ICHOM

International Consortium for Health Outcomes Measurement

Congenital Heart Disease
DATA COLLECTION REFERENCE GUIDE

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Congenital Heart Disease

We are thrilled that you are interested in measuring outcomes for congenital heart disease according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes, is included in the appendix.

Our aim is to make Standard Sets freely accessible to healthcare institutions worldwide to begin measuring, and ultimately benchmark the outcomes they achieve. In order to have a guide from which we can benchmark outcomes, we require feedback from initial implementation efforts. As such, this Reference Guide may undergo revisions on a regular basis. If you have any suggestions or would like to provide feedback, please contact info@ichom.org

Working Group Members for Congenital Heart Disease

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Congenital Heart Disease in partnership with ICHOM, under the leadership of Gerard Martin, ICHOM Standard Set Chair. The work was supported by Kevin Hummel, ICHOM Research Fellow, Sarah Whittaker, ICHOM Project Leader, and Nick Sillett, ICHOM Research Associate.

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Supporting Organizations

The Congenital Heart Disease Standard Set is made possible only through the support of the following organizations.

Thank You.

Scope of the Congenital Heart Disease Standard Set

For congenital heart disease, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

Conditions	ICD 10: Congenital CHD (Q20.0-9, Q21.0-9,Q22.0-9, Q23.0-9, Q24.0-9, Q25.0-9, Q25.71-72, Q25.79, Q26.0-9)
Disease Stage	Minor | Moderate | Major or Complex | Critical (AHA/ACC and Worldbank Severity Levels)
Population	Pediatrics (<18 years of age) and Adults (≥ 18 years of age)
Treatment approaches	Overall Health | Mental Health | Physical Health | Social Health
Excluded conditions	Any disorder that is an acquired or non-congenital CHD (e.g. cardiomyopathy, myocarditis)

ICHOM Standard Set for Congenital Heart Disease

Case-Mix Variables

Measure	Patient Population	Supporting Information	Timing	Data Source
Demographic Factors				
Sex	All patients	The patient's sex at birth	Baseline	Patient/ Administrative
Age	All pediatric patients	Patient's month and year of birth	Baseline	Patient/ Administrative
	All adult patients (≥ 18 years of age)	Patient's year of birth		
Level of Education	All adult patients (≥ 18 years of age) and parents of pediatric patients	Mapping of the ICHOM definition of level of education to the level of schooling as defined by ISCED [International Standard Classification ICHOM mapping 'None': Level 0: Early Childhood Education; designed with a holistic approach to support children's early cognitive, physical, social and emotional development and introduce young children to organized instruction outside of the family context to develop some of the skills needed for academic readiness and to prepare them for entry into primary education. Designed for children 0-2 years Level 1: Primary Education; designed to provide students with fundamental skills in reading, writing, and mathematics (i.e. literacy and numeracy) and establish a solid foundation for learning and understanding core areas of knowledge, personal and social development, in preparation for lower secondary education. Typically lasts until ages 10-12 ICHOM mapping 'Primary': Level 2: Lower secondary education; lays the foundation for lifelong learning and human development upon which education systems may then expand further educational opportunities. Students enter between ages 10-13 and usually finish between 14-16 years. Level 3: Upper secondary education, designed to complete secondary education in preparation for tertiary education or provide skills relevant to employment, or both. Students usually enter between 14-16 and finish by ages 17-18. ICHOM mapping 'Secondary': Level 4: Post-secondary non-tertiary education; provides learning experiences building on secondary education, preparing for labour market entry as well as tertiary education. The content of level 4 programmes is not sufficiently complex to be regarded as tertiary education, although it is clearly post-secondary. Level 5: short-cycle tertiary education; designed to	Baseline and annually	Patient/ Parent

		provide participants with professional knowledge, skills, and competencies. Typically, they are practically-based, occupationally-specific, and prepare students to enter the labour market. ICHOM mapping 'Tertiary': Level 6: Bachelor's or equivalent level; often designed to provide participants with intermediate academic and/or professional knowledge, skills and competencies, leading to a first degree or equivalent qualification Level 7: Master's or equivalent level; designed to provide participants with advanced academic and/or professional knowledge, skills and competencies, leading to a second degree or equivalent qualification. Level 8: Doctoral or equivalent level; designed primarily to lead to an advanced research qualification)		
Parent's Marital Status	All pediatric patient		Baseline and annually	Parent
Marital Status of Patient	All adult patients (≥ 18 years of age)		Baseline and annually	Patient/ Adminstrative
Parent's Employment Status	All pediatric patient		Baseline and annually	Parent
Employment Status of Patient	All adult patients (≥ 18 years of age)		Baseline and annually	Patient/ Adminstrative
Baseline Clinical Factors/Health Status				
Congenital Heart Disease Severity	All patients	Worldbank classifications •Minor: long-term symptom free survival expected without intervention in most cases (including: small L->R shunts (ASD, VSD, PDA), bicommissural aortic valve) •Major: intervention required often in early infancy, for optimal long-term outcome (Including: TOF, DORV, large VSD/PDA, complete AV canal, truncus arteriosus, AP window, single ventricle physiology, unobstructed TAPVC, ALCAPA, severe outflow tract obstruction) •Critical: incompatible with survival without specific intervention in newborn period or early infancy. (Including: TGA, obstructed TAPVC, duct-dependent pulm or systemic circulation) •CHD that manifests at an older age: Diagnosis seldom made in early childhood; intervention required to prevent long-term sequelae in adulthood (Including: Moderate or large ASD, some forms of coarctation, some patients with Ebstein's anomaly, relatively less severe forms of aortic and pulmonary valve stenosis, congenitally	Baseline	Clinician/ Healthcare provider/ Administrative

		corrected transposition of the great arteries with intact ventricular septum).		
Congenital Heart Disease Type	All patients	IPCCC Codes: http://ipccc.net/wp-content/uploads/2018/01/ICD-11-ISNPCHD-Card-Young-Dec2017-corrected.pdf	Baseline	Clinician/ Healthcare provider
Comorbidities	All patients	Separate options used for adult and pediatric populations.	Baseline and annually	Clinician /Healthcare provider
Gestational Age	All pediatric		Baseline	Clinician /Healthcare provider
Oxygen Saturation	All patients		Baseline and annually	Clinician /Healthcare provider
Treatment Related Factors				
Intervention Type	All patients		Baseline and annually	Clinician /Healthcare provider
Age at intervention/# of interventions	All patients		Baseline and annually	Clinician /Healthcare provider
Age at Diagnosis	All patients		Baseline	Clinician /Healthcare provider
Length of Hospital Stay	All patients		Baseline and annually	Clinician /Healthcare provider
Residual Lesions	All patients	Technical Performance Score (https://www.jtcvs.org/article/S0022-5223(13)00831-3/pdf)	Baseline and annually	Clinician /Healthcare provider
Complications	All patients	Surgical or Catheterization events from https://www.uab.edu/medicine/wdpchs/images/data_collection_forms/2018-04-20/6_Post_Operative_Events_Form.pdf and https://www.ncdr.com/WebNCDR/docs/default-source/public-data-collection-documents/impact_v1_datacollectionform_1-0-1.pdf?sfvrsn=2, respectively	Baseline and annually	Clinician /Healthcare provider
Pacemaker/ implantable cardioverter-defibrillator implantation	All patients		Baseline and annually	Clinician /Healthcare provider
Access to Congenital Heart Disease Specialist	All patients		Baseline and annually	Patient/Parent

