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A study to determine if South African medical practitioners in urban areas follow the Southern African hypertension society guideline for the treatment and management of uncomplicated hypertension

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A Study to Determine if South African Medical Practitioners in Urban Areas Follow the Southern African Hypertension Society Guideline for the Treatment and Management of Uncomplicated Hypertension

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in part fulfillment of the requirements for the degree
of
M.Sc.(Med) (Pharmaceutical Affairs)

Johannesburg 2005

DECLARATION

I, Diederik Johannes Van Niekerk, declare that this research report is my own work. It is being submitted for examination (re-examination) in part fulfilment for the degree of Master of Science in Medicine (Pharmaceutical Affairs) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree at this or any other University.

Signed by:

_____

DIEDERIK JOHANNES VAN NIEKERK (ID: 760106 5123 083)

On this …… day of ……., 2005

SIGNATURE OF SUPERVISOR

Signed by:

_____

PROF. A. WOODIWISS

On this ……. day of ……., 2005

DEDICATION

Vir Oupa – Ons mis jou:

Diederik Johannes Van Niekerk

1912-2001

ABSTRACT

The prescription habits of general practitioners are continually under the scrutiny of ethical critics. There are numerous factors that influence a practitioner's decision as to which antihypertensive agents to prescribe for the treatment of hypertension. As outlined in various international and national guidelines for the management of hypertension, the recommended treatment depends on ethnicity, current life-style, diet, smoking, age, gender, family history and possible underlying or secondary conditions such as diabetes mellitus, heart failure, isolated systolic hypertension, myocardial infarction, pregnancy, and evidence of coronary artery disease (CAD), stroke or peripheral vascular disease.

Currently the control of blood pressure in patients with hypertension is far from optimal with over 70% of hypertensive patients being reported as having imperfect control. A number of factors related to the patient, the practitioner or the medication may explain the high incidence of inadequate blood pressure control. One possible explanation for the poor control of blood pressure may be that practitioners fail to comply with the guidelines.

Hence the aim of my study was firstly to determine whether a practitioner's decision as to which medication to prescribe in the treatment of hypertension is influenced by the Southern African Hypertension Society Guidelines. Secondly, in an attempt to assess the validity of the results of the primary analysis, the actual prescription habits (MediCross® database) were assessed and compared to the general practitioner's recall of their prescription habits.

Questionnaires were distributed to 320 MediCross® practitioners and prescription habits were identified and substantiated by the screening of an existing MediCross® database. I chose as my sample MediCross® general practitioners, as they are demographically representative of all major urban areas in South Africa; likely to be open-minded to supporting research and answering questionnaires (as MediCross® is part of a Clinical Research Site Management Organisation); and I had access to the database of the prescriptions made by MediCross® practitioners hence enabling me to fulfil my second objective. However, it must be kept in mind that these practitioners are representative of general practitioners in urban areas only (as the title of my research report indicates).

My results show that 33.1% adhere to the guidelines (when a non-conservative definition of diuretics is used); 27% have heard of the guidelines and have a copy of them. When asked to give their own opinion however, 39% thought they adhered to the guidelines. The results also show that ACE inhibitors are the most commonly prescribed drug class for uncomplicated hypertension but a comparison to a MediCross® database, of which the quality is questionable, does not support this.

As the response rate to the questionnaires was only 24.7%, these results **are only a pilot study**; however they suggest that few general practitioners use the guidelines or even have a copy of the guidelines. This pilot study suggests that the guidelines need to be distributed more widely. Furthermore the general practitioners that responded to the questionnaire indicated that the management of hypertension is difficult in that there is no single treatment regimen appropriate for all populations and each different

patient. It was also their view that clinical guidelines for the management of hypertension should more accurately reflect the uncertainty of when to initiate treatment and individual variation if they are going to take these guidelines seriously and comply with them.

ACKNOWLEDGEMENTS

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Van Zyl Kruger (Managing Director: Hurricane Consulting®) – Access to MediCross® database for secondary objective analysis.

Dr. Gareth Lowndes (MSc Course Coordinator and Lecturer) – Administrative support and guidance.

LIST OF ABBREVIATIONS

ACE - Acetylcholine esterase

ATC - Anatomic Therapeutic Code

BP - Blood Pressure

CHD - Coronary Heart Disease

CI - Confidence Interval

CVD - Cardiovascular Disease

DBP - Diastolic Blood Pressure

H_a - Alternate Hypothesis

H_o - Null Hypothesis

HREC - Human Research Ethics Committee

JNC - Joint National Committee

MI - Myocardial Infarction

MS® - Microsoft®

SAHS - Southern African Hypertension Society

SAMF - South African Medicines Formulary

SAMJ - South African Medical Journal

SAS® - Statistical Analysis System®

SBP - Systolic Blood Pressure

WHO - World Health Organisation

WITS - University of the Witwatersrand

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1. INTRODUCTION

Hypertension is a chronic disease which affects a large percentage (25%) of the adult population worldwide [1,2]. In order to decrease the risk of cardiovascular mortality, it is imperative to reduce blood pressure to normal levels (<140/90 mm Hg for uncomplicated cases of hypertension) in these subjects [3]. Indeed a progressive decrease in cardiovascular mortality in North America, Western Europe, Japan and Australasia has been observed in the second half of the twentieth century [4]. This reduction in mortality has largely been attributed to the considerable improvement in the control of hypertension in these regions during this time period. The Health Examination Surveys in the United States have demonstrated that whereas 10% of hypertensive subjects had their blood pressure lowered to below 140/90 mmHg in 1976 – 1980, by 1988 – 1991 this proportion had risen to 27% [5]. However, it is important to note that this still leaves over 70% of hypertensive subjects with imperfect control (or no treatment at all), as has been reported in many countries [6]. Moreover, there are worrying signs that the rate of improvement previously reported has now plateaued or even reversed in some cases. In the United Kingdom, a recent survey indicated that only 6% of hypertensive patients had their blood pressure lowered to 140/90 mmHg [3]. Related to these values indicating poor blood pressure control in a large proportion of patients with hypertension, is recent evidence in the United States of America that age-adjusted stroke mortality rates have increased slightly and that the rate of decline in coronary heart disease (CHD) mortality has now decreased.

Even more worrying is the rapid development of the 'second wave' epidemic of cardiovascular disease that is now flowing through developing countries and the former socialist republics. It is evident that death and disability from CHD and cerebrovascular disease are increasing so rapidly in these parts of the world that they will rank no. 1 and no. 4, respectively, as causes of the global burden of disease by the year 2020 [7]. Given the central role of elevated blood pressure in the pathogenesis of both CHD and stroke, it is clear that one of the biggest challenges facing public health authorities and medical practitioners is the control of hypertension worldwide, both in individual patients and at the population level.

The 1998 "WHO – International Society of Hypertension Guidelines for the Management of Hypertension" were written to guide specialist physicians responsible for the care of patients with high blood pressure. These guidelines are complemented by a companion set of *Practice Guidelines* for general practitioners and other clinicians caring for patients with hypertension in various regions around the world, including South Africa. The 1999 Guidelines concentrated on the management of patients with 'mild' hypertension, since there is often uncertainty among clinicians and policy makers about how to manage this condition. Since the determinants of cardiovascular disease in hypertensive patients are substantially multifactorial, these Guidelines provide recommendations for risk reduction through blood pressure lowering, in a context that recognizes the importance of strategies for the management of other risk factors that commonly affect individuals with hypertension.

It is well established that in Western populations, stroke, CHD and other common cardiovascular diseases, such as heart failure, have multiple determinants. The main established predictors of these diseases are discussed below. How well these factors

predict cardiovascular disease in non-Western populations is less certain, although recent evidence from eastern Asian populations suggests that for blood pressure and blood cholesterol there may be similar associations in the East and in the West [8]. There is very little direct evidence about the determinants of common cardiovascular diseases in other large populations such as those of sub-Saharan Africa, India or South America. Furthermore, available medications and their costs differ from country to country. Hence, it is important that guidelines are tailored for each country. Hence, the Southern African Hypertension Society published the Southern African Hypertension Society Guideline in 2001. This guideline is based on the guidelines set out by the major international health care organizations and societies such as the World Health Organisation – International Society for Hypertension, the Joint National Committee VI (JNC VI) and the British Hypertension Society. Furthermore, the Southern African Hypertension Society Guideline is endorsed by the South African Medical Association Guideline Committee. Note that subsequent to me embarking on my research project the South African Guidelines have been revised and the revisions published (SAMJ March 2004 vol 94, number 3). For my research project I focused on the guidelines published in 2001 [15].

Hypertension is a major health challenge in South Africa. The Southern African Hypertension Society Guideline is targeted at all healthcare professionals in both the public and private health sectors. It reflects realistic objectives that can be applied widely and aims to diminish the impact of hypertension in this country. The control of hypertension in conjunction with other major risk factors such as cigarette smoking, dyslipidaemia and diabetes mellitus, constitutes the ideal approach to the primary prevention of artherosclerotic disease, and remains a major challenge for the community at large.

As a major contributor to cardiovascular disease (CVD), hypertension is very costly. In 1991, CVD accounted for R4-5 billion in direct and indirect costs [9], which was 7.5% of the direct healthcare spending in South Africa [10]. The Southern African Hypertension Society Guideline adopts the approach of a formal estimation of cardiovascular risk which will allow for the treatment of those South Africans at highest risk and those who can maximally gain from lifestyle and drug interventions at the lowest cost, given South Africa’s limited resources.

The first guideline for the management of hypertension at primary healthcare level was issued by the Southern African Hypertension Society in 1995 [15]. The current document is modeled on recent national [12] and international [13] recommendations, particularly those that are strongly evidence-based [14], and emphasizes the trend toward risk stratification and the tighter control of blood pressure (BP) once management has been started.

Factors that influence blood pressure control are the treating general practitioner, drug therapy, patient lifestyle including diet, smoking, alcohol use, physical activity, ethnicity, socio-economic status, as well as underlying and related diseases [15]. These factors are all addressed in the Southern African Hypertension Society Guidelines. However, whether these guidelines are adopted and adhered to by general practitioners largely influences blood pressure control. Despite the importance of the role of the general practitioner in implementing the guidelines there is a paucity of research in South Africa. Results of a small study involving only 15 doctors and 10

nurses in the Western Cape suggested that the guidelines were consulted infrequently [16]. Various themes including involvement of doctors in the development of the guidelines; time constraints; health system problems; conflict with local practices; and patient beliefs were identified as barriers to implementation [16]. However the results of this small study conducted in the Western Cape may not reflect the attitudes of general practitioners from other regions of South Africa. Hence further studies are required.

Questions which need to be addressed include: “Are guidelines at all relevant when deciding on the treatment of a patient?” “Why do we need guidelines?” “Do general practitioners understand the concept of guidelines versus regulations?” “What really influences a general practitioner when he prescribes medication for the treatment of a disease, in this case uncomplicated hypertension?” These are just some of the questions on which this research report aims to shed some objective clarity.

Due to the fact that drug therapy is one of the most easily measured parameters in the Southern African Hypertension Society Treatment Guidelines, and the data on drug prescription habits of MediCross® was available for research purposes, this research project focused on only the drug therapy of hypertension. The guidelines suggest the following step wise approach to drug therapy (see Figure 1 below).

As a step towards answering the question of why BP is not controlled in such a large proportion of patients, the aim of this research study was to determine if South African general practitioners comply with the Southern African Hypertension Society Guideline, as published by the Southern African Hypertension Society and endorsed by the South African Medical Association Guideline Committee. The extent to which a general practitioner’s prescription habits may have been influenced by the Council for Medical Schemes algorithm and the prescribed minimum benefits offered to medical aid members was beyond the scope of this research report and hence was not addressed.

The **primary objective** of this research study was to determine if South African MediCross® general practitioners, that practice in urban areas are managing and treating patients with hypertension according to the Southern African Hypertension Society Guideline Step Wise Approach.

In an attempt to compare and assess the validity of the results of the primary analysis, the MediCross® prescription database was analysed to determine which drugs are most commonly prescribed for uncomplicated hypertension. Hence, my **secondary objective** was to identify the drug treatments (trade names) that are most commonly prescribed for the treatment of uncomplicated hypertension in MediCross® Clinics.

