
Education	
None	3.36 %(8)
Primary	24.79 %(59)
Matric/beyond	71.85 %(171)

Marital status	
Single	15.97 %(380)
Married	56.30 %(134)
Divorced	5.46 %(13)
Widowed	21.85 %(52)

4.2 Presence of co-morbidities

In Table 2, 43.28% of participants had a co-morbidity with hypertension however, 63.64% of them did not consider their hypertension more burdensome than their co-morbidities.

Table 2. Hypertension and co-morbidities

Co-Morbidity	**Frequency**	**%**	**C.I**
NO	135	56.72 %	50.17-63.11
YES	103	43.28 %	36.89-49.83
TOTAL	238	100.00 %	
Report of Hypertension a problem	**Frequency**	**%**	
NO	63	63.64 %	53.36- 73.07
YES	35	35.35 %	26.01- 45.60
TOTAL	99	100.00 %	

4.3 Blood pressure control

The results of the proportions of participants with controlled and uncontrolled blood pressures are shown in Table 3. The proportion of participants with controlled blood pressure was 40.34% at current visit and 39.92% if all visits over three consecutive months were included.

Table 3. Blood pressure control (n=239)

BP control (All visits)	**%(n)**	**C.I**
UNCONTROLLED	60.08 %(143)	53.56- 66.36
CONTROLLED	39.92 %(95)	33.64- 46.44
TOTAL	100.00 %	
BP control_(Current visit)		
UNCONTROLLED	59.66 %(142)	53.13- 65.95
CONTROLLED	40.34 %(96)	34.05- 46.87
TOTAL	100.00 %	

4.4 Treatment durations by sociodemographic and BP control groups

The results of the mean duration of treatments are shown in Table 4. The mean treatment duration was 113.8 months (SD 106.6). Widows (P=0.00), whites (p=0.03), age group 45 to 64 years old (p=0.04), and females (p=0.04) had significant longer mean durations of treatment respectively. There was no significant difference in duration between participants with controlled BP and those uncontrolled.

Table 4. BP control, sociodemographics and mean treatment duration

Variables	MSBP	Std Dev	P value(statistical significance)
Overall	143.72	19.32	
Age			
25-34 yrs	145.58	21.75	0.43
35-44 yrs	141.25	16.23	
45-64 yrs	145.18	19.96	
65-74 yrs	139.96	16.30	
75-84 yrs	147.47	26.04	
Marital status			
Single	147.13	19.66	0.00
Married	141.93	17.48	
Divorced	153.46	17.71	
Widowed	143.77	23.12	
Sex			
Male	145.31	19.35	0.30
Female	142.66	19.10	
Educational level			
No-education	141.88	10.68	0.91
Primary	143.03	22.66	

matric/beyond	144.04	18.44	
Race			
White	140.82	19.93	0.02
African	147.77	18.40	
Other races	138.14	8.40	

4.5.1 Distribution of mean systolic blood pressures by sociodemographic groups

Divorced participants and Africans were significantly more likely to have a higher mean systolic blood pressure as shown in table 5.1 below.

Table 5 .1. Systolic blood pressure and Sociodemographic groups (n=239)

Variables	MSBP	Std Dev	P value
Overall	143.72	19.32	
Age			
25-34 yrs	145.58	21.75	0.43
35-44 yrs	141.25	16.23	
45-64 yrs	145.18	19.96	
65-74 yrs	139.96	16.30	
75-84 yrs	147.47	26.04	
Marital status			
Single	147.13	19.66	0.00
Married	141.93	17.48	
Divorced	153.46	17.71	
Widowed	143.77	23.12	
Sex			
Male	145.31	19.35	0.30
Female	142.66	19.10	
Educational level			
No-education	141.88	10.68	0.91
Primary	143.03	22.66	
Matric/beyond	144.04	18.44	
Race			
White	140.82	19.93	0.02

African	147.77	18.40	
Other races	138.14	8.40	

4.5.2 Distribution of mean diastolic blood pressures by sociodemographic groups

Single and male participants were significantly more likely to have a higher mean diastolic blood pressure as shown in Table 5.2 below.

