**IMPROVING HYPERTENSION OUTCOME MEASUREMENT IN LOW- AND MIDDLE-INCOME COUNTRIES**

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**Short title: IMPROVING HYPERTENSION OUTCOME MEASUREMENT**

**Word count: 5722**

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**ABSTRACT**

High blood pressure is the leading modifiable risk factor for mortality, accounting for almost one in five deaths worldwide. In low-income countries, nine percent of deaths are estimated to be attributable to high blood pressure. Hypertension control remains a challenge, especially in low-resource settings. One approach to improvement is the prioritization of patient-centered care. However, consensus on the outcomes that matter most to patients is lacking. We aimed to define a Standard Set of patient-centered outcomes for evaluating hypertension management in low- and middle-income countries.

The International Consortium for Health Outcomes Measurement convened a Working Group of 18 experts and patients representing 15 countries. We used a modified Delphi voting process to reach consensus on a Set of outcomes, case-mix variables, and a timeline to guide data collection. Additionally, literature reviews, patient interviews, a patient validation survey, and an open review of the Set by hypertension experts informed the Set.

The Set contains 18 clinical and patient-reported outcomes that are important to patients and reflect evidence-based hypertension management, and case-mix variables to allow comparisons between providers. The domains included are hypertension control, cardiovascular complications, health-related quality of life, financial burden of care, medication burden, satisfaction with care, health literacy, and health behaviors.

We present a core list of outcomes for evaluating hypertension care. The measures take into consideration the unique challenges healthcare providers and patients face in low- and middle-income countries, yet is relevant to all settings. We believe that this Set is a vital step towards international benchmarking in hypertension care and, ultimately, value-based hypertension management.

**Keywords:** hypertension, quality of life, value-based healthcare, outcomes, core outcome set, low- and middle-income countries, patient-centered care, ICHOM

**INTRODUCTION**

High blood pressure, the leading modifiable risk factor for mortality, is estimated to account for 19% of deaths worldwide, or 10.5 million deaths per year.1,2 Overall, nine percent of deaths in low-income countries can be attributed to high blood pressure. This compares to 21% of deaths in middle-income countries and 18% of deaths in high-income countries.2 One in three adults over age 20 are estimated to have hypertension3 and the number of people living with hypertension has nearly doubled over the past 40 years from 594 million to 1.13 billion.4 Care and treatment for patients with hypertension is estimated to constitute 10% of global healthcare expenditures.5 As the number of people living with hypertension continues to grow, so will the economic burden on healthcare systems and governments.

Although behavior change and pharmacotherapy are effective treatments for hypertension, control remains a challenge. Only 8% of people with hypertension achieve adequate blood pressure control in LMICs as compared to 28% in high-income countries.3 Among those with diagnosed hypertension, 20% achieve blood pressure control in LMICs and 42% achieve blood pressure control in high-income countries.3 With three-quarters of the world’s hypertensive population residing in LMICs, the urgency for identifying what approaches to management result in the best outcomes for patients is evident.3

Researchers, practitioners and policymakers have called for standardized measures to assess healthcare6, and cardiovascular disease7 care more specifically, from the perspective of patients. Proposals of indicators have been made; however, these do not emphasize the patient perspective.8,9 To our knowledge, hypertension registries also neglect patient-reported outcomes. Despite the current lack of patient-centered hypertension research, where patient-centeredness refers to the meaningful enagagement of patients in their care and ensuring their priorities are taken into consideration, the global health community is increasingly aware that the patient perspective should be taken into account when measuring quality of care.

The International Consortium for Health Outcomes Measurement (ICHOM) is a non-profit organization headquartered in Boston, MA in the USA and with offices in London, UK and Mexico City. ICHOM was founded in 2012 with the aim of encouraging the healthcare community to focus on value for the patient, where “value” is defined as the health outcomes achieved relative to the cost of achieving these outcomes.10 Currently, ICHOM is piloting the feasibility of collecting data from multiple international institutions with the aim of understanding the variation in their outcomes and working towards improving care for patients [Dias A, Roberts C, Lippa J, et al.

The first step in determining the value of care is to identify the outcomes that matter to patients. To this end, ICHOM develops condition-specific core outcome sets with a focus on priorities of care identified by patients. To date, ICHOM has published 24 Standard Sets11, including three focused on cardiovascular disease (stroke12, heart failure (publication pending), and coronary artery disease13). These Standard Sets are intended to facilitate global outcome comparisons, in turn driving improvements in care and are freely available for use on ICHOM’s website.14

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Here, we describe the process and results of convening an international Working Group (WG) to create a consensus-driven set of patient-centered outcomes for adult patients seeking care for primary arterial hypertension. Special emphasis was placed on ensuring relevance for patients in LMICs.

**METHODS**

**The data that support the findings of this study are available from the corresponding author upon reasonable request.**

*Standard Set scope*

The WG convened by ICHOM aimed to develop a minimum set of patient-centered outcome and case-mix variables to evaluate the care provided to adults (aged ≥ 18) with primary hypertension (BP ≥ 140/90 mmHg) living in LMICs. While some outcomes may apply to patients with secondary arterial hypertension, this patient population was not the focus of the project. Outcomes specific to pediatric populations and hypertension in pregnancy were excluded. The Standard Set is registered with the COMET core outcome set database at http://www.comet-initiative.org.

*The ICHOM Hypertension in LMICs Working Group*

ICHOM invited individuals to the WG based on their expertise in hypertension management, experience with healthcare delivery in LMICs or, in the case of patient representatives, their personal experience of living with hypertension. We identified WG members through their published work or recommendations from other WG members. The WG was comprised of 18 clinicians, researchers, and hypertensive patients, representing 15 countries throughout North America, South America, Africa, Asia, and Europe (Supplemental Table S1). Patient representatives contributed to outcome domain selection, which occurred during the first part of the Standard Set development process. A smaller project team (PL, RZ, OO, EO, MS) managed the WG and supported content development.

*Selection of outcome and case-mix domains*

A PubMed literature review to identify outcomes reported in hypertension studies resulted in 2,543 articles (Supplemental Table S2). We excluded 1,429 articles, as they did not meet the inclusion criteria (English language, published in 2005 or onwards, patient population aged ≥ 18 years old with a diagnosis of primary arterial hypertension, and a focus on patient-reported or clinical outcomes), resulting in 1,114 articles, which we reviewed to extract potential outcomes. To ensure that the identified outcomes were relevant to LMICs, we conducted a supplementary search focused on LMICs. This search identified 139 articles, of which 87 were removed after the inclusion and exclusion criteria were applied, resulting in 52 publications, which we reviewed to extract additional potential outcomes. Additionally, we searched 15 existing registries collecting data on hypertension (Supplemental Table S3) and invited WG members to add to the list of potential outcomes.

We followed a similar process to identify case-mix variables, to be used for risk adjustment or stratification. The are factors that are usually outside of the control of the provider but impact the outcomes and therefore need to be accounted for when making comparisons between settings. (Supplemental Table S4). We searched the registries identified during the outcomes extraction. Additionally, we searched the literature to identify landmark hypertension treatment clinical trials. We identified 16 trials from which we extracted reported baseline variables.

*Patient WG member input*

Patient WG members participated in the selection of outcomes during the first half of the process. They took part in WG calls together with the clinicians. When a patient was unable to attend a scheduled call, the project leader had a separate call with them to ensure they agreed with the conclusions reached during the call. Patient representative votes had equal weight to the professionals on the WG.

*Process*

Using established ICHOM methodology12,13, we developed the Standard Set over eight teleconference calls between October 2016 and September 2017 (Figure 1). Prior to each call, the project team prepared a proposal informed by the literature and patient input. The WG reviewed and discussed proposals presented by the project team during the calls. Following each call, WG members voted via electronic survey. A threshold of 70% was used to determine group consensus. Decision points that remained inconclusive after voting were carried forward for further discussion during the next call. The full protocol is published online at <http://www.ichom.org/medical-conditions/hypertension-in-low-and-middle-income-countries/>.

*Modified Delphi voting method*

The WG employed a modified Delphi process at two points (after Calls 1 and 4) of the Standard Set development to determine what outcome domains and case-mix variables to include in the Standard Set. Variables identified during the literature search were presented for ranking on a 9-point Likert scale. Items ranked between 7 and 9 by more than 70% of the WG after the first round were included. The remaining items were carried forward to the second round of voting. After the second round, items ranked between 7 and 9 by over 70% of the WG were included, while those ranked between 1 and 3 by 70% were excluded. Items that did not meet the criteria for inclusion or exclusion were re-discussed in the following call before being presented for a final Yes/No vote, which was decided by a simple majority.

