

# Utility of medicines information leaflets in hypertensive care in a setting with low health literacy: A cross-sectional study

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## Abstract

**Introduction:** Higher levels of health literacy improve utilization of health information, medication adherence and outcomes. Few studies evaluate the utility of medicines information in hypertensive care in settings with low health literacy.

**Aim:** To determine the level of health literacy and utility of medicines information leaflets (MILs) among hypertensive patients in public health care in Namibia.

**Methods:** A hospital-based survey among hypertensive patients receiving care at a referral hospital in Namibia from the 8 June 2018 to 29 June 2018. Patient's health literacy and utility of MIL were assessed using three literacy tools and a survey questionnaire. Quantitative data were analysed using descriptive statistics and qualitative thematic content analysis for factors associate with the utility of the MIL.

**Results:** Of the 139 patients, 63% were female and the mean age was 45.7 (range: 19.0–84.0) years. Over 85.6% had of low literacy skills (Rapid Estimate of Literacy in Medicine (REALM) score <44, that is, unable to read simple health materials), 38.8% had positive Single Item Literacy Screener (SILS) scores ( $\geq 2$ , require help to read medicines information) and 66.9% had inadequate skills for comprehension, appraisal and decision-making with regard to health information (Health Literacy Skills Instrument-Short Form (HLSI-SF) score <70%). The level of access to and utility of MIL were low, 32.4% and 34.6%, respectively. The main factors associated with poor utility of the MIL were low patient health literacy, lack of guidelines on the use of MIL and MIL written in non-native languages.

**Conclusion:** Low rates of health literacy and utility of MIL were observed among hypertensive patients in Namibia. The integration of health literacy programmes, and MIL guidelines are needed to promote utility of medicine information and improve medication adherence.

## Keywords

Access, health literacy, medicine information leaflets, Namibia, utility

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## Introduction

Inadequate literacy is a major barrier to access to public health care, particularly among patients in sub-Saharan Africa.<sup>1–3</sup> Current evidence suggests that limited literacy negatively impacts on a wide array of health outcomes, including childhood health, mental health and in patients with chronic diseases.<sup>4–6</sup> However, there are limited data on the impact of health literacy on the utility of medicine information among hypertensive patients in the sub-Saharan Africa where the burden of the disease is highest.<sup>7,8</sup>

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Over half (9.4 million) of deaths due to cardiovascular diseases (CVDs) globally are linked to hypertension, the majority of which are among patients in low- and middle-income countries (LMICs) in the sub-Saharan Africa.<sup>9,10</sup> With an estimated prevalence of 45%, Namibia has one of the highest burden of hypertension in sub-Saharan Africa.<sup>11–13</sup> This is a concern given the universal access to cost-free hypertensive care and medicines in Namibia. Nashilongo et al.<sup>14</sup> estimated that 58% of hypertensive patients in the suburbs of Windhoek do not adhere to their medication. These findings concur with the World Health Organization (WHO) estimates that over half of patients do not use their medication correctly.<sup>15,16</sup> Moreover, adherence to antihypertensive medication is critical in the prevention of cardiovascular complications.<sup>17</sup>

Several studies identified low health literacy rates among hypertensive patients as a major risk factor for sub-optimal utility of medicine information, medication adherence and blood pressure control.<sup>1,13,18,19</sup> The WHO describes health literacy as the ability to engage with health information and services.<sup>20–22</sup> This requires patients to access, comprehend, critique and use health information and services to make health-related decisions such as adhering to medicines prescribed.<sup>20</sup> A study across 14 sub-Saharan countries based on data from national demographic surveys estimated health literacy rates to range from 4% to 65.7%, with Namibia having the highest rate.<sup>6,23</sup> This is helped by the fact that in 2015 the National Health Literacy Programme of Namibia estimated over 76% enrolment into adult literacy programmes. However, a study by Likando et al. challenges that adult literacy rarely translates into functional literacy to independently perform tasks such as improving medicine use based on the information contained in medicine leaflets.<sup>24–26</sup> Sub-optimal utility of medicines information is a public health concern in patients with chronic non-communicable diseases (NCDs) such as hypertension that require adequate levels of health literacy for medication adherence and self-care.<sup>19,27,28</sup>

The implementation of the United Nations Sustainable Development Goals (SDGs) in most countries in sub-Saharan Africa has enhanced access to universal health literacy programmes and the utility of medicines information.<sup>1,29,30</sup> In Namibia, the National Human Rights Action Plan, Namibia patient's charter and the Medicines and Related Substance Control Act provide a legal framework for patients to the right to access information on treatment and medicines information leaflets (MILs).<sup>31–33</sup> In this legal framework, all patients who receive health care are entitled to obtain MILs written in the official language that includes basic information on the medicine. For patients to effectively utilize MIL requires adequate level of health literacy, that is, the ability to read and comprehend medicines information with limited support and make decisions regarding to their health.<sup>34,35</sup> Several studies give conflicting information on the utility of MIL in LMICs, some indicating low and others high utility.<sup>35–38</sup>

Nevertheless, despite the relatively high adult literacy rates in Namibia, there are limited data on the health literacy levels (reading, comprehension and numeracy of health materials) and its impact on the utility of medicines information in public health care. Consequently, the study sought to address this by assessing the level of health literacy, access to, and utility of, MIL, among hypertensive patients and professionals at public health facilities in Namibia. The findings can be used to guide future policies for equitable access to medicines information at the point of care among public health facilities across Namibia as well as across sub-Saharan Africa.

