Blood Pressure Monitoring in Community Pharmacy

A thesis submitted in partial fulfilment

of the requirements of the

Degree of Doctorate in Pharmacy

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2024

To my parents, for their outpouring love, encouragement, support and strength throughout my whole academic journey.

To my fiancé, for his patience and loyalty these past 3 years.

Acknowledgements

I would like to thank my supervisor Prof Lilian Azzopardi and co-supervisor Dr Francesca Wirth for their invaluable support and guidance throughout this research. I would like to extend my gratitude to Prof Liberato Camilleri for his assistance with statistical analysis and the Validation Panel for their fruitful contribution. Heartfelt thank you goes to all the academics and administrative staff at the Department of Pharmacy.

Sincere gratitude to the management at Brown's Pharma Ltd for supporting my study. Thank you goes to all my colleagues especially, my team, at Brown's Mellieħa for their support. I am forever grateful to all the participants who took interest and found time to take part in my study, surely this research would not have been possible without them.

On a personal note, I would like to thank my family and friends for their support and motivation. In particular, Miriana and Toyah who have been a tremendous support throughout these many years of friendship.

Funding: University of Malta Research Grant (PHRRP03).

Abstract

Ambulatory blood pressure monitoring (ABPM) is the gold standard for diagnosing hypertension and assessing 24-hour blood pressure (BP). ABPM complements home BP monitoring (HBPM) by assessing white coat hypertension, diagnosing masked hypertension, and providing information on nighttime dip and morning surge.

The aims of the research were to identify pharmacist-led contributions in patient empowerment of BP self-monitoring and the application of ABPM in community pharmacies. The objectives were to: 1) Appraise HBPM and ABPM devices, 2) Propose pharmacist interventions supporting patient empowerment of BP self-monitoring, 3) Assess feasibility of introducing ABPM in community pharmacies.

In phase 1, HBPM and ABPM devices available on the market were appraised in terms of cost, technical specifications and accessibility. In phase 2, a data collection sheet to assess practice of BP patient self-monitoring and an action plan to facilitate patient empowerment were developed and validated. The data collection sheet and action plan were implemented by means of an interview to 120 participants on antihypertensive therapy recruited from 4 community pharmacies by convenience sampling. In phase 3, 10 patients satisfying the inclusion criteria (newly diagnosed with hypertension, recent change in medication and/or dose, or patient reported non-compliance to hypertension management), were recruited by purposive sampling from phase 2 for 24-hour ABPM. The feasibility of introducing ABPM in community pharmacies was evaluated.

For phase 1, 25 HBPM devices and 3 ABPM devices available locally were analysed and compared. For phase 2, 66 out of 120 participants claimed to own an automatic upper arm oscillometric HBPM device. For the participants who self-monitor BP (55%), ways to improve HPBM technique, frequency and follow up of BP results were identified by the

researcher. For the participants who do not self-monitor (45%), benefits of HBPM and devices available were explained by the researcher. Out of the 66 participants who self-monitor, 30 participants were found to have elevated BP. Using the chi-square test, no statistical significance ($p>0.05$) was found between self-monitoring and BP reading. An action plan was devised for each participant by the researcher depending on the participant's needs, mainly addressing monitoring frequency, BP reading results and the participant's action towards home BP readings. For phase 3, GIMA® 24 hours ABPM + Pulse Rate Monitor was chosen based on cost and availability. Ten participants accepted and 10 refused since they believed ABPM would be burdensome (n=6) or felt embarrassed to be seen with the device (n=4). Successful 24-hour ABPM was achieved in 9 participants. Each appointment required 30-60 minutes of pharmacist's time, led to a report which was used by the pharmacist to provide patient recommendations. Four patients were referred to their physician. Despite challenges related to sleep disturbance (n=2) and bruising (n=2), application of ABPM was well-accepted by the rest of the patients.

Pharmacist-led ABPM service in community pharmacies in a collaborative care context is feasible and contributed to identifying patients requiring further assessment. The action plan developed addressed strategies applicable to patients defaulting HBPM. Pharmacists must prioritise those patients with uncontrolled BP despite self-monitoring, identifying reasons and ways to improve HBPM.

Keywords: ambulatory blood pressure monitoring, home blood pressure monitoring, patient empowerment, pharmacist intervention, self-monitoring

Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

ABPM	Ambulatory Blood Pressure Monitoring
ACC	American College of Cardiology
AHA	American Heart Association
ANSI/AAMI/ISO	American National Standards Institute/ Advancement of Medical Instrumentation/International Organization for Standardization
BHS	British Hypertension Society
BIHS	British and Irish Hypertension Society
BP	Blood Pressure
CCD	Chronic Coronary Disease
CDTM	Collaborative Drug Therapy Management
CE	Conformité Européenne
DALY	Death and Daily Adjusted Life Years
DM	Diabetes Mellitus
ESC	European Society of Cardiology
ESH	European Society of Hypertension
HBPM	Home Blood Pressure Monitoring
IDH	Isolated Diastolic Hypertension
IP	International Protocol
ISH	International Society of Hypertension
JSH	Japanese Society of Hypertension
MACE	Major Adverse Cardiovascular Events

MAP	Mean Arterial Pressure
MTM	Medication Therapy Management
NHS	National Health System
NICE	National Institute for Care and Health Excellence
PD	Parkinson's Disease
PH	Primary Hypertension
PP	Pulse Pressure
SCORE	Systemic Coronary Risk Evaluation
SH	Secondary Hypertension
UK	United Kingdom
VDL	Validated Device Listing™
WHO	World Health Organization

Chapter 1

Introduction

1.0 Introduction

Hypertension is the leading modifiable risk factor for morbidity and mortality globally, imposing challenges on the public health sector (Huang et al, 2023). Blood pressure (BP) was measured for the first time in 1733 by Stephen Hales in which a glass tube was inserted into an artery of a horse and a rise and fall in pulse by an average of three inches at and after each pulse was observed. This observation indicated the variability in the nature of BP levels (Schutte et al, 2022). Diagnosis of hypertension may not always be simple since BP is characterised by short-term and long-term fluctuations resulting due to complex interactions between intrinsic circadian rhythm and cardiovascular regulatory mechanisms with external stimuli (Kwon et al, 2020; Stergiou et al, 2021).

Epidemiology studies show that in 2021, the prevalence of hypertension in America averaged to approximately 39% of the adult population and in the United Kingdom (UK), hypertension prevalence averaged to 50% of patients aged 65 years and older (Andraos et al, 2021; McManus et al, 2021). It is predicted that by the year 2025, around 1.5 billion people will suffer from hypertension globally (Paudel et al, 2023). Prevalence of hypertension is lower across Northern and Western Europe compared to Eastern and Southern Europe (Mancia et al, 2023a). Two-thirds of adults suffering from hypertension worldwide live in developing countries, posing challenges to healthcare systems (Soubra & Elba, 2023).

1.1 Classification of Hypertension

The International Society of Hypertension (ISH) recommends a diagnosis of hypertension when a person's in-office systolic BP is ≥140 mmHg and a diastolic BP of ≥90 mmHg following repeated readings. If possible, diagnosis should not be based on one office visit, but at least 2-3 office visits spanned across 1-4 weeks (Unger et al, 2020). The European Society of Hypertension (ESH) guidelines recommend that everyone's BP should not exceed 140/90 mmHg. Patients with a high cardiovascular risk must achieve an in-office BP goal <130/80 mmHg. The diastolic blood pressure of all hypertensive patients should be targeted to below 80 mmHg irrespctive of comorbidities (Mancia et al, 2023b).

In patients with chronic coronary disease (CCD) events, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommends a BP target of <130/80 mmHg to reduce cardiovascular events and death (Virani et al, 2023). The lowered BP threshold came about from the Systolic Blood Pressure Intervention Trial, where a decreased rate of cardiovascular events was observed in patients in the intensive arm (<120 mmHg). In real practice, attention must be taken that at very low BP targets coronary perfusion in CCD patients is sufficient (Vidal-Petiot et al, 2023).

In the UK, guidelines by the National Institute for Care and Health Excellence (NICE) recommend higher BP level thresholds; BP level of <140/90 mmHg in adults under 80 years and a BP level of <150/90 mmHg in adults over 80 years.[1] Classification of office BP by the ESH guidelines and ACC/AHA guidelines are summarised in Table 1.1.

Systolic BP is more significant with respect to higher cardiovascular risk compared to diastolic BP. Elevated systolic BP is a major risk factor for coronary artery disease and a modifiable risk factor for cardiovascular death (Razo et al, 2022). Since 1990, the number of patients suffering from high systolic BP increased from 2.18 billion to 4.06 billion internationally. Elderly patients tend to have a higher increase in systolic BP whilst diastolic BP remains stable or possibly decreases (Huang et al, 2023). In 2018, the AHA updated its guidelines to recommend that older hypertensive patients should have a systolic BP below 130 mmHg (Whelton et al, 2018). In 2019, death and daily adjusted life years (DALY) associated with high systolic BP were found to increase with age in both sex groups but were found to be higher in older men than older women at all ages (Huang et al, 2023).

[1]National Institute for Health and Care Excellence (NICE). Hypertension in adults: diagnosis and management [Internet]. London: NICE; 2023 [cited 2024 May 31]. Available from URL: https://www.nice.org.uk/guidance/ng136/chapter/recommendations

Table 1.1 - Classification of Office BP readings according to European Society of Hypertension and American College of Cardiology/American Heart Association Guidelines

Category	Systolic (mmHg)	Diastolic (mmHg)
ESH thresholds		
Optimal	<120	<80
Normal	120-129	80-84
High normal	130-139	85-89
Grade 1 hypertension	140-159	90-99
Grade 2 hypertension	160-179	100-109
Grade 3 hypertension	≥180	≥110
Isolated systolic hypertension	≥140	<90
Isolated diastolic hypertension	<140	≥90
ACC/AHA thresholds		
Normal	<120	<80
Elevated	120-129	<80
Stage 1 Hypertension	130-139	80-90
Stage 2 Hypertension	≥140	≥90

Reproduced from: Mancia G, Kreutz R, Brunström M, Burnier M, Grassi G, Januszewicz A, et al. 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). Journal of Hypertension. 2023;41(12):1874-2071. DOI: 10.1097/HJH.0000000000003480;

Virani SS, Newby LK, Arnold SV, Bittner V, Brewer LC, Demeter SH et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. 2023;148(9):e9-119. DOI: 10.1161/CIR.0000000000001168

A major risk factor for cardiovascular disease is isolated diastolic hypertension (IDH) which is defined as systolic BP <140 mmHg and a diastolic BP of ≥90 mmHg. This phenomenon is common in overweight and obese patients, particularly central obesity, and is more common in males than in females (Romero et al, 2021). In an observational study by Vidal-Petiot et al (2023), it was noted that a diastolic BP of 70-79 mmHg was associated with a much lower risk for cardiovascular complications such as stroke, myocardial infarction and death in comparison to a diastolic BP of 80-89 mmHg. A decrease in diastolic BP is associated with an overall risk reduction for cardiovascular disease in individuals with IDH (Suzuki et al, 2023).

Compared to office BP readings, the threshold for diagnosing hypertension using home blood pressure monitoring (HBPM) is lower. HBPM values are considered to be 5 mmHg lower than office BP values, therefore hypertension threshold for HBPM is ≥135/85 mmHg (Williams et al, 2018). The diagnostic BP threshold and target BP threshold recommended by different guidelines for HBPM are summarised in Table 1.2.

Table 1.2 - Hypertension Thresholds for HBPM according to Various Guidelines

Guidelines	Diagnostic BP threshold (mmHg)	Target BP threshold (mmHg)
American College of Cardiology/American Heart Association, 2017	≥130/80	<130/80
European Society of Cardiology/European Society of Hypertension, 2023	≥135/85	≤130/80
International Society of Hypertension, 2020	≥135/85	<135/85
Japanese Society of Hypertension, 2019	≥135/85	<125/75 (age < 75 years) or <135/85 (age ≥ 75 years)
National Institute for Care and Health Excellence, 2022	≥135/85 (age < 80 years) or ≥145/85 (age > 80 years)	<135/85 (age < 80 years) or <145/85 (age > 80 years)

Reproduced from: Kario K. Home blood pressure monitoring: current status and new developments. American Journal of Hypertension. 2021;34(8):783-94. DOI: 10.1093/ajh/hpab017

High-risk patients such as those with diabetes, chronic kidney disease, post-renal transplantation, heart failure, known cardiovascular and peripheral arterial disease must be initiated hypertensive treatment immediately if BP is elevated (Flack & Adekola, 2020). The Systemic Coronary Risk Evaluation (SCORE) is a computerised method designed to estimate the risk of developing a cardiovascular event within the next 10 years in high-risk or low-risk European countries. In 2021, European Guidelines made use of an updated version of SCORE, SCORE2, which calculates the 10-year risk of both fatal and non-fatal cardiovascular events in healthy patients aged 40-69 years having untreated

risk factors or risk factors that have been stable for many years. For elderly patients over 70 years, SCORE2-OP is available (Mancia et al, 2023b).

1.2 Primary Hypertension

Among the many cases of hypertension, 95% of these cases are identified as primary hypertension (PH) (Franco et al, 2022). PH is a result of a complex interaction between non-specific environmental and genetic factors. Endothelial dysfunction is the result of an imbalance between vasodilators and vasoconstrictors leading to an excessive increase in vasoconstrictor substances. Besides endothelial dysfunction, arterial stiffening must be considered in PH. Arterial stiffening is caused by dyslipidaemia, ageing or hypertension itself. Increase in oxidative stress is detrimental to PH (Litwin & Kułaga, 2021; Franco et al, 2022). Although rare in childhood, PH affects 11% of 18-year-olds. It is believed that PH in adolescents would have been pre-determined perinatally. PH in children and adolescents is characterised by multiple interrelated neuro-immuno-metabolic abnormalities (Litwin & Feber, 2020).

An increase in oxidative stress and a low total antioxidant capacity are typical features of many cardiovascular diseases including PH. Vitamin A, C, D and melatonin are amongst the antioxidants believed to have antihypertensive and vasoprotective effects (Franco et al, 2022). Vitamin D regulates hypertension by acting on the smooth muscle cells and endothelial cells. Activation of the renin-angiotensin-aldosterone system and abnormal regulation of nitric oxide are two mechanisms that have been proposed linking Vitamin D deficiency to cardiovascular risk (De la Guía-Galipienso et al, 2021). Although the exact mechanism of Vitamin C on the reduction of PH is not fully understood, it is believed that Vitamin C improves the activity of nitric oxide and improves endothelial

function in the branchial and coronary arteries (Guan et al, 2020). Randomised controlled trials on the effect of melatonin on hypertension are required, however it has been observed that controlled-release melatonin may reduce nocturnal BP by roughly 5/2 mmHg and improves the parasympathetic nervous system (Lee et al, 2022). This may have clinical relevance in those patients with uncontrolled nocturnal BP.

1.3 Secondary Hypertension

Epidemiology data has shown that around 10% of hypertensive patients suffer from secondary hypertension (SH). SH originates from a specific cause, thus requiring specific diagnostic approaches. SH is often associated with a high to very high risk of morbidity and mortality. The most common causes of SH include primary aldosteronism, pheochromocytoma, Cushing's syndrome and obstructive sleep apnoea (Pena-Hernandez et al, 2020; Rossi et al, 2020). Young patients under 40 years with grade 2 or 3 hypertension, history of hypertension in childhood, acute worsening of BP, sudden hypertensive crisis and severe hypertension in pregnancy (>160/110 mmHg) are suggestive features of secondary hypertension (Mancia et al, 2023b).

1.3.1 White Coat Hypertension

In 1984, Kleinert et al came up with the term 'white coat hypertension', referring to patients having a high BP reading in a medical environment and/or in the presence of a physician, but not during daytime ambulatory BP monitoring. If a patient's systolic and diastolic BP are ≥140/90 mmHg in a medical office but below 135/85 mmHg at home, then the patient can be diagnosed with white coat hypertension. The prevalence of white coat hypertension in the general population is between 9% to 23%, and 30% of the patients with an elevated office BP reading are diagnosed with white coat hypertension (Zhu et al, 2020). The occurrence of white coat hypertension is more common with increasing age, women and in non-smokers (Williams et al, 2018). According to the 2017 ACC/AHA guidelines, confirmation of white coat hypertension should be done by ambulatory blood pressure monitoring (ABPM) if a decision is taken not to treat or not to intensify treatment (Whelton et al, 2018). Extremely elevated office BP without signs of target organ damage and variability in office BP may be an indication of white coat hypertension (Wang et al, 2020; Huang et al, 2021b). The association between white coat hypertension and cardiovascular risk is unclear. Some evidence suggests that patients with white coat hypertension have a moderate cardiovascular risk. Other studies suggest that patients with white coat hypertension do not have any additional cardiovascular risks (Nuredini et al, 2020). Patients with white coat hypertension with low cardiovascular risk may not be prescribed treatment (Unger et al, 2020).

1.3.2 Masked Hypertension

Masked Hypertension is the opposite of white coat hypertension in which the BP of a patient is repeatedly normal in clinic visits but presents with raised BP during daytime or nighttime ambulatory BP reading. If the patient's BP reading is below 140/90mmHg in a medical office but ≥135/85 mmHg at home, then the patient can be diagnosed with masked hypertension (Wang et al, 2020). Risk factors for masked hypertension include young age, diabetes, obesity, excessive alcohol intake, smoking, stress and anxiety (Jordan et al, 2018; Cheng et al, 2022). Normal office BP reading in high risk patients with or without signs of target organ damage is a factor that can lead to masked hypertension (Huang et al, 2021b).

1.3.3 Resistant Hypertension

Resistant hypertension is defined as seated office BP higher than 140/90 mmHg. A patient with resistant hypertension is a patient who is on three or more antihypertensive medications including a diuretic and is compliant to the medications. Pseudoresistance (non-adherence to medication, suboptimal antihypertensive therapy and poor HBPM technique) must be excluded in order to properly diagnose a patient with resistant hypertension (Unger et al, 2020). Patients with resistant hypertension have a very high rate of target organ damage and cardiovascular disease especially in patients that suffer also from diabetes or chronic kidney disease. Patients with resistant hypertension have nearly 50% chance of suffering from myocardial infarction, stroke, heart failure, kidney failure or even death (Ebinger et al, 2023). Refractory hypertension is a subgroup of resistant hypertension and is more alarming than resistant hypertension. Refractory hypertension is defined as uncontrolled hypertension despite co-prescription of five or more antihypertensive drugs from different pharmacological classes (Matanes et al,

2022). The ISH guidelines recommend screening patients for secondary causes if resistant hypertension persists despite patient being on three or more antihypertensive treatments (Unger et al, 2020).

1.4 Risk Factors of Hypertension

Neurohormonal systems are responsible for ensuring adequate tissue and organ perfusion throughout the body. Modifiable and non-modifiable risk factors have an effect on the neurohormonal system resulting in elevation in BP (Litwin & Kułaga, 2021).

1.4.1 Modifiable Risk Factors

Prevalence of hypertension is not as low as usually perceived to be in young adults. Modifiable risk factors for hypertension have a big impact on hypertension and reduction strategies must be in place to reduce their prevalence (Mancia et al, 2023a). Incidence of hypertension increases in obese individuals (Litwin & Kułaga, 2021). A high salt diet, physical inactivity, tobacco and alcohol consumption are major contributors to the prevalence of hypertension (Wang & Lloyd-Jones, 2021). In a study carried out in Kenya, non-alcoholic drinkers had 70% less chance of suffering from hypertension compared to those who consume alcohol (Ondimu et al, 2019). Elevated high-density lipoprotein levels were associated with higher mortality in individuals with hypertension (Chen et al, 2023). Alteration in the microbial ecosystem may lead to horrible consequences on a patient's cardiovascular system as the gut's microbiota regulates BP via communication with the nervous system, endocrine system and immune systems (Naqvi et al, 2021). An association exists between work stress, occupational lead exposure, noise exposure and prevalence of hypertension (Kang, 2022).

