ICHOM Hypertension in Low- and Middle-Income Countries Standard Set

Introduction
The International Consortium for Health Outcomes Measurement (ICHOM) is a non-profit organisation that was founded by thought leaders at Harvard Business School, Boston Consulting Group and the Karolinska Institute in 2012. The organisation's mission is to drive the adoption of value-based healthcare principles in the healthcare community. We define "value" as the outcomes of care achieved for patients, relative to the cost of achieving these outcomes. Outcomes are the end-results of care that people who live with a health condition experience.

ICHOM promotes the measurement of outcomes in a standardised way globally, enabling comparisons to be made between organisations, and across countries and regions. To this end, we develop Standard Sets of outcomes that capture the results of care that are most important to patients. While process and cost measures have their place, and providers should rightfully be monitoring these, it is outcomes that patients care about. If patients are to be at the centre of health care, focusing on their priorities must become the focus of every stakeholder involved in their care.

ICHOM Standard Sets
ICHOM Standard Sets are condition-specific. They comprise a core set of outcome measures that are either patient-reported, clinician-reported or administrative data, alongside a core set of case-mix variables (e.g. demographic factors, treatment variables, relevant medical and social history) that allow for case-adjustment and meaningful comparisons.

The purpose of ICHOM Standard Sets is not to replace existing treatment guidelines. They are intended to be used to measure outcomes of care in a standardised way, regardless of the treatment or management approach. By restructuring care-delivery around outcomes and promoting superior outcomes, healthcare systems can improve quality and curb inefficiencies. This will benefit every stakeholder across the healthcare spectrum. For example, providers will strive to deliver better outcomes at the lowest possible cost, which will encourage innovation in approaches to care, payers and governments will be able to tie reimbursements to outcomes to promote innovation, and suppliers are driven to market their products on value, showing improved patient outcomes relative to costs.
Glossary

**Outcome:** The effects of care on the health status of patients and populations. ICHOM places special emphasis on results people living with a medical condition care about most when seeking treatment. These include functional improvement and the ability to live normal, productive lives.

**Outcome domain:** A conceptually distinct element (e.g. quality of life)

**Outcome measure:** A tool used to measure outcome domains (e.g. questionnaires or clinical tools)

**Case-mix variable:** Variables used for adjustment in statistical analyses. These include but are not limited to demographic factors, co-morbidities, treatment factors and socioeconomic factors.

Aims and Objectives

This project aims to develop a minimum set of outcomes with a set of relevant case-mix variables that will be used to evaluate the care provided to people living with hypertension, with a particular focus on patients in low- and middle-income countries.

Scope

The scope of the work covers adults 18 years and above with a diagnosis of primary hypertension (IDC 10: I10) defined as a blood pressure above 140/90mmHg. The scope will exclude those with a diagnosis of secondary hypertension. In deciding on this scope, the Working Group acknowledges the difficulty of ruling out secondary causes of hypertension in all cases, especially in low resource settings. They also recognise that many of the outcomes relevant to primary hypertension will also be relevant in secondary hypertension. However, secondary hypertension by definition has an underlying cause that may require specific interventions. Addressing these is beyond the scope of this work.

Methods

To develop standard sets, ICHOM convenes an international Working Group (WG) of clinicians, registry leaders, researchers and people living with hypertension. Individuals are invited to the WG based on their expertise in hypertension care or experience in healthcare delivery in a low- or middle-income country. In the case of patient representatives, the invitation is based on their experience of receiving care for hypertension in a low- or middle-income country.

ICHOM’s methodology involves four parallel processes as illustrated in Figure 1. The Working Group process involves a series of structured teleconference calls, each with a specific aim. Each call is followed by a vote via an online survey. The survey acts as a formal documentation of the Working Group’s consensus. A threshold of 70% will be used to determine agreement. If consensus is not reached on an item, it is carried forward for further discussion to the next call. After the discussions of outcomes and case-mix variables (usually Call 1 and Call 4), there is a 3-round modified Delphi survey, which is illustrated in detail in Figure 2.

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The efforts of the Working Group are supported by a Project Team which consists of the Working Group chair, a research fellow, an ICHOM project leader and an ICHOM research associate. The Project Team researches the literature and other existing efforts and puts forward a proposal for discussion during each call. The Project Team may reach out to individual Working Group members with specific expertise in the area being researched for support, if appropriate.

Specific aims of each teleconference call

Working Group Launch

The Launch Call aims to introduce Working Group members to each other and to present the project and scope of the work.

Call 1 – Outcome domains

The aim of Call 1 is to discuss what outcome domains should be included in the set. In preparation for the call, the Project Team will review the literature and existing registries for outcomes currently collected. The outcomes identified will form the basis of the discussion. Outcomes will be divided into three categories:

1. Outcomes that reflect the most important end-results for people with hypertension.
2. Outcomes that are important but may not belong in a minimum set.
3. Outcomes that apply only to a subset of patients, may be impractical to capture or may have questionable relevance to quality improvement.