## Methods

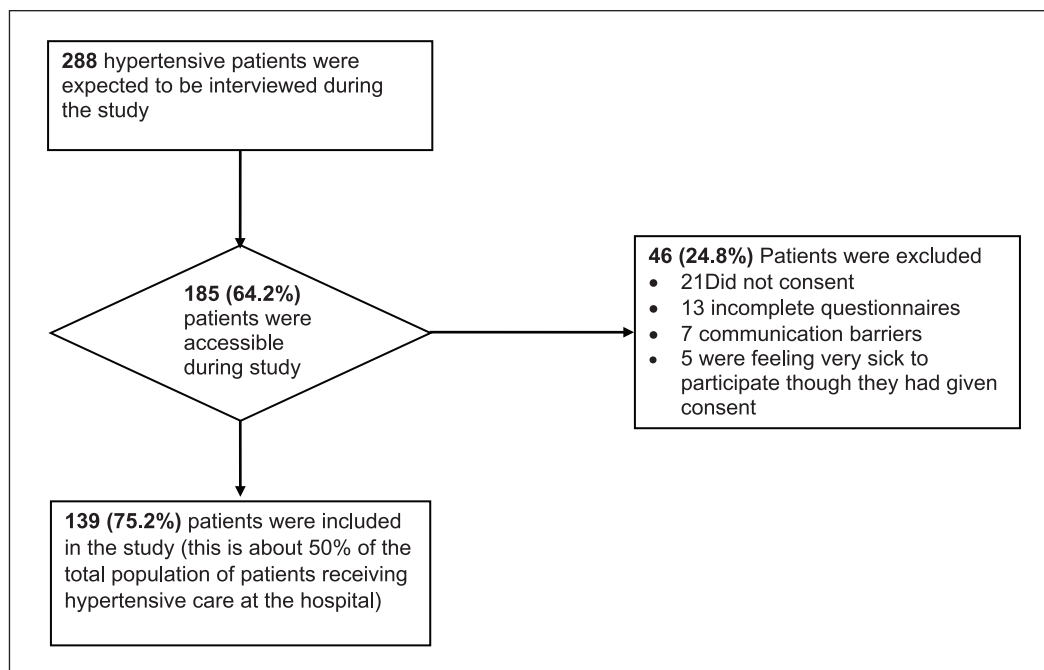
### *Study design and population*

The study consisted of two surveys, one among hypertensive patients and the other among health care professionals. The first survey assessed the levels of health literacy and utility of the MIL among hypertensive patients. This was conducted at Katutura Intermediate Hospital (KIH), a tertiary referral hospital from 8 June 2018 to 29 June 2018 using patient exit interviews. The hospital has annual turnover of 7000 patients on medication for NCDs including antihypertensive medication. A sample of 185 patients was estimated using Leslie Kish method.<sup>39,40</sup> The study included only patients on antihypertensive treatment with at least one medication for a period of 3 months or more and gave written consent to participate. The study excluded patients who did not consent to participate, too sick to participate and/or unable to communicate due to language barrier (Figure 1).

Second, a survey was conducted among healthcare professionals (HCPs), that is, pharmacists, pharmacists-assistants and nurses, involved in dispensing antihypertensive medication, HCPs were interviewed using a semi-structured questionnaire to assess the factors associated with access to, and utility of, the MIL. The questionnaire assessed perceptions regarding the need, usefulness, availability, benefits and barriers to using the MIL.

### *Data collection procedure*

Data on access to, and utility of, the MIL and associated factors were collected from hypertensive patients receiving care at the outpatient department of KIH. Patients were systematically (i.e. every third patient) recruited over the study period based on daily attendance registers. Patients were interviewed for access and utility of the MIL using a semi-structured questionnaire and health literacy using three tools. These were the Single Item Literacy Screener (SILS), Health Literacy Skills Instrument-Short Form (HLSI-SF) and Rapid Estimate of Literacy in Medicine (REALM) tools (see below). The three health literacy tools were subsequently assessed for comprehension, reading skills and



**Figure 1.** Sample selection for inclusion of patients in the study.

numeracy skills. All the tools were piloted among 10 patients receiving antihypertensive care at the Intermediate hospital between 22 May 2018 and 24 May 2018 for suitability of the question items using semi-structured interviews. The face validity of the tools was subsequently established by the research team (S.M., D.K., E.H.) using 10 questionnaires for appropriateness of question items and standardized prior to the conducting interviews. Interviews to assess for health literacy and utility of the MIL were conducted in English. For some patients, the questionnaires on utility of the MIL were interpreted in Afrikaans and Oshiwambo, two widely spoken local languages in Namibia. Each interview lasted between 20 and 30 min per patient.

In addition, data were collected from the HCPs involved in the prescribing and dispensing of antihypertensive medication at the hospital. Data were collected using structured questionnaire interviewer-administered interviews that assessed for factors associated with the MIL and to promote access and utility of the MIL in antihypertensive care at the hospital. The study only included HCPs involved in hypertensive care and were on duty during the study interview.

### Health literacy assessment tools

The level of health literacy among the hypertensive patients was assessed using three tools (REALM, SILS and HLSI-SF), which assess different dimensions of health literacy. The REALM assessed for the basic reading skills (literacy), the SILS assessed for the need for the support when reading health-related materials and the HLSI-SF

assesses for comprehension and health seeking behaviours. A combination of three tools was used because no single tool comprehensively assess all the dimensions of health literacy.

First, the REALM tool assess the patient's ability to read medicine information.<sup>41,42</sup> The REALM tool consists of 66 health terms. The patient is scored with a point for the number of words that they read and pronounce with a maximum of 66 points. REALM scores 0–18 indicate that a patient is unable to read easy health information, 19–44 indicate that patients are only be able to read simple materials and a score above 44 indicates that the patient is able to read and understand health information. In this study, a REALM score of less than 44 was regarded as low literacy and unable to read or utilize information on the MIL.

Second, an SILS tool was used to assess the patient's need for support in reading health-related materials.<sup>43</sup> Patients responded to a single question item 'How often do you need to have someone help you when you read medicine information leaflets, or other written material from your doctor or pharmacy?' The SILS is scored with 1 (never), 2 (rarely), 3 (sometimes), 4 (often) and 5 (always). Negative SILS score ( $\leq 2$ ) indicates that the patient never or rarely needs help when reading health-related materials, while a positive SILS score ( $> 2$ ) indicates that a patient experiences difficulty in reading health-related materials and requires support.

Third, a 10-item HLSI-SF assesses patient's comprehension, numeracy, health information seeking, decision-making and navigation skills.<sup>44</sup> The HLSI-SF assessment requires patients to read a pre-designed MIL (print-prose),

listen and correctly respond to recorded voices. The HLSI-SF is designed to measure patient's ability to remember and understand information they read on the print-prose, and find health information they need on printed documents. The tool also measures the ability to proficiently interpret figures and doing simple calculations according to the quantitative aspects of the print-prose, to remember and understand the information they heard or explain the health issue to an HCPs, ease to find the health information they needed and reason out concepts. Each correctly answered item on the HLSI-SF is scored one point and the incorrect zero. A percentage HLSI-SF score  $\geq 70\%$  is considered as an adequate level of health literacy,  $>80\%$  proficient,  $70\%$ – $80\%$  basic and  $<70\%$  below basic.