Currently, no European country has a screening program in place for asymptomatic patients. In a study in North Alabama, America, 801 patients underwent biometric screening involving blood pressure, blood glucose and serum cholesterol measurement. From the total number of patients, 180 patients were considered high risk and were referred to a physician, out of which 5.6% had elevated systolic BP and 6.0% had elevated diastolic BP. The high prevalence of hypertension identified in this study highlights the importance of early detection and intervention (Brown et al, 2024).

1.4.2 Non-Modifiable Risk Factors

The prevalence of hypertension varies significantly between males and females throughout the lifespan. Hypertension is more common in males than in females, however females experience a sharper incline in BP from the age of 30 onwards. Females are at a higher risk of suffering from a number of adverse cardiovascular outcomes at a lower BP threshold compared to males. Incidence of hypertension increases with age, with sex hormones and interactions between the renin-angiotensin-aldosterone system being amongst the commonest mechanisms causing this increase in BP (Connelly et al, 2022). Ethnicity also plays a crucial role in the prevalence of hypertension. In a study carried out by Tomitani et al (2021) involving 1061 Japanese participants and 904 Thai participants, the Japanese had higher 24-hr BP levels, higher daytime BP readings and a greater morning surge compared with the Thai participants.

1.5 Reasons for Inadequate Control of Hypertension

The impact of undiagnosed hypertension may be underestimated by healthcare professionals. Patients may find it difficult to make an appointment with their healthcare professional. In certain instances, physicians are satisfied with the initial reduction in BP after initiating treatment despite not having reached the BP target. Combination therapy is preferred over monotherapy. Unsuccessful response to antihypertensive medications could be due to co-morbidities such as obesity, diabetes and dyslipidaemia (Mancia et al, 2023b).

Lack of compliance to antihypertensive medication is one of the main reasons for uncontrolled hypertension. Drug cost is a possible barrier whenever medication is not provided for free. In a study carried out by Schulz et al (2016) in Germany over a two-year period, 79.3% of all antihypertensive drug users were classified as non-persistent whereas 56.3% were classified as non-adherent. Diuretics resulted in the highest non-persistent and non-adherent rates, whereas the lowest rates were for beta-blockers. The asymptomatic nature of hypertension contributed to the lack of compliance to medication especially if side effects were experienced. Patients on angiotensin receptor blockers were twice as likely to be more adherent than patients on diuretics (Schulz et al, 2016). In a study carried out in Lithuania by Treciokiene et al (2022), out of 72,088 participants, 56% were initially started on monotherapy treatment, of which almost 49% were dispensed an angiotensin converting enzyme inhibitor, and the remaining 44% were started on combination therapy. After one year, 57% of the participants were non-persistent to treatment. Younger patients (≤39 years) had higher odds of treatment discontinuation. Lack of hypertension control is an additional economic burden on the public health settings due to increased hospitalization and increased visits to the emergency

department. Improving adherence and HBPM techniques should be a research priority (Mancia et al, 2023a).

1.6 Pharmacist Contribution in Hypertension Management

In recent years, the role of community pharmacists has evolved and the pharmacy services offered in community pharmacies have expanded. A study by Murry et al (2023) carried out in Ireland assessed the use of pharmacy services amongst adults aged 50 years and over. The study involved 5,782 participants, 55.5% were female and mean age was 68 years. Despite low use of non-dispensing services in Ireland, BP monitoring was the most requested service following requests for advice on medicines (Murry et al, 2023). Community pharmacists can assist patients in accurately measuring their BP since many patients purchase BP devices from the pharmacy. Pharmacists, having a good relationship with patients, are able to provide education on proper medication adherence, BP control and recommend referral where necessary (Tsuyuki et al, 2023).

In order to improve early detection and adequate control of hypertension, the German Cardiac Society and the Federal Union of German Associations of Pharmacists developed two guideline worksheets to screen patients with known or suspected hypertension. The worksheets were based on office BP criteria as defined by European Society of Cardiology/European Society of Hypertension (ESC/ESH) guidelines and offer a strategy plan depending on the severity and urgency of the measured BP values as summarised in Table 1.3 (Schulz et al, 2020). Evaluation of the implementation of these guidelines in 18 community pharmacies showed that about 64% of the participating pharmacies wanted to continue using the guideline worksheets. Some pharmacists suggested that this guideline-directed BP algorithm should be offered as a service against a small fee (Schulz et al, 2020).

Table 1.3 - Referral Guidelines in Community Pharmacies in Germany

(A) Screening for hypertension

<80 years	80 years and older	Recommendation (please tick)
>140 mmHg SBP ***or*** >90 mmHg DBP	>160 mmHg SBP ***or*** >90 mmHg DBP	☐ **Please, make an appointment with your physician within 4 weeks**
130–140 mmHg SBP ***or*** 85–90 mmHg DBP	130–160 mmHg SBP ***or*** 85–90 mmHg DBP	☐ **Please, repeat blood pressure measurements at least annually**
<130 mmHg SBP ***and*** <85 mmHg DBP	<130 mmHg SBP ***and*** <85 mmHg DBP	☐ **Please, repeat blood pressure measurements at least every 3 years**

(B) Patients with hypertension

<65 years	65 years and older	Recommendation (please tick)
>130 mmHg SBP ***or*** >80 mmHg DBP	>140 mmHg SBP ***or*** >80 mmHg DBP	☐ **Please, make an appointment with your physician within 4 weeks**
<120 mmHg SBP ***or*** <70 mmHg DBP	<120 mmHg SBP ***or*** <70 mmHg DBP	☐ **Please, at your next appointment, inform your physician**
120–130 mmHg SBP ***and*** 70–80 mmHg DBP	120–140 mmHg SBP ***and*** 70–80 mmHg DBP	☐ **Please, continue to measure your blood pressure regularly**

Reproduced from: Schulz M, Griese-Mammen N, Schumacher PM, Strauch D, Freudewald L, Said A, et al. Development and implementation of blood pressure screening and referral guidelines for German community pharmacists. The Journal of Clinical Hypertension. 2020;22(10):1807-16. DOI: 10.1111/jch.14020

In a randomised clinical trial by Moreira et al (2023) carried out in a Brazilian community pharmacy, the efficacy of HBPM within a collaborative drug therapy management (CDTM) was studied. Patients in the control group were given a BP monitor, an explanation on how to perform HBPM and the general practitioner made any necessary changes in the treatment based on the BP values obtained from HBPM. In the intervention group, participants were given a HBPM device and were enrolled in a CDTM protocol with a pharmacist. The pharmacist made recommendations to the prescriber regarding any necessary antihypertensive drug therapy changes. In this study, combining HBPM with CDTM favoured the deprescribing of antihypertensive drugs in overly treated elderly patients. Deprescribing improved medication adherence and reduced medication

burden. Systolic BP in the intervention group reduced significantly compared to the control group (Moreira et al, 2023).

In a study carried out in Shahid Madani Heart Centre in Iran by Khiali et al (2021), 126 patients were randomly divided into two groups, usual care group and pharmacist-led group. In the usual care group, the cardiologist checked the BP of the patients using a mercury sphygmomanometer twice weekly, Monday and Wednesday. In the pharmacist-led group, patients were trained on how to properly use a HBPM device and were asked to use the device in front of the investigator to ensure that the patient is adopting the right technique. The pharmacist kept in touch with the patients through a weekly phone call. An improvement in systolic BP was seen in the first month, but not in the third and sixth month for both groups. Despite improvement in BP control, the study failed to achieve statistical significance in mean BP difference in both groups (Khiali et al, 2021).

Positive influence by pharmacists on medication adherence of antihypertensive medication was demonstrated in a study by Golna et al (2023) in Greece, in which 23.7% of the participants suffered from hypertension. Over a span of four months, pharmacist reminders and advice to patients had a positive impact on medication adherence in all patients on antihypertensive treatment. Improved medication adherence was demonstrated in patients whose treatment involves more than two tablets daily (Golna et al, 2023). This positive improvement in medication adherence was noted in another study by Spears et al (2020) in America. This study involved a pharmacist-led adherence program involving motivational interviews for changes in behaviour. An improvement in adherence to antihypertensive, antihyperlipidaemic and antidiabetic drugs was noted at the end of the study. In a randomised control trial by Paudel et al (2023), better quality of

life, improved medication adherence and BP control were noted in Nepal, a poor income country, within 4 months of pharmacist intervention.

In a study by Hias et al (2024), patients were given an appointment with a pharmacist at a hypertension clinic at the University Hospital in Leauven, Belgium. Improvement in participants was noted, hence inclusion of a pharmacist in this hypertension clinic was proposed as a valuable addition to the team to provide patient education, optimise medication regimens and adherence. A clinical pharmacist was successfully added to the hypertension team (Hias et al, 2024).

In the United States, pharmacists carry out medication therapy management (MTM) with patients to improve patient outcome such as increased medication adherence, avoidance of drug related side effects and improvement of clinical outcomes in chronic conditions such as hypertension. MTMs provide long-term health and social benefits. Current reimbursement models may not encourage pharmacists to devote sufficient time to providing comprehensive MTM services, especially in a number of European countries (Schultz et al, 2021).

1.7 Office Blood Pressure Monitoring

Traditionally, diagnosis of hypertension has been made by office BP measurements (Siddique et al, 2021). The accuracy of BP readings is dependent on various factors such as device type, measurement technique, and user-related factors (Albuquerque et al, 2020). In 1898, the Italian physician Scipione Riva-Rocci introduced the cuff-based sphygmomanometer which paved way for the measurement of systolic BP. In 1905, the Russian military physician Nikolai Korotkov extended Riva-Rocci's method by describing the auscultatory measurement, which made both systolic and diastolic BP readings feasible (Brown, 1989; Panula et al, 2023). Sphygmomanometers have evolved from mercury to aneroid, to hybrid and eventually to oscillometric devices (Siddique et al, 2021).

Even though office BP measurement is the most used method for BP monitoring and management, it does not consider any fluctuations in BP levels due to the intrinsic dynamic behavior of BP (Stergiou et al, 2021; Schutte et al, 2022). BP levels taken at home are at times lower than BP levels taken in the clinic. Office BP readings are known to be the subject to white coat hypertension as a consequence of patient anxiety attributed to healthcare settings (Schutte et al, 2022). The inability to diagnose masked hypertension is another drawback of office BP. Observer errors contribute to inaccurate readings of office BP. Incorrect interpretation of Korotkoff sounds as a result of poor hearing or confusion in auditory sounds is the main cause of observer errors in office BP. Drawbacks of office BP measurement have paved the way for development of out-of-office devices such as HBPM and ABPM devices (Siddique et al, 2021).

1.8 Out-of-Office Blood Pressure Monitoring

The use of out-of-office BP measurements was recommended by the 2017 ACC/AHA guidelines (Whelton et al, 2018) and is recommended to date by the 2023 ESC/ESH guidelines (Mancia et al, 2023b) to confirm a diagnosis of hypertension and to efficiently alter antihypertensive medications. Out-of-office BP readings have a stronger association with target end-organ damage and cardiovascular disease events compared to office BP readings. The 2018 Chinese guidelines recommend the use of out-of-office BP monitoring to evaluate the effect of BP-lowering medication and to diagnose white coat hypertension and masked hypertension (Liu et al, 2019).

1.8.1 Ambulatory Blood Pressure Monitoring

The first ABPM device was developed in 1962 (Lo et al, 2021). An ABPM device typically makes use of oscillometric technology performed over a period of 24 hours, although longer monitoring times have been performed (Cepeda et al, 2023). ABPM has become a very important technique for the diagnosis of hypertension, assessment of cardiovascular risk and therapeutic drug monitoring since it provides a 24-hour profile, including daytime and nighttime readings. The study of BP response to the circadian rhythm and environmental changes can be studied with ABPM (Cheng et al, 2022). Due to fluctuations in BP throughout the day and night, ABPM is a better predictor of cardiovascular outcomes and mortality compared to a single office visit (Kwon et al, 2020), an observation that was already included in the Canadian hypertension guidelines in 1999 (Myers et al, 1999). Nighttime BP is six times more informative for cardiovascular morbidity and death in comparison with office systolic BP (Angeli et al, 2023). The possibility of initiating antihypertensive therapy due to falsely elevated BP reading is reduced with ABPM. A confirmatory ABPM reading is required after 3 months

of first white coat hypertension diagnosis and repeated after 6 months (Dadlani et al, 2019).

In a study carried out in Ghana by Nsutebu et al (2020) which involved 253 patients, 19.5% were diagnosed white coat hypertension and 16.1% were diagnosed with masked hypertension when given an ABPM device for 24 hours. Mean arterial pressure (MAP) and pulse pressure (PP) are also calculated during ABPM. MAP is the average arterial pressure during one cardiac cycle and a MAP between 65 mmHg and 70 mmHg is ideal to ensure adequate organ perfusion pressure throughout all organs (Hernandez et al, 2022). PP is the numerical difference between systolic and diastolic BP readings. A high PP is an indication of stiff arterial walls and is linked with major cardiovascular events, while low PP indicates that insufficient blood is being pumped out of the heart with each heartbeat (Angeli et al, 2023).

An elevated nighttime BP is an indication of organ damage which may lead to death. Nighttime ambulatory systolic BP gives more information regarding cardiovascular death rates than clinic systolic BP and twice more informative than daytime ambulatory systolic BP (Liuzzo & Volpe, 2023). Twenty four-hour systolic BP readings were found to be very strongly associated with all-cause death compared with office systolic BP readings in a study carried out at 223 primary care centers from all over Spain involving 59,124 patients. All-cause death was high in patients suffering from masked hypertension and sustained hypertension, possibility of cardiovascular death was high in patients with masked hypertension (Staplin et al, 2023).

During ABPM patients are encouraged to keep a diary card, perform normal daily activities (except bathing) and relax the arm during inflation of the cuff. To obtain a satisfactory ABPM, the measurements must be taken at least every 30 minutes through a 24-hour period, 20 valid daytime and 7 nighttime readings are recorded, and 70% of the 24-hour readings are valid (Sanchez et al, 2020). Thresholds for hypertension diagnosis using ABPM are a 24-hour average of ≥130/80 mmHg, daytime average of ≥135/85 mmHg and nighttime average of ≥120/70 mmHg (O'Brien et al, 2018). According to the 2017 ACC/AHA guidelines, an office BP of 120/80 mmHg is equivalent to 120/80 mmHg daytime ABPM reading, 100/65 mmHg nighttime ABPM reading and 115/75 mmHg in a 24-hour ABPM reading (Dadlani et al, 2019). According to the Jackson Heart Study carried out in America, an office systolic BP reading of 140 mmHg was equivalent to 138 mmHg daytime ABPM reading, 129 mmHg nighttime ABPM reading and 134 mmHg in a 24-hour ABPM reading (Ravenell et al, 2017). Comparison of office BP readings and HBPM readings with ABPM readings are summarised in Table 1.4.

Table 1.4 - Comparison of Office BP readings, HBPM and ABPM readings

	Home blood pressure (mmHg)	Office blood pressure (mmHg)	Ambulatory blood pressure (mmHg)		
			24-h	Day	Night
ACC/AHA 2017 thresholds					
Stage 1 hypertension	130/80	130/80	125/75	130/80	110/65
Stage 2 hypertension	135/85	140/90	130/80	135/85	120/70
Severe hypertension	145/90	160/100	145/90	145/90	140/85
ESH 2023 thresholds					
Hypertension	≥135/85	≥140/90	≥130/80	≥135/85	≥120/70
NICE 2022 thresholds					
Stage 1 hypertension	135/85 - 149/94	140/90 - 159/99		135/85 - 149/94	
Stage 2 hypertension	≥150/95	160/100 - <180/120		≥150/95	
Stage 3 hypertension		≥180/120			

Adapted from: Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C et al. 2017 ACC/ AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2018; 138(17):e484–594. DOI: 10.1161/CIR.0000000000000596;

Mancia G, Kreutz R, Brunström M, Burnier M, Grassi G, Januszewicz A, et al. 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). Journal of Hypertension. 2023;41(12):1874-2071. DOI: 10.1097/HJH.0000000000003480;

National Institute for Health and care Excellence (NICE). Hypertension in adults: diagnosis and management [Internet]. London: NICE; 2023 [cited 2024 May 31]. Available from URL: https://www.nice.org.uk/guidance/ng136/chapter/recommendations

The uniqueness of ABPM is its ability to quantify a patient's dipping status. Non-dipping of nocturnal hypertension is a result of improper control of BP and is an indication of cardiovascular and cerebrovascular risk (Kwon et al, 2020; Angeli et al, 2023). Nighttime systolic and diastolic BP should decrease by 10% to 20% from daytime BP. In a study carried out in Hong Kong by Lo et al (2021), it was demonstrated that non-dippers have an inferior prognosis in major adverse cardiovascular events (MACE), coronary events and all-cause mortality. Reverse dipping (or riser pattern) is associated with the highest risk of fatal stroke and haemorrhagic stroke. Isolated nocturnal hypertension, in which BP is optimal during the daytime but elevated at nighttime is a special form of masked hypertension. Extreme dippers are patients whose nighttime BP decreases by more than 20% in comparison to daytime BP. Extreme dipping results in nocturnal hypoperfusion which can lead to organ damage (Cheng et al, 2022).

Zhu et al (2024) assessed the differences in 24-hour ambulatory, daytime and nighttime systolic BP in patients with uncontrolled BP in Bangladesh, Pakistan and Sri Lanka. Compared to Sri Lanka, 24-hour ambulatory, daytime and nighttime systolic BP were higher in Bangladesh. No significant difference was observed between the findings in Pakistan and Sri Lanka. Systolic BP was the highest in Bangladesh, followed by Pakistan and Sri Lanka. From this study, it was concluded that 24-hour ABPM must be mitigated to overcome cardiovascular risk, particularly in Bangladesh.

Despite the many advantages of ABPM over office BP monitoring, there are also limitations. In a study carried out in Ghana it was noted that the use of ABPM in low/middle-income regions is hindered by the lack of expertise in interpreting ABPM reports and the cost of the service (Nsutebu et al, 2020). Patients who find ABPM devices burdensome or experienced disrupted sleep during monitoring are more likely to refuse another ABPM testing in the future. Patients, especially younger patients, may feel embarrassed to wear the ABPM monitor in public which could be a reason for patients refusing ABPM (Omboni et al, 2023). The advantages and limitations of ABPM are summarised in Table 1.5.

Table 1.5 - Advantages and Disadvantages of ABPM

Advantages	Disadvantages
Assesses BP during daily activities	May cause bruising
Confirms resistant or uncontrolled hypertension	May cause discomfort especially during sleep
Detects hypotension	Patients may be reluctant to use
Detects nocturnal hypertension and non-dippers	Rather expensive
Detects white coat hypertension or masked hypertension	
Determines 24-hour antihypertensive drug efficacy	
Objective results over 24 hours	
Stronger predictor of cardiovascular morbidity and mortality	

Reproduced from: Sanchez RA, Boggia J, Penaherrera E, Barroso WS, Barbosa E, Villar R, et al. Ambulatory blood pressure monitoring over 24 h: A Latin American Society of Hypertension position paper—accessibility, clinical use and cost effectiveness of ABPM in Latin America in year 2020. Journal of Clinical Hypertension. 2020;22(4):527-43. DOI: 10.1111/jch.13816

Use of ABPM in children and adolescents has significantly increased since publication of the AHA guideline on paediatric ABPM in 2014. Adolescents ≥13 years of age should have an office BP reading of <130/80 mmHg and an average 24-hour ABPM reading of <125/75 mmHg. Hypertension during childhood remains one of the major risk factors for the development of heart disease in adulthood (Flynn et al, 2022).

