WHITE PAPER

ICHOM International Consortium for Health Outcomes Measurement

WHITE PAPER: A GAP ANALYSIS BETWEEN THE INTERNATIONAL CONSORTIUM FOR HEALTH OUTCOMES MEASUREMENT HEART FAILURE STANDARD SET AND A GLOBAL SELECTION OF REAL-WORLD DATA SOURCES

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White Paper: A Gap Analysis Between The International Consortium For Health Outcomes Measurement Heart Failure Standard Set And A Global Selection Of Real-World Data Sources

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ABOUT THIS REPORT

This report highlights the main findings from a gap analysis conducted to compare the data capture patterns of heart failure real-world data sources across the globe when using the variables recommended by the ICHOM Heart Failure Standard Set. This study is the result of a collaboration between ICHOM, the Mapi, an ICON plc Company and Novartis.

EXECUTIVE SUMMARY

Uncertainty regarding impact of treatments on outcomes, coupled with unsustainable growth in healthcare expenditures, has driven interest in the development of standardised health outcome measures. Global standardisation allows the comparison of treatment effects across different populations and assesses the quality of healthcare, both essential strategies towards transitioning to value-based healthcare.

The International Consortium for Health Outcomes Measurement (ICHOM) is a non-profit organisation dedicated to transforming healthcare systems worldwide by enabling the measurement and reporting of patient outcomes in a standardised way. To this end, ICHOM works with leading physicians, outcomes researchers, and patient advocates from around the world to define the minimum standard sets of outcomes per medical condition that matter most to patients. Together with associated risk factors and defined time points for their measurement, these outcomes constitute an **ICHOM Standard Set**.

In 2016, ICHOM released a patient-centred Standard Set for monitoring, comparing, and improving the outcomes of care for patients with heart failure (HF). It is ICHOM's belief that the standardized outcomes measurement will open up new opportunities to compare performance of healthcare systems globally, allowing clinicians to share knowledge, and rapidly improve the care provided to patients.

To understand to what extent the diagnosis and monitoring of HF in the real world differs from the ICHOM Standard Set, a gap analysis was performed between the ICHOM HF Standard Set and a selection of HF real-world data sources worldwide. This work was the result of a collaboration between ICHOM, the Mapi, an ICON plc Company, and Novartis.

To perform the gap analysis the following methodology was applied:

1. Identification and selection of data sources or studies via a systematic search
2. Development of a Data Abstraction Tool (DAT) to systematically collect data from the identified data sources
3. Literature search complemented with communication with data source holders to fill in the DAT form
4. Execution of the "Gap Analysis": estimation of alignment between the ICHOM HF Standard Set and the selected data sources

The gap analysis revealed how differently the care domains constituting the ICHOM HF Standard Set are covered amongst the geographical region analysed. Overall, data captured in data sources from North America and Europe more closely resembled the ICHOM HF Standard Set, whereas the ones from Africa deviated the most. When considering psychosocial and burden of care variables, major gaps were observed in all the regions analysed. Patient demographics, resource use and mortality variables were consistently captured across all regions.

Generating meaningful information on patient outcomes is essential for Health Systems to ensure continuous system improvements. To this end, all relevant stakeholders in the cycle of care need to reach a consensus on which interventions drive the best possible outcomes for HF patients, and what those best outcomes are. Our overarching goal in sharing this gap analysis with leading patient representatives, healthcare professionals, data holders, and policymakers is threefold: 1) to raise awareness of specific care domains that are being inadequately captured across data sources; 2) to foster a dialogue between the key stakeholders involved in the full cycle of care with regards to a consensus metric to be implemented in the management of HF and 3) to provide practical recommendations to aid local data holders with the implementation of the HF Standard Set, which ultimately will lead to an improvement of Health Systems.

INTRODUCTION

The ICHOM Heart Failure Standard Set and its role in the transition to value-based healthcare

HF is a serious medical condition which has a profound impact on patient survival and patient health-related quality of life (HRQoL). It is estimated that HF affects 40 million people worldwide.[1] With the continuous increase of the elderly population, the prevalence of this condition and its associated costs and burden are expected to rise exponentially over the next decade.[2] In a world with limited resources, there is a need to transform healthcare systems incorporating patient-centred practices and ultimately offer true value to patients and their caregivers.[3]

Patient trust in healthcare systems is based on the assumption that the patient's best interests are being considered during the decision-making process. However, although patient-centred care is becoming a widely-used concept in the medical setting, it is still poorly understood and often neglected.[4] Patient-centred care implies that the patient's values, needs and preferences should guide the clinical decision and the patient's desire for information should be respected.[5, 6]

$$\text{VALUE} = \frac{\text{PATIENT HEALTH OUTCOMES ACHIEVED}}{\text{COST OF DELIVERING THOSE OUTCOMES}}$$

At ICHOM, we believe that patients are the only ones who can genuinely identify, from their own personal perspective, which health outcomes are essential, and evaluate if these are being achieved. After all, patients are the ones living with the condition and experiencing its impact in every aspect of their lives "twenty-four seven".