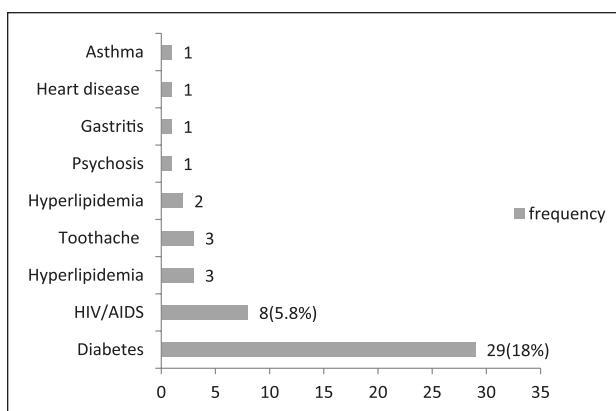
### Data analysis

The primary outcomes of the study were level of health literacy (reading, comprehension and numeracy) and utility of MIL among hypertensive patients. The secondary outcome was the factors associated with the utility of the MIL in hypertensive care. Quantitative data on health literacy, utility and access to MIL were entered in EpiData v3.1 software for management and exported to SPSS v23 software for descriptive analysis. The REALM assessment graded health literacy as adequate for a score of  $\geq 44$ , SILS  $\leq 2$ , that is, no need for assistance to read the MIL and  $70\%$  for HLSI-SF for comprehension, numeracy and decision-making. The factors associated with the utility of MIL were analysed qualitatively using content thematic analysis using manual colour coding to generate themes and subthemes. The level of access to MILs was estimated, respectively, by the proportion (%) of patients that 'always' received a MIL for their antihypertensive medication as required by the Medicines and Substance Act of Namibia. 'Do you always receive the leaflets for your medication?' The level of utility of MIL was determined by the proportion of patients (%) that self-reported that they have ever made reference to the MIL with regards to their antihypertensive medication. The HLSI-SF was assessed for construct validity in the Namibian population using factor analysis.

In addition, data from HCPs were qualitatively analysed using content analysis for themes on the factors associated with, and potential strategies, to improve access and utility of MIL in antihypertensive care at the health facility.

### Ethics

The study was approved by Research and Ethics Committees of the Ministry of Health and Social Services and Katutura Intermediate Hospital (MoHSS042018). All respondents gave a written informed consent and confidentiality of data was maintained through anonymizing of questionnaires by use of codes rather than patient identifiers and all questionnaires secured at the University of Namibia.



**Figure 2.** Co-morbidities among hypertensive patients at Intermediate hospital Katutura.

HIV: human immunodeficiency virus; AIDS: acquired immunodeficiency syndrome.

## Results

### Characteristics of study populations

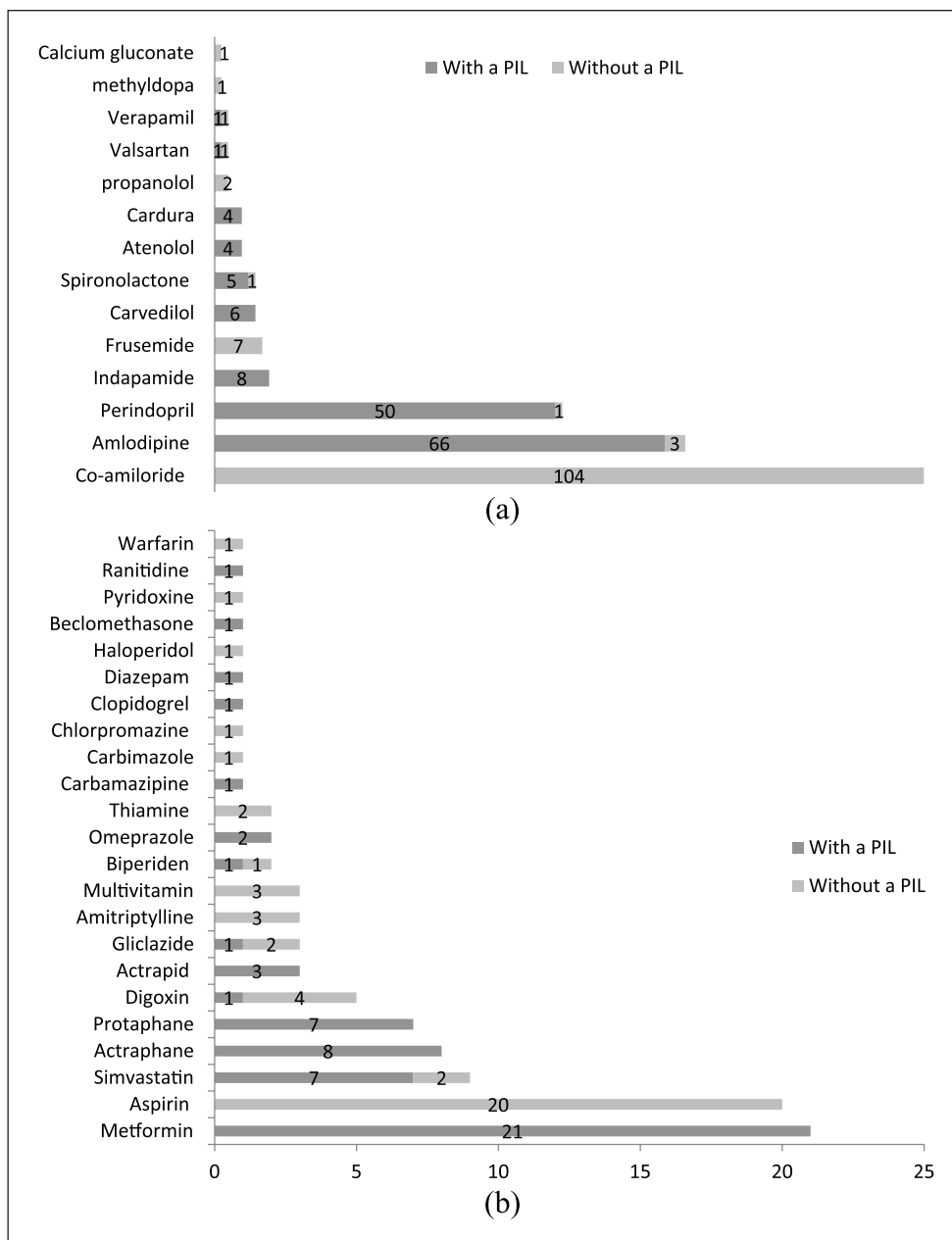
Of the 185 target sample, 139 hypertensive patients were recruited giving a response rate of  $75.1\%$  ( $n=139/185$ ). The majority of the patients were female ( $61.2\%$ ) and were not formally employed ( $63.3\%$ ). The average age was 45.7 years (range: 19.0–84.0), the majority not married ( $58.3\%$ ) and attained at least primary level education ( $54.7\%$ , that is, grade 10). Of the 139 patients,  $90.6\%$  were on follow-up visits,  $18\%$  had diabetes mellitus and  $5.8\%$  HIV/AIDS (Figure 2). Of the 139 patients, the majority were prescribed hydrochlorothiazide/amiloride ( $74.8\%$ , that is, co-amiloride<sup>®</sup>) or amlodipine ( $49.6\%$ ) for their hypertension. Low dose aspirin ( $14\%$ ) and metformin ( $14\%$ ) were the most prescribed co-medications (Figure 3).