1.8.2 International Community Pharmacy-driven ABPM Service

Since 2015, the United States Preventive Task Force has made recommendations to screen adults over 18 years for hypertension and confirm any suspicion or initial diagnosis of hypertension using an ABPM device in line with NICE guidelines (Jones et al, 2020; Pena-Hernandez et al, 2020). The most cited barrier to ABPM in the United States is accessibility, which is contrary to the situation in the United Kingdom where ABPM services are offered in community pharmacies.[2] A study carried out by Dixon et al (2020) in Virginia was the first study to develop, evaluate and possibly implement ABPM in community pharmacy in the Unites States. Out of the 52 patients who enrolled in the study, 46 patients had satisfactory readings with at least 20 morning readings and 7 evening readings. Participants were satisfied with service provided by the pharmacist and agreed that the service should be implemented in community pharmacies. The importance of a pharmacy-driven ABPM service is important for patients who have BP phenotypes requiring changes in therapy and further monitoring, such as sustained hypertension (Dixon et al, 2020).

[2]National Health System (NHS). NSH Community Pharmacy Blood Pressure Check Service [Internet]. United Kingdom [cited 2024 May 31]. Available from URL: https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-blood-pressure-check-service

Between 2007 and 2013, ABPM data from 46,978 patients attending primary care were compared with 1,698 attending community pharmacies in Dublin, Ireland. Patients recruited from primary care and those recruited from the pharmacies had similar characteristics. Twenty percent of the patients from both primary care and pharmacies were diagnosed with white coat hypertension, with potential for considerable cost savings resulting from reduced prescribing of antihypertensive drugs. In pharmacies, white coat hypertension was more prevalent in men, whereas in primary care it was more prevalent in women. Dipping of hypertension was more common in pharmacies than in primary care. It is evident that the demand for ABPM is high, therefore this service should be available in the primary care and in community pharmacies. The results of this study demonstrated the feasibility of providing ABPM in community pharmacies. Patients were satisfied with the pharmacy service especially due to the flexible pharmacy opening hours. Some community pharmacies have invested in 24-hour ABPM machines and results are received by the physician working within the pharmacy (James et al, 2014).

Italian community pharmacies have introduced 24-hour ABPM with medical telereporting and telecounseling with the aim to offer better hypertension screening to a greater number of patients. The Telemonitoring of Blood Pressure in Local Pharmacies (TEMPLAR) project was set up, in accordance with the Italian regulations, to analyse the feasibility of 24-hour ABPM performed in Italian pharmacies. The study involved 11,080 participants from the northern regions and 6,186 from the southern regions. The data obtained from the ABPM readings were uploaded on a reliable telemedicine web platform after the ABPM device was removed. This allows the physician to access the patient's readings, and if necessary the physician is able to contact the pharmacist to provide the necessary counselling on the patient's antihypertensive management especially in those patients diagnosed with white coat hypertension and masked hypertension. The results of

this study support the recommendations that ABPM should be available in community pharmacies provided that such testing is offered after community pharmacists have been properly trained (Omboni et al, 2019).

1.8.3 ABPM in Special Populations

A study was carried out in Germany to determine the extent of hypertension control in patients with type II diabetes in a real-world clinical setting. BP control can be adequately controlled due to the readily available ABPM devices to primary care physicians. Secondary hypertension was the exclusion criteria for the study. For the patient's BP to be considered controlled, mean ABPM had to be below 130/80 mmHg, daytime BP below 135/85 mmHg and nighttime BP below 120/70 mmHg. Only 13.9% of 919 patients whose ABPM data was available had controlled hypertension according to ABPM results. A bit less than 20% of the patients were diagnosed with uncontrolled BP despite being on four or more antihypertensive medications. ABPM was found to be greatly important in diagnosing masked and isolated hypertension in type II diabetics (Mengden et al, 2017).

Masked hypertension is common amongst patients with diabetes mellitus (DM). Almost half of diabetic patients, despite having office BP readings within range, have ambulatory BP values within the hypertension range, indicating the presence of masked hypertension. High nocturnal BP and a very high morning BP surge are common in patients suffering from both hypertension and type II DM. An increase of 10 mmHg in nighttime systolic BP is associated with a 35% increase risk of cardiovascular events. An elevated 24-hour PP is also associated with a high risk of cardiovascular events in diabetic patients (Kario et al, 2020). In a trial involving African Americans, empagliflozin greatly reduced 24-hour ambulatory systolic BP by weeks 12 and 24 versus placebo (Ferdinand et al, 2019). Adequate ABPM readings are an important therapeutic target since it has been shown that

ABPM is a better predictor of cardiovascular events than office BP, even in patients with DM (Kario et al, 2020).

Early detection of hypertension may be useful at diagnosing Parkinson's Disease (PD) at the early motor or premotor stages. Thirty-two participants were included in a study by Shen et al, 2022 in Shanghai. The participants were divided into two groups, early PD and advanced PD group. Reverse dipping was higher (81.0%) in the advanced PD group than that in the early PD group (36.4%). Both nighttime systolic and diastolic BP were higher in the advanced PD group than in the early PD group. Results reflect the impaired autonomic nervous system in the advanced PD patients. Abnormal BP regulation in PD patients should be given priority and diagnosed early in order to carry out the necessary interventions to prevent serious clinical complications (Shen et al, 2022).

Metabolic syndrome is closely related with ambulatory BP, where patients with metabolic syndrome have double the risk of developing hypertension. Masked hypertension, abnormal nighttime BP dipping and exaggerated morning surge are common in metabolic syndrome, therefore patients must be monitored for adequate 24-hour BP control (Huang et al, 2021a). In the Jackson Heart Study carried out in America, out of 359 participants, 62.3% of the participants with metabolic syndrome were diagnosed with masked hypertension (Colantonio et al, 2017).

1.8.4 Home Blood Pressure Monitoring

The use and recognition of HBPM has increased drastically over the last 20 years (Kario, 2021). HBPM is an effective and practical approach for the diagnosis of BP, likely to be free from environmental/emotional stress unlike office BP monitoring (Wang et al, 2022). The use of HBPM devices is recommended in the 2017 ACC/AHA guidelines (Whelton et al, 2018), 2020 ISH guidelines (Unger et al 2020), and current NICE[1] and ESC/ESH (Mancia et al, 2023b) guidelines to monitor treatment response, assess white coat hypertension, and diagnose masked hypertension. According to the ISH guidelines, when diagnosing hypertension BP should be measured in both arms. If a consistent difference of >10 mmHg is observed between the two arms, the arm showing the higher BP readings should be used and referral to a physician should be considered (Unger et al, 2020). One of England's National Health System (NHS) initiatives was the distribution of HBPM devices, with the sole intention to support patient wellbeing at home. Since October 2020, the NHS has distributed over 220,000 BP monitors around England.[3]

Guidelines recommend the use of automated devices with upper-arm cuffs instead of wrist or finger devices for HBPM (Andraos et al, 2021). Measurements obtained are inaccurate if a wrist device is not placed at the level of the heart or if the wrist is flexion or hyperextension position (Ihm et al, 2022). Finger oscillometric BP monitors are not recommended for BP self-monitoring as BP measured on a finger is very different to that measured in the upper arm (Wang et al, 2020).

[1]National Institute for Health and Care Excellence (NICE). Hypertension in adults: diagnosis and management [Internet]. London: NICE; 2023 [cited 2024 May 31]. Available from URL: https://www.nice.org.uk/guidance/ng136/chapter/recommendations

[3]National Health System (NHS). Home blood pressure monitoring [Internet]. United Kingdom [cited 2024 May 31]. Available from URL: https://www.england.nhs.uk/ourwork/clinical-policy/cardiovasculard/home-blood-pressure-monitoring/

HBPM uses similar technology to ABPM, however HBPM allows patients to monitor their BP at a time that suits them and is more practical and inexpensive (Kario, 2021). Even though ABPM is the gold-standard measurement, ABPM and HBPM are complementary approaches, and the interchangeability of the two monitoring techniques provide great versatility in the clinical application of out-of-office BP monitoring (Huang et al, 2021b; Angeli et al, 2023). HBPM is strongly recommended in cases where ABPM is not available or not well tolerated (Cepeda et al, 2023). The Japanese guidelines state that in cases of differences between OBPM and HBPM, HBPM-based diagnosis should be favoured (Umemura et al, 2019). The HONEST study proved that morning elevated BP determined by HBPM is a better predictor of future occurrence of cardiovascular events than OBPM (Kario et al, 2016). A home systolic BP <125 mmHg is associated with the lowest risk of cardiovascular disease events in patients suffering from hypertension and DM or have a history of stroke (Kario et al, 2019). A reduction of 2 mmHg reduces the perceived diastolic hypertension prevalence by 17% (Campbell et al, 2020).

A study carried out in France determined that, from a total of 2,054 participants, one in five participants who took part in this study possessed a HBPM device. Hypertensive patients were more likely to own a HBPM device compared to normotensive patients. Patients aware that they suffer from hypertension and own a HBPM device were better treated by their physicians compared to participants who did not have a HBPM device (Vallée et al, 2020). The advantages and limitations of HBPM are summarised in Table 1.6. Despite the advantages of HBPM, only one-quarter of US adults report HBPM (Bellows et al, 2022).

Table 1.6 - Advantages and Disadvantages of HBPM

Advantages	Limitations
Better predictor of cardiovascular events than office BP	Accuracy of automated oscillometric devices in the presence of arrhythmias are questionable
Eliminates observer error	Certain devices on the market have not been validated for accuracy
Good acceptance by patients	May lead to too frequent monitoring
Greater association with organ damage than office BP	Measurements do not reflect BP during usual daily activities
Identifies white coat hypertension and masked hypertension	Need for training
Improves BP control	Nocturnal BP detection is limited
Improves compliance with hypertensive medications	Readings during physical activity and during sleep are not possible
Improves hypertension awareness	Recording bias
More reproducible than office BP	Some patients may decide to self-modify their drug treatment plan without consulting a doctor
Multiple daily measurements can be taken	
Not outside the usual environment of the individual	

Reproduced from: Stergiou GS, Kario K, Kollias A, McManus RJ, Ohkubo T, Parati G, et al. Home blood pressure monitoring in the 21st century. Journal of Clinical Hypertension. 2018;20(7):1116-21. DOI: 10.1111/jch.13284

Patients must be educated on the importance of choosing a validated device and on its appropriate use. Obsessive use of HBPM devices is strongly discouraged. Patients must understand the importance of not altering their antihypertensive medications without consulting a physician (Andraos et al, 2021; Kario, 2021). For diagnosis and before every office visit, the ESH recommends BP monitoring for 7 consecutive days (never for less than 3 days), morning before breakfast, drug intake and vigorous activity, and before going to bed, 2 hours after dinner. Two readings must be taken, with 2 minutes between each reading (Stergiou et al, 2021; Mancia et al, 2023b). This is often referred to as the "722" protocol, 2 measurements in 1 occasion, 2 occasions a day over 7 consecutive days (Lin et al, 2022). Education on the proper technique of HBPM is essential for accurate BP readings (Unger et al, 2020). Improper HBPM technique leads to variability in BP as summarised in Table 1.7. Acute alcohol, caffeine use, nicotine use or exposure and bladder distension also inaccurately increase systolic and diastolic BP (Kallioinen et al, 2017).

Table 1.7 - Changes in BP due to Improper HBPM Technique

Improper HBPM technique	Range of change in systolic/diastolic blood pressure
Cold environment	+5 to +32/+4 to +23
Insufficient rest	+4.2 to +11.6/+1.8 to +4.3
Legs crossed at knee	+2.5 to +14.9/+1.4 to +10.8
Unsupported back	0/+6.5
Unsupported arm	+4.9/+2.7 to +4.8
Talking during measurement	+4 to +19/+5 to +14.3
Fast deflation rate	-9 to -2/+2.1 to +6.3
Arm lower than heart level	+3.7 to +23/+2.8 to +12

Reproduced from: Kallioinen N, Hill A, Horswill MS, Ward HE, Watson MO. Sources of inaccuracy in the measurement of adult patients' resting blood pressure in clinical settings: a systematic review. Journal of Hypertension. 2017;35(3):421. DOI: 10.1097/HJH.0000000000001197

The future of HBPM devices involves the development of validated non-invasive cuff-less BP monitoring, as well as devices able to monitor temperature and environmental conditions, and BP monitors able to generate data to inform systems of artificial intelligence (Kario, 2021).

All three BP techniques are essential for adequate control of BP. All three techniques have their advantages and disadvantages. Comparison of the characteristics of office BP monitoring, HBPM and ABPM are summarised in Table 1.8.

Table 1.8 - Comparison of the three BP Techniques

	OBP	**ABPM**	**HBPM**
Cost	Low	High	Low
Hypertension diagnosis thresholds	140/90 mmHg	24h: 130/80 mmHg Day: 135/85 mmHg Night: 120/70 mmHg	135/85 mmHg
Improvement in patient involvement and adherence	No	No	Yes
Nighttime blood pressure	No	Yes	No
Operator dependency	Yes	No	No
Patients' acceptance	Good	Sometimes poor	Usually good
Reproducibility	Poor	Good	Good
White coat effect	Yes	No	No

Reproduced from: Sanchez RA, Boggia J, Penaherrera E, Barroso WS, Barbosa E, Villar R, et al. Ambulatory blood pressure monitoring over 24 h: A Latin American Society of Hypertension position paper—accessibility, clinical use and cost effectiveness of ABPM in Latin America in year 2020. The Journal of Clinical Hypertension. 2020;22(4):527-43. DOI: 10.1111/jch.13816

1.9 Validation of BP devices

In Europe, for a BP device to be placed on the market, a conformity assessment must be carried out by a Notified Body. A conformity assessment usually involves an audit of the manufacturer's quality system and a review of the technical documentation regarding the performance and safety of the product. The device must pass the conformity assessment for it to be granted a Conformité Européenne (CE) mark and must clearly bear the CE mark for it to be placed on the market to be used for its intended purpose. Since May 2021, all manufacturers must comply with the Medical Device Regulation prior to placing new medical devices on the market. European Member States will only allow a medical device to be placed on the market if this does not compromise the health and safety of the patients and achieves the performances intended by the manufacturer. Clear instructions on how to use the medical device must be provided. After undergoing the relevant testing by the Notified Body, an identification number to each approved product must be affixed. Any batch failing to conform to the Regulation is not placed on the market. In the post-production phase, the manufacturer must keep an up-to-date systematic procedure regarding the experience gained about the medical device placed on the market and, where necessary, take corrective actions.[4]

Devices for BP measurement must be reliable and accurate and only devices that are validated by an established protocol should be used (Lee et al, 2024). There are over 3,000 commercially available BP monitors, however only 6% to 15% are validated (Picone et al, 2020). Published data regarding accuracy is not available for many of these devices. Inaccurate BP monitors lead to inaccurate hypertension diagnosis, drug treatment and

[4]European Medicines Agency (EMA). Medical Devices [Internet]. Netherlands [cited 2024 May 31]. Available from URL: https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

management on an international scale (Sharman et al, 2020). Investigators independent of the manufacturer must carry out validation testing of BP monitors and must be adherent to an international standardised validation protocol. Formal clinical validation for BP devices to be placed on the market is not obligatory in all countries. As a result, only 20% of the devices available have undergone validation by established protocols (Stergiou et al, 2018).

International scientific organisations, such as the Advancement of Medical Instrumentation, British Hypertension Society and European Society of Hypertension Working Group on BP monitoring have developed protocols for the validation of automated BP monitors. Comparison of methodological and technical differences between the ESH-International Protocol (ESH-IP) and American National Standards Institute/ Advancement of Medical Instrumentation/International Organisation for Standardization (ANSI/AAMI/ISO) are summarised in Table 1.9. Validation results must be published in a peer-review journal (Picone et al, 2020). Organisations such as Hypertension Canada, STRIDE BP®, British and Irish Hypertension Society (BIHS), Validated Device Listing™ (VDL), Deutshce Hochdruckliga (German Hypertension League) and Japanese Society of Hypertension (JSH) provide online lists of validated BP monitors as summarised in Table 1.10 (Stergiou et al, 2021). Use of these organisations is encouraged in the ESH guidelines (Mancia et al, 2023b).

Table 1.9 - Comparison of methodological and technical differences between ESH-International Protocol and American National Standards Institute/ Advancement of Medical Instrumentation/International Organization for Standardization

	ESH-IP	ANSI/AAMI/ISO
Efficacy Measure	Similar level of device accuracy required by both. Estimated probability of error is 85% (equivalent to ≤ 10mmHg). This level of accuracy is realistic but not ideal.	
Sample Size	33 participants	85 participants – this results in a better study power and sensitivity but is more costly.
General and Special Populations	General population for adults aged 25 years or over. Carries out a separate study for special populations such as pregnancy.	General population over 12 years, then an additional 35 participants for every special population. Forty-five pregnant women required.
Reference BP Measurements	Mercury sphygmomanometer	Any manometer with a maximum error of ± 1mmHg.
Method for comparison between test device with reference measurements	Same-arm sequential BP measurement procedure.	
Limb size and cuffs	Only special groups such as obese.	Requires a certain number of participants per cuff size.
Ambulatory monitors and stress testing	N/A	Presents requirements for ABPM devices and devices for exercise stress testing.
Pass Criteria	Pass/fail criteria for individual BP readings and individual participants based on the number of readings with absolute test-reference BP differences ≤ 5, 10, 15 mmHg.	Pass/fail criteria for individual BP readings and individual participants based on mean BP difference and their standard deviations.

Adapted from: Stergiou GS, Alpert BS, Mieke S, Wang J, O'Brien E. Validation protocols for blood pressure measuring devices in the 21st century. Journal of Clinical Hypertension. 2018;20(7):1096-9. DOI: 10.1111/jch.13294

STRIDE BP® is an international device listing non-profit organisation, unlike the majority of the rest of the organisations which are only national, with the sole intention to improve BP measurement by providing a list of accurate office, home and ambulatory BP monitors. STRIDE BP® works with the ESH, ISH and the World Hypertension League. STRIDE BP® gathers all validation studies of BP monitors published in PubMed that have been carried out using an established protocol. For every validation of a device a vigorous review is performed and "STRIDE BP® Validation Study Checklist Report" is developed. The office, home and ambulatory devices listed on the STRIDE BP® are the only ones that have passed the STRIDE BP® review process. STRIDE BP® provides a list of preferred devices; namely upper-arm cuff monitors, have had a validation study published within the past 10 years and in case of HBPM devices have automatic data storage (Picone et al, 2020). STRIDE BP® provides a different list of devices which should be used in children and pregnancy unlike any other international device listing organisations. Reasons for rejection of validation studies by STRIDE BP® include insufficient sample size, inadequate reference device and inadequate data analysis (Stergiou et al, 2019).

Table 1.10 - Comparison of Current Device Listings Organisations

Organisation	National/International	Comment
STRIDE BP®	International	1. Accepts AAMI/ISO, British Hypertension Society (BHS) and ESH protocols 2. Has different sections on home, office, ambulatory, children and pregnancy 3. Joint initiative of the ESH, ISH and World Hypertension League
dabl Education Trust	International	1. Considers AAMI/ISO protocol as questionable. Accepts BHS and EHS protocols.
MEDAVAL	International	1. Not affiliated with a specific organization 2. Contains information on BP monitors, blood glucose monitors and pulse oximeters.
Hypertension Canada	National: Canada	1. Accepts the AAMI/ISO, BHS and ESH protocols 2. Ranks devices into gold or silver status
German Hypertension League	National: Germany	1. German language only
JSH	National: Japan	1. Japanese language only
BIHS	National: UK/Ireland	1. Provides a separate list for home use and specialist use 2. Provides a list of devices that have failed validation 3. Accepts the BHS or ESH protocol
VDL	National: USA	1. Accepts AAMI/ISO and BHS protocols 2. Initiative of the American Medical Association

Reproduced from: Padwal R, Berg A, Gelfer M, Tran K, Ringrose J, Ruzicka M, et al. The hypertension Canada blood pressure device recommendation listing: empowering use of clinically validated devices in Canada. The Journal of Clinical Hypertension. 2020;22(5):933-6. DOI: 10.1111/jch.13868

1.10 Research Question, Aims and Objectives

The research question was: how can community pharmacists contribute to BP monitoring?