In 2016, the ICHOM HF Standard Set was released as the result of an international collaborative effort from a working group that included: clinician leaders, researchers, and patient representatives across the globe. It received support from the American Heart Association, the British Heart Foundation, the Heart Failure Association of the European Society of Cardiology and the Bwrdd Lechyd Aneurin Bevan Health Board (**Appendix 1**).[7]

In alignment with other ICHOM Standard Sets, the HF Standard Set outlines the minimum set of variables, providing the metric to measure if outcomes that matter most to HF patients are being achieved. The ICHOM HF Standard Set was defined with an innovative approach that is both comprehensive and pragmatic, allowing providers to track patient outcomes within routine clinical practice, ultimately enabling global standardization that should catalyse a new wave of innovative learning rooted in a patient-centred approach. Feedback from patients, healthcare professionals and data holders about their experience with the implementation of the ICHOM HF Standard Set will contribute to potential refinements of the Standard Set itself.

The ICHOM HF Standard Set includes four main domains of outcomes: functional, psychosocial, burden of care to patients, and survival. In addition, by including case-mix variables (risk factors that have been shown to affect the prognosis of HF patients) the patient baseline characteristics are properly recorded and may be used as stratification factors in putative global comparisons (**Table 1 and 2**).

TABLE 1 | HEART FAILURE STANDARD SET BASELINE CHARACTERISTICS AND CASE-MIX VARIABLES

Category	Variable	Data source
Demographic factors	Age	Patient-reported
	Sex	
	Ethnicity	Clinician-reported
Baseline health status	Atrial fibrilation	Patient/Clinician-reported
	Prior MI	Clinician-reported
	Smoking	Patient/Clinician-reported
	Alcohol use	
	Hypertension	Clinician-reported
	Height & weight (BMI)	Patient/Clinician-reported
	Diabetes	
	Chronic lung disease	
	Renal dysfunction	Clinician-reported
	Ejection fraction	
	Diagnostic categories	
Burden of care to patients	Medications initiated	Clinician-reported
	Device procedure type	
	Cardiac surgery procedure type	
	Cardiac rehabilitation	

TABLE 2 | HEART FAILURE STANDARD SET OUTCOMES

Outcome category	Outcome domain	Tool
Functional	Maximum level of physical exertion	KCCQ-12 and NYHA
	Symptom control (SOB)	
	Symptom control (Fatigue and Tiredness)	
	Living independently and self-care	KCCQ-12 and PROMIS Physical Function
	Employment	KCCQ-12
	Peripheral oedema	
	Symptom control (disturbed sleep)	
Psychosocial	Health-related Quality of Life	KCCQ-12
	Depression & anxiety	PHQ-2
	Confidence & self-esteem	KCCQ-12
Burden of care to patients	Medication side effects	Clinician-reported
	Financial burden	Patient-reported
	Complications of treatment	Administrative data
	Number of hospital appointments	
	Number of hospital readmissions	
	Length of hospital stay	
Survival	Mortality	Administrative data

KCCQ-12 - Kansas City Cardiomyopathy Questionnaire short version **NYHA** - New York Heart Association Functional Classification
PHQ-2 - Patient Health Questionnaire

ICHOM is focused on the holistic care of the patient. Rather than restricting its recommendations to listing validated variables to be recorded, the ICHOM HF Standard Set defines the time points when these outcomes should be captured to ensure that results are tracked during a complete cycle of care and that a reliable monitoring of HF patients is achieved.

A standardised data collection identifies the unmet clinical needs in order to shape public policy and guide research. Providers implementing the ICHOM Standard Sets, report that transparency in reporting improved performance and collaborative learning is a major step in their core strategy towards continued improvement and value in healthcare.[8-10]

Recognising the relevance of an international community to accelerate the transition to value-based healthcare globally, ICHOM has recently launched a prospective, observational pilot benchmarking programme, with the goal to compare standardised outcomes between international partners and enable the identification of more effective treatment strategies.[11] In the future, this model could allow providers using the ICHOM HF Standard Set to benchmark the results they are achieving for HF patients.

The ultimate goal of data within ICHOM's patient-centred framework will be to serve and be of use to HF patients and patient caregivers, helping them to make the best- informed decisions with regards to their health. For instance, patients could track their own health outcomes and select the provider that offers them the most value.