Of the 14 HCPs recruited,  $57.1\%$  were females. The mean age and working experience of the HCPs was  $34.1 \pm 7.0$  (range: 25.0–52.0) and  $10.8 \pm 7.3$  (range: 2.0–30.0) years, respectively.

### Health literacy among hypertensive patients

Of the 139 patients,  $85.6\%$  were unable to easily read medicine information (REALM score: 0–18) and  $14.4\%$  were only able to read simple materials (REALM score: 19–44) (Table 1). None of the patients were able to read complex health information such as MILs, that is, none had a REALM score  $\geq 44$ .

On the SILS assessment,  $38.8\%$  ( $n=54/139$ ) of the patients had positive scores ( $>2$ ), that is, they have limited reading ability and they need support when reading medicine information. These patients experience difficulty in reading health-related materials and would require support (Table 1).



**Figure 3.** (a) Antihypertensives dispensed with medicine information leaflet. (b) Other chronic medication dispensed with or without a MIL. PIL: patient information leaflet.

On average, patients had a health literacy level on HLSI-SF assessment of  $58.5\% \pm 18.5\%$  (range: 16.7%–100%). In addition, 66.9% of the patients had inadequate health literacy (HLSI-SF score  $<70\%$ , Figure 4). That is, two-thirds of patients had limited ability to comprehend, communicate and make decisions regarding medicine information. In particular, 46% of the patients remembered and understood information they had read on the print-prose, 27.3% found health information they needed on printed documents and 42.4% proficiently interpreted figures and had performed simple calculations according to

the print documentation. In addition, 47.5% of the patients remembered and had understood the information they heard or explained a health issue to an HCPs according to the oral domain and 25.2% easily found the health information they needed and reasoned out concepts according to the Internet domain (Table 1).

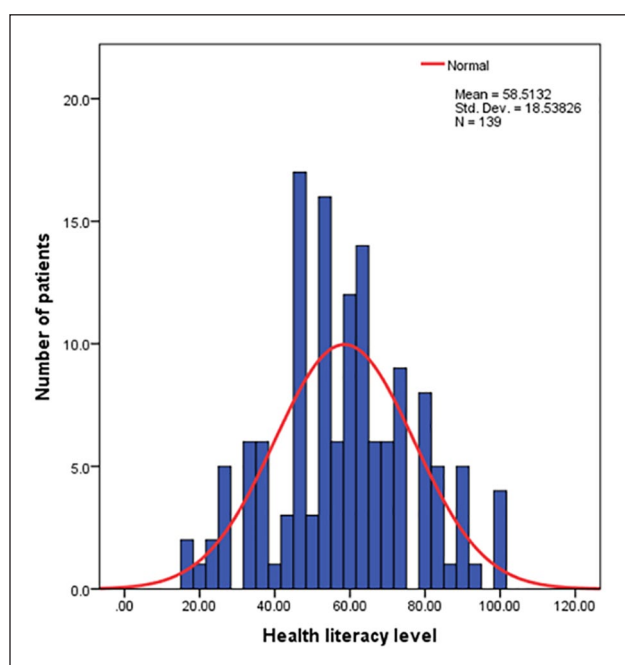
#### Access of MIL in hypertensive care

Of the 139 patients, 32.4% ( $n=45$ ) always receive a MIL for their antihypertensive medication at hospital (Table 2).

**Table 1.** Patient access and use of MIL.

Characteristic	Yes	No
Does the patient have a leaflet for any medication?	103 (74.1)	36 (25.9)
Do you think you would like to have a leaflet for all your medicines?	129 (92.8)	10 (7.2)
Do you always receive the leaflet?	45 (32.4)	94 (67.6)
Pharmacy staff should give you the leaflet	124 (89.2)	15 (10.8)
Where do you get the leaflet from the pharmacy?	139 (100)	0 (0)
Do you receive information regarding any of the leaflets you were given?	28 (21.1)	111 (79.9)
If you received information regarding any leaflet, was the information helpful?	26 (92.9)	2 (7.1)
Do you think you can read the information on all leaflets for your medications?	112 (80.6)	27 (19.4)
Do you think the leaflets are written in a language you can understand?	112 (80.6)	27 (19.4)
Do you make reference to the leaflet?	48 (34.6)	96 (65.4)
Do you think the leaflet is useful?	131 (94.2)	8 (5.8)

MIL: medicines information leaflet.



**Figure 4.** Health literacy level using the Health Literacy Skills Instrument-Short Form.

The level of access of MILs for the antihypertensive medications was higher with amlodipine (44.5%) and perindopril (36%) compared to other medications. None of the patients received MILs for co-amiloride, the most used antihypertensive (Figure 3).

Over 80% of the patients were aware of the right to access the MIL, but 74.1% had never requested for a leaflet. Most patients, 79.9% ( $n=111/139$ ), never received information on how and where to access, and instructions on the use of the MIL (Table 2).

Most HCPs had never received training on optimizing access to, and utility of, MIL (78.6%). HCPs were not aware of hospital-based policies/guideline to enhance the use of MILs (85.7%). However, 35.7% were aware of the

national legal frameworks for the distribution of the MIL, 28.6% citing the Pharmacy Act. Of the 14 HCPs, 28.6% ( $n=4$ ) always dispensed antihypertensive medicines with an MIL. Most HCPs (64.3%) acknowledged the importance of MILs, that is, the MIL provides patients with more information on the medicines prescribed (57.2%), makes patients more knowledgeable and responsible (71.4%) and encourages patient involvement in treatment (28.6%) (Tables 3 and 4).

#### Utility of MIL in hypertensive care

Of the 139 patients, 34.5% ( $n=48$ ) always refer to the MIL. Of the 28 patients who received information on the use of the MIL, 92.9% found it useful. Overall, most patients perceive the MIL as useful (94.2%,  $n=131/139$ ), easy to read and understand (80.6%) and prefer to access the MIL from pharmacy professionals (89.2%) (Table 2). Patients who are unable to read and understand the information on the MIL typically requested assistance from a peer or a family member. 'Although I cannot read English, I give my daughter to read for me always when I get it'. Most patients (67.6%) prefer using the MIL to other sources of medicine information because it is easy to manage or keep (66.9%).

