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How are standard sets made and implemented? An overview of the oncology and cardiology orientated standard sets

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Agenda

- **The methodology for developing a Standard Set**
- **Cardiovascular Standard Sets**
- **Breast Cancer Standard Set**
- **Q&A**

The lack of outcome measurements that represent what truly matters most to patients is a global barrier to driving healthcare improvement

Problem	Result
1 Paucity of outcomes data beyond basic mortality measures	Lack of information for patients and providers on whether what we do works
2 Where available, outcomes are hard to compare and not standardised	Slow pace of change and inability to learn from others
3 Outcomes are often not patient focused	Success not defined from patient perspective

How do we define a health outcome?

"Outcomes are the results people care about most when seeking treatment, including functional improvement and the ability to live normal, productive lives." – ICHOM

We need standardisation so that we can meaningfully and reliably compare the *same* outcomes

Comparing apples with oranges is a lot harder than….

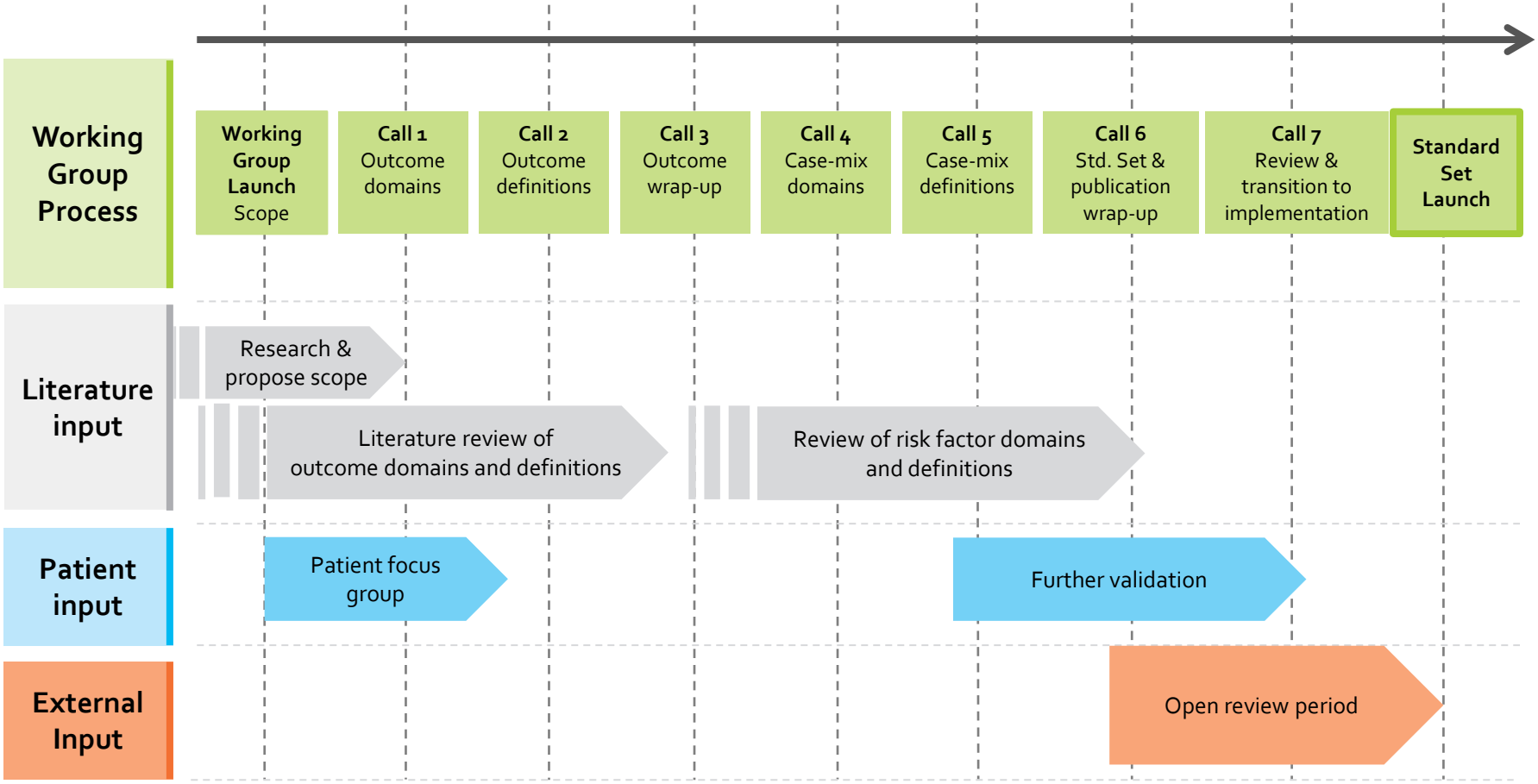
…comparing apples with apples

Measuring different outcomes in different ways makes it impossible to meaningfully compare