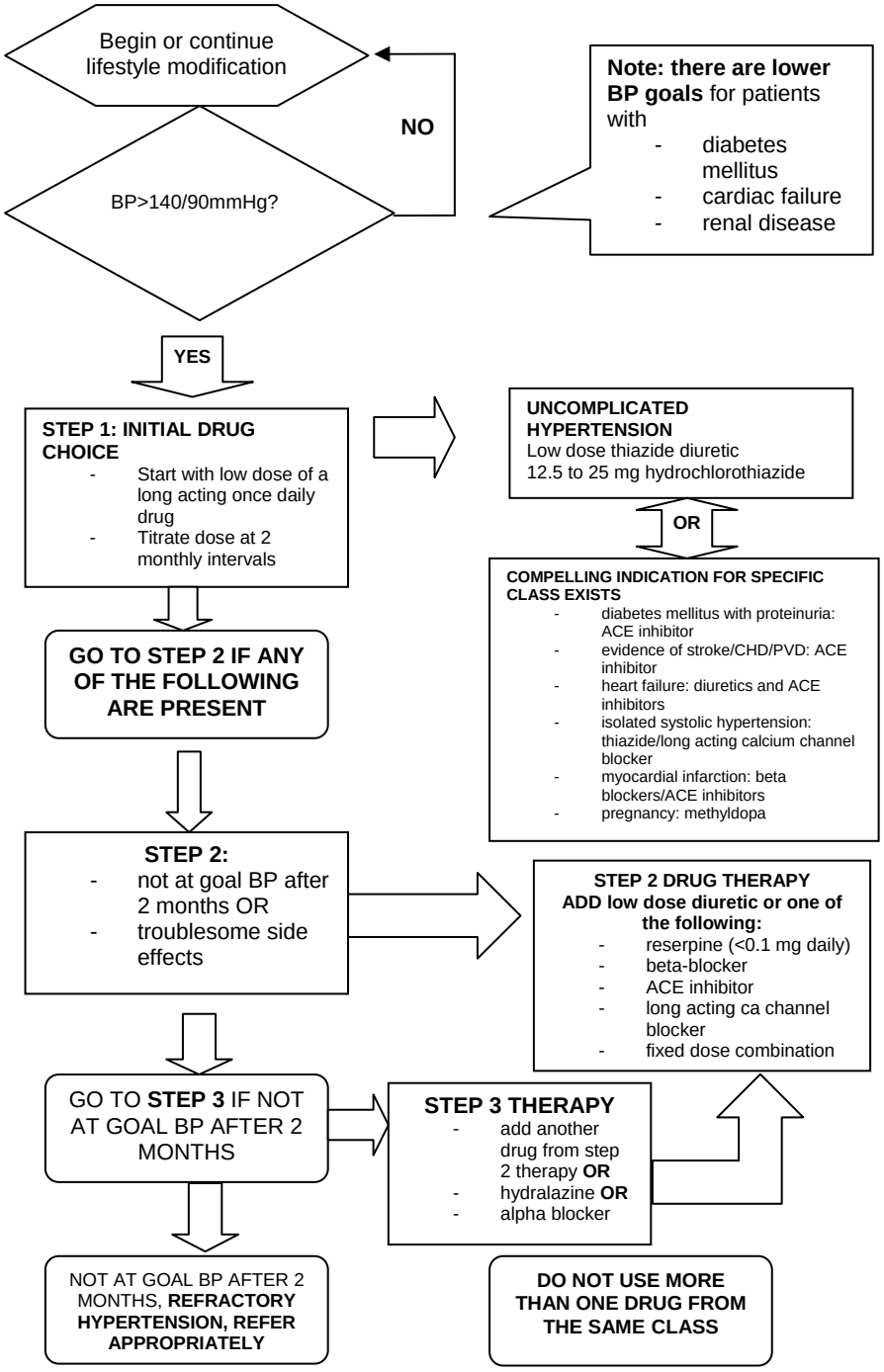


Figure 1: Southern African Hypertension Guidelines Hypertension Treatment Algorithm [17].

2. METHODOLOGY

Before commencement of the research study, the research proposal was submitted to the WITS Human Research Ethics Committee (HREC) for approval. The research study only commenced after favourable approval was obtained (Appendix I). Parallel to the Ethics Committee application, a submission was also made to the University of the Witwatersrand Post Graduate Committee for the conduct of this research study. The University Post Graduate Committee approved the proposal unconditionally (Appendix II).

2.1 Population

For the purposes of this research study, a population of general practitioners were needed that represented the 'average' general practitioners as most South Africans know them. The population of general practitioners had to be demographically representative of all major urban areas in South Africa and they had to be familiar and open to research and research questionnaires. MediCross®, with it's 49 clinics in towns and cities across South Africa (see appendix map – Appendix VII), and more than 300 general practitioners that practise free and independently, is the only private group that could offer such a large population that fit the above-mentioned criteria. With MediCross® being part of a Clinical Research Site Management Organisation, all MediCross® general practitioners have been introduced to research and are more open minded to supporting research and answering questionnaires. Furthermore, access was granted to data used for the purposes of the secondary objective of this research project and thus it would make scientific sense to try and investigate the same population as was used for the primary objective.

Data on the prescription habits of general practitioners, practising within the MediCross® Group across South Africa, were gathered with a questionnaire designed for the purpose of this research study (Appendix III). For this purpose, all of the general practitioners currently practising in the MediCross® Group across South Africa, were contacted, either via telephone or via telefax, and asked to complete the attached questionnaire.

As at 31 July 2003, there were 49 MediCross® Clinics across South Africa (Appendix V). Approximately 320 general practitioners from all 49 clinics were asked to complete the questionnaire. They were contacted telephonically or via telefax. A list with the names, addresses, telephone numbers, fax numbers and the general practitioners practising at each of the MediCross® Clinics, was obtained from Mr. Pieter Dorfling, a director of the MediCross® Group (Appendix V). He was informed of the intentions to contact all of the general practitioners and interview them. He made it clear that the general practitioners only have agreements with MediCross® and that they were not MediCross® employees, thus they are free to participate or not, whichever they were to choose. Mr. Dorfling was also informed of the intention to use data generated in the MediCross® Clinics for the secondary analysis. Rights to this data were sold to Hurricane Consulting®.

Mr. Van Zyl Kruger from Hurricane Consulting® was approached during the design of this research protocol and he agreed to share the data for the purposes mentioned above (secondary objective). Data provided by Hurricane Consulting®, were gathered

in the period from 01 November 2000 to 31 December 2003 by a data capturer at each MediCross® Clinic. Data captured included demographics, diseases treated and medications prescribed, all stratified by clinic. The database is totally anonymous (no patient or doctor identifiers) and is being managed and updated by Hurricane Consulting® for MediCross® as a marketing tool for the conduct of the feasibility of clinical trials in the MediCross® Clinics. With this database, MediCross® can easily inform potential clinical trial clients if they have patients that qualify for trials and what the geographical distribution of these patients are.

2.2 Primary Objective

The **primary objective** of this research study was to determine if South African general practitioners, that practice in urban areas are managing and treating patients with hypertension according to the Southern African Hypertension Society Guideline Step Wise Approach.

Interviewing of general practitioners, for purposes of the primary objective, commenced in August 2003. Initially, general practitioners were phoned and interviewed telephonically, but it was soon discovered that general practitioners were not interested in taking calls for this purpose. Furthermore, interviewing of more than 300 general practitioners telephonically, would take much longer than expected, due to the availability constraints of the general practitioners. Subsequently it was decided to send the one page questionnaire via fax to all 320 general practitioners with a cover page inviting them to participate in an anonymous questionnaire. They were asked to complete the questionnaire honestly and a return fax number was provided. By December 2003 all 320 general practitioners were contacted and a total of 81 general practitioners responded, either by agreeing to answer the questionnaire telephonically or by completing the faxed questionnaire and sending it back via fax.

In order to facilitate responder rate and make it easier to answer a simple questionnaire was constructed with only 12 questions. For ease of answering the general practitioners were requested to supply tradenames of medications.

2.3 Secondary Objective

The **secondary objective** was to identify the drug treatments (trade names) that are most commonly prescribed for the treatment of uncomplicated hypertension in MediCross® Clinics.

To answer the secondary objective, which was to determine which drugs were most frequently prescribed for the treatment of uncomplicated hypertension in the time period that the data was gathered (01 November 2000 to 31 December 2003), the MediCross® data base was used .

2.4 Data Analysis and Statistics

Once all the questionnaires had been completed and gathered, questionnaires were assigned identification numbers (1-81). Data from the 81 respondents were captured in a Microsoft Excel spreadsheet. Once captured, the Excel spreadsheet was validated

100%. Medications listed in question 2, 3 and 12 were post-coded using the South African Medicines Formulary (SAMF) coding system. [36]

Because of the geographical distribution of MediCross® clinics in South Africa (Appendix VII), an assumption was made that the MediCross® medical practitioners are representative of medical practitioners in South Africa that practice in urban areas.

The null hypothesis (H_o) is defined as: medical practitioners in South Africa **follow** the Southern African Hypertension Society Guideline in the prescription of hypertensive drug treatments for patients suffering from uncomplicated hypertension.

The alternate hypothesis (H_a) is defined as: medical practitioners in South Africa **do not follow** the Southern African Hypertension Society Guideline in the prescription of hypertensive drug treatments for patients suffering from uncomplicated hypertension.

Data analysis and graphic presentation of data were performed using SAS® version 8.2. (analysis) and MS Excel® (data capturing, coding and graphs).

2.4.1 For the Primary Objective:

Data gathered from the questionnaires were analysed as follows: frequency tables were drawn up for each categorical question, in order to look at the data in a descriptive manner. Coding was performed (using the SAMF coding system), on data gathered from questions 2, 3 and 12, once all the questionnaires were completed and data entered into Excel®.

To evaluate the primary objective, data were analysed in the following way:

- For all questionnaires with "YES" answered in Q1 (i.e. Yes, I treat Hypertensive patients), a frequency table was drawn up for all Q2 answers and for all Q3 answers separately (i.e. the general practitioner is prescribing the correct medication); Q2 and Q3 evaluated how compliant the general practitioner was to the SAHS Hypertension Treatment Guidelines.
- A comparative analysis was performed for the 2x1 table frequencies of Q2 and Q3 separately, in order to evaluate whether there was a statistical significant difference between the reported compliance percentage of the general practitioner to the SAHS Hypertension Treatment Guidelines compared to 100% compliance, as specified by these guidelines. The comparison between these percentages (or proportions) was performed using the following methods (H_0: $p_1 = p_2$ and H_A: $p_1 \neq p_2$):

    1. A 95% confidence interval (CI) was calculated for the reported "YES" proportion and a 95% CI for the 100% proportion – if these CI's overlapped, there was no statistical difference between these 2 proportions;
    2. A 95% CI was calculated for the difference between the 2 proportions as specified in (1) above – if 0 was included in the interval, then there is no statistical significant difference between these 2 proportions;
    3. Additionally, a Z-statistic was used, to evaluate whether there was a statistical significant difference between these 2 proportions.

A p-value of 0.05 was considered to be statistically significant; all statistical tests were 2-tailed; 95% confidence intervals were calculated, where applicable.

It is important to note the following:

1. For the purposes of the above calculations, the ideal of 100% compliance should be used. However the Z-statistic calculation is not possible with a value of 100%. Hence a value as close to 100% as possible was used in each case. In other words an ideal percentage based on one value smaller than (<) the total was used (e.g. 99.2% for Q2 and 99.3% for Q3).

2. The primary objective contain data of 81 respondents and is regarded pilot in nature, since no formal sample size calculation was performed.

The evaluation of Q7 was used to cross-check whether the general practitioner was actually compliant with the guidelines, from his/her point of view.

Q1 determined the population of general practitioners that treated patients with uncomplicated hypertension. As mentioned above, Q2 and Q3 evaluated how compliant the general practitioner was to the SAHS Hypertension Treatment Guidelines. Q12 provided a calculated estimate of which drug general practitioners thought they most frequently prescribed for uncontrolled hypertension. This was used for a comparison with results from the secondary analysis. An investigation into the possible problems and helpful suggestions were made by looking at the results of Q4, 5, 6, 8, 9, 10, 11 and 13.

2.4.2 For the Secondary Objective:
Data from the MediCross® Database, as described above, were investigated and all hypertensive drug classes with their frequencies listed, in order to determine which drugs were most frequently prescribed for hypertension (regardless of whether hypertension was complicated or uncomplicated).

Data were presented graphically, using histograms.

3. RESULTS

Eighty one (81) MediCross® general practitioners/ radiologists out of a possible 320 names responded. Seventy nine (79) were general practitioners and 2 were radiologists, hence giving a response rate of 24.7%.

As the questionnaires were completed anonymously I do not have demographic data (gender, race) of the general practitioners that responded. However from the facsimile numbers it was apparent that they were fairly wide spread across urban areas of South Africa.

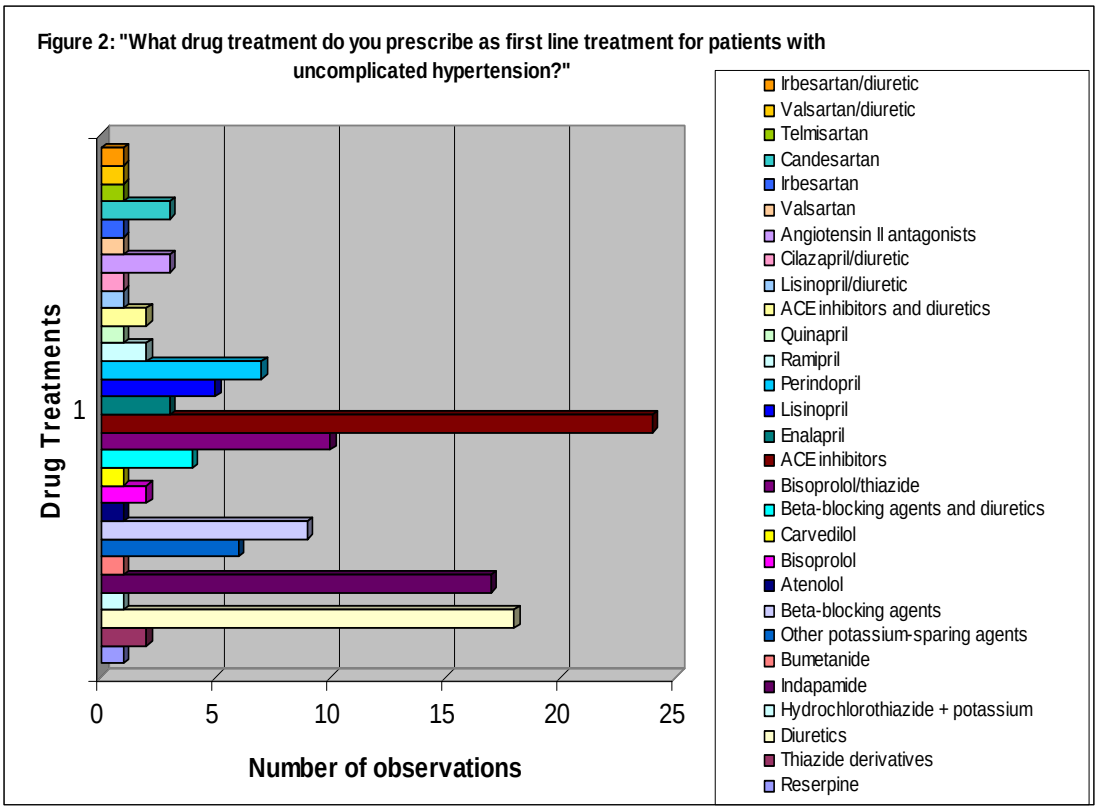
3.1 Results of the Primary Analysis:

In response to the question "*Do you treat patients with uncomplicated hypertension?"* 97.5% of the doctor's said (yes) they did treat patients with uncomplicated hypertension.