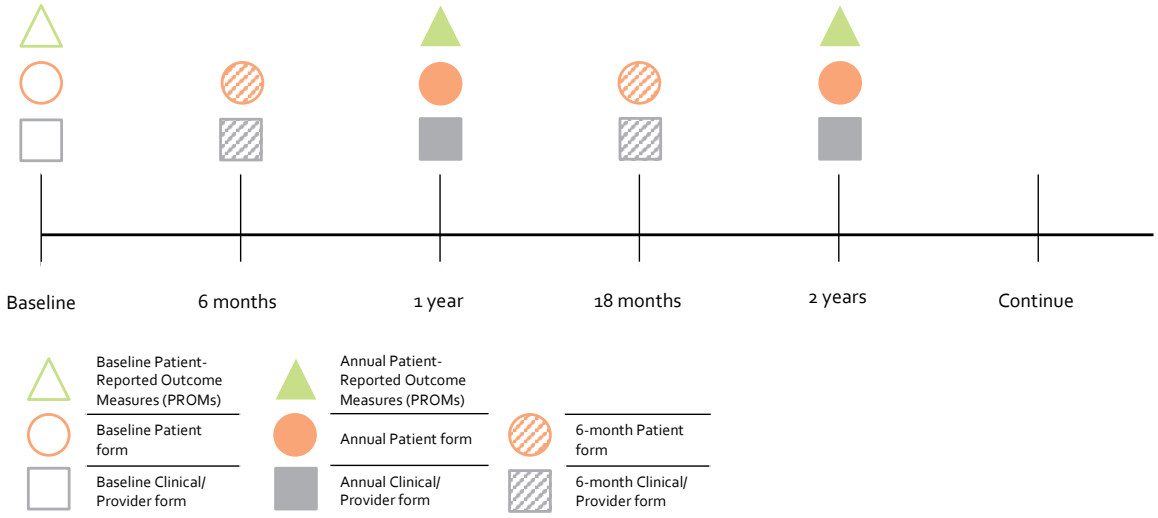
Outcomes

Outcome	Patient Population	Measure	Timing	Data Source
Overall Health				
Health-Related Quality of Life/ Perceived Health Status	Pediatric patients ≥ 8 years of age	Pediatric Cardiac Quality of Life (PCQLI)	Baseline and annually	Patient/ Parent
	All adult patients (≥ 18 years of age)	PROMIS Scale v1.2 – Global Health	Baseline and annually	Patient
Quality of Life	Pediatric patients ≥ 9 years of age	Satisfaction with Life Scale - Child	Baseline and annually	Patient
	All adult patients (≥ 18 years of age)	Satisfaction with Life Scale	Baseline and annually	Patient
Physical Health				
Survival	All patients	If patient has died: date, attributable to CHD, cause of death or if in relation to hospital stay or procedure	Every 6 months	Clinician /Healthcare provider/ Administrative
Growth	All pediatric patients	WHO Growth Charts	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years	Clinician /Healthcare provider
Activity Level	All adult patients (≥ 18 years of age) and pediatric patients ≥ 5 years of age	6 Minute Walk Test	Baseline and annually	Clinician /Healthcare provider
Heart Failure	All patients	Indicate if diagnosed with heart failure and its New York Heart Association Functional Class	Baseline and annually	Clinician /Healthcare provider
Arrhythmias	All patients	Occurrence of arrhythmia or sudden cardiac arrest	Baseline and annually	Clinician /Healthcare provider
Development	All pediatric patients	If child has been diagnosed with cerebral palsy or developmental delay.	Baseline and annually	Parent
Pregnancy	All adult patients (≥ 18 years of age)	If patient has been pregnant. If so, questions about clinical counseling, number of pregnancies, terminations and complications. If not, why not.	Baseline and annually	Patient
Social Health				
Productivity	Pediatric patients ≥ 5 years of age	# of school days missed in past year because of CHD	Baseline and annually	Parent
	All adult patients (≥ 18 years of age)	Work Productivity and Activity Impairment Questionnaire- General Health v2.0	Baseline and annually	Patient

Outcome	Patient Population	Measure	Timing	Data Source
Family Quality of Life	All pediatric patients	The working group chose not to include a measure at this time for adult family quality of life because there was not a free, feasible measure.	Baseline and annually	Parent
Financial Burden	All patients	If CHD is causing a financial burden and if this affects care access.	Baseline and annually	Patient/ parent
Mental Health				
Development	All pediatric patients	Previous diagnosis of mental health issues.	Baseline and annually	Parent
Depression	All adult patients (≥ 18 years of age)	Patient Health Questionnaire (PHQ-9)	Baseline and annually	Patient
Anxiety	All adult patients (≥ 18 years of age)	General Anxiety Disorder (GAD-7)	Baseline and annually	Patient
Cognition	All adult patients (≥ 18 years of age)	The working group chose not to include a measure at this time for adult cognition because there was not a free, feasible measure.	Baseline and annually	Patient

Follow-Up Timeline

The following timeline illustrates when Standard Set variables should be collected from patients and clinicians.



Collecting Patient-Reported Outcome and Clinical Measures

Congenital Heart Disease Survey Used – (reporter)	Licensing Information	Scoring Information
Pediatric Cardiac Quality of Life (PCQLI) - **Patient**	No fee is required for use of the PCQLI, but users must register with Ann and Robert H. Lurie Children's Hospital of Chicago. This has been translated into other languages. More information is available at https://www.luriechildrens.org/en/specialties-conditions/heart-center/research/pcqli/	The Disease Impact and Psychosocial Impact subscale scores are calculated using the same formula. This is done by summing the response values in the subscale and subtracting the total number of items. This value is then divided by the item number multiplied by four. The resulting value is then multiplied by 50 to generate the subscale score. The total score is generated from summing the Disease Impact and Psychosocial Impact subscale scores. More information is available at: https://www.luriechildrens.org/globalassets/media/pages/specialties--conditions/specialities/heart-center/documents/pcqli-users-guide-10jul2015.pdf
PROMIS Scale v1.2 – Global Health - **Patient**	Respondent-ready PDFs the instrument for all measurement systems are available at www.HealthMeasures.net in "Search & View Measures." These measures may be used in paper or electronic form for single use (i.e., solely for the user's own individual clinical trial, academic research study, healthcare or clinical application, community-based or educational program, or other discrete application with a defined timeline, area of focused health measurement, and deliverables or research products) without permission or fees as long as the text is not changed.	The scale can either be scored using the online HealthMeasures Scoring Service (https://www.assessmentcenter.net/ac_scoringservice) where the data file can be uploaded and a Global Health score produced. This can also be scored by hand, where the summed raw scores from each item can be converted into T-score values using conversion tables found in the PROMIS Global Scoring Manual.
Satisfaction with Life Scale - Child - **Patient**	The scale is available for free and without a licence from: http://www.midss.org/content/satisfaction-life-scale-child-swls-c . It is only available in English.	The scores from each question are summed, giving a total score between 5 and 25.
Satisfaction with Life Scale - **Patient**	The scale is available for free and without a licence from: http://www.midss.org/sites/default/	The scores assigned to each question are summed to create a total score. These total scores refer to the cutoffs detailed here: http://www.midss.org/sites/default/files/understanding_swls_scores.pdf

	files/swls_english.pdf . It is only available in English	
Work Productivity and Activity Impairment Questionnaire - General Health v2.0 - **Patient**	The scale is available for free and without a licence from: http://www.reillyassociates.net/WPAI_GH.html . Other translations are available.	The outcomes from the WPAI are expressed as impairment percentages with higher numbers indicating greater impairment and less productivity. The scores generated are for work time missed due to health, impairment while working due to health, overall work impairment due to health and activity impairment due to health all expressed as percentages. Full instructions to calculate these are available on under WPAI:GH: http://www.reillyassociates.net/WPAI_Scoring.html .
Patient Health Questionnaire (PHQ-9) - **Patient**	The PHQ-9 is free for all health care organizations, and a license is not needed. There are translations available. More information may be found at https://www.phqscreeners.com.	Each question has four possible answers with a value from 0 to 3, with 0 representing "not at all" and 3 "nearly every day". The scores are added up, generating a total score between 0 to 27. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe and severe depression, respectively. The PHQ-9 Scoring Guide can be located at https://www.phqscreeners.com.
General Anxiety Disorder (GAD-7) - **Patient**	The GAD-7 is free and requires no license for its use. There are translations available. More information may be found at https://www.phqscreeners.com	Each question has four possible answers with a value from 0 to 3, with 0 representing "not at all" and 3 "nearly every day". The scores are added up, generating a total score between 0 to 21. Scores of 5, 10 and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively. The GAD-7 Scoring Guide can be located at https://www.phqscreeners.com.
WHO Growth Charts - **Clinician**	The Growth Charts are freely available without use of a licence from the World Health Organisation website (available at: https://www.who.int/childgrowth/standards/en/ or https://www.who.int/growthref/en/ for 0-5 or 5-19 years of age, respectively).	For the charts, the weight, head circumference, length and height measurements of the child are recorded. These are plotted by age onto the specific Growth Chart for the child's biological sex. The child's centile should be recorded, either the exact centile it falls on or the two it falls between. These charts are available from: https://www.who.int/childgrowth/standards/en/ and https://www.who.int/growthref/en/ for children 0-5 and 5-19 years of age, respectively.
6 Minute Walk Test - **Clinician**	This test is not an officially licensed measure, therefore it can be used without restriction.	Because the 6 Minute Walk Test is not an officially licensed measure, it does not have specific scoring instructions. Instead, clinicians must record the distance, in metres, covered by the patient when they quickly walk on a hard, flat surface.