Framing principles for ICHOM Standard Sets

1. Outcomes are defined around the medical condition, not the specialty or the procedure
2. The Standard Set is a "minimum set" focused on the outcomes that matter most to patients
3. Patients are directly involved in defining the Standard Set
4. Patient-reported outcomes are included in every Standard Set to capture symptom burden, functional status and health-related quality of life
5. A "minimum set" of initial conditions/risk factors is included to facilitate meaningful Global comparisons
6. Time points and sources of data collection are clearly defined to ensure comparability of results

Each Standard Set is be supported by evidence, patient input and open review



ICHOM have developed 23 Standard Sets, covering 54% of the global burden of disease

We have already developed 23 standard sets

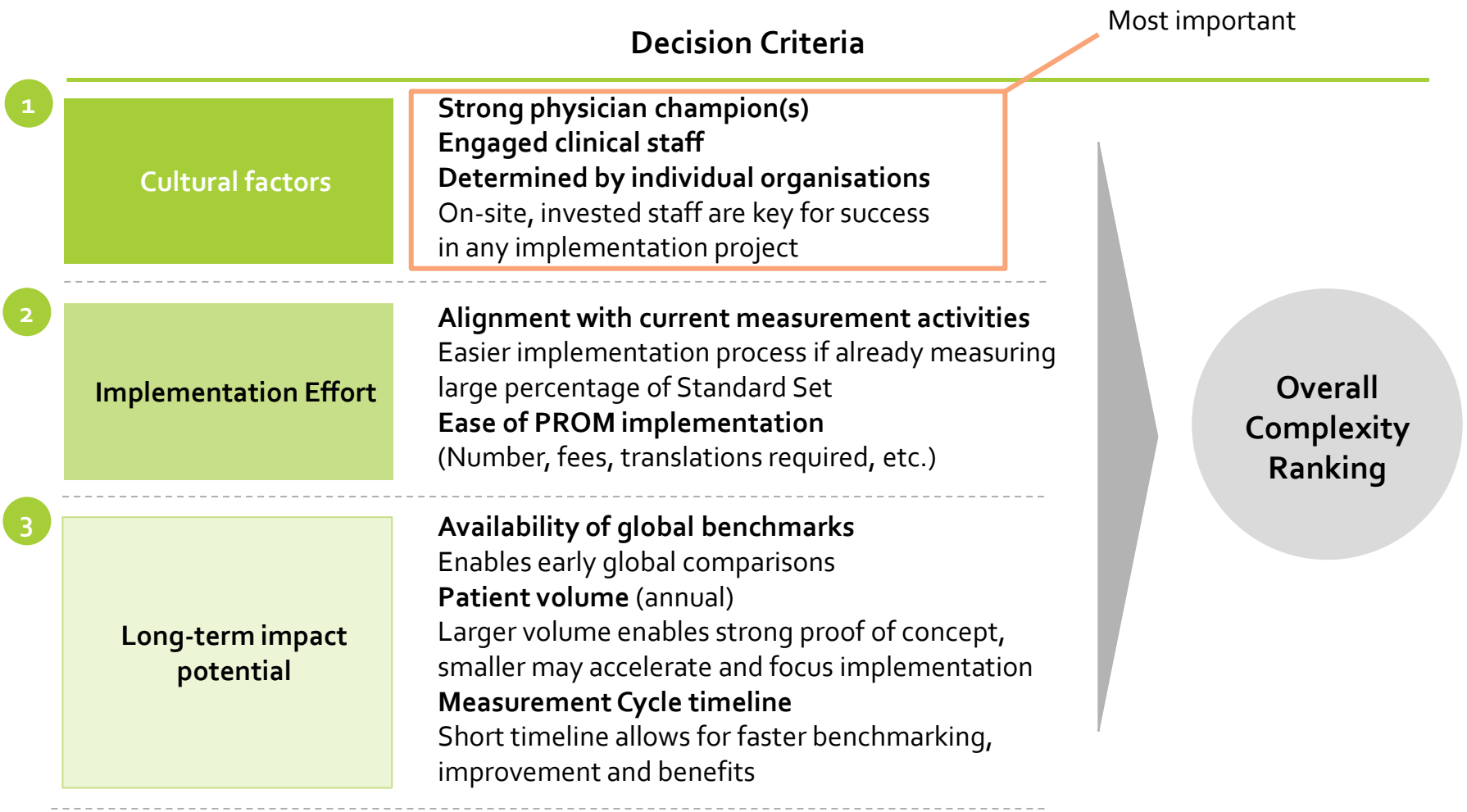
With conditions in progress

1. Adult population health
2. Pediatric overall health
3. Oral health
4. Inflammatory arthritis
5. Diabetes

Numbers not representing prioritization/ likelihood

*Focused on low and middle income countries

The criteria for selecting which Standard Set to implement can be categorised into three domains, and ranked in overall complexity



ICHOM Standard Sets are freely available to promote global adoption

Flyer

- Two-page overview of ICHOM Standard Set and Working Group
- Flyers are available at www.ichom.org