Table 1: Do you treat patients with uncomplicated hypertension?

	Number of observations (n)	Percentage of total (%)
Yes	79	97.5
No	2	2.5
Total	81	100.0

In response to the question "*What drug treatment do you prescribe as, first line treatment for patients with uncomplicated hypertension?*", more doctors (18.5%) prescribed ACE inhibitors, with diuretics (13.8%) and indapamide (13.1%) being the next most popular drugs, respectively.



In order to determine whether doctors adhered to the guidelines for the prescribing of first-line drug therapy, two definitions of adherence were used. The more conservative definition allowed for no interpretation of the guidelines for first line treatment and literally only allowed for hydrochlorothiazide and potassium (low-dose thiazide diuretic). The less conservative definition allowed for more than one interpretation of first-line treatment and allowed for "thiazide-like" diuretics, hydrochlorothiazide and potassium, indapamide, bumetanide and other potassium-sparing agents. Table 2 below shows the medication prescribed as first line therapy and whether they adhere to the guidelines according to these two definitions.

Table 2: "What drug treatment do you prescribe as first line treatment for patients with uncomplicated hypertention?"

Drug treatment code	Drug treatment name	Number of observations (n)	Adherent (Yes/No) according to more conservative definition	Adherent (Yes/No) according to less conservative definition
C02AA02	Reserpine	1	No	No
C02DA	Thiazide derivatives	2	No	No
C03	Diuretics	18	No	Yes
C03AB03	Hydrochlorothiazide + potassium	1	Yes	Yes
C03BA11	Indapamide	17	No	Yes
C03CA02	Bumetanide	1	No	Yes
C03DB	Other potassium-sparing agents	6	No	Yes
C07A	Beta-blocking agents	9	No	No
C07AB03	Atenolol	1	No	No
C07AB07	Bisoprolol	2	No	No
C07AG02	Carvedilol	1	No	No
C07B	Beta-blocking agents and diuretics	4	No	No
C07BB07	Bisoprolol/thiazide	10	No	No
C09A	ACE inhibitors	24	No	No
C09AA02	Enalapril	3	No	No
C09AA03	Lisinopril	5	No	No
C09AA04	Perindopril	7	No	No
C09AA05	Ramipril	2	No	No
C09AA06	Quinapril	1	No	No
C09BA	ACE inhibitors and diuretics	2	No	No
C09BA03	Lisinopril/diuretic	1	No	No
C09BA08	Cilazapril/diuretic	1	No	No
C09C	Angiotensin II antagonists	3	No	No
C09CA03	Valsartan	1	No	No
C09CA04	Irbesartan	1	No	No
C09CA06	Candesartan	3	No	No
C09CA07	Telmisartan	1	No	No
C09DA03	Valsartan/diuretic	1	No	No
C09DA04	Irbesartan/diuretic	1	No	No
Total		130 *		

* Note: This value is greater than (>) the total number of 79 who responded to Q2 because more than 1 drug treatment, per general practitioner, was indicated in certain cases; all drug treatments were included in the analysis

a) Adherence using the more conservative definition (first line treatment)

Proportion adherent: p_1 = 1/130 = 0.8% compared to ideal p_2 = 129/130 = 99.2%

i) 95% confidence interval (95% CI) for p_1 and p_2 individually:
95% CI for p_1 = 0.8% = [0.0; 2.27%];
95% CI for p_2 = 99.2% = [97.73; 100.00%]

Since these two 95% CI's do not overlap, there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

ii) 95% CI for difference between p_1 and p_2:
95% CI for p_2-p_1 = [96.34; 100.00%]

Since 0 is not included in this 95% CI, one can conclude that there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

iii) Hypothesis test: Z-statistic = 15.88; p-value = < 0.0001

This hypothesis test concludes that there is a significant statistical difference between the 2 proportions compared, namely: 1/130 = 0.8% versus 129/130 = 99.2%: p_2 is significantly larger than p_1 (a p-value < 0.05 is regarded as being statistically significant).

b) Adherence using the less conservative definition (first line treatment)

Proportion adherent: p_1 = 43/130 = 33.1% compared to p_2 = 129/130 = 99.2%

i) 95% confidence interval (95% CI) for p_1 and p_2 individually:
95% CI for p_1 = 33.1% = [24.99; 41.16%];
95% CI for p_2 = 99.2% = [97.73; 100.00%]

Since these two 95% CI's do not overlap, there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

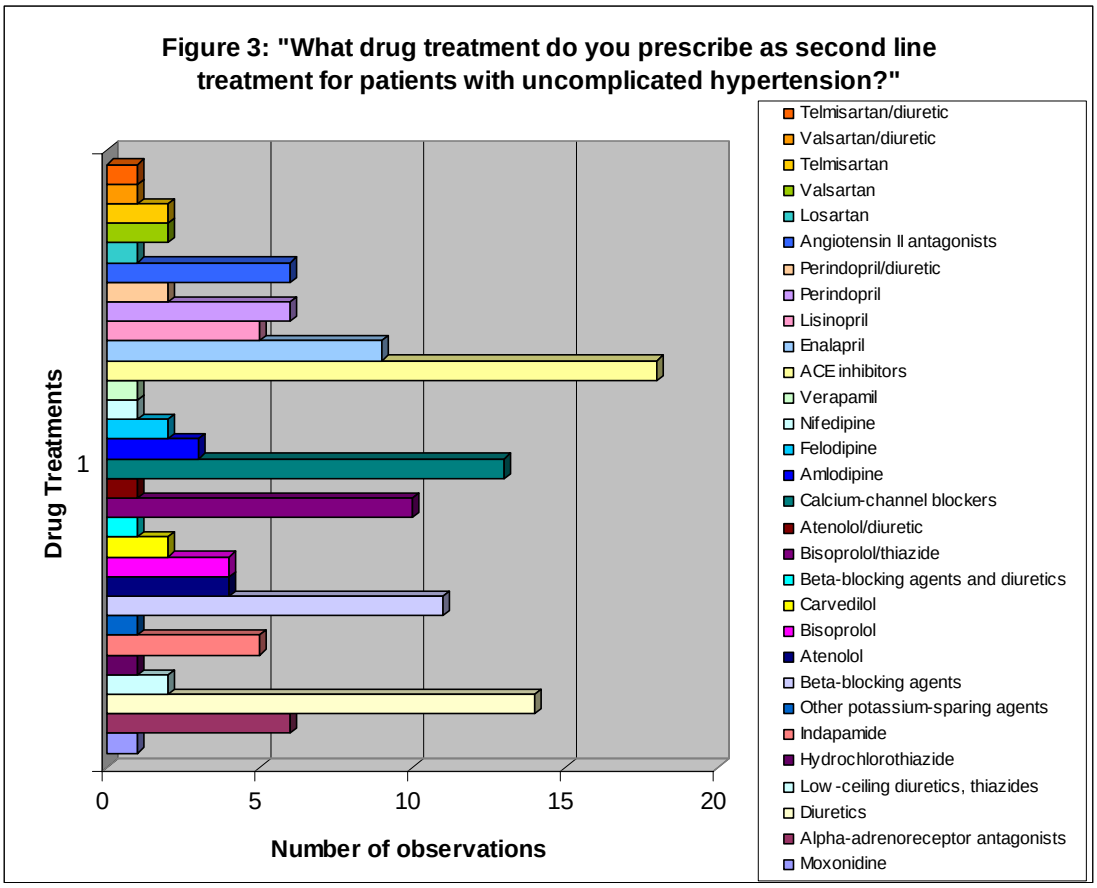
ii) 95% CI for difference between p_1 and p_2:
95% CI for p_2-p_1 = [57.93; 74.38%]

Since 0 is not included in this 95% CI, one can conclude that there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

iii) Hypothesis test: Z-statistic = 11.27; p-value = < 0.0001

This hypothesis test concludes that there is a significant statistical difference between the 2 proportions compared, namely: 43/130 = 33.1% versus 129/130 = 99.2%: p_2 is significantly larger than p_1 (a p-value < 0.05 is regarded as being statistically significant).

In response to the question "*What drug treatment do you prescribe as second line treatment for patients with uncomplicated hypertension?*" most general practitioners (13.2%) prescribed ACE inhibitors, with diuretics (10.3%) and calcium-channel blockers (9.6%) being the next most popular drugs respectively.



In order to determine whether doctors adhered to the guidelines for the prescribing of second-line drug therapy, the two definitions of adherence were used again. The more conservative definition allowed for the more conservative interpretation in first-line prescribing and no subsequent interpretation of the guidelines for second line treatment, in other words only drugs that are listed in the step-wise approach in the guidelines. This literally only allowed for low-ceiling diuretics (thiazides), hydrochlorothiazide and potassium (low-dose thiazide diuretic), reserpine, beta-blocking agents, ACE-inhibitors, and long acting calcium channel blockers. The less conservative definition, again, allowed for more than one interpretation of second-line treatment and hence allowed for any diuretics, hydrochlorothiazide and potassium (thiazide diuretic), reserpine, beta-blocking agents, ACE-inhibitors, any calcium channel blockers or any fixed dose combinations. Table 3 below shows the medication prescribed as second line therapy and whether they adhere to the guidelines according to these two definitions.

Table 3: "What drug treatment do you prescribe as second line treatment for patients with uncomplicated hypertention?"

Drug treatment code	Drug treatment name	Number of observations (n)	Adherent (Yes/No) according to more conservative definition	Adherent (Yes/No) according to less conservative definition
C02AC05	Moxonidine	1	No	No
C02CA	Alpha-adrenoreceptor antagonists	6	No	No
C03	Diuretics	14	No	Yes
C03A	Low-ceiling diuretics, thiazides	2	Yes	Yes
C03AA03	Hydrochlorothiazide	1	Yes	Yes
C03BA11	Indapamide	5	Yes	Yes
C03DB	Other potassium-sparing agents	1	No	Yes
C07A	Beta-blocking agents	11	Yes	Yes
C07AB03	Atenolol	4	Yes	Yes
C07AB07	Bisoprolol	4	Yes	Yes
C07AG02	Carvedilol	2	Yes	Yes
C07B	Beta-blocking agents and diuretics	1	Yes	Yes
C07BB07	Bisoprolol/thiazide	10	Yes	Yes
C07CB03	Atenolol/diuretic	1	Yes	Yes
C08	Calcium-channel blockers	13	Yes	Yes
C08CA01	Amlodipine	3	Yes	Yes
C08CA02	Felodipine	2	Yes	Yes
C08CA05	Nifedipine	1	Yes	Yes
C08DA01	Verapamil	1	Yes	Yes
C09A	ACE inhibitors	18	No	No
C09AA02	Enalapril	9	Yes	Yes
C09AA03	Lisinopril	5	Yes	Yes
C09AA04	Perindopril	6	Yes	Yes
C09BA04	Perindopril/diuretic	2	No	No
C09C	Angiotensin II antagonists	6	No	No
C09CA01	Losartan	1	No	No
C09CA03	Valsartan	2	No	No
C09CA07	Telmisartan	2	No	No
C09DA03	Valsartan/diuretic	1	No	No
C09DA07	Telmisartan/diuretic	1	No	No
Total		136 *		

* Note: This value is greater than (>) the total number of 79 who responded to Q3 because more than 1 drug treatment, per general practitioner, was indicated in certain cases; all drug treatments were included in the analysis

a) Adherence using the more conservative definition (second line treatment)

Proportion adherent: p_1 = 81/136 = 59.6% compared to ideal p_2 = 135/136 = 99.3%

i) 95% confidence interval (95% CI) for p_1 and p_2 individually:
95% CI for p_1 = 59.6% = [51.31; 67.81%];
95% CI for p_2 = 99.3% = [97.83; 100.00%]

Since these two 95% CI's do not overlap, there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

ii) 95% CI for difference between p_1 and p_2:
95% CI for p_2-p_1 = [31.33; 48.08%]

Since 0 is not included in this 95% CI, one can conclude that there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

iii) Hypothesis test: Z-statistic = 8.10; p-value = < 0.0001

This hypothesis test concludes that there is a significant statistical difference between the 2 proportions compared, namely: 81/136 = 59.6% versus 135/136 = 99.3%: p_2 is significantly larger than p_1 (a p-value < 0.05 is regarded as being statistically significant).

b) Adherence using the less conservative definition (second line treatment)

Proportion adherent: p_1 = 96/136 = 70.6% compared to ideal p_2 = 135/136 = 99.3%

i) 95% confidence interval (95% CI) for p_1 and p_2 individually:
95% CI for p_1 = 70.6 % = [62.93; 78.25%];
95% CI for p_2 = 99.3% = [97.83; 100.00%]

Since these two 95% CI's do not overlap, there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

ii) 95% CI for difference between p_1 and p_2:
95% CI for p_2-p_1 = [20.89; 36.47%]

Since 0 is not included in this 95% CI, one can conclude that there is a statistical significant difference between these 2 proportions: p_2 is significantly larger than p_1.

iii) Hypothesis test: Z-statistic = 6.61; p-value = < 0.0001

This hypothesis test concludes that there is a significant statistical difference between the 2 proportions compared, namely: 96/136 = 70.6% versus 135/136 = 99.3%: p_2 is significantly larger than p_1 (a p-value < 0.05 is regarded as being statistically significant).