Patients identified the most useful information on the MIL as the indications for the medicine (27.5%), storage instructions (22.9%), description of the medicine prescribed (19.8%) and dosage instructions (18.3%). Most patients preferred to receive the MIL from outpatient pharmacies professionals (79.1%) compared to *doctors* (12.2%) or other HCPs.

The main reason patients read the MIL was insufficient information on their medication from either the doctor or the pharmacist. 'They don't give us enough information on the medicine even the disease, especially the doctors like now you are telling me these medicines are for blood pressure but the doctor didn't tell me about it'. 'The pharmacy tells us more information about the medicine than the

**Table 2.** Patient study – qualitative analysis of patient access and use of MIL ( $n = 135$ ).

Themes	Sub-themes	$n$ (%) per theme	Patients' quotations
First category: Useful aspects of the MIL	1: Indications	36 (27.5) <sup>a</sup>	'Use and safety of the medicine', 'Use and side effects', 'Use and storage of the medicine', 'Use of the medicine'
	2: Storage instructions	30 (22.9) <sup>a</sup>	'storage', 'storage and description of the medicine', 'storage and how to use the medicine', 'storage and interactions', 'storage and side effects', 'storage and use of the medicine'
	3: All aspects	27 (20.6) <sup>a</sup>	'All parts', 'Everything'
	4: Description of the medicine	26 (19.8) <sup>a</sup>	'Description of the medicine', 'Description and side effects of the medicine', 'Description and use of the medicine', 'Description of the medicine, how to use the medicine and side effects', 'Description of the medicine', 'Description, safety and storage of the medicine'
	5: Dosage and directions for use	24 (18.3) <sup>a</sup>	'Dosage, directions for use and storage', 'How the medicine works, how to can I take it', 'How to use the medicine', 'How to use the medicine and it's indications', 'How to use, storage and overdose of the medicine'
	6: Safety	14 (10.7) <sup>a</sup>	'Safety and description of the medicine', 'Safety of the medicine', 'Safety, interactions and dosage'
	7: Side effects	13 (9.9) <sup>a</sup>	'Side effects', 'Side effects and interactions', 'Side effects, safety and precautions of the medicine', 'Description and side effects of the medicine'
	8: Precautions	12 (9.2) <sup>a</sup>	'Precautions', 'Precautions and description', 'Precautions and directions for use', 'Precautions and use of the medicine', 'Precautions, description and use of the medicine', 'Age for use, cautions and interactions'
	9: Interactions	8 (6.1) <sup>a</sup>	'Storage, interactions and dosage', 'Storage, interactions with food and other drugs', 'Interactions, storage and counseling points'
	10: Counselling points	7 (5.0) <sup>a</sup>	'Storage, precautions, indications and age restrictions for use', 'Storage, use and what to do if you forget to take', 'Storage, description and counseling points', 'Warning, overdose, directions for use and counseling points'
Second category: Where patients preferred to obtain the MIL from	11: Overdose	5 (3.8) <sup>a</sup>	'Overdose and storage', 'Overdose and use', 'Overdose'
	1: The pharmacy	110 (79.1) <sup>a</sup>	'All pharmacies, not just the main pharmacy', 'No other option', 'Pharmacy', 'We should be told where to collect it from', 'Pharmacist or Doctor'
	2: Doctors	17 (12.2) <sup>a</sup>	'Doctor'
	3: Everyone giving medicines	6 (4.3) <sup>a</sup>	'Anyone giving the medicine', 'Anywhere', 'Everywhere you get medicines including clinics', 'Everyone giving out medicines', 'From people who understand the leaflet', 'Hospital', 'Someone that knows'
	4: Both doctors and nurses	2 (1.4) <sup>a</sup>	'Doctors and nurses'
	5: Did not know	2 (1.4) <sup>a</sup>	'I don't know', 'No idea'
	6: Nurses	2 (1.4) <sup>a</sup>	'Nurses'
	7: Receive a message with the information via media platforms	1 (0.7) <sup>a</sup>	'Get a text message on the information on the MIL'
8: Clinics	1 (0.7) <sup>a</sup>	'Nearest clinic'	

(Continued)

Table 2. (Continued)

Themes	Sub-themes	n (%) per theme	Patients' quotations
Third category: Suggested ways to increase MIL accessibility	1: Making copies	73 (52.5) <sup>a</sup>	'Copies from the manufacturer and not the government', 'Distribute to other pharmacies', 'It is accessible', 'It is accessible already', 'It is already accessible', 'It is fine as it is. do not bother', 'Make copies', 'Make copies and distribute', 'Make copies and distribute them, make the letters bigger', 'Make copies and distribute with meds without leaflets', 'Make copies and distribute with pre-packs', 'Make copies and educate patients about leaflet', 'Make copies and educate patients about leaflets', 'Make copies and educate us', 'Make copies and give with each and every medicine', 'Make copies and give with pre-packs', 'Write all the information on the box', 'Write the information on the medicine box'
	2: Deliberate effort to give each person a copy of the MIL	31 (22.3) <sup>a</sup>	'Give everyone who comes to the pharmacy', 'Give everyone with each medicine', 'Give it at the pharmacy', 'Give it to the patients every time', 'Give with all medicines not some', 'Give with each medicine', 'Give with every drug', 'Give with medicines', 'Give with prepacks also', 'I always get it, just give us the leaflets', 'Leaflet should always be given with the medicine', 'Leaflet should always be in the box', 'Leaflet should be given with all medicines always', 'Make copies for medicines in plastics and open box to make sure it is in also', 'The leaflet must always be given because some people know how to read', 'The Pharmacy must give everyone the leaflet', 'They should just give us with every medicine'
	3: Educate the people/ making them aware of the MIL	20 (14.4) <sup>a</sup>	'Be told the importance of the leaflet', 'Copies and give with each medicine and educate us on how to use the leaflet', 'Educate patients on the use of the leaflet and give us copies', 'Educate the people about the leaflet', 'Explain to us how to use it', 'Make copies and tell patients how to use it', 'Pharmacist must ask questions', 'Pharmacist must explain the leaflets', 'Show us how to use it or read it for use', 'Tell patient to read the leaflet', 'Tell people to ask for the leaflet', 'Tell the patients to read it just needs common sense', 'Tell the people to read the leaflet'
	4: Making it more understandable	16 (11.5) <sup>a</sup>	'Be made more understandable', 'Be translated to different languages', 'Make it short and simple in English and Afrikaans', 'Make it shorter and precise', 'Put it in Oshiwambo, the language I understand', 'Should be written in different languages', 'They must be clear', 'Translate into different languages', 'Translate into native languages we understand', 'Translate it into native languages so patients can read and understand', 'Translate to native languages', 'Translate to other languages and ask people individually where they do not understand', 'Using local languages to make everyone understand'
	5: Do not know what should be done	12 (8.6) <sup>a</sup>	'I do not know'
	6: Making a MIL website for Namibia	10 (7.2) <sup>a</sup>	'Make a leaflet website', 'Make a leaflet website like South Africa', 'Make a website if there are not enough copies or ask manufacturer to give copies', 'Make copies and educate us and also make a website', 'Make copies and educate us because we do not know, also make a leaflet website', 'Make copies and give with prepacks or make a Leaflet website', 'Make copies and leaflet website for Namibia', 'Make copies and make website', 'Make copies or a leaflet website'
	7: Notices	4 (2.9) <sup>a</sup>	'Make meetings and conferences', 'Paste it around or just write on the medication box', 'Paste where people gather for collection of medicines', 'Put the leaflets on the notice board for those medicines without the leaflet'
	8: MIL was not necessary	3 (2.2) <sup>a</sup>	'Does not matter for those few medicines without a leaflet', 'If patients understand the information they are given then there is no need to give leaflet', 'It does not matter if there is none for other medicines'