Table 5.2. Diastolic blood pressure and Sociodemographic groups (n=239)

Variables	MDBP	Std Dev	P value
Overall	87.25	10.25	
Age			
25-34 yrs	89.17	10.95	0.05
35-44 yrs	86.11	10.14	
45-64 yrs	88.74	9.98	
55-64 yrs	86.22	10.40	
65-74 yrs	85.21	9.50	
75-84 yrs	82.20	12.80	
Marital status			
Single	88.40	10.16	0.00
Married	87.22	10.08	
Divorced	86.92	8.77	
Widowed	86.85	11.19	
Gender			
Male	88.99	10.87	0.03

Female	86.10	9.67	
Educational level			
No-education	85.81	9.94	0.23
Primary	88.95	10.68	
Matric/beyond	89.15	4.60	
Race			
White	84.00	7.82	0.06
African	85.68	10.57	
Other races	87.95	10.19	

4.6 Burden of treatment

The severity of the burden of treatment amongst study participants is shown in Table 6 below. Majority (75%) of participants had a low burden of treatment.

Table 6-BOT components

Total BOT	**%(n)**
NONE	15.25 %(36)
LOW	75.00 %(177)
MODERATE	9.75 %(23)
HIGH	0%
TOTAL	100.00 %
BOT related to health system navigation	**%(n)**
None	43.22%(102)
Low	41.10%(97)
Moderate	14.83%(35)
High	0.85%(2)
Total	100.00%
BOT related to life style changes & support	
None	22.55%(53)
Low	48.94%(115)
Moderate	22.98%(54)
High	5.53%(13)
Total	100.00%

4.7 RESULTS OF TESTS OF ASSOCIATIONS

4.7.1 Mean BOT scores and sociodemographic groups

The results of the comparison of the mean burden of treatment amongst various groups is shown in Table 7 below. Mean BOT for participants was 19.7. Single participants were significantly more likely to have a higher mean burden of treatment, P=0.00.

TABLE 7. Mean BOT by Socio-demographics (n=239)

Variables	Mean TBOT	Std Dev	p value
Overall	19.7	19.75	
Age			
25-34 yrs	20.50	20.84	0.40
35-44 yrs	23.25	21.71	
45-64 yrs	21.34	20.54	
65-74 yrs	15.08	15.45	
75-84 yrs	14.27	20.53	
Race			
White	20.78	20.70	0.58
African	18.64	18.98	
Others	14.86	12.13	
Gender			
Male	21.26	20.43	0.32
Female	18.64	19.30	
Marital status			
Single	22.53	19.64	0.00
Married	19.66	19.35	

Divorced	20.62	22.01	
Widowed	17.67	20.77	
Educational level			
No education	19.50	28.43	0.91
Primary	20.56	21.91	
Matric/beyond	19.39	18.62	

4.7.2 Socio-demographics and blood pressure control

No significant association between sociodemographic characteristics and blood pressure control were observed in table 8 below.

Table 8. Blood pressure control and Sociodemographics

Variable regress BP control	**Coefficient**	**Std Error**	**F-test**	**P-Value**
Age	0.00	0.00	2.67	0.10
Co-morbidity	-0.04	0.07	0.28	0.60
Education	-0.01	0.06	0.03	0.88
Marital	-0.04	0.04	0.98	0.33
Race	-0.06	0.06	1.14	0.29
Sex	-0.03	0.07	0.21	0.64
Constant	1.34	0.28	23.41	0.00

4.7.3 BOT and blood pressure control

In Table 9, participants with uncontrolled blood pressure were more likely to have a higher BOT1 score for issues around medication regimen p=0.04.