With respect to the question ”*What should the blood pressure of a hypertensive patient ideally drop to?*”, 2 general practitioners chose not to complete this question. The data obtained from the remaining 77 general practitioners is represented in table 4 below.

Table 4: “What should the blood pressure of a hypertensive patient ideally drop to?”

Descriptive statistics	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
n	77	77
Mean	130.25	83.27
Median	130.00	83.00
Standard Deviation	8.99	5.04
Minimum	100.00	70.00
Maximum	145.00	90.00

Sixty (60) (**78%**) general practitioners responded that they have heard of the SAHS guidelines; of those 60 only 21 (35% of those who have heard and **27%** of the total) admitted to having a hard copy of these guidelines. Whereas when these 60 were asked if they followed the SAHS guidelines, 30 (50% of those who have heard and **39%** of the total) said that they did.

Figure 4a: Pie chart indicating physicians that have heard of the guidelines and physicians that have never heard of the guidelines, with a breakdown of physicians with and without hardcopies

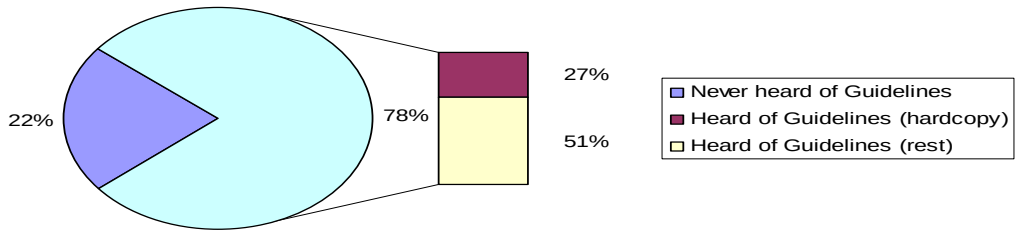
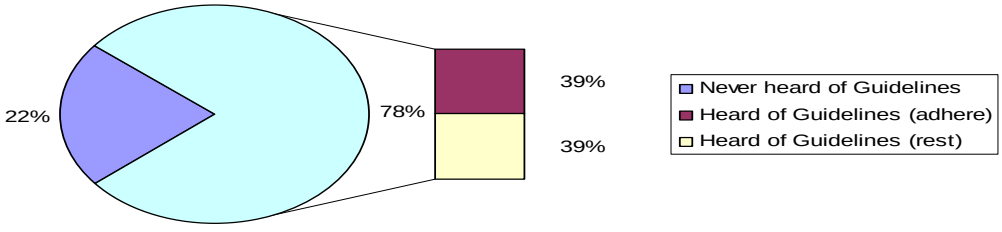


Figure 4b: Pie chart indicating physicians that have heard of the guidelines and physicians that have never heard of the guidelines, with a breakdown of physicians that do and do not adhere to the guidelines

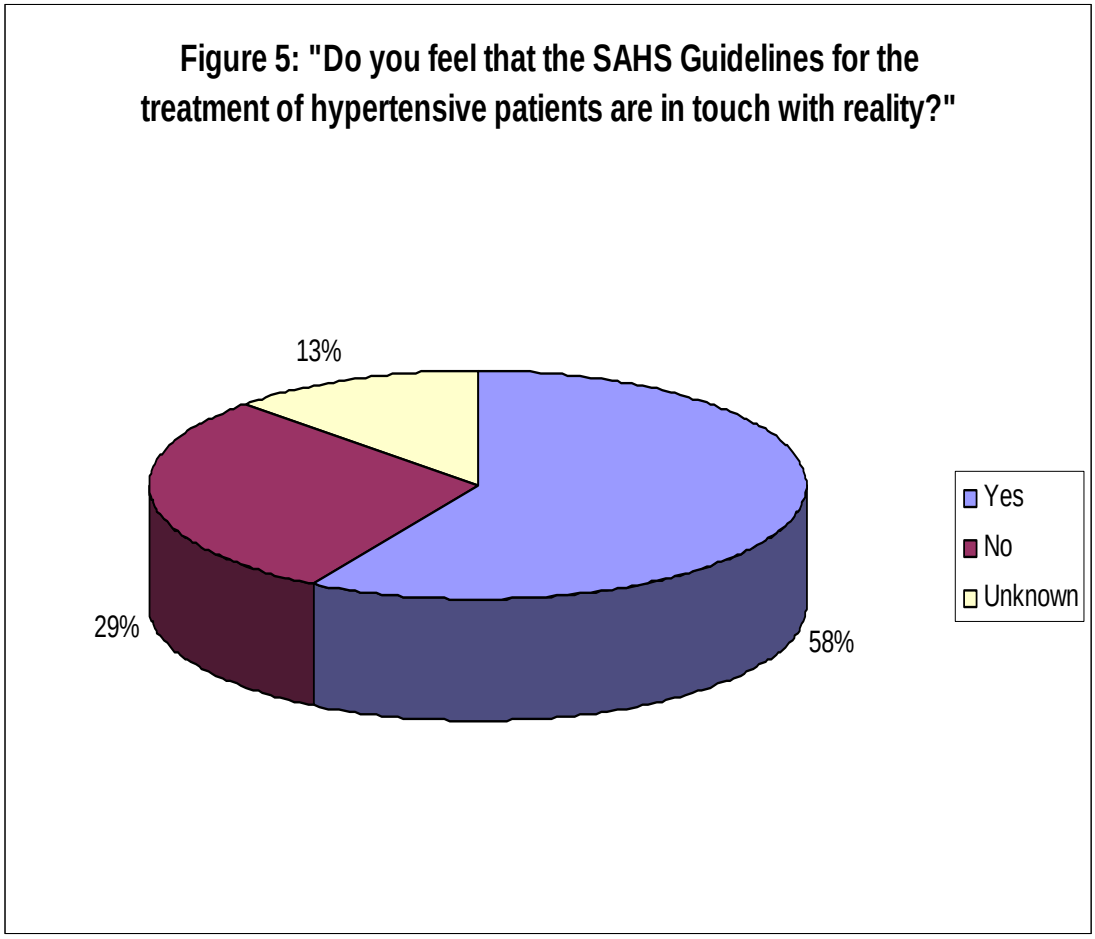


When asked why the general practitioners did not adhere to the guidelines the following responses were obtained.

Table 5: "If NO, why not?" (Responses to this question included the following categories)

Category:	Number of responses in this category:
Did not know about or did not have the guidelines	16 (41.0%)
Preferred using the JNC guidelines	4 (10.3%)
Preferred to treat each patient individually or as a unique individual	11 (28.2%)
Had no specific reason	2 (5.1%)
Preferred their own logic	1 (2.6%)
Patients could afford it they preferred starting off (first-line) with the most effective treatment	1 (2.6%)
No handy references available	3 (7.7%)
Too many guidelines	1 (2.6%)
Total:	39

When asked if the general practitioners thought that the guidelines were in touch with reality (or practical and implementable), 42 (54.54%) general practitioners felt that the SAHS guidelines are in touch with reality. Some of the general practitioners responded unknown (see pie chart below).



When asked why the general practitioners thought that the guidelines were not in touch with reality, the following responses were obtained.

Table 6: "If not, why?" (Responses to this question included the following categories)

Category:	Number of responses in this category:
Preferred not to start patients on a diuretic	1 (4.2%)
Guidelines do not take different populations into account	4 (16.7%)
Guidelines are not aggressive enough in treatment	4 (16.7%)
Guidelines do not take all factors into consideration	4 (16.7%)
Not effective for patients in an uncontrolled environment	1 (4.2%)
Guidelines are geared towards an academic environment and not private practice	4 (16.7%)
Guidelines do not take into consideration the side effects of the drugs	2 (8.3%)
Guidelines are too time consuming	4 (16.7%)
Total:	24

The general practitioners were asked for suggestions on how to make the guidelines more useful. These are their suggestions.

Table 7: "Can you make any suggestions to make the guidelines more practical and implementable?" (Responses to this question included the following categories)

Category:	Number of responses in this category:
Guidelines should consider more modern drugs and not ignore them just because of cost	4 (16%)
Guidelines should consider more drugs that prevent cardiac heart failure	1 (4%)
More input from general practitioners should be obtained and not specialist general practitioners	3 (12%)
Guidelines should consider factors such as compliance, cost, side-effects	4 (16%)
More emphasis should be placed on follow-up	1 (4%)
Guidelines should be more in line with JNC VII	3 (12%)
Medical aids and payment of drugs via medical aids should be considered in guidelines	3 (12%)
More should be done to make the guidelines public and known	4 (16%)
Guidelines should be distributed as handy pocket guides, desk pads, etc	2 (8%)
Total:	25

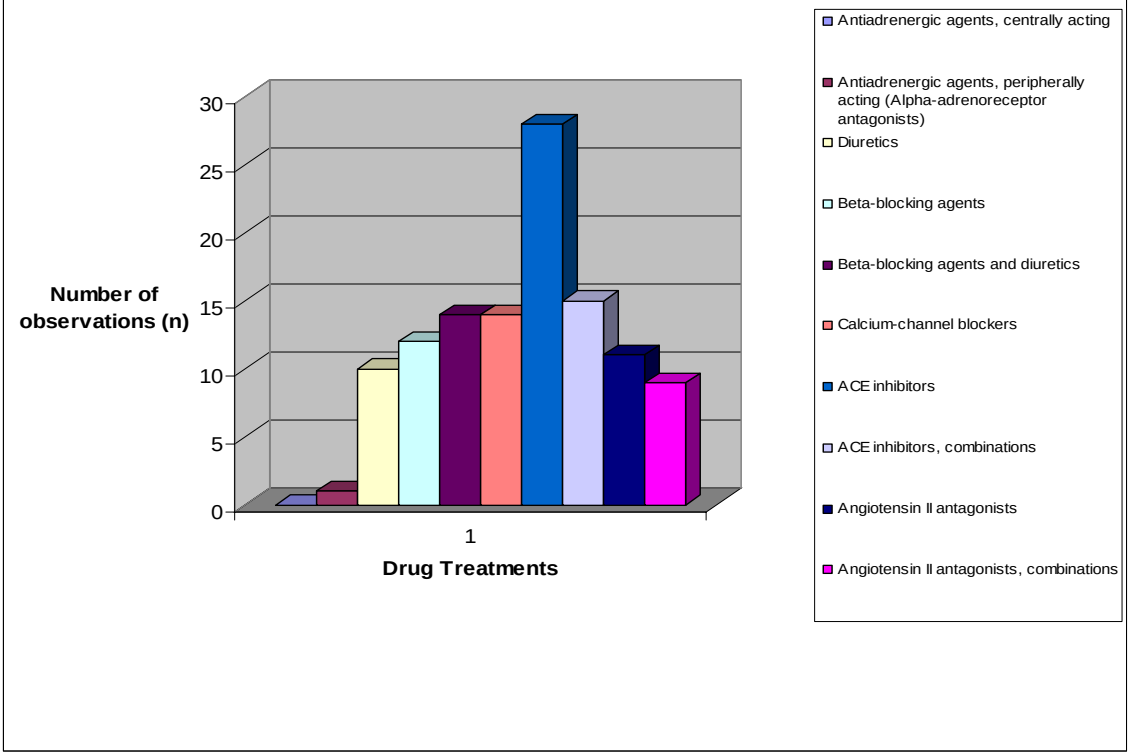
The table below indicates the drugs which the general practitioners estimated that they prescribed most frequently irrespective of whether for 1st or 2nd line therapy. As can be clearly seen from the histogram below, the general practitioners estimated that they most frequently prescribed the ACE inhibitor group (24.56%) with the next most frequent being the ACE inhibitor combinations (13.16%). These were closely followed by Calcium Channel Blockers (12.28%) and Beta-blocking agents in combination with diuretics (12.28%). If, however, the ACE inhibitors, whether in

combination or not, is collapsed into one group (37.72%), it is clear that these were the most popular drug class for uncontrolled hypertension by a margin. If the same is done for the other classes, it is clear that the Beta-blocking agents (22.81%) were the second most popular group of drugs.

Table 8: "Give an estimate of what drug you most frequently prescribe for uncontrolled hypertension?"

Drug treatment code	Drug treatment name	Number of observations (n)	Percentage (%)
C02A	Antiadrenergic agents, centrally acting	0	0
C02C	Antiadrenergic agents, peripherally acting (Alpha-adrenoreceptor antagonists)	1	0.88
C03	Diuretics	10	8.77
C07A	Beta-blocking agents	12	10.53
C07B	Beta-blocking agents, combinations	14	12.28
C08	Calcium-channel blockers	14	12.28
C09A	ACE inhibitors	28	24.56
C09B	ACE inhibitors, combinations	15	13.16
C09C	Angiotensin II antagonists	11	9.65
C09D	Angiotensin II antagonists, combinations	9	7.89
	Total	114	100

Figure 6: "Give an estimate of what drug you most frequently prescribe for uncontrolled hypertension."