ICHOM

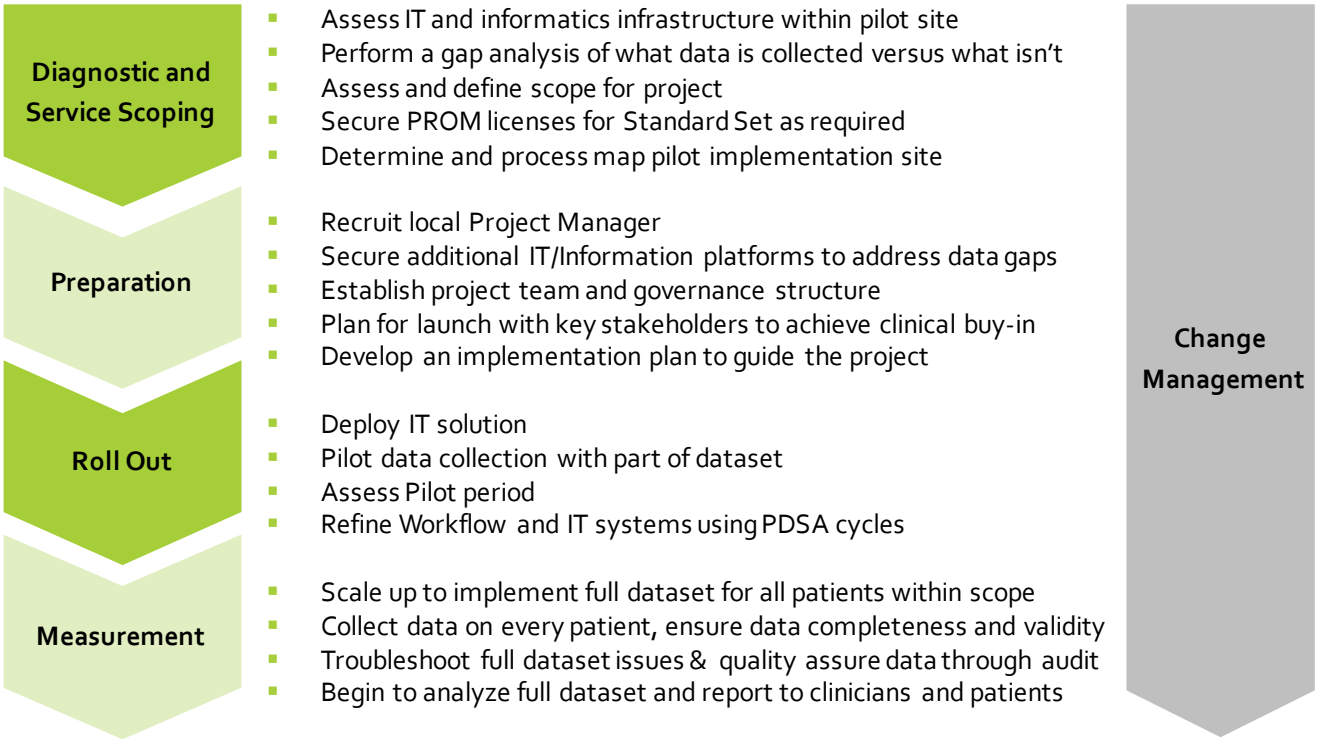
International Consortium for Health Outcomes Measurement

The Growing ICHOM Community

There is a growing community of healthcare providers implementing the ICHOM Standard Sets. To support your organization in implementing the set and the measurement of outcomes data, we have outlined a framework to guide the implementation and reporting of patient-centered outcomes. For further information or to enquire about Implementation support offered by ICHOM, please contact the Implementation team: implement@ichom.org

Implementation framework:

The framework below, outlines the structured process to guide the implementation of an ICHOM Standard Set at your organization. Typically, an implementation project takes 9 months to complete.



ICHOM is also able to support organizations with a variety of support models:

1. Capacity building – direct advisory support
2. Community models –supporting a community of providers in outcomes adoption and innovation
3. Education – workshops and short courses regarding Value Based Healthcare and implementation skills

Translating the Set Tools:
PROMs within the ICHOM Sets are available in a number of languages. To check the availability of translations, we advise contacting the Tool authors directly to obtain and translate the PROM surveys into your desired language. To independently translate PROM surveys, if permitted by its license, we recommend following the 10 steps outlined below:*[1]

Step 1	Preparation	Initial work carried out before the translation work begins
Step 2	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
Step 3	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
Step 4	Back Translation	Translation of the new language version back into the original language
Step 5	Back Translation Review	Comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised in the process of resolving the issues
Step 6	Harmonization	Comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepancies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems
Step 7	Cognitive Debriefing	Testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation
Step 8	Review of Cognitive Debriefing Results and Finalization	Comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepancies
Step 9	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
Step 10	Final Report	Report written at the end of the process documenting the development of each translation

*These ten steps follow the ISPOR Principles of Good Practice: The Cross-Cultural Adaptation Process for Patient-Reported Outcomes Measures [1] Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., et al. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. Value in Health, 8(2), 94–104. doi:10.1111/j.1524-4733.2005.04054.x.

For any questions about implementation please contact us at: implement@ichom.org

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Congenital Heart Disease Standard Set as consistently as possible to the Working group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Demographic Factors

Variable ID:	SEX
Variable:	Sex
Definition:	Please indicate the patient's sex at birth.
Supporting Definition:	For statistical purposes, the following category codes, labels and definitions are preferred: CODE 1 Male: Persons who have male or predominantly masculine biological characteristics, or male sex assigned at birth. CODE 2 Female: Persons who have female or predominantly feminine biological characteristics, or female sex assigned at birth. CODE 3 Other: Persons who have mixed or non-binary biological characteristics (if known), or a non-binary sex assigned at birth The value meaning of 'Other' has been assigned to Code 3 for this value domain, which replaces 'Intersex or indeterminate' for the superseded value domain Sex code N. Terms such as 'indeterminate,' 'intersex', 'non-binary', and 'unspecified' are variously used to describe the 'Other' category of sex. The label 'Other' is used because a more descriptive term has not been widely agreed within the general community. Sex refers to the chromosomal, gonadal and anatomical characteristics associated with biological sex. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient/Administrator
Type:	Code
Response Options:	1 = Male 2 = Female 3 = Other 999 = Undisclosed

Variable ID:	PEDSDOB
Variable:	Date of Birth
Definition:	Patient year and month of birth
Supporting Definition:	Used to calculate age
Inclusion Criteria:	All pediatric patients