Table 9. BOT and blood pressure control

BOT*CONTROL	MEAN BOT	STD DEV	P VALUE
*TBOT*Control*			
uncontrolled B.P	20.3357	20.0955	0.53
controlled B.P	18.7053	19.3065	
*BOT1*Control* *Issues around medication regimen*			
uncontrolled B.P	2.9441	5.7712	0.04
controlled B.P	1.6316	3.0459	
*BOT2*Control* *Navigating healthcare system*			
uncontrolled B.P	6.0699	8.4016	0.43
controlled B.P	6.9579	8.7238	
*BOT3*Control* *Life-style modification& support*			
uncontrolled B.P	11.3636	10.3920	0.46
controlled B.P	10.2842	11.8534	

4.7.4 Sociodemographic variables and mean systolic and diastolic blood pressures

In Table 10, sex (p=0.02), race (p=0.04) and age (p=0.02) were significantly associated with mean diastolic blood pressures.

Table 10

Variable(Regress MSBP)	**Coefficient**	**95% confidence**	**limits**	**Std Error**	**F-Test**	**P value**
AGE1	*-0.93*	*-3.06*	*1.21*	*1.08*	*0.73*	*0.39*
SEX	*-3.13*	*-8.34*	*2.09*	*2.65*	*1.40*	*0.24*
RXT DURAT	*-0.00*	*-0.03*	*0.02*	*0.01*	*0.03*	*0.86*
MARITAL	*1.25*	*-1.42*	*3.92*	*1.35*	*0.85*	*0.36*
EDUCTION	*1.24*	*-3.46*	*5.94*	*2.39*	*0.27*	*0.60*
RACE	*4.58*	*0.02*	*9.13*	*2.31*	*3.92*	*0.05*
CONSTANT	*140.57*	*123.46*	*157.68*	*8.69*	*261.90*	*0.00*
Variable(Regress MDBP)	***Coefficient***	***95% confidence***	***limits***	***Std Error***	***F-Test***	***P value***
AGE1	*-1.30*	*-2.40*	*-0.20*	*0.56*	*5.44*	*0.02*
MARITAL	*0.89*	*-0.48*	*2.27*	*0.70*	*1.63*	*0.20*
SEX	*-3.14*	*-5.83*	*-0.46*	*1.36*	*5.31*	*0.02*
RACE	*2.51*	*0.17*	*4.85*	*1.19*	*4.45*	*0.04*
RXT DURAT	*-0.00*	*-0.02*	*0.01*	*0.01*	*0.56*	*0.45*
EDUCATION	*2.05*	*-0.37*	*4.47*	*1.23*	*2.78*	*0.10*
CONSTANT	*88.33*	*79.52*	*97.15*	*4.47*	*389.82*	*0.00*

CHAPTER 5

DISCUSSION AND LIMITATIONS

5.0 Discussion

Participants' characteristics

Results from the study showed that age>45 years accounted for the majority of study participants with a cumulative percentage of 83.19% (see Table 1). This is consistent with literature that highlights the rising incidence of hypertension in older population groups. The clinical implication is that blood pressure screening should be intensified in older population groups in contact with health facilities, as a public health measure for preventing adverse cardiovascular events. However, regarding BOT, this study did not find any significant relationship between BOT and age (See Table 7), inconsistent with findings of previous BOT studies that show higher BOT with younger people.[29,36] Considering the small sample size in the current study, further larger studies involving multiple centres are required to explore this relationship, and provide guidance in South Africa.

Whites (54.20%) accounted for the greater proportion of participants compared to other population groups (see Table1). This varies with similar studies in the same district and nationally, which reported values that showed Blacks account for the majority of all patients with hypertension,[15-16] and for the majority of the population.[39] It is important to state that this study commenced in November 2016 at the same time that the patients were redirected to their local clinics corresponding to their residence. This redirection of patients to peripheral clinics, Tsepiso, Sharpeville, Bophelong, Boipatong, might have reduced the proportions of Blacks and skewed the sociodemographic characteristics of the study population when compared to previous studies in the same health centre - to the extent that White people now constitute the majority of patients attending the outpatient services in the facility. Population information for the area, however alludes a higher demographics for whites in the Vanderbijlpark area if surrounding black townships are excluded.[40-41] Consequently, due caution should be exercised when generalising the findings of this study nationally.