MIL: medicines information leaflet.

<sup>a</sup>This frequency or percentage was determined using a tally system to account for each option stated in a single quote, because within a single quote many options may have been stated.



**Table 3.** Patient study – health literacy as measured by the REALM, SILS and HLSI-SF.

Interpretation of the result	Literacy domain measured	Frequency (%)
1. Rapid Estimate of Adult Literacy in Medicine (REALM tool) for identification of people at risk for poor literacy skills 0–18 words: Patient is unable to read easy materials, will need repeated oral instructions and materials mainly composed of pictures or audios or videos 19–44 words: Will not be able to read prescription labels, will need easy materials	Reading grade of 3rd grade and below Reading grade of 4th–6th grade	119 (85.6) 20 (14.4)
2. Single Item Literacy Screener (SILS): Identification of limited reading ability (how often you need help when reading medicine information) Scores: Negative scores: No difficulty reading health-related materials Positive scores: Experience difficulty reading medicine-related materials	≤2 – Never and rarely >2 – Sometimes, often and always	85 (61.2) 54 (38.8)
3. Health Literacy Skills Instrument-Short Form (HLSI-SF tool) Individual scores: Remembers and understands information read (Print prose) Cannot remember or understand information they read May remember and understand some information they read Remembers and understands all information read Ability to find health information needed (Print documents) Cannot find health information from documents Likely not to find health information from documents Higher probability of finding the information Always able to find health information from documents Good at math (Print quantitative) Will not be able to work with figures and do calculations Average ability to work with figures and do calculations Proficient in working with figures and doing calculations Ability to remember an understand information they heard (Oral) Could not remember or understand information they heard once Could remember and understand the information they heard once Ability to locate health information needed and reason out concepts (Internet) Cannot locate health information and reasoning ability is very low Can sometimes locate health information and reasoning ability is moderate Able to locate health information and has high reasoning ability	0.00 50.00 100.00 0.00 33.33 66.67 100.00 0.00 50.00 100.00 0.00 50.00 100.00 0.00 50.00 100.00 0.00 50.00 100.00 Adequate: 70%–100% (range: 70%–100%) Not categorized by the tool: 60%–66.67% Inadequate: <60% (range: 16.7%–56.7%)	19 (13.7) 64 (46.0) 56 (40.3) 2 (1.4) 43 (30.9) 56 (40.3) 38 (27.3) 14 (10.1) 66 (47.5) 59 (42.4) 73 (52.5) 66 (47.5) 32 (23.0) 72 (51.8) 35 (25.2) 39 (28.1) 32 (23.1) 68 (48.8)
Overall Health Literacy: Adequate health literacy level Cannot be categorized because decreases precision Inadequate health literacy		

REALM: Rapid Estimate of Literacy in Medicine; SILS: Single Item Literacy Screener; HLSI-SF: Health Literacy Skills Instrument-Short Form.

**Table 4.** Themes generated from the qualitative analysis of healthcare worker suggested strategies to improve access and use of the MIL among patients (n = 14).

Categories	Sub-categories	Themes	n (%) per theme	Health workers' quotations
First category: Usually dispense chronic medication with a MIL	1: If yes, types of chronic medications	Yes	9 (64.3)	'Not always', 'Sometimes', 'Yes unless medicines are prepacked'
		No	5 (35.7)	'All', 'All including psychiatric meds', 'All of them, we are rotated', 'All types', 'All, rotated to all pharmacies', 'Antihypertensives, sugar lowering, ARVs etc.', 'Antipsychotics, HPT diabetes eMILepsey all', 'HPT, diabetes, asthma, eMILepsey, HIV all', 'Prepacking and packing for dispensary dispensing'
		All	10 (71.4) <sup>a</sup>	'Antiretrovirals, antihypertensive, sugar lowering', 'HPT, diabetes, asthma, eMILepsey, HIV', 'TB, HPT, HIV, diabetes'
Second category: It is important for patients to be given a MIL	If yes, reason	Some	4 (28.6) <sup>a</sup>	
		Yes	9 (64.3)	
		No	5 (35.7)	
Policies/regulatory framework for distribution of MIL	If no, reason	For further information on medicines	8 (57.2) <sup>a</sup>	'For further information on drugs', 'For more information on treatment', 'For the patient to read and understand about their treatment', 'Know more about their meds', 'Patient will get more information', 'Read more information', 'So they understand the purpose and contraindications', 'To get more information on their treatment'
		Patient involvement	2 (14.3) <sup>a</sup>	'So you involve patient on their treatment'
		Information overload and confuse patient	3 (21.4) <sup>a</sup>	'Information overload for patient- we give just enough', 'May confuse patient too much too much jargon'
Policies/regulatory framework for distribution of MIL	If yes, what does it state	Instill fear	2 (14.3) <sup>a</sup>	'Patient information overload and instill fear', 'The patient may not take medicine because of fear of Side Effects'
		Information already given	2 (14.3) <sup>a</sup>	'We give enough information'
		Yes	5 (35.7)	
Policies/regulatory framework for distribution of MIL	If yes, what does it state	No	2 (14.3)	
		I don't know	7 (50.0)	
		Give MIL with all medicines	4 (28.6) <sup>a</sup>	'All meds should be given with a MIL- in ACT', 'Give MIL with all meds', 'Give MIL with each medicine', 'MIL to be given with all meds'
Policies/regulatory framework for distribution of MIL	If yes, what does it state	In the Act	2 (14.3) <sup>a</sup>	'In Pharmacy act'