When asked for any additional comments, the following responses were obtained.

Table 9: "Additional comments" (Responses to this question included the following categories)

Category:	Number of responses in this category:
The guidelines are pointless as treatment is now totally dictated by our medical aids	4 (16%)
I need a copy of the SAHS Treatment Guidelines	3 (12%)
I would like a copy of the results of this study	2 (8%)
Important to remember that guidelines should only guide and not dictate	3 (12%)
There are too many guidelines for doctors to adhere to	3 (12%)
I find the guidelines positive and helpful	6 (24%)
I find the guidelines a waste of my time	4 (16%)
Total:	25

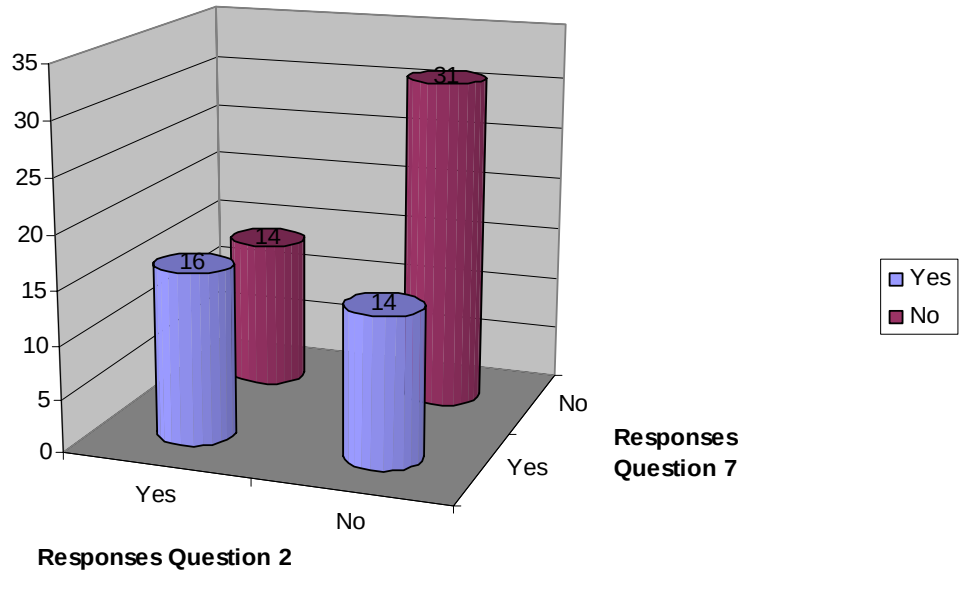
In order to determine who was adhering to the guidelines as opposed to who thought they were adhering to the guidelines (with respect to first-line therapy), responses to Q2 were compared to responses to Q7. Q2 was coded as "yes" if the drug that the general practitioner prescribed was according to the guidelines using the less conservative approach.

Table 10: Comparison of Q7 vs Q2:

Q2/Q7	Yes	No
Yes	16	14
No	14	31

Missing: 2xNo (2 respondents had missing results for Q2)

Figure 7: Comparison of Question 2 vs Question 7

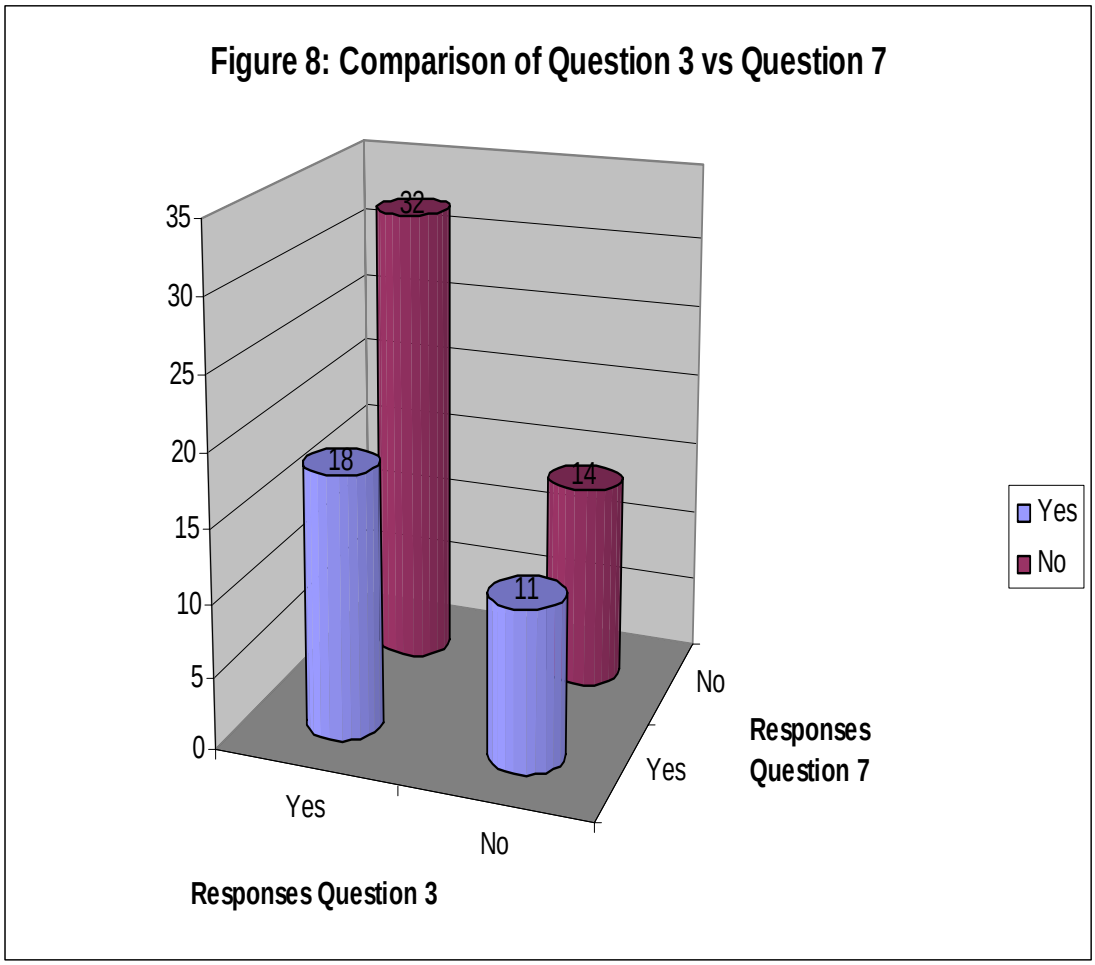


In order to determine who was adhering to the guidelines as opposed to who thought they were adhering to the guidelines (with respect to second-line therapy), responses to Q3 were compared to responses to Q7. Q3 was coded as "yes" if the drug that the general practitioners prescribed was according to the guidelines using the less conservative approach.

Table 11: Comparison of Q7 vs Q3:

Q3/Q7	Yes	No
Yes	18	32
No	11	14

Missing: 1xYes, 1xNo (2 respondents had missing results for Q3)



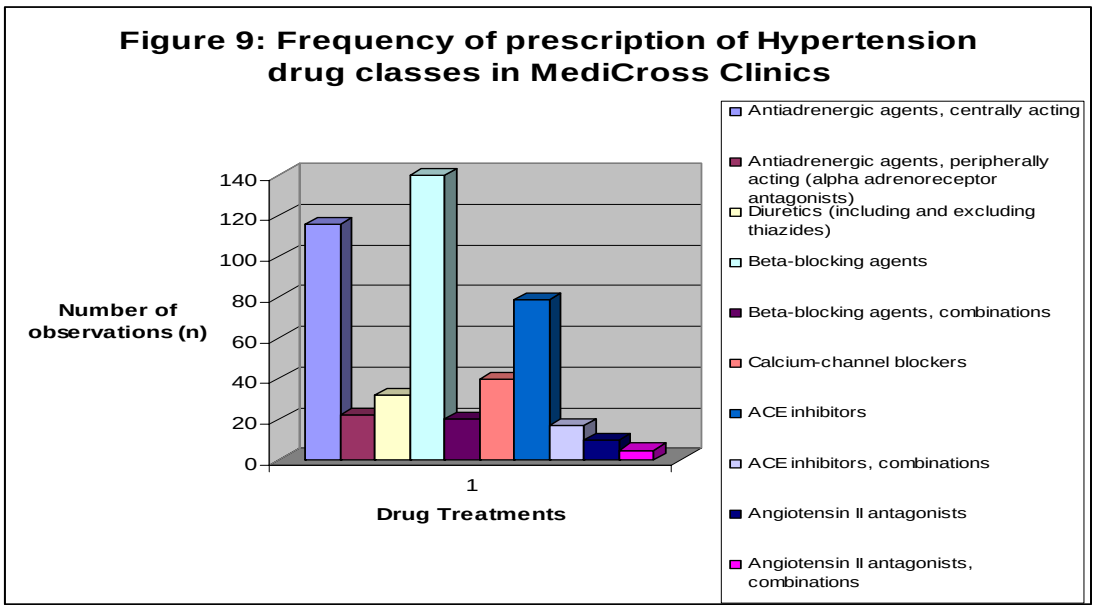
3.2 Results of the Secondary Analysis:

Table 12: Frequency of prescription of Hypertension drug classes in MediCross® Clinics

Drug class (SAMF drug treatment code and grouping – see table 8)	Number of observations (n)	Percentage (%)
Antiadrenergic agents, centrally acting	116	24.12
Antiadrenergic agents, peripherally acting (alpha adrenoreceptor antagonists)	22	4.57
Diuretics (including and excluding thiazides)	32	6.65
Beta-blocking agents	140	29.11
Beta-blocking agents, combinations	20	4.16
Calcium-channel blockers	40	8.32
ACE inhibitors	79	16.42
ACE inhibitors, combinations	17	3.53
Angiotensin II antagonists	10	2.08
Angiotensin II antagonists, combinations	5	1.04
Total	481	100.00

The above table was only discussed descriptively and no formal comparisons were made. Data from the MediCross® database was grouped according to the SAMF drug class system, in the same classes as Table 8.

According to the MediCross® database the most frequently described drugs appeared to be the Beta-blocking agents (29.11%), followed by the centrally acting Antiadrenergic agents (24.12%) and the ACE inhibitors. If the Beta-blocking agents and ACE inhibitors, whether in combination or not, are collapsed, this order stays the same with the Beta-blocking agents at 33.27% and the ACE inhibitors at 19.95%. This is not in line with the frequency of the most prescribed drugs from question 2 and 3, which were ACE inhibitors (although ACE inhibitors were frequent in the MediCross® dataset at 19.95%). This also appears to be different from the drugs thought to be most frequently prescribed by general practitioners in question 12, which was also found to be the ACE inhibitors.



4. DISCUSSION

4.1 Introduction

The null hypothesis (H_o) for this research report was defined as: medical practitioners in South Africa **follow** the Southern African Hypertension Society Guideline in the prescription of hypertensive drug treatments for patients suffering from uncomplicated hypertension.

The alternate hypothesis (H_a) was defined as: medical practitioners in South Africa **do not follow** the Southern African Hypertension Society Guideline in the prescription of hypertensive drug treatments for patients suffering from uncomplicated hypertension.

The study shows that, even with a less conservative approach (of the definition of diuretics is used) to the Southern African Hypertension Society Guidelines, general medical practitioners from urban areas of South Africa do not follow the guidelines for the prescription of antihypertensive medication. Furthermore, it was also shown that the group of general practitioners that did not comply was substantially larger than the group who did comply. The statistical analyses that were performed, shows that there is a statistically significant difference between the two groups. The study also shows that although some general practitioners are under the impression that they are complying with the guidelines, they are in fact not.

The secondary analysis showed that Beta-blocking agents are the most frequently prescribed drugs for the treatment of uncomplicated hypertension in MediCross® Clinics in South Africa; this was not in line with the findings of the primary analysis questionnaire on the most frequently prescribed medication for uncomplicated hypertension in South Africa, whether it be first or second line.

With a response rate of 81 out of a possible 320, it was clear that this could only be regarded as a **pilot study** (25.3%). 79 general practitioners (97.5% of responders) indicated that they did treat patients with uncomplicated hypertension and 2 general practitioners (2.5% of responders) indicated that they did not treat patients with uncomplicated hypertension (Table 1) as they were radiologists with the MediCross® Group. In other words 100% of general practitioners did treat patients with uncomplicated hypertension, which could be expected.

4.2 Discussion on Choice of MediCross® General Practitioners

From the start, the questions arose; “would MediCross® general practitioners be representative of the general practitioner in South Africa?”, “can an assumption be made that MediCross® doctors are a nationally representative?”. Some would say that they are limited by corporate guidelines, strategies and costs of bulk buying in what they are allowed to prescribe. Others would argue that, although there might be limited truth to this, it does or should not impact on the general practitioners choice of therapeutic drug class since they have an ethical obligation to prescribe what is scientifically required. A further argument, could be that the capitation model of healthcare provision under which MediCross® operates, could influence the choices of drugs prescribed. To try and put all of these questions, arguments and possible assumptions into perspective, one has to take a closer look at the company.

MediCross® was formed in 1992. Today it is a managed healthcare provider network of 49 Family and Dental Centres, and other healthcare service providers, located in most urban areas within each of the provinces of South Africa (Appendix VII) [33]. Nevertheless there is a greater representation in the Gauteng region with 23 of the 49 being located in this area. With respect to the respondents in my study, they were distributed fairly evenly across the urban areas of South Africa.