Participants with a matric or higher education accounted for 78% (see Table 1), similar to a study in KwaZulu Natal that put the proportion of patients with hypertension having a matric/tertiary qualifications at 62.3%.[30] Similar studies in Saudi Arabia, reported 60% for those with higher school and tertiary qualifications.[33] It may be that the urban setting in which these studies were conducted may be responsible for the greater proportion of participants with higher education .Urbanisation may be associated with greater educational yearnings, changes in lifestyle, and higher socioeconomic status, which has implications on the prevalence of hypertension.[24, 27] However a study in Limpopo in South Africa found a high prevalence of hypertension among rural dwellers[39] and further showed that the prevalence was lower amongst rural dwellers with tertiary education .[39] The clinical implication of these conflicting reports is to avoid focusing on specific age groups as implied earlier but screen all presenting adults and intensify treatment regardless of age on a case by case basis.

Women accounted for a greater proportion, 60.08%, of participants (see Table 1). This conforms with a previous study in the same facility that showed females accounted for 63.8% of patients with hypertension.[14] Later studies have also shown a greater female preponderance for hypertension.[15-16,30,33,42] Women are more likely to have other causes of hypertension when compared to men,[42]and this may account for the greater proportion of females attending hypertensive clinics. Considering that the majority of study participants were females, this imposes a big clinical burden on the health system, especially as women tend to have poorer outcomes compared to men.[27] Aggressive campaigns for blood pressure measurements at all contacts with female patients may help in hypertension discovery and management. Given that women have better health-seeking behaviour than men[15], this behaviour could be leveraged to screen, intensify treatment and explore burden of treatment that may impede blood pressure control.

A greater proportion of participants were married or co-habiting in this study (56.30 %), consistent with findings of previous studies in the district and

elsewhere.[15,18] It has been reported that companionship mitigates the burden of treatment,[5,6] and BOT is likely to be higher in single participants. Literature also reports that having a spouse is associated with better blood pressure control,[17] although this study did not find any association between BP control and marital status. Nonetheless, spousal support may be exploited to encourage clinic attendance, improve medication adherence and reduce BOT among men with hypertension.

Presence of co-morbidity

This study showed that 43.28% of participants had a co-morbidity with their hypertension, but the majority of 66.62% did not consider their hypertension more problematic than their co-morbidities (see Table 2). Studies in Malaysia report a co-morbidity rate of 87.5%, with significant influence on worsening blood pressure control.[23] A local study reported poorer blood pressure control in patients with diabetes co-morbidity.[42] BOT is expected to rise with co-morbidities,[1-5] and this has important implications for adherence to therapeutic regimens and disease control. Hence, screening for co-morbidities in patients with hypertension is not only crucial for clinical treatment,[16] but also for support to manage the associated increased BOT.

Blood pressure control

In this study, the blood pressure control rates of 40.34% and 39.92% at current visit and in the last three months were low (see Table 3) and comparable to reports elsewhere.[18-24] While poor control of blood pressure may be multifactorial, studies elsewhere have cited poor lifestyle (smoking, diet, alcohol, obesity) and weak social support network as possible factors responsible for the low control rate.[15,19,22] Although the total BOT in this study was low, poor blood pressure control was significantly associated with medication-regimen BOT, suggesting a need for further studies to explore to what extent BOT influences blood pressure control in this setting.

In this study, there was no significant association between sociodemographic characteristics and blood pressure control (see Table 8). This varies with an earlier study in the same district, which reported significantly increased odds of

uncontrolled blood pressure among widowed and divorced participants.[15] Although this study did not demonstrate such relationship with blood pressure control, it did however show that divorced participants were significantly more likely to have a higher mean systolic blood pressure and single participants were significantly more likely to have a higher mean diastolic blood pressure(see improving BP control Tables 5.1 and 5.2) compared to other marital groups. Companionship mitigates BOT by providing spousal support and removing the inherent stress of living alone.[5,6] It is therefore important to explore patients' contextual situation in terms of support for medication adherence and dietary compliance as a means of mitigating BOT.