The aims of the research were to identify pharmacist-led contributions in patient empowerment of BP self-monitoring and the application of ABPM in community pharmacies.

The objectives were to:

1) Appraise HBPM and ABPM devices,

2) Propose pharmacist interventions supporting patient empowerment of BP self-monitoring,

3) Assess feasibility of introducing ABPM in community pharmacies.

Chapter 2

Methodology

2.1 Study design

The study design consisted of three phases (Figure 2.1). In the first phase of the study, HBPM and ABPM devices available on the local market were analysed and compared, and accessibility on the local market was appraised.

In the first part of the second phase, a data collection sheet intended to assess patient practice of BP self-monitoring and an action plan to facilitate patient empowerment were developed and validated. Reliability testing of the data collection sheet and action plan was undertaken. The second part involved implementation of the data collection sheet and action plan in four community pharmacies chosen by convenience sampling, and 30 participants from each pharmacy above the age of 18 years, diagnosed with hypertension and taking at least one antihypertensive medication were recruited by convenience sampling. Each participant's BP was measured, and a flow chart explaining correct HBPM techniques was used during the patient session.

For the third phase of the study, 10 participants from phase 2 of the study (newly diagnosed with hypertension, recent change in medication and/or dose, or patient reported non-compliance to management of hypertension) were recruited by purposive sampling and given an ABPM device identified in phase 1. The feasibility of ABPM within a collaborative practice in community pharmacies was analysed.

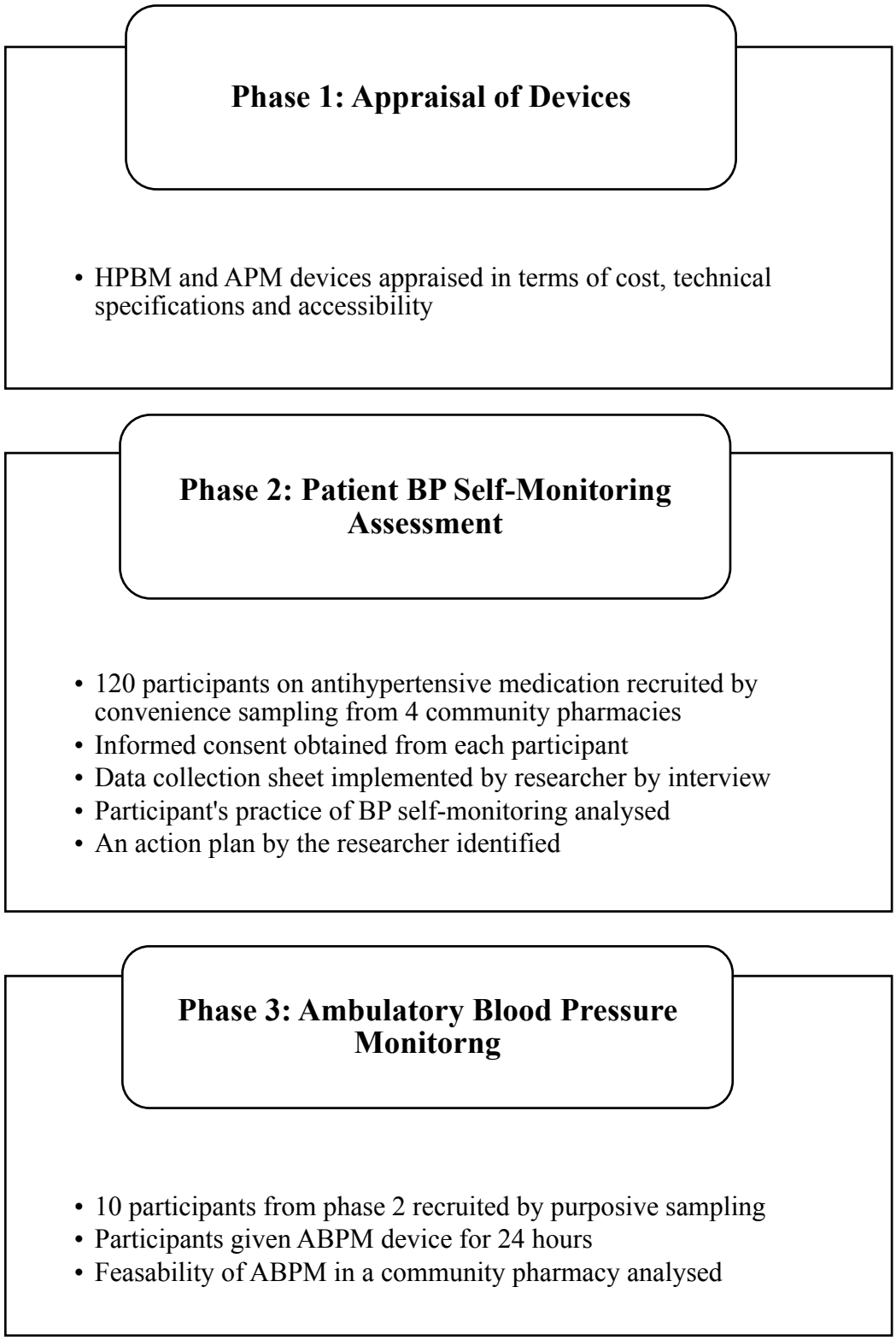

Figure 2.1 - Summary of Methodology

2.2 Study Approvals

Approval from Browns Pharma Ltd and from the managing pharmacist of each location (intermediaries for paticipant recruitment) were obtained. Ethical approval from the University of Malta Faculty of Medicine and Surgery Research Ethics Committee was obtained - MED-2023-00210 (Appendix 1).

2.3 Phase 1: Appraisal of Devices

Local agents were contacted to check for availability of HBPM and ABPM devices. HBPM devices were analysed and compared in terms of measurement method, measurement range, accuracy, user interface properties, presence of an arrhythmia detector, pulse rate detector, in-built Bluetooth feature and cost. ABPM devices were analysed in terms of measurement mode, pulse rate, SpO2 monitor, in-built Bluetooth feature, operating system compatibility and cost. For each device, status of validation by Stride BP® was checked.

2.4 Phase 2: Patient BP Self-Monitoring Assessment

The second phase of the study consisted of two parts; development and validation of a data collection sheet and action plan, and their implementation in community pharmacies to assess BP self-monitoring.

2.4.1 Development and Validation of Data Collection Sheet and Action Plan

A data collection sheet and action plan were developed in both English and Maltese (Appendix 2). The data collection sheet and action plan were validated by an expert panel consisting of two pharmacists, two physicians and two lay persons. The expert panel were entrusted with validation of the data collection sheet and action plan for content, layout, clarity and comprehensiveness. Comments by the physicians were that the data collection sheet was practical, detailed and comprehensive. The lay persons agreed that the data collection sheet was easy to follow. A recommendation made by a pharmacist was to design a flowchart explaining the correct HBPM techniques that participants should follow when monitoring BP at home. This recommendation was accepted and a flowchart was designed in English and Maltese (Appendix 3). After making the amendments suggested by the expert panel, reliability testing was carried out.

2.4.2 Reliability Testing of Data Collection Sheet and Action Plan

For reliability testing, the managing pharmacist of one of the pharmacy locations invited 10 participants to participate by convenience sampling. The researcher documented the necessary information on the data collection sheet and identified an action plan for each participant. The managing pharmacist carried out the same procedure on the same 10 participants by also documenting the information on the data collection sheet and identifying an action plan. The 10 participants recruited for reliability testing were not part of the 120 participants included in the final sample population.

Interrater reliability was calculated using the Kappa test with SPSS version 29 and was found to be 0.974. This result indicates an almost perfect agreement between the researcher and managing pharmacist (Table 2.1). The researcher and the managing pharmacist agreed that the data collection sheet is easy to follow, comprehensive and practical. This pilot study demostrated that the time taken for the data collection sheet to be completed and for an action plan to be identified takes a maximum of 30 minutes (mean time: 20 minutes, range: 10-30 minutes). Due to the agreement in outcomes between the researcher and managing pharmacist and an interrater reliability Kappa result close to 1, the developed data collection sheet was deemed to be reliable and applicable to be implemented.

Table 2.1 - Kappa Interrater Reliability Test

Measurement of Agreement Kappa Value	Standard Error	P-Value
0.974	0.011	<0.001

2.4.3 Participant Recruitment

Participants were recruited from four community pharmacies selected by convenience sampling; two pharmacies from the Western District (Attard, Iklin), one from the Northern Harbor District (Mensija) and one from the Northern District (Naxxar).

The managing pharmacist of each location agreed to recruit 30 participants (a total of 120 participants) above the age of 18 yeras, diagnosed with hypertension and taking at least one antihypertensive medication. The managing pharmacist was provided with an ‘Invitation Letter’, ‘Information Sheet’ and a ‘Consent Form’, all available in English and Maltese. The ‘Invitation Letter’ was used to invite persons to the study. The managing pharmacist provided

both written and verbal information about the study to interested participants by means of the 'Information Sheet'. If the interested participants agreed to participate, they were asked to sign the 'Consent Form'. The participants then underwent an interview of maximum 30 minutes (mean time: 20 minutes, range: 10-30 minutes) during which the researcher assessed the participant's practice of BP self-monitoring and an action plan was identified. Patients were recruited over a period of four months, between September 2023 and Janaury 2024.

2.4.4 Implementation of the Data Collection Sheet and Action Plan

Each data collection sheet was assigned a code to maintain anonymity of the participant. The data collection sheet included patient demographics; the locality the interview was performed, gender and age. All the participant's current antihypertensive medications were documented on the data collection sheet. If the participant owned a HBPM device, the participant was asked the brand of the device, when was the device bought and if it has ever been calibrated. The researcher analysed patient practice of BP self-monitoring using the data collection sheet. The participant's BP was measured by the researcher during the interview by a validated oscillometric upper arm BP monitor, A&D® UA-651. The same oscillometric BP device was used in all locations. During BP reading, the participant sat on a chair with both feet flat on the floor, back supported against a chair and arm rested on the table elevated at heart level (Unger et al, 2020). If the BP reading was outside the normal range of 120/80 mmHg – 129/84 mmHg (Mancia et al, 2023b), the participant was given a Referral Note and referred to a physician (Appendix 4). The researcher identified an action plan depending on whether the HBPM reading obtained was within target, whether the frequency of BP monitoring was adequate and whether the action taken by the participant based on HBPM readings obtained was adequate or not. A flowchart explaining good HBPM techniques, including documentation of BP readings and utilisation of records at physician visits, was provided to the participants. A hands-on

demonstration on how to properly use an automatic upper arm oscillometric device was given to those participants requiring improvement in HBPM technique. Participants who do not self-monitor were given reasons for the importance of HBPM and on devices available on the market. The data collection sheet is summarised in Table 2.2.

Table 2.2 - Summary of Data Collection Sheet

Description
• Relevant participant characteristics were collected via interview. Participant's BP reading measured, with referral to physician for further monitoring for participants with BP not within the normal range of 120-80 mmHg-129/84 mmHg. • Participants who self-monitor BP assessed on HBPM technique, frequency and follow up of results obtained with physicians. • Personalised pharmacist advice to optimise BP self-monitoring technique and relevant follow up within a collaborative practice outlined for participants who self-monitor. • For participants who do not self-monitor, pharmacist intervention to overcome self-monitoring challenges was provided.

2.5 Phase 3: Ambulatory Blood Pressure Monitoring

Based on the results of phase 1, GIMA® 24 hours ABPM + Pulse Rate monitor was purchased and used in all locations. The ABPM device was transported carefully in its original box from one pharmacy to another. Twenty out of the 120 participants who were newly diagnosed with hypertension, had a change in medication and/or dose within the last 2 months, or reported non-compliance to management of hypertension were invited for 24-hour ABPM. Ten out of 20 participants accepted the invitation. Two appointments were set up with the participants, the second appointment set 24 hours after the first reading. Participants were advised to bathe or shower prior to the first appointment and to wear a loosely fitted shirt or tank top as the base layer of clothing when coming for the appointment. During the first appointment, the measurement of the mid-arm circumference was taken and then the participant was fitted with the appropriate ABPM cuff on the non-dominant upper arm. The participant's BP was first measured using the calibrated oscillometric upper arm BP monitor, A&D® UA-651, followed by manually with the ABPM device. If the readings from both devices were the same, ABPM was started. The participant was encouraged to perform usual daily activities and to place the monitor in close proximately or under the pillow during the night. It was explained to the participant that the arm must be relaxed whilst the cuff is inflating or deflating. The ABPM device measured BP every 30 minutes between 6AM to 10PM (daytime) and every hour from 10PM to 6AM (nighttime). The participant was advised to be in bed at 10PM and wake up at 6AM. The participant was instructed to examine the extremity of the limb on which the ABPM device was fitted for normal colour, warmth and sensitivity and was strongly advised to remove the ABPM device if any abnormality in the limb was observed during the 24-hour reading.

During the second appointment, the ABPM device was returned, the data was downloaded from the ABPM device via a USB wire to the laptop and a report for each participant was generated. The 24-hour ABPM was considered satisfactory if ≥ 20 daytime readings and ≥ 7 nighttime readings were obtained (Sanchez et al, 2020). The participant was given a hard copy of the report, to be given to their physician.

2.6 Statistical Analysis

All data gathered was inputted in a Microsoft Excel® spreadsheet. The data was analysed with IBM SPSS® version 29. Chi-square test was used to anaylse the association between two categorial variables; HBPM versus gender, age, locality, co-morbidities, number of years taking antihypertensive medication, number of daily antihypertensive medication and BP level respectively. A 0.05 level of significance was adopted.

Chapter 3

Results

3.1 Phase 1: Appraisal of HBPM and ABPM devices

Twenty-five HBPM devices were identified to be available locally. All HBPM devices use oscillometric technology, have a BP accuracy of ±3 mmHg and a pulse rate accuracy of ±5% of the value. The minimum and maximum measurement range for BP and pulse rate are 0-300 mmHg and 30-200 beats/minute respectively. Omron® M1 is able to store the last BP reading taken whereas other devices such as Medisana® BU 535 is able to store a total of 240 readings. Storage of readings is an important feature which facilitates physician accessibility to BP readings. Average values of stored readings are generated by HBPM devices such as Medicare® LifeSense A2 and Medel® Control. The World Health Organization (WHO) classification indicator (green, yellow or red marking depending on BP reading) displayed on the screen of A&D® devices informs users whether BP is within ideal range or not. Three different models of Omron® devices have an in-built movement detector which guides users at positioning cuff in the right position, reducing the risk of obtaining an inaccurate BP reading. Medicare® LifeSense A2 and Omron® M7 Intelli IT both connect to smartphones by Bluetooth, transferring all data onto an application for easy accessibility to BP readings. Fourteen out of 25 devices are validated by STRIDE BP®. Other devices such as Boso® Medilife Compact S and Medicare LifeSense MD1803 are validated by German Hypertension League and BIHS respectively (Appendix 5).

From 9 ABPM devices appraised, only three GIMA® ABPM monitors are available on the local market. For the three devices, pulse rate ranges from 0-250 beats/minute, BP measurement can be carried out manually or automatically set at a fixed time interval. One of the devices is able to transfer data via Bluetooth, whereas another device measures the oxygen saturation of the patient. The devices are compatible with Windows XP/8/8.1/10 (32-bit & 64-bit version). Cost of devices range from €435.00 to €542.80 (Appendix 6).

3.2 Phase 2: HBPM Assessment and Patient Empowerment

In phase 2, 69 female participants and 51 male participants were recruited for implementation of the data collection sheet and action plan. The majority of the participants were 69-78 years (40%) (Table 3.1). Forty-three participants (35.8%) have been on antihypertensive medication for 11-20 years. Half of the participants had one other comorbidity; diabetes (35%) and hyperlipidaemia (25.8%) were the most common conditions. Fifty-eight participants (48.3%) took only one antihypertensive medication; amlodipine 5mg being the most prescribed medication (42.5%). The mean number of co-morbidities was 2 and mean number of daily antihypertensive medications was 2 (Table 3.2). From the sample of 120 participants, 66 participants (55%) claimed to own an automatic upper arm oscillometric HBPM device and perform self-monitoring.

Table 3.1 - Patient Demographics (N=120)

Patient Information		**Number of participants**
Gender	Male	51
	Female	69
Age (Years)	18-48	8
	49-58	19
	59-68	29
	69-78	48
	79+	16

Table 3.2 - Patient Information about Co-morbidities and Medication (N=120)

Patient Information		Number of participants
Number of co-morbidities	1	60
	2	16
	3	7
	4	1
Co-morbidities	Diabetes	42
	Hyperlipidaemia	31
	Asthma	11
	Hypothyroidism	9
	Crohn's Disease	5
	Fibromyalgia	3
	Gastro-oesophageal reflux disease	3
	Glaucoma	2
	Heart Failure	2
	Osteoporosis	2
	Psoriasis	2
	Other: Atrial Fibrillation; Chronic kidney disease; Gout; Rheumatoid Arthritis; Tinnitus	1 each
Number of antihypertensive medications	1	58
	2	45
	3	16
	4	1
Number of years on antihypertensive medication	Less than 1 year	12
	1-5 years	22
	6-10 years	32
	11-20 years	43
	≥ 21 years	9
	Do not remember	2

Table 3.3 shows that 38 female participants and 28 male participants owned a HBPM device. Using the chi-square test, no correlation was found between HBPM monitoring and gender ($p>0.05$).

Table 3.3 - Gender vs HBPM (N=120)

		HBPM	
		Yes	No
Gender	Male	28 (42.4%)	23 (42.6%)
	Female	38 (57.6%)	31 (57.4%)

$X^2(1) = 0$, $p = 0.985$

Table 3.4 shows that participants aged 69-78 years were the most likely to own a HBPM device. An increase in the number of participants who owned a HBPM device is observed from 18-78 years. No statistical significance was found between age and HBPM ($p>0.05$).

Table 3.4 - Age vs HBPM (N=120)

		HBPM	
		Yes	No
Age	18-48	3 (4.5%)	5 (9.3%)
	49-58	12 (18.2%)	7 (13.0%)
	59-68	13 (19.7%)	16 (29.6%)
	69-78	29 (43.9%)	19 (35.1%)
	79+	9 (13.6%)	7 (13.0%)

$X^2(4) = 3.292$, $p = 0.510$

Table 3.5 shows no correlation between locality and HBPM ($p>0.05$). Relatively the same number of participants from the 4 different localities owned a HBPM device.

Table 3.5 - Locality vs HBPM (N=120)

		HBPM	
		Yes	No
Locality	Naxxar	15 (22.7%)	15 (27.8%)
	Iklin	17 (25.8%)	13 (24.1%)
	Attard	16 (24.2%)	14 (25.9%)
	Mensija	18 (27.3%)	12 (22.2%)

$X^2(3) = 0.673$, $p = 0.879$

Not all participants had other co-morbidities, 36 participants suffered only from hypertension. Out of the 46 participants suffering from other co-morbidities and who owned a HBPM device, 36 participants were diagnosed with one other co-morbidity (78.2%) (Table 3.6). No correlation was found between co-morbidities and HBPM ($p>0.05$).