*External input*

The ICHOM Project Leader (OO) conducted a group interview with ten hypertensive patients in Nigeria to identify their priorities of care via teleconference. Due to the logistics involved in setting up the discussion, a convenience sample of ten patients who were available and willing to participate on the day of their routine outpatient follow-up was selected. The intent was not to obtain data generalizable to patients with hypertension globally, but to validate whether the outcome domains identified by the WG reflected priorities of care from the patients’ perspective.

The final list of outcomes selected by the WG was presented to patients from Nepal and Portugal via a paper and online survey, respectively. Patients who attended the outpatient hypertension clinic at Universidade de Lisboa and B.P. Koirala Institute of Health Sciences were asked to complete an anonymous survey. The inclusion criteria for being invited to participate were having a diagnosis of hypertension and being aged 18 years or older. Patients were asked to rank the importance of each outcome on a 9-point Likert scale. In Portugal, patients were provided with a link to an online survey which they could complete in their own time. Patients in Nepal completed the survey through a handheld tablet or mobile device with the support of volunteers recruited for the role.

Prior to completion of the Standard Set, the WG also sought feedback on the outcomes, case-mix variables, timeline and general feasibility for implementation from the wider hypertension community through an electronic survey. The anonymous survey was link was distributed via ICHOM’s website and social media channels. WG members were also asked to distribute the survey through the professional networks.

*Statistics*

*Ethics review*

The ICHOM project team obtained ethical approval for the patient engagement work from the Nepal Health Research Council (Reg.no. 426/2016), the Nigerian Institute of Medical Research Institutional Review Board (IRB/17/009), and the Centro Académico de Medicina de Lisboa Institutional Review Board (No. 25/17). All participants in the focus group provided written consent for their participation.

*Role of the funding source*

Funding for the development of the Standard Set was provided by the Novartis Foundation. Fareed Mirza, head of Healthcare and Outcomes Research at Novartis Foundation, was a non-voting member of the Working Group.

**RESULTS**

*Recommended set of core outcomes*

The project team presented the WG with 68 outcomes. This included outcomes identified in the literature and registry search as well as those added by WG members. After three rounds of voting and discussion, the WG settled on the 18 outcomes in Table 1 (Figure 2, Supplemental Table S5). Outcomes were voted for inclusion based on the following criteria: importance to patients with hypertension, ease of measuring, and whether they were modifiable with quality improvement efforts. The final list is grouped into four categories: survival and disease control, burden of care, health behaviors and literacy, and patient-reported health status (Table 1).

Salt-intake, physical activity, and diabetes were initially voted for inclusion as outcomes, as they are important factors that should be addressed in hypertension management. Following further debate, the WG decided to recategorize them as case-mix variables, as they are not outcomes in themselves, but important determinants of hypertension outcomes. Hospital admissions due to complications of hypertension, dementia/cognitive impairment, retinopathy, lasting dietary change, financial burden, understanding/knowledge of condition and treatment, and empowerment/autonomy/self-efficacy were also originally voted for inclusion in the Standard Set. However, following further discussion, the WG decided to exclude these as outcome variables. Hospital admissions were excluded because hospitalization is dependent on multiple factors including the health system and sometimes the patient’s ability to pay. Dementia/cognitive impairment was excluded due to the many types of dementia not due to hypertension and the difficulty in differentiating vascular dementia from other types of dementia. Retinopathy, lasting dietary change, financial burden, understanding/knowledge of condition and treatment, and empowerment/autonomy/self-efficacy were eventually excluded due to the difficulty of capturing in routine clinical care. Although financial burden was excluded, the Standard Set does capture financial barriers to care and medication.

*Survival and Disease Control*

The primary goals of managing hypertension are to reduce the occurrence of cardiovascular events and prolong survival. The WG voted to include blood pressure control, disease complications, and overall and cause-specific survival. Blood pressure control was defined as blood pressure below 140/90 mmHg. However, the WG is aware that this threshold will need to be adjusted under certain clinical circumstances and as hypertension guidelines are periodically updated. The following disease complications could be reported via clinician or administrative data: hospital admission, hypertensive urgency or emergency, ischemic heart disease (acute myocardial infarction and angina), cerebrovascular disease (stroke and transient ischemic attack), atrial fibrillation, heart failure, peripheral artery disease, and chronic kidney disease.

*Burden of Care*

The burden associated with managing hypertension is important to patients and can be a barrier to seeking appropriate care. The Standard Set assesses access to care and treatment, medication burden, and adverse events and side effects of medication. Access to care is measured using a two-part question adapted from the European Union Survey on Income and Living Conditions (EU SILC).17 Medication burden is captured as the number of pills taken daily. Specific adverse events and side effects are collected as part of the Standard Set: falls, acute kidney injury, peripheral edema, fatigue, electrolyte imbalances, hypokalemia, cough, erectile dysfunction, and urinary frequency.

*Health Behaviors and Literacy*

Healthcare providers have the opportunity to influence health behaviors that affect the outcomes of blood pressure management.We suggest measuring medication adherence via the Hill-Bone questionnaire18, physical activity via the International Physical Activity Questionnaire (IPAQ-short)19,20, and health literacy via the Beliefs about Medications Questionnaire (BMQ-Specific)21.

*Patient-Reported Health Status*

We suggest using patient-reported outcome measures to quantify health-related quality of life, erectile function, and satisfaction with care. The EQ-5D-3L, which is composed of five questions on mobility, self-care, usual activities, pain/discomfort and anxiety/depression is the WG’s preferred tool due to its widespread use and validation.22 The WG acknowledges that the VR-12, PROMIS-10 and SF-12 are equally valid tools for measuring health-related quality of life. There are validated crosswalks that permit the conversion of scores across these tools, making comparisons between them possible. A single question developed by the Patient-Reported Outcomes Measurement Information System (PROMIS) can be asked of male patients to self-report erectile function.23

Patient satisfaction was voted for inclusion by the WG. The WG recognized that patient satisfaction is not an outcome in the strictest sense but noted that it was important to patients. Additionally, patients’ perceptions of their care impact their adherence to treatment advice. As the majority of patient satisfaction surveys focus on providers’ adherence to specific processes, the WG decided to use a global question. If patients are found to be unsatisfied, or if patient satisfaction is an area of interest, a more detailed patient satisfaction tool, such as the Patient Assessment of Chronic Illness Care (PACIC), may be used for further evaluation.24

*Recommended Set of Case-Mix Variables*

The project team presented the WG with 44 potential case-mix variables (supplemental Table S6). After three rounds of voting and discussion the WG narrowed this down to 12 case-mix variables. As cardiovascular events are both critical risk adjustment variables and end results of care, the WG decided that cardiovascular events should be both case-mix and outcome variables. For purposes of data collection, these variables are considered outcomes. Sodium intake and overall cardiovascular risk were originally voted in as outcomes, as modifying these are goals of treatment. However, following much discussion, the WG decided that they would be more appropriately captured as case-mix variables. The case-mix variables are grouped into two categories: demographics (age, sex, education) and clinical history, lifestyle and other risk factors (diabetes, antihypertensive drug use and class, lipid-lowering drug use and class, BMI, smoking status, and family history of cardiovascular disease) (Table 2). The WG selected some case-mix variables on the basis that these variables are commonly collected to calculate 10-year cardiovascular risk using tools such as Globorisk25,26 and the WHO cardiovascular risk prediction charts.27

*External input*

The WG sought external input from patients through a group interview and a patient survey. They also sought input from the wider hypertension community through an open review survey.

The group interview with ten patients (4 males, 6 females, aged 34 to 60, median age 52) with hypertension attending a hypertension clinic at a teaching hospital in Kwara State, Nigeria did not identify additional outcomes that had not already been included in the Standard Set (supplemental Table S7). The main themes identified by the patients were finances (cost of treatment, loss of income, reduced productivity), medical consequences of hypertension (stroke and heart attacks), controlling blood pressure and restoring good health, restrictions the condition places on lifestyle (e.g. salt consumption), and side effects of medication.