The call will be followed by a 3-round modified Delphi survey during which the WG ranks the importance of each of the proposed outcome domains on a Likert scale of 1-9. The detailed scoring plan is presented in Figure 2.

Call 2 – Outcome definitions

There are two aims for Call 2:

1. To discuss any outcome domains that remain inconclusive after the second round of the modified Delphi survey before presenting them for a final “Yes/No” vote.
2. In preparation for this call, the PT will prepare definitions of the already conclusively included domains. For outcomes that are to be clinician-reported, this will include the most appropriate methods for assessment and cut-offs. Wherever possible, we will aim to align with existing international definitions. For patient-reported variables, we will propose a validated PROM if available. The proposal will be based on a review of existing PROMs in line with recommendations made by ISOQOL.

Depending on the volume of material to be discussed, the discussion on outcome definitions may be spread across into two calls.

Call 3 – Outcome wrap-up

In Call 3 the Working Group will aim to finalise any outstanding issues around the outcome domains, including time-points for data collection and the data source (i.e. administrative data, clinician-reported data or patient-reported data).

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2 Reeve et al., ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research, Qual Life Res (2013) 22:1889–1905
They will also aim to review the results of the patient focus groups and patient surveys, which are described in more detail below.

**Call 4 – Case-mix domains**  
Once the outcome domains have been selected and finalised, the Working Group goes through a similar process to select and define case-mix variables. The Project Team prepares a list of potential case-mix variables by searching the literature to identify what variables have been used in major hypertension studies. Following the call, there will be another 3-round modified-Delphi survey as described in Figure 2.

**Call 5 – Case-mix definitions.**  
The Project Team presents a proposal for definitions of the case-mix variables voted for inclusion by the Working Group after the first and second rounds of the modified-Delphi process. Variables which remained inconclusive after the second round will be discussed during this call, before being presented for a final “Yes/No” vote.

**Call 6 – Standard Set wrap up**  
In Call 6, the Working Group will discuss any outstanding definitions case-mix variables were not discussed during the previous call. They will also review the results of the open review survey which is described in more detail below.

**Call 7 – Review and transition to implementation**  
The Working Group reviews the final set and devises a strategy for piloting, implementation and benchmarking.

**External input**  
**Patient engagement**  
Patient focus group interviews will be held with patients from LMICs living with hypertension to identify their preferences for care. The outputs from the focus group interviews will be compared to the outcomes selected by the Working Group to ensure the group is capturing what matters the most to patients. Any outcomes mentioned during the patient interviews that have not already been voted for inclusion by the Working Group will be reviewed and considered for inclusion.

Once the draft list of outcomes has been finalised, it will be presented to a wide audience of patients through online and paper surveys. Patients will be asked to rank the importance of each of the proposed outcomes to ensure the outcomes included rank highly for patients. They will also have the opportunity to suggest outcomes they believe should be included.

Ethics approval for the patient focus groups and surveys will be sought from the appropriate authorities.

**Open review**  
Once the outcomes and case-mix variables have been selected, the draft will be presented to a wide group of stakeholders in hypertension care including clinicians, researchers, policy experts, health service management professionals and representatives from the life sciences industry. It aims to confirm the suitability of the outcome and case-mix variables included in the set. The purpose is to seek feedback on the appropriateness of the definitions used, the practicality of implementation and any potential obstacles to future benchmarking. As with the patient engagement work, the results will be fed back to the Working Group for consideration.
Figure 1: Overview of the Standard Set development process

- Working Group Process
  - Working Group Launch
  - Meeting 1: Outcome domains
  - Meeting 2: Outcome definitions
  - Meeting 3: Outcome wrap-up
  - Meeting 4: Case-mix domains
  - Meeting 5: Case-mix definitions
  - Meeting 6: Standard Set and publication wrap-up
  - Meeting 7*: Review & transition to implementation

- Literature input
  - Literature review of outcome domains and definitions
  - Literature review of risk factor domains and definitions

- Patient input
  - Patient focus group (FG)
  - Validation of outcome domains (distribute survey via patient organisations)

- External input
  - Open review period

* Most meetings are telephonic or via video

Figure 2 – Modified Delphi survey.

- Modified-Delphi Round 1
  - 70% ranked 7-9: Include
  - 70% ranked 1-3: Enter into Round 2
  - All others: Enter into Round 2

- Modified-Delphi Round 2
  - 70% ranked 7-9: Include
  - 70% ranked 1-3: Exclude
  - All others: Enter into Round 3

- Modified-Delphi Round 3 (Yes/No vote)
  - ≥50% vote YES: INCLUDE
  - < 50% vote NO: EXCLUDE