Table 3.6 - Co-morbidities vs HBPM (n=84)

		HBPM	
		Yes	No
Co-morbidities	1	36 (78.2%)	24 (63.2%)
	2	8 (17.4%)	8 (21.1%)
	3	1 (2.2%)	6 (15.8%)
	4	1 (2.2%)	-

$X^2(3) = 6.266$, $p = 0.099$

Two participants could not recall how many years they have been on antihypertensive medication. Out of the 64 participants who self-monitor and recalled how many years they have been taking BP lowering medication; 25 participants have been taking antihypertensive medication for 11-20 years (39.1%) (Table 3.7). No statistical significance was found between HBPM and the number of years on antihypertensive medication ($p>0.05$).

Table 3.7 - Number of Years Taking Antihypertensive Medication vs HBPM (n=118)

		HBPM	
		Yes	No
Number of years taking antihypertensive medication	< 1 year	7 (10.9%)	5 (9.3%)
	1-5 years	11 (17.2%)	11 (20.4%)
	6-10 years	17 (26.5%)	15 (27.7%)
	11-20	25 (39.1%)	18 (33.3%)
	≥ 21 years	4 (6.3%)	5 (9.3%)

$X^2(4) = 0.868$, $p = 0.929$

Out of the 66 participants who owned a HBPM device, 30 participants took only 1 antihypertensive medication (45.5%) whereas 10 participants took 3 antihypertensive medications (15.2%) (Table 3.8). No statistical significance was found between HBPM and number of daily antihypertensive medications ($p>0.05$).

Table 3.8 - Number of Daily Antihypertensive Medications vs HBPM (N=120)

		HBPM	
		Yes	No
Number of daily antihypertensive medication	1	30 (45.5%)	28 (51.8%)
	2	26 (39.3%)	19 (35.2%)
	3	10 (15.2%)	6 (11.1%)
	4	-	1 (1.9%)

$X^2(3) = 1.978$, $p = 0.577$

For the participants who self-monitor BP, ways to improve HPBM technique, frequency and follow up of BP results were identified by the researcher. Figure 3.1 summarises the lack of adequate monitoring frequency observed in this study. Only 7 participants (10%) self-monitor BP once a day, whereas 21 participants (32%) self-monitor when they remember. None of the participants who own a HBPM device claimed that they never self-monitor. Out of the 66 participants who self-monitor, 30 participants were found to have elevated BP. Participants whose BP was found outside the ideal range of 120/80 mmHg-129/84 mmHg were referred to the physician using a Referral Note. The action plan devised by the researcher for each participant depending on the participant's BP and self-monitoring BP frequency is shown in Figure 3.2.

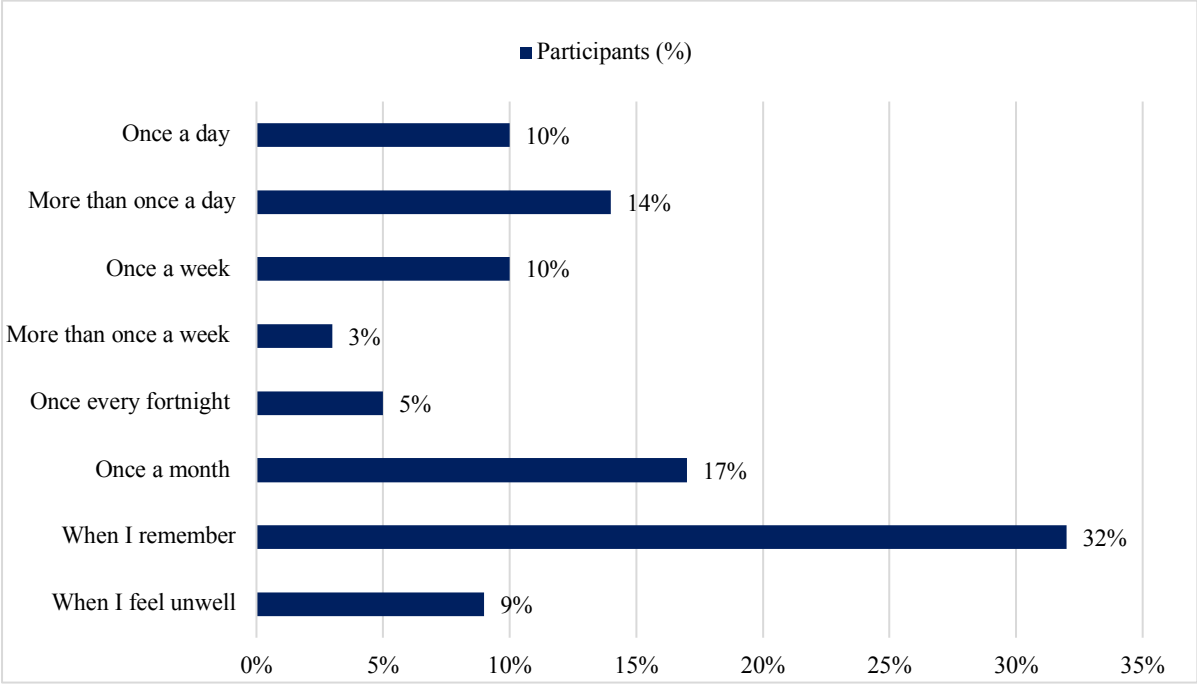

Figure 3.1 - Monitoring Frequency (n=66)

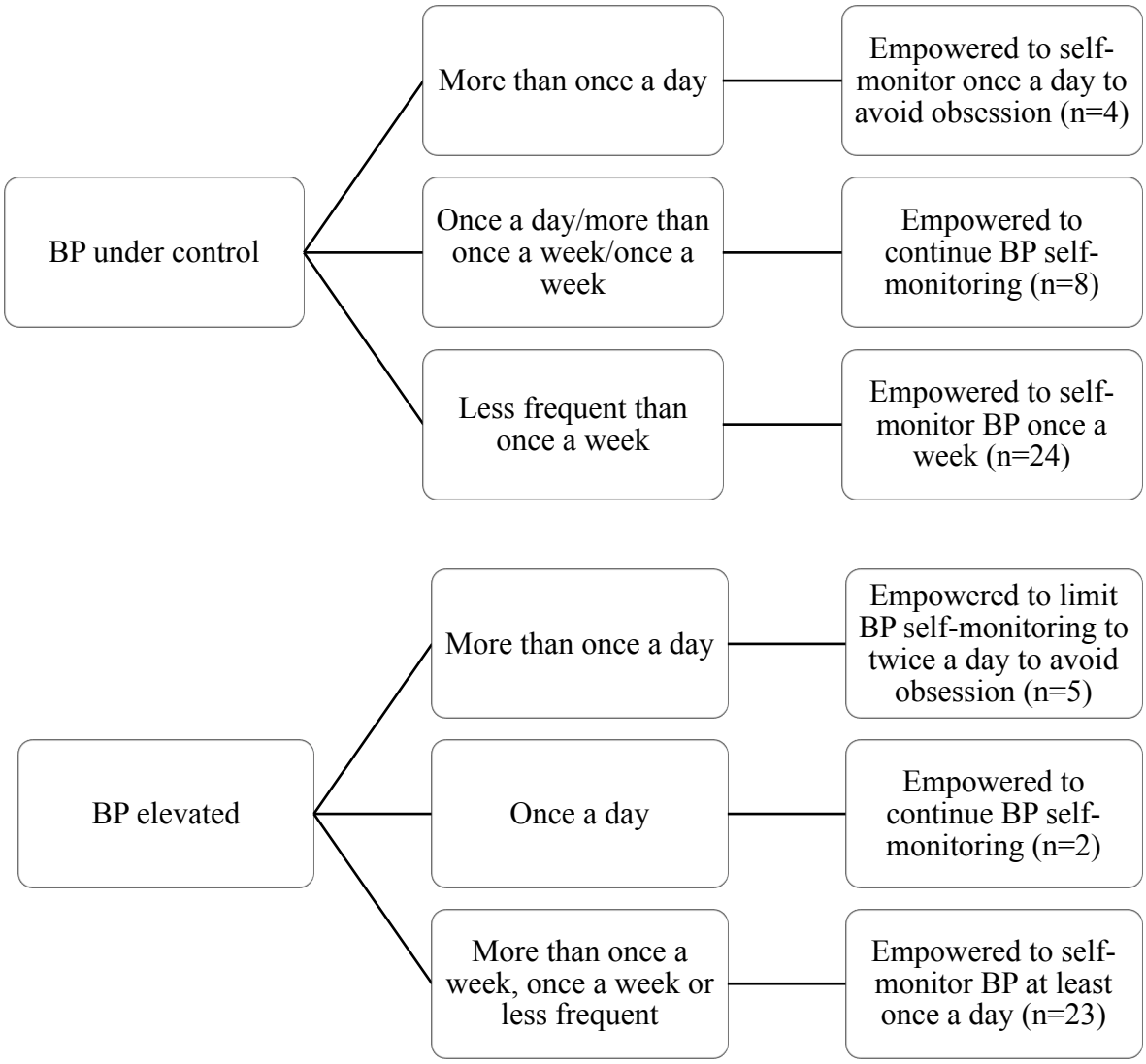

Figure 3.2 - Action Plan Depending on the Participant's BP and HBPM Frequency (n=66)

Table 3.9 shows that out of the 66 participants who self-monitor, 36 had controlled BP. No association was found between BP readings and HBPM ($p>0.05$).

Table 3.9 - BP Level vs HBPM (N=120)

		HBPM	
		Yes	No
BP level	Controlled	36 (54.5%)	28 (51.9%)
	Elevated	30 (45.5%)	24 (44.4%)
	Low	-	2 (3.7%)

$X^2(2) = 2.492$, $p = 0.288$

The researcher further explained to the participants that the time of the day at which the BP is monitored and the technique used for monitoring is very important to obtain accurate, reliable readings. Only 15 participants (23.0%) monitor their BP in the morning, half of the participants self-monitor at any time of the day whenever they remember (Figure 3.3). The researcher explained to the participants that monitoring in the morning should be done within 1 hour after waking up, before breakfast, drug intake and vigorous physical activity. Monitoring in the evening should be done before going to bed, 2 hours after dinner. If the time interval between dinner and going to bed is less than 2 hours, then monitoring should be done before dinner (Kario et al, 2021; Lin et al, 2022). Participants were assessed on HBPM technique including resting time, intake of caffeinated beverages and emptying the bladder before BP reading, and maintaining correct posture and silence during monitoring. The technique being the most defaulted was bladder emptying prior to BP monitoring (78.8%) (Table 3.10).

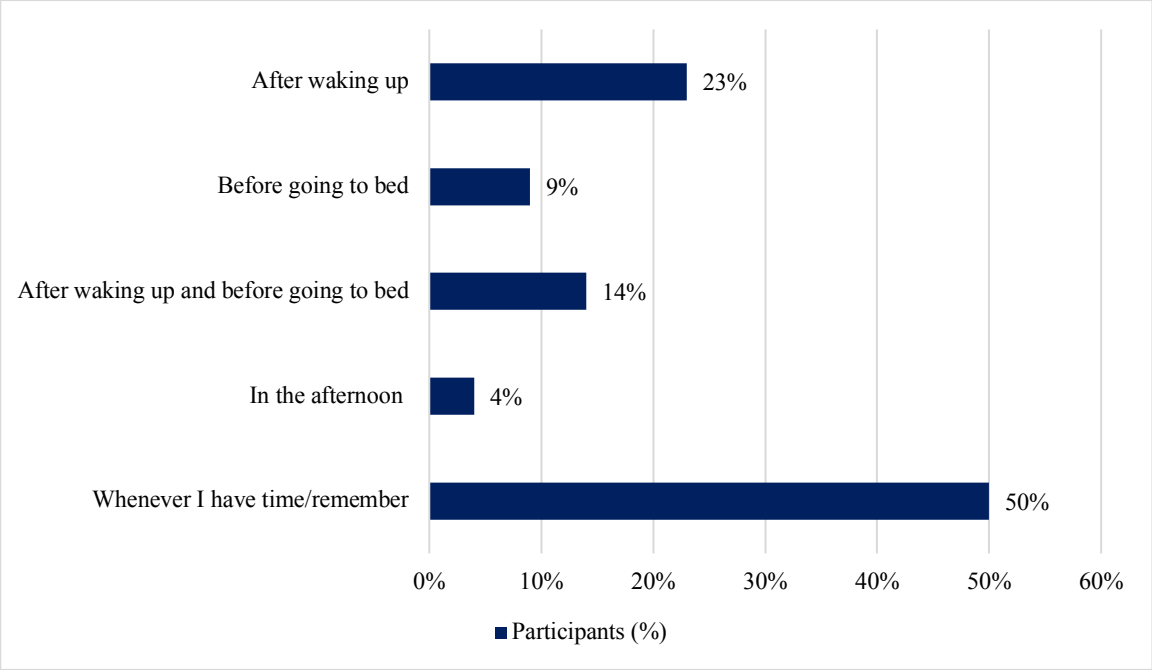

Figure 3.3 - Time of Day at which Participants Monitor their BP (n=66)

Table 3.10 - Monitoring Techniques (n=66)

Monitoring Techniques	Number of Participants Stating Yes
Before monitoring your BP do you:	
Rest for 5 minutes in a quiet room?	51
Smoke or drink coffee?	6
Empty your bladder?	14
Whilst monitoring your BP do you:	
Remain silent?	49
Keep your back rested against chair, arm rested on table with cuff placed at the level of your heart?	62
Take at least two readings with a two-minute interval?	44

Using devices which are accurate is also very important to obtain reliable readings. Nineteen participants were able to recall the brand of the device from memory, 14 participants are making use of a device validated by STRIDE BP® such as A&D® (50%), Beurer® (29%) and PIC® (21%) (Figure 3.4). The remaining 5 participants were explained the importance of using a validated device. Only 3 out of 66 participants (4.55%) take their HBPM device for calibration once a year (n=1), every 2 years (n=1), or every 3 years (n=1). The importance of annual calibration was explained to the remaining 63 participants.

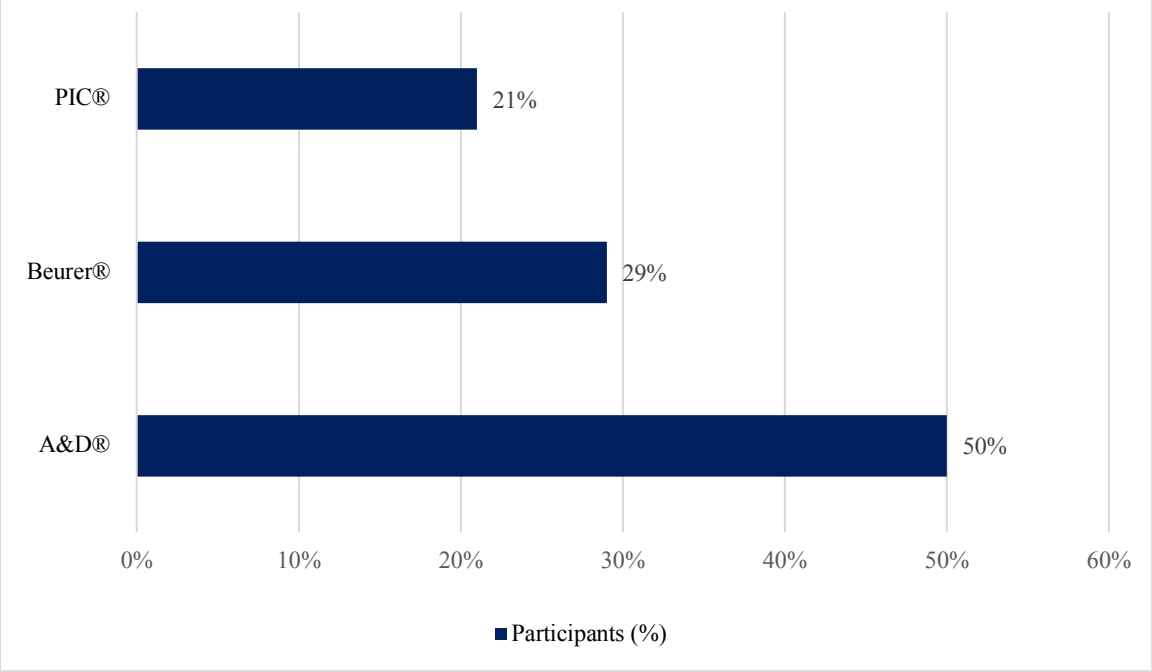

Figure 3.4 - Use of Validated Devices (n=14)

Out of the 30 participants who do not have controlled BP, 19 participants (63.3%) keep a record of the readings obtained, of which 13 participants (68.4%) utilise the records at physician visits. Participants were explained regarding the importance of informing the pharmacist or physician if BP is not within the ideal range of 120/80 mmHg-129/84 mmHg. Only 4 participants (<1%) would act if BP is found between 130/85 mmHg-139/89 mmHg, 25.7% and 18.1% would act if BP is ≥140/90 mmHg and ≥150/90 mmHg respectively. Only 13 participants (19.7%) would prefer to speak to the pharmacist before going to the physician if BP is elevated.

For the participants who do not self-monitor (45%), benefits of HBPM and devices available were explained by the researcher. Fear of not using the HBPM device properly was the most common reason as to why participants opt not to own a HBPM device (40%). 'Other' reasons include not being able to afford one (n=1), would own one only if it is given for free by the government (n=1), or was never recommended by GP/pharmacist (n=1) (Figure 3.5).

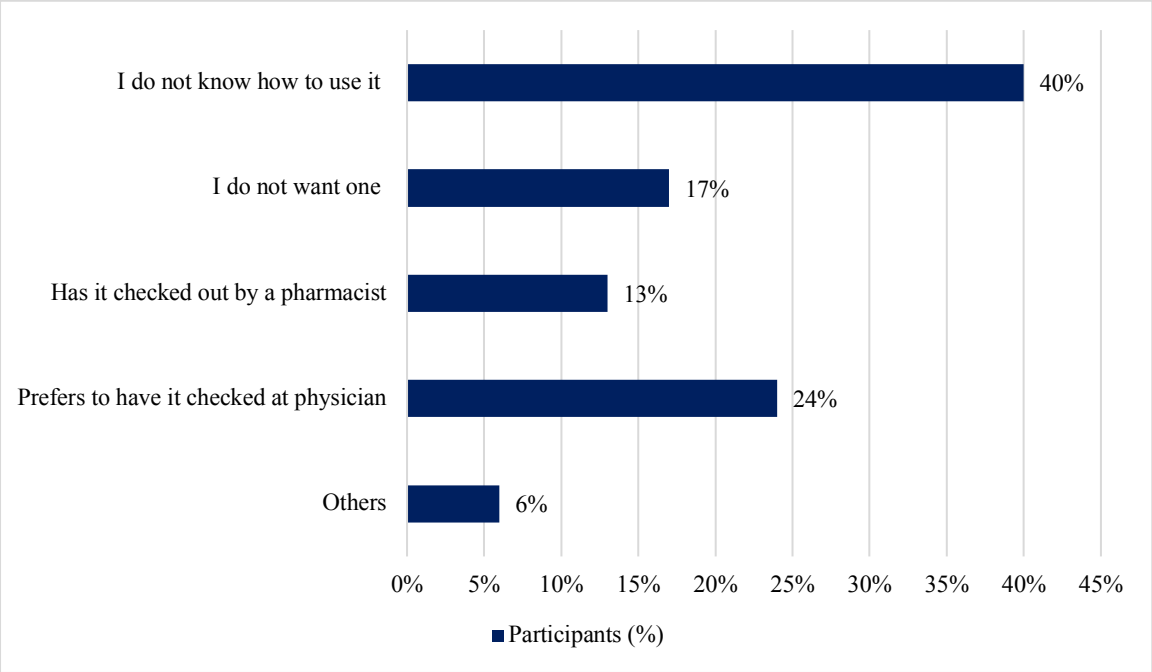

Figure 3.5 - Reasons for Not Owning a HBPM Device (n=54)

3.3 Phase 3: Feasibility of ABPM

The 20 participants eligible for ABPM had a change in medication and/or dose, meeting the inclusion criteria for this arm of the study (Figure 3.6). Ten participants refused ABPM as they believed the monitoring will be burdensome (n=6) or felt embarrassed to be seen with the monitor (n=4). The 10 participants who accepted all showed up to the scheduled appointments.