The patient survey received 103 responses from patients in Nepal and Portugal. The majority of the responses received were from Nepal (95%). 57% or respondents reported they were male, 39% reported they were female and 4% did not indicate their sex. 19% of respondents were aged 18-40 years, 40% were aged between 41-64 years and 41% or respondents were aged 65 years and above.

All outcomes, other than erectile dysfunction and peripheral artery disease, were rated as highly important (scores of 7-9) by over 70% of patients (Supplemental Table S9).

Feedback via the open review survey was received from 54 physicians, nurses, nurse practitioners, community healthcare workers, physician assistants, researchers, representatives from the life sciences industry, and healthcare strategists and business leaders (supplemental Table S10). The countries represented were Ghana, Malaysia, Tanzania, Portugal, the Netherlands, Uganda, the United States, India, Iran, Venezuela, Nigeria, Canada, Sweden, Chile, Australia, Spain, Brazil, Japan, the Maldives, and the Philippines. 59% of the responses came from low- and middle-income countries, 24% of responses came from high income countries. 17% of respondents did not provide their country of residence. The introduction to the survey clearly stated that the target population for the set was primarily patients who were receiving care in low- or middle income settings. Twenty out of twenty-two (91%) agreed with the inclusion of the outcome domains (supplemental Table S11). The most commonly envisioned barriers to use of the Standard Set were: time consuming and included too many questions, lack of staff to implement the Standard Set, a lack of funding to implement the Standard Set, and poor record keeping and a lack of required data, reported by 13/54 (24%), 5/54 (15%), 3/54 (7%), and 3/54 (7%) of respondents respectively.

*Reference Guide / Data Collection and Implementation*

The Reference Guide includes the recommended questions, sources for data, a data dictionary, and a suggested timeline for data collection (available at <http://www.ichom.org/medical-conditions/hypertension/>). Its purpose is to summarize for healthcare providers all the outcomes and case-mix variables within the set. The data dictionary in the appendix outlines in detail each variable, including its definitions, response options and specific timepoints within the patient’s care path when the data should be collected.

**DISCUSSION**

Although tools to measure patient-reported outcomes for cardiovascular disease do exist7, patient-reported outcome measures (PROMs) specific to hypertension are extremely limited. More hypertension-specific tools must be created to better understand the perspective of patients with hypertension. The proposal described here adds to the current literature by focusing on a set of quality improvement indicators that take what matters most to patients into account. The aim was to create a minimum Standard Set of patient-centered outcomes that can be used to measure the quality of care received by patients with hypertension in LMICs. However, it must be kept in mind that this Standard Set is only for those who access healthcare providers. This Standard Set will not lead to measurement of those in LMICs who are unaware of their hypertension or unable to afford a visit to a healthcare provider.

The global representation of the WG allowed us to have input from experts with experience working in a wide variety of settings ranging from rural clinics in low-income countries to well-resourced tertiary hospitals in middle- and high-income countries. However, although the WG was composed of a diverse group, the response rate to the WG surveys varied, ranging from 70% to 82% for votes on outcomes and 62% to 85% for votes on case-mix variables.

The outcome validation process with limited to a small group of patients attending a tertiary center in Nigeria. The intention was not to draw conclusions on the generalizability of these responses, but for the WG to use get a sense of whether any major categories had been missed during the literature review.

We acknowledge the difficulties in recommending a Standard Set for use across LMICs, which are heterogeneous in terms of resources, biomedical beliefs, and patient-provider interaction. Considering that many LMICs lack vital registration systems15 and fewer than 40% of deaths worldwide are registered16, the WG acknowledges that cause of death may be difficult to ascertain in many low-resource settings. Although many of the PROMs recommended in the Standard Set have been translated and validated across multiple settings, this is not true for all of them. The proposed measures for health literacy, quality of life, beliefs about medications, and medication adherence have not been tested for reliability and validity in most LMICs and as such, their cultural relevance should be evaluated in studies that plan to address these outcomes.  Due to the heterogeneity in the use of PROMs, both between and within countries, the Standard Set is flexible, allowing providers to include additional measures that are most appropriate for their practice in terms of affordability and familiarity. For example, the minimum Standard Set recommends measuring chronic kidney disease via urine dipstick; however, other tests may be used if resources allow.

The WG decided not to use eGFR as the chronic kidney disease indicator because, although serum creatinine and eGFR are commonly-used markers of renal disease in high-income countries, eGFR is not validated for use in many LMICs.28 However at least two studies were recently funded to derive correction factors for use in LMIC settings where there is no valid formula to date. Additionally, the cost of serum creatinine or urinary albumin to creatinine ratio testing can be prohibitive. Therefore, as the very minimum, we recommend diagnosing renal disease via urine dipstick using electronic readers to measure proteinuria and rule out infectious and other causes of urinary abnormalities.

The Standard Set recommends assessing cardiovascular risk, but does not dictate which cardiovascular risk score to use. The WG debated suggesting the WHO/ISH risk prediction charts, which are well established and widely used in many LMICs, and the more recently developed Globorisk, which estimates country-specific cardiovascular risk scores. The WG is aware of a WHO effort to produce country-specific risk scores; however, we do not know when this work will be complete. Ultimately, because risk scores are frequently updated, new ones are developed, and providers may have a risk score that they are already comfortable using, we recommend that the common components of risk scores be measured and then the healthcare provider can choose to calculate the risk using the risk score of their preference. Similarly, we recommend measuring quality of life via the EQ-5D-3L, but offer that the provider can replace the EQ-5D-3L with the SF-12, VR-12, or PROMIS-10, as appropriate.

Another limitation is the potential lack of ability to distinguish between secondary and primary hypertension. The WG recommends that users of the Standard Set rule out secondary causes of hypertension. The WG recognizes it may be difficult to exclude secondary causes of hypertension in LMIC settings, but notes that an estimated 90% to 95% of hypertension is idiopathic.29,30

We took into consideration feedback from professionals from around the globe on the appropriateness of the included outcomes and the potential barriers to implementation while developing the Standard Set. However, there is a need to pilot the Standard Set to determine its feasibility, and test its usability and acceptability in each unique LMIC setting.

**PERSPECTIVES**

The WG has defined a consensus recommendation of the minimum outcomes and case-mix variables to collect for patients with hypertension in routine clinical practice in LMICs. This Standard Set will aid healthcare providers to measure the outcomes that matter most to patients. This important first step in improving quality of care will increase the comparability of data on patients with hypertension across providers, facilities, healthcare systems, and geographies. This will enable benchmarking of risk-adjusted outcomes between providers in different settings and allow them identify opportunities for improvement.

For this work to proceed, the Standard Set must be validated as a comprehensive measurement tool in various settings, which can be done as part of a pilot program to measure the quality of care for patients with hypertension in LMICs. While the Standard Set was developed with LMICs in mind, it is also relevant to patients in high-income countries. Additional validation studies should be conducted to test the appropriateness of the Standard Set for high-income countries, specifically low-income patients in high-income countries.

**ACKNOWLEDGEMENTS**

We thank Dr. Kolo Philip Manma (Department of Medicine, University of Ilorin, Nigeria) and Dr. Prajjwal Pyakurel (School of Public Health and Community Medicine, B.P. Koirala Institute of Health Sciences, Nepal) for their help with patient interviews and surveys in Nigeria and Nepal.