It has grown to a point where it now has more than 320 doctors and 150 dentists practising at its facilities and handles in excess of 275,000 patients a month. For the purposes of this study, there was only an attempt to contact the doctors [34].

MediCross® is a Network Healthcare Holdings Limited Group Company, which was purchased in October 2002. Netcare® currently owns 80% of MediCross®, with the balance being held by NetPartner Investments [34]. A more indepth view of the company and its policies requires an in depth view of the company profile. In the interests of accuracy and to avoid possible misrepresentation (should I misinterpret a company policy in the translation into my own words) as to what this company stands for I chose to directly quote sections out of the Corporate Profile of MediCross®. As per University regulations these quotes have been identified by " " and are written in italics. Furthermore, these sections, as obtained from the MediCross® website, have been reproduced with the permission of MediCross® (see Appendix VI).

A Corporate Profile of MediCross® informs us that *"MediCross® is a managed healthcare provider network traditionally servicing the Fee-For-Service medical aid and private primary healthcare market. More recently MediCross® has expanded the parameters of its operation, utilising its expertise in the fields of Practise Management and Managed Healthcare. The MediCross® Family Medical and Dental Centres offers its patients the benefits of convenience, top quality healthcare and affordability. Strong emphasis is placed on personal attention and a holistic approach to family healthcare. MediCross® is dedicated to serving the needs of the entire family, and as such the medical facilities are designed to cater for patients of all ages- from infants through to the elderly."* [34]

"With a current shareholding of 80% owned by Network Healthcare Holdings Limited (The Netcare® Group) and the remaining 20% being held by Netpartner Investments Limited, the MediCross® Healthcare Group has experienced substantial growth and penetration in both the fee-for-service and managed healthcare arenas. Established in 1992 and born out of the belief that accessible, effective healthcare should be available to everyone at a price they can afford and without compromising the quality of service or overall treatment outcome, MediCross® has cemented it's position as a formidable player in the primary healthcare provider market. This internationally accredited network affords the patient, funder and provider the opportunity of being exposed to internationally recognised standards of patient care, health and safety regulations, and facility management that guarantee the delivery of a superior healthcare product." [34]

For the purposes of this study, it has to be taken into account that the Netcare® Group (including MediCross®), derives a large proportion of its income from pharmacies and the sale of drugs. This immediately raises the question: "Is it possible that there are formularies which may limit the drug choice not only overall but also within

medical aid plans to which the patient belongs? How does this impact on the care given?" Thus the question of pharmacy ownership also needs to be addressed. These questions are addressed below.

"The 320 General Practitioners and 150 Dental Practitioners that currently practice within the existing MediCross® Family Medical and Dental Centres ***are not employed by MediCross®****, but rather comply to a contractual relationship and therefore maintain their professional independence, autonomy and integrity. These practitioners are supported within the facilities by teams of Physiotherapists, Dieticians and Psychologists, with another 150 medical specialists consulting at the various Centres on a permanent or part-time basis."* [34]

This is a very important fact for the purposes of this study and must be considered in further assumptions.

"The MediCross® system holds certain benefits for both patients as well as providers. Patients are assured of quality medical care through practitioner credentialing and selection, as well as employing a variety of unique tools and controls to ensure the delivery of consistent quality outcomes and the maintenance of pre-determined practice and practitioner performance criteria. These include:

- *Comprehensive Practice Audits that measure and monitor every aspect of each MediCross® Family Medical and Dental Centre and individual practitioner.*
- *An Independent Peer Review System, where each practitioner is regularly evaluated against set parameters and against his colleagues.*
- *Access to Clinical guidelines based on internationally accepted treatment protocols*
- *Disease Management Programmes.*
- *A Scientific Medicine Formulary is continually updated and utilised to eliminate wastage and the unnecessary use of costly drugs without compromising standards. Compliance to the formulary is strictly monitored through the monthly practice audit.*
- *Continued Professional Development or Continuing Medical Education that keeps the professionals in the MediCross® system abreast of the latest advancements in healthcare."* [34]

Based upon the above bullet points, in particular the last one, it was my impression that the MediCross® general practitioners may be better informed than the average and hence the results may reveal the best case scenario. Based upon the poor responder rate, I am reluctant to conclude that the results of my pilot study actually reflect the best case scenario.

"These mechanisms allow for appropriate evidence based medicine to be practised and cost-efficiency to be monitored. The ability to control healthcare costs is reinforced by the fact that the prescription rate in the MediCross® system is at least 20% less than that of other general practitioners nationally." [34]

"As well as providing healthcare services at industry negotiated fee-for-service tariff rates for the medical aid and private patient, MediCross® offer a range of unique, comprehensive managed healthcare plans on a capitated basis (a fixed monthly fee) to look after the patient's individual healthcare requirements. Managed Healthcare is a means of providing healthcare services within a defined network of service providers, who in turn assume the responsibility and therefore the risk of providing quality, cost-effective care, while ensuring that only appropriate services are delivered. Under this model, emphasis is placed on keeping the patient well, rather than treating episodes of illness. In this environment the primary healthcare practitioner is responsible for managing downstream utilisation of services and effectively becomes the custodian of the patient's healthcare funds." [34]

"Demand for more affordable healthcare has resulted in the MediCross® Managed Healthcare product range, which offers extensive access to primary care services in return for an affordable fixed monthly premium. These products are currently listed as Options with ten open medical schemes and another two in-house medical aid schemes. The final product may vary, but essentially, differing levels of cover give the patient access to general practitioners, conservative dentistry, medicines (Acute and Chronic), pathology and radiology. The affordability of these products is evidenced by the fact that patients, by choosing a MediCross® managed care product can save up to 40% on comparable medical scheme contributions, without limiting benefits. There are currently approximately 40 000 beneficiaries on the various MediCross® managed healthcare products." [34]

If you take the above direct quotes (hence in italics and " " as per University regulations) from the Corporate Profile of MediCross® into account and the fact that uncomplicated hypertension, although very prevalent, is generally not a complicated condition to treat, again it was felt that for the purposes and context of this study, it would be reasonably safe to make the assumption that doctors will be honest in answering the questionnaire and where educated and aware of the SAHS Guidelines, and would follow them within reason. This was obviously done in the context of the information provided about the company and the environment in which these doctors practise medicine.

In support of this the mission and philosophy of the company is quoted as *"One of MediCross®' aims is to provide all South Africans with the opportunity to access outstanding private healthcare. While it supports the concept of a competitive private healthcare system, the rise in medical costs in South Africa has led to the need to find creative ways to provide effective and affordable healthcare. MediCross® has successfully managed these costs through its Managed Healthcare programmes, which have allowed costs and treatment to be carefully monitored and controlled. MediCross®' Managed Healthcare system has allowed the company to control medical costs without having to in any way compromise on care."*

Further claims from MediCross® on the competitive advantage that their products have include: *"With the emphasis on containing costs within the South African private healthcare industry, it has become ever more important for provider networks and funders to consider Managed Healthcare as a viable alternative to reduce the cost of healthcare delivery. MediCross® supports the view that business principles should be applied in the management of healthcare, but not at the expense of quality."* [34]

"Managed Healthcare therefore requires a delivery system that can influence the utilisation of services and measure performance outcomes without compromising quality of care. Managed care is also a means of taking responsibility for managing and providing quality, cost effective care, and ensuring that only appropriate services are rendered to patients." [34]

"MediCross®' Managed Healthcare Programmes are based on a fixed monthly fee to the practitioner that is paid per patient in advance in exchange for providing the necessary healthcare services. The emphasis of the MediCross® Managed Healthcare programme is on preventative care, rather than on treating episodes of illness. Unlike the traditional fee-for-service system, the MediCross® Healthcare programmes reward the doctor for keeping his or her patient healthy and for providing the best possible care. The healthier the doctor is able to keep his patient, the less the patient will visit and the lower the cost incurred in treating illness." [34]

"MediCross® Managed Healthcare programmes have been jointly developed with the doctors practising in the MediCross® facilities and other healthcare providers. Therefore, rather than medical schemes determining the benefit structure as is traditionally the case, the doctor helps to determine the benefit structure and assumes some of the risk for the patient's wellbeing." [34]

If one takes a more in-depth look at the managed healthcare products that are offered, MediCross® has developed a number of different products that are based around the practitioner who plays a central role in the process. The MediCross® Managed Healthcare Programmes are backed by the MediCross® Practitioners Association and supported by the professionals in the MediCross® system.

"MediCross® is a network of healthcare providers, not a medical scheme. The MediCross® Managed Healthcare Programme, however, provides the mechanism for a comprehensive healthcare solution. Together with a client medical scheme, the MediCross® options can offer a comprehensive primary healthcare benefit package that also includes cover for specialist care, hospitals and ancillary benefits." [34]

"MediCross® has developed different managed healthcare programmes (please see Managed Healthcare Products section) with incremental levels of benefits. There is an entry level product aimed at the emerging market and providing a basic healthcare cover that is aimed particularly at young individuals in the lower income category. An intermediate product offers comprehensive healthcare at a very affordable rate whereas the top of the range product offers benefits competing with current fee-for-service schemes at the top end of the market. This means that there is an option to suit all individuals, as well as at the same time catering for requirements of small and large employer groups and the medical schemes themselves." [34]

Based upon the above direct quotes (hence in italics and " " as per University regulations) from the Corporate Profile of MediCross® it is unlikely that belonging to a MediCross® managed general practice would influence the general practitioners decision as to which drugs to prescribe. Indeed some general practitioners stated that their reason for not adhering to the guidelines was that they felt that their patients could afford newer more expensive drugs and that it would be unfair to provide them with anything less. If the general practitioners had been bound by costs and hence influenced by MediCross® such reasons for poor adherence to the guidelines would have been unlikely.

The final important question for discussion on this issue, as mentioned above, is the availability and ownership of pharmacies. A detailed services search for all MediCross® Clinics, showed that more than 80% of all the clinics in South Africa have a Pharmacross Pharmacy® situated in the same clinic facility. The Pharmacross Pharmacy® group is wholly owned by the Netcare® Group and this can clearly be a cause for concern when the results of this study are interpreted. Taking the limited information available, as discussed above, into account, the fact that treatment guidelines are designed with the on-site pharmacies in mind, cannot be excluded and should be considered when assuming that this population is nationally comparable.

Thus, taking all of the above into account, it was felt that it would be acceptable, but not fool-proof, to assume that the choices and practices of these general practitioners would, within reason, not unduly be influenced by external influences and corporate guidelines, although the possibility cannot be excluded. Therefore within the scope and reason of this study, patients were not treated differently to any other general practitioner (or patient) in urban areas of South Africa.

It may be criticized that MediCross® doctors are not necessarily representative of all doctors. Indeed, I have clarified throughout that these results reflect those of general practitioners in urban areas only. Although an attempt was made to ensure that there was graphical representation (the 49 MediCross® practices are distributed across all provinces), the 81 General practitioners who responded were primarily from all the urban areas including Pretoria, Johannesburg, Bloemfontein, Kimberley, Cape Town, Durban, Port Elizabeth.

4.3 General Discussion of Results

For the primary analysis, the responses to **question 2** were compared with the 1st step of the step-wise treatment approach in the guidelines (Figure 1). According to the guidelines, as a first step, general practitioners should prescribe a ‘low dose of a long acting once daily drug’ and more specifically a ‘low dose thiazide diuretic – 12.5 to 25 mg hydrochlorothiazide’ for uncomplicated hypertension. Analysis done with this criteria showed that only 1 or 0.8% of cases, were compliant with the guidelines when prescribing first line medication. Because this percentage was so low, a second analysis was performed using less ‘strict’ criteria, in other words allowing a wider range of drugs for the first line treatment of uncomplicated hypertension as acceptable. Drugs allowed into the analysis included all diuretics (see Table 2). Compliance was found to be much higher at 43 or 33.1% of cases for this analysis. Although no other literature could be found to support this, it possibly shows that general practitioners interpret the guidelines for first line treatment as thiazide **like** diuretics or diuretics alone. Another reason might be that general practitioners do not want to target treatment at a blood pressure threshold alone as this is inefficient, and that treatment is targeted much more accurately at a specified level of absolute cardiovascular risk [18].

Taking the responses for first-line therapy into account, literature also suggests that the need for drug therapy in uncomplicated, mild hypertension should be based on the absolute risk of cardiovascular complications, estimated by considering age, sex, serum cholesterol level, diabetes mellitus status, and smoking habits, in addition to blood pressure. Doctors cannot estimate absolute risk accurately informally or

intuitively, and the next generation of guidelines should incorporate a simple but accurate method for estimating cardiovascular risk, similar to that in the New Zealand guidelines [18].

Further analysis for purposes of the primary objective, compared the responses to **question 3** with the 2nd step of the step-wise treatment approach in the guidelines (Figure 1). According to the guidelines, as a second step, general practitioners should ADD a low dose diuretic or one of the following: reserpine (<0.1 mg daily), beta-blocker, ACE inhibitor, long acting Ca-channel blocker, or a fixed dose combination. Analysis performed according to this criteria showed that 81 or 59.6% of cases, were compliant with the guidelines when prescribing a second line drug treatment for uncomplicated hypertension. To be consistent with the analyses performed for question 2, a less 'conservative' analysis was performed again, allowing for more acceptable second line treatment drugs. These mainly included any diuretics (not only low-ceiling or low dose) and again this analysis yielded a better compliance with the guidelines of 96 or 70.6% of the cases. From these results, it almost seems as if more general practitioners interpret guidelines on prescribing diuretics [first line (thiazide) vs second line (plain)] in less detail, not considering the difference between the thiazide diuretic and the plain diuretics. Again no literature was found to support this. For the second line treatment, it should however be mentioned that the difference between the 'detailed'/'conservative' and 'less detailed'/'less conservative' approach is not very big (only 15 extra general practitioners were included in the larger compliance of the second analysis for second line treatment). As described in the results section, the results for question 2 compared to an ideal compliance, shows a statistically significant difference (for the 'conservative' as well as 'less conservative' approach). The same is true for the question 3 comparisons. It is thus clear that medical practitioners in South African urban areas do not comply with the SAHS guidelines.