FIGURE 1 | GAP ANALYSIS METHODOLOGY

1

Identification and selection of data sources

- Literature review and identification of HF real-world data sources for data abstraction
- A total of 286 unique data sources were selected for data abstraction (out of 1,030 identified sources)

2

Development of the DAT and communication with data source holders

- The DAT was developed in Excel for the systematic collection of information about each of the selected data sources
- To complement the data abstraction, data source holders were surveyed via email

3

Matching exercise and categorization of results

- There was an attempt to match each ICHOM HF Standard Set variable with a corresponding variable in the selected data sources. Three outcomes were possible:
    - Positive match: if the selected data source included the ICHOM HF Standard Set variable
    - Negative match: if the selected data source did not include the ICHOM HF Standard Set variable
    - Unknown match: if it was unclear whether the selected data source included or excluded the ICHOM HF Standard Set variable
- For each data source, the alignment between the ICHOM HF Standard Set and the selected data sources was quantified by dividing the number of positive matches by the sum of positive and negative matches. For the sake of simplification, unknown matches were excluded from the analysis. Results were then categorized into the following strata:
    - 'Minor' gap: ≥66% alignment
    - 'Medium' gap: 34-65% alignment
    - 'Major' gap: ≤33% alignment

MEASURING THE GAP

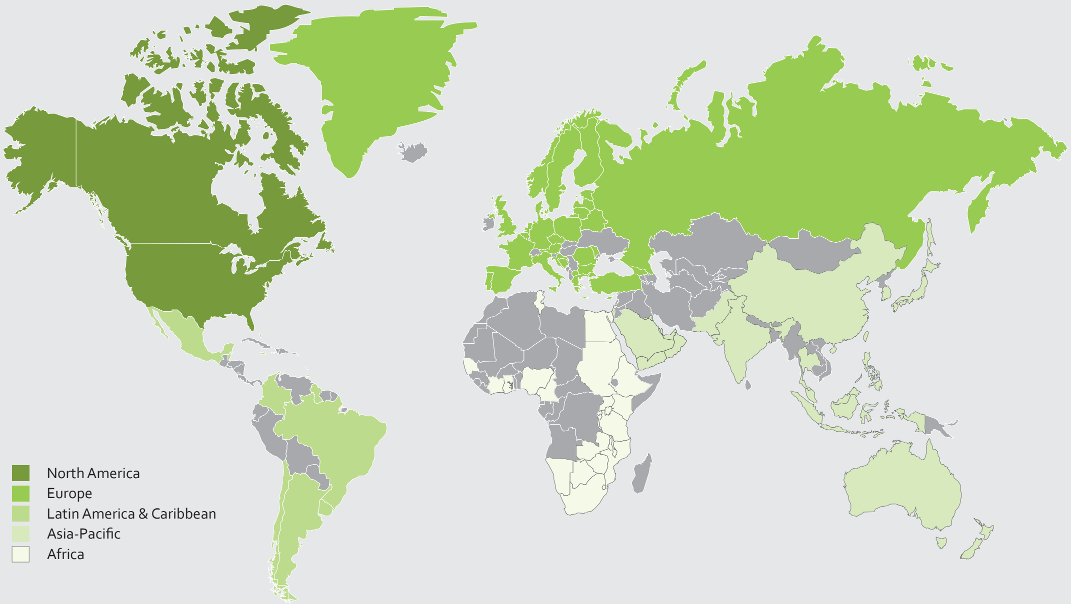
Recognising the core role that patient information, which is included in real-world data sources, plays in contributing to a global standardisation of outcomes measures, it is essential to identify existing challenges in data availability that could prevent a transition to a value-based healthcare model.

In order to quantify the alignment between the variables included in the ICHOM HF Standard Set and the parameters captured by HF real-word data sources, a multistep approach was implemented (see **Figure 1**). The first step in this process was to identify existing HF real-world data sources across the globe. Note that the aim was to achieve a broad geographical coverage, rather than a comprehensive list of all existing data sources. The countries where HF data sources were identified are depicted in **Figure 2**. Although we collected information at the data source- and country-level, the results presented in the next section are aggregated into world regions (See **Figure 2** and **Appendix 2**).

Types of Real-World Data Sources considered for the Gap Analysis:

We considered any type of real-world data, including data generated from non-interventional studies, disease registries, patient surveys, electronic medical and health records and administrative claims. Interventional studies were considered out of scope.