**Source of Funding**

Novartis Foundation

**Conflicts of Interest / Disclosures**

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| --- | --- |
| Name | **Conflicts of Interest** |
| Rachel Zack | None |
| Oluwakemi Okunade | None |
| Elizabeth Olsen | None |
| Matt Salt | None |
| Albertino Damasceno | Astra Zeneca, Merck - personal fee for conference |
| Anastase Dzudie | None |
| António Vaz Carneiro\* | None |
| Celso Amodeo | Servier laboratory, Merck - personal fees (scientific board);  Novartis – personal fees (paper);  ACHE laboratory – personal fees (speaker) |
| Dorothea Nitsch | GSK – funding to conduct kidney research in Africa |
| Ernesto Schiffrin | Novartis, Actelion - Honoraria (Ad Boards);  Servier - Research Grant (Discovery grant unrelated to Servier products) |
| Fareed Mirza\* | None |
| Gbenga Ogedegbe | None |
| Manuela Fiuza | None |
| Thi Nam Phuong DO | speaker fees from Astra Zeneca, Boehringer Ingelheim, MSD, Novartis, Sanofi Aventis, Servier and investigator research from Astra Zeneca, MSD, Servier |
| Norm Campbell | Novartis Foundation - Personal Fees (Consultant to hypertension control programs in low resources setting) 2016-2017. Midway Corporation (Consultant for accurate measurement of blood pressure (2017) |
| Otavio Berwanger | None |
| Raghupathy Anchala | None |
| Vladislav Podpalov | Conflicts of interest:  Patents:  #17881 - issued by the Republic of Belarus: risk prediction tools for myocardial infarction or stroke in patients with arterial hypertension  #17892 - issued by the Republic of Belarus: risk prediction tools for risk of death depending on blood circulation disease in patients with arterial hypertension  #17891, issued by the Republic of Belarus – risk prediction tool on predicting the risk of death in patients with hypertension |
| Yook-Chin Chia | Pfizer - Speaker honorarium, Sponsorship to conferences, research grant Abbott, Novartis, MSD, Sanofi, Astra, Reckitt-Benckiser, Orient-Europharma, GSK, Boehringer Ingelheim, Servier, Merck, Merck-Serono, Bayer, Zeullig- Speaker Honorarium Patents - UMMC, licencee Asia Diabetes Foundation, NGO study |
| Peter Lamptey | None |

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**NOVELTY AND SIGNIFICANCE**

1. **What Is New**

* **The ICHOM Working Group has developed a core set of measures that will allow comparison of outcomes for hypertension care across various settings.**
* **Emphasis is placed on relevance to low- and middle income settings.**

1. **What is Relevant?**

* **The priority during the development of the set was to ensure that the outcomes reflect the priorities of hypertensive patients.**
* **The set aims to facilitate outcomes measurement and identifying variation in outcomes across settings, which can be targeted to improve care for patients.**

1. **Summary**

* **We present a standard Set of outcomes to evaluate hypertension management in LMICs.**

**FIGURE LEGENDS**

Figure 1. Timeline of Standard Set development

Figure 2. Overview of outcome selection process (Adapted from Kirkham et al. 2016)

Figure 3. Recommended Timeline for data collection for patients with hypertension

**TABLES**

Table 1. Summary of Outcomes included in the ICHOM Standard Set for Hypertension in Low- and Middle-Income Countries

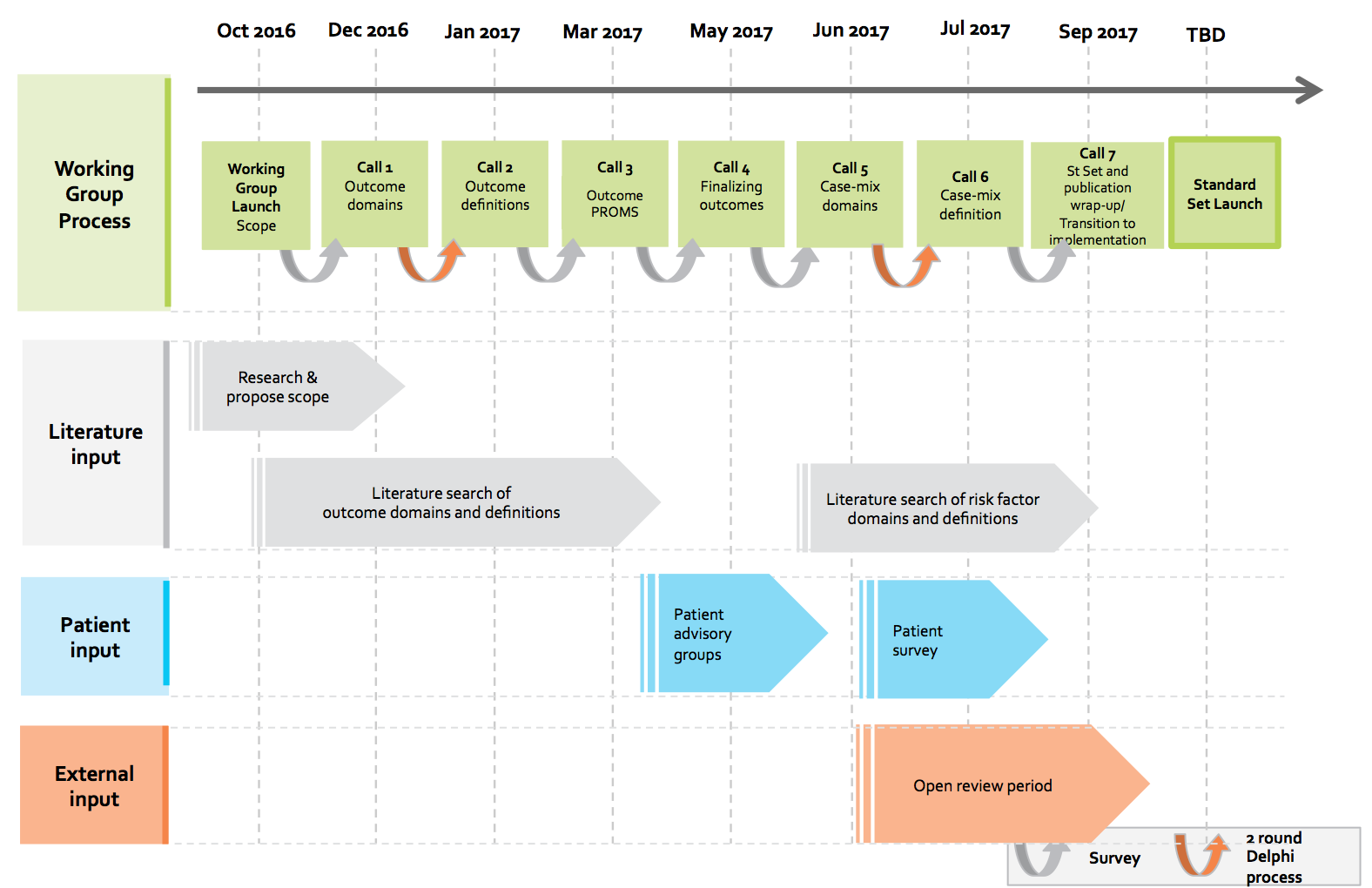
|  |  |  |
| --- | --- | --- |
|  | **Measure** | **Data**  **Source\*** |
| **Survival and disease control** | | |
| Blood pressure | Patient blood pressure reading in mmHg | CR |
| Overall survival and cardiovascular survival | Has the patient died? Cause of death, if known | CR or A |
| Medication side effects and adverse events | Has the patient experienced any adverse events or unwanted side effects of medication? | CR |
| Ischemic heart disease | Does the patient have ischemic heart disease? | CR |
| Cerebrovascular disease | Does the patient have cerebrovascular disease? | CR |
| Atrial fibrillation | Does the patient have atrial fibrillation? | CR |
| Heart failure | Does the patient have heart failure? Underlying cause? | CR |
| Peripheral artery disease | Does the patient have peripheral artery disease? | CR |
| Chronic renal disease | Does the patient have evidence of chronic renal disease? | CR |
| Hypertensive urgency or hypertensive emergency | Has the patient had a blood pressure reading above 180/120 mmHg in the past 12 months? (if yes, was there evidence of acute end-organ damage?) | CR |
| **Burden of care** |  |  |
| Access to care | Was there any time during the past 12 months when you really needed to consult your healthcare provider but you did not? | PR |
| Access to medication | Were you able to obtain the medication prescribed by your healthcare provider in the appropriate dose and formulation? | PR |
| Pill burden | What is the total number of pills or tablets that you take daily? | PR |
| **Patient-reported health status** | | |
| Quality of life | Tracked via the EQ5D-3L (preferred), PROMIS Global 10, VR-12, or SF-12 | PR |
| Erectile dysfunction | PROMIS single question on erectile dysfunction (SFEFN101) | PR |
| Patient-satisfaction | Single global question | PR |
| **Health behaviors and literacy** | | |
| Health beliefs | Beliefs about Medicines Questionnaire (BMQ) | PR |
| Medication adherence | Hill-Bone Questionnaire | PR |
| \* A = administrative data, PR = patient-reported data, CR = clinician-reported data | | |