Reference Guide

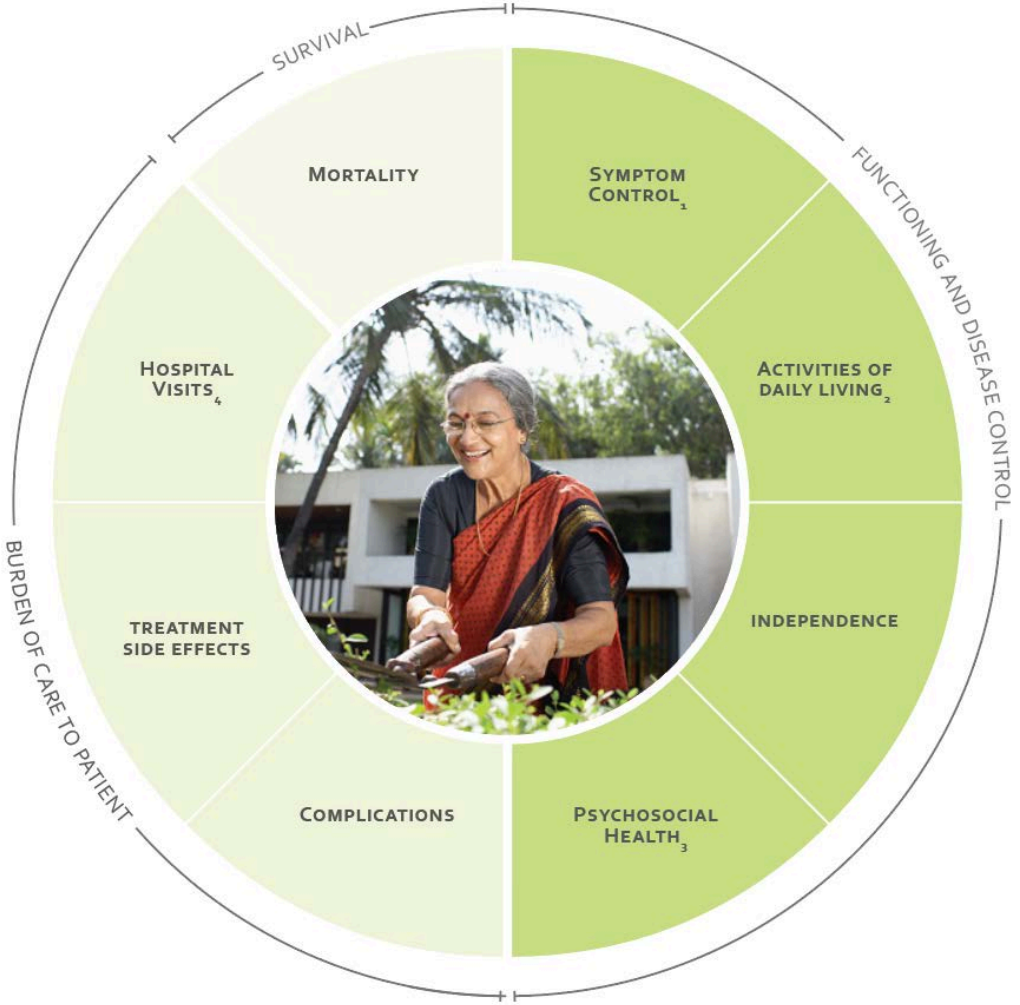
- Full detail of Standard Set for institutions interested in collecting
- Includes measure definitions, coding instructions, and sample questionnaires
- Reference Guides available at www.ichom.org

Academic Publication

- Peer-reviewed publication
- Explains process to arrive at Standard Set and motivation for selected measures
- **Click here** for example