This study showed no significant differences in blood pressure control between the racial and gender groups (see Table 8), which is in conflict with earlier studies in the same facility and nationally in South Africa.[15,24] As a result due caution should also be exercised in generalising this study, while larger multicenter studies on BOT and blood pressure control should be carried out.

The current study demonstrated no significant difference in blood pressure control amongst various age groups. However, the age group 45 to 54 were significantly more likely to have a higher mean diastolic blood pressure (p=0.01), when compared to other ages (see Table 5.2). Linear regression analysis also showed a negative correlation for ages with mean diastolic blood pressure falling with increasing age groups, p=0.02(see Table 10). Literature is conflicting with issues around age groups and blood pressure control: some indicating that the age group 40 to 49 is better controlled, [26] others reporting better control in those >65 years.[28] Nonetheless, these low rates of blood pressure control have clinical and public health implications in that complications and mortality are worsened and the prevalence of hypertension is expected to increase particularly in developing countries where resources may be scarce, already engulfed with infectious disease programmes and where there is poor policy response to curb non-communicable diseases.[15,39]

In this study, Whites were on a significantly longer duration of treatment compared to Blacks (see Table 4). It is possible that the higher educational levels

amongst Whites could make them more aware and knowledgeable about hypertension, and seek treatment earlier.[15]

Female participants in this study had significant longer mean treatment durations when compared to males (see Table 4) consistent with local and international reports, they seek help and utilise health facilities earlier than males,[15] and males exhibit lower awareness of their hypertension compared to females.[22] Reports from Africa indicate that ante-natal attendances, post-natal care and childhood illnesses increase the contact of women with health facilities and hence their greater awareness and earlier treatment initiation for a broad range of health conditions.[37] Reports in the US also allude to a higher proportion of females being aware of their hypertension due to vigorous education and campaigns targeting women because of the increased risk of CVD.[35] Studies in Nepal have also reported a positive association between being female and on treatment for hypertension.[22] Community mobilisation and use of CHWs from WBOT teams should increase the awareness of blood pressure screening amongst males and in Black communities. Furthermore, clinicians should utilise every contact time with patients with hypertension to intensify treatment, since this study did not show any significant association between Blood pressure control and Mean duration of treatment.

Burden of treatment

The majority of study participants (75%) had a low mean BOT (see Table 6), however, the reported BOT related to medication regimen, although low was significantly higher for participants with uncontrolled BP (p=0.04). This highlights the issues of treatment non-adherence and non-rational prescription. As stated earlier, physicians may be unaware of the BOT imposed on their patients by the disease, their drug prescriptions and measures that could be undertaken to mitigate them.[7] BOT escalates as multiple chronic diseases emerge in an individual, which culminates in treatment non-adherence.[5] Physicians often respond to poor disease control by escalating treatment regimens, without exploring non-adherence as being responsible, thereby worsening BOT in patients with already high subjective treatment loads.[4] It is therefore imperative

that healthcare practitioners, in a patient-centred and non-judgmental approach, enquire about challenges patients' face with daily medication regimen and prescribe rationally.

The mean BOT was significantly higher among single participants compared to other marital groups (see Table 7). This is consistent with literature reports from qualitative studies that companionship and enlisting support were means by which patients mitigated their BOT.[5-6,43] Enlisting companionship network, mitigates tasks imposed by healthcare systems. Where companionship is lacking, policy implications should direct targeted health promotions using media and WBOT systems should be intensified. CHWs visits should be directed to elderly widowed patients to provide treatment support.

Although this study showed that the BOT related to lifestyle and support was low (see Table 6), a study looking at that of patients with COPD reported that implementing dietary recommendations and smoking cessation were considered difficult by participants.[44] This is not supported by this study, as >70% of participants reported none or low BOT. Nevertheless, larger and more representative studies, especially qualitative ones, are needed to explore, in detail, how lifestyle management influences BOT and blood pressure control.