FIGURE 2 | COUNTRIES INCLUDED IN THE GAP ANALYSIS



Data sources from countries highlighted in green were included in the gap analysis

MAIN RESULTS

CASE-MIX VARIABLES

Demographic variables

Recording baseline demographic variables is essential to describe the patient population and improve the interpretability of comparisons.[12]

Results from this gap analysis have demonstrated that the majority of the data sources screened have the patient demographic characteristics available, with the exception of "ethnicity" for which medium gaps were identified for the European, Latin-American and Asia-Pacific regions (see **Table 3**). Similar to other parameters captured in the ICHOM HF Standard Set, "ethnicity" is an important factor to consider when assessing a patient's risk. Nonetheless, several factors could contribute to the absence of reporting ethnicity, such as the ambiguity of the term and regulations of specific countries.[13]

TABLE 3 | GAP ANALYSIS FOR DEMOGRAPHIC VARIABLES BY REGION

ICHOM STANDARD SET VARIABLE	ALIGNMENT BETWEEN ICHOM & DATA SOURCES (%)					
	GLOBAL* (N=286)	North America (N=71)	Europe (N=113)	Latin America (N=12)	Asia-Pacific (N=69)	Africa (N=7)
Age	100	100	100	90	100	100
Sex	100	100	100	100	100	100
Ethnicity	71	98	45	50	61	100

Colour of each cell indicates the percentage of data sources having the ICHOM-recommended variable (Red: ≤33%, Yellow: 34-65%, Green: ≥66%)
*Global includes data sources with multi-country data

Baseline health status

The baseline health status listed in the ICHOM HF Standard Set (**Table 4**), represents key clinical characteristics for both the diagnosis and the monitoring of HF, and represents risk factors that have been shown to help predict outcomes.[14, 15] Thus, it is recommended that the baseline health status variables be recorded for all patients with HF.

Results of the gap analysis showed that the availability of baseline health status variables varied across the world (see **Table 4**). From a global perspective, only minor gaps were identified for hypertension, diabetes, smoking status, obesity, diagnostic measures and ejection fraction. However, obesity was not available in any of the seven data sources identified in Africa. Regional variations with medium gaps were identified in Africa for hypertension and medium and major gaps for obesity in Latin-America and Africa, respectively (**Table 4**). Atrial fibrillation was modestly available across the regions (**Table 4**). It is reassuring to observe that hypertension is thoroughly available globally, since it is considered one of the leading causes of HF and, it should be taken into consideration for the choice of therapy. Obesity has been shown to be an independent risk factor for the development of HF,[16, 17] thus, monitoring this variable is crucial to promoting regional strategies that may reduce the HF population burden.[18]

Significant variation was observed across the regions for the remaining case-mix variables, including major, medium and minor gaps for acute renal failure, alcohol use, prior myocardial infraction (MI), atrial fibrillation and chronic lung disease (**Table 4**). These are important and frequent risk factors that can accelerate HF progression and, have been associated with increased morbidity and mortality.[16, 18, 19]

The majority of the data sources mapped had the ejection fraction variable available, which is not always the case in real-world studies.[20, 21] This finding reveals one of the limitations of this analysis which identifies the availability of variables rather than if they are being recorded in a systematic manner. Variables included in case report forms (CRF) may not be systematically recorded for the majority of the patients. Moreover, the prior MI variable was derived from the concomitant conditions section, thus, there is the possibility that prior MI may be available in the data sources screened, however, under a different definition and thus it was not captured.

The gaps identified could be the result of multiple factors; for instance, reporting of "alcohol use" may be restricted by local laws and regulations that may ban alcohol consumption in certain regions. Other limiting factors may reside in the need to perform additional costly tests (e.g. electrocardiogram, cardiac enzymes, spirometry, etc.), wherein availability may be limited in low and middle-income countries. Lastly, absence of proper linkage between neighbouring health systems may also prevent access to available information.

TABLE 4 | GAP ANALYSIS FOR BASELINE HEALTH STATUS VARIABLES BY REGION

ICHOM STANDARD SET VARIABLE	**ALIGNMENT BETWEEN ICHOM & DATA SOURCES (%)**					
	GLOBAL* (N=286)	North America (N=71)	Europe (N=113)	Latin America (N=12)	Asia-Pacific (N=69)	Africa (N=7)
Hypertension	79	74	73	89	90	60
Diabetes	91	94	89	100	90	100
Acute Renal Failure	41	22	47	56	43	20
Smoking Status	96	100	85	100	100	0
Alcohol Use	65	86	63	88	38	0
Prior MI	39	42	41	78	29	20
Atrial Fibrilation	42	33	42	67	43	40
Chronic Lung Disease	41	31	46	67	35	20
Obesity (BMI)	89	98	81	57	91	0
Preserved/Reduced Ejection Fraction	93	97	89	100	95	100
Diagnostic Measures	95	97	93	91	97	100

Colour of each cell indicates the percentage of data sources having the ICHOM-recommended variable (Red: ≤33%, Yellow: 34-65%, Green: ≥66%)
*Global includes data sources with multi-country data

TREATMENT VARIABLES

The ICHOM HF Standard Set treatment variables identify the treatment pathways that are providing true value to patients. Only minor gaps were found for "medications initiated" across all regions (**Table 5**). Of note, the ICHOM HF Standard Set recommends presenting this variable as a free-text entry given the heterogeneity existing in the number of pharmacotherapies available in each country.