Table 2. Summary of case-mix variables included in the ICHOM Standard Set for Hypertension in Low- and Middle-Income Countries

|  |  |  |
| --- | --- | --- |
|  | **Measure** | **Data**  **Source\*** |
| **Demographic factors** | | |
| Age | Indicate the patient’s date of birth | A |
| Sex | Indicate the patient’s sex at birth | A |
| Education level | Please indicate highest level of schooling completed | PR |
| **Baseline clinical factors** | | |
| Diabetes | Indicate if the patient has a documented history of diabetes mellitus (regardless of duration of disease or need for anti-diabetic agents) | CR |
| Smoking status | Do you smoke? How long ago did you give up smoking? | PR |
| Family history | Family history of cardiovascular disease | PR or CR |
| BMI | Indicate the patient’s height. Indicate the patient’s weight. | CR |
| Physical activity | IPAQ (The International Physical Activity Questionnaire) | PR |
| Sodium intake | WHO STEPS Questions | PR |
| **Treatment variables** | | |
| Treatment approach | What is the management approach? | CR |
| Antihypertensive drug class | Is patient on any of the following drug classes? | CR |
| Lipid-lowering drug class | Is patient on any of the following drug classes? | CR |
| \* A = administrative data, PR = patient-reported data, CR = clinician-reported data | | |

**FIGURES**

Figure 1. Timeline of Standard Set development



PROMS = Patient-reported outcome measures

Figure 2. Overview of outcome selection process (Adapted from Kirkham et al. 2016)

Identification of a list of 68 potential outcomes from literature review, registries search and WG member suggestions

**Generation of outcomes list - ICHOM Project Team**

WG member participation = 70% (12/17)

Scoring of 68 outcomes using the scale 1-9 (1-3= not essential, 4-6= nice to have, 7-9= essential)

24 outcomes voted for inclusion

44 outcomes did not reach consensus and were carried forward to Delphi Round 2

**Delphi Round 1**

WG member participation = 70% (12/17)

44 outcomes scored using the scale 1-9 (1-3= not essential, 4-6= nice to have, 7-9= essential)

10 items voted for inclusion

23 items voted for exclusion

11 items remained inconclusive

**Delphi Round 2**

WG member participation = 82% (14/17)

11 outcomes scored as Yes/No

2 outcomes voted for inclusion

9 outcomes voted for exclusion

**Yes/No Vote**

18 outcomes included. See Table 1.

**Final Core Outcome Set**

36 outcomes up for discussion

9 outcomes excluded because difficult to measure

4 outcomes recategorized as case-mix variables

3 outcomes summarized under HRQoL

1 outcome summarized under medication side effects

Overall survival and cardiovascular survival combined

**Consolidation**

103 patients responded to survey.

All outcomes, other than erectile dysfunction and peripheral artery disease, were rated as highly important (scores of 7-9) by over 70% of patients.

**Survey of patients with hypertension in Portugal and Nepal**

Qualitative interview with 10 Nigerian patients with hypertension attending the hypertension clinic at University of Ilorin Teaching Hospital

Patients did not identify any outcomes not already included in the Standard Set

**Interviews of Nigerian patients with hypertension**

**External input**

**Professional Feedback**

54 responded to online survey.

20/22 (91%) agreed with the inclusion of the outcome domains.

The most commonly envisioned barriers to use of the Standard Set, reported by 13/54 (24%), 5/54 (15%), 3/54 (7%), and 3/54 (7%) of respondents were that the Standard Set was time consuming and included too many questions, there was a lack of staff to implement the Standard Set, a lack of funding to implement the Standard Set, and poor record keeping and a lack of required data, respectively.

**Open review survey**

**Results of professional open review survey**

**Results of survey of patients with hypertension**

Figure 3. Recommended Timeline for data collection for patients with hypertension



**ONLINE SUPPLEMENT**

Table S1. Hypertension in LMIC Working Group members

|  |  |  |  |
| --- | --- | --- | --- |
| **Country** | **Working Group Member** | **Affiliation** | **Role** |
| Belarus | Vladislav Podpalov | Vitebsk State Medical University/Belarusian Hypertension Society | President / Honoured Professor of the Republic of Belarus |
| Brazil | Otavio Berwanger | Hospital do Coração | Director of Research Institute |
| Celso Amodeo | Brazilian Society of Cardiology | Director of Communications |
| Cameroon | Anastase Dzudie Tamdja | PASCAR / University of Yaounde | Associate Professor of Cardiology |
| Canada | Norm Campbell | University of Calgary | Professor of Medicine (internal medicine) |
| Ernesto L. Schiffrin | McGill University / Jewish General Hospital | Professor and Vice Chair/ Physician-in-Chief (hypertension) |
| Malaysia | Yook-Chin Chia | Sunway University /University of Malaya/ Malaysian Society of Hypertension | President / Professor of Primary Care medicine |
| Ghana | Peter Lamptey *(Chair)* | FHI360 / London School of Hygiene & Tropical Medicine | President Emeritus / Professor of Global NCD |
| India | Raghupathy Anchala | Indian Institute of Public Health, Hyderabad – The Public Health Foundation of India | Associate Professor of Epidemiology and Public Health Specialist |
| Mozambique | Albertino Damasceno | Eduardo Mondlane University | Associate Professor of Medicine (cardiology) |
| Portugal | António Vaz Carneiro\* | Centro de Estudos de Medicina Baseada na Evidência, Faculdade de Medicina da Universidade de Lisboa, Portuga | Associate Professor of Medicine |
| Manuela Fiuza\* | Universidade de Lisboa | Associate Professor of Cardiology |
| Switzerland | Fareed Mirza\*\* | Novartis Foundation | Head, Healthcare and Outcomes Research |
| United Kingdom | Dorothea Nitsch | London School of Hygiene & Tropical Medicine | Professor of Clinical Epidemiology/Programme Co-Director/Honorary Consultant Nephrologist |
| United States | Gbenga Ogedegbe | New York University Langone Medical Center | Professor of Medicine |
| Vietnam | Thi Nam Phuong DO | Heart Institute of Ho Chi Minh City | Cardiologist |
| Two patient representatives, one from Tanzania and one from Mexico, participated in the WG process for selecting outcomes | | | |
| \*Both representatives from Universidade de Lisboa shared a single vote on the WG.  \*\*Fareed Mirza is an employee of the Novartis Foundation. He is a non-voting WG member. | | | |