Timing:	Baseline
Data Source:	Patient/Administrator
Type:	Numerical
Response Options:	MM/YYYY
Variable ID:	YOB
Variable:	Date of Birth
Definition:	In what year were you born?
Supporting Definition:	Used to calculate age
Inclusion Criteria:	All adult patients
Timing:	Baseline
Data Source:	Patient/Administrator
Type:	Numerical
Response Options:	YYYY
Variable ID:	EDU
Variable:	Level of Education
Definition:	Please indicate your highest level of schooling completed.
Supporting Definition:	(Mapping of the ICHOM definition of level of education to the level of schooling as defined by ISCED [International Standard Classification]. **ICHOM mapping 'None':** Level 0: Early Childhood Education; designed with a holistic approach to support children's early cognitive, physical, social and emotional development and introduce young children to organized instruction outside of the family context to develop some of the skills needed for academic readiness and to prepare them for entry into primary education. Designed for children 0-2 years Level 1: Primary Education; designed to provide students with fundamental skills in reading, writing, and mathematics (i.e. literacy and numeracy) and establish a solid foundation for learning and understanding core areas of knowledge, personal and social development, in preparation for lower secondary education. Typically lasts until ages 10-12 **ICHOM mapping 'Primary':** Level 2: Lower secondary education; lays the foundation for lifelong learning and human development upon which education systems may then expand further educational opportunities. Students enter between ages 10-13 and usually finish between 14-16 years. Level 3: Upper secondary education, designed to complete secondary education in preparation for tertiary education or provide skills relevant to employment, or both. Students usually enter between 14-16 and finish by ages 17-18. **ICHOM mapping 'Secondary':** Level 4: Post-secondary non-tertiary education; provides learning experiences building on secondary education, preparing for labour market entry as well as tertiary education. The content of level 4 programmes is not sufficiently complex to be regarded as tertiary education, although it is clearly post-secondary. Level 5: short-cycle tertiary education; designed to provide participants with professional knowledge, skills, and competencies. Typically, they are practically-based, occupationally-specific, and prepare students to enter the labour market. **ICHOM mapping 'Tertiary':** Level 6: Bachelor's or equivalent level; often designed to provide participants with intermediate academic and/or professional knowledge, skills and competencies, leading to a first degree or equivalent qualification Level 7: Master's or equivalent level; designed to provide participants with advanced academic and/or professional knowledge, skills and competencies, leading to a second degree or equivalent qualification. Level 8: Doctoral or equivalent level; designed primarily to lead to an advanced research qualification)
Inclusion Criteria:	All adult patients and parents of pediatric patients

Timing:	Baseline/Annually
Data Source:	Patient/Administrator
Type:	Single answer
Response Options:	None Primary Secondary Tertiary
Variable ID:	MAR_STATUS
Variable:	Marital Status of the patient
Definition:	What is your marital status?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline/Annually
Data Source:	Patient
Type:	Single answer
Response Options:	Single Married or in a domestic partnership Separated or divorced Widowed
Variable ID:	MAR_STATUS_PAR
Variable:	Parent's Marital Status
Definition:	What is your marital status?
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annually
Data Source:	Parent
Type:	Single answer
Response Options:	Single Married or in a domestic partnership Separated or divorced Widowed
Variable ID:	EMP_STATUS
Variable:	Employment Status of the patient
Definition:	What is your employment status?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline/Annually
Data Source:	Patient
Type:	Single answer
Response Options:	Unemployed Part-time employment Full-time employment Retired
Variable ID:	EMP_STATUS_PAR
Variable:	Parent's Employment Status
Definition:	What is your employment status?
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annually
Data Source:	Parent
Type:	Single answer
Response Options:	Unemployed Part-time employment Full-time employment Retired

Baseline Clinical Factors

Variable ID:	CHD_SEV
Variable:	Congenital Heart Disease Severity
Definition:	The severity of the patient's congenital heart disease
Supporting Definition:	Worldbank, American College of Cardiology Classifications: **Minor**: long-term symptom free survival expected without intervention in most cases (including: small L->R shunts (ASD, VSD, PDA), bicommissural aortic valve) **Major**: intervention required often in early infancy, for optimal long-term outcome (Including: TOF, DORV, large VSD/PDA, complete AV canal, truncus arteriosus, AP window, single ventricle physiology, unobstructed TAPVC, ALCAPA, severe outflow tract obstruction) **Critical**: incompatible with survival without specific intervention in newborn period or early infancy. (Including: TGA, obstructed TAPVC, duct-dependent pulm or systemic circulation) **CHD that manifests at an older age:** Diagnosis seldom made in early childhood; intervention required to prevent long-term sequelae in adulthood (Including: Moderate or large ASD, some forms of coarctation, some patients with Ebstein's anomaly, relatively less severe forms of aortic and pulmonary valve stenosis, congenitally corrected transposition of the great arteries with intact ventricular septum)
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Minor Major Critical CHD that manifests at an older age

Variable ID:	CHD_TYPE
Variable:	Congenital Heart Disease Type IPCCC Code
Definition:	The CHD type of the patient in the form of IPCCC code
Supporting Definition:	IPCCC Codes: http://ipccc.net/wp-content/uploads/2018/01/ICD-11-ISNPCHD-Card-Young-Dec2017-corrected.pdf
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	IPCCC Code

Variable ID:	COMORB_PED
Variable:	Comorbidities (Pediatric)
Definition:	Indicate if the patient has any of the following comorbidities: Congenital defect or chromosomal abnormality, non-cardiac Prematurity (< 37 weeks) Multiorgan system failure Sepsis or shock at time of cardiac correction Cancer (brain, leukemia) Shock and/or sepsis Heart Failure Feeding intolerance (requiring feeding tube) Stroke Developmental delay Respiratory failure

	Pneumonia Seizure Candidiasis (fungal infection of blood)
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	List
Response Options:	Congenital defect or chromosomal abnormality, non-cardiac Prematurity (< 37 weeks) Multiorgan system failure Sepsis or shock at time of cardiac correction Cancer (brain, leukemia) Shock and/or sepsis Heart Failure Feeding intolerance (requiring feeding tube) Stroke Developmental delay Respiratory failure Pneumonia Seizure Candidiasis (fungal infection of blood)
Variable ID:	COMORB_ADU
Variable:	Comorbidities (Adult)
Definition:	Indicate if the patient has any of the following comorbidities: Congenital defect or chromosomal abnormality, non-cardiac Prematurity (< 37 weeks) Multiorgan system failure Sepsis or shock at time of cardiac correction Heart Failure Peripheral Vascular disease (intermittent claudication or past bypass surgery for PVD), history of gangrene, or untreated thoracic/abdominal aneurysm Stroke or Transient Ischemic Attack (TIA) Dementia COPD Peptic ulcer disease Connective tissue disease Liver disease Diabetes Moderate to severe chronic kidney disease Solid Tumor, leukemia or lymphoma AIDS
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	List
Response Options:	Congenital defect or chromosomal abnormality, non-cardiac Prematurity (< 37 weeks) Multiorgan system failure Sepsis or shock at time of cardiac correction Heart Failure Peripheral Vascular disease (intermittent claudication or past bypass surgery for PVD)

	history of gangrene, or untreated thoracic/abdominal aneurysm Stroke or Transient Ischemic Attack (TIA) Dementia COPD Peptic ulcer disease Connective tissue disease Liver disease Diabetes Moderate to severe chronic kidney disease Solid Tumor, leukemia or lymphoma AIDS
Variable ID:	GES_AGE
Variable:	Gestational Age
Definition:	Indicate the gestational age of the patients in weeks
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Number of weeks
Variable ID:	OXY_SAT
Variable:	Oxygen Saturation
Definition:	Oxygen saturation (Spo2) is the percentage of hemoglobin binding sites in the blood stream occupied by oxygen. Normal values are >98 but this may vary with altitude. To be measured non-invasively with pulse oximetry.
Supporting Definition:	
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	SaO2 >95 SaO2 85-95 SaO2 75-84 SaO2 <75

Treatment Related Factors

Variable ID:	INT_TYPE
Variable:	Intervention Type
Definition:	List any of the inteventions the patient has undergone from the following:
Supporting Definition:	**References for selection list**: Martin, et al. The IMPACT Registry: IMproving Pediatric and Adult Congenital Treatments. Seminars in Thoracic and CV Surgery. 2010 World Society of Congenital Heart Surgeons: https://www.uab.edu/medicine/wdpchs/images/data_collection_forms/2018-04-20/4_Tier_1_Surgery_Form.pdf
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	List
Response Options:	Surgical AVSD repair (complete, intermediate, partial) Coarctation repair (end to end, extended, subclavian flap, patch, interposition, other, extra-anatomic bypass)