Regarding "cardiac surgery" or "device procedure type" variables, these were available in the majority of the data sources mapped across North America, Europe and Asia-Pacific regions, however, medium and major gaps were identified in Latin America and Africa, respectively (**Table 5**). Although treatments such as, coronary revascularisation or the employment of devices to treat arrhythmias can be life-saving, the required infrastructures and investment to implement them may be limited or non-existent in low and middle-income countries/regions.[22]

Medium or major gaps were found for the "cardiac rehabilitation" variable in all geographical regions (**Table 5**). Cardiac rehabilitation programmes are not necessarily available to patients in the same facility, if at all, thus, due to limitations of data linkage, this could lead to tracking challenges for this variable.

TABLE 5 | GAP ANALYSIS FOR TREATMENT VARIABLES BY REGION

ICHOM STANDARD SET VARIABLE	ALIGNMENT BETWEEN ICHOM & DATA SOURCES (%)					
	GLOBAL* (N=286)	North America (N=71)	Europe (N=113)	Latin America (N=12)	Asia-Pacific (N=69)	Africa (N=7)
Medications Initiated	95	97	93	91	97	100
Device Procedure Type	85	89	84	71	85	0
Cardiac Surgery Type	89	97	87	57	94	0
Cardiac Rehabilitation	21	40	13	33	27	0

Colour of each cell indicates the percentage of data sources having the ICHOM-recommended variable (Red: ≤33%, Yellow: 34-65%, Green: ≥66%)
*Global includes data sources with multi-country data

OUTCOMES

FUNCTIONAL AND PSYCHOSOCIAL OUTCOMES: PATIENT-REPORTED OUTCOMES

Patient-Reported Outcomes Measures (PROMs) are paramount to the establishment of value-based healthcare. PROMs provide a standardised and scientifically-validated way to measure patient perception of their own functionality and wellbeing. PROMs promote synergy between patients and the healthcare team by empowering patients, increasing patient understanding of their condition and allowing them to monitor their progress over time.[23, 24]

The three validated PROMs, included in the ICHOM HF Standard Set, aim to track functional and psychosocial outcomes that are most meaningful to patients. The Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) includes the following domains: physical limitations, symptom frequency, severity, and change over time, self-efficacy and knowledge, social interference, and HRQoL. Of note, a KCCQ-12 score correlates with the survival and hospitalisation of patients with HF.25 The Patient-Reported Outcomes Measurement Information System (PROMIS) generates information with regards to the patient's physical function. Finally, the Patient Health Questionnaire-2 (PHQ-2) enquires about the frequency of depressed mood and anhedonia over the past two weeks.

MIND THE GAP

PROMs were amongst the variables least available in the HF data sources mapped across the world, with a coverage ranging from 20% to 2%, depending on the instrument considered. This gap is critical considering that the ultimate goal of healthcare systems should be to deliver care that brings most value to patients.

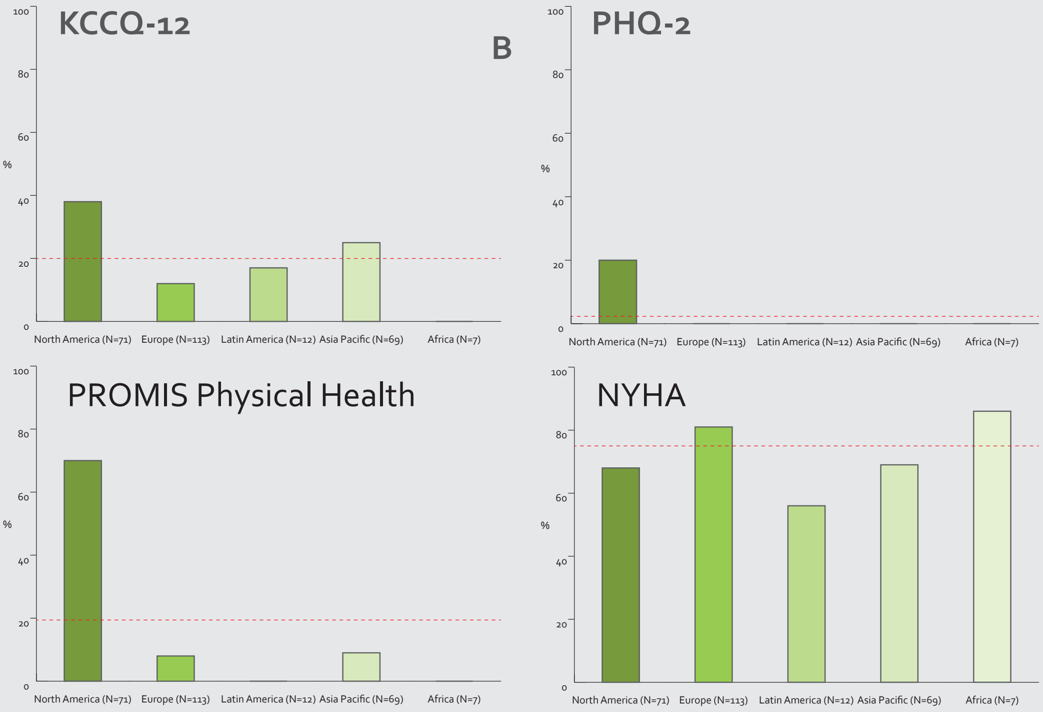
Despite the relevance of recording PROMs in a patient-centred health system, we found that the majority of the data sources mapped did not record PROMs (**Table 6**). Major gaps were found in the measurement of KCCQ-12, PHQ-2 and PROMIS with merely 20%, 4% and 19% global coverage overall, respectively (**Figure 3**). North America was the only region where HF data sources had PROMIS available (70%), however, the results were not encouraging for KCCQ-12 and PHQ, with 38% and 20% coverage, respectively (**Table 6** and **Figure 3**).