Heart Failure Standard Set

ICHOM Standard Set for Heart Failure: Outcomes



Treatment approaches covered

- Pharmacotherapy
- Invasive therapy
- Rehabilitation

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British Heart Foundation

HEART FAILURE ASSOCIATION OF THE ESC

American Heart Association®
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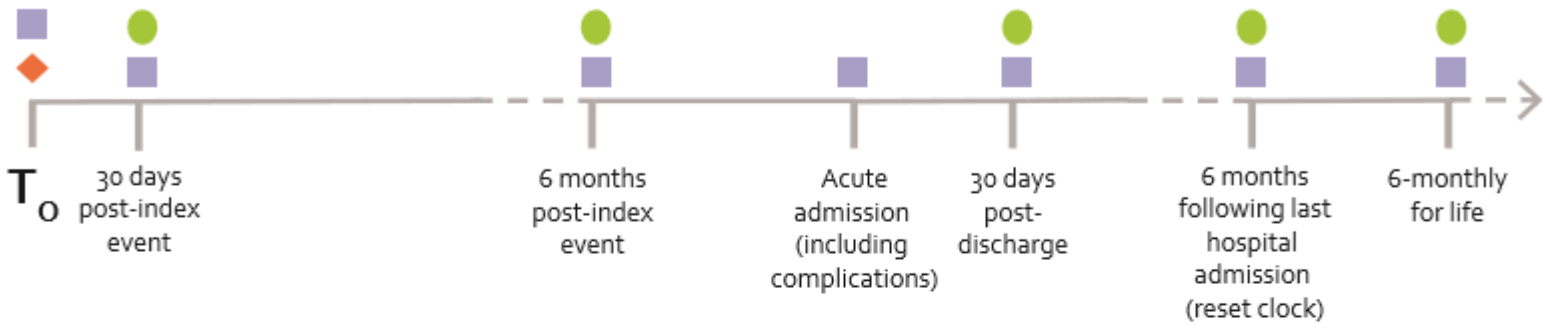
ICHOM Standard Set for Heart Failure: case mix variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Demographic Factors				
All patients	Age	Date of birth	At index event for HF	Administrative data
	Sex	Sex at birth		
	Ethnicity	Note that regulations on reporting ethnicity may differ per country		
Baseline health status				
All patients	Hypertension	Yes/No	At index event for HF	Clinician-reported
	Diabetes			
	Renal dysfunction	Need for dialysis		
	Smoking status (current or in past year)	Yes/No		
	Alcohol use (>1 drink a day)			
	Prior MI			
	Atrial fibrillation			
	Chronic lung disease	Oxygen dependency		
	Body mass index	Height and weight		
	Ejection Fraction	Determined by echocardiogram		
	Diagnostic categories	N/A		

Collecting Patient- and Clinician-Reported Outcome Measures

Heart Failure Survey Used	Licensing Information	Scoring Guide
KCCQ-12 – Kansas City Cardiomyopathy Questionnaire-Short Version	You can obtain a license to use this instrument at your institution by visiting **http://cvoutcomes.org/licenses**	See link on the left
NYHA – New York Heart Association Functional Classification	The NYHA is free for all health care organizations, and a license is not needed.	
PROMIS Physical Function Short Form 4a – Patient-Reported Outcome Measurement Information System	PROMIS Physical Function is free for all health care organizations, and a license is not needed. For more information, please visit **http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures**	See link on the left
Patient Health Questionnaire (PHQ-2)	The PHQ-2 is free for all health care organizations, and a license is not needed.	The scoring guide may be found at **http://www.phqscreeners.com/instructions/instructions.pdf**

The following timeline is proposed to capture the outcome domains for patients with HF



T_0 Index event* for Heart Failure (first clinical encounter since entry to the the Set or new Diagnosis)