Table S2. Literature search strategy for outcomes

|  |  |  |
| --- | --- | --- |
| **Search terms used for PubMed searches** | **Results** | **Final # of articles reviewed** |
| hypertension[Majr] OR “blood pressure” [Majr] OR hypertension[ti] OR “blood pressure”[ti])  NOT ("pulmonary hypertension"[ti] OR "pulmonary arterial hypertension"[ti] OR child\*[ti] OR maternal[ti] OR pregnant[ti])  NOT (animals [mh] NOT humans [mh])  AND  (((("Quality of Life"[Mesh] OR "Quality Indicators, Health Care"[Mesh] OR "Patient Outcome Assessment"[Mesh] OR "Treatment Outcome"[Mesh] OR Quality of life[tiab] OR QOL[tiab] OR quality indicator\*[tiab] OR patient reported outcome\*[tiab] OR patient related outcome\*[tiab] OR patient outcome\*[tiab] OR patient assessment\*[tiab] OR treatment outcome\*[tiab] OR outcome\*[ti])  AND  (index[tiab] OR indices[tiab] OR instrument[tiab] OR instruments[tiab] OR measure\*[tiab] OR questionnaire\*[tiab] OR profile\*[tiab] OR scale\*[tiab] OR scor\*[tiab] OR status[tiab] OR survey\*[tiab] OR rating\*[tiab] OR tool[tiab] OR tools[tiab] OR metric\*[tiab] OR reporting[tiab])  AND  (randomized controlled trial[All Fields] OR randomized controlled trials[All Fields] OR randomised controlled trial[All Fields] OR randomised controlled trials[All Fields] OR randomized controlled trial[pt] OR Review[pt] OR systematic[sb]))  OR  ("Quality Indicators, Health Care"[Mesh] OR "Patient Outcome Assessment"[Mesh] OR quality indicator\*[tiab] OR patient reported outcome\*[tiab] OR patient related outcome\*[tiab] OR patient outcome\*[tiab] OR patient assessment\*[tiab] OR outcome report\*[tiab] OR "Patient Outcome Assessment"[Mesh:NoExp] OR "Patient-Centered Care"[Mesh] OR "Patient Satisfaction"[Mesh] OR "Physician-Patient Relations"[Mesh] OR "Nurse-Patient Relations"[Mesh] OR patient centered[tw] OR patient participation[tw] OR patient involvement[tw] OR patient preference\*[tw] OR patient’s preference\*[tw] OR patients' preference\*[tw] OR patient satisfaction[tw] OR patient's satisfaction[tw] OR patients' satisfaction[tw] OR patient expectation\*[tw] OR patient's expectation\*[tw] OR patients' expectation\*[tw] OR (patient reported[tw] AND outcome\*[tw]) OR shared decision\*[tw] OR physician patient[tw] OR doctor patient[tw] OR clinician patient[tw] OR nurse patient[tw]))  OR  ((("randomized controlled trials as topic"[MeSH Terms] OR (("randomized controlled trial"[Publication Type] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomized controlled trial"[All Fields] OR "randomised controlled trial"[All Fields]) OR randomized controlled trial,[All Fields] OR ("randomized controlled trial"[Publication Type] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomized controlled trials"[All Fields] OR "randomised controlled trials"[All Fields]))) OR (("randomized controlled trial"[Publication Type] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomised controlled trial"[All Fields] OR "randomized controlled trial"[All Fields]) OR ("randomized controlled trial"[Publication Type] OR "randomized controlled trials as topic"[MeSH Terms] OR "randomised controlled trials"[All Fields] OR "randomized controlled trials"[All Fields]))) OR randomized controlled trial[Publication Type])  AND ((("Quality of Life"[Mesh] OR "Outcome Assessment (Health Care)"[Mesh]) OR "Outcome and Process Assessment (Health Care)"[All Fields]) OR "Quality Indicators, Health Care"[Mesh]))  AND ("2005/01/01"[PDAT] : "3000/12/31"[PDAT])  AND (English[la]) | 2,543 | 1,114  (1,429 excluded due to not meeting inclusion criteria: (English language, published in 2005 or onwards, patient population of adults aged ≥ 18 years old with a diagnosis of primary hypertension, and a focus on patient-centered or clinical outcomes)) |
| LMIC (World Bank) search terms from Cochrane (http://epoc.cochrane.org/lmic-filters)  AND (Hypertension[tiab]  NOT (animals [mh] NOT humans [mh])  AND (barriers[tiab]))  AND ("2005/01/01"[PDAT] : "3000/12/31"[PDAT])  AND (English[la]) | 139 | 52  (87 excluded due to not meeting inclusion criteria: English language, published in 2005 or onwards, patient population of adults aged ≥ 18 years old with a diagnosis of primary hypertension, and a focus on patient-centered or clinical outcomes) |

Table S3. Registries searched for outcomes

|  |
| --- |
| **Registry** |
| International Registry for ambulatory blood pressure and arterial stiffness telemonitoring (VASOTENS) |
| China Ambulatory and Home BP Registry (CABPR) |
| Korean Registry of Target Organ Damages in Hypertension (KorHR) |
| Registro Campania Salute Network on Hypertension (RCSN) |
| The Swedish Primary Care Cardiovascular Database (SPCCD) |
| International Database of Ambulatory Blood Pressure in relation to Cardiovascular Outcome (IDACO) |
| I RBH - First Brazilian Hypertension Registry (1RBH) |
| Estudio Cardiometabólico Valenciano Escarval-Risk study (Escarval) |
| Spanish Society of Hypertension Ambulatory Blood Pressure Monitoring Registry (SABPM) |
| International Ambulatory Blood Pressure Registry: Telemonitoring of Hypertension and Cardiovascular Risk Project (ARTEMIS) |
| Korean Ambulatory Blood Pressure Monitoring Registry (Kor-ABP) |
| American Society of Hypertension Registry Initiative (ASHRI) |
| Egyptian Hypertension clinics (EHC) |
| Department of primary care medicine clinic - university of Malaya (PCMUM) |
| Hypertension Outcomes and Surveillance Teams (HOST) |

Table S4. Literature search strategy for case-mix variables. We extracted baseline variables reported by 16 landmark anti-hypertensive drug trials found in the literature review described below

|  |  |
| --- | --- |
| **PubMed search terms** | **Results** |
| hypertension[ti]  AND review[publication type] AND randomized controlled trial  AND ("2005/01/01"[PDAT] : "3000/12/31"[PDAT])  AND (English[la])  NOT ("pulmonary hypertension"[ti] OR "pulmonary arterial hypertension"[ti] OR "portal hypertension"[ti] OR  "ocular"[ti] OR child\*[ti] OR maternal[ti] OR pregnan\*[ti])  NOT (animals[mh] NOT humans[mh]) | 322 |

Table S5. Results from Working Group votes on potential outcome variables found through reviews of literature and registries

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2-Round Delphi % rating “very important” (7-9)** | | **Final voting rounds % voted “yes”** | **Inclusion in Standard Set as an outcome?** |
| **Potential outcome** | **Round 1** | **Round 2** | **Round 3** |  |
| # of Working Group members participating in vote | 12/17 (70%) | 12/17 (70%) | 14/17 (82%) |  |
| Cardiovascular survival | 100 | NA | NA | Captured under overall survival |
| Blood pressure | 100 | NA | NA | Yes |
| Overall cardiovascular risk | 92 | NA | NA | Recategorized as case-mix variable. |
| Health related quality of life (HRQoL) | 75 | NA | NA | Yes |
| Satisfaction with care | 83 | NA | NA | Yes |
| Independence | 83 | NA | NA | Captured under HRQoL |
| Wellbeing | 75 | NA | NA | Captured under HRQoL |
| Physical functioning | 75 | NA | NA | Captured under HRQoL |
| Adherence to medication | 83 | NA | NA | Yes |
| Acute adverse events | 92 | NA | NA | Yes |
| Access to care | 92 | NA | NA | Yes |
| Health beliefs | 75 | NA | NA | Yes |
| Hospitalization | 75 | NA | NA | Later excluded |
| Hypertensive crisis | 75 | NA | NA | Yes |
| Stroke/TIA | 92 | NA | NA | Yes |
| Myocardial Infarction/ Angina | 92 | NA | NA | Yes |
| Atrial fibrillation | 92 | NA | NA | Yes |
| Heart failure | 92 | NA | NA | Yes |
| Renal disease/ renal failure / proteinuria | 75 | NA | NA | Yes |
| Understanding / Knowledge of condition and treatment | 75 | NA | NA | Later excluded |
| Diabetes/ insulin resistance | 83 | NA | NA | Recategorized as case-mix variable. |
| Access to drugs | 92 | NA | NA | Yes |
| Survival - all cause | 58 | 83 | NA | Yes |
| Sexual dysfunction | 67 | 83 | NA | Yes |
| Empowerment / autonomy / self-efficacy | 67 | 91 | NA | Later excluded |
| Self-management | 58 | 75 | NA | Later excluded |
| Social role disability | 50 | 75 | NA | Later excluded |
| Discontinuation of treatment | 67 | 42 | NA | No |
| Falls secondary to hypotension | 58 | 67 | 29 | Captured under medication side effects |
| Bradycardia / heart rate | 58 | 42 | NA | No |
| Dizziness | 58 | 50 | 21 | No |
| Fatigue | 58 | 33 | NA | Captured under medication side effects |
| Cough | 58 | 42 | NA | Captured under medication side effects |
| Headaches | 50 | 58 | 21 | No |
| Peripheral artery disease | 50 | 75 | NA | Yes |
| Abdominal aortic aneurysm | 50 | 58 | 29 | No |
| Retinopathy | 67 | 75 | NA | Later excluded |
| Dementia / cognitive impairment | 58 | 75 | NA | Later excluded |
| Smoking cessation | 50 | 67 | 35 | No |
| Patient - provider relationship | 67 | 58 | 29 | No |
| Financial burden | 67 | 100 | NA | Later excluded |
| Lasting dietary change | 58 | 58 | 50 | Later excluded |
| BMI / weight | 67 | 33 | NA | No |
| Number of medications / pill burden / polypharmacy | 50 | 75 | NA | Yes |
| Mood / anxiety / depression | 42 | 8 | NA | No |
| Arrhythmia/palpitations | 42 | 42 | NA | No |
| Urinary problems | 33 | 50 | 42 | Captured under medication side effects |
| Edema | 25 | 58 | 57 | Captured under medication side effects |
| Carotid artery damage (clinically detected or detected on imaging) | 42 | 25 | NA | No |
| Arthralgia | 17 | 8 | NA | No |
| Myalgia | 17 | 17 | NA | No |
| Gastro-intestinal complaints | 8 | 17 | NA | No |
| Cold symptoms (refers to respiratory tract side effects) | 8 | 17 | NA | No |
| Back pain | 17 | 8 | NA | No |
| Bronchitis | 17 | 8 | NA | No |
| Nausea | 17 | 8 | NA | No |
| Flushing | 33 | 8 | NA | No |
| Diarrhoea | 8 | 8 | NA | No |
| Dyspnoea | 42 | 8 | NA | No |
| Urticaria | 33 | 25 | NA | No |
| Left ventricular hypertrophy | 42 | 50 | 42 | No |
| Endothelial function | 17 | 25 | NA | No |
| Biomarkers | 8 | 17 | NA | No |
| Arterial stiffness | 25 | 17 | NA | No |
| Pulse wave velocity | 25 | 42 | NA | No |
| Appointment adherence | 42 | 50 | 29 | No |
| Physical activity levels / lasting lifestyle change | 75 | 64 | NA | Recategorized as case-mix variable. |
| Reduced salt intake | 75 | 57 | NA | Recategorized as case-mix variable. |