TABLE 6 | GAP ANALYSIS FOR FUNCTIONAL AND PSYCHOSOCIAL OUTCOMES VARIABLES BY REGION

ICHOM STANDARD SET OUTCOME	ALIGNMENT BETWEEN ICHOM & DATA SOURCES (%)					
	GLOBAL* (N=286)	North America (N=71)	Europe (N=113)	Latin America (N=12)	Asia-Pacific (N=69)	Africa (N=7)
NYHA	🟩 74	🟩 68	🟩 81	🟨 56	🟩 69	🟩 86
KCCQ-12	🟥 20	🟨 38	🟥 12	🟥 17	🟥 25	🟥 0
PHQ-2	🟥 4	🟥 20	🟥 4	🟥 0	🟥 0	🟥 0
PROMIS Physical Health	🟥 19	🟩 70	🟥 8	🟥 0	🟥 9	🟥 0

Colour of each cell indicates the percentage of data sources having the ICHOM-recommended variable (Red: ≤33%, Yellow: 34-65%, Green: ≥66%)
*Global includes data sources with multi-country data

FIGURE 3 | GAP ANALYSIS FOR FUNCTIONAL AND PSYCHOSOCIAL OUTCOMES VARIABLES BY REGION



Red line represents the average gap across the included data sources (n=286)
KCCQ-12 (Average gap = 20%); PHQ-2 (Average gap = 20%); PROMIS Physical Health (Average gap = 19%);
NYHA (Average gap = 75%)

There could be many reasons for the low collection of PROMs in the mapped HF data sources. The time required, limited resources or the lack of optimisation may represent important hurdles. For instance, even if PROMs can be self-administered, their implementation requires additional time from staff to explain to patients how to fill out the form. Systems without electronic records, or other methods to promote patient input, can find the initial adoption of PROMs during routine clinical practice challenging. Lack of local translation versions of PROMs can be a hurdle as well.

It is important to note that utilisation of the KCCQ instrument requires a paid license, thus, costs and logistics associated with it may represent an additional obstacle. The ICHOM HF Standard Set provides licensing information for the recommended PROMS instruments.

Finally, the lack of awareness regarding the significance of PROMS to assess the effectiveness of healthcare interventions from the patient's perspective, as well as the lack of familiarisation with the tool and how it can it be implemented during routine clinical practice, can also contribute to these gaps. For centuries clinicians have been at the centre of healthcare. The lack of information and training for healthcare professionals and patients/carers regarding the benefit of a significant patient participation, is a global barrier that needs to be overcome.

In addition to PROMs, the ICHOM HF Standard Set also recommends tracking the severity of HF using the New York Heart Association (NYHA) classification. NYHA focuses on the patient's exercise capacity and the symptomatic status of the disease. Only minor gaps were seen across the world, with the exception of Latin America, where approximately half of the data sources did not record the NYHA classification (**Table 6 and Figure 3**).

BURDEN OF CARE FOR PATIENTS AND SURVIVAL

The "burden of care" variables listed in the ICHOM HF Standard Set aim at providing a holistic measure of the HF impact on patients, as well as information on resource use. These include medication side effects and complications to hospitalisation data and financial burden.

The timely and accurate detection and reporting of adverse events or medication side effects is crucial for the clinician so he can have the opportunity to swiftly address the cause of their patient's concern, resulting in an overall improvement in the patient's care. In addition, it may allow the identification of trends that ultimately lead to a better understanding of treatment efficacy and safety profile in the real world.[26] It is alarming to observe that the majority of the data sources mapped had no availability of "medication side effects" and "complications of treatments"(31% and 33% overall, respectively) (**Table 7**).