	Norwood (BT shunt, RV-PA conduit) HLHS biventricular repair Glenn (unidirectional, bidirectional, Bilateral bidirectional) Hemi-fontan PAPVC (traditional, scimitar, Warden) Single ventricle (fontan extracardiac fenestrated, fontan extracardiac non-fenestrated, fontan complete lateral tunnel, fontan complete extra-intra cardiac, Fontan complete internal conduit, Fontan complete other, Fontan other) TOF (ventriculotomy, transannular patch, rv-pa conduit, PA reconstruction, valvotomy) TAPVC repair ASO Ebsteins repair Truncus arteriosis repair VSD repair (primary, patch, device, multiple, creation/enlargement) Additional procedures: WDPCHS Form 2a (https://www.uab.edu/medicine/wdpchs/images/data_collection_forms/2018-04-20/5_Tier_2_Surgery_Form.pdf) Cath Coarctation procedure ASD closure PDA closure Aortic valvuloplasty Pulmonary valvuloplasty Pulmonary artery stenting Percutaneous Pulmonary Valve implantation" Other
Variable ID:	INT_AGE
Variable:	Age at Intervention
Definition:	For every interventions listed previously, note the date of occurrence
Supporting Definition:	N/A
Inclusion Criteria:	If patients have responded to "Intervention Type"
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Date
Response Options:	MM/YYYY in same order as responses listed in "Intervention Type"
Variable ID:	INT_HOSP_STAY
Variable:	Length of Stay
Definition:	For each intervention, list the total length of hospital stay in days
Supporting Definition:	N/A
Inclusion Criteria:	If patients have responded to "Intervention Type"
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Number of days in same order as responses listed in "Intervention type"
Variable ID:	CHD_DIAG_AGE
Variable:	Age at Diagnosis
Definition:	List the date of diagnosis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician /Healthcare provider

Type:	Date
Response Options:	MM/YYYY
Variable ID:	CHD_RESID_LES
Variable:	Residual Lesions
Definition:	Indicate the patient's Technical Performance Score
Supporting Definition:	Technical Performance Score (https://www.jtcvs.org/article/S0022-5223(13)00831-3/pdf) Class 1: Optimal Class 2: Adequate Class 3: Inadequate N/A: No TPS assigned The final score for each operation was determined by the subprocedure scores and was considered class 1 (no residual defect, optimal) if all subprocedure scores were optimal, class 2 (minor residual, adequate) if !1 subprocedures were adequate, and class 3 (major residual, inadequate) if !1 subprocedures were graded as inadequate. Any unplanned reintervention, whether surgical or catheter based, on the anatomic area initially treated at the index surgery or the need for permanent pacemaker placement resulted in a class 3 (inadequate) score.
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Class 1 Class 2 Class 3 N/A
Variable ID:	SURG_COMPS
Variable:	Surgical Complications
Definition:	Indicate occurrence of any of the following surgical complications Arrhythmia (requiring intervention) Bleeding (requiring reoperation) Cardiac dysfunction resulting in low cardiac output Cardiac failure Chylothorax or effusion requiring drainage Endocarditis IVH >grade 2 Mechanical circulatory support MODS Neurologic deficit during or after the OR Paralyzed diaphragm Pericardial effusion requiring drainage Peripheral nerve injury Pneumonia Post-op respiratory insufficiency requiring mechanical ventilation >7 days or re-intubation or trach Pulmonary vein obstruction Renal failure Seizure Sepsis Spinal cord injury Stroke (ischemic) Subdural bleed Systemic vein obstruction Unplanned cardiac reoperation Vocal cord dysfunction

	Wound dehiscence Mediastinitis Superficial wound infection
Supporting Definition:	**Reference for complication list:** https://www.uab.edu/medicine/wdpchs/images/data_collection_forms/2018-04-20/6_Post_Operative_Events_Form.pdf
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	List
Response Options:	Arrhythmia (requiring intervention) Bleeding (requiring reoperation) Cardiac dysfunction resulting in low cardiac output Cardiac failure Chylothorax or effusion requiring drainage Endocarditis IVH >grade 2 Mechanical circulatory support MODS Neurologic deficit during or after the OR Paralyzed diaphragm Pericardial effusion requiring drainage Peripheral nerve injury Pneumonia Post-op respiratory insufficiency requiring mechanical ventilation >7 days or re-intubation or trach Pulmonary vein obstruction Renal failure Seizure Sepsis Spinal cord injury Stroke (ischemic) Subdural bleed Systemic vein obstruction Unplanned cardiac reoperation Vocal cord dysfunction Wound dehiscence Mediastinitis Superficial wound infection
Variable ID:	CATH_COMPS
Variable:	Catheterization Complications
Definition:	Indicate occurrence of any of the following catheterization complications: Cardiac arrest Arrythmia (requiring intervention) New heart valve regurgitation Tamponade Air Embolus Embolic stroke Device malposition or thrombus Device embolization New dialysis requirement Event requiring intubation Event requiring mechanical circulation Bleeding event Transfusion

Supporting Definition:	**Reference for complication list:** https://www.ncdr.com/WebNCDR/docs/default-source/public-data-collection-documents/impact_v1_datacollectionform_1-0-1.pdf?sfvrsn=2
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	List
Response Options:	Cardiac arrest Arrythmia (requiring intervention) New heart valve regurgitation Tamponade Air Embolus Embolic stroke Device malposition or thrombus Device embolization New dialysis requirement Event requiring intubation Event requiring mechanical circulation Bleeding event Transfusion
Variable ID:	IMPLANT_PM
Variable:	Pacemaker implantation
Definition:	Does the patient have a pacemaker implanted?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Yes/No
Variable ID:	IMPLANT_ICVD
Variable:	Implantable cardioverter- defibrillator implantation
Definition:	Does the patient have an implantable cardioverter defibrillator?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline/Annually
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Yes/No
Variable ID:	CHD_ACCESS_PED
Variable:	Access to Congenital Heart Disease Specialist
Definition:	Are you able to see a congenital heart disease (CHD) specialist as advised?
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No
Variable ID:	CHD_ACCESS_ADULT
Variable:	Access to Adult Congenital Heart Disease Specialist
Definition:	Are you able to see an adult congenital heart disease (ACHD) specialist as advised?
Supporting Definition:	N/A

Inclusion Criteria:	All adult patients
Timing:	Baseline/Annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No

Outcomes

Survival

Variable ID:	VITALSTATUS
Variable:	Vital Status
Definition:	Indicate if the person is deceased, regardless of cause
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Single answer
Response Options:	Yes/No/Unknown
Variable ID:	DATEOFDEATH
Variable:	Date of death
Definition:	Indicate the date of death
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Indicate if the person is deceased, regardless of cause"
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Date
Response Options:	MM/DD/YYYY
Variable ID:	CAUSEOFDEATH
Variable:	Was death related to CHD
Definition:	Indicate if death is noted to be directly attributable to congenital heart disease.
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Indicate if the person is deceased, regardless of cause"
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Single answer
Response Options:	Yes/No/Unknown
Variable ID:	CAUSEOFDEATH_CHD
Variable:	Cause of death (CHD)
Definition:	Indicate cause of death if related to CHD
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Indicate if death is noted to be directly attributable to congenital heart disease."
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Single answer
Response Options:	Heart failure Myocardial infarction (non-sudden) Arrhythmia (non-sudden) Pulmonary embolism (non-sudden) Hemorrhage Endocarditis Shunt occlusion Aortic rupture/dissection Arrhythmia