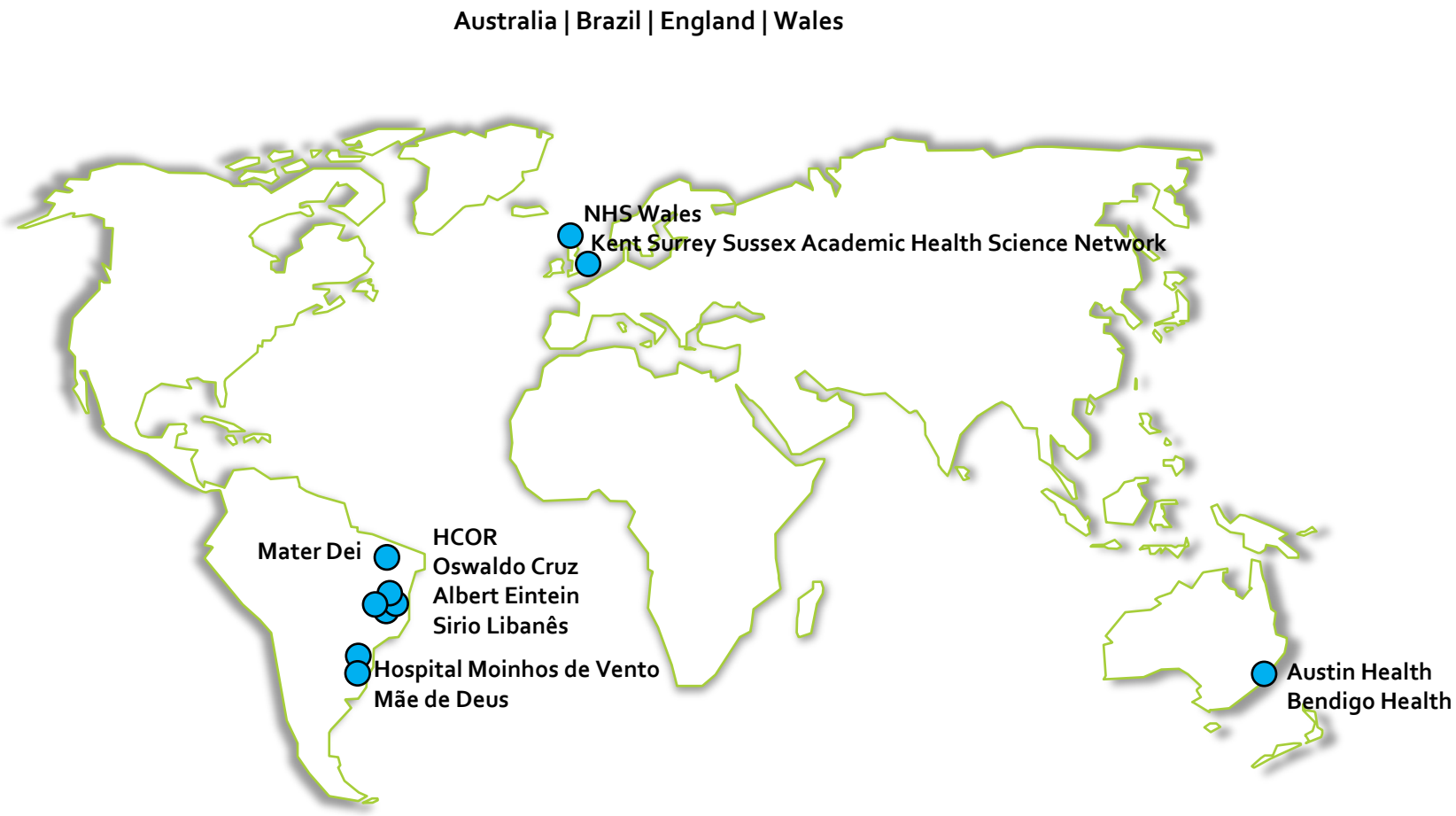
Baseline characteristics **(link)**

PROMs (patient reported outcome measures) **(link)**

Clinician reported outcomes **(link)**

***The index event represents the entry into the set. This could either be after diagnosis/first encounter in an outpatient setting, or at discharge from hospital if the initial presentation was severe enough to require admission.**

The HF Standard Set is now being implemented and/or measured in at least 11 organizations across 4countries



Stroke Standard Set

Our end-product: a Standard Set, with domains that should be systematically measured, and clear definitions

Details

1 Includes mood and global cognitive function
2 Includes pain and fatigue
3 Includes mobility, feeding, ability to return to usual activities, and self care and grooming
4 Includes social participation and ability to communicate
5 Tracked via the PROMIS SF v1.1 Global Health, with additional single item questions for mobility, feeding, self care and grooming, and ability to communicate. The Simplified modified Rankin Scale questionnaire (smRSq) is recommended to be included.

Scope

- Adults only (>18 years)
- Patients who have been hospitalized for an index **ischemic stroke** (IS) or **intracereberal hemorrhage** (ICH)
- Patients with subarachnoid hemorrhage (SAH) are **excluded**
- Inclusion of **transient ischemic attack** (TIA) or patients with IS or ICH who are evaluated but not hospitalized is optional

Treatment Approaches

- IV Thrombolysis, Thrombectomy, Hemicraniectomy

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The full list of risk adjustment variables included in the Stroke Standard Set

Risk Factor/Initial Condition	
Demographics	**Stroke type and severity**
Age	
Sex	
Ethnicity	Stroke type
Living location	Stroke severity
Living alone	Duration of symptoms
Pre-stroke functional status	
Treatment/care related	**Vascular and systemic**
	Prior Stroke
Length of stay	Prior TIA
Diagnostic evidence base	Prior MI
Rehabilitation	Coronary artery disease
Discharge destination	Atrial fibrillation
Comfort care*	Diabetes mellitus
Thrombolytic therapy	Hypertension
Thrombectomy	Hyperlipidemia
Hemicraniectomy	Smoking status
	Alcohol use

Collecting Patient- and Clinician-Reported Outcome Measures

Collecting Patient- and Clinician-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
Patient Reported Outcomes Measurement Information System Short Form version 1.1 Global Health (PROMIS-10) - **Patient/ Proxy**	The PROMIS-10 is free for all health care organizations, and a license is not needed. There are translations available for Spanish, French, German, and Dutch. Translations will soon be available for Portugese and Mandarin. More information may be found at http://www.nihpromis.org/measures/translations	The scoring guide may be found on page 9, as well as at https://www.assessmentcenter.net/documents/Scoring%20PROMIS%20Global%20short%20form.pdf
Simplified Modified Rankin Scale Questionnaire (smRSq) - **Clinician**	There is no patent on thes smRSq or fee for using it in clinical practice; however Lippincott Williams & Wilkins (LWW) own the rights to the published article where the smRSq is introduced. There is a cost of USD700 to use the flow chart diagram from within this article but permission is not needed for the assessment of the questions in patients. The smRSq is also a sub-section of the regular smRSq, which is also without license fee. The smRSq flow chart can be found at http://stroke.ahajournals.org/content/42/8/2276 "Simplified Modified Rankin Scale Questionnaire Reproducibility Over the Telephone and Validation With Quality of Life" Stroke 2011; 42: 2276-2279 © 2011 American Heart Association, Inc. Wolters Kluwer Health	To facilitate the use of the smRSq, instructions are provided in the Appendix on page 11.