Table S6. Results from WG votes on 44 potential case-mix variables found through reviews of literature and registries

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2-Round Delphi % rating “very important” (7-9)** | | **Final voting rounds % voted “yes”** | **Inclusion in Standard Set as case-mix variable?** |
|  | **Round 1** | **Round 2** | **Round 3** |  |
| # of Working Group members participating in vote | 11/13 (85%) | 8/13 (62%) | 7/13 (54%) |  |
| **Demographic factors** |  |  |  |  |
| Age | 100 | NA | NA | Yes |
| Sex | 100 | NA | NA | Yes |
| Race /ethnicity | 27 | 38 | NA | No |
| Education | 82 | NA | NA | Yes |
| Annual income | 9 | 25 | NA | No |
| Country of birth | 0 | 0 | NA | No |
| Social and job stress | 18 | 0 | NA | No |
| Poor housing conditions | 9 | 0 | NA | No |
| **Clinical history and co-morbidities** |  |  |  |  |
| Stroke | 100 | NA | NA | No, included as outcome |
| TIA | 100 | NA | NA | No, included as outcome |
| Prior Myocardial infarct | 100 | NA | NA | No, included as outcome |
| Coronary artery disease | 91 | NA | NA | No, included as outcome |
| Atrial fibrillation | 82 | NA | NA | No, included as outcome |
| Arrhythmias | 18 | 13 | NA | No |
| Heart failure | 100 | NA | NA | No, included as outcome |
| Peripheral artery disease | 82 | NA | NA | No, included as outcome |
| Chronic kidney disease | 91 | NA | NA | No, included as outcome e |
| Dementia | 0 | 0 | NA | No |
| Diabetes | 100 | NA | NA | Yes |
| Left Ventricular hypertrophy | 18 | 13 | NA |  |
| Duration of hypertension | 9 | NA | NA | No |
| Metabolic syndrome | 27 | NA | NA | No |
| **Medication history** |  |  |  |  |
| Statin use / Lipid lowering therapy | 36 | 50 | 71 | Yes |
| Aspirin | 18 | 50 | 43 | No |
| NSAID use | 27 | 25 | NA | No |
| Glucose lowering therapy | 27 | 50 | NA | No |
| Antihypertensive agents / Antihypertensive drug class | 100 | NA | NA | Yes |
| **Lifestyle and other risk factors** |  |  |  |  |
| Smoking status | 100 | NA | NA | Yes |
| Alcohol consumption | 9 | 13 | NA | No |
| Weight/ BMI/ waist circumference | 100 | NA | NA | Yes |
| Family history of CVD | 36 | 25 | NA | Yes |
| Family history of premature CVD | 100 | NA | NA | No |
| Family history of hypertension | 27 | 13 | NA | No |
| Heart rate | 45 | 38 | NA | No |
| **Clinical and Lab tests** |  |  |  |  |
| Serum creatinine | 45 | 63 | 86 | Yes, optional |
| eGFR | 36 | 38 | NA | No |
| Ratio of urinary albumin to creatinine, microalbuminuria | 18 | 25 | NA | No |
| Fasting total cholesterol / hypercholesterolemia | 27 | 50 | 43 | No |
| LDL cholesterol | 18 | 25 | NA | No |
| Fasting HDL cholesterol | 9 | 25 | NA | No |
| Fasting total triglycerides | 9 | 25 | NA | No |
| Fasting plasma glucose | 27 | 50 | 71 | Yes, optional |
| Urinary sodium | 0 | 0 | NA | No |
| HbA1c | 9 | 13 | NA | No |

Table S7. Results from patient interviews in Nigeria

|  |  |  |
| --- | --- | --- |
| Question | Response | Frequency |
| What worries you the most when you think about your hypertension or your blood pressure? | * Financial burden of hypertension   + “Sometimes if you don’t have money to buy drugs or take care of your family, automatically, my HTN gets worse. Being unable to afford treatment is stressful.” | 3 |
| * Restoration of health | 1 |
| * Risk factors   + “HTN puts me at risk for more serious conditions.” | 1 |
| * Concern for family and community   + “How will my family feel about my health and this situation? Concerned – afraid of death and afraid of acute effects of the condition itself.” | 3 |
| * Diet   + “Unable to eat what I want to eat & it is challenging to be placed on a strict diet.” | 2 |
| About what have you spoken to your doctor or your healthcare provider related to hypertension? | * Side effects   + “There side effects of some of the drugs we’re taking are hard to live with; going through the literature to self-educate is hard – what is natural? Is there anything that doesn’t have a side effect? What can I do to avoid these side effects?” | 1 |
| * Stress around medication | 1 |
| Have you found that having hypertension has affected parts of your life outside of your health (work, personal relationships, etc.)? | * Drowsiness and sleep habits related as drug side effects | 1 |
| * Loss of normal function related to work ability (physical functioning, fatigue) | 2 |
| * Stress on body (related to physical functioning) | 1 |
| What challenges or difficulties have you faced in controlling your blood pressure to an adequate level? | * Financial difficulties (cost of care) | 4 |
| * Societal challenges (pressure to take care of nuclear, immediate, in-law family)   + “In Africa, we have extended family systems so the pressure is on you from your nuclear and immediate family as well as extended family and in-laws, especially for women.” | 4 |
| What is the worst thing in your mind about having hypertension? | * Financial (spending money on drugs) | 3 |
| * Diet – monitoring salt intake, eating small quantities | 2 |
| * Functional limitations & earning wages | 1 |
| * Restoration to good health | 1 |
| * Having good information – education 🡪 how will hypertension be cured & what medications are right for the condition | 1 |
| If there is one thing, what do you think is the most important goal to achieve or end result when it comes to hypertension? | * To bring blood pressure down and restore health | 2 |
| * Prevent heart attacks | 1 |
| * Prevent stroke | 1 |
| * Minimize side effects | 1 |

Table S8. Demographics of respondents to patient surveys in Nepal and Portugal, n=103

|  |  |
| --- | --- |
| **Characteristic** | **N (%)** |
| Country |  |
| Nepal | 98 (95%) |
| Portugal | 5 (5%) |
| Sex |  |
| Male | 59 (57%) |
| Female | 40 (39%) |
| Unreported | 4 (4%) |
| Age group, years |  |
| 18-40 | 20 (19%) |
| 41-64 | 41 (40%) |
| 65+ | 42 (41%) |
| Unreported | 0 (0%) |