	Pulmonary embolism Myocardial infarction
Variable ID:	CAUSEOFDEATH_NON-CHD
Variable:	Cause of death (non-CHD)
Definition:	Indicate cause of death if not related to CHD
Supporting Definition:	N/A
Inclusion Criteria:	If responded "No" to "Indicate if death is noted to be directly attributable to congenital heart disease."
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Single answer
Response Options:	Infectious diseases Neoplasms Endocrine, Nutritional, and metabolic diseases Diseases of the Nervous System Diseases of the Respiratory System Congenital malformations and chromosomal abnormalities Accidents Suicides Alcohol-related diseases Substance abuse-related diseases Other
Variable ID:	CAUSEOFDEATH_PROC
Variable:	Was death related to CHD procedure or hospital stay
Definition:	Indicate if the death was within 30 days of a procedure for CHD or while still in the hospital after a procedure for CHD
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Indicate if the person is deceased, regardless of cause"
Timing:	Every 6 months
Data Source:	Administrative or clinical
Type:	Single answer
Response Options:	Yes/No/Unknown

Heart Failure

Variable ID:	HEARTFAIL
Variable:	Heart Failure Diagnosis
Definition:	Indicate whether the patient is currently diagnosed with Heart failure
Supporting Definition:	Heart failure defined as any cardiac disorder that impairs the ability of the ventricle to either fill properly or eject optimally (National Heart, Lung, Blood Institute [NHLBI]) or NYHA Functional Class II-IV (AHA)
Inclusion Criteria:	All patients
Timing:	Baseline/Annual
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Yes/No/Unknown
Variable ID:	HEARTFAIL_CLASS_PED
Variable:	Heart Failure Classification for Pediatric Heart Failure
Definition:	Indicate the heart failure classification according to the Ross Heart Failure Classification
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients that responded "Yes" to "Indicate whether the patient is currently diagnosed with Heart failure" and responded "No" to "Indicate if death is noted to be directly attributable to congenital heart disease."
Timing:	Baseline/Annual

Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Ross Heart Failure Classification
Variable ID:	HEARTFAIL_CLASS_ADU
Variable:	Heart Failure Classification for Adult Heart Failure
Definition:	Indicate the heart failure classification according to the NHYA Functional Classification
Supporting Definition:	N/A
Inclusion Criteria:	Adult patients that responded "Yes" to "Indicate whether the patient is currently diagnosed with Heart failure" and responded "No" to "Indicate if death is noted to be directly attributable to congenital heart disease."
Timing:	Baseline/Annual
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	NYHA Functional Classification

Arrhythmia

Variable ID:	ARRHYTH
Variable:	Occurrence of arrhythmia
Definition:	Indicate if there has been an occurrence of arrhythmia
Supporting Definition:	Arrhythmia defined as atrial tachycardia (including supra ventricular tachycardia [SVT], atrial flutter, atrial fibrillation, and or other symptomatic atrial tachycardia), PVCs, ventricular tachycardia or fibrillation, junctional tachycardia or bradycardia, or other bradycardia that is symptomatic requiring intervention, including pharmacotherapy, corrective procedure, or lifestyle modifications (including those who undergo unsuccessful treatment)
Inclusion Criteria:	All patients
Timing:	Baseline/Annual
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Yes/No/Unknown
Variable ID:	SUDD_ARREST
Variable:	Occurrence of sudden cardiac arrest
Definition:	Indicate if there has been an occurrence of sudden cardiac arrest
Supporting Definition:	Sudden cardiac arrest defined as absence of signs of circulation within 1 hour of being symptom free (AHA Circulation Cardiac Arrest Guidelines 2015)
Inclusion Criteria:	All patients
Timing:	Baseline/Annual
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	Yes/No/Unknown

Development

Variable ID:	DEV_PHYS
Variable:	Diagnosis of physical disabilities
Definition:	Has a doctor, other health care provider, or educator EVER told you that this child has: Cerebral palsy Developmental delay
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annual
Data Source:	Parent
Type:	List

Response Options:	Cerebral Palsy Developmental Delay
Variable ID:	DEV_MENT
Variable:	Diagnosis of developmental delay
Definition:	Has a doctor, other health care provider, or educator EVER told you that this child has: Anxiety Problems Depression Behavioral or Conduct Problems Intellectual Disability Speech or other language disorder Learning Disability Any other mental health condition ADHD
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	Baseline/Annual
Data Source:	Parent
Type:	List
Response Options:	Anxiety Problems Depression Behavioral or Conduct Problems Intellectual Disability Speech or other language disorder Learning Disability Any other mental health condition ADHD

Pregnancy

Variable ID:	PREGNANCY
Variable:	Has the patient been pregnant
Definition:	Have you ever been pregnant?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No
Variable ID:	PREGNANCY_COUNS
Variable:	Did the patient receive counselling
Definition:	Did you receive clinical counseling or care from a cardiologist during your pregnancy?
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Have you ever been pregnant?"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No
Variable ID:	PREGNANCY_#
Variable:	Number of pregnancies
Definition:	How many pregnancies have you had?
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Have you ever been pregnant?"
Timing:	Baseline and annually

Data Source:	Patient
Type:	Numerical
Response Options:	Number of pregnancies
Variable ID:	PREGNANCY_LIVE
Variable:	Number of live births
Definition:	How many live births have you had?
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Have you ever been pregnant?"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Numerical
Response Options:	Number of live births
Variable ID:	PREGNANCY_TERM
Variable:	Number of terminations
Definition:	How many terminations have you had?
Supporting Definition:	N/A
Inclusion Criteria:	If responded "Yes" to "Have you ever been pregnant?"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Numerical
Response Options:	Number of terminations
Variable ID:	PREGNANCY_TERM_ADV
Variable:	Was the patient advised to have a termination
Definition:	Did you have a termination because you were medically advised to?
Supporting Definition:	N/A
Inclusion Criteria:	If responded with a value greater than o to "Number of terminations"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No
Variable ID:	PREGNANCY_TERM_ADV
Variable:	Was the patient advised to have a termination
Definition:	Did you have a termination because you were medically advised to?
Supporting Definition:	N/A
Inclusion Criteria:	If responded with a value greater than o to "Number of terminations"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	Yes/No
Variable ID:	PREGNANCY_NO
Variable:	Why has the patient never been pregnant
Definition:	Why have you never been pregnant?
Supporting Definition:	N/A
Inclusion Criteria:	If responded "No" to "Have you ever been pregnant?"
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	I do not wish to I was medically advised not to I was unable to conceive Other

Productivity

Variable ID:	SCHOOL_CHD

Variable:	School missed due to CHD
Definition:	Indicate number of school days missed in past year because of CHD
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 5 years of age
Timing:	Baseline and annually
Data Source:	Parent
Type:	Single answer
Response Options:	0-10 11-20 >20

Financial Burden

Variable ID:	CHD_FINANCE
Variable:	Is CHD causing a financial burden
Definition:	Is the congenital heart disease condition causing a financial burden to you?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient or parent
Type:	Single answer
Response Options:	Yes/No
Variable ID:	CHD_ACCESS
Variable:	Is CHD affecting care access
Definition:	Do you have difficulty accessing the care you need for congenital heart disease because of the financial burden?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Patient or parent
Type:	Single answer
Response Options:	Yes/No

Patient-Reported Outcomes

Variable ID:	PCQLI_Q00
Variable:	**Overall Health Question of Pediatric Cardiac Quality of Life Inventory**
Definition:	In general, would you say your child's health is…
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor
Variable ID:	PCQLI_Q01
Variable:	Question 1 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she feels different from everybody in a bad way.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer

Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q02
Variable:	Question 2 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she can't do the physical activities he/she want to do.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q03
Variable:	Question 3 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she misses too much school/college/work.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q04
Variable:	Question 4 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she feel guilty about the stress his/her heart disease causes our family.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q05
Variable:	Question 5 of Pediatric Cardiac Quality of Life Inventory
Definition:	School/college/work is difficult for him/her.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral

	4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q06
Variable:	Question 6 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she gets unwanted attention.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q07
Variable:	Question 7 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she is afraid of medical procedures.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q08
Variable:	Question 8 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she gets tired easily.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	All pediatric patients
Timing:	Pediatric patients ≥ 8 years of age
Data Source:	Baseline and annually
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q09
Variable:	Question 9 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she takes too much medicine.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q10