This study showed no significant association between overall BOT and blood pressure control, although there was significant association between medication regimen BOT and blood pressure control (see Table 9). While an earlier study in the same facility found that therapy was key to blood pressure control,[16] other studies elsewhere have suggested that BOT is negatively associated with adherence to treatment.[5-7] Put together, non-patient factors such as healthcare providers' poor adherence to treatment guidelines, physician inertia in instituting appropriate therapy and other facility-based factors may explain the poor blood pressure control in the current research setting.

5.1 Limitations and biases

This study has some limitations:

Firstly, causality relationships cannot be inferred since the study was cross sectional. Secondly, generalisation of findings to the broader South African

context is limited since the redirection of patients may have skewed the sample, to the extent that ethnic populations were not proportionally represented.

Thirdly, the consecutive sampling size could have introduced selection bias[45] and given that the study was conducted during the day, workers with hypertension who may have presented after hours or on weekends and patients involved in the Kgathelopele programme, who receive medications at home without monthly review at the clinic, would have been missed. Fourthly, patients from other clinics in the facility, such as the ARV clinics, who had hypertension, were not recruited, introducing a sampling bias. Fiftly the instruments used for BP measurements and their technique of re-calibration may have introduced a measurement bias[45] Lastly, although having a high internal consistency, the burden of treatment questionnaire was developed in France and may not be completely representative of issues relevant in African settings. Validation studies are therefore needed in South Africa.

The applicability of the studies reviewed above, and the emerging themes to the setting of this current study, may have some limitations. Firstly, these studies are sited in developed world, involving academic medical centres and urban hospitals. Secondly, most are silent on racial composition of study participants and did not utilise the multiple chronic disease models. Notwithstanding these limitations, this study contributes to literature on this subject, being the first in South African primary care to assess burden of treatment among patients with hypertension and its relationship with blood pressure control.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Despite prevalent poor blood pressure control, participants in this study reported a low total BOT. However, a significantly higher BOT in the drug regimen component was found among participants with uncontrolled blood pressure. Considering that only a minority reported moderate to high score in the three components of BOT, the findings of this study suggests that other elements of the processes of care, such as poor healthcare providers' adherence to guidelines and inertia in intensifying treatment (rather than BOT associated with medication regimen), may be responsible for the prevalent poor blood pressure control in South African primary care settings.

Given the limitations of this study, qualitative and quantitative studies that are designed better, especially longitudinal ones, are required to understand BOT among patients with hypertension in South Africa. In addition, the use of a burden of treatment measurement tool, derived from the developed world, warrants scrutiny as to its appropriateness for the South African context. Validation studies for the BOT questionnaire are therefore direly needed in South Africa.

6.2 Recommendations

1. Since this was a quantitative study, further qualitative exploration of BOT in hypertension is needed to gain deeper understanding of this phenomenon and inform the development of a measurement tool appropriate for South Africa.

2. The TBQ questionnaire needs to be validated for the South African context.

3. Healthcare providers' adherence to clinical protocols and guidelines need to be assured through audits of practice and monitoring of blood pressure control in the district health information system. In addition, regular continued medical education and quality improvement projects focused on the processes of care of patients with hypertension may assist.

4. Emerging themes from reviewed studies showed that BOT appears to be a complex concept that may not be static but dynamic as chronic diseases progress in patients. Hence longitudinal rather than cross sectional studies may

be the best in assessing long term in a group of patients with single or multiple chronic diseases. It is imperative to carry out qualitative research on the BOT concept in African settings to allow themes appropriate to the African setting to emerge. In addition, longitudinal study frameworks need to be developed to measure the dynamics of BOT over time in patients with chronic diseases in low-income countries.

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8.0

APPENDICES

APPENDIX 1: PARTICIPANT CHARACTERISTIC FORM

CHARACTERISTICS	
AGE (YEARS**)**	
SEX	
FEMALE	
MALE	
RACE	
AFRICAN	
WHITES	
OTHERS	
EDUCATIONAL LEVEL	
NONE	
PRIMARY SCHOOL	
MATRIC/BEYOND	
MARITAL STATUS	
SINGLE	
MARRIED/COHABIT	
DIVORCED	
WIDOWED	
WHEN WHERE YOU DIAGNOSED WITH	

HYPERTENSION?	
ASIDE HYPERTENSION DO YOU SUFFER FROM ANY OTHER MEDICAL CONDITION?	
IF YES WHICH IS MORE PROBLEMATIC?	