A study performed in Spain [19] has shown similarly, that although a significant reduction in blood pressure control and in a percentage of patients with inadequate BP control, recommendations of the sixth JNC are widely not adopted in clinical practice. More doctors were not prescribing recommended drugs [19]. The opposite however is true for academic settings; where a study in the US has shown that a high level of awareness of primary care faculty and residents to diagnose hypertension according to JNC VI guidelines, may reflect a greater compliance with, or reliance upon, national guidelines in an academic setting, compared with general practice [20].

Responses to **question 8** of the questionnaire for this study provided some insight into possible reasons for general practitioners not complying with the guidelines. These were categorized into general categories (see table 5) and included the following:

- Did not know about or have a copy of the guidelines.
- Preferred using the JNC guidelines.
- Preferred to use their own knowledge and intuition.
- Preferred to treat each patient as an individual.
- Preferred to treat patients who can afford it more aggressively early on.
- Had no specific reason.

Responses to **question 9 and 10** of the questionnaire for this study also provided some insight into why doctors might feel that the guidelines are not practical and 'in touch with reality'. Fifty eight and a third percent (58.33%) of the doctors interviewed felt that the guidelines were practical, 12.5% were unsure and the remaining 29.17% felt that the guidelines were unpractical. This means that 41.76% were not convinced of the guidelines' validity and implementability, which might be another explanation of the lack of compliance as found in this study. Reasons why doctors felt that the guidelines were not practical were listed in table 6 and included issues like pricing, medical insurance (aid), side-effects, differences in risk profiles and assessment thereof and the aggressiveness of treatment. On this same topic, responses to **question 11** produced some suggestions as to how doctors felt guidelines could be made more practical and these also pointed towards perceptions of why guidelines might be lacking. As can be expected, the responses were mostly related to those given in question 10.

The responses to questions 8, 9, 10 and 11 make it fairly clear why doctors in this population do not comply with the guidelines. They feel that the guidelines are not practically implementable and they feel that the guidelines limit their initiative. An important factor, that was mentioned by many of the doctors and that needs more exploration, is the role that medical insurance (aid) plays in influencing what drugs the doctors prescribe. Many doctors felt that guidelines are 'useless' purely because pricing and medical insurance dictates treatment more than any other factor.

Other studies have shown similar factors influencing doctors' decisions on drug treatment of uncomplicated hypertension [17, 21]. Determining factors mentioned, that support the findings and responses above, includes **patient preferences, socioeconomic factors and differences in risk of CVD complications** [21].

Patient values and preferences need to be an integral part of evidence-based decisions. The clinician cannot presume full responsibility for determining what is in the best interest of their patients. Instead, a shared decision-making approach is advocated, in which patients are the experts at judging their own values. For this approach to work, patients first need to be properly informed about their condition, the treatment options, and the outcomes of treatments, including possible complications. Side-effects that compromise functional capacity are of particular relevance. Trade-offs between short-term and long-term outcomes should be articulated. This strategy seems to work [21]. A recent trial showed that use of cardiovascular risk chart in patient education was associated with better BP control [22]. Other research has suggested improved medication adherence when patients are involved in decisions regarding treatment choices [23]. The value of various decision aids for patients has been reviewed through the Cochrane Collaboration [24].

Drug costs is a major consideration for hypertensive subjects. The choice of an antihypertensive drug should be based on its value to the patient and society. There are marked differences in cost between classes of antihypertensive drugs and in some instances even between agents within a class. Guidelines ought to incorporate the role of cost and socioeconomic factors in making treatment decisions. If two antihypertensive agents offer a similar reduction in risk of cardiovascular complications, but they clearly differ in cost, the less expensive agent is more cost-effective and should be recommended. The unnecessary and unwarranted use of

expensive agents precludes the use of these resources for other effective preventative efforts. Generic formulations of all antihypertensive medications should be recommended when they are available. Guidelines ought to acknowledge the role of socioeconomic factors in making treatment decisions [21].

This supports the fact that many general practitioners prefer to prescribe a newer generation drug for first-line treatment and since this study was carried out at private practices and most of the patients treated by these general practitioners have some kind of medical insurance, cost would not be an influencing factor, as diuretics are generally less expensive drugs. In fact some general practitioners indicated (see Table 5 above) that they do not follow the guidelines because they feel that their patients can afford the so-called newer and more expensive drugs and that it would be unfair to provide anything less.

Cardiovascular complications of hypertension differ in different populations. For example, stroke incidence is higher than acute MI in Asian populations, and in elderly whites. Important differences exist between drug classes in their effect on the risks of stroke, acute MI, heart failure, and renal complications [25]. Thus, population differences in types of CVD complications are other factors to consider both in the assessment of risk, and in the selection of drugs.

However one looks at it, there are many factors that can influence a general practitioner's choice to follow the guidelines or not and these should be subjected to further investigation. Indeed, as my pilot study indicates further research into these issues is certainly required.

Question 7 asked general practitioners if they follow the SAHS Hypertension Treatment Guidelines when prescribing drug treatments for hypertensive patients. Analysis of the responses showed that 30 or 38.96% of general practitioners responded positively, in other words they believe that they are being compliant with the guidelines. Forty seven (47) or 61.04% responded negatively and believe that they are not complying with the guidelines. To confirm if general practitioners might be under the wrong impression regarding their compliance, for example they might think they are compliant and they are actually not or vice versa, a comparison was performed between questions 7 and 2 (Table 10) and between questions 3 and 7 (Table 11).

Of the 30 general practitioners who believed that they were compliant, only 16 were actually compliant with the prescription of first line drug treatment (Table 10). This means that 14 or 47.7% of the general practitioners were not compliant even though they thought they were. This alone, suggests strongly that more investigation is needed into general practitioner education on the use of the guidelines for first line drug therapy.

Of the 30 general practitioners who believed that they were compliant, only 18 were actually compliant with the prescription of second line drug treatment (Table 11). This means that 11 (two general practitioners did not answer question 3) or 37.9% of the general practitioners were not compliant, even though they thought they were. Again, this strongly suggests that education in the application of the guidelines for second line therapy is most likely lacking.

Of the 45 general practitioners who believed that they were not compliant, only 31 were actually not compliant with the prescription of first line therapy (Table 10). This means that 14 or 31.1% of the general practitioners were compliant without their knowledge and again can be is assumed that they were not adequately educated in the use of the guidelines.

Of the 46 general practitioners who believed that they were not compliant, only 14 were actually not compliant with the prescription of second line therapy (Table 11). This means that 32 (two general practitioners did not answer question 3) or 69.6% were compliant with guidelines without their knowledge and again it can be assumed that they were not adequately educated in the use of the guidelines.

Question 4 assessed what the general view on the ideal blood pressure is. Results are reported in Table 4 with the median SBP being 130 mmHg and the median DBP being 83 mmHg. The average suggested ideal SBP was 130.25 mmHg with a standard deviation of 8.99 mmHg and the average suggested ideal DBP was 83.27 mmHg with a standard deviation of 5.04 mmHg. The minimum suggested SBP was 100 mmHg and the maximum suggested SBP was 145 mmHg. The minimum suggested DBP was 70 mmHg while the maximum suggested DBP was 90 mmHg.

The above SBP and DBP results correlate well with the international perception, but literature shows that even in international circles there are still major differences in opinion of what an ideal BP should be [18]. The BP level at which antihypertensive therapy should be introduced and the goal of intervention has not been adequately addressed in clinical trials. The form and intensity of treatment, and the level to be sought, should be influenced by the magnitude of risk as well as other individual clinical and non-clinical factors. Grading of recommendations and evidence for thresholds and targets should also be included [21].

Question 5 asked general practitioners if they had ever heard of the SAHS Hypertension Treatment Guidelines. Results are reported in Figure 4a and 4b. It was found that 60 or 78% of the general practitioners had heard of the guidelines and that 17 or 22% had not heard of the guidelines. As a follow-up to question 5, question 6 asked general practitioners if they had a hard copy of the SAHS Hypertension Treatment Guidelines. 21 General practitioners (27%) indicated that they had copies of the guidelines and 56 (73%) indicated that they did not have a hard copy. The results of the responses to this question should serve as a indication to the SAHS if they are doing enough to make general practitioners aware of these guidelines and their availability.

Question 12 asked general practitioners to provide an estimate of what drugs they most frequently prescribe for uncontrolled hypertension in the hope that this could be compared to the results of the secondary analysis. The most frequently prescribed drug (37.72% of total), as reported by the general practitioners on the questionnaire (Table 8), proved to be the ACE inhibitors. More detail on the comparison of this result with that of the secondary analysis will be discussed below.

Lastly, **question 13** provided general practitioners the opportunity to note any additional comments. It was clear from most comments that the guidelines should

only be viewed as guidelines that provide direction and that they are not law. Further positive comments included requests for the guidelines and requests for results of this research project. One comment that was made stated “Big difference between academic and private practice medication. Patients do not allow so much “cheap-changes” in private practice – they want effective and immediate treatment with a low side effect profile”. Perhaps this summarises and supports reasons for the lack of compliance, as previously mentioned.

Data from the MediCross® database showed, as part of the secondary analysis, that Beta-blocking agents (selective, non-selective, plain and in combination) have been the most commonly prescribed medication for the treatment of uncomplicated hypertension over the last 2 – 3 years (33.27%) (See Table 12 for more detail). This is not the same as the results yielded by question 12 (ACE inhibitors). More investigation will be needed to assess possible reasons for the difference in results.

Literature does however support the results of the primary analysis and it has been found that ACE inhibitors are the most frequently prescribed antihypertensives in first-world health settings, especially in patients with congestive heart failure [26]. This also confirms that the results of this study will probably be more relevant to the private health sector of urban areas of South Africa as this sector compares well to first world healthcare sectors.

Having said all of this, it should be noted that the data obtained from MediCross® is questionable. The number of hypertensives treated is low. Another concern is that there were only 4 prescriptions in 3 years for thiazide diuretics alone. Then there are some curious combinations of drugs and drug-classes. The secondary analysis was done, in part, to compare and assess the validity of the results of the primary analysis. Although at the outset on embarking on this study, I was of the opinion that the database consisted of prescriptions, it is not clear if the drug names provided were actually those supplied rather than prescribed. Indeed it is possible that the prescriptions were changed and different drugs dispensed as the results of the general practitioners recall (Table 8) were not comparable to those of the analysis of the data base (Table 12). It should be stressed again that this database was received on face value, assuming a reasonable degree of accuracy, however, retrospectively it became clear during the analysis that the accuracy is questionable. This may be due to a number of reasons of which improper database administration and management is the most likely cause. Nevertheless, the concerns about the accuracy of this database certainly cast some doubt on the results of the secondary analysis.

4.4 Survey Methods

For the purposes of this study, a questionnaire was utilized as the primary data collection tool. Initially, telephonic interviews were planned and they were executed for the first 5 participants. Of these, 1 candidate was not interested to participate and 4 did participate. It was clear from these 5 candidates that telephonic interviews were going to be very time consuming as the general practitioners were occupied with patient consultations and did not want to make time available over the phone. When general practitioners were available to take telephone calls, they were extremely

rushed and the questionnaire had to be administered in a hurried fashion. It became clear that the time constraints on general practitioners were going to make proper interviewing very difficult. Furthermore, it would take a number of phone calls from the investigator to be able to talk to one general practitioner. With a target population of 320 doctors and no formal funding for the study, it was decided that a telephonic interviewing process would take too much time and would be too costly, even though if done, might have yielded a better response rate. Although a previous study has used focus group discussions and in-depth interviews [17], these can only be done in small select groups who are unlikely to representative of all general practitioners. Furthermore, practicalities would have resulted in these interviews or discussion groups having been conducted in possibly only one region of South Africa and hence the results would not have been nationally representative.

In order to approach the general practitioners a covering letter, providing a brief standardized outline of the study was generated. Wording in the cover letter was as follows:

("Please see attached questionnaire. I am a M.Sc.(Med) student from the WITS medical school and as you can see from the questionnaire, I am conducting a research project for academic purposes. I have collaborated with the MediCross® head-office and Mr. P. Dorfling has given me written permission to contact you in this regard. I will try to determine (with your help) how relevant and practical the SAHS guidelines are and if general practitioners do actually follow them when prescribing treatment. Please note that participation is voluntary and anonymous and consists of yourself answering the attached questionnaire. It should not take you more than a few minutes. Please use ***tradenames*** *as far as possible.*

Your particpation is greatly appreciated and will determine more accurate results (the more participants, the more accurate my statistical conclusions).

Please fax the answered questionnaire to me at (011) 319 8705 at your earliest convenience.

It was decided to fax the cover letter and questionnaire to the remaining 315 doctors. It was decided not to change the questionnaire for the purpose of standardization.

All questionnaires that were received (faxed back), were allocated with an ID number and filed as source documentation. These are available for monitoring purposes and will be archived for at least one year.