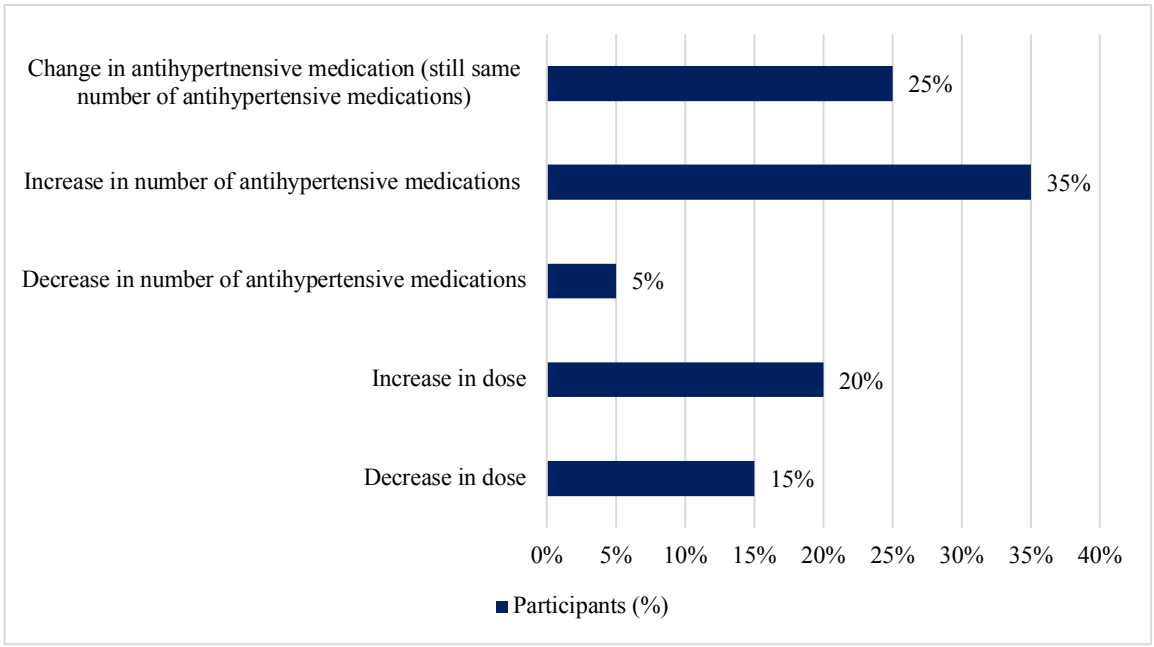

Figure 3.6 - Change in Antihypertensive Medication/Dose (n=20)

The report that was generated for each participant included diastolic and systolic BP readings, MAP, PP and pulse rate. The report was easily interpreted by the researcher and explained to each participant. Nine out of 10 participants satisfied the number of valid readings required, ≥20 daytime readings and ≥7 nighttime readings to achieve a successful 24-hour ABPM. One of the participants experienced an air leakage which resulted in an error after 18 hours, obtaining only 19 daytime readings, rendering ABPM unsatisfactory. Table 3.11 summarises diastolic BP, systolic BP and pulse rate readings within and outside the ideal range (presented as a percentage) of the 9 participants who successfully achieved the 24-hour ABPM.

Table 3.11 - Percentage time of BP Level per Participant within the 24-hour ABPM (n=9)

	Participant number:	1	2	3	4	5	6	7	8	9
Systolic BP readings	>135 mmHg	22.5%	40%	23.1%	69.8%	5.1%	5%	-	2.4%	10.3%
	100 -135 mmHg	77.5%	60%	76.9%	30.2%	89.7%	92.5%	97.6%	85.4%	84.6%
	<100 mmHg	-	-	-	-	5.1%	2.5%	2.4%	12.2%	5.1%
Diastolic BP readings	>85 mmHg	20%	67.5%	23.1%	16.3%	7.7%	25%	-	4.9%	12.8%
	60-85 mmHg	72.5%	30%	71.8%	83.7%	79.5%	70%	80.5%	78%	79.5%
	<60 mmHg	7.5%	2.5%	5.1%	-	12.8%	5%	19.5%	17.1%	7.7%
Heart rate	>100 bpm	-	-	-	-	-	2.5%	-	-	-
	60-100 bpm	100%	60%	87.2%	100%	92.3%	95%	36.6%	95.1%	66.7%
	<60 bpm	-	40%	12.8%	-	7.7%	2.5%	63.4%	4.9%	33.3%
Morning Systolic BP surge (mmHg)*		1.0	-22.5	6.0	18.0	8.0	7.5	6.0	0.5	3.5
Nighttime Dipping (%)*		-1.6	3.5	10.9	7.5	12.0	13.5	10.0	20.0	17.1

*Since participants did not keep a diary card, it was assumed that participants were asleep between 10PM and 6AM.

Participant 1 had normal diurnal BP readings but elevated nocturnal readings, participant 2 and 4 had elevated BP readings throughout the whole 24 hours, and participant 6 had normal systolic readings but elevated diastolic readings. These four participants were given a referral note and were encouraged to take the ABPM results to their physician. Upon visiting the physician, participant 2 had an increase in dose from valsartan 160mg OD to BD, participants 1 and 4 were started on amlodipine 5mg OD NOCTE, participant 6 was not given a change in treatment but was advised to reduce stress. These 4 participants reported to the researcher an improvement in BP control after physician visit. The other participants had good BP readings throughout the 24-hour monitoring, indicating the change in treatment prior to ABPM was correct. The researcher reminded all the participants on the importance of low salt intake, healthy BMI, regular exercise, low alcohol consumption, no smoking, reduction in stress and adequate BP monitoring.

From the 10 participants who underwent ABPM, 5 participants practice HBPM. From the 5 participants who practice BP self-monitoring, 3 were referred to the physician. Participant 1 and 3 experienced bruising, participant 6 and 8 complained of sleep disturbance. For the rest of the participants, ABPM was well accepted.

3.4 Dissemination of Results

Abstracts were accepted for poster presentation at the 82nd International Pharmaceutical Federation World Congress, September 2024 and at the 52nd European Society of Clinical Pharmacy symposium, October 2024 (Appendix 7).

Chapter 4

Discussion

4.1 Community Pharmacist Intervention in BP Management

The contribution of pharmacists, being highly accessible health care providers, towards hypertension management involves educating patients on the condition, BP monitoring and medication adherence (Soubra & Elba, 2023). Despite HBPM being an excellent tool for hypertension management, the present study failed to achieve statistical significance between BP level and self-monitoring ($p = 0.288$). Similarly, in a study carried out in France by Vallée et al (2020), statistical difference in possession of a HBPM monitor was not found between hypertensive participants with controlled BP and hypertensive participants with uncontrolled BP (59.3% vs 59.2%, $p = 0.975$). HBPM has proven to be more effective at achieving better BP control when there is effective communication between the hypertensive patient and health care professionals, and an effective treatment compliance strategy is implemented (Divisón-Garrote et al, 2023). This highlights the importance of educating patients on BP levels and targets specified in the ESH guidelines (Mancia et al, 2023b), where normal BP level is between 120/80 mmHg-129/84 mmHg, and BP values of 130/85 mmHg-139/89 mmHg are considered high-normal and action must be taken. In a study in Egypt by Soubra & Elba (2023) patients who were knowledgeable on correct BP targets demonstrated better BP control. Reporting home BP values guides pharmacists and physicians in taking decisions regarding treatment management. If measured home BP readings are not reported to healthcare professionals, there will be no modification in treatment to reflect HBPM readings resulting in uncontrolled BP (Rhee et al, 2023).

Awareness of validated devices available and a stronger pharmacist advocacy to improve patient understanding on the use of upper arm cuff HBPM devices is required to ensure that BP readings obtained are reliable. Health care professionals and patients should be encouraged to make use of web-based listings of validated devices such as STRIDE BP®

(www.stridebp.org) (Wang et al, 2021). Devices must be calibrated to ensure reliability. Lack of knowledge regarding calibration was also observed in the UK in a study by Hodgkinson et al (2020), where participants were asked whether they would like to have their HBPM monitor calibrated. Only 58 of 653 responders reported having had previously calibrated their HBPM device, 22 had the device calibrated within the previous 2 years, 25 had it calibrated ≥ 2 years ago, and 11 could not remember the date of previous testing (Hodgkinson et al, 2020).

Besides validation and calibration, frequency and timing of BP monitoring is very important. If BP is found to be within the limits of high-normal or high (≥ 130/85 mmHg) during HBPM, patients must practice the "722" protocol, taking 2 readings in morning before breakfast, drug intake and vigorous activity, and before going to bed, 2 hours after dinner (Lin et al, 2022). Changes in BP normally oscillates in cycles, with a reduction during nighttime and an increase during daytime. This oscillation coincides with the nature of haematologic and endocrine parameters which may trigger cardiovascular events. Organ damage and cardiovascular risk is increased in the absence of nocturnal BP reduction and in the presence of morning BP surge (Renna et al, 2023). Adequate out-of-office normotension requires that daytime, nocturnal and mean 24-hour BP are controlled during ABPM (Filippone et al, 2023).

In a study by Renna et al (2023) in Western Argentina, the relationship between circadian BP variation and MACE including cardiovascular mortality, non-fatal ischaemic heart disease, non-fatal stroke, heart failure and atrial fibrillation, was investigated using 24-hour ABPM. It was observed that 21% of the participants had an elevated systolic sleep-through morning surge, imposing an increased risk of stroke irrespective of age. This may have a detrimental impact on the prevalence of dementia and long-term disability. A release of catecholamines and angiotensin in the early morning is believed to be the result of the morning surge due to an

increase in the sympathetic activity and vascular tone (Renna et al, 2023). In another study, The Japan ABPM Prospective Study carried out by Hoshide & Kario (2021) investigated the association between nighttime BP dipping patterns and nocturnal hypertension with cardiovascular outcomes in hypertensive patients. Patients were divided into two groups based on the reduction of systolic BP during nighttime versus daytime, namely dippers (≥10%) and non-dippers (<10%). An increase of 10 mmHg in morning BP surge was found to be associated with 8% increased risk of stroke, hence morning surge warrants more attention amongst BP measurements (Renna et al, 2023).

HBPM alone is not able to detect outliers in BP unlike ABPM and for this reason HBPM and ABPM complement each other. In this study, 5 out of the 10 participants who performed ABPM also practiced HBPM, 3 out of these 5 participants required referral, which is a small yet significant proportion. Due to time constrains and financial reasons, it is not feasible to perform ABPM for every hypertensive patient. Performing ABPM in patients newly diagnosed with hypertension, or having a recent change in medication or dose, or reporting non-compliance to hypertension management has improved hypertension control in 4 out of 10 patients selected from community pharmacies in the present study.

4.2 Feasibility of ABPM

A challenge encountered with ABPM in the present study was the incompatibility of the ABPM software with modern operating systems. The operating systems that support the device used, GIMA® 24 hours ABPM + Pulse rate monitor, are Windows XP/Seven, 8, 8.1, 10. When purchasing an ABPM device, one must ensure that the operating system of the computer in use is compatible with the software of the device. Incompatibility of the device's software with the operating systems would render ABPM futile since a report with the patient's BP readings would not be able to be generated. All GIMA® ABPM devices are supported by the same operating systems. The software of ABPM devices such as A&D®, Meditech®, Microlife® and Somnomedics® are supported by more modern operating windows including Windows 10/11. The user interface of GIMA® 24 hours ABPM + Pulse rate monitor was easy to follow and no difficulties were encountered with operating the device.

All participants were given clear instructions on what can and cannot be done during monitoring. In this study, participants were not asked to document their activities during ABPM as this was a pilot study carried out with the intention of evaluating feasibility of service provision. Participants explained that they were able to go on with their normal daily activities and most of the participants went to work as usual. Only two participants complained of sleep disturbance. The monitor, being small in size, did not interfere with the participant's day to day activities. For those participants who preferred to be more discreet about the monitoring, the monitor was easily hidden under clothes but the wire connecting the cuff with the monitor was quite long. This issue is resolved with ABPM devices by Somnomedics® as these devices do not have a separate monitor, instead the monitor slides over the cuff itself. Patients may be less reluctant to perform ABPM since the burden of carrying around a monitor is eliminated.

All 10 participants that participated in this study for ABPM were satisfied with the service provided by the pharmacist and all agreed that this service should be offered in community pharmacies. Participants appreciated the time allocated to them by the pharmacist for explanation of results and suggestions to improve hypertension control. This is in line with international studies carried out in Ireland (James et al, 2014), Italy (Ombani et al, 2019) and the United States (Dixon et al, 2020) in which patients were satisfied with the ABPM service offered in community pharmacies and agreed on its implementation. In a study by Soubra & Elba (2023) patients were satisfied with the interventions and services provided by the pharmacists in relation to hypertension management. This further suggests that patients are aware that pharmacists are highly involved in providing pharmaceutical care practice (Soubra & Elba, 2023).

Due to the length of the appointments, it would be advisable for the service to be implemented in pharmacies with an appointment and not as a walk-in service. The time chosen for the appointment must be convenient for both the patient and the pharmacist. In this way the pharmacist would be able to allocate the necessary time for the patient's needs and the patient would not require to wait for a long time, reducing time away from work and other commitments. If the pharmacy has an in-house physician, it would be wise to schedule the appointment during that time as a facilitator for patients requiring referral. Patients suffering from hypotension can also benefit from this service.

4.3 Significance of the Study

In this study, validated HBPM devices and interventions required by the pharmacists to improve HBPM were identified. For those patients who self-monitor, the proposed pharmacist interventions have the potential to improve patient knowledge on HBPM technique, frequency and follow up of results with healthcare professionals. For those patients who do not self-monitor, a clear understanding of its advantages and importance was provided. This study has shed light on the importance of pharmacists in the identification of patients in the community who despite self-monitoring, still have uncontrolled BP. The main reason identified is that patients are not aware of ideal BP targets and when to act. Pharmacists must dedicate more time in explaining the ideal BP targets to patients and when to seek advice from a healthcare professional, contributing to better BP control as addressed in the research question.

The introduction of ABPM service in community pharmacies is feasible. As seen in this study, collaborative care practice between the pharmacist and physician results in better hypertension control. Introduction of ABPM in community pharmacies enables patients requiring the service to have easier accessibility to it, reducing waiting time that would otherwise be required when ABPM is done at the hospital.

Uncontrolled hypertension can lead to significant health complications which negatively affect a patient's quality of life and increases healthcare costs. Identifying patients with hypertension either through HBPM and/or ABPM can reduce the workload and economic burden on the public healthcare system as well as the need for hospitalisation due to uncontrolled hypertension.

4.4 Strengths and Limitations

The research had several strengths. The validated data collection sheet thoroughly assessed the participant's HBPM technique, frequency and follow up of results with physician. The BP of the participant was assessed by the researcher during the patient interview session and was not based on patient recall. The action plan contributes to improving patients' knowledge on HBPM and empowering appropriate self-monitoring of BP. This was the first study that assessed the feasibility of ABPM in community pharmacies in Malta. This research contributes to support services for better hypertension control, paving the way for a better economical and efficient healthcare system.

The research limitations included the sample size for ABPM which was small, study sites were restricted to a group of pharmacies chosen by convenience sampling in the central part of Malta and Southern districts were not included. The data collection sheet did not assess participant's compliance to antihypertensive medication, a factor which is reported as a major impacting factor on hypertension control. HBPM technique was self-reported, the researcher did not observe participants performing HBPM and participants were not asked to empty bladder prior to BP monitoring during the patient interview session. Participants were not instructed to document activities carried out during ABPM. Pharmaeconomic considerations of ABPM were not evaluated.

4.5 Recommendations for Further Work

A longitudinal study can be conducted using a larger sample size and for a longer duration. Involving more localities from different districts around Malta could be considered. Patients could be invited for another interview after 6 months to determine whether the advice given by the pharmacist to improve HBPM was taken up by the patient and if improvement in BP control is noted. A framework could be implemented to aid pharmacists in identifying patients defaulting HBPM and consequently having uncontrolled BP despite self-monitoring.

Implementing a toolkit to accompany the ABPM service to aid pharmacists in identifying important information from the report such a nighttime dip and morning surge should be considered for further work. A toolkit would contribute to standardisation of reporting ABPM results amongst pharmacists.

A study to determine the economic aspects of ABPM in community pharmacy is recommended to establish how much patients would be willing to pay for the service whilst covering the expenses to run the service. ABPM could be repeated after 2 months in patients who were referred to determine whether the change in medication and/or dose made by the physician achieved the desired hypertension control. A study to determine pharmacist perception on providing an ABPM service could be considered.

4.6 Conclusion

The research identified pharmacist interventions supporting patient empowerment in the management of hypertension. Use of non-validated devices, lack of patient knowledge regarding correct BP targets and insufficient follow-up of results with physicians and pharmacists may lead to uncontrolled BP despite self-monitoring. Pharmacists may act on these shortcomings to empower patients for better self-monitoring and hypertension control. This sheds light on the contribution of community pharmacists to prioritise patients whose BP is elevated despite self-monitoring, identifying reasons and ways for improvement.

Pharmacists are able to contribute to hypertension management in multiple ways including dispensing, patient counselling on disease state, education on the importance of medication adherence and lifestyle modification. With the introduction of ABPM in community pharmacies, as shown in this study, pharmacists are in a position to lead hypertension monitoring, improve early identification of patients with elevated BP or those requiring antihypertensive therapy adjustments. Patients showed satisfaction with the service and the explanation of results provided by the pharmacist. Improvement in BP was reported by patients who were referred following ABPM in community pharmacy.

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Appendices

Appendix 1: Approval

L-Università ta' Malta

Faculty of
Medicine & Surgery

University of Malta
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Ref No: MED-2023-00210

19 September 2023

Ms Michaela Vella
Santa Marija ,
P. Brydon Street
NXR 2325 Naxxar, Malta

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Blood Pressure Monitoring in Community Pharmacy

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee

Appendix 2: Data Collection Sheet (English and Maltese)

Pharmacy location: _____

1. **Gender:**

- ☐ Male
- ☐ Female
- ☐ Other
- ☐ Prefer not to say

2. **Age (years):**

- ☐ 18-28
- ☐ 29-38
- ☐ 39-48
- ☐ 49-58
- ☐ 59-68
- ☐ 69-78
- ☐ 79-88
- ☐ 89+

3. **For how long have you been taking medications for high blood pressure?**

- ☐ Less than 1 year
- ☐ 1-5 years
- ☐ 6-10 years
- ☐ 11-20 years
- ☐ ≥ 21 years
- ☐ I do not remember

4. **Do you suffer from other health conditions?**

- ☐ None
- ☐ Asthma
- ☐ Diabetes
- ☐ Chronic kidney disease
- ☐ Glaucoma

Other: _____

5. **Which blood pressure medication(s) are you taking? (Researcher to list generic name, dose, dosage regimen)**

Generic Name	Dose	Dosage Regimen

6. **Have you had a change in your blood pressure medications or dose within the past 2 months?**

- ☐ Change in antihypertensive medication (still same number of antihypertensive medications)
- ☐ Increase in number of antihypertensive medications
- ☐ Decrease in number of antihypertensive medications
- ☐ Icrease in dose
- ☐ Decrease in dose
- ☐ No change

7. **Do you own a blood pressure monitor at home? (If no skip to question 25)**

- ☐ Yes
- ☐ No

8. **Do you know the brand of your blood pressure monitor? (If no skip to quesion 10)**

- ☐ Yes (brand of blood pressure monitor: _____)
- ☐ No

9. **Verification by researcher to assess if blood pressure monitor used by participant is validated according to STRIDE BP (https://stridebp.org).**

- ☐ Yes
- ☐ No

10. **How many years have passed since you bought your current blood pressure monitor?**

- ☐ 0-2
- ☐ 3-5
- ☐ 6-8
- ☐ 9+
- ☐ I do not remember

11. How often do you use your blood pressure monitor?

- Once a day
- More than once a day
- Once a week
- More than once a week
- Once every fortnight
- Once a month
- When I remember

Other: _____

12. At what time of the day do you check your blood pressure?

- After waking up
- Before going to bed
- After waking up **and** before going to bed
- In the afternoon
- Whenever I have time/remember

Other: _____

13. Do you check your blood pressure before or after a meal?

- Before eating
- After eating
- Before a meal **and** after a meal
- Whenever I remember

Other: _____

14. Do you take your antihypertensive medications before or after you measure your blood pressure?

- Before
- After

15. Before monitoring your blood pressure do you:

A) Rest for 5 minutes in a quiet room?