APPENDIX 2

TREATMENT BURDEN QUESTIONNAIRE [12] (Cronbach alpha 0.9)

CODE NUMBER:

INSTRUCTION: Take a moment and consider everything you have to do to take care of your health. For the following items, please rate the overall burden or problem associated with each.

Does not apply

0- Not a problem 1 2 3 4 5 6 7 8 9 10–Big problem

1. **The taste, shape or size of your tablets**

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

2. **The number of times you should take your medication daily**

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

3. **The efforts you make not to forget to take your medications (for example: managing your treatment when you are away from home, preparing and using pillboxes...)**

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

4. **The necessary precautions when taking your medication (for example: taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down...**)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

INSTRUCTION: Please answer the following question

Does not apply

0-Not a problem 1 2 3 4 5 6 7 8 9 10–Big problem

5. Lab tests and other exams (for example: blood tests or radiology): frequency, time spent and associated nuisances or inconveniences

Does not apply

0=Not a problem to 10=Big problem .Patient self-score……

6. Self-monitoring (for example, taking your blood pressure): frequency, time spent and associated nuisances or inconveniences

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

7. Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

8. The difficulties you could have in your relationship with healthcare providers (for example: feeling not listened to enough or not taken seriously)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

9. Arranging medical appointments and/or transportation (doctors' visits, lab tests and other exams) and reorganising your schedule around these appointments

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

INSTRUCTION: Please answer the following question

Does not apply

0-Not a problem 1 2 3 4 5 6 7 8 9 10–Big problem

10. The administrative burden related to healthcare (for example: all you have to do for hospitalisations, insurance reimbursements and/or obtaining social services)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

11. The financial burden associated with your healthcare (for example: out of pocket expenses or expenses not covered by insurance...)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

12. The burden related to dietary changes (for example: avoiding certain foods or alcohol, having to quit smoking...)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

13. The burden related to doctors' recommendations to practice physical activity (for example: walking, jogging, swimming...)

Does not apply

0=Not a problem to 10= ig problem. Patient self-score……

14. How does your healthcare impact your relationships with others (for example: being dependent on others and feeling like a burden to them, being embarrassed to take your medications in public...)

Does not apply

0=Not a problem to 10=Big problem. Patient self-score……

INSTRUCTION: Please answer the following question

Not at all 1 2 3 4 5 6 7 8 9 all the time

15. **'The need for medical healthcare on a regular basis reminds me of my health problems'**

0=Not at all to 10=all the time. Patient self-score……

APPENDIX 3

HYPERTENSION CONTROL FORM [13, 14, 19]

CODE NUMBER:

BLOOD PRESSURE OVER LAST 3 MONTHS VISITS	**CONTROLLED** <140/90 MmHq	**UNCONTROLLED** >140/90MMHq

APPENDIX 4: **Information**

Good Day,

I am Dr K. Pender from the Department of Family Medicine at the University of the Witwatersrand medical school. I am investigating the Burden of Treatment and blood pressure control of patients with hypertension attending this health facility Johan Heyns CHC.

Why are we doing this? Information we are getting from research from other countries is pointing to the fact that if the burden the treatment of a condition places on the patient is high, bad outcomes, such as worsening of the disease, may occur. In Sedibeng District, in South Africa, a sizeable number of patients attending Public Health clinics suffer from high blood pressure and many of them still have blood pressures above 140/90MMHq. We are trying to understand the burden the treatment for their high blood pressure places on them and if this may be responsible for their poor control.

What do we expect from the participants in the study? We will be assisting you to complete a questionnaire in order to determine what level of burden the treatment of your condition causes you, and determine what factors contribute to this. We will also collect personal information from you. We will look into your patient file to determine if your blood pressure over the last 3 months visits has been <140/90MMHq at each visit.