Table S9. Results from patient surveys in Nepal and Portugal, n=103

|  |  |  |
| --- | --- | --- |
| For each outcome, patients were asked to “please rate how important each of the outcomes are to you (1=not important, 9 very important).” |  |  |
| **Outcome** | **Percentage of WG members scoring item**  **7-9 (%)** | **Median score of item [IQR]** |
| Overall survival - how long a person lives irrespective of the eventual cause of death | 94 | 8 [7, 9] |
| Cardiovascular survival - how long a person lives and whether they die of a cardiovascular cause such as heart attack or stroke | 97 | 8 [7, 9] |
| Blood pressure - pressure of blood in the circulatory system; used to diagnose hypertension | 93 | 8 [7, 9] |
| Overall cardiovascular risk - the probability that a person will develop cardiovascular diseases such as heart attacks, strokes, etc. | 99 | 8 [8, 9] |
| Physical activity/lifestyle - any physical or daily activity a person does to promote their good health | 89 | 8 [7, 9] |
| Salt reduction - how much salt a person consumes and whether they are able to reduce it | 84 | 8 [7, 8] |
| Acute adverse events - side effects or unwanted effects of treatment | 82 | 8 [7, 9] |
| Health-related quality of life - the changes to your quality of life caused by your health (medical condition and treatments) | 85 | 8 [7, 9] |
| Wellbeing - the state of being comfortable, healthy, or happy | 85 | 8 [7, 9] |
| Independence - ability to be free of the control or supervision of some other person, to live or work independently | 83 | 7 [7, 8] |
| Social role disability - ability to carry out usual roles, such as work and social activates | 80 | 7 [7, 8] |
| Physical functioning - ability to carry out various activities that require physical capability, ranging from self-care to more vigorous activities | 83 | 8 [7, 8] |
| Pill burden - number of pills or tablets consumed on a weekly basis | 88 | 8 [7, 9] |
| Financial burden - the economic changes cause by treatments and disease to patients | 94 | 9 [7, 9] |
| Access to care - being able to obtain healthcare when you need it | 89 | 8 [7, 9] |
| Access to drugs - being able to access what is prescribed by doctor in the correct form and dosage | 91 | 8 [7, 9] |
| Hospitalization - admission to the hospital for treatment | 84 | 8 [7, 9] |
| Erectile dysfunction - difficulty getting or maintaining an erection, sometimes known as impotence | 45 | 6 [5, 8] |
| Men only | 50 | 7 [6, 8] |
| Women only | 30 | 6 [3, 7] |
| Peripheral artery disease - circulatory problem leading to reduced blood flow to your limbs, which can be painful and lead to other complications | 63 | 7 [6, 8] |
| Hypertensive urgency / emergency - severe increase in blood pressure that can lead to a stroke or may damage organs like your kidneys or the back of your eyes | 94 | 8 [8, 9] |
| Heart failure - failure of the heart to pump blood effectively through the body | 97 | 8 [8, 9] |
| Myocardial infarction / angina - heart attack or chest pain caused by exertion due to reduced blood flow to your heart muscle | 96 | 8 [8, 9] |
| Stroke / TIA - lasting damage to part of the brain due to reduced blood flow to the brain; in a TIA (or mini-stroke), the damage is reversible | 95 | 9 [8, 9] |
| Atrial fibrillation - irregular and very fast heart rate; can cause heart palpitations, fatigue and shortness of breath but sometimes patients don't know they have it | 88 | 8 [7, 8] |
| Renal disease - failure of kidneys to adequately filter wastes from the blood | 84 | 8 [7, 9] |
| Understanding of condition - the degree to which a person understands their diagnosis and treatment | 83 | 7 [7, 8] |
| Health beliefs - the beliefs an individual holds regarding what causes illness, how it can be cured or treated, and who should be involved in the process | 83 | 7 [7, 8] |
| Empowerment/autonomy - extent to which people have control over decisions and actions affecting their health | 79 | 7 [7, 8] |
| Self-management - ability of a person to manage decisions and behaviors that affect their health | 80 | 7 [7, 8] |
| Satisfaction with care - extent to which a person is content with the health care which they received from their provider | 82 | 8 [7, 8] |
| Medication adherence - extent to which a person takes medications as prescribed by their health care providers | 87 | 8 [7, 8] |
|  |  |  |
| Do you feel that these outcomes listed broadly capture all of the important outcomes that matter or have mattered most to you? | Yes = 95%  No = 4%  Abstained = 1% | |
|  | | |

Table S10. Demographics of respondents to open review survey, n=54

|  |  |
| --- | --- |
| Characteristic | N (%) |
| Geographic distribution (WHO Region) |  |
| Africa | 23 (43%) |
| Europe | 8 (15%) |
| Eastern Mediterranean | 1 (2%) |
| Western Pacific | 4 (7%) |
| Americas | 8 (15%) |
| South-East Asia | 10 (19%) |
| Not specified | 9 (17%) |
| Profession |  |
| Physician | 31 (57%) |
| Nurse or nurse practitioner | 8 (15%) |
| Researcher (non-clinician) | 7 (13%) |
| Life sciences representative | 2 (4%) |
| Community health care worker | 2 (4%) |
| Other or unknown | 4 (7%) |

Table S11. Results from open review survey, n=54

|  |  |  |  |
| --- | --- | --- | --- |
| Question | Yes, N (%) | No, N (%) | Blank, N (%) |
| Do you agree that Blood pressure, survival and medication side effects and adverse events should be measured by all providers treating hypertensive patients in LMICs? | 38 (70) | 4 (7) | 12 (22) |
| Do you feel the questions are appropriately worded? | 35 (65) | 7 (13) | 12 (22) |
| Do you agree that ischaemic heart disease, cerebrovascular disease, atrial fibrillation and heart failure should be measured by all providers treating hypertensive patients in LMICs? | 35 (65) | 7 (13) | 12 (22) |
| Do you feel the questions are appropriately worded? | 36 (67) | 6 (11) | 12 (22) |
| Do you agree that peripheral artery disease, renal disease, admission to hospital and hypertensive urgency and hypertensive emergency should be measured by all providers treating hypertensive patients in LMICs? | 39 (72) | 3 (6) | 12 (22) |
| Do you feel the questions are appropriately worded? | 36 (67) | 7 (13) | 11 (20) |
| Do you agree that financial burden, access to care, access to drugs and pill burden should be measured by all providers treating hypertensive patients in LMICs? | 33 (61) | 4 (7) | 17 (31) |
| Do you feel the questions are appropriately worded? | 31 (57) | 4 (7) | 19 (35) |
| Do you agree that the domains presented above should be measured by all providers treating hypertensive patients in LMICs? | 32 (59) | 4 (7) | 18 (33) |
| Do you agree that the question proposed to assess patient satisfaction is appropriate? If not, why not? | 34 (63) | 3 (6) | 17 (31) |
| Do you agree that the single question: "How would you rate your ability to get and keep an erection? (If you use pills, injections, or a penis pump to help you get an erection, please answer this question thinking about the times that you used these aids.)" is appropriate to assess erectile dysfunction? If not, why not? | 25 (46) | 11 (20) | 18 (33) |
| Do you agree that the EQ-5D-3L questionnaire displayed above is appropriate to asses Health-related quality of life in hypertensive patients living in LMICs? | 30 (56) | 6 (11) | 18 (33) |
| Do you agree that the BMQ questionnaire displayed above is appropriate to asses Health literacy in hypertensive patients living in LMICs? | 29 (53) | 6 (11) | 19 (35) |
| Do you agree that the Hillbone (medication sub-scale) questionnaire displayed above is appropriate to assess medication adherence in hypertensive patients living in LMICs? | 31 (57) | 5 (2) | 18 (33) |
| Do you agree that the IPAQ questionnaire is appropriate to assess physical activity in hypertensive patients living in LMICs? | 29 (53) | 4 (9) | 21 (39) |
| Do you agree that the WHO STEPS Dietary Salt questions with the displayed showcard are appropriate to assess salt intake in hypertensive patients living in LMICs? | 29 (53) | 5 (9) | 20 (37) |
| In general, do you agree with inclusion of the outcome domains presented above in the Standard Set? If not, why not? | 32 (59) | 2 (4) | 20 (37) |
| Do you agree with the time points for data collection? If not, please indicate why. | 31 (57) | 4 (7) | 19 (35) |
| Do you think the data collection is feasible? If not, please indicate why. | 31 (57) | 3 (6) | 20 (37) |
| Would your organization/s be interested in implementing this Standard Set of outcomes? | 31 (57) | 5 (9) | 18 (33) |
|  | Response | | N |
| What the barriers or challenges to implementation of the Hypertension in LMIC Standard Set do you envision? | Time consuming/too many questions | | 13 |
| Lack of staff to implement | | 5 |
| Lack of funding | | 3 |
| Poor record keeping/ required data not available | | 3 |
| Language – validated translations of tools | | 2 |
| Patient literacy levels | | 2 |
| Appropriateness to local needs | | 1 |
| None | | 3 |