Resource utilization data such as, the average length of stay in hospitals, is often used as an indicator of system efficiency.[27] Overall, a shorter hospital stay will reduce the cost per discharge and allow a redistribution of resources within the health system. However, it is important to highlight that these variables need to be linked to health outcomes achieved by patients, in order to truly enable health systems to become more efficient as they transition into value-based healthcare.

TABLE 7 | GAP ANALYSIS FOR BURDEN OF CARE

ICHOM STANDARD SET OUTCOME	ALIGNMENT BETWEEN ICHOM & DATA SOURCES (%)					
	GLOBAL* (N=286)	North America (N=71)	Europe (N=113)	Latin America (N=12)	Asia-Pacific (N=69)	Africa (N=7)
Medication Side Effects	31	20	42	17	27	0
Financial Burden	17	40	21	0	9	0
Complications of Treatment	33	20	33	50	36	0
Number of Hospital Appointments	59	77	61	44	38	100
Number of Hospital Readmissions	91	96	90	80	91	100
Length of Hospital Stay	86	94	86	56	87	100
Mortality	94	97	94	75	98	100

Colour of each cell indicates the percentage of data sources having the ICHOM-recommended variable (Red: ≤33%, Yellow: 34-65%, Green: ≥66%)
*Global includes data sources with multi-country data

The “number of hospital readmissions” and “mortality” were broadly available across all regions, whereas medium gaps were identified for the “number of hospital appointments” across Europe, Asia-Pacific and Latin-America and “length of hospital stay” in Latin America (**Table 7**).

The economic impact of cardiovascular diseases on HF patients is well recognised, due to increased health spending and high out-of-pocket expenditure. However, there were major gaps in the measurement of “financial burden” for patients in all regions, with the exception of North America where medium gaps were identified among the data sources screened (**Table 7**).

How can healthcare systems close the gap?

The present analysis quantified the alignment between the variables included in the ICHOM HF Standard Set and those available in HF real-word data sources. These results revealed the existence of prominent gaps for certain variables in the ICHOM HF Standard Set, with significant geographical variations.

Possible reasons why some variables are seldom available may include: lack of awareness of the importance of key variables, and lack of resources (whether human, infrastructure, capital and/or time) to enable the collection of key parameters.

The ICHOM HF Standard Set includes patient, clinician and administrative-reported data. Depending on what data is already being locally collected during the process of care, the full implementation of the ICHOM HF Standard Set may range between marginal changes in data capture to a completely new process. The following sections provide a series of practical recommendations to aid local data holders with the implementation of the HF Standard Set, building on ICHOM’s experience on implementing other Standard Sets.

1. Set realistic goals based on your familiarity with the HF Standard Set and on existing resources

The first step in the implementation of the ICHOM HF Standard Set should be to perform a local gap analysis to identify where gaps exist. To this aim, we recommend making use of the DAT that the Mapi, an ICON plc Company, developed for this global-scale gap analysis. This includes all the data sources selected for the current gap analysis and it may be used by local data holders to identify and compare local gaps with regional or global reporting patterns. The tool can be found on the ICHOM webpage (www.ichom.org) and is available free of charge.

Once local gaps have been identified, the next step would be to assess which resources may already be directly or indirectly used to enable data capture. A process map is crucial to understanding how data is available, to identifying existing or potential obstacles, and to developing corrective actions. It is important to consider the totality of existing data sources and the perspectives of multiple stakeholders, e.g. clinicians, nurses, administrative staff, and patients.

2. Use PDSA cycles

The Plan, Do, Study, Act (PDSA) cycles are a tried and tested method that helps teams develop a plan for their chosen intervention, test it on a small scale (do), observe and learn from the pilot (study) ensuring a successful implementation of the change (act).28 This can be applicable to real-world data collection. A short and small pilot can provide useful information to ensure all the elements for adequate data collection are in place, before full implementation.

3. Create partnerships

A critical success factor for the proper implementation of the ICHOM HF Standard Set in routine clinical practice is to engage all stakeholders involved in the full cycle of care. Patients should take centre stage, followed by healthcare professionals, data holders and communities in general.

a. Patients and Patient Advocates

The creation of partnerships between patients, care teams and data holders can be of great benefit to all parties. For instance, patient advocates can help other patients by explaining how to complete PROMs – this will likely reduce the burden on healthcare professionals and improve data quality. Furthermore, patient advocates can support the training of healthcare professionals on data capture by providing their personal perspective and feedback about the process.

b. Health Care Professionals

Engage healthcare professionals, doctors and nurses by beginning to highlight the overall benefits in establishing the ICHOM HF Standard Set. Train staff and participants as necessary, and create a sense of ownership so everyone feels committed to a common goal.

c. Data holders and communities

Community involvement can be of great value. Electronic medical records can be helpful in linking data across local healthcare providers and data holders, allowing for optimization of local resources and contributing to an overall patient-centred care engagement by the healthcare community.29By sharing data and insights, providers and data holders can learn from each other, motivate participants and facilitate changes for the implementation of the ICHOM HF Standard Set.