The following timeline is proposed to capture the outcome domains for patients with stroke

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

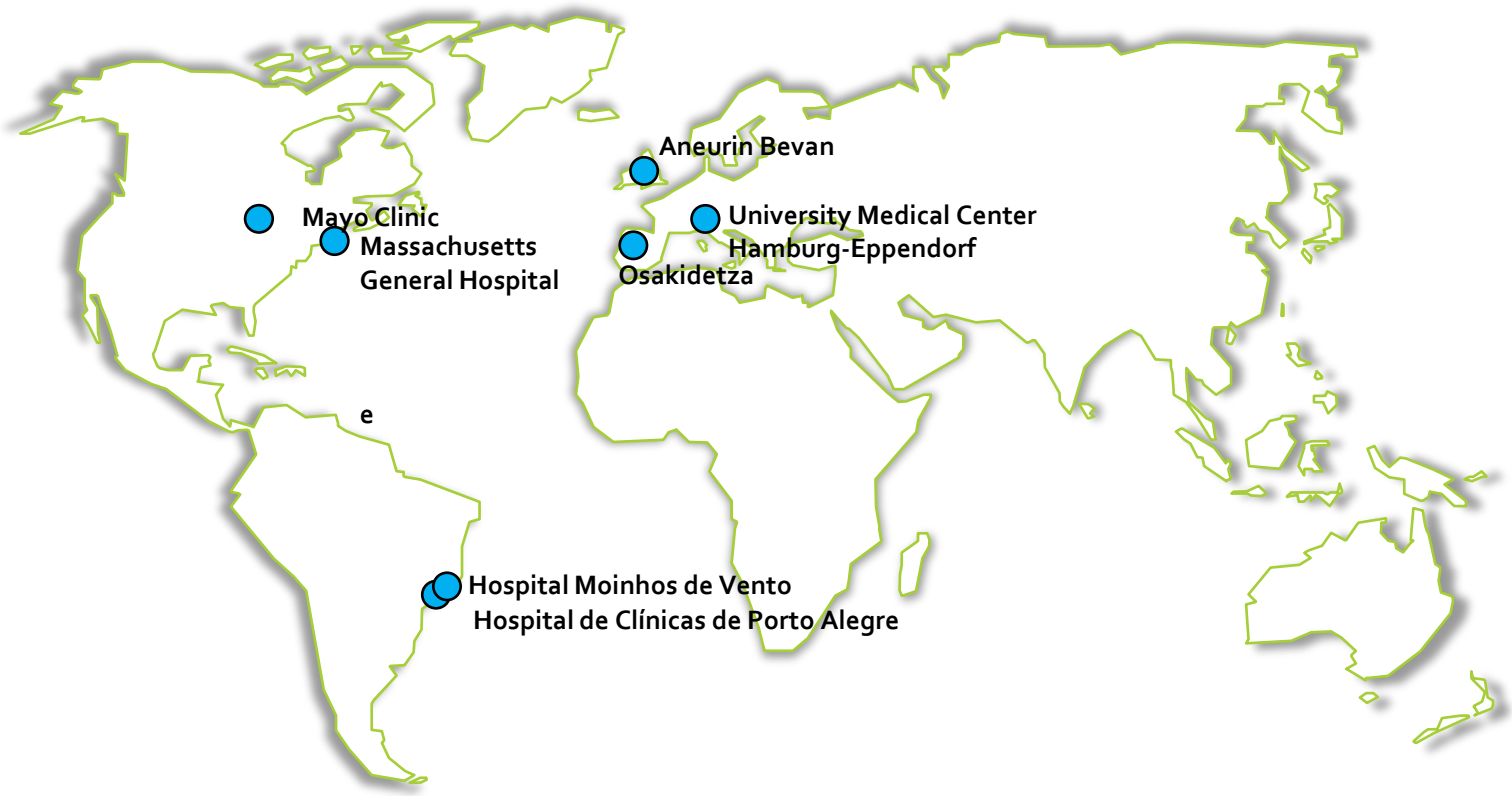
If a second stroke occurs between discharge and the "90 day post index" collection, you should reset the measurement scale, treating them as a new patient.