- Yes
- No

B) Smoke or drink coffee?

- Yes
- No

C) Empty your bladder?

- Yes
- No

16. Whilst monitoring your blood pressure do you:

A) Remain silent?

- Yes
- No

B) Keep your back rested against chair, arm rested on table with cuff placed at level of your heart?

- Yes
- No

C) Take at least two readings with a two-minute interval?

- Yes
- No

17. Do you keep a record of your blood pressure results? (If no skip to question 19)

- Yes
- No

18. Do you utilise your recorded readings?

- Yes
- No

19. Have you ever taken your blood pressure monitor for calibration? (If no skip to question 21)

- Yes
- No

20. How often do you take your blood pressure monitor for calibration?

- Once a year
- Every 2 years
- Every 3 years
- Every 4 years
- Every 5 or more years

21. Blood pressure reading obtained when measured by researcher:

Blood Pressure	Pulse

22. Blood pressure readings indicate:

- Blood pressure is controlled
- Blood pressure is elevated
- Blood pressure is low

(If blood pressure reading obtained is low or high the patient is referred to GP for further monitoring)

23. When would you take action regarding your blood pressure readings?

- When readings are high (specify what high is to you _____**)**
- When readings are low (specify what low is to you _____**)**
- Not feeling well
- Never

Other: _____

24. What kind of action do you take?

- I contact my pharmacist
- I contact my GP
- I do not inform anyone
- I adjust the dose without consulting a healthcare professional

Other: _____

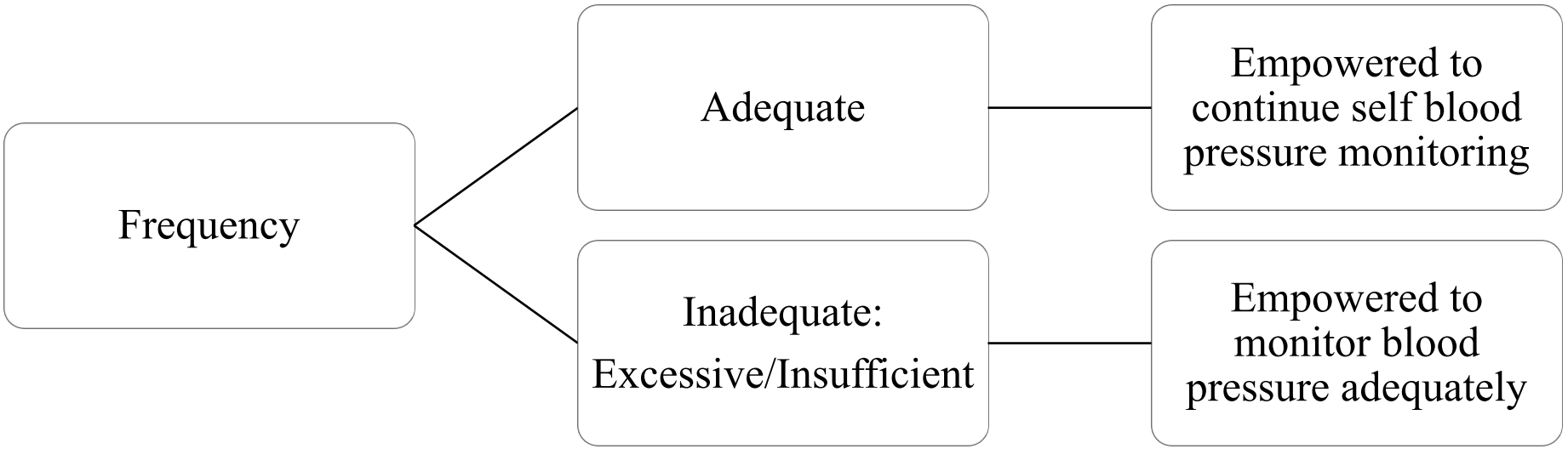
25. Why do you choose not to own a blood pressure monitor?

- I do not afford one
- I do not feel I need one
- I do not know how to use it
- I do not want one
- I would like to own one only if it is given to me for free by the Government
- It was never recommended to me by the GP/pharmacist
- Other: _____

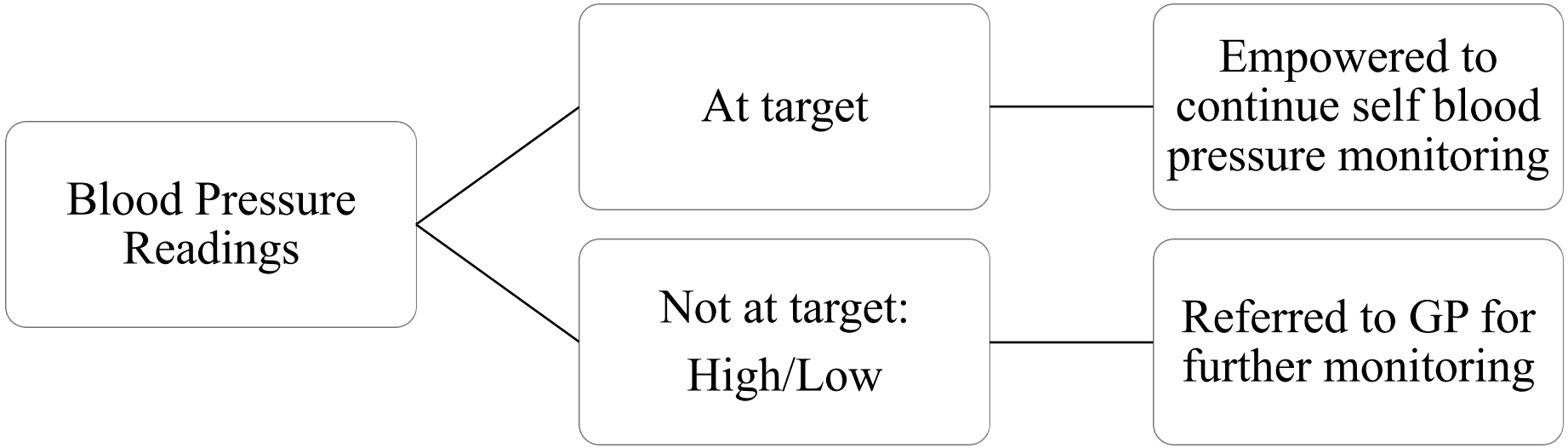
Patients who do not self-monitor are explained the benefits of blood pressure self-monitoring:

- Avoids repeated visits to the general practitioner.
- Can be used over a long period of time to monitor day-to-day blood pressure variability.
- Inexpensive.
- Patient is engaged in blood pressure measurement.
- Patient is more relaxed at home than the doctor's office.

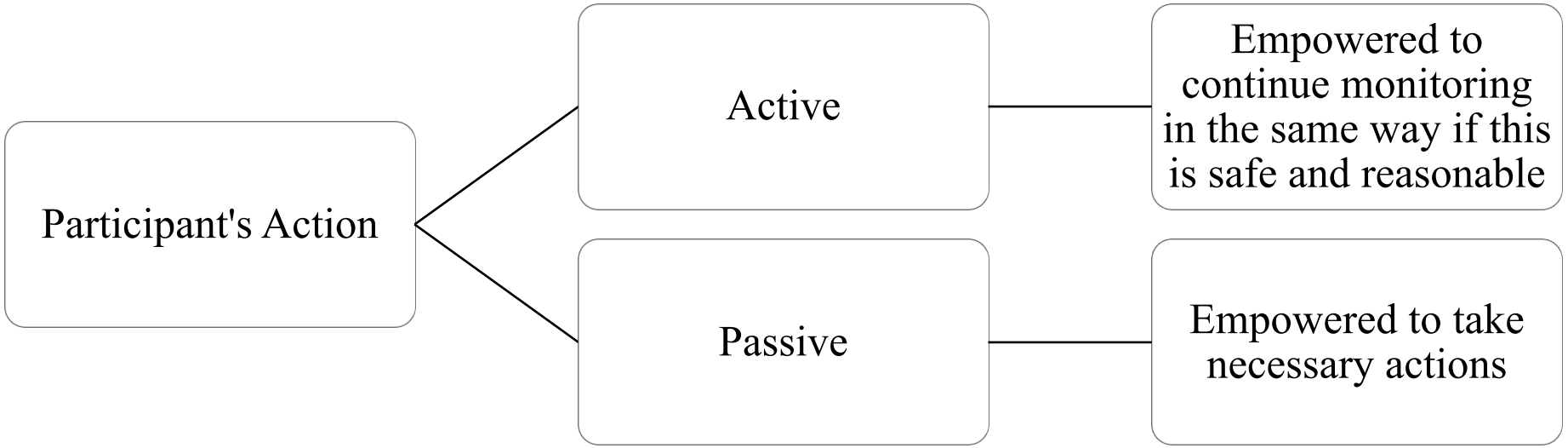
Summary Sheet – Frequency of Monitoring



Summary Sheet – Participant's Blood Pressure Readings



Summary Sheet – Participant's Action regarding his/her Blood Pressure Readings



Lokalita’ tal-ispiżerija: _____

1. **Sess**

 Raġel
 Mara
 Oħrajn
 Nippreferi ma ngħidx

2. **Eta’ (snin)**

 18-28
 29-38
 39-48
 49-58
 59-68
 69-78
 79-88
 89+

3. **Għal kemm żmien ilek tieħu l-mediċini tal-pressjoni?**

 Inqas minn sena
 1-5 snin
 6-10 snin
 11-20 sena
 21 sena jew iktar
 Ma niftakarx

4. **Tbati minn kundizzjonijiet oħra ta’ saħħa?**

 L-ebda kundizzjoni oħra
 Ażżma
 Dijabete
 Mard kroniku tal-kliewi
 Glawkoma

Oħrajn: _____

5. **Liem mediċina/i tal-pressjoni qiegħed/qiegħda tieħu? (Ir-riċerkatriċi tagħmel lista tal-isem ġeneriku, doża, l-iskeda tal- mediċini)**

Isem Ġeneriku	Doża	Skeda

6. Kellek xi tibdil fil- mediċini tal-pressjoni jew tibdil fid-doża fl-aħħar xahrejn?

- Tibdil fil-mediċini tal-pressjoni (bqajt bl-istess ammont ta' mediċini tal-pressjoni)
- Żieda fin-numru ta' mediċini tal-pressjoni
- Tnaqqis fin-numru ta' mediċini tal-pressjoni
- Żieda fid-doża
- Tnaqqis fid-doża
- L-ebda bidla

7. Għandek magna biex tkejjel il-pressjoni id-dar? (Jekk le aqbeż għall-mistoqsija numru 25)

- Iva
- Le

8. Taf id-ditta tal-magna tal-pressjoni li tuża? (Jekk le aqbeż għall-mistoqsija numru 10)

- Iva (il-marka tal-magna tal-pressjoni: _____)
- Le

9. Verifika mir-riċerkatriċi jekk il-magna tal-pressjoni tal-parteċipant/a hijiex validata skont STRIDE BP (https://stridebp.org).

- Iva
- Le

10. Kemm għaddew snin minn meta xtrajt il-magna tal-pressjoni?

- 0-2
- 3-5
- 6-8
- 9+
- Ma niftakarx

11. Kemm il-darba tuża l-magna tal-pressjoni?

- Darba f'ġurnata
- Iktar minn darba f'ġurnata
- Darba f'ġimgħa
- Iktar minn darba f'ġimgħa
- Darba kull ħmistax
- Darba f'xahar
- Meta niftakar

Oħrajn: _____

12. F'liem ħin tal-ġurnata tiċċekkja l-pressjoni?

- Wara li nqum filgħodu
- Qabel ma norqod
- Wara li nqum filgħodu **u** qabel ma norqod
- Wara nofsinhar
- Meta jkolli ċans/niftakar

Oħrajn: _____

13. Tiċċekkja l-pressjoni qabel jew wara li tiekol?

- Qabel ma niekol
- Wara li niekol
- Qabel **u** wara li niekol
- Meta niftakar

Oħrajn: _____

14. Tieħu l- mediċina/i tal-pressjoni qabel jew wara li tiċċekkja l-pressjoni?

- Qabel
- Wara

15. Qabel ma tiċċekkja l-pressjoni:

A) Tistrieħ għal 5 minuti ġo kamra kwieta?

- Iva
- Le

B) Tpejjep jew tixrob kafe'?

- Iva
- Le

Ċ) Tbattal il-bużżieqa tal-awrina?

- Iva
- Le

16. Waqt li tkun qed tiċċekkja l-pressjoni:

A) Tibqa' kwiet/a?

- Iva
- Le

B) Iżżomm dahrek mistrieħ/a mad-dahar tas-siġġu, idejk mistrieħa fuq il-mejda bil-magna imqiegħda fil-livell tal-qalb?

- Iva
- Le

Ċ) Tieħu mill-inqas żewġ qari b'intervall ta' żewġ minuti?

- Iva
- Le

17. Iżżomm rekord tar-riżultati tal-pressjoni tiegħek? (Jekk le aqbeż għall-mistoqsija numru 19)

- Iva
- Le

18. Tagħmel użu mir-riżultati tal-pressjoni tiegħek?

- Iva
- Le

19. Gieli ħadt il-magna tal-pressjoni tiegħek għall-kalibrazzjoni? (Jekk le aqbeż għall-mistoqsija numru 21)

- Iva
- Le

20. Kemm il-darba tieħu l-magna tal-pressjoni tiegħek għall-kalibrazzjoni?

- Darba f'sena
- Kull sentejn
- Kull 3 snin
- Kull 4 snin
- Kull 5 snin jew iktar

21. Qari tal-pressjoni tad-demm miksub meta mkejjel mir-riċerkatriċi:

Pressjoni	Polz

22. Il-qari tal-pressjoni jindika:

- Il-pressjoni qiegħda tajba
- Il-pressjoni qiegħda għolja
- Il-pressjoni qiegħda baxxa

(Jekk il-qari tal-pressjoni miksub huwa baxx jew għoli, il-pazjent jintbagħat għand it-tabib għal aktar monitoraġġ)

23. Meta tieħu azzjoni rigward il-qari tal-pressjoni tiegħek?

- Meta l-qari jkun għoli (speċifika x'inhu għoli għalik _____)
- Meta l-qari jkun baxx (speċifika x'inhu baxx għalik_____**)**
- Meta ma nħossnix sew
- Qatt

Oħrajn: _____

24. X'tip ta' azzjoni tieħu?

- Inkellem l-ispiżjar/a tiegħi
- Inkellem it-tabib/a tiegħi
- Ma ninforma lil ħadd
- Inbiddel id-doża mingħajr ma nkellem l-ebda professjonist tas-saħħa

25. Għalfejn tagħżel li ma jkollokx magna tal-pressjoni?

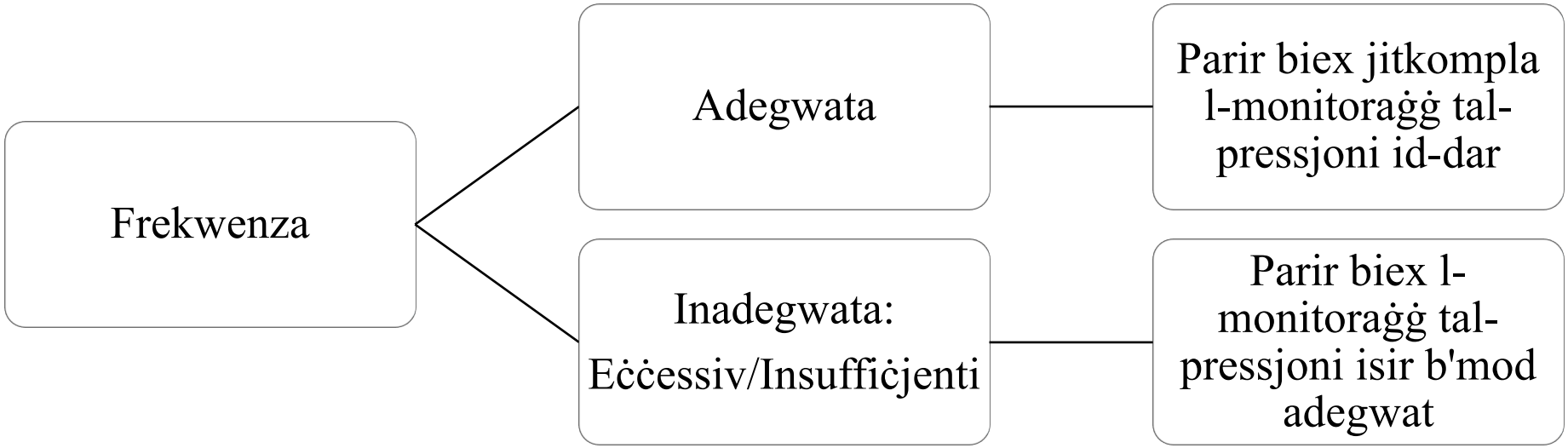
- Ma naffordjax waħda
- Ma nħossx li għandi bżonn waħda
- Ma nafx nużha
- Ma rridx waħda
- Nixtieq ikolli waħda kieku neħodha b'xejn mingħand il-Gvern
- Qatt ma kienet irrakkomandata mingħand tabib(a)/spiżjar(a)?