(Continued)

Table 4. (Continued)

Categories	Sub-categories	Themes	n (%) per theme	Health workers' quotations
Benefits of issuing the MIL to patients	If yes, what are they	Yes	13 (92.9)	'Give detailed information on drug that we otherwise can't give', 'Increase patient forgets information is readily available', 'More detailed information on counseling points', 'More information for patient', 'More information if used correctly by patient', 'More information that we wouldn't have gotten time to give', 'Patient may get more information if they forget', 'Refer if need more information or forgot what was counseled'
		No	1 (7.1)	
		More information	10 (71.4) <sup>a</sup>	
Concerns of issuing MIL to patients		Involve patient in treatment	4 (28.6) <sup>a</sup>	'More knowledgeable patient so more responsible', 'Patient awareness=adherence=better health outcomes', 'Patient educate themselves more about medicines they are taking', 'Patient to read and understand about their treatment'
		Side effects of the medicine preventing patients to take the medicines	6 (42.9) <sup>a</sup>	'Patient may fear using the medicines because of Side effects', 'Patient stop taking medicines because of side effects', 'Patients frightened by SE and not ARVs', 'Patients not using medicines after reading side effects'
		Lack of timely information update on the MIL	3 (21.4) <sup>a</sup>	'Confuse patient when off-label use and discontinue use because of side effects', 'Not all information is updated and cause confusion with patients', 'Not all information is updated on MIL so will be a problem'
		patient's ability to read and understand the MIL	2 (14.3) <sup>a</sup>	'Ability to read and understand and use medication', 'Some manufacturers give package insert instead of MIL so lots of jargon'
		Ignorance on the MIL	2 (14.3) <sup>a</sup>	'Most patients don't take MIL into consideration'
		No concerns	2 (14.3) <sup>a</sup>	'None'
Not enough copies of the MIL supplied by manufacturers	2 (14.3) <sup>a</sup>	'Not enough copies of the MIL to give all patients', 'MIL copies not enough'		

(Continued)

Table 4. (Continued)

Categories	Sub-categories	Themes	n (%) per theme	Health workers' quotations
Challenges met in making or increasing access and use of MIL among patients with chronic illnesses		Insufficient number of copies of MIL to distribute with prepacks/ after breaking the bulk	10 (71.4) <sup>a</sup>	'Few copies in relation to number of prepacks', 'Mostly prepacks and not enough MIL to give people', 'Not enough copies of MIL, patient not knowing about MIL', 'Not enough copies of MIL, give list of common side effects only', 'Not enough MIL to distribute with pre-packs', 'MIL not enough for pre-packs', 'Pre-packs yet I MIL only'
		Patients not educated on the MIL/illiterate	5 (35.7) <sup>a</sup>	'Not enough copies, patient not educated on MIL, no follow up with manufacturer', 'Patients either illiterate or font of words too small', 'Patient not able to read, language barrier, unequal distribution', 'The MIL are not enough, teaching patients about MIL'
		Availing required numbers of copies	2 (14.3) <sup>a</sup>	'Availing the required number of copies'
		None/no challenges perceived	2 (14.3) <sup>a</sup>	'None', 'None because don't always give MIL'
		Manufacturers to provide many copies of the MIL for bulk medicines	8 (57.1) <sup>a</sup>	'Address importance of putting extra MIL by manufacturer', 'It's a challenge, if bulk ask copies from supplier'
		Start a website for the MIL for all medicines registered in Namibia	5 (35.7) <sup>a</sup>	'Ask copies for bulk from supplier and make easy MIL website', 'Supplier give more copies and NMRC start simple MIL website', 'Suppliers should provide as per ACT and website if possible', 'Suppliers to give more copies, Namibia to start MIL website'
		Namibia Medicines Regulatory Council (NMRC) to ensure that all bulk medicines are supplied with copies of the MIL	5 (35.7) <sup>a</sup>	'NMC ensure manufacturer puts many MIL', 'NMRC to ensure manufacturers supply copies of MIL/ website', 'NMRC ensure enough MIL with bulk medicines and even for 100mL bottles', 'Regulatory authority to ensure suppliers give copies of MIL for medicines'
		Educating patients on the MIL	2 (14.3) <sup>a</sup>	'Educate patients on MIL and ensure copies are present', 'Teach patients to use it and make copies'
		Make it more understandable	1 (7.1) <sup>a</sup>	'Use of simple words in MIL and supplier to give more copies'

MIL: medicines information leaflet.

<sup>a</sup>This frequency or percentage was determined using a tally system to account for each option stated in a single quote, because within a single quote many options may have been stated.

doctors but when I read the MIL I get more information'. 'The pharmacy people do not have time to really explain, they just say how to take the medicine'. Moreover, 58.3% ( $n=81/139$ ) stated that the information on the MIL sometimes conflicts with that given at the hospital, and this requires further consultation with a doctor or pharmacist.

### *Factors influencing the access and utility of MIL*

Most patients (60.4%) were not satisfied with the quality and amount of medicine information they received especially from physicians. Patients reported limited access to the MIL at the hospital pharmacy and proposed that 'manufacturers provide many copies of the MIL for all medicines' (52.5%), 'pharmacy staff make a deliberate effort to give each patient a MIL' (22.3%), 'educate the patients' (14.4%) and 'make the MIL more understandable' (11.5%) (Table 3).

Some HCPs (35.7%) disregarded the importance of giving MIL to patients citing, information overload causing confusion among patients (21.4%), the side effects listed in the MIL would instil fear among patients resulting in medicine discontinuation (14.3%) and they had already given patients enough information (14.3%). The HCPs' concerns on the distribution of MIL to patients included the following: (1) the side effects of the medicines would prevent patients from taking their medicines (28.6%), (2) lack of up-to-date and objective information on the MIL (21.4%), (3) patient's inability to read and understand the MIL (14.3%), (4) patients' ignorance on the MIL (14.3%) and (5) not enough copies of the MIL supplied by manufacturers (14.3%) (Table 3).