The following questionnaires should be administered at the indicated time points

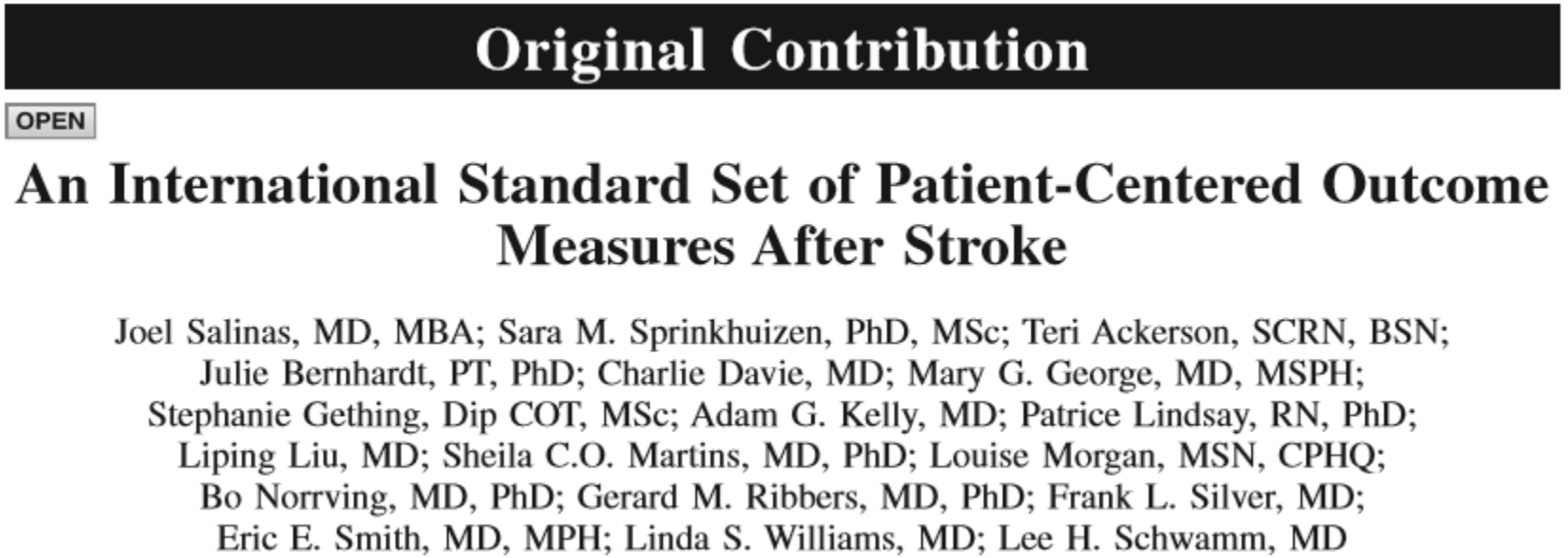
- Survival
- Clinical Form
- Patient-Reported Form
- Administrative Form

The Stroke Standard Set is now being implemented and/or measured in at least 7 organizations across 5 countries

USA | Brazil | Germany | Wales | Spain



The full description of this Standard Set is now in press in AHA Journal



Original Contribution

OPEN

An International Standard Set of Patient-Centered Outcome Measures After Stroke

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Breast Cancer Standard Set

Our end-product: a Standard Set, with domains that should be systematically measured, and clear definitions

Scope

- All patients (men and women) with newly pathologically diagnosed invasive breast cancer (stage I-IV) and ductal carcinoma in situ (DCIS).

Treatment Approaches

- (Reconstructive) Surgery | Radiotherapy | Chemotherapy | Hormonal Therapy | Targeted Therapy |

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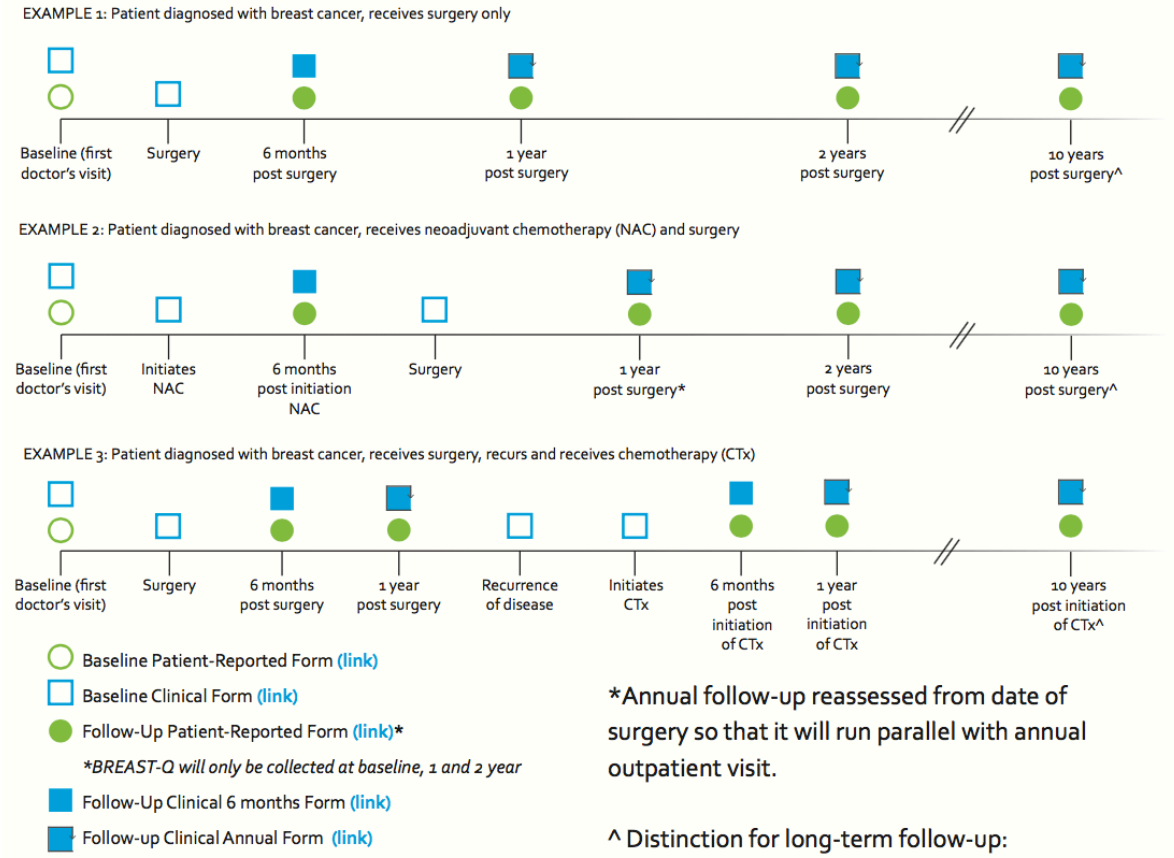
The full list of risk adjustment variables included in the Breast Cancer Standard Set