Oħrajn: _____

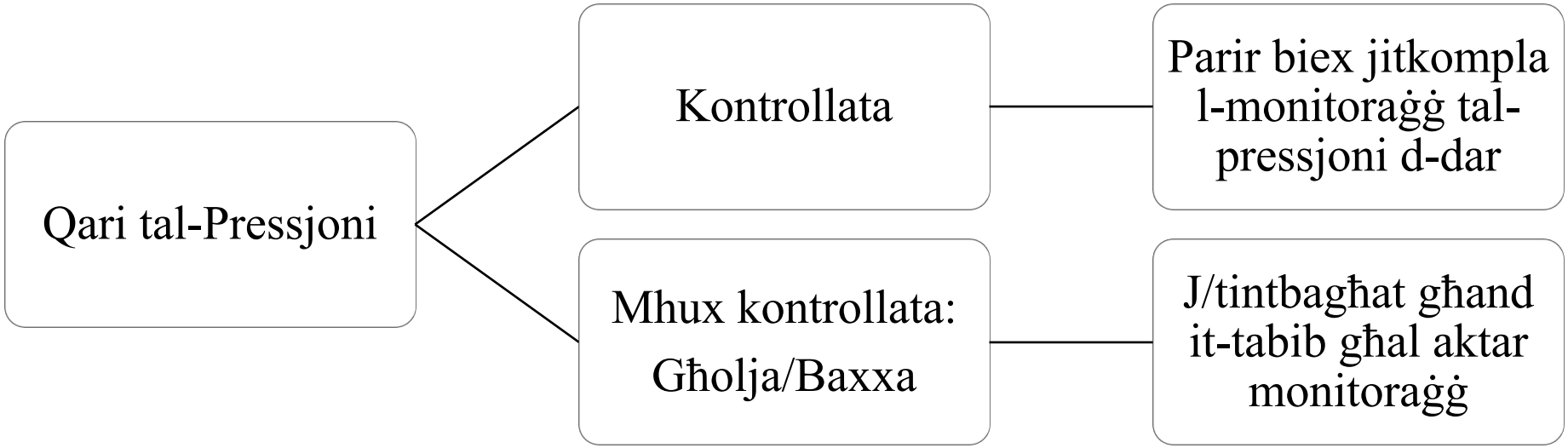
Pazjenti li ma jiċċekjawx il-pressjoni tad-demm tagħhom stess huma spjegati l-benefiċċji tal-monitoraġġ tal-pressjoni id-dar:

- Tevita żjarat ripetuti għand it-tabib tiegħek.
- Tista' tintuża fuq perjodu ta' żmien biex tiċċekkja l-varjabilita' tal-pressjoni tad-demm minn jum għal jum.
- Ma tiswix ħafna flus.
- Il-pazjent huwa nvolut fil-monitoraġġ tal-pressjoni tiegħu stess
- Il-pazjent huwa iktar rilassat id-dar milli fl-uffiċju tat-tabib.

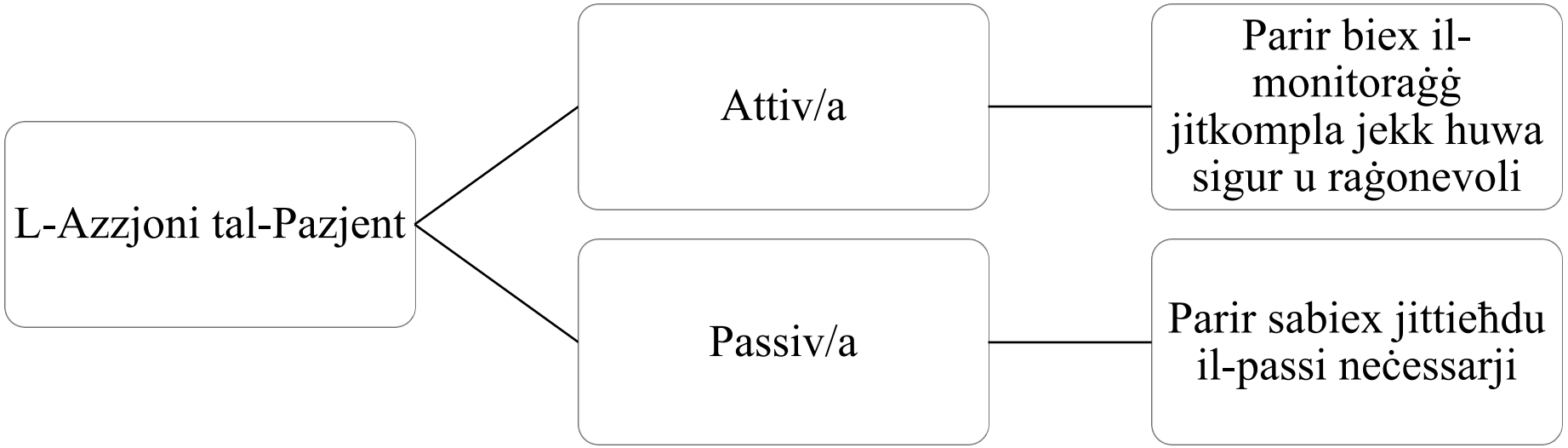
Sommarju – Frekwenza tal-Monitoraġġ



Sommarju – Qari tal-Pressjoni tad-Demm tal-Parteċipant



Sommarju – L-Azzjoni tal-Parteċipant rigward il-Qari tal-Pressjoni tiegħu/tagħha



Appendix 3: Flowchart (English and Maltese)

Summary Sheet – Correct Home Blood Pressure Monitoring Technique

Morning reading: within 1 hour of waking and after urination	Morning reading: before breakfast and before drug intake	Evening reading: before going to bed
Before reading: rest for 5 minutes in a quiet room	Before reading: do not smoke, drink coffee or exercise	Before reading: empty the bladder
During reading: back rested against a chair, arm rested on table and feet on the floor	At least 2 readings, with a 2-minute interval	Record your readings and discuss readings with your pharmacist or doctor

Sommarju – Teknika Korretta tal-Awtomonitoraġġ tal-Pressjoni tad-Demm

Qari ta' filgħodu: sa siegħa wara li tqum u wara li tbattal il-burżieqa tal-awrina	Qari ta' filgħodu: qabel l-ikla ta' filgħodu u qabel tieħu l-medicini	Qari ta' filgħaxija: qabel ma tmur torqod
Qabel il-qari: strieħ għal 5 minuti ġo kamra kwieta	Qabel il-qari: tpejjipx, tixrobx kafe' u tagħmilx eżerċizzju	Qabel il-qari: battal il-borża tal-awriena
Waqt il-qari: żomm dahrek mistrieħ/a mad-dahar tas-siġġu, idejk mistrieħa fuq il-mejda u żomm saqajk mal-art	Mill-inqas żewġ qari b'intervall ta' żewġ minuti	Żomm rekord tal-qari u iddiskuti l-qari mal-ispiżjar/a jew tabib/a

Appendix 4: Physician Referral Note

Date: _____

Name: _____

ID number: _____

Test Result:

Blood Pressure Measurement (mmHg)	Heart Rate (bpm)

Reason for referral:

The patient is being referred to you for further monitoring as his/her blood pressure reading is not within the normal range of 120/80 mmHg – 129/84 mmHg[1].

Comments:

_____

_____

_____

_____

Thank you.

Michaela Vella

Researcher
PharmD Dissertation

[1]Mancia G, Kreutz R, Brunström M, Burnier M, Grassi G, Januszewicz A, et al. 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). Journal of Hypertension. 2023;41(12):1874-2071. DOI: 10.1097/HJH.0000000000003480

Data: _____

Isem: _____

Numru tal-ID: _____

Riżultat tat-test:

Riżultat tal-Pressjoni tad-Demm (mmHg)	**Rata tat-Taħbit tal-Qalb (bpm)**

Raġuni għar-referenza:

Il-pazjent/a qed jiġi/tiġi riferut/a għandek għal aktar monitoraġġ għaliex il-qari tal-pressjoni tad-demm tiegħu/tagħha mhux fil-medda normali ta' 120/80 mmHg – 129/84 mmHg[1].

Kummenti:

_____

_____

_____

_____

Grazzi.

Michaela Vella

Riċerkatriċi
Dissertazzjoni tal-PharmD

[1]Mancia G, Kreutz R, Brunström M, Burnier M, Grassi G, Januszewicz A, et al. 2023 ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). Journal of Hypertension. 2023;41(12):1874-2071. DOI: 10.1097/HJH.0000000000003480

Appendix 5: Appraisal of HBPM Devices

Brand Name	Measurement Range	User Interface	Arrhythmia detector	Validated by STRIDE BP®	Cost
Yuwell® YE660B	Pressure: 0 – 280 mmHg Pulse: 40 – 200 beats/minute	Stores 74 readings	Yes	No	€55.00
Gima® Smart Automatic Monitor	Pressure: 0 – 295 mmHg Pulse: 40 – 199 beats/minute	2 users – 60 memories per user WHO classification indicator Average value of latest 3 readings	Yes	No	€47.20
Medicare® LifeSense A2 MD 1803	Pressure: 0 – 295 mmHg Pulse: 40 – 199 beats/minute	3 users – stores 40 readings per user WHO classification indicator Average value of latest 3 readings	Yes	No	€49.95
Gima® Jolly Monitor	Pressure: 0 – 300 mmHg Pulse: 40 – 180 beats/minute	4 users – stores 30 readings per user Average of all saved measured values	Yes	No	€59.50

Gima® Talking Monitor	Pressure: 0 – 300 mmHg Pulse: 40 – 180 beats/minute	Stores 60 readings WHO classification indicator Voice function	Yes	No	€70.80
Medel® Control	Pressure: 0 – 300 mmHg Pulse: 40 – 199 beats/minute	4 users – stores 30 readings per user WHO classification indicator Average value of all stored readings Average value of the morning measurements for the last 7 days	Yes	No	€32.43
Yuwell® YE660D	Pressure: 0 – 300 mmHg Pulse: 40 – 200 beats/minute	Stores 90 readings Average value of latest 3 readings	Yes	No	€50.00
Sure Sign®	Pressure: 40 – 260 mmHg Pulse: 40 – 160 beats/minute	2 users – stores 60 memories per user WHO classification indicator	Yes	No	€39.51

Medisana® BU 535	Pressure: 40 – 260 mmHg Pulse: 40 – 180 beats/minute	2 users – stores 120 memories per user WHO classification indicator Average of all saved measured values	Yes	No	€59.95
Medisana® BU 535 Voice	Pressure: 40 – 260 mmHg Pulse: 40 – 180 beats/minute	2 users – stores 120 memories per user WHO classification indicator Average of all saved measured values Voice function	Yes	No	€64.95
Boso® Medilife Compact S	Pressure: 40 – 280 mmHg Pulse: 40 – 200 beats/minute	Stores 30 readings Average value of all stored readings	Yes	No	€59.90

A&D® UA-651	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Stores 30 readings WHO classification indicator Average of all saved measured values	Yes	Yes	€52.33
A&D ® UA-611	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Stores 30 readings WHO classification indicator Average of all saved measured values	Yes	Yes	€49.51
A&D® UA-767F	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Movement error indicator Stores 60 readings WHO classification indicator Average of all saved measured values	Yes	Yes	€69.95
A&D® UA-767SW	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Movement error indicator Stores 60 readings WHO classification indicator	Yes	Yes	€62.50

		Average of all saved measured values			
Omron® M1 HEM-7121J-AF	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Stores last reading	Yes	Yes	€42.98
Omron® M2 HEM-7121-E	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Stores 30 readings	Yes	Yes	€53.50
Omron® M3 Comfort HEM-7155-E	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Movement detector 2 users – stores 60 readings per user	Yes	Yes	€75.00

Omron® M6 Comfort Digital HEM-7321-E	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Movement detector 2 users – stores 100 readings per user Blood pressure light indicator in case that values exceed the European Society of Hypertension standards for domiciliary Average value of latest 3 readings	Yes	Yes	€72.92
Omron® M7 Intelli IT HEM-7361-EBK	Pressure: 0 – 299 mmHg Pulse: 40 – 180 beats/minutes	Movement detector 2 users – stores 100 readings per user Average weekly value of morning and night measurements	Yes	Yes	€74.58
Beurer® BM 40	Pressure: 0 – 300 mmHg Pulse: 30 – 180 beats/minute	2 users – stores 60 readings per user WHO classification indicator Average of all saved measured values Average of morning and evening blood	Yes	Yes	€49.95

		pressure for the last 7 days			
Pic® CardioAfib	Pressure: 30 – 260 mmHg Pulse: 40 – 199 beats/minute	2 users – stores 120 readings per user Carries out triple measurement for accuracy	Yes	Yes	€58.15
Medisana® Pro Monitor	Pressure: 30 – 280 mmHg Pulse: 40 – 200 beats/minute	2 users – stores 99 readings per user Average value of latest 3 readings	Yes	Yes	€65.63
Hartmann Veroval® Duo	Systolic measurement: 50 – 250 mmHg Diastolic measurement: 40 – 180 mmHg Pulse range: 30 – 199 beats/minute	2 users – stores 100 memories per user WHO classification indicator Average of all stored measured values	Yes	Yes	€87.78

		Average morning and evening blood pressure readings of the last 7 days			
Pic® Easy Rapid	Systolic Blood Pressure: 60 – 230 mmHg Diastolic Blood Pressure: 40 – 130 mmHg Pulse rate: 40 – 199 beats/minute	2 users – stores 60 readings per user Average value of latest 3 readings	Y**es**	Yes	€53.21

Appendix 6: Appraisal of ABPM Devices

Brand Name	Measurement Mode	Pulse Rate	SpO2 Monitor	Bluetooth	Operating System Compatibility	Validated by STRIDE BP®	Cost
GIMA® 24 hours ABPM + Pulse rate monitor	Manual or Automatic: 15/30/60/120 /240 minutes	Yes 40 – 240 beats/minute	No	No	Windows XP/8/8.1/10 (32-bit & 64-bit version)	No	€435.00
GIMA® 24 hours ABPM + Pulse rate monitor with Bluetooth	Manual or Automatic: 15/20/30/40/60/90/120/240 minutes	Yes 40 – 240 beats/minute	No	Yes	Windows XP/8/8.1/10 (32-bit & 64-bit version)	No	€507.40
GIMA® 24 hours ABPM + Pulse rate + SpO2 Monitor	Manual or Automatic: 5/10/15/20/30/ 45/60/90 minutes	Yes 0 – 250 beats/minute	Yes	No	Windows XP/8/8.1/10 (32-bit & 64-bit version)	No	€542.80

Brand Name	Measurement Mode	Pulse Rate	SpO2 Monitor	Bluetooth	Operating System Compatibility	Other features	Validated by STRIDE BP®	Cost
A&D® TM-2441	Oscillometric Measurement Automatic: 5/10/15/20/30/60/120 minutes Systolic: 60-280mmHg Diastolic: 30-160mmHg	Yes 30-200 beats/minute	No	Yes	Windows 10 (64-bit version)/11	Temperature, pressure and activity can be graphed alongside blood pressure due to the presence of a multi-sensor.	Yes	€1,221.00
Meditech® ABPM-06	Oscillometric measurement Manual or Automatic: 5/10/15/20/25/30/40/60/90 minutes 30-280mmHg	Yes 40-240 beats/minute	No	No	Windows XP/7/8/10/11	Automatic cuff size detection. Built-in voice recording. IP22 water ingress protection.	Yes	€1,364.00
Microlife® WatchBP® 03	Oscillometric measurement Manual or Automatic 15/20/30/60 minutes 30-280mmHg	Yes 40-200 beats/minute	No	No	Windows 10/11	50 data memories for tablet intake recordings.	Yes	€1,499.44
Somnomedics® ABPMpro Basic Set	Oscillometric measurement Automatic: 3/5/10/15/20/30/60 minutes Systolic: 60-230mmHg	Yes	No	No	Windows 10/11	The main device slides directly on to the cuff. Recording of activity and body position.	Yes	€1,910.24

	Diastolic: 40-130mmHg							
Somnomedics® ABPMpro ECG Holter Set	Oscillometric measurement Automatic: 3/5/10/15/20/30/60 minutes Systolic: 60-230mmHg Diastolic: 40-130mmHg	Yes	No	No	Windows 10/11	The main device slides directly on to the cuff. Recording of activity and body position. 3-Channel ECG sensor (Holter).	Yes	€2,595.00
Somnomedics® ABPM Research Set	Oscillometric measurement Automatic: 3/5/10/15/20/30/60 minutes or PTT-based Systolic: 60-230mmHg Diastolic: 40-130mmHg	Yes	No	No	Windows 10/11	The main device slides directly on to the cuff. Recording of activity and body position. 3-Channel ECG sensor (Holter) & Plethysmograph sensor (for continuous, non-invasive blood pressure measurement without inflation of the cuff based on the pulse transit time)	Yes	€5,470.54

Appendix 7: Dissemination of Results

FIP Abstract

Blood Pressure Monitoring in Community Pharmacy

Michaela Vella, Francesca Wirth, Lilian M. Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background
Pharmacists are able to contribute to hypertension management by being involved in educating patients on the importance of home blood pressure monitoring (HBPM).

Purpose
To propose pharmacist interventions supporting patient empowerment of blood pressure (BP) self-monitoring.

Method
A data collection sheet to assess practice of BP self-monitoring and an action plan to facilitate patient empowerment were developed and validated. A flowchart explaining correct HBPM techniques was designed. The data collection sheet and the action plan were implemented by means of an interview to 120 participants on antihypertensive therapy recruited from 4 community pharmacies chosen by convenience sampling. During the interview, the participants' BP was measured by the researcher using a validated automatic upper arm BP measuring device.

Results
From a total of 120 participants, 55% claimed to own an automatic upper arm oscillometric HBPM device. For the participants who self-monitor BP, ways to improve HPBM technique, frequency and follow up of BP results were identified by the researcher. For the participants who do not self-monitor (45%), benefits of HBPM and devices available were explained by the researcher. Lack of adequate monitoring frequency was observed: 31.8% self-monitor when they remember. The technique most defaulted was bladder emptying prior to monitoring (79%). Out of the 66 participants who self-monitor, 30 participants were found to have elevated BP. Using the chi-square test, no statistical significance ($p>0.05$) was found between self-monitoring and BP reading. An action plan was devised for each participant by the researcher depending on the participant's needs, mainly addressing monitoring frequency, BP reading results and the participant's action towards home BP readings.

Conclusion

Interventions required by pharmacists to improve HBPM were identified. Correct BP targets must be better explained to patients by pharmacists, encouraging correct action to be taken by seeking advice from a healthcare professional when home BP readings are not within target. Pharmacists must prioritize those patients with uncontrolled BP despite self-monitoring, identifying reasons and ways to improve HBPM.

ESCP Abstract

Pharmacist-led Ambulatory Blood Pressure Monitoring in Community Pharmacy

Michaela Vella, Francesca Wirth, Lilian M. Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background
Ambulatory blood pressure monitoring (ABPM) is the gold standard for diagnosing hypertension and assessing 24-hour BP. ABPM compliments home BP monitoring (HBPM) by assessing white coat hypertension, diagnosing masked hypertension, and providing information on nighttime dip and morning surge.

Aim
To appraise ABPM devices and assess the feasibility of pharmacist-led ABPM in community pharmacy.

Method
ABPM devices available on the market were appraised. Ten patients satisfying the inclusion criteria (newly diagnosed with hypertension, recent change in medication/dose, patient-reported non-compliance to hypertension management) were recruited by purposive sampling for 24-hour ABPM from 4 community pharmacies selected by convenience sampling. Two appointments, 24 hours apart, were set up for each participant. A report with ABPM readings was generated for each participant and interpreted. Participants with mean 24-hour BP ≥130/80 mmHg were referred to a physician using a referral letter.

Results
Nine ABPM devices were appraised, of which 3 were available locally. Based on cost and availability, 'GIMA 24-hour ABPM + Pulse Rate Monitor' was selected, which has a BP measurement range of 0 to 290 mmHg and costs €435. After ethics approval, 10 participants accepted and 10 refused since they believed ABPM is burdensome (n=6) or felt embarrassed being seen with the device (n=4). Of the 10 participants (5 male, 5 female, age range 35-69 years), 4 were diagnosed with hypertension <1 year and 5 perform HBPM. Successful 24hour ABPM was achieved in 9 participants. Each appointment required 30-60 minutes of pharmacist time, led to a report used by the pharmacist to provide patient recommendations, and ABPM results were provided to the participants. Four participants were referred to their physician due to elevated mean BP readings (24hour, nocturnal or diastolic BP). Application of ABPM was well-accepted, with challenges related to sleep disturbance and bruising reported by 4 participants.

Conclusion
Accessibility to ABPM in community pharmacies provides an opportunity for pharmacist-led enhanced patient monitoring and out-of-office BP management. Pharmacist-led ABPM service in community pharmacies in a collaborative care context is feasible and contributed to identifying patients requiring further assessment. Pharmacist and patient education on the importance of ABPM is essential for adequate hypertension management.