Variable:	Question 10 of Pediatric Cardiac Quality of Life Inventory
Definition:	Adults around him/her are overprotective.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q11
Variable:	Question 11 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she has no energy.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q12
Variable:	Question 12 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she hangs back when doing he/she is doing physical activities.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q13
Variable:	Question 13 of Pediatric Cardiac Quality of Life Inventory
Definition:	Other people are uncomfortable around him/her.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q14
Variable:	Question 14 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she is in pain.
Supporting Definition:	In the context of 'Because of my child's heart problem…'

Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q15
Variable:	Question 15 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she is likely to have other health problems.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q16
Variable:	Question 16 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she cannot wear what he/she wants.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q17
Variable:	Question 17 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she spends too much time dealing with his/her health.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q18
Variable:	Question 18 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she takes medicine that causes bad side effects.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)

Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q19
Variable:	Question 19 of Pediatric Cardiac Quality of Life Inventory
Definition:	His/her condition is likely to get worse.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q20
Variable:	Question 20 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she gets special treatment at home/school/work.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q21
Variable:	Question 21 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she misses social activities.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q22
Variable:	Question 22 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she engages in risk-taking behaviours.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree

	3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q23
Variable:	Question 23 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she is afraid of dying.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q24
Variable:	Question 24 of Pediatric Cardiac Quality of Life Inventory
Definition:	It is difficult for him/her to get around from place to place.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q25
Variable:	Question 25 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she feels angry.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q26
Variable:	Question 26 of Pediatric Cardiac Quality of Life Inventory
Definition:	Other people treat him/her differently.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree

Variable ID:	PCQLI_Q27
Variable:	Question 27 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she looks different from everybody in a bad way.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q28
Variable:	Question 28 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she worries about his/her future.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PCQLI_Q29
Variable:	Question 29 of Pediatric Cardiac Quality of Life Inventory
Definition:	He/she feels helpless.
Supporting Definition:	In the context of 'Because of my child's heart problem…'
Inclusion Criteria:	Pediatric patients ≥ 8 years of age
Timing:	Baseline and annually
Data Source:	Patient or Parent (Proxy)
Type:	Single answer
Response Options:	1 = Strongly agree 2 = Agree 3 = Neutral 4 = Disagree 5 = Strongly disagree
Variable ID:	PROGH_Q01
Variable:	**Question 1 of PROMIS v1.2 - Global Health**
Definition:	In general, would you say your health is:
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q02
Variable:	Question 2 of PROMIS v1.2 - Global Health
Definition:	In general, would you say your quality of life is:

Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q03
Variable:	Question 3 of PROMIS v1.2 - Global Health
Definition:	In general, how would you rate your physical health?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q04
Variable:	Question 4 of PROMIS v1.2 - Global Health
Definition:	In general, how would you rate your mental health, including your mood and your ability to think?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q05
Variable:	Question 5 of PROMIS v1.2 - Global Health
Definition:	In general, how would you rate your satisfaction with your social activities and relationships?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q06
Variable:	Question 6 of PROMIS v1.2 - Global Health

Definition:	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q07
Variable:	Question 7 of PROMIS v1.2 - Global Health
Definition:	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent
Variable ID:	PROGH_Q08
Variable:	Question 8 of PROMIS v1.2 - Global Health
Definition:	In the past 7 days… How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Always 2 = Often 3 = Sometimes 4 = Rarely 5 = Never
Variable ID:	PROGH_Q09
Variable:	Question 9 of PROMIS v1.2 - Global Health
Definition:	In the past 7 days… How would you rate your fatigue on average?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually

Data Source:	Patient
Type:	Single answer
Response Options:	1 = Very Severe 2 = Severe 3 = Moderate 4 = Mild 5 = None
Variable ID:	PROGH_Q10
Variable:	Question 10 of PROMIS v1.2 - Global Health
Definition:	In the past 7 days… How would you rate your pain on average?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 - 10 scale (0 being 'No Pain', 10 being 'Worst pain imaginable')
Variable ID:	SWLS-C_Q01
Variable:	**Question 1 of Satisfaction with Life Scale - Child**
Definition:	In most ways my life is close to the way I would want it to be
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 9 years of age
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Disagree a lot 2 = Disagree a little 3 = Don't agree or disagree 4 = Agree a little 5 = Agree a lot
Variable ID:	SWLS-C_Q02
Variable:	Question 2 of Satisfaction with Life Scale - Child
Definition:	The things in my life are excellent
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 9 years of age
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Disagree a lot 2 = Disagree a little 3 = Don't agree or disagree 4 = Agree a little 5 = Agree a lot
Variable ID:	SWLS-C_Q03
Variable:	Question 3 of Satisfaction with Life Scale - Child
Definition:	I am happy with my life
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 9 years of age
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Disagree a lot 2 = Disagree a little 3 = Don't agree or disagree

	4 = Agree a little 5 = Agree a lot
Variable ID:	SWLS-C_Q04
Variable:	Question 4 of Satisfaction with Life Scale - Child
Definition:	So far I have gotten the important things I want in life
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 9 years of age
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Disagree a lot 2 = Disagree a little 3 = Don't agree or disagree 4 = Agree a little 5 = Agree a lot
Variable ID:	SWLS-C_Q05
Variable:	Question 5 of Satisfaction with Life Scale - Child
Definition:	If I could live my life over, I would have it the same way
Supporting Definition:	N/A
Inclusion Criteria:	Pediatric patients ≥ 9 years of age
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Disagree a lot 2 = Disagree a little 3 = Don't agree or disagree 4 = Agree a little 5 = Agree a lot
Variable ID:	SWLS_Q01
Variable:	**Question 1 of Satisfaction with Life Scale**
Definition:	In most ways my life is close to my ideal
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Strongly disagree 2 =Disagree 3 =Slightly disagree 4 =Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
Variable ID:	SWLS_Q02
Variable:	Question 2 of Satisfaction with Life Scale
Definition:	The conditions of my life are excellent
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Strongly disagree 2 =Disagree 3 =Slightly disagree 4 =Neither agree nor disagree

	5 = Slightly agree 6 = Agree 7 = Strongly agree
Variable ID:	SWLS_Q03
Variable:	Question 3 of Satisfaction with Life Scale
Definition:	I am satisfied with my life
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Strongly disagree 2 =Disagree 3 =Slightly disagree 4 =Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
Variable ID:	SWLS_Q04
Variable:	Question 4 of Satisfaction with Life Scale
Definition:	So far I have gotten the important things I want in life
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Strongly disagree 2 =Disagree 3 =Slightly disagree 4 =Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
Variable ID:	SWLS_Q05
Variable:	Question 5 of Satisfaction with Life Scale
Definition:	If I could live my life over, I would change almost nothing
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	1 = Strongly disagree 2 =Disagree 3 =Slightly disagree 4 =Neither agree nor disagree 5 = Slightly agree 6 = Agree 7 = Strongly agree
Variable ID:	WPAI-GH_Q01
Variable:	**Question 1 of Work Productivity and Activity Impairment Questionnaire-General Health v2.0**
Definition:	Are you currently employed (working for pay)?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually

Data Source:	Patient
Type:	Single answer
Response Options:	Yes or No
Variable ID:	WPAI-GH_Q02
Variable:	Question 2 of Work Productivity and Activity Impairment Questionnaire- General Health v2.0
Definition:	During the past seven days, how many hours did you miss from work because of your health problems?
Supporting Definition:	Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. Do not include time you missed to participate in this study.
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Numerical
Response Options:	Number of hours
Variable ID:	WPAI-GH_Q03
Variable:	Question 3 of Work Productivity and Activity Impairment Questionnaire- General Health v2.0
Definition:	During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Numerical
Response Options:	Number of hours
Variable ID:	WPAI-GH_Q04
Variable:	Question 4 of Work Productivity and Activity Impairment Questionnaire- General Health v2.0
Definition:	During the past seven days, how many hours did you actually work?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Numerical
Response Options:	Number of hours
Variable ID:	WPAI-GH_Q05
Variable:	Question 5 of Work Productivity and Activity Impairment Questionnaire- General Health v2.0
Definition:	During the past seven days, how much did your health problems affect your productivity while you were working?
Supporting Definition:	Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problems affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 - 10 scale (0 being 'Health problems had no effect on my work', 10 being 'Health problems completely prevented me from working')
Variable ID:	WPAI-GH_Q06