Risk Factor/Initial Condition	Measure Details
Demographic Factors	
Gender	N/A
Date of birth	
Body mass index	Height and weight
Ethnicity	Determined by country
Educational level	Level of schooling completed
Relationship status	Relationship status
Menopausal status	Current menopausal status
Baseline Clinical Factors	
Comorbidities	Modified Self-administered Comorbidity Questionnaire (SCQ)
Laterality	Laterality of breast cancer
First or new primary tumor	First primary or new primary on contralateral or ipsilateral breast
Baseline Tumor Factors	
Date of diagnosis	Initial date of histological diagnosis
Histological type	Histological type of tumor
Mutation status	Genetic mutation predisposing breast cancer
Tumor grade (invasive)	Grade of invasive component of tumor
Tumor grade (DCIS)	Grade of DCIS component of tumor
Clinical stage	Clinical stage per AJCC 7th
Pathological M stage	Pathological stage per AJCC 7th
Pathological TNM stage	
Size of invasive component of tumor	Size of invasive component of largest tumor (in mm)
Number of lymph nodes resected	N/A
Number of lymph nodes involved	Number of lymph nodes involved according to TNM stage AJCC 7th
Estrogen receptor status	Presence of estrogen receptor status
Progesteron receptor status	Presence of progesteron receptor status
Her-2 receptor status	Presence of Her-2 receptor status

The following timeline is proposed to capture the outcome domains for patients with Breast Cancer



*Annual follow-up reassessed from date of surgery so that it will run parallel with annual outpatient visit.

^ Distinction for long-term follow-up:

- Local disease
  Up to 10 years follow-up
- Metastatic disease:
  Annually for life

Collecting Patient-Reported Outcome Measures

Survey	Licensing and Cost Information	Target Audience	Translations
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)	The EORTC QLQ-C30 is free for all health care organizations, but a license is needed See link at left for use. More information can be found at http://groups.eortc.be/qol/eortc-qlq-c30	Patient	List of translations available at http://groups.eortc.be/qol/
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-BR23)	The EORTC QLQ-BR23 is free for all health care organizations, but a license is needed See link at left for use. More information can be found at http://groups.eortc.be/qol/eortc-qlq-c30	Patient	List of translations available at http://groups.eortc.be/qol/
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-LM21)	Licensing information: The EORTC-LMC21 is free for all health care organizations, but a license is needed for use. For more information, please visit: http://groups. eortc.be/qol/eortc-qlq-c30	Patient	List of translations available at http://groups.eortc.be/qol/
BREAST-Q Patient Reported Outcomes Instrument (BREAST-Q)	Licensing information: The BREAST-Q is free for any not-profit health care organizations, but a user agreement is needed. For any for-profit healthcare organization a license fee has to be paid and a license agreement is required. For more information, please visit: https:// eprovide.mapi-trust.org/instruments/ breast-q#contact_and_conditions_of_ use	Patient	List of translations available at https://eprovide.mapi-trust.org/instruments/breast-q#languages
Functional Assessment of Cancer Therapy Endocrine Subscale (FACT-ES)	Licensing information has not been finalized with developer. Updates will be made to the online Reference Guide.	Patient	Afrikaans, Chinese (Simplified), Chinese (Traditional), Czech, Danish, Dutch, Finnish, Frenc, German, Greek, Hebrew, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Russian, Spanish, Swedish, Tagalog, Thai, Turkish, Ukrainian

More information on this ICHOM Standard Set can be found on www.ichom.org

This has been published with positive comments in the literature

JAMA Oncology | Special Communication

A Standard Set of Value-Based Patient-Centered Outcomes for Breast Cancer

The International Consortium for Health Outcomes Measurement (ICHOM) Initiative

Ong, W.L. et al. 2017. A Standard Set of Value-Based Patient-Centered Outcomes for Breast Cancer: The International Consortium for Health Outcomes Measurement (ICHOM) Initiative. *JAMA Oncology.* [Online]. 3(5), 677-685. [7 November 2017]. Available from: https://www.ncbi.nlm.nih.gov/pubmed/28033439

Q &A