Strategies suggested by HCPs to improve access to, and utility of, the MIL included the following: (1) manufacturers provide many copies of the MIL for bulk medicines (57.1%), (2) development of a website/electronic platform where MILs for all medicines registered in Namibia can be accessed (35.7%), (3) the Namibia Medicines Regulatory Council (NMRC) to ensure that all bulk medicines are supplied with copies of the MIL (35.7%), (4) the need for patient education on the MIL (14.3%) and (5) the MIL to be made more understandable (7.1%) (Table 3).

## **Discussion**

We believe this is the first study to assess the level of health literacy, and utility of MILs, among hypertensive patients at a public referral hospital in Namibia. This is important since inadequate health literacy, access and the utility of MILs were seen among hypertensive patients in Namibia. The inability of hypertensive patients to access and utilize medicine information is a major public health concern given the high public health burden of hypertension and non-adherence to antihypertensive medicines in Namibia.<sup>7,8</sup>

Our study found low health literacy rates among antihypertensive patients using the three different tools, REALM, SILS and HLSI-SF. Over 85% antihypertensive patients are unable to read simple health information (REALM: 0–18), 38.8% require support to read materials (SILS > 2) and 66.9% have limited ability to comprehend and make decisions regarding health information (HLSI-SF < 70%). This is a concern given that the utility of medicine information, adherence to hypertensive medication and blood pressure control require health literacy.<sup>45</sup> Our findings concur with several studies in sub-Saharan Africa that found low and varying rates of health literacy among patients on chronic medication and its impact on medication adherence and blood pressure control.<sup>19,23,28,46</sup> Several studies advocate that hypertensive patients in low-literacy settings require repeated oral instructions and materials with illustrations in addition to written materials to comprehend and optimally use the information on the MIL, and we will be addressing this in future activities in Namibia.

Second, the study found limited access to MIL at the hospital (32.4%). This is despite most patients being aware of their right to medicines information and the usefulness of MIL (Table 1). Moreover, access to MIL varied by the type antihypertensive medication. For example, none of the patients accessed MIL for hydrochlorothiazide/amloride, the most prescribed antihypertensive. These findings are similar to another study which reported that very few patients receive MIL with their medications.<sup>47,48</sup> Our study also found a low level of utility of the MIL among hypertensive patients in public health care (34.6%; Table 1), which is a concern given, as mentioned, the high prevalence of hypertension in Namibia.<sup>8</sup> The findings are comparable to a study conducted in Belgium which showed that MIL were infrequently read, that is, one out of every four patients.<sup>49</sup> The study in Belgium also reported that patients aged  $\geq 65$  years always read the MIL while others never read the MIL, women read the MIL more often than men and the most frequently read parts of the MIL were on dosage and side effects.<sup>49</sup> Nevertheless, the majority of patients in our study acknowledge the importance of MIL in promoting medication adherence, health education, as a reference and complement limited or contradictory verbal information (i.e. appropriate use and storage) given at the hospital by various HCPs (Table 3). Our findings partly differ though from the study by Mottram and Reed that found that patients thought the section on storage conditions was of little importance.<sup>50</sup> In Namibia, patients argued that information on the storage conditions of medications was important because the weather varies widely throughout the year, which they believed may negatively impact on the efficacy of their medication. Encouragingly, several studies concur with our findings that access to appropriate, user-friendly medicine information that is easily read empowers patients regarding self-management and the safe use of medication for their NCDs.<sup>35,51–53</sup>

Finally, the study also found that limited access to MIL in hypertensive care in Namibia was due to a number of logistical factors, that is, limited copies of MIL from manufacturers for bulk supplies; programmatic factors, that is, lack of guidelines/systems for the distribution of MIL at health facilities; and behavioural factors, that is, HCPs negative perception on MIL distribution to patients (Table 3). For instance, some HCPs believed that some patients may interrupt antihypertensive treatment if they become aware of serious adverse effects associated with their medication (Table 3). Our findings concur with those of Dixon-Woods et al. who reported that the use of MIL is greatly influenced by perceptions of individual patients, HCP's role, the value of the leaflets, the quality of leaflets and the presence of appropriate topics that necessitate the use of the MIL. Similarly, Mottram and Reed<sup>50</sup> and Tong et al.<sup>54</sup> agree that the inclusion of information on adverse effects in the MIL impacts negativity on the use of medications among some patients. Similarly, the limited utility of MIL in this study was partly due to a low health literacy (28.1%) among the patients (Table 1); lack of awareness/education on the MIL, programmatic factors, that is, the pharmacy staff not making a deliberate effort to distribute the MIL and insufficient copies available; and beliefs, that is, patients believing they had already received enough information from pharmacy staff and doctors (Table 3). This was also seen in another study which showed that some patients believed they had received adequate information about the medicines from the HCPs and consequently did not read the MIL.<sup>55</sup> Mottram and Reed reported that some healthcare workers (HCWs) deemed some patients as not suitable to receive MILs, which is contrary to the right to this information.<sup>50</sup> Nonetheless, despite the inability to read the MIL, most patients in our study requested for universal access to MILs given that a family member or community peer would help read the MIL if needed particularly if written in common and understandable languages, that is, Afrikaans or English (Table 1).

In conclusion, health literacy, access to and utility of medicine information among hypertensive care are currently sub-optimal in Namibia. The main factors influencing access to, and utility of, patient information leaflets in hypertensive care in Namibia are first low health literacy levels, second non-availability of MIL at points of care, third lack of guidelines at points of care and finally negative beliefs among patients and HCPs. There is need for targeted interventions to integrate health literacy programmes in hypertensive care at public health facilities to enhance responsible self-care practices and outcomes among hypertensive patients in Namibia. In addition, there is need for policies to guide the effective implementation of systems to enhance access and utility of medicine information at points of care in the public health care. We will be following this up in future studies.

## Limitations and strengths

The results of this study should be interpreted with limitations. First, this single-centre study adopted a cross-sectional design and the results may not be generalizable. Second, the study used a small sample size of hypertensive patients and may have under/overestimated the level of access to and utility of the MIL. Nevertheless, this is the first study in sub-Saharan Africa to assess health literacy, access to and utility of MIL among both patients and HCPs using three health literacy tools. The study also provided preliminary information on the factors influencing the utility of medicine information in hypertensive care. In addition, this is the first study to assess the role of health literacy on the utility of medicine information in a high hypertension burden country in sub-Saharan Africa. Consequently, we believe that the findings of this study provides preliminary evidence on the level of access and utility of MIL which can be used to guide future research to improve access to and utility of the MIL among hypertensive patients in public health settings in LMICs including sub-Saharan Africa as well as low-literacy settings.

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