4. Leverage technology when possible

The use of locally available technology into routine clinical practice can be a great help in reducing the gaps identified between the real-world data sources and the ICHOM HF Standard Set, especially for the collection of PROMs data.

PROMs are typically collected with pen and paper. However, physical questionnaires are impractical for frequent data collection points. The inclusion of PROMs in electronic records can help reduce the burden of collecting and processing data. By using technology such as, mobile phone messaging applications, for example, Short Message Service (SMS), Multimedia Message Service (MMS) or online platforms that are suitable for frequent data collection, patients can complete PROMs in advance of their clinical appointment, optimising patient and clinician time.[30, 31]

TAKE AWAY MESSAGE

Global healthcare systems are shifting to a value-based model with the patient playing a central role in the process. The ICHOM HF Standard Set provides a patient-centred framework for the measurement of outcomes that matter most to patients with HF. It lifts the burden on data sources from going through a complex process of agreeing on what to measure, how, and when, by providing a simple list of meaningful variables with recommended data capture time points. The worldwide implementation of the ICHOM HF Standard Set by providers and data holders is a crucial first step to the establishment of a true value-based healthcare system.

This gap analysis was the first effort to quantify the alignment between the variables included in an ICHOM Standard Set and those available in real-word data sources across the globe. The results emphasize an extra effort is required to align HF real-world data sources to the ICHOM HF Standard Set for clinical and patient-reported variables, with an emphasis on PROMs.

LIMITATIONS

Data source selection and representability

The data sources included in the gap analysis were not randomly selected. Instead, the selection aimed at ensuring a broad geographical representation. In practice, this meant that in countries with a high number of data sources, those selected constitute a small sample of the totality, whereas in countries with a low number of data sources, those selected, constitute the majority of those available. Thus, the number of selected data sources varied significantly between regions (e.g. from seven in Africa to 113 in Europe) and the impact that individual data sources had in the overall gap analysis differed by region.

Response bias

The abstraction of information available in the data sources was performed from publicly available information and corroborated through a survey to the data holders. This survey was sent in the local language whenever a translation expert was available, which was not the case for the entirety of the data sources. Overall, the response rate received from the surveyed data sources was 30%.

Information bias

The gap analysis measures the difference between variables available in the data sources screened, however, it provides no information if these variables are being recorded in a systematic manner for all patients. Thus, these results most likely represent an under-estimation of the actual gaps existent in the real world. This was especially evident with the apparent high availability of ejection fraction variable, which does not match the elevated levels of attrition identified in real-world studies. Moreover, considering the methodology to calculate the gap analyses based on the ratio of positive matches over the sum of positive with negative matches, this excluded the cases where the availability of the variables was unclear, again suggesting that the gaps identified may be an underestimation. For further details please consult the DAT online.

Cross Sectional versus Longitudinal Observation

In this study the analysis was limited to a point in time observation, thus it is unknown how the continuous and timely measurement of the ICHOM HF Standard Set is implemented in the real world.

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APPENDIX

1. Working Group Members and Supporting Organisations for the ICHOM Standard Set for Heart Failure

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Heart Failure in partnership with ICHOM, under the leadership of Dr. Theresa McDonagh, Professor of Heart Failure at Kings College Hospital in London and Clinical Lead for the National Heart Failure Audit in the United Kingdom.

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United States
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Frederick Masoudi
Lynne Stevenson

Wales
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GIG CYMRU NHS WALES
Bwrdd Iechyd Aneurin Bevan Health Board

American Heart Association®
life is why™

British Heart Foundation

HEART FAILURE ASSOCIATION OF THE ESC

EUROPEAN SOCIETY OF CARDIOLOGY®

2. List of countries included in geographical regions

North American Region

Canada, USA.

European Region

Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Macedonia, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Romania, Russia, Serbia, Spain, Sweden, Turkey, UK.

Asia-pacific Region

Australia, Bahrain, China, Hong Kong, India, Indonesia, Israel, Japan, Kuwait, Malaysia, New Zealand, Oman, Pakistan, Philippines, Qatar, United Arab Emirates, and, Saudi Arabia, Singapore, South Korea, Taiwan, Thailand, Yemen.

Latin-American & Caribbean Region

Argentina, Bahamas, Barbados, Belize, Brazil, Chile, Colombia, Guyana, Jamaica, Martinique, Mexico, Trinidad-Tobago, Uruguay, US Virgin Islands.

Africa

Botswana, Cameroon, Egypt, Ethiopia, Ghana, Ivory Coast, Kenya, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Senegal, South Africa, Sudan, Tanzania, Tunisia, Uganda, Zambia, Zimbabwe.

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