Variable:	Question 6 of Work Productivity and Activity Impairment Questionnaire- General Health v2.0
Definition:	During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?
Supporting Definition:	By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 - 10 scale (0 being 'Health problems had no effect on my daily activities', 10 being 'Health problems completely prevented me from doing my daily activities')
Variable ID:	PHQ9_Q01
Variable:	**Question 1 of PHQ-9 Depression**
Definition:	Little interest or pleasure in doing things
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q02
Variable:	Question 2 of PHQ-9 Depression
Definition:	Feeling down, depressed, or hopeless
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q03
Variable:	Question 3 of PHQ-9 Depression
Definition:	Trouble falling or staying asleep, or sleeping too much
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day

Variable ID:	PHQ9_Q04
Variable:	Question 4 of PHQ-9 Depression
Definition:	Feeling tired or having little energy……
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q05
Variable:	Question 5 of PHQ-9 Depression
Definition:	Poor appetite or overeating
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q06
Variable:	Question 6 of PHQ-9 Depression
Definition:	Feeling bad about yourself — or that you are a failure or have let yourself or your family down
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q07
Variable:	Question 7 of PHQ-9 Depression
Definition:	Feeling bad about yourself — or that you are a failure or have let yourself or your family down
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q08

Variable:	Question 8 of PHQ-9 Depression
Definition:	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving .around a lot more than usual
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_Q09
Variable:	Question 9 of PHQ-9 Depression
Definition:	Thoughts that you would be better off dead or of hurting yourself in some way
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	PHQ9_DIFF
Variable:	Difficulty question of PHQ-9 Depression
Definition:	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	- Not difficult at all - Somewhat difficult - Very difficult - Extremely difficult'
Variable ID:	GAD7_Q01
Variable:	**Question 1 of GAD-7 Anxiety**
Definition:	Feeling nervous, anxious or on edge
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q02
Variable:	Question 2 of GAD-7 Anxiety

Definition:	Not being able to stop or control worrying
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q03
Variable:	Question 3 of GAD-7 Anxiety
Definition:	Worrying too much about different things
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q04
Variable:	Question 4 of GAD-7 Anxiety
Definition:	Trouble relaxing
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q05
Variable:	Question 5 of GAD-7 Anxiety
Definition:	Being so restless that it is hard to sit still
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q06
Variable:	Question 6 of GAD-7 Anxiety
Definition:	Becoming easily annoyed or irritable
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?

Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_Q07
Variable:	Question 7 of GAD-7 Anxiety
Definition:	Feeling afraid as if something awful might happen
Supporting Definition:	Over the last 2 weeks, how often have you been bothered by the following problems?
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
Variable ID:	GAD7_DIFF
Variable:	Difficulty question of GAD-7 Anxiety
Definition:	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients
Timing:	Baseline and annually
Data Source:	Patient
Type:	Single answer
Response Options:	- Not difficult at all - Somewhat difficult - Very difficult - Extremely difficult'

Clinician-Reported Outcomes

Variable ID:	WHOGROWTH_EA_HC
Variable:	**WHO Early Ages Growth Chart Head Centile**
Definition:	Centile of Head Measurement
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years of age
Data Source:	Clinician / Healthcare provider
Type:	Value
Response Options:	Centile
Variable ID:	WHOGROWTH_EA_LHC
Variable:	WHO Early Ages Growth Chart Length/Height Centile
Definition:	Centile of either the Length or Height Measurement, depending on age
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years of age
Data Source:	Clinician / Healthcare provider

Type:	Value
Response Options:	Centile
Variable ID:	WHOGROWTH_EA_WC
Variable:	WHO Early Ages Growth Chart Weight Centile
Definition:	Centile of Weight Measurement
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years of age
Data Source:	Clinician / Healthcare provider
Type:	Value
Response Options:	Centile
Variable ID:	WHOGROWTH_SA_HC
Variable:	**WHO School Ages Growth Chart Height Centile**
Definition:	Centile of the Height Measurement
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years of age
Data Source:	Clinician / Healthcare provider
Type:	Value
Response Options:	Centile
Variable ID:	WHOGROWTH_SA_WC
Variable:	WHO School Ages Growth Chart Weight Centile
Definition:	Centile of Weight Measurement
Supporting Definition:	N/A
Inclusion Criteria:	All pediatric patients
Timing:	At ages 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, 10 years and 18 years of age
Data Source:	Clinician / Healthcare provider
Type:	Value
Response Options:	Centile
Variable ID:	6MWT
Variable:	**6 Minute Walk Test Distance**
Definition:	Distance Covered During 6 Minutes of Walking
Supporting Definition:	N/A
Inclusion Criteria:	All adult patients and pediatric patients ≥ 5 years of age
Timing:	Baseline and annually
Data Source:	Clinician / Healthcare provider
Type:	Value
Response Options:	Distance in metres

Working Group Member Conflicts of Interests

At the beginning of the Working group process, we ask all Working Group members to declare any conflicts of interests they have. We then circulate these within the Group to ensure transparency.

Name	Affiliation	Declarations
Farhan Ahmad	Pakistan's Children's Heart Foundation, Pakistan	None declared
Ekaterina Anikeeva	Research Institute for Complex Issues of Cardiovascular Diseases, Russia	None declared
Amy Basken	Conquering CHD, USA	Medtronic- Sponsorship (nominal support for our annual legislative conference)
Malin Berghammer	University West, Queen Silvia Children's Hospital, Gothenburg, Sweden; Swedish Heart Children Association, Sweden	None declared
Tomas Chalela	Fundacion Cardioinfantil, Colombia	None declared
Julie Chauhan	All India Institute of Medical Science, New Delhi, India	None declared
Ulisses Alexandre Croti	Hospital da Criança e Maternidade (Hospital de Base), FAMERP Medical School, Brazil	None declared
Luis Antonio Garcia	Kardias A.C. Foundation, Universidad Nacional Autónoma de México, Mexico	None declared
Babar Hasan	The Aga Khan University, Pakistan	None declared
Lisa Hom	ICHOM, USA	None declared
Kevin Hummel	University of Utah at Intermountain Healthcare Primary Children's Hospital, USA	None declared
Kathy Jenkins	Harvard Medical School, Boston Children's Hospital, USA	NuMed- research grant (data coordinating center for device trial) Medtronic- research grant (data coordinating center for device trial) Measure developer for risk-adjustment method for congenital heart surgery mortality that is commonly used and part of an AHRQ indicator
Richard Jonas	World Society for Pediatric and Congenital Heart Surgery, Children's National Medical Center, USA	None declared
Monique Kemp	Global ARCH, South Africa	None declared
Laila Ladak	The Aga Khan University, Pakistan; The University of Sydney, Australia	None declared
Nicolas L. Madsen	Cincinnati Children's Hospital, University of Cincinnati School of Medicine, Cincinnati, Ohio, USA	Philips- grant (Fees are directed to testing and developing bedside monitor configurations and parameters.)
Almudena March	Kardias A.C. Foundation, National Institute of Pediatrics, ABC Medical Center, Mexico	None declared
Gerard Martin	Children's National Hospital, USA	None declared
Michael Oketcho	Uganda Heart Institute, Uganda	None declared
Disty Pearson	Global ARCH, ACHA, Northeastern University, Boston Children's Hospital, USA	None declared
Shannon Quinney	ICHOM, UK	None declared
Juan Samaniego De La Parra	Mexico	None declared
Joan Sanchez de Toledo	Hospital Sant Joan de Deu, Universitat de Barcelona, Spain; University of Pittsburgh, USA	None declared
Steven Schwartz	The Hospital for Sick Children, University of Toronto, Canada	None declared
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Bistra Zheleva	Children's HeartLink, USA	Medtronic Foundation- grant and event sponsorship (we receive funding for programs implemented by Children's HeartLink)

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change

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