A questionnaire can be defined as a tool designed to elicit and record, or guide the elicitation and recording of, recalled exposures from subjects of a study. It contains questions to be put to the subject, and may also include answers to those questions from which the subject must choose those which are appropriate to him or her. The objectives of questionnaire design are:

- to obtain measurements of exposure variables essential to the objectives of the study
- to minimize error in these measurements

- to create an instrument which is easy for the interviewer and subject to use, and for the investigator to process, and analyse.

The objectives are potentially in conflict, and any questionnaire usually represents a compromise among them. For example, it may be necessary to trade off some ease in processing and analysis against ease in completion by the interviewer or the subject. Similarly, the addition of some questions essential to the objectives of the study, for example questions about sexual behaviour in a study of the aetiology of cancer of the cervix, may make a questionnaire more difficult for an interviewer to administer and more threatening to the respondent. Judgement must be exercised in making decisions about the content and structure of questionnaires. Where compromise is necessary, the designer should favour decisions that maximize the usefulness of the questionnaire to the objectives of the study and minimize error in measurement [27].

In this study there was a compromise on maximizing the usefulness of the questionnaire to the objectives of the study and as a consequence error in measurement was not considered very carefully.

The content of a questionnaire is generally designed to investigate the minimum amount of an individual's total experience that will provide sufficient information concerning the problem under study [27]. Just as the objectives of the study determine the variables to be measured as a whole, they also determine the specific items to be covered in the questionnaire. If a question does not contribute to the achievement of the objectives, it has no place in the questionnaire.

The topics to be covered in a questionnaire and the detail in which they are covered are limited first and foremost by the length of time that subjects are willing to spend on the questioning process. While there are inevitable exceptions, it may be taken as a general rule that the maximum time that can be spent administering a questionnaire by face-to-face interview is 1-2 hours and, by telephone, 40 minutes to 1 hour. Self-administered questionnaires are at an added disadvantage in that the subject can gain an impression of the size of the response task before deciding whether to embark on it. Response rates among the general public appear not to be appreciably depressed by questionnaires of up to a maximum of 12 pages in length [28]. In other words the shorter the questionnaire the better.

As mentioned above, there is often a conflict between collecting information considered to be necessary to the objectives of the study, keeping the questionnaire an acceptable length, and minimizing other aspects of respondent burden. In resolving this conflict, it is important not only to collect the minimum amount of information necessary to the objectives of the study, but also to ensure that questionnaire length and respondent burden are kept to levels that do not threaten participation by subjects or cause material increase in error. Although respondent burden was low in the questionnaire in this study, it can be said that the fact that the questions were perhaps not very clearly defined and detailed, could have contributed to a high respondent burden. The increased burden on the respondent could have contributed to several consequences:

- risk of partial non-completion increased as this was a self administered questionnaire

- reduction of the quality of data obtained
- threatened response rate (which was clearly visible in this study)
- an alienation to survey research and cooperation due to poorly designed questionnaires (past and future) [29]

Questions used in the questionnaire can generally be classified as either 'open-ended' or 'closed-ended'. Open-ended questions are questions to which no answers are provided by the investigator. Only the question is asked, and the respondent's answer is recorded verbatim e.g. questions 2, 3, 4, 8, 10, 11, 12, 13 for the questionnaire used in this study. In an interview, extensive probing may be used to ensure that all relevant aspects of the topic are covered by the answer. Closed-ended questions are questions for which the range of possible answers is specified by the investigator and the respondent is asked to make a choice from among the answers provided.

Open-ended questions should be used for the eliciting and recording of simple facts to which there are a large number of answers – for example, age, occupation, country of birth, number of cigarettes smoked in a day, amount of alcohol drunk in a particular period of time, etc. The use of closed-ended questions for these topics leads to loss of information and, when asking about a socially undesirable behaviour, a greater degree of error. An additional advantage of open-ended questions is that the amount of a particular behaviour reported in closed categories may be influenced by the cut-off values chosen for the categories. It appears that the categories offered are seen as normative by the respondents and their responses are influenced away from the extremes, particularly if one or other extreme is viewed as socially undesirable. When the likely answer to an open-ended question is neither simple nor factual, the use of such a question increases the burden on both respondent and interviewer and produces answers that are difficult both to code and to analyse. This can clearly be seen from questions 8, 10, 11, 12, 13 in the questionnaire used here.

The alternative answers offered in a closed-ended question should be simple and brief, and mutually exclusive if only one is to be selected. If more than one response could be selected, it may be best to seek explicit 'yes/no' responses for each of the categories. If the response categories provided are not exhaustive of all possible responses, a final open category (e.g. 'Other. Please give details…') should be given. A 'Don't know' option may also be offered if the possibility exists that some subjects will truly not know the answer. It has been shown however, that the exclusion of the 'Don't know' option gave an appreciably higher proportion of usable responses for many items without adversely affecting response rate or intramethod reliability [30]. For these reasons the inclusion of a 'sometimes' option was avoided. It was felt that there would be a tendency for most responders to choice this option in favour of either definitive option (yes or no), especially if they did not know as to which definitive answer was more desirable.

Another important factor to consider in questionnaire design is question wording. There are two important issues to be considered in question wording:

- How does one arrive at a suitable wording in the first place?
- Are small changes in wording likely to lead to differences in response?

Table 13 [31] gives a list of questions that should be asked about the wording of each question in a questionnaire.

Table 13: Questions that should be asked about the wording of each question in a questionnaire [31].

• Will the words be uniformly understood by the subject population?
• Does it contain abbreviations, unconventional phrases, or jargon?
• Is it vague?
• Is it too precise?
• Is it biased?
• Is it threatening?
• Does it contain more than one concept?
• Does it contain a double negative?
• Are the answers mutually exclusive?
• Does it assume too much about the respondent's behaviour?
• Is an unambiguous time reference provided?
• Is the question cryptic?

The words used in a questionnaire should be the usual 'working tools' of the respondents. They should be neither too difficult nor too simple. Difficult words may not be understood, and simple words (where better but more difficult words could have been used) may appear condescending, may not convey the right meaning, and may needlessly lengthen the questionnaire. Where doubt exists, however, there is a virtue in simplicity [32]. Abbreviations, unconventional phrases, and jargon present the same problems as difficult words; they may not be understood or, perhaps worse, they may be misunderstood. In this questionnaire one abbreviation was used (SAHS – "Southern African Hypertension Society") in questions 5, 6, 7 9. However unlikely it is that this abbreviation was misunderstood in the context of the questionnaire and taking into consideration that the respondents were well educated, it cannot be ruled out that this abbreviation was perhaps misinterpreted or not understood at all.

Questions may contain vague words – words that vary substantially in their meaning among different people. 'Usually', 'normally', and 'regularly' are three commonly used vague descriptors of frequency. In many circumstances they can be replaced by more precise quantifiers. Furthermore, while precision is desirable, particularly when estimating amount or duration, respondent burden may be increased unduly if too much precision is requested.

Biased questions are questions that suggest to the respondent that a particular answer is preferred from among all possible answers. 'Leading' questions are well known and should be easily avoided. In this light, it can be argued that questions 9-11 of the questionnaire used in this study can be viewed as biased questions. The same can be said about questions 6 and 7 and the fact that they might be viewed as threatening questions.

Questions in this questionnaire were evaluated and found not to include any double negatives, multiple concepts in one question, mutually exclusive answers, assumptions about the respondents, unambiguous time references, or cryptic questions.

Pre-testing is an essential part of the development of all questionnaires, regardless of whether or not they have been substantially based on previous questionnaires. The objectives of pre-testing are to identify questions that are poorly understood, ambiguous, or evoke hostile or other undesirable responses. Some of the questions that a pre-test should answer are [31]:

- Are all the words understood?
- Are the questions interpreted similarly by all respondents?
- Does each closed-ended question have an answer that applies to each respondent?
- Are some questions not answered?
- Do some questions elicit uninterpretable answers?

The steps that should be followed in pre-testing a questionnaire are summarized in Table 14 [28].

Table 14: Steps in the pre-testing and final development of a questionnaire [28].

1. Obtain peer evaluation of the draft questionnaire.
2. Test the revised questionnaire on a sample of convenience (e.g. yourself, relatives, friends and colleagues).
3. Prepare instructions for use of the revised questionnaire and train interviewers for a pilot test. Problems requiring revision of the questionnaire may be uncovered in this process.
4. Pre-test the questionnaire on a sample (20-50) of respondents representative of the population from which your subjects will be drawn.
5. Obtain comments of interviewers and subjects, preferably in writing.
6. Revise questions that cause difficulty.
7. Pre-test and revise again.
8. Prepare revised instructions and train interviewers for implementation of the study. Revise questionnaire if this process uncovers more problems.
9. Monitor performance of the questionnaire during the early phase of the study and be willing to stop, revise, and pre-test again if necessary.

After completion of administration, each question should be read back with its answer and the respondent asked how he or she arrived at the answer. Probing may be necessary to clarify the answer to this question. A serious of questions should then be asked about how each concept in the original question was understood. A pre-test interview can be taped and listened to by the investigator (if not administered by himself) [33]. Due to time constraints and a lack of understanding of the necessity of pre-testing, the questionnaire in this study was not pre-tested. This may indeed have impacted on the validity of the questionnaire administered (and hence the results obtained) in this study.

Presentation of the questionnaire in printed form is important, especially when it is to be self-administered both for ease of use and to give it an authoritative appearance that will encourage response. The first page should include the title of the study, the name of the organization conducting it, and the date. In addition, a graphic illustration may make a self-administered questionnaire more attractive to its target population.

Pages and questions should be numbered consecutively, and subsections of questions should be indented and identified with letters rather than numbers. As far as possible, questions should not extend over more than one page. Following this rule will generally increase the amount of space between questions and it is indeed important that the questionnaire not be too congested.

In a self-administered questionnaire the last page should provide space and a specific invitation for any comments that the subject may wish to make. Interviewer-administered questionnaires should provide for the entry of the starting and finishing times and the interviewer's comments.

4.5 Study Limitations

Given the discussions above, I should state that there are indeed three limitations to my pilot study. Firstly, the MediCross® general practitioners may not necessarily be representative of all general practitioners in urban areas of South Africa. Indeed the general practitioners who responded tended to be located primarily in the bigger city (urban) regions.

Secondly, the questionnaire was not piloted which may have led to invalid interpretations and hence responses. Although a simple 13 question self-administered approach was used to minimize respondent burden in the aim of maximizing responder rate, the responder rate was indeed very poor. The poor responder rate itself is a further limitation in that these responders may not be representative of the whole group. Further limitations pertaining to possible leading questions, threatening questions and the use of many open-ended questions has also been discussed.

Thirdly, the accuracy of the MediCross® database has been questioned, hence casting some doubt on the results of the secondary objective.

Given these limitations in mind, I would urge that further, more thorough investigations be performed. Such studies would need to be extensive and hence would we time and labour intensive. I would recommend that in-depth interviews and focus group discussions be conducted in all regions of South Africa. Studies should be conducted separately to canvas opinions in urban versus rural general practitioners, as it is possible that opinions may differ. It is also important that in these studies the general practitioners should be representative of all races and both genders.

5. CONCLUSIONS

In my pilot study, the primary analysis showed that, even with a less conservative approach (with respect to the definition of diuretics) to the Southern African Hypertension Society Guidelines, general medical practitioners in urban areas of South Africa do not follow appear the guidelines for the prescription of antihypertensive medication.

The secondary analysis showed that Beta-blocking agents are the most frequently prescribed drugs for the treatment of uncomplicated hypertension in MediCross® Clinics in South Africa; this was not in line with the findings of the primary analysis questionnaire on the most frequently prescribed medication for uncomplicated hypertension in South Africa, whether it be first or second line.

The results of my pilot study suggest that the practitioner's perception is that the definition of hypertension and its management is contentious. Furthermore, the treatment of hypertension seems to vary widely. It is the concern of the practitioner's that there is no optimal BP or multifactor CVD risk level at which BP-lowering treatment should be initiated in all situations. Nor is there a single treatment regimen appropriate for all populations and every patient. It is clear from the general practitioners responses that, clinical guidelines for the management of hypertension should accurately reflect that uncertainty and variation if they are going to take these guidelines seriously and comply with them. Furthermore it is of concern that although at least 2/3 of practitioner's that responded had heard of the Southern African Hypertension Society Guideline, less than one third had a hard copy of the guidelines.

There is no doubt that the production of clinical guidelines requires much effort, resources, and commitment of time on the part of many. Their publication is the culmination of both scientific and social processes intended to include all relevant evidence as well as all appropriate stakeholders. Their formulation needs judgment, compromise, and simplification to achieve consensus. However, based on the responses from the practitioner's, the inclusion of diverse views in accompanying editorial or discussion segments may help to put guidelines into perspective and make them more popular with general practitioners.

As guidelines assemble the available data from basic biomedical science, epidemiology, and clinical science in an accessible form from which general practitioners and patients can make reasoned decisions for individual cases, they are indeed invaluable. However, the results of my pilot study suggest that the current guidelines are neither widely accepted, nor effectively implemented. Further studies are required to address these questions in more detail and across all general practitioners in South Africa.

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7. APPENDIX DATA (I, II, etc)

7.1 APPENDIX I: WITS Ethics Committee approval letter dated 18 Jul 03

7.2 APPENDIX II: WITS Post-Graduate Committee approval letter dated 01 Jul 03

7.3 APPENDIX III: MediCross® Medical Practitioners Questionnaire

7.4 APPENDIX IV: Address list of MediCross® Clinics across South Africa

7.5 APPENDIX V: Name list of MediCross® General practitioners

7.6 APPENDIX VI: Copy of e-mail from Pieter Dorfling (MediCross®)

7.7 APPENDIX VII: MediCross® Clinic distribution map