Are there benefits to the participants? Yes. If we notice a high burden of treatment with you and identify the factors causing this we will invite you to discuss ways to overcome this.

May I withdraw from the study? Certainly, you may do this at any time without having to give a reason. Remember that the study is completely voluntary and not taking part in it, or withdrawing from it, will not affect how we relate or manage your high blood pressure at each of your clinic visits.

What about confidentiality? Information regarding you will not be released to anyone. Only the researcher will have a list of names and codes to enable the code to be linked to a particular patient. This list will be kept locked in an office. All names will be expunged before data analysis and information collected will be kept for 5 years, after which it will be destroyed.

Risks and reimbursement. There will be no risk posed to you as a participant in this research. Benefits will be an invitation, if you have a high Burden of Treatment, to discuss how to overcome this.

Ethics approval. This research has been approved by WITS HREC. Please feel free to contact the following people below if you have any queries or reports to make.

Contact details: Prof P Cleaton-Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za

Ms Z Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Administrative Officers 011 717 2700/2656/1234/1252

zanele.ndlovu@wits.ac.za;

Rhulani.mkansi@wits.ac.za;

Lebo.moeng@wits.ac.za

If you have any queries, more information may be obtained from Dr Pender on telephone number 0833914759.

If you are happy to take part in the study, please read and sign the attached consent form.

Thank you

Dr K. Pender(Researcher)

12/09/2016----------

APPENDIX 5 **: Consent form**

I agree to participate in the study: **BURDEN OF TREATMENT AND BLOOD PRESSURE CONTROL OF PATIENTS WITH HYPERTENSION AT A PRIMARY CARE FACILITY IN SEDIBENG DISTRICT, GAUTENG PROVINCE,** as outlined in the information sheet

Patient: Name ..... Signature .....

Date .....

R14/49 Dr Kevin Pender

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160804

NAME: (Principal Investigator)	Dr Kevin Pender
DEPARTMENT:	Family Medicine Johan Heyns Community Health Centre, Vanderbijlpark
PROJECT TITLE:	Burden of Treatment and Blood Pressure Control of Patients with Hypertention at a Primary Care Facility in Sedibeng District, Gauteng Province
DATE CONSIDERED:	26/08/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr O.B Omole
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	07/10/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in August and will therefore be due in the month of August each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Kevin Pender 15:54 (0 minutes ago)
to me

---------- Forwarded message ---------
From: **Paul Wicks** <pwicks@patientslikeme.com>
Date: Tue, 01 Mar 2016, 14:12
Subject: Re: TBQ questionnaire
To: Kevin Pender <kevinpender012@gmail.com>
Cc: <openscience@patientslikeme.com>

Dear Dr Pender,

You can read more about the TBQ here: https://www.openresearchexchange.com/public/library/instruments/49/overview

and here: http://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-12-109

Dr Tran may also have more up to date information, you can email him: thi.tran-viet@htd.aphp.fr

Best wishes

Paul

On Tue, Mar 1, 2016 at 9:00 AM, Kevin Pender <kevinpender012@gmail.com> wrote:

> Dear Administrator,
> I write to request the Treatment Burden Questionnaire. Am currently about to begin a research " Evaluating the treatment burden of primary care patients with comorbidities attending Johan Heyns CHC." I have read about the TBQ with a cronbach alpha of 0.9.
> I am located in South Africa at the Sedibeng District Health Services Gauteng province.
> Thanks for your anticipated cooperation.
> Sincerely
> Dr K. Pender

Paul Wicks, PhD.
VP of Innovation
patientslike**me**
m: +44 (0)7813 037 069

----- Forwarded message ---------
From: **Paul Wicks** <pwicks@patientslikeme.com>
Date: Mon, 07 Mar 2016, 22:28
Subject: Re: TBQ questionnaire
To: Kevin Pender <kevinpender012@gmail.com>

Pretty sure it's either in the manuscript or in the "View" tab here: https://www.openresearchexchange.com/public/library